



Pfizer Ireland Pharmaceuticals
Ringaskiddy Active Pharmaceutical Ingredient Plant
P.O. Box 140, Ringaskiddy, Co. Cork, Ireland
Tel: +353-21-4378701
Website: www.pfizer.ie

Pfizer Ireland Pharmaceuticals

Enforcement Team B,
Office of Environmental Enforcement,
South/South-West Region,
Environmental Protection Agency,
Inniscarra,
Co. Cork.

19-Apr-2024

Ref. IE Licence Register Number P0013-06 (Pfizer Ringaskiddy)

Re: For Agency Approval: Update to site inventory of materials:

Dear Sir/Madam,

The construction and commissioning of the new facility, the Ringaskiddy Clinical Manufacturing Facility [RCMF] is now complete and available for operation. The RCMF will manufacture active pharmaceutical ingredients [API's] to support clinical trials for new products commencing in Q2 2024. It consists of production, laboratories and support facilities to support Pfizer's Worldwide Research and Development, and Medicine (WRDM) Global Research and Development effort.

The API's will be manufactured using both traditional batch operations in single campaigns typically and Flexible API Supply Technologies [FAST] / continuous manufacturing. In terms of process manufacturing capability, the facility contains a standard flexible batch equipment set (the Batch Pool System) and a fume-hood based continuous equipment set and support equipment (The FAST System). Batch crystallisers, Filter-Dryer and Pack-Off systems are available to support both the Batch Pool and the FAST equipment. Unit operations in the RCMF are the same as in current manufacturing facilities. In terms of scale, for batch operations, there is small and large train batch equipment with the capacity of manufacturing up to 40-50kg and 80 to 100kg respectively. The offload from the FAST equipment is the same as from the batch equipment.

Successful products may then move to full manufacturing scale operations such as OSP1, OSP3, OSP4 or OSP5 [formerly known as the NPTL/NPLC New Product Technology Laboratory / New Product Launch Capacity].

The manufacture of API's is due to commence in Q2 2024 in the RCMF. Because of the nature of the business in the RCMF the processes will change over rapidly and changes to production plans can and will happen at very short notice (as little as 6-8 weeks) depending on funding for process development, clinical data etc. It's planned to introduce up to 10-12 new products to the RCMF in 2024 with the dynamic production plan in place.

Late last year, Pfizer Inc. announced the closure of its Global Research and Development facility at Sandwich in Kent, UK as part of global cost cutting measures. Sandwich focussed on research and development of new products and was currently working on a range of new materials and products. Due to the sudden closure of this facility, it's planned to transfer a number of speciality materials from Sandwich to Ringaskiddy for the purposes of storage initially but it's intended that these materials will be used in processing at a later stage in the RCMF.

We request Agency approval to use the following new materials. It's intended that some of the materials will be used to process API's commencing early Q2, 2024 and other materials will initially be stored in the RCMF warehouse and subsequently be used in API manufacture in the future in the RCMF.

The following new materials will be introduced to site for the manufacture of PF-08015237

- PF-04494988 (2-Bromo-6-fluorobenzaldehyde)
- PF-04197090
- PF-07982394
- Trimethyl orthoformate
- 2-chloro-1-methylpyridinium p-toluenesulfonate [CMPT]
- PF-08015237

The SDS for the new materials are attached in Appendix 1. 4 of the materials are non-hazardous, PF-04494988 (2-Bromo-6-fluorobenzaldehyde) and Trimethyl orthoformate are hazardous. PF-04494988 is assigned the hazardous phrases H302, H315, H319 and H335. H225 and H319 are the hazard phrases assigned to trimethyl orthoformate. These hazard phrases are assigned to materials which are routinely used so no new hazard phrases are being added to the inventory of materials.

In addition to the new materials listed above, the following will also be used in the process: Toluene, p-toluenesulfonic acid monohydrate, tetrahydrofuran, Methyl ethyl ketone, 4-Methyl morpholine, Sodium chloride [23%], potassium tert butoxide in THF, 36% hydrochloric acid and Isopropanol. These materials are previously approved by the Agency and are in routine use.

The following new materials will be introduced to site for the manufacture of PF-07220060, Step C

- PF-07220060 [Seed / step product]
- PF-07229478
- PF-06821006-09

The SDS for the new materials are attached in Appendix 1. These 3 materials are non-hazardous so no new hazard phrases are being added to the inventory of materials.

In addition to the new materials listed above, the following will also be used in the process: IPA, sulfolane, *N,N*-Diisopropylethylamine [DIPEA] and potassium phosphate tribasic. These materials are previously approved by the Agency and are in routine use.

As mentioned above, the research facility at Sandwich is closing and Agency approval is required to initially store the following materials but it's intended that these materials will be used in the manufacture of the following products at some stage in the RCMF.

The following new materials will be initially stored and subsequently used in PF-07220060

- PF- 07227325
- 2,4,5-trichloropyrimidine
- Bis(neopentyl glycolato)diboron

The SDS for the new materials are attached in Appendix 1. 2 of the materials are non-hazardous, 2,4,5-trichloropyrimidine is hazardous. It's assigned the hazardous phrases H315, H319 and H335. These hazard phrases are assigned to materials which are routinely used so no new hazard phrases are being added to the inventory of materials.

The following new materials will be initially stored and subsequently used in PF-07081532/PF-06882961

- PF-06873286-15
- PF-06878031
- PF-06882961-82
- PF-06877636
- PF-06829020
- PF-05318079

The SDS for the new materials are attached in Appendix 1. All of the materials are non-hazardous solids except PF-06878031 which is hazardous. It's assigned the hazardous phrases H315, H319, H317, H402 and H411. These hazard phrases are assigned to materials which are routinely used so no new hazard phrases are being added to the inventory of materials.

The following new materials will be initially stored and subsequently used in PF-07104091

- PF-07212416
- PF-07823177
- PF-07313698
- PF-07104091 Monohydrate
- Ene-reductase Enzyme ER043-026F
- Alcohol Dehydrogenase KR051-1683F [filtered]

Note that the enzymes are not live organisms, they do not contain any animal products and no animal products were used in the manufacture of them. The SDS for the new materials are attached in Appendix 1. PF-07212416, PF-07823177 and PF-07313698 are non-hazardous solids. The remaining materials have H [Hazard] Phrases, H334 assigned to the 2 enzymes and H341 assigned to PF-07104091 which are routinely used on site. No new Hazard phrases are being added to the inventory of materials.

The following outlines the impact of the introduction of the new materials. As explained below, there is no impact resulting from the introduction of the materials whether they will be used in processing or just stored in the RCMF warehouse.

Impact on air emissions:

There will be no new emissions to air resulting from these process. Only solvents / volatile materials used in the process may be routed to the vessel headspace and onto the vent header and abatement system within each manufacturing plant. Depending on their volatility, vapours may be routed to the headspace. All of the solvents listed above are previously approved by the Agency and routinely used on site except for trimethyl orthoformate. These solvents are volatile and vapours will be routed to the vent header and VOC abatement system in OSP1. The existing air emissions abatement systems servicing all manufacturing buildings are capable of handling the emissions from these materials explained as follows.

The above products will be initially manufactured in the RCMF so air emissions from these processes and all processes in the RCMF manufacturing facility are managed by the existing VOC emission abatement system for OSP1. Treated emissions from the OSP1 abatement system are directed to atmosphere via the licensed emission point, A2-2 [V3] which is continuously monitored. In the event that the OSP1 VOC abatement system is unavailable for use, vapours can be routed to the OSP3 VOC abatement system. Should these steps be manufactured in OSP1, OSP3 or OSP4 manufacturing facilities, air emissions from this process and all processes in either OSP1, OSP3 or OSP4 manufacturing facilities are managed by the existing OSP1, OSP3 or OSP4 abatement systems. OSP3 VOC Absorption System is the main VOC emission abatement systems for OSP3 and OSP5 and the OSP1 VOC Absorption system is the main abatement system for OSP1 and RCMF and the Thermal Oxidiser is the main abatement system for OSP4. Treated emissions from OSP1/ RCMF, OSP3 / OSP5 and OSP4 abatement systems are directed to atmosphere via the licensed emission points A2-2 [V3], A2-4 [V5] and A2-5 [V13] respectively which are continuously monitored.

In the case of the VOC Absorption Plants serving OSP3/OSP5 and OSP1/RCMF, the licensed volumetric flowrate of the fans is 2,700 m³/hour for OSP3 and 3,000m³/hr for OSP1. The operational volumetric flow range is variable and currently typically in the range 300-1,200 m³/hour (approx. 30% of design). All reaction vessels are fitted with condensers to minimise the carry-over of solvent into the header. Vessels used in the process are connected to the existing headers, all flowrates are governed by the existing header vacuum pumps and not by the individual vessel unit operations, and therefore there will be no change to these volumetric flowrates. The manufacture of these steps can therefore take place fully within the existing design envelope of the VOC Absorption Plants, and solvents/VOCs will be efficiently removed as per design and continuously monitored by a CEMS.

In the case of OSP4, abatement is provided by a flameless thermal oxidiser. Similar to OSP1 and OSP3, all reaction vessels are fitted with condensers to minimise the carry-over of solvent into the header. Vessels in OSP4 are manifolded to a contained common header, which is then routed to the oxidation bed. The enthalpy of the header is continuously monitored, and the volumetric flowrate is automatically adjusted by header fans such that the total enthalpy within the oxidation bed remains constant and below the flammable limit (flameless thermal oxidation). The supplemental fuel is natural gas, and this is simultaneously automatically adjusted by control

valves in conjunction with header flow adjustment, to achieve this constant enthalpy. Natural gas provides the majority of the enthalpy and so significant spare capacity is available in the thermal oxidiser. The manufacture of these steps will therefore take place fully within the existing design envelope of the OSP4 thermal oxidiser, and solvents/VOCs will be efficiently removed as per design and continuously monitored by a CEMS.

The manufacture of these steps can therefore take place fully within the existing design envelope of the VOC Absorption Plants and the flameless thermal oxidiser, and solvents/VOCs will be efficiently removed as per design and continuously monitored by a CEMS.

Tables 1, 2 and 3 identify the solvents / volatile materials used in the processes and their associated ELV's for A2-2 [V3], licensed emissions point for OSP1, A2-4 [V5] licensed emissions point for OSP3 and A2-5 [V13] / respectively. The abatement system in OSP1 / OSP3 are governed by the TA Luft standard and OSP4 is governed by a Total Organic Carbon emission limit.

Table 1: A2-2 [V3]: ELV's for licensed emission point from OSP1 Operations

Solvent	1997 TA Luft Class	Emission Limit Value [ELV]	Ringaskiddy average kg/hr [2023]	Ringaskiddy average kg/hr [2022]
Pyridine	TA Luft Organics Class I	20mg/m ³ (at mass flows >0.1 kg/hr)	0.00021 kg/hr	0.00022 kg/hr
Acetonitrile, THF	TA Luft Organics Class II	100mg/m ³ (at mass flows >2.0 kg/hr)	0.00023 kg/hr	0.00016 kg/hr
Methanol, IPA	TA Luft Organics Class III	150mg/m ³ (at mass flows >3.0 kg/hr)	0.00036 kg/hr	0.00065 kg/hr

Table 2: A2-4 [V5]: ELV's for licensed emission point from OSP3 / NPTL Operations

Solvent	1997 TA Luft Class	Emission Limit Value [ELV]	Ringaskiddy average kg/hr [2023]	Ringaskiddy average kg/hr [2022]
Pyridine	TA Luft Organics Class I	20mg/m ³ (at mass flows >0.1 kg/hr)	0.00064 kg/hr	0.00041 kg/hr
Acetonitrile, THF	TA Luft Organics Class II	100mg/m ³ (at mass flows >2.0 kg/hr)	0.00102 kg/hr	0.00041 kg/hr
Methanol, IPA	TA Luft Organics Class III	150mg/m ³ (at mass flows >3.0 kg/hr)	0.00143 kg/hr	0.00050 kg/hr

Table 3: A2-5 [V13]: ELV for TOC for licensed emission point from OSP4 Operations

Parameter	Emission Limit Value [ELV] 30-minute mean (mg/m ³)	Ringaskiddy average 30-minute mean mg/m ³ [2023]	Ringaskiddy average 30-minute mean mg/m ³ [2022]
Volatile organic compounds (excluding Particulate matter) expressed as total organic carbon	20 mg/m ³	0.62 mg/m ³	0.47mg/m ³

Tables 1, 2 and 3 above provide a summary of the annual emissions data from A2-2 [V3], A2-4 [V5] and A2-5 [V13], from 2022 and 2023 and all emissions from the OSP1, OSP3 and OSP4 air emissions abatement systems comply with the relevant ELV's. The solvents used in this process are routinely used and historical data confirms that the on-site VOC emissions abatement systems are capable of abating these materials. The introduction of this process will not result in any impact or change to air emissions from the site.

Impact on emissions to sewer:

The introduction of these new steps will not impact on emissions to sewer. We confirm that no waste stream containing any of these materials will be routed to the wastewater treatment plant, WWTP. The RCMF is identical to the other production facilities in that there are dedicated mother liquor tanks [2 of] to collect waste streams from the processes. Waste streams will be segregated and sent to Production Services for final processing but they will not be treated in the WWTP. Aqueous based waste streams will be sent off site for suitable treatment by the approved waste management broker. Solvent containing waste streams are either recovered on or off-site or sent to high calorific value waste for off-site treatment, final treatment is typically dependent upon volume, composition, etc. Identical to other production facilities, the RCMF has a dedicated weak effluent vessel which will collect floor washings etc and these will be transferred to the WWTP via the effluent system and discharged at SE1 [TE1] in accordance with the requirements of the licence.

Impact on emissions to surface water:

There will be no emissions to surface water resulting from the storage and use of these materials. All drains within the manufacturing facilities are process drains. Contents of the process drains are treated in the on-site waste-water treatment plant and discharged at SE1 [TE1] in accordance with the licence requirements. Refer to section above on how waste streams containing these materials would be managed. There are no surface water drains in areas where either drums of raw materials or drums of waste are stored.

Impact on storage facilities:

The new materials will be supplied in containers. The RCMF has its own dedicated drum store for liquids and warehouse for solid materials. Should the processes move from the RCMF, there is sufficient storage capacity within both the main warehouse and existing drumpad for the storage of these raw materials. Drummed solids are typically stored in the main warehouse. Drummed liquids are stored in the drumpad which is remotely bundled to the WWTP. There are dedicated contained areas within the vicinity of each manufacturing facility to contain both the raw materials and the associated waste drums. Procedures are implemented to ensure all waste drums are labelled at the point of generation. Such waste drums are transferred to dedicated areas within the main warehouse and drum laydown area as appropriate. All waste drums are removed off site by our approved waste management broker which is Indaver Ireland Ltd. Dedicated Indaver resources manage the shipment of waste from site and tracking of materials to final disposal. Disposal of such waste is recorded in the annual environmental report.

Ringaskiddy is a multipurpose manufacturer of many products, manufactured on a campaign basis. At any one time, there could be circa 20 process steps being manufactured between all the equipment trains within the

manufacturing plants. To ensure production plan requirements are met, drummed raw materials are constantly moving onto site for initial storage, moving to the relevant manufacturing plant for use and the associated waste materials are then moved from the plants to dedicated storage areas for disposal. We confirm that there is sufficient contained storage on site for the drums that will be used in this process.

Impact on firewater retention capacity:

The introduction of these new product steps don't have any impact on fire water retention capacity. The materials in question do not change the profile of materials being introduced, and no new hazard phrases are introduced. The new materials don't change the risk rating of the site.

In summary, we request Agency approval to store and use the above listed materials on site. As described above, there will be very no environmental impact resulting from the use of these materials on site.

In accordance with Agency guidance, the Inventory of Materials for the RCMF shall be updated to include the above materials and shall be retained onsite for inspection by the Agency as required.

We trust that this is to the satisfaction of the Agency.

Yours sincerely,

Pfizer Ireland Pharmaceuticals

Ringaskiddy Active Pharmaceutical Ingredient Plant

Geraldine Rooney

Geraldine Rooney

Environment, Health and Safety Department

Appendix 1:

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Version 6.5

Revision Date 08.03.2024

Print Date 15.04.2024

GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifiers**

Product name : 2-Bromo-6-fluorobenzaldehyde

Product Number : 709824

Brand : Aldrich

REACH No. : A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

CAS-No. : 360575-28-6

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company : Merck Life Science N.V.
Haarlerbergweg 21 A
1101 CH AMSTERDAM
NETHERLANDS

Telephone : +31 078 620-5411

Fax : +31 078 620-5421

E-mail address : technischeservicebenelux@merckgroup.com

1.4 Emergency telephone

Emergency Phone # : +(31)-858880596 (CHEMTREC)
112 (Alarmnummer)

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture**

Acute toxicity, (Category 4) H302: Harmful if swallowed.

Skin irritation, (Category 2) H315: Causes skin irritation.

Eye irritation, (Category 2) H319: Causes serious eye irritation.



Specific target organ toxicity -
single exposure, (Category 3),
Respiratory system

H335: May cause respiratory irritation.

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008

Pictogram



Signal Word

Warning

Hazard Statements

H302

Harmful if swallowed.

H315

Causes skin irritation.

H319

Causes serious eye irritation.

H335

May cause respiratory irritation.

Precautionary Statements

P261

Avoid breathing dust.

P264

Wash skin thoroughly after handling.

P271

Use only outdoors or in a well-ventilated area.

P301 + P312

IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell.

P302 + P352

IF ON SKIN: Wash with plenty of water.

P305 + P351 + P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Supplemental Hazard
Statements

none

Reduced Labeling (<= 125 ml)

Pictogram



Signal Word

Warning

Hazard Statements

none

Precautionary Statements

none

Supplemental Hazard
Statements

none

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information:

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.



Toxicological information:

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Stench.

Stench.

SECTION 3: Composition/information on ingredients

3.1 Substances

Formula : C₇H₄BrFO
Molecular weight : 203,01 g/mol
CAS-No. : 360575-28-6

Component	Classification	Concentration
2-Bromo-6-fluorobenzaldehyde		
CAS-No. 360575-28-6	Acute Tox. 4; Skin Irrit. 2; Eye Irrit. 2; STOT SE 3; H302, H315, H319, H335	<= 100 %

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4: First aid measures

4.1 Description of first-aid measures

General advice

Show this material safety data sheet to the doctor in attendance.

If inhaled

After inhalation: fresh air.

In case of skin contact

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower.

In case of eye contact

After eye contact: rinse out with plenty of water. Call in ophthalmologist. Remove contact lenses.

If swallowed

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available



SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water Foam Carbon dioxide (CO₂) Dry powder

Unsuitable extinguishing media

For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

Carbon oxides

Hydrogen bromide gas

Hydrogen fluoride

Combustible.

Vapors are heavier than air and may spread along floors.

Forms explosive mixtures with air on intense heating.

Development of hazardous combustion gases or vapours possible in the event of fire.

5.3 Advice for firefighters

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

5.4 Further information

Suppress (knock down) gases/vapors/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Avoid inhalation of dusts. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up dry. Dispose of properly. Clean up affected area. Avoid generation of dusts.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Tightly closed. Dry.



Handle and store under inert gas.

Storage class

Storage class (TRGS 510): 11: Combustible Solids

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with workplace control parameters

8.2 Exposure controls

Personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses

Skin protection

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN 16523-1 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Material tested:KCL 741 Dermatril® L

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Material tested:KCL 741 Dermatril® L

Body Protection

protective clothing

Respiratory protection

required when dusts are generated.

Our recommendations on filtering respiratory protection are based on the following standards: DIN EN 143, DIN 14387 and other accompanying standards relating to the used respiratory protection system.

Recommended Filter type: Filter type P2



The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

Control of environmental exposure

Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Physical state	solid
b) Color	No data available
c) Odor	No data available
d) Melting point/freezing point	Melting point/range: 43 - 47 °C
e) Initial boiling point and boiling range	No data available
f) Flammability (solid, gas)	No data available
g) Upper/lower flammability or explosive limits	No data available
h) Flash point	> 110 °C - closed cup
i) Autoignition temperature	No data available
j) Decomposition temperature	No data available
k) pH	No data available
l) Viscosity	Viscosity, kinematic: No data available Viscosity, dynamic: No data available
m) Water solubility	No data available
n) Partition coefficient: n-octanol/water	log Pow: 2,288
o) Vapor pressure	No data available
p) Density	No data available
Relative density	No data available
q) Relative vapor density	No data available
r) Particle characteristics	No data available



s) Explosive properties No data available

t) Oxidizing properties No data available

9.2 Other safety information

Relative vapor density 7,01 - (Air = 1.0)

SECTION 10: Stability and reactivity

10.1 Reactivity

Forms explosive mixtures with air on intense heating.

A range from approx. 15 Kelvin below the flash point is to be rated as critical.

The following applies in general to flammable organic substances and mixtures: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature) .

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

Strong heating.

10.5 Incompatible materials

Strong oxidizing agents

10.6 Hazardous decomposition products

In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD50 Oral - 500,1 mg/kg

Oral: No data available

Inhalation: No data available

Dermal: No data available

Skin corrosion/irritation

Remarks: No data available

Serious eye damage/eye irritation

Remarks: No data available

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

No data available

Carcinogenicity

No data available



Reproductive toxicity

No data available

Specific target organ toxicity - single exposure

Inhalation - May cause respiratory irritation.

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

11.2 Additional Information**Endocrine disrupting properties****Product:**

Assessment

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

SECTION 12: Ecological information**12.1 Toxicity**

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties**Product:**

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available



SECTION 16: Other information

Full text of H-Statements

H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative



Further information

The information is believed to be correct but is not exhaustive and will be used solely as a guideline, which is based on current knowledge of the chemical substance or mixture and is applicable to appropriate safety precautions for the product. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

Copyright 2020 Sigma-Aldrich Co. LLC. License granted to make unlimited paper copies for internal use only.

The branding on the header and/or footer of this document may temporarily not visually match the product purchased as we transition our branding. However, all of the information in the document regarding the product remains unchanged and matches the product ordered. For further information please contact mlsbranding@sial.com.





SAFETY DATA SHEET

Revision date 28-Nov-2023

Version 2

Page 1 / 8

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name PF-04197090
Product Code(s) PF00817
Synonyms GBT022118
Trade Name: Not established
Chemical Family: Not determined

PF-04197090
CAS No 211053-49-5

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical process intermediate

1.3. Details of the supplier of the safety data sheet

Pfizer Research and Development
445 Eastern Point Road
Groton, CT USA
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous according to Regulation (EC) 1272/2008 and/or other applicable regulations.

OSHA Classification
Physical Hazard

Combustible Dust

2.2. Label elements

Signal word

(OSHA) Warning

Hazard statements

OSHA - May form combustible dust concentrations in air

Supplemental Hazard

Compound, not fully tested, hazards unknown.

2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for this substance (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the

SAFETY DATA SHEET

Product Name PF-04197090
Revision date 28-Nov-2023

Page 2 / 8
Version 2

potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
PF-04197090 (CAS #: 211053-49-5)	100		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate
No information available

Additional information

- Not Assigned
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects No data available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

SAFETY DATA SHEET

Product Name PF-04197090
Revision date 28-Nov-2023

Page 3 / 8
Version 2

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Formation of toxic gases is possible during heating or fire.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Avoid use of a filtered vacuum to clean spills of dry solids. Contain the source of the spill or leak. Clean spill area thoroughly. Collect spilled material by a method that controls dust generation.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Protect from moisture. Store at room temperature in properly labeled containers. Keep away from heat, sparks, and flames.

7.3. Specific end use(s)

SAFETY DATA SHEET

Product Name PF-04197090
Revision date 28-Nov-2023

Page 4 / 8
Version 2

Specific use(s) Pharmaceutical process intermediate.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

PF-04197090

Pfizer Occupational Exposure Band (OEB):

OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m³ to < 100ug/m³)

8.2. Exposure controls

Engineering controls

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

Environmental exposure controls

No information available.

Personal protective equipment

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Eye/face protection

Wear safety goggles as minimum protection. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection

Wear 2 layers of impervious disposable gloves (e.g. Nitrile, etc.) to prevent skin contact. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection

Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection

Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state

Solid

Color

White to tan

Odor

No information available.

Odor threshold

No information available

SAFETY DATA SHEET

Product Name PF-04197090
Revision date 28-Nov-2023

Page 5 / 8
Version 2

Molecular formula	C5 H11 N O2
Molecular weight	117.15
Property	Values
pH	No data available
Melting point / freezing point	70 - 75 °C
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

Partition Coefficient: (Method, pH, Endpoint, Value)

PF-04197090

Predicted 7.4 Log D -2.088

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

DSC: Endotherm of 189 J/g at 47 °C Exotherm of > - 775 J/g at 280 °C.

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

SAFETY DATA SHEET

Product Name PF-04197090
Revision date 28-Nov-2023

Page 6 / 8
Version 2

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information:	Toxicological properties have not been investigated.
Acute toxicity	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

Carcinogenicity Not listed as a carcinogen by IARC, NTP or US OSHA.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated.

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Partition Coefficient: (Method, pH, Endpoint, Value)
PF-04197090

SAFETY DATA SHEET

Product Name PF-04197090
Revision date 28-Nov-2023

Page 7 / 8
Version 2

Predicted 7.4 Log D -2.088

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental Hazard(s):	Not applicable

Special precautions for user:	Not applicable
Additional Information	Transportation classification is based on data and/or procedures that may not be reflected on this document. The classification was conducted as per defining criteria in the international transportation regulations and the shipper's knowledge of the material.

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

PF-04197090	
CERCLA/SARA Section 313 de minimus %	Not Listed

SAFETY DATA SHEET

Product Name PF-04197090
Revision date 28-Nov-2023

Page 8 / 8
Version 2

California Proposition 65
EINECS

Not Listed
Not Listed

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Data Sources: Pfizer proprietary drug development information.

Reason for revision Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date 28-Nov-2023

Prepared By Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.



SAFETY DATA SHEET

Revision date 28-Jul-2023

Version 1

Page 1 / 8

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name PF-07982394
Product Code(s) PF00737
Trade Name: Not established
Chemical Family: Not determined
PF-07982394
CAS No 2865897-82-9

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical process intermediate

1.3. Details of the supplier of the safety data sheet

Pfizer Research and Development
445 Eastern Point Road
Groton, CT USA
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous according to Regulation (EC) 1272/2008 and/or other applicable regulations.

OSHA Classification Physical Hazard

Combustible Dust

2.2. Label elements

Signal word

Warning (OSHA)

Hazard statements

OSHA - May form combustible dust concentrations in air

Supplemental Hazard

Compound, not fully tested, hazards unknown.

2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for this substance (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all

SAFETY DATA SHEET

Product Name PF-07982394
Revision date 28-Jul-2023

Page 2 / 8
Version 1

cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
PF-07982394 (CAS #: 2865897-82-9)	100		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

No information available

Additional information

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects No data available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

SAFETY DATA SHEET

Product Name PF-07982394
Revision date 28-Jul-2023

Page 3 / 8
Version 1

Suitable Extinguishing Media Dry chemical, CO₂, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Formation of toxic gases is possible during heating or fire.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Avoid use of a filtered vacuum to clean spills of dry solids. Contain the source of the spill or leak. Clean spill area thoroughly. Collect spilled material by a method that controls dust generation.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical process intermediate.

SAFETY DATA SHEET

Product Name PF-07982394
Revision date 28-Jul-2023

Page 4 / 8
Version 1

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

PF-07982394

Pfizer Occupational Exposure Band (OEB):

OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m³ to < 100ug/m³)

8.2. Exposure controls

Engineering controls

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels to below the OEB range.

Environmental exposure controls

No information available.

Personal protective equipment

Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Eye/face protection

Wear safety goggles as minimum protection. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection

Wear 2 layers of impervious disposable gloves (e.g. Nitrile, etc.) to prevent skin contact. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection

Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection

Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state

Solid

Color

White

Odor

No information available.

Odor threshold

No information available

Molecular formula

C15 H13 N O4

Molecular weight

271.27

SAFETY DATA SHEET

Product Name PF-07982394
Revision date 28-Jul-2023

Page 5 / 8
Version 1

<u>Property</u>	<u>Values</u>
pH	No data available
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

Partition Coefficient: (Method, pH, Endpoint, Value)

PF-07982394

Predicted 7.4 Log D -0.456

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

DSC:

Endotherm of 196 J/g at 124 °C. Exotherm of -18 J/g at 186 °C
and -178 J/g at 264 °C

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

SAFETY DATA SHEET

Product Name PF-07982394
Revision date 28-Jul-2023

Page 6 / 8
Version 1

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information:	Toxicological properties have not been investigated.
Acute toxicity	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

Carcinogenicity Not listed as a carcinogen by IARC, NTP or US OSHA.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated.

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Partition Coefficient: (Method, pH, Endpoint, Value)

PF-07982394

Predicted 7.4 Log D -0.456

SAFETY DATA SHEET

Product Name PF-07982394
Revision date 28-Jul-2023

Page 7 / 8
Version 1

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental Hazard(s):	Not applicable

Special precautions for user:	Not applicable
Additional Information	Transportation classification is based on data and/or procedures that may not be reflected on this document. The classification was conducted as per defining criteria in the international transportation regulations and the shipper's knowledge of the material.

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

PF-07982394

CERCLA/SARA Section 313 de minimus %
California Proposition 65

Not Listed
Not Listed

SAFETY DATA SHEET

Product Name PF-07982394
Revision date 28-Jul-2023

Page 8 / 8
Version 1

EINECS

Not Listed

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Data Sources: Pfizer proprietary drug development information.

Reason for revision New data sheet.

Revision date 28-Jul-2023

Prepared By Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

SAFETY DATA SHEET

Version 6.5
Revision Date 08/27/2023
Print Date 09/01/2023

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifiers**

Product name : Trimethyl orthoformate

Product Number : 305472
Brand : Aldrich
CAS-No. : 149-73-5

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Synthesis of substances

1.3 Details of the supplier of the safety data sheet

Company : S-A Co, LLC (STL)
3050 Spruce Street
SAINT LOUIS MO 63103
UNITED STATES

Telephone : +1 314 771 5765
Fax : +1 800 325 5052

1.4 Emergency telephone

Emergency Phone # : 800-424-9300 CHEMTREC (USA) +1-703-
527-3887 CHEMTREC (International) 24
Hours/day; 7 Days/week

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)**

Flammable liquids (Category 2), H225
Eye irritation (Category 2A), H319

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 GHS Label elements, including precautionary statements

Pictogram



Signal Word

Danger

Hazard statement(s)	
H225	Highly flammable liquid and vapor.
H319	Causes serious eye irritation.
Precautionary statement(s)	
P210	Keep away from heat/ sparks/ open flames/ hot surfaces. No smoking.
P233	Keep container tightly closed.
P240	Ground/bond container and receiving equipment.
P241	Use explosion-proof electrical/ ventilating/ lighting/ equipment.
P242	Use only non-sparking tools.
P243	Take precautionary measures against static discharge.
P264	Wash skin thoroughly after handling.
P280	Wear protective gloves/ eye protection/ face protection.
P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313	If eye irritation persists: Get medical advice/ attention.
P370 + P378	In case of fire: Use dry sand, dry chemical or alcohol-resistant foam to extinguish.
P403 + P235	Store in a well-ventilated place. Keep cool.
P501	Dispose of contents/ container to an approved waste disposal plant.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none

SECTION 3: Composition/information on ingredients

3.1 Substances

Synonyms	: Trimethoxymethane
Formula	: C ₄ H ₁₀ O ₃
Molecular weight	: 106.12 g/mol
CAS-No.	: 149-73-5
EC-No.	: 205-745-7

Component	Classification	Concentration
trimethyl orthoformate	Flam. Liq. 2; Eye Irrit. 2A; H225, H319	<= 100 %

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4: First aid measures

4.1 Description of first-aid measures

General advice

Show this material safety data sheet to the doctor in attendance.

If inhaled

After inhalation: fresh air.

In case of skin contact

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower.

In case of eye contact

After eye contact: rinse out with plenty of water. Call in ophthalmologist. Remove contact lenses.

If swallowed

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Carbon dioxide (CO₂) Foam Dry powder

Unsuitable extinguishing media

For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

Carbon oxides

Combustible.

Pay attention to flashback.

Vapors are heavier than air and may spread along floors.

Development of hazardous combustion gases or vapours possible in the event of fire.

Forms explosive mixtures with air at ambient temperatures.

5.3 Advice for firefighters

In the event of fire, wear self-contained breathing apparatus.

5.4 Further information

Remove container from danger zone and cool with water. Prevent fire extinguishing water from contaminating surface water or the ground water system.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Do not breathe vapors, aerosols. Avoid substance contact. Ensure adequate ventilation. Keep away from heat and sources of ignition. Evacuate the danger area, observe emergency procedures, consult an expert. For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains. Risk of explosion.

6.3 Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent material (e.g. Chemisorb®). Dispose of properly. Clean up affected area.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on protection against fire and explosion

Keep away from open flames, hot surfaces and sources of ignition. Take precautionary measures against static discharge.

Hygiene measures

Change contaminated clothing. Wash hands after working with substance. For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Keep container tightly closed in a dry and well-ventilated place. Keep away from heat and sources of ignition.

Storage class

Storage class (TRGS 510): 3: Flammable liquids

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Appropriate engineering controls

Change contaminated clothing. Wash hands after working with substance.

Personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses

Skin protection

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN 16523-1 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).

Full contact

Material: butyl-rubber

Minimum layer thickness: 0.7 mm

Break through time: 480 min

Material tested: Butoject® (KCL 898)

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN 16523-1 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).

Splash contact

Material: Viton®

Minimum layer thickness: 0.7 mm

Break through time: 60 min

Material tested: Vitoject® (KCL 890 / Aldrich Z677698, Size M)

Body Protection

Flame retardant antistatic protective clothing.

Respiratory protection

Recommended Filter type: Filter type ABEK

The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer.

These measures have to be properly documented.

required when vapours/aerosols are generated.

Our recommendations on filtering respiratory protection are based on the following standards: DIN EN 143, DIN 14387 and other accompanying standards relating to the used respiratory protection system.

Control of environmental exposure

Do not let product enter drains. Risk of explosion.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- | | |
|-------------------|---|
| a) Appearance | Form: clear, liquid
Color: colorless |
| b) Odor | pungent |
| c) Odor Threshold | No data available |

Aldrich - 305472

Page 5 of 10

d) pH	No data available
e) Melting point/freezing point	Melting point: -53 °C (-63 °F) at ca.1,013.25 hPa
f) Initial boiling point and boiling range	101 - 102 °C 214 - 216 °F - lit.
g) Flash point	13 °C (55 °F) at ca.1,013.25 hPa - closed cup - DIN 51755 Part 1
h) Evaporation rate	No data available
i) Flammability (solid, gas)	No data available
j) Upper/lower flammability or explosive limits	Upper explosion limit: 44.6 %(V) Lower explosion limit: 1.4 %(V)
k) Vapor pressure	10 hPa at 7 °C (45 °F)
l) Vapor density	3.66 - (Air = 1.0)
m) Density	0.97 g/cm ³ at 25 °C (77 °F) - lit.
Relative density	ca.0.9720 °C - DIN 51757
n) Water solubility	10 g/l at 20 °C (68 °F)
o) Partition coefficient: n-octanol/water	log Pow: 0.09 at 20 °C (68 °F) - Bioaccumulation is not expected.
p) Autoignition temperature	255 °C (491 °F) at 1,013.25 hPa - DIN 51794
q) Decomposition temperature	No data available
r) Viscosity	No data available
s) Explosive properties	No data available
t) Oxidizing properties	none

9.2 Other safety information

Relative vapor density	3.66 - (Air = 1.0)
------------------------	--------------------

SECTION 10: Stability and reactivity

10.1 Reactivity

Vapors may form explosive mixture with air.

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature) .

10.3 Possibility of hazardous reactions

Violent reactions possible with:

Strong oxidizing agents

Water
acids

10.4 Conditions to avoid

Avoid moisture.
Warming.

10.5 Incompatible materials

No data available

10.6 Hazardous decomposition products

In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD50 Oral - Rat - 3,130 mg/kg

Symptoms: Irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract.

Remarks: (Lit.)

LC50 Inhalation - Rat - male - 4 h - 40 mg/l - vapor

Symptoms: Possible damages:, mucosal irritations

Remarks: (ECHA)

Dermal: No data available

Skin corrosion/irritation

Skin - Rabbit

Result: No skin irritation

(OECD Test Guideline 404)

Serious eye damage/eye irritation

Eyes - Rabbit

Result: Eye irritation

(OECD Test Guideline 405)

Respiratory or skin sensitization

Maximization Test - Guinea pig

Result: negative

(OECD Test Guideline 406)

Germ cell mutagenicity

Test Type: Ames test

Test system: Salmonella typhimurium

Metabolic activation: with and without metabolic activation

Result: negative

Remarks: (ECHA)

Test Type: Micronucleus test

Species: Mouse

Method: OECD Test Guideline 474

Result: negative

Carcinogenicity

IARC: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

NTP: No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

Reproductive toxicity

No data available

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

11.2 Additional Information

RTECS: RM6650000

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Other dangerous properties can not be excluded.

Handle in accordance with good industrial hygiene and safety practice.

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish static test LC50 - Leuciscus idus (Golden orfe) - 412 mg/l - 48 h
(DIN 38412 T15)

Toxicity to bacteria

12.2 Persistence and degradability

Biodegradability aerobic - Exposure time 13 d
Result: 97 % - Readily biodegradable.
Remarks: (ECHA)

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Endocrine disrupting properties

No data available

12.7 Other adverse effects

Discharge into the environment must be avoided.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Waste material must be disposed of in accordance with the national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself.

SECTION 14: Transport information

DOT (US)

UN number: 3272 Class: 3 Packing group: II

Proper shipping name: Esters, n.o.s.

Reportable Quantity (RQ):

Poison Inhalation Hazard: No

IMDG

UN number: 3272 Class: 3 Packing group: II EMS-No: F-E, S-D

Proper shipping name: ESTERS, N.O.S. (trimethyl orthoformate)

IATA

UN number: 3272 Class: 3 Packing group: II

Proper shipping name: Esters, n.o.s. (trimethyl orthoformate)

SECTION 15: Regulatory information

SARA 302 Components

This material does not contain any components with a section 302 EHS TPQ.

SARA 313 Components

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Massachusetts Right To Know Components

No components are subject to the Massachusetts Right to Know Act.

SECTION 16: Other information

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

Copyright 2020 Sigma-Aldrich Co. LLC. License granted to make unlimited paper copies for internal use only.

The branding on the header and/or footer of this document may temporarily not visually match the product purchased as we transition our branding. However, all of the information in the document regarding the product remains unchanged and matches the product ordered. For further information please contact misbranding@sial.com.

Version: 6.5

Revision Date: 08/27/2023

Print Date: 09/01/2023

SAFETY DATA SHEET

Version 6.1
Revision Date 06/21/2022
Print Date 08/09/2022

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Product name : 2-Chloro-1-methylpyridinium p-toluenesulfonate

Product Number : CDS021472
Brand : Aldrich
CAS-No. : 7403-46-5

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Synthesis of substances

1.3 Details of the supplier of the safety data sheet

Company : S-A Co, LLC (STL)
3050 Spruce Street
SAINT LOUIS MO 63103
UNITED STATES

Telephone : +1 314 771 5765
Fax : +1 800 325 5052

1.4 Emergency telephone

Emergency Phone # : 800-424-9300 CHEMTREC (USA) +1-703-527-3887 CHEMTREC (International) 24 Hours/day; 7 Days/week

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to the Globally Harmonized System (GHS).

2.2 GHS Label elements, including precautionary statements

Not a hazardous substance or mixture according to the Globally Harmonized System (GHS).

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none

SECTION 3: Composition/information on ingredients

3.1 Substances

Formula : C13H14ClNO3S
Molecular weight : 299.77 g/mol

Aldrich - CDS021472

Page 1 of 8

CAS-No. : 7403-46-5
EC-No. : 231-008-4

No components need to be disclosed according to the applicable regulations.

SECTION 4: First aid measures

4.1 Description of first-aid measures

If inhaled

After inhalation: fresh air.

In case of skin contact

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower.

In case of eye contact

After eye contact: rinse out with plenty of water. Remove contact lenses.

If swallowed

After swallowing: make victim drink water (two glasses at most). Consult doctor if feeling unwell.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water Foam Carbon dioxide (CO₂) Dry powder

Unsuitable extinguishing media

For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

Nature of decomposition products not known.

Combustible.

Development of hazardous combustion gases or vapours possible in the event of fire.

5.3 Advice for firefighters

In the event of fire, wear self-contained breathing apparatus.

5.4 Further information

Prevent fire extinguishing water from contaminating surface water or the ground water system.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Avoid inhalation of dusts. Evacuate the danger area, observe emergency procedures, consult an expert.

For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up dry. Dispose of properly. Clean up affected area. Avoid generation of dusts.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Tightly closed. Dry.

Storage class

Storage class (TRGS 510): 11: Combustible Solids

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Appropriate engineering controls

Change contaminated clothing. Wash hands after working with substance.

Personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses

Skin protection

Handle with impervious gloves.

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please

contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm

Break through time: 480 min

Material tested:KCL 741 Dermatril® L

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm

Break through time: 480 min

Material tested:KCL 741 Dermatril® L

Respiratory protection

required when dusts are generated.

Our recommendations on filtering respiratory protection are based on the following standards: DIN EN 143, DIN 14387 and other accompanying standards relating to the used respiratory protection system.

Control of environmental exposure

Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Appearance	Form: solid
b) Odor	No data available
c) Odor Threshold	No data available
d) pH	No data available
e) Melting point/freezing point	No data available
f) Initial boiling point and boiling range	No data available
g) Flash point	()Not applicable
h) Evaporation rate	No data available
i) Flammability (solid, gas)	No data available
j) Upper/lower flammability or explosive limits	No data available
k) Vapor pressure	No data available
l) Vapor density	No data available
m) Density	No data available
Relative density	No data available
n) Water solubility	No data available

- o) Partition coefficient: No data available
n-octanol/water
- p) Autoignition No data available
temperature
- q) Decomposition No data available
temperature
- r) Viscosity No data available
- s) Explosive properties No data available
- t) Oxidizing properties none

9.2 Other safety information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

The following applies in general to flammable organic substances and mixtures: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature) .

10.3 Possibility of hazardous reactions

Violent reactions possible with:
Strong oxidizing agents

10.4 Conditions to avoid

no information available

10.5 Incompatible materials

No data available

10.6 Hazardous decomposition products

In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Oral: No data available

Inhalation: No data available

Dermal: No data available

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

No data available

Carcinogenicity

IARC: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

NTP: No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

Reproductive toxicity

No data available

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

11.2 Additional Information

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

SECTION 12: Ecological information**12.1 Toxicity**

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Endocrine disrupting properties

No data available

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Waste material must be disposed of in accordance with the national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself. See www.retrologistik.com for processes regarding the return of chemicals and containers, or contact us there if you have further questions.

SECTION 14: Transport information

DOT (US)

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

Further information

Not classified as dangerous in the meaning of transport regulations.

SECTION 15: Regulatory information

SARA 302 Components

This material does not contain any components with a section 302 EHS TPQ.

SARA 313 Components

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards

Acute Health Hazard

Massachusetts Right To Know Components

No components are subject to the Massachusetts Right to Know Act.

SECTION 16: Other information

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See

www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

Copyright 2020 Sigma-Aldrich Co. LLC. License granted to make unlimited paper copies for internal use only.

The branding on the header and/or footer of this document may temporarily not visually match the product purchased as we transition our branding. However, all of the information in the document regarding the product remains unchanged and matches the product ordered. For further information please contact mlsbranding@sial.com.

Version: 6.1

Revision Date: 06/21/2022

Print Date: 08/09/2022



SAFETY DATA SHEET

Revision date 17-Apr-2024

Version 1

Page 1 / 9

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name PF-08015237
Product Code(s) PF00835
Trade Name: Not established
Chemical Family: Not determined

PF-08015237
CAS No -

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical process intermediate

1.3. Details of the supplier of the safety data sheet

Pfizer Research and Development
445 Eastern Point Road
Groton, CT USA
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous according to Regulation (EC) 1272/2008 and/or other applicable regulations.

OSHA Classification
Physical Hazard

Combustible Dust

2.2. Label elements

Signal word

(OSHA) Warning

Hazard statements

OSHA - May form combustible dust concentrations in air

Supplemental Hazard

Compound, not fully tested, hazards unknown.

2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for this substance (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the

SAFETY DATA SHEET

Product Name PF-08015237
Revision date 17-Apr-2024

Page 2 / 9
Version 1

potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
PF-08015237 (CAS #: -)	100		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate
No information available

Additional information Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects No data available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

SAFETY DATA SHEET

Product Name PF-08015237
Revision date 17-Apr-2024

Page 3 / 9
Version 1

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO₂, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Formation of toxic gases is possible during heating or fire.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Contain the source of the spill or leak. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean spill area thoroughly.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

SAFETY DATA SHEET

Product Name PF-08015237
Revision date 17-Apr-2024

Page 4 / 9
Version 1

7.3. Specific end use(s)

Specific use(s) Pharmaceutical process intermediate.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

PF-08015237

Pfizer Occupational Exposure Band (OEB):

OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m³ to < 100ug/m³)

8.2. Exposure controls

Engineering controls

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

Environmental exposure controls

No information available.

Personal protective equipment

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Eye/face protection

Wear safety goggles as minimum protection. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection

Wear 2 layers of impervious disposable gloves (e.g. Nitrile, etc.) to prevent skin contact. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection

Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection

Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

SAFETY DATA SHEET

Product Name PF-08015237
Revision date 17-Apr-2024

Page 5 / 9
Version 1

Physical state Solid
Color White
Odor No information available.
Odor threshold No information available
Molecular formula C27 H25 Br N2 O6
Molecular weight 553.41

Property

pH No data available
Melting point / freezing point 137 - 139
Boiling point / boiling range
Flash point No information available
Evaporation rate No data available
Flammability (solid, gas) No data available
Flammability Limit in Air
Upper flammability limit: No data available
Lower flammability limit: No data available

Vapor pressure No data available
Vapor density No data available
Relative density No data available
Water solubility No data available
Solubility(ies) Tetrahydrofuran, Dichloromethane, Dimethylsulfoxide, Dimethylacetamide, Dimethylformamide
Partition coefficient No data available
Autoignition temperature No data available
Decomposition temperature No data available
Kinematic viscosity No data available
Dynamic viscosity No data available
Particle characteristics
Particle Size No information available
Particle Size Distribution No information available
Explosive properties No information available

Partition Coefficient: (Method, pH, Endpoint, Value)

PF-08015237

Predicted 7.4 Log D 4.058

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

DSC:

Endotherm of 80 J/g at 127 °C and 26 J/g at 155 °C. Exotherm of -138 J/g at 200 °C and -110 J/g at 274 °C.

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

SAFETY DATA SHEET

Product Name PF-08015237
Revision date 17-Apr-2024

Page 6 / 9
Version 1

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information:	Toxicological properties have not been investigated.
Acute toxicity	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

Carcinogenicity Not listed as a carcinogen by IARC, NTP or US OSHA.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: May persist in the aquatic environment. Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated.

12.1. Toxicity

No information available

SAFETY DATA SHEET

Product Name PF-08015237
Revision date 17-Apr-2024

Page 7 / 9
Version 1

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Partition Coefficient: (Method, pH, Endpoint, Value)

PF-08015237

Predicted 7.4 Log D 4.058

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental Hazard(s):	Not applicable

Special precautions for user:	Not applicable
Additional Information	Transportation classification is based on data and/or procedures that may not be reflected on this document. The classification was conducted as per defining criteria in the

SAFETY DATA SHEET

Product Name PF-08015237
Revision date 17-Apr-2024

Page 8 / 9
Version 1

international transportation regulations and the shipper's knowledge of the material.

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

PF-08015237

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Data Sources: Pfizer proprietary drug development information.

Reason for revision New data sheet.

Revision date 17-Apr-2024

Prepared By Pfizer Global Environment, Health, and Safety

SAFETY DATA SHEET

Product Name PF-08015237
Revision date 17-Apr-2024

Page 9 / 9
Version 1

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.



SAFETY DATA SHEET

Revision date 06-Sep-2023

Version 3.01

Page 1 / 9

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name PF-07220060
Product Code(s) PZ03955
Trade Name: Not established
Compound Number VC-001139631
Chemical Family: Not determined
PF-07220060
CAS No PROPRIETARY

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical active

1.3. Details of the supplier of the safety data sheet

Pfizer Research and Development
445 Eastern Point Road
Groton, CT USA
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous according to Regulation (EC) 1272/2008 and/or other applicable regulations.

OSHA Classification
Physical Hazard

Combustible Dust

2.2. Label elements

Signal word

Warning

Hazard statements

OSHA - May form combustible dust concentrations in air

Supplemental Hazard

High thermal potential. Compound, not fully tested, additional hazards may exist.

2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for this substance (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the

SAFETY DATA SHEET

Product Name PF-07220060
Revision date 06-Sep-2023

Page 2/9
Version 3.01

potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
PF-07220060 (CAS #: PROPRIETARY)	100		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
PF-07220060 PROPRIETARY	>600	No data available	No data available	No data available	No data available

Additional information

Non-hazardous ingredients provided for completeness.
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and No data available

SAFETY DATA SHEET

Product Name PF-07220060
Revision date 06-Sep-2023

Page 3 / 9
Version 3.01

effects

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO₂, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Dust can form an explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Formation of toxic gases is possible during heating or fire. May include oxides of carbon and nitrogen and products of chlorine fluorine

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Remove all sources of ignition. Contain the source of the spill if it is safe to do so. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean spill area thoroughly.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to

SAFETY DATA SHEET

Product Name PF-07220060
Revision date 06-Sep-2023

Page 4 / 9
Version 3.01

the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical active.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

PF-07220060

Pfizer OEL TWA-8 Hr: 20 µg/m³

8.2. Exposure controls

Engineering controls Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Environmental exposure controls No information available.

Personal protective equipment Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Eye/face protection Wear safety glasses as minimum protection. (Safety glasses must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection Wear impervious gloves (e.g. Nitrile, etc.) as minimum protection. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection Wear impervious protective clothing when handling this compound. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	solid
Color	White
Odor	No information available.
Odor threshold	No information available

SAFETY DATA SHEET

Product Name PF-07220060
Revision date 06-Sep-2023

Page 5/9
Version 3.01

Molecular formula C22 H29 Cl F N5 O4
Molecular weight 481.96

Property

pH

Melting point / freezing point

Boiling point / boiling range

Flash point

Evaporation rate

Flammability (solid, gas)

Flammability Limit in Air

Upper flammability limit:

Lower flammability limit:

Vapor pressure

Vapor density

Relative density

Water solubility

Solubility(ies)

Partition coefficient

Autoignition temperature

Decomposition temperature

Kinematic viscosity

Dynamic viscosity

Particle characteristics

Particle Size

Particle Size Distribution

Explosive properties

Values

No data available

No data available

No information available

No data available

No data available

No data available

No data available

No data available

No data available

No data available

0.008 mg/mL (pH 8.91)

Methyl isobutyl ketone, Methyl ethyl ketone, 2-propanol/water (36/65), Methyl ethyl ketone/water (96/4), 1-propanol/water (88/12)

No data available

No data available

No data available

No data available

No data available

No information available

No information available

No information available

Partition Coefficient: (Method, pH, Endpoint, Value)

PF-07220060

Predicted 7.4 Log D 2.454

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

DSC:

Exotherm of -54 J/g at 212 °C and -556 J/g at 284 °C

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity

No data available.

10.2. Chemical stability

Stability

Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

SAFETY DATA SHEET

Product Name PF-07220060
Revision date 06-Sep-2023

Page 6 / 9
Version 3.01

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information:	Toxicological properties have not been thoroughly investigated.
Known Clinical Effects:	Based on clinical trials in humans, possible adverse effects following exposure to this compound may include: neutropenia, diarrhea, hematological effects, nausea, decreased red blood cell count (anemia), thrombocytopenia, vomiting, exhaustion.
Acute toxicity	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

Acute Toxicity: (Species, Route, End Point, Dose)

PF-07220060

Rat Oral Maximally Tolerated Dose > 600 mg/kg
Dog Oral Maximally Tolerated Dose > 80 (BID 40) mg/kg

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

PF-07220060

14 Day(s) Rat Oral 30 mg/kg/day NOAEL Bone marrow, Thymus, Spleen, Male reproductive system, Gastrointestinal System
21 Day(s) Dog Oral 20 (10 BID) mg/kg/day Maximally Tolerated Dose Gastrointestinal system
1 Month(s) Rat Oral 60 mg/kg/day NOAEL Gastrointestinal system, Blood, Male reproductive system
1 Month(s) Dog Oral 100 (50 BID) mg/kg/day NOAEL None identified

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

PF-07220060

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative
In Vitro Micronucleus TK6 cells Negative
In Vivo Micronucleus Rat Equivocal

Carcinogenicity Not listed as a carcinogen by IARC, NTP or US OSHA.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

SAFETY DATA SHEET

Product Name PF-07220060
Revision date 06-Sep-2023

Page 7 / 9
Version 3.01

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated.

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Partition Coefficient: (Method, pH, Endpoint, Value)

PF-07220060

Predicted 7.4 Log D 2.454

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

SAFETY DATA SHEET

Product Name PF-07220060
Revision date 06-Sep-2023

Page 8 / 9
Version 3.01

UN number: Not applicable
UN proper shipping name: Not applicable
Transport hazard class(es): Not applicable
Packing group: Not applicable
Environmental Hazard(s): Not applicable

Special precautions for user: Not applicable

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

PF-07220060

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Data Sources: Pfizer proprietary drug development information.

Reason for revision Updated Section 11 - Toxicology Information.

SAFETY DATA SHEET

Product Name PF-07220060
Revision date 06-Sep-2023

Page 9 / 9
Version 3.01

Revision date 06-Sep-2023

Prepared By Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.



SAFETY DATA SHEET

Revision date 10-Oct-2023

Version 1

Page 1 / 8

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name PF-07229478
Product Code(s) PF00795
Trade Name: Not established
Chemical Family: Not determined
PF-07229478
CAS No 2380323-09-9

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical process intermediate

1.3. Details of the supplier of the safety data sheet

Pfizer Research and Development
445 Eastern Point Road
Groton, CT USA
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous according to Regulation (EC) 1272/2008 and/or other applicable regulations.

OSHA Classification
Physical Hazard

Combustible Dust

2.2. Label elements

Signal word

(OSHA) Warning

Hazard statements

OSHA - May form combustible dust concentrations in air

Supplemental Hazard

Compound, not fully tested, hazards unknown.

2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for this substance (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all

SAFETY DATA SHEET

Product Name PF-07229478
Revision date 10-Oct-2023

Page 2 / 8
Version 1

cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
PF-07229478 (CAS #: 2380323-09-9)	100		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate
No information available

Additional information Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects No data available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

SAFETY DATA SHEET

Product Name PF-07229478
Revision date 10-Oct-2023

Page 3 / 8
Version 1

Suitable Extinguishing Media Dry chemical, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Formation of toxic gases is possible during heating or fire.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Avoid use of a filtered vacuum to clean spills of dry solids. Contain the source of the spill or leak. Clean spill area thoroughly. Collect spilled material by a method that controls dust generation.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Restrict access to work area. Avoid open handling. Ground and bond all bulk transfer equipment. Minimize dust generation. Use process containment, local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eyes, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

7.3. Specific end use(s)

SAFETY DATA SHEET

Product Name PF-07229478
Revision date 10-Oct-2023

Page 4 / 8
Version 1

Specific use(s) Pharmaceutical process intermediate.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

PF-07229478

Pfizer Occupational Exposure Band (OEB):

Default (control exposure to the range of 1ug/m³ to <10ug/m³)

8.2. Exposure controls

Engineering controls

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels to below the OEB range.

Environmental exposure controls

No information available.

Personal protective equipment

Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Eye/face protection

Wear safety glasses as minimum protection. (Safety glasses must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection

Wear impervious gloves (e.g. Nitrile, etc.) if skin contact is possible. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection

Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection

Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state

Solid

Color

White to off-white.

Odor

No information available.

Odor threshold

No information available

Molecular formula

C17 H17 Cl2 F N4 O

SAFETY DATA SHEET

Product Name PF-07229478
Revision date 10-Oct-2023

Page 5 / 8
Version 1

Molecular weight	383.2
Property	Values
pH	No data available
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	Insoluble in water
Solubility(ies)	Methanol, Ethanol, Acetone
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

Partition Coefficient: (Method, pH, Endpoint, Value)

PF-07229478

Predicted 7.4 Log D 3.387

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

DSC:

Endotherm of 16 J/g at 76 °C and 45 J/g at 116 °C. Exotherm of -659 J/g at 218 °C.

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

SAFETY DATA SHEET

Product Name PF-07229478
Revision date 10-Oct-2023

Page 6 / 8
Version 1

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information:	Toxicological properties have not been thoroughly investigated.
Acute toxicity	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

PF-07229478

Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative

Genetic Toxicity Comments: The above genetic toxicity study was a preliminary assay.

Carcinogenicity Not listed as a carcinogen by IARC, NTP or US OSHA.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: May persist in the aquatic environment. Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated.

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

SAFETY DATA SHEET

Product Name PF-07229478
Revision date 10-Oct-2023

Page 7 / 8
Version 1

Bioaccumulation

Partition Coefficient: (Method, pH, Endpoint, Value)

PF-07229478

Predicted 7.4 Log D 3.387

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental Hazard(s):	Not applicable

Special precautions for user: Not applicable
Additional Information Transportation classification is based on data and/or procedures that may not be reflected on this document. The classification was conducted as per defining criteria in the international transportation regulations and the shipper's knowledge of the material.

Section 15: REGULATORY INFORMATION

SAFETY DATA SHEET

Product Name PF-07229478
Revision date 10-Oct-2023

Page 8 / 8
Version 1

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

PF-07229478

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Data Sources: Pfizer proprietary drug development information.

Reason for revision New data sheet.

Revision date 10-Oct-2023

Prepared By Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.



SAFETY DATA SHEET

Revision date 11-Oct-2023

Version 1

Page 1 / 8

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name PF-06821006-09

Product Code(s) PF00786

Trade Name: Not established

Chemical Family: Not determined

PF-06821006-09

CAS No

-

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical process intermediate

1.3. Details of the supplier of the safety data sheet

Pfizer Research and Development
445 Eastern Point Road
Groton, CT USA
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous according to Regulation (EC) 1272/2008 and/or other applicable regulations.

OSHA Classification

Physical Hazard

Combustible Dust

2.2. Label elements

Signal word

(OSHA) Warning

Hazard statements

OSHA - May form combustible dust concentrations in air

Supplemental Hazard

Compound, not fully tested, hazards unknown.

2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for this substance (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all

SAFETY DATA SHEET

Product Name PF-06821006-09
Revision date 11-Oct-2023

Page 2 / 8
Version 1

cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
PF-06821006-09 (CAS #: -)	100		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

No information available

Additional information

- Not Assigned

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects No data available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

SAFETY DATA SHEET

Product Name PF-06821006-09
Revision date 11-Oct-2023

Page 3 / 8
Version 1

Suitable Extinguishing Media Dry chemical, CO₂, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Formation of toxic gases is possible during heating or fire.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Avoid use of a filtered vacuum to clean spills of dry solids. Contain the source of the spill or leak. Clean spill area thoroughly. Collect spilled material by a method that controls dust generation.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical process intermediate.

SAFETY DATA SHEET

Product Name PF-06821006-09
Revision date 11-Oct-2023

Page 4 / 8
Version 1

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

PF-06821006-09

Pfizer Occupational Exposure Band (OEB):

OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m³ to < 100ug/m³)

8.2. Exposure controls

Engineering controls

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels to below the OEB range.

Environmental exposure controls

No information available.

Personal protective equipment

Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Eye/face protection

Wear safety goggles as minimum protection. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection

Wear 2 layers of impervious disposable gloves (e.g. Nitrile, etc.) to prevent skin contact. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection

Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection

Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state

Solid

Color

White

Odor

No information available.

Odor threshold

No information available

Molecular formula

C5 H14 N O6 P

Molecular weight

215.14

SAFETY DATA SHEET

Product Name PF-06821006-09
Revision date 11-Oct-2023

Page 5 / 8
Version 1

<u>Property</u>	<u>Values</u>
pH	No data available
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

DSC: Endotherm of 171 J/g at 185 °C. Exotherm of -306 J/g at 269 °C.

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

 Sensitivity to Mechanical Impact No data available.

 Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

SAFETY DATA SHEET

Product Name PF-06821006-09
Revision date 11-Oct-2023

Page 6 / 8
Version 1

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information:	Toxicological properties have not been investigated.
Acute toxicity	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

Carcinogenicity Not listed as a carcinogen by IARC, NTP or US OSHA.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided. Environmental properties have not been investigated.

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

SAFETY DATA SHEET

Product Name PF-06821006-09
Revision date 11-Oct-2023

Page 7 / 8
Version 1

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental Hazard(s):	Not applicable

Special precautions for user:	Not applicable
Additional Information	Transportation classification is based on data and/or procedures that may not be reflected on this document. The classification was conducted as per defining criteria in the international transportation regulations and the shipper's knowledge of the material.

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

PF-06821006-09	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

SAFETY DATA SHEET

Product Name PF-06821006-09
Revision date 11-Oct-2023

Page 8 / 8
Version 1

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Data Sources: Pfizer proprietary drug development information.

Reason for revision New data sheet.

Revision date 11-Oct-2023

Prepared By Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.



SAFETY DATA SHEET

Revision date 01-Mar-2023

Version 2

Page 1 / 8

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name PF-07227325
Product Code(s) PF00541
Synonyms VC-001163206
Trade Name: Not established
Chemical Family: Not determined

PF-07227325
CAS No 2380323-07-7

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical process intermediate

1.3. Details of the supplier of the safety data sheet

Pfizer Research and Development
445 Eastern Point Road
Groton, CT USA
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous according to Regulation (EC) 1272/2008 and/or other applicable regulations.

OSHA Classification
Physical Hazard

Combustible Dust

2.2. Label elements
Signal word

Warning (OSHA)

Hazard statements

OSHA - May form combustible dust concentrations in air

Supplemental Hazard

Compound, not fully tested, hazards unknown.

2.3. Other hazards
Other hazards

An Occupational Exposure Value has been established for this substance (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the

SAFETY DATA SHEET

Product Name PF-07227325
Revision date 01-Mar-2023

Page 2 / 8
Version 2

potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
PF-07227325 (CAS #: 2380323-07-7)	100		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate
No information available

Additional information Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects No data available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

SAFETY DATA SHEET

Product Name PF-07227325
Revision date 01-Mar-2023

Page 3 / 8
Version 2

Suitable Extinguishing Media Dry chemical, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Formation of toxic gases is possible during heating or fire.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Avoid use of a filtered vacuum to clean spills of dry solids. Contain the source of the spill or leak. Clean spill area thoroughly. Collect spilled material by a method that controls dust generation.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

7.3. Specific end use(s)

SAFETY DATA SHEET

Product Name PF-07227325
Revision date 01-Mar-2023

Page 4 / 8
Version 2

Specific use(s) Pharmaceutical process intermediate.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

PF-07227325

Pfizer Occupational Exposure Band (OEB):

OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m³ to < 100ug/m³)

8.2. Exposure controls

Engineering controls

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels to below the OEB range.

Environmental exposure controls

No information available.

Personal protective equipment

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Eye/face protection

Wear safety goggles as minimum protection. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection

Wear 2 layers of impervious disposable gloves (e.g. Nitrile, etc.) to prevent skin contact. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection

Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection

Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure. (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.) Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state

Solid

Color

White to brown

SAFETY DATA SHEET

Product Name PF-07227325
Revision date 01-Mar-2023

Page 5 / 8
Version 2

Odor No information available.
Odor threshold No information available
Molecular formula C13 H16 Br F N2 O
Molecular weight 315.1813

<u>Property</u>	<u>Values</u>
pH	No data available
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

Partition Coefficient: (Method, pH, Endpoint, Value)

PF-07227325
Predicted 7.4 Log D 3.185

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

DSC: Endotherm of 91 J/g at 96 °C and 46 J/g at 335 °C. Exotherm of -35 J/g at 225 °C and >-589 J/g at 335 °C.

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

SAFETY DATA SHEET

Product Name PF-07227325
Revision date 01-Mar-2023

Page 6 / 8
Version 2

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information:	Toxicological properties have not been investigated.
Acute toxicity	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

Carcinogenicity Not listed as a carcinogen by IARC, NTP or US OSHA.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: May persist in the aquatic environment. Releases to the environment should be avoided. The environmental characteristics of this material have not been fully evaluated.

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

SAFETY DATA SHEET

Product Name PF-07227325
Revision date 01-Mar-2023

Page 7 / 8
Version 2

Partition Coefficient: (Method, pH, Endpoint, Value)

PF-07227325

Predicted 7.4 Log D 3.185

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental Hazard(s):	Not applicable

Special precautions for user:	Not applicable
Additional Information	Transportation classification is based on data and/or procedures that may not be reflected on this document. The classification was conducted as per defining criteria in the international transportation regulations and the shipper's knowledge of the material.

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

SAFETY DATA SHEET

Product Name PF-07227325
Revision date 01-Mar-2023

Page 8 / 8
Version 2

PF-07227325

CERCLA/SARA Section 313 de minimus %
California Proposition 65
EINECS

Not Listed
Not Listed
Not Listed

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Data Sources:	Pfizer proprietary drug development information.
Reason for revision	Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection.
Revision date	01-Mar-2023
Prepared By	Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Version 6.5

Revision Date 16.02.2023

Print Date 07.03.2023

GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifiers**

Product name : 2,4,5-Trichloropyrimidine

Product Number : 652032

Brand : Aldrich

REACH No. : A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

CAS-No. : 5750-76-5

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich Chemical Pvt Limited
Industrial Area, Anekal Taluka
Plot No 12,
12 Bommasandra - Jigani Link Road
560100 BANGALORE
INDIA

1.4 Emergency telephone

Emergency Phone # : +91 98802 05043

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification according to Regulation (EC) No 1272/2008**

Skin irritation (Category 2), H315

Eye irritation (Category 2), H319

Specific target organ toxicity - single exposure (Category 3), Respiratory system, H335

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 Label elements**Labelling according Regulation (EC) No 1272/2008**

Pictogram



Signal Word

Warning



Hazard statement(s)	
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
Precautionary statement(s)	
P261	Avoid breathing mist or vapors.
P264	Wash skin thoroughly after handling.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves/ eye protection/ face protection.
P302 + P352	IF ON SKIN: Wash with plenty of water.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Supplemental Hazard Statements	none

Reduced Labeling (<= 125 ml)

Pictogram



Signal Word	Warning
Hazard statement(s)	none
Precautionary statement(s)	none
Supplemental Hazard Statements	none

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
Lachrymator.

SECTION 3: Composition/information on ingredients

3.1 Substances

Formula	: C ₄ HCl ₃ N ₂
Molecular weight	: 183,42 g/mol
CAS-No.	: 5750-76-5

Component	Classification	Concentration
2,4,5-Trichloropyrimidine		
CAS-No. 5750-76-5	Skin Irrit. 2; Eye Irrit. 2; STOT SE 3; H315, H319, H335	<= 100 %

For the full text of the H-Statements mentioned in this Section, see Section 16.



SECTION 4: First aid measures

4.1 Description of first-aid measures

General advice

Show this material safety data sheet to the doctor in attendance.

If inhaled

After inhalation: fresh air.

In case of skin contact

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower.

In case of eye contact

After eye contact: rinse out with plenty of water. Call in ophthalmologist. Remove contact lenses.

If swallowed

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water Foam Carbon dioxide (CO₂) Dry powder

Unsuitable extinguishing media

For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

Carbon oxides

Nitrogen oxides (NO_x)

Combustible.

Vapors are heavier than air and may spread along floors.

Forms explosive mixtures with air on intense heating.

Development of hazardous combustion gases or vapours possible in the event of fire.

5.3 Advice for firefighters

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

5.4 Further information

Suppress (knock down) gases/vapors/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system.



SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Do not breathe vapors, aerosols. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.
For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent material (e.g. Chemizorb®). Dispose of properly. Clean up affected area.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Tightly closed.

Storage class

Storage class (TRGS 510): 10: Combustible liquids

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with workplace control parameters

8.2 Exposure controls

Personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses

Skin protection

required

Body Protection

protective clothing

Respiratory protection

required when vapours/aerosols are generated.

Our recommendations on filtering respiratory protection are based on the following standards: DIN EN 143, DIN 14387 and other accompanying standards relating to the used respiratory protection system.



Recommended Filter type: Filter type ABEK

The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

Control of environmental exposure

Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Physical state	liquid
b) Color	colorless
c) Odor	No data available
d) Melting point/freezing point	No data available
e) Initial boiling point and boiling range	No data available
f) Flammability (solid, gas)	No data available
g) Upper/lower flammability or explosive limits	No data available
h) Flash point	> 109,9 °C
i) Autoignition temperature	No data available
j) Decomposition temperature	No data available
k) pH	No data available
l) Viscosity	Viscosity, kinematic: No data available Viscosity, dynamic: No data available
m) Water solubility	No data available
n) Partition coefficient: n-octanol/water	No data available
o) Vapor pressure	No data available
p) Density	1,6001 g/cm ³ at 25 °C - lit.
Relative density	No data available
q) Relative vapor density	No data available
r) Particle characteristics	No data available
s) Explosive properties	No data available



t) Oxidizing properties No data available

9.2 Other safety information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Forms explosive mixtures with air on intense heating.
A range from approx. 15 Kelvin below the flash point is to be rated as critical.

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature) .

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

Strong heating.

10.5 Incompatible materials

Strong oxidizing agents Strong oxidizing agents, Strong acids

10.6 Hazardous decomposition products

In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Oral: No data available
Inhalation: No data available
Dermal: No data available

Skin corrosion/irritation

Remarks: No data available

Serious eye damage/eye irritation

Remarks: No data available

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

No data available

Carcinogenicity

No data available

Reproductive toxicity

No data available

Specific target organ toxicity - single exposure

Inhalation - May cause respiratory irritation.

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available



11.2 Additional Information

Endocrine disrupting properties

Product:

Assessment

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

burning sensation, Cough, wheezing, laryngitis, Shortness of breath, Headache, Nausea, Vomiting, To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

SECTION 12: Ecological information

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

No data available

SECTION 14: Transport information

14.1 UN number

ADR/RID: -

IMDG: -

IATA: 3334

Aldrich- 652032

Page 7 of 9

The life science business of Merck operates as MilliporeSigma in the US and Canada



14.2 UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Aviation regulated liquid, n.o.s. (2,4,5-Trichloropyrimidine)

14.3 Transport hazard class(es)

ADR/RID: -

IMDG: -

IATA: 9

14.4 Packaging group

ADR/RID: -

IMDG: -

IATA: III

14.5 Environmental hazards

ADR/RID: no

IMDG Marine pollutant: no

IATA: no

14.6 Special precautions for user

No data available

Further information : No data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

Other regulations

Take note of Dir 94/33/EC on the protection of young people at work.

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

SECTION 16: Other information

Full text of H-Statements referred to under sections 2 and 3.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 Causes skin irritation.



Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

Copyright 2020 Sigma-Aldrich Co. LLC. License granted to make unlimited paper copies for internal use only.

The branding on the header and/or footer of this document may temporarily not visually match the product purchased as we transition our branding. However, all of the information in the document regarding the product remains unchanged and matches the product ordered. For further information please contact mlsbranding@sial.com.



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Version 6.3

Revision Date 24.08.2021

Print Date 13.11.2021

GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifiers**

Product name : Bis(neopentyl glycolato)diboron

Product Number : 518808

Brand : Aldrich

REACH No. : A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

CAS-No. : 201733-56-4

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich Chemical Pvt Limited
Industrial Area, Anekal Taluka
Plot No 12,
12 Bommasandra - Jigani Link Road
560100 BANGALORE
INDIA

1.4 Emergency telephone

Emergency Phone # : +91 98802 05043

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture**

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.

2.2 Label elements

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.

2.3 Other hazards - none**SECTION 3: Composition/information on ingredients****3.1 Substances**

Aldrich- 518808

Page 1 of 7

The life science business of Merck operates as MilliporeSigma in the US and Canada



Synonyms : 5,5,5',5'-Tetramethyl-2,2'-bi-1,3,2-dioxaborinane

Formula : C₁₀H₂₀B₂O₄

Molecular weight : 225,89 g/mol

CAS-No. : 201733-56-4

No components need to be disclosed according to the applicable regulations.

SECTION 4: First aid measures

4.1 Description of first-aid measures

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration.

In case of skin contact

Wash off with soap and plenty of water.

In case of eye contact

Flush eyes with water as a precaution.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Carbon oxides

Borane/boron oxides

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

No data available

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Avoid breathing vapors, mist or gas.

For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains.



6.3 Methods and materials for containment and cleaning up

Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on protection against fire and explosion

Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

Hygiene measures

General industrial hygiene practice.
For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

Handle and store under inert gas.

Storage class

Storage class (TRGS 510): 13: Non Combustible Solids

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with workplace control parameters

8.2 Exposure controls

Personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

Body Protection

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place., The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.



Respiratory protection

Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- | | |
|---|--|
| a) Appearance | Form: solid |
| b) Odor | No data available |
| c) Odor Threshold | No data available |
| d) pH | No data available |
| e) Melting point/freezing point | Melting point/range: 180,5 - 184,5 °C |
| f) Initial boiling point and boiling range | No data available |
| g) Flash point | No data available |
| h) Evaporation rate | No data available |
| i) Flammability (solid, gas) | No data available |
| j) Upper/lower flammability or explosive limits | No data available |
| k) Vapor pressure | No data available |
| l) Vapor density | No data available |
| m) Density | No data available |
| Relative density | No data available |
| n) Water solubility | No data available |
| o) Partition coefficient: n-octanol/water | No data available |
| p) Autoignition temperature | No data available |
| q) Decomposition temperature | No data available |
| r) Viscosity | Viscosity, kinematic: No data available
Viscosity, dynamic: No data available |
| s) Explosive properties | No data available |
| t) Oxidizing properties | No data available |

9.2 Other safety information

No data available



SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

Strong oxidizing agents

10.6 Hazardous decomposition products

In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Oral: No data available

Inhalation: No data available

Dermal: No data available

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

No data available

Carcinogenicity

No data available

Reproductive toxicity

No data available

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

11.2 Additional Information

No data available



SECTION 12: Ecological information

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging

Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADR/RID: -

IMDG: -

IATA: -

14.2 UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: -

IMDG: -

IATA: -

14.4 Packaging group

ADR/RID: -

IMDG: -

IATA: -

14.5 Environmental hazards

ADR/RID: no

IMDG Marine pollutant: no

IATA: no

14.6 Special precautions for user

Further information

Not classified as dangerous in the meaning of transport regulations.



SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

International Chemical Weapons Convention :
(CWC) Schedules of Toxic Chemicals and
Precursors

Restrictions on the marketing and use of certain :
dangerous substances

Regulation (EC) No 649/2012 of the European :
Parliament and the Council concerning the
export and import of dangerous chemicals

Candidate List of Substances of Very High :
Concern for Authorisation

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

SECTION 16: Other information

Further information

Copyright 2020 Sigma-Aldrich Co. LLC. License granted to make unlimited paper copies for internal use only.

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

The branding on the header and/or footer of this document may temporarily not visually match the product purchased as we transition our branding. However, all of the information in the document regarding the product remains unchanged and matches the product ordered. For further information please contact mlsbranding@sial.com.





SAFETY DATA SHEET

Revision date: 27-Aug-2019

Version: 1.0

Page 1 of 6

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: PF-06873286-15

Trade Name: Not established

Chemical Family: Not determined

CAS Number Proprietary

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against Intended Use: Pharmaceutical process intermediate

Details of the Supplier of the Safety Data Sheet

Pfizer Worldwide Research & Development
445 Eastern Point Road
Groton, Connecticut
USA
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:

Chemtrec (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:

International Chemtrec (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

Label Elements

Signal Word: Warning

Hazard Statements: May form combustible dust concentrations in air

Precautionary Statements: P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking

Supplemental Hazards: Very high thermal potential.
Compound, not fully tested, additional hazards may exist.

Other Hazards

An Occupational Exposure Value has been established for this substance (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

SAFETY DATA SHEET

Material Name: PF-06873286-15
Revision date: 27-Aug-2019

Page 2 of 6
Version: 1.0

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
PF-06873286-15	Proprietary	Not Listed	Not Listed	100

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. FIRST AID MEASURES

Description of First Aid Measures

- Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

- Symptoms and Effects of Exposure:** No data available
- Medical Conditions Aggravated by Exposure:** None known

Indication of the Immediate Medical Attention and Special Treatment Needed

- Notes to Physician:** None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

- Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire. May include oxides of carbon and nitrogen and products of sulfur and fluorine.
- Fire / Explosion Hazards:** Dust can form an explosive mixture in air. During processing, dust may form explosive mixture in air.

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

SAFETY DATA SHEET

Material Name: PF-06873286-15
Revision date: 27-Aug-2019

Page 3 of 6
Version: 1.0

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of the spill if it is safe to do so. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

Specific end use(s): Pharmaceutical process intermediate

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

PF-06873286-15

Pfizer Occupational Exposure Band (OEB): OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m³ to < 100ug/m³)

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Wear 2 layers of impervious disposable gloves (e.g. Nitrile, etc.) to prevent skin contact. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety goggles as minimum protection. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

SAFETY DATA SHEET

Material Name: PF-06873286-15
Revision date: 27-Aug-2019

Page 4 of 6
Version: 1.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solid	Color:	White
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	C32 H34 F N3 O7 S2	Molecular Weight:	655.77

Solvent Solubility:	No data available
Water Solubility:	No data available
pH:	No data available.
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)	

PF-06873286-15

No data available

Decomposition Temperature (°C):	No data available.
--	--------------------

Evaporation Rate (Gram/s):	No data available
Vapor Pressure (kPa):	No data available
Vapor Density (g/ml):	No data available
Relative Density:	No data available
Viscosity:	No data available

Flammability:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: Toxicological properties have not been investigated.

SAFETY DATA SHEET

Material Name: PF-06873286-15
Revision date: 27-Aug-2019

Page 5 of 6
Version: 1.0

11. TOXICOLOGICAL INFORMATION

Carcinogen Status: Not listed as a carcinogen by IARC, NTP or US OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided. Environmental properties have not been investigated.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

PF-06873286-15	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

SAFETY DATA SHEET

Material Name: PF-06873286-15
Revision date: 27-Aug-2019

Page 6 of 6
Version: 1.0

15. REGULATORY INFORMATION

16. OTHER INFORMATION

Data Sources: Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 5 - Fire Fighting Measures.
Updated Section 8 - Exposure Controls / Personal Protection. Added Pfizer OEB (Section 8).

Revision date: 27-Aug-2019
Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet



SAFETY DATA SHEET

Revision date 07-Sep-2023

Version 7

Page 1 / 10

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name PF-06878031
Product Code(s) PZ03509
Trade Name: Not established
Chemical Family: Not determined

Contains

PF-06878031
CAS No 2230200-76-5

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical process intermediate

1.3. Details of the supplier of the safety data sheet

Pfizer Research and Development
445 Eastern Point Road
Groton, CT USA
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

Skin corrosion/irritation	Category 2 - (H315)
Serious eye damage/eye irritation	Category 1 - (H318)
Skin sensitization	Category 1 - (H317)
Acute aquatic toxicity	Category 3 - (H402)
Chronic aquatic toxicity	Category 2 - (H411)

OSHA Classification
Physical Hazard Combustible Dust

2.2. Label elements

Signal word Danger

Hazard statements
H315 - Causes skin irritation
H318 - Causes serious eye damage
H317 - May cause an allergic skin reaction

SAFETY DATA SHEET

Product Name PF-06878031
Revision date 07-Sep-2023

Page 2 / 10
Version 7

H411 - Toxic to aquatic life with long lasting effects
OSHA - May form combustible dust concentrations in air

Precautionary Statements

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P264 - Wash face, hands and any exposed skin thoroughly after handling
P272 - Contaminated work clothing should not be allowed out of the workplace
P273 - Avoid release to the environment
P280 - Wear eye protection/ face protection
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/physician
P391 - Collect spillage
P501 - Dispose of contents/container in accordance with all local and national regulations
Very high thermal potential. Compound, not fully tested, additional hazards may exist.

Supplemental Hazard



2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for this substance (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
PF-06878031 (CAS #: 2230200-76-5)	100		Not Listed	Skin Irrit.2 (H315) Skin Sens 1 (H317) Eye Dam.1 (H318) Aquatic Acute 3 (H412) Aquatic Chronic 2 (H411)	Not Listed	No data available	No data available

Full text of H- and EUH-phrases: see section 16

SAFETY DATA SHEET

Product Name PF-06878031
Revision date 07-Sep-2023

Page 3 / 10
Version 7

Acute Toxicity Estimate

No information available

Additional information

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects No data available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Dust can form an explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Formation of toxic gases is possible during heating or fire. May include oxides of carbon and nitrogen and products of chlorine

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

SAFETY DATA SHEET

Product Name PF-06878031
Revision date 07-Sep-2023

Page 4 / 10
Version 7

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.
Methods for cleaning up Contain the source of the spill if it is safe to do so. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean spill area thoroughly.
Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Avoid open handling. Ground and bond all bulk transfer equipment. Minimize dust generation. Use process containment, local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store at 2 - 8 °C in properly labeled containers. Store in properly labeled containers. Keep away from heat, sparks, and flames.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical process intermediate.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

PF-06878031

Pfizer Occupational Exposure Band (OEB):

OEB 3 - Severe Eye Irritant, Sensitizer (control exposure to the range of 10ug/m³ to < 100ug/m³, provide additional precautions to protect from skin contact)

8.2. Exposure controls

Engineering controls

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

SAFETY DATA SHEET

Product Name PF-06878031
Revision date 07-Sep-2023

Page 5 / 10
Version 7

Environmental exposure controls	No information available.
Personal protective equipment	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Eye/face protection	Wear safety goggles as minimum protection. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).
Hand protection	Wear 2 layers of impervious disposable gloves (e.g. Nitrile, etc.) to prevent skin contact. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).
Skin and body protection	Wear impervious disposable protective clothing to prevent skin contact. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).
Respiratory protection	Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	solid
Color	White
Odor	No information available.
Odor threshold	No information available
Molecular formula	C14 H15 Cl N2 O3
Molecular weight	294.74
Property	Values
pH	No data available
Melting point / freezing point	118.4 - 120 °C
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	1.2368 g/cm ³
Water solubility	0.64 g/L (20 °C) (pH 6.4)
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available

SAFETY DATA SHEET

Product Name PF-06878031
Revision date 07-Sep-2023

Page 6 / 10
Version 7

Dynamic viscosity No data available
Particle characteristics
Particle Size No information available
Particle Size Distribution No information available
Explosive properties No information available

Partition Coefficient: (Method, pH, Endpoint, Value)

PF-06878031
Predicted 7.4 Log D 1.601
Measured Log P 1.12

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

Self-reactive substances and mixtures

SADT (°C)

Not a Division 4.1 material
> 75 UN Recommendations on the Transport of Dangerous Goods, Model Regulations Manual of Tests and Criteria Test H.4: Heat accumulation storage test

9.2.2. Other safety characteristics

DSC:

Exotherm of -1369 J/g at 133 °C.

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information: Toxicological properties have not been thoroughly investigated.
Acute toxicity Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation Causes serious eye damage.
Skin corrosion/irritation Causes skin irritation.
Respiratory or skin sensitization May cause an allergic skin reaction.
STOT - single exposure Based on available data, the classification criteria are not met.
STOT - repeated exposure Based on available data, the classification criteria are not met.

SAFETY DATA SHEET

Product Name PF-06878031
Revision date 07-Sep-2023

Page 7 / 10
Version 7

Reproductive toxicity Based on available data, the classification criteria are not met.
Germ cell mutagenicity Based on available data, the classification criteria are not met.
Carcinogenicity Based on available data, the classification criteria are not met.
Aspiration hazard Based on available data, the classification criteria are not met.

Irritation / Sensitization: (Study Type, Species, Severity)

PF-06878031

Skin Corrosivity (*In vitro* , RHE) Not applicable Negative
Skin Sensitization (*In chemico* , DPRA) Not applicable Positive
Sensitization (*In vitro* , KeratinoSens) Not applicable Positive
Skin Irritation (*In vitro* , RhE) Not applicable Positive
Skin Sensitization - LLNA Mouse Positive
Eye Irritation Rabbit Severe

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

PF-06878031

Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Positive
Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vitro Chromosome Aberration Hamster Lung Cells Negative
In Vivo Micronucleus Mouse Bone Marrow Negative
In Vitro Mammalian Cell Mutagenicity Mouse Lymphoma Negative

Carcinogenicity Not listed as a carcinogen by IARC, NTP or US OSHA.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated. Harmful to aquatic organisms Toxic to aquatic life with long lasting effects

12.1. Toxicity

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

PF-06878031

Pseudokirchneriella subcapitata (Green Alga) OECD ErC50 72 hours 12 mg/L
Pseudokirchneriella subcapitata (Green Alga) OECD NOEC 72 hours 0.116 mg/L
Daphnia Magna (Water Flea) OECD EC50 48 hours 29.8 mg/L
Gobiocypris rarus Rare Minnow OECD LC50 96 hours 2.82 mg/L

12.2. Persistence and degradability

Persistence and degradability

Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

PF-06878031

OECD Activated sludge Ultimate (CO2 Evolution) 0 % in 28 Day(s) Not readily biodegradable

SAFETY DATA SHEET

Product Name PF-06878031
Revision date 07-Sep-2023

Page 8 / 10
Version 7

12.3. Bioaccumulative potential

Bioaccumulation

Partition Coefficient: (Method, pH, Endpoint, Value)

PF-06878031

Predicted 7.4 Log D 1.601

Measured Log P 1.12

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

This material is regulated for transportation as a hazardous material/dangerous good.

UN number: UN 3077
UN proper shipping name: Environmentally Hazardous Substance, Solid, n.o.s (Methyl (S)-2-(chloromethyl)-1-((oxetan-2-yl)methyl)-1H-benzo[d]imidazole-6-carboxylate)
Transport hazard class(es): 9
Packing group: III
Environmental Hazard(s): Marine Pollutant

5 kg/5L Exception:

UN3082 and UN3077 materials contained in good quality packaging in the quantities listed below are not subject to the dangerous goods transportation regulations by any mode:

* Single packagings containing a net quantity of 5 liters or less for liquids or a net mass of 5 kg or less for solids.

* Combination packagings containing a net quantity per inner packaging of 5 liters or less for liquids or a net mass of 5 kg or less for solids.

Special precautions for user: Not applicable

SAFETY DATA SHEET

Product Name PF-06878031
Revision date 07-Sep-2023

Page 9 / 10
Version 7

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

PF-06878031

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

Skin corrosion/irritation-Cat.2; H315 - Causes skin irritation. Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction. Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage. Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life. Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects.

Data Sources:

Pfizer proprietary drug development information.

Reason for revision

Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 14 - Transport Information.

SAFETY DATA SHEET

Product Name PF-06878031
Revision date 07-Sep-2023

Page 10 / 10
Version 7

Revision date 07-Sep-2023

Prepared By Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.



SAFETY DATA SHEET

Revision date 21-Mar-2024

Version 5

Page 1 / 9

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name PF-06882961-82
Product Code(s) PZ03449
Synonyms Danuglipron; PF-06882961 tromethamine; Danuglipron tromethamine
Trade Name: Not established
Chemical Family: Not determined
PF-06882961-82
CAS No 2230198-03-3
REACH Registration Number -

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical active

1.3. Details of the supplier of the safety data sheet

Pfizer Research and Development
445 Eastern Point Road
Groton, CT USA
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous according to Regulation (EC) 1272/2008 and/or other applicable regulations.

OSHA Classification
Physical Hazard Combustible Dust

2.2. Label elements

Signal word Warning

Hazard statements OSHA - May form combustible dust concentrations in air

Supplemental Hazard Very high sensitivity to ignition. Compound, not fully tested, additional hazards may exist.

2.3. Other hazards

Other hazards An Occupational Exposure Value has been established for this substance (see Section 8).

Note: This document has been prepared in accordance with standards for workplace safety, which

SAFETY DATA SHEET

Product Name PF-06882961-82
Revision date 21-Mar-2024

Page 2 / 9
Version 5

require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
PF-06882961-82 (CAS #: 2230198-03-3)	100	-	Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate
No information available

Additional information

- Not Assigned

Non-hazardous ingredients provided for completeness. Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

SAFETY DATA SHEET

Product Name PF-06882961-82
Revision date 21-Mar-2024

Page 3 / 9
Version 5

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Very high sensitivity of a dust cloud to ignition, based on minimum ignition energy. Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Formation of toxic gases is possible during heating or fire. May include oxides of carbon and nitrogen

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Contain the source of the spill if it is safe to do so. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids, due to the potential for electrostatic discharge and the strong dust explosion potential and very high sensitivity to ignition. Clean spill area thoroughly.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. All conductive elements of the system that contact the dry substance should be properly bonded and grounded and equipped with proper explosion relief or suppression systems. This material should not be flowed through nonconductive ducts or pipes because of the potential for electrostatic discharge ignition. Restricting the use of high resistivity materials, such as plastics, should be considered. Use process containment, local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

SAFETY DATA SHEET

Product Name PF-06882961-82
Revision date 21-Mar-2024

Page 4 / 9
Version 5

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical active.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

PF-06882961-82

Pfizer Occupational Exposure Band (OEB):

OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m³ to < 100ug/m³)

8.2. Exposure controls

Engineering controls Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

Environmental exposure controls No information available.

Personal protective equipment Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Eye/face protection Wear safety goggles as minimum protection. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection Wear 2 layers of impervious disposable gloves (e.g. Nitrile, etc.) to prevent skin contact. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

SAFETY DATA SHEET

Product Name PF-06882961-82
Revision date 21-Mar-2024

Page 5 / 9
Version 5

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	solid
Color	White
Odor	No information available.
Odor threshold	No information available
Molecular formula	C31 H30 F N5 O4 . C4 H11 N O3
Molecular weight	676.73

<u>Property</u>	<u>Values</u>
pH	No data available
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available

Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	~1 mg/mL (25 °C)
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

Partition Coefficient: (Method, pH, Endpoint, Value)

PF-06882961

Predicted 7.4 Log D 0.999

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

Formation of explosive dust/air mixtures

Minimum Ignition Energy (mJ)

6

Milled to:

97.06% < 63 µm

As Received:

d10 - 4.349

d50 - 36.423

d90 - 101.338

% < 500 µm - 100.00

% < 200 µm - 100.00

% < 63 µm - 72.36

DSC:

Endotherm of 86.67 J/g at 158 °C, Exotherm of -750.10 J/g at 158

SAFETY DATA SHEET

Product Name PF-06882961-82
Revision date 21-Mar-2024

Page 6 / 9
Version 5

°C. Medium thermal potential.

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge Very high sensitivity to ignition.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information:

Toxicological properties have not been thoroughly investigated.

Known Clinical Effects:

Based on clinical trials in humans, possible adverse effects following exposure to this compound may include: nausea, vomiting, headache, difficult digestion (dyspepsia), diarrhea, lack of appetite.

Acute toxicity

Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation

Based on available data, the classification criteria are not met.

Skin corrosion/irritation

Based on available data, the classification criteria are not met.

Respiratory or skin sensitization

Based on available data, the classification criteria are not met.

STOT - single exposure

Based on available data, the classification criteria are not met.

STOT - repeated exposure

Based on available data, the classification criteria are not met.

Reproductive toxicity

Based on available data, the classification criteria are not met.

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

Carcinogenicity

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Acute Toxicity: (Species, Route, End Point, Dose)

PF-06882961

Non-human Primate Oral Maximally Tolerated Dose 500 mg/kg

Non-human Primate Subcutaneous NOAEL 5 mg/kg

Safety Pharmacology:

PF-06882961: *In vivo* Cardiovascular increased blood pressure and decreased QT interval (25 mg/kg or greater)

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

PF-06882961-82

1 Month(s) Rat Oral 250 mg/kg/day NOAEL Heart, Gastrointestinal System, Thymus

1 Month(s) Rat Oral 500 mg/kg/day NOAEL None identified

6 Month(s) Rat Oral 250 mg/kg/day NOAEL Eyes

6 Week(s) Monkey Oral 100 mg/kg/day NOAEL None identified

SAFETY DATA SHEET

Product Name PF-06882961-82
Revision date 21-Mar-2024

Page 7 / 9
Version 5

14 Week(s) Monkey Oral 100 mg/kg/day NOEL Gastrointestinal system
9 Month(s) Monkey Oral 150 mg/kg/day NOEL None identified

PF-06882961

21 Day(s) Rat Oral 500 mg/kg/day NOEL None identified
21 Day(s) Monkey Oral 50 (25 BID) mg/kg/day Maximally Tolerated Dose Gastrointestinal system
6 Month(s) Monkey Oral 50 mg/kg/day LOAEL Heart, Kidney
3 Month(s) Rat Oral 150 mg/kg/day NOEL None identified

Repeated Dose Toxicity Comments: PF-06882961: The above repeated dose toxicity studies (21 Day Oral Rat and 21 Day Oral Monkey) are based on preliminary information.

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

PF-06882961-82

Embryo / Fetal Development Rat Oral 500 mg/kg/day NOEL No effects at maximum dose
Embryo / Fetal Development Rabbit Oral 250 mg/kg/day NOEL No effects at maximum dose
Reproductive & Fertility Rat Oral 500 mg/kg/day No effects at maximum dose

PF-06882961

Reproductive & Fertility-Males Rat Oral 500 mg/kg/day NOEL No effects at maximum dose

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

PF-06882961

In Vitro Micronucleus TK6 Cells Positive
In Vivo Micronucleus Rat Bone Marrow Negative
Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

Genetic Toxicity Comments: PF-06882961: The above genetic toxicity study (*In Vitro* Micronucleus) was a preliminary assay.

Carcinogenicity Not listed as a carcinogen by IARC, NTP or US OSHA.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated. Based on available data, the classification criteria are not met.

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Partition Coefficient: (Method, pH, Endpoint, Value)

PF-06882961

Predicted 7.4 Log D 0.999

SAFETY DATA SHEET

Product Name PF-06882961-82
Revision date 21-Mar-2024

Page 8 / 9
Version 5

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental Hazard(s):	Not applicable

Special precautions for user:	Not applicable
Additional Information	Transportation classification is based on data and/or procedures that may not be reflected on this document. The classification was conducted as per defining criteria in the international transportation regulations and the shipper's knowledge of the material.

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

PF-06882961-82	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed

SAFETY DATA SHEET

Product Name PF-06882961-82
Revision date 21-Mar-2024

Page 9 / 9
Version 5

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Data Sources:	Pfizer proprietary drug development information.
Reason for revision	Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 3 - Composition / Information on Ingredients.
Revision date	21-Mar-2024
Prepared By	Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.



SAFETY DATA SHEET

Revision date: 27-Aug-2019

Version: 2.0

Page 1 of 6

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: PF-06877636

Trade Name: Not established

Chemical Family: Not determined

CAS Number 2230201-28-0

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against Intended Use: Pharmaceutical process intermediate

Details of the Supplier of the Safety Data Sheet

Pfizer Worldwide Research & Development
445 Eastern Point Road
Groton, Connecticut
USA
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International Chemtrec (24 hours): +1-703-527-3887

Emergency telephone number:

Chemtrec (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

Label Elements

Signal Word: Warning

Hazard Statements: May form combustible dust concentrations in air

Supplemental Hazards: Compound, not fully tested, hazards unknown.

Other Hazards

An Occupational Exposure Value has been established for this substance (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

SAFETY DATA SHEET

Material Name: PF-06877636
Revision date: 27-Aug-2019

Page 2 of 6
Version: 2.0

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
PF-06877636	2230201-28-0	Not Listed	Not Listed	100

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. FIRST AID MEASURES

Description of First Aid Measures

- Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

- Symptoms and Effects of Exposure:** No data available
- Medical Conditions Aggravated by Exposure:** None known

Indication of the Immediate Medical Attention and Special Treatment Needed

- Notes to Physician:** None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

- Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire. May include oxides of carbon and nitrogen and products of fluorine.
- Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

SAFETY DATA SHEET

Material Name: PF-06877636
Revision date: 27-Aug-2019

Page 3 of 6
Version: 2.0

Measures for Cleaning / Collecting:	Contain the source of the spill if it is safe to do so. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean spill area thoroughly.
Additional Consideration for Large Spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

Specific end use(s): Pharmaceutical process intermediate

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

PF-06877636

Pfizer Occupational Exposure Band (OEB): OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m³ to < 100ug/m³)

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Wear 2 layers of impervious disposable gloves (e.g. Nitrile, etc.) to prevent skin contact. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety goggles as minimum protection. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

SAFETY DATA SHEET

Material Name: PF-06877636
Revision date: 27-Aug-2019

Page 4 of 6
Version: 2.0

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solid	Color:	White
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	C32 H32 F N5 O4	Molecular Weight:	569.6

Solvent Solubility: Methyl ethyl ketone, Isopropanol

Water Solubility: No data available

pH: No data available.

Melting/Freezing Point (°C): No data available

Boiling Point (°C): No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

PF-06877636

Predicted 7.4 Log D 4.262

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: Toxicological properties have not been investigated.

Carcinogen Status: Not listed as a carcinogen by IARC, NTP or US OSHA.

SAFETY DATA SHEET

Material Name: PF-06877636
Revision date: 27-Aug-2019

Page 5 of 6
Version: 2.0

12. ECOLOGICAL INFORMATION

Environmental Overview: May persist in the aquatic environment. Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential:

Partition Coefficient: (Method, pH, Endpoint, Value)

PF-06877636

Predicted 7.4 Log D 4.262

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Transportation classification is based on data and/or procedures that may not be reflected on this document. The classification was conducted as per defining criteria in the international transportation regulations and the shipper's knowledge of the material.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

PF-06877636

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed

Not Listed

Not Listed

SAFETY DATA SHEET

Material Name: PF-06877636
Revision date: 27-Aug-2019

Page 6 of 6
Version: 2.0

15. REGULATORY INFORMATION

16. OTHER INFORMATION

Data Sources: Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 5 - Fire Fighting Measures.
Updated Section 8 - Exposure Controls / Personal Protection. Added Pfizer OEB (Section 8).

Revision date: 27-Aug-2019
Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet



SAFETY DATA SHEET

Revision date 07-Dec-2021

Version 1.01

Page 1 / 8

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name PF-06829020
Product Code(s) PF00269
Synonyms tert-butyl 4-(6-chloropyridin-2-yl)piperidine-1-carboxylate
Trade Name: Not established
Chemical Family: Not determined

PF-06829020
CAS No 1266118-78-8

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical intermediate

1.3. Details of the supplier of the safety data sheet

Pfizer Research and Development
445 Eastern Point Road
Groton, CT USA
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous

OSHA Classification
Physical Hazard Combustible Dust

2.2. Label elements

Signal word Warning

Hazard statements OSHA - May form combustible dust concentrations in air

Supplemental Hazard Compound, not fully tested, hazards unknown.

2.3. Other hazards

Other hazards An Occupational Exposure Value has been established for this substance (see Section 8).

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the

SAFETY DATA SHEET

Product Name PF-06829020
Revision date 07-Dec-2021

Page 2 / 8
Version 1.01

potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
PF-06829020 (CAS #: 1266118-78-8)	100		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate
No information available

Additional information

Non-hazardous ingredients provided for completeness.
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects No data available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

SAFETY DATA SHEET

Product Name PF-06829020
Revision date 07-Dec-2021

Page 3 / 8
Version 1.01

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Dust can form an explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Avoid use of a filtered vacuum to clean spills of dry solids. Contain the source of the spill or leak. Clean spill area thoroughly. Collect spilled material by a method that controls dust generation.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under hood/fume cupboard. Avoid inhalation and contact with skin, eyes, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

SAFETY DATA SHEET

Product Name PF-06829020
Revision date 07-Dec-2021

Page 4 / 8
Version 1.01

7.3. Specific end use(s)

Specific use(s) Pharmaceutical intermediate.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

PF-06829020

Pfizer Occupational Exposure Band (OEB):

OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m³ to < 100ug/m³)

8.2. Exposure controls

Engineering controls

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels to below the OEB range.

Environmental exposure controls

No information available.

Personal protective equipment

Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Eye/face protection

Wear safety goggles as minimum protection. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection

Wear 2 layers of impervious disposable gloves (e.g. Nitrile, etc.) to prevent skin contact. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection

Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection

Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state

Solid

Color

White to off-white

Odor

No information available.

SAFETY DATA SHEET

Product Name PF-06829020
Revision date 07-Dec-2021

Page 5 / 8
Version 1.01

Odor threshold No information available
Molecular formula C₁₅H₂₁CIN₂O₂
Molecular weight 296.8

<u>Property</u>	<u>Values</u>
pH	No data available
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

Partition Coefficient: (Method, pH, Endpoint, Value)
PF-06829020
Predicted 7.4 Log D 3.523

9.2. Other information
No information available

9.2.1. Information with regard to physical hazard classes
No information available

9.2.2. Other safety characteristics
No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

SAFETY DATA SHEET

Product Name PF-06829020
Revision date 07-Dec-2021

Page 6 / 8
Version 1.01

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information:	Toxicological properties have not been investigated.
Acute toxicity	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

Carcinogenicity Not listed as a carcinogen by IARC, NTP or US OSHA.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: May persist in the aquatic environment. Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated.

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Partition Coefficient: (Method, pH, Endpoint, Value)
PF-06829020

SAFETY DATA SHEET

Product Name PF-06829020
Revision date 07-Dec-2021

Page 7 / 8
Version 1.01

Predicted 7.4 Log D 3.523

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental Hazard(s):	Not applicable

Special precautions for user:	Not applicable
Additional Information	Transportation classification is based on data and/or procedures that may not be reflected on this document. The classification was conducted as per defining criteria in the international transportation regulations and the shipper's knowledge of the material.

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

PF-06829020	
CERCLA/SARA Section 313 de minimus %	Not Listed

SAFETY DATA SHEET

Product Name PF-06829020
Revision date 07-Dec-2021

Page 8 / 8
Version 1.01

California Proposition 65
EINECS

Not Listed
Not Listed

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Data Sources: Pfizer proprietary drug development information.

Reason for revision New data sheet.

Revision date 07-Dec-2021

Prepared By Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.



SAFETY DATA SHEET

Revision date 06-Dec-2021

Version 1.01

Page 1 / 8

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name	PF-05318079
Product Code(s)	PF00271
Synonyms	3-fluoro-4-(hydroxymethyl)benzotrile
Trade Name:	Not established
Compound Number	WYE-311897
Chemical Family:	Not determined
PF-05318079	
CAS No	219873-06-0

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use	Pharmaceutical intermediate
------------------------	-----------------------------

1.3. Details of the supplier of the safety data sheet

Pfizer Research and Development 445 Eastern Point Road Groton, CT USA 1-800-879-3477	Pfizer Ireland Pharmaceuticals OSG Building Ringaskiddy, Co. Cork. Ireland +353 21 4378701
E-mail address	pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone	Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887
---------------------	---

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous

OSHA Classification Physical Hazard	Combustible Dust
---	------------------

2.2. Label elements

Signal word	Warning
Hazard statements	OSHA - May form combustible dust concentrations in air
Supplemental Hazard	Compound, not fully tested, hazards unknown.

2.3. Other hazards

Other hazards	An Occupational Exposure Value has been established for this substance (see Section 8).
----------------------	---

Note:	This document has been prepared in accordance with standards for workplace safety, which
--------------	--

SAFETY DATA SHEET

Product Name PF-05318079
Revision date 06-Dec-2021

Page 2 / 8
Version 1.01

require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
PF-05318079 (CAS #: 219873-06-0)	100		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate
No information available

Additional information

Non-hazardous ingredients provided for completeness.
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects No data available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

SAFETY DATA SHEET

Product Name PF-05318079
Revision date 06-Dec-2021

Page 3 / 8
Version 1.01

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Dust can form an explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Carbon monoxide, carbon dioxide, nitrogen oxides and fluorine-containing compounds

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Avoid use of a filtered vacuum to clean spills of dry solids. Contain the source of the spill or leak. Clean spill area thoroughly. Collect spilled material by a method that controls dust generation.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under hood/fume cupboard. Avoid inhalation and contact with skin, eyes, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

SAFETY DATA SHEET

Product Name PF-05318079
Revision date 06-Dec-2021

Page 4 / 8
Version 1.01

7.3. Specific end use(s)

Specific use(s) Pharmaceutical intermediate.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

PF-05318079

Pfizer Occupational Exposure Band (OEB):

OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m³ to < 100ug/m³)

8.2. Exposure controls

Engineering controls

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels to below the OEB range.

Environmental exposure controls

No information available.

Personal protective equipment

Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Eye/face protection

Wear safety goggles as minimum protection. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection

Wear 2 layers of impervious disposable gloves (e.g. Nitrile, etc.) to prevent skin contact. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection

Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection

Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state

Solid

Color

White to off-white

SAFETY DATA SHEET

Product Name PF-05318079
Revision date 06-Dec-2021

Page 5 / 8
Version 1.01

Odor No information available.
Odor threshold No information available
Molecular formula C8H6FNO
Molecular weight 151.14

<u>Property</u>	<u>Values</u>
pH	No data available
Melting point / freezing point	63 - 68
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available

Vapor pressure	No data available
Vapor density	No data available
Relative density	1.27
Water solubility	No data available
Solubility(ies)	No data available
Partition coefficient	1.21
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

Partition Coefficient: (Method, pH, Endpoint, Value)

PF-05318079
Predicted 7.4 Log D 0.941

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

SAFETY DATA SHEET

Product Name PF-05318079
Revision date 06-Dec-2021

Page 6 / 8
Version 1.01

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information:	Toxicological properties have not been investigated.
Acute toxicity	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

Carcinogenicity Not listed as a carcinogen by IARC, NTP or US OSHA.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated.

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Partition Coefficient: (Method, pH, Endpoint, Value)

SAFETY DATA SHEET

Product Name PF-05318079
Revision date 06-Dec-2021

Page 7 / 8
Version 1.01

PF-05318079

Predicted 7.4 Log D 0.941

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental Hazard(s):	Not applicable

Special precautions for user:	Not applicable
Additional Information	Transportation classification is based on data and/or procedures that may not be reflected on this document. The classification was conducted as per defining criteria in the international transportation regulations and the shipper's knowledge of the material.

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

PF-05318079

SAFETY DATA SHEET

Product Name PF-05318079
Revision date 06-Dec-2021

Page 8 / 8
Version 1.01

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Data Sources: Pfizer proprietary drug development information.

Reason for revision New data sheet.

Revision date 06-Dec-2021

Prepared By Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.



SAFETY DATA SHEET

Revision date 06-Apr-2023

Version 2

Page 1 / 8

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name PF-07212416
Product Code(s) PF00327
Trade Name: Not established
Chemical Family: Not determined
PF-07212416
CAS No PROPRIETARY

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical intermediate

1.3. Details of the supplier of the safety data sheet

Pfizer Research and Development
445 Eastern Point Road
Groton, CT USA
1-800-879-3477
E-mail address pfizer-MSDS@pfizer.com

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous according to Regulation (EC) 1272/2008 and/or other applicable regulations.

OSHA Classification
Physical Hazard Combustible Dust

2.2. Label elements
Signal word (OSHA) Warning

Hazard statements OSHA - May form combustible dust concentrations in air

Supplemental Hazard Compound, not fully tested, hazards unknown.

2.3. Other hazards

Other hazards An Occupational Exposure Value has been established for this substance (see Section 8).

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all

SAFETY DATA SHEET

Product Name PF-07212416
Revision date 06-Apr-2023

Page 2 / 8
Version 2

cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
PF-07212416 (CAS #: PROPRIETARY)	100		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate
No information available

Additional information Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects No data available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

SAFETY DATA SHEET

Product Name PF-07212416
Revision date 06-Apr-2023

Page 3 / 8
Version 2

Suitable Extinguishing Media Dry chemical, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Dust can form an explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Carbon monoxide, carbon dioxide, and oxides of nitrogen may be generated in a fire.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Avoid use of a filtered vacuum to clean spills of dry solids. Contain the source of the spill or leak. Clean spill area thoroughly. Collect spilled material by a method that controls dust generation.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Restrict access to work area. Avoid open handling. Ground and bond all bulk transfer equipment. Minimize dust generation. Use process containment, local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eyes, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

7.3. Specific end use(s)

SAFETY DATA SHEET

Product Name PF-07212416
Revision date 06-Apr-2023

Page 4 / 8
Version 2

Specific use(s) Pharmaceutical intermediate.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Pfizer Occupational Exposure Band (OEB) Statement:

The Pfizer Risk Group Classifications for biological entities are based on available and relevant data, that may include: individual risk/route of transmission, pathogenicity, severity of exposure, community impact, and available preventative or post-exposure treatment.

PF-07212416

Pfizer Occupational Exposure Band (OEB):

Default (control exposure to the range of 1ug/m³ to <10ug/m³)

8.2. Exposure controls

Engineering controls

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels to below the OEB range.

Environmental exposure controls

No information available.

Personal protective equipment

Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Eye/face protection

Wear safety glasses as minimum protection. (Safety glasses must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection

Wear impervious gloves (e.g. Nitrile, etc.) if skin contact is possible. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection

Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection

Whenever any air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure. (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state

Solid

Color

White to off-white

Odor

No information available.

Odor threshold

No information available

Molecular formula

C15H17N5O3

Molecular weight

315.33

SAFETY DATA SHEET

Product Name PF-07212416
Revision date 06-Apr-2023

Page 5 / 8
Version 2

<u>Property</u>	<u>Values</u>
pH	No data available
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

Partition Coefficient: (Method, pH, Endpoint, Value)

PF-07212416

Predicted 7.4 Log D -0.186

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

DSC:

Exotherm of -8 J/g at 198 °C and -79 J/g at 261 °C and -159 J/g at 370 °C.

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

SAFETY DATA SHEET

Product Name PF-07212416
Revision date 06-Apr-2023

Page 6 / 8
Version 2

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information:	Toxicological properties have not been thoroughly investigated.
Acute toxicity	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

PF-07212416

Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative

Genetic Toxicity Comments: The above genetic toxicity study was a preliminary assay.

Carcinogenicity Not listed as a carcinogen by IARC, NTP or US OSHA.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated. Based on available data, the classification criteria are not met.

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

SAFETY DATA SHEET

Product Name PF-07212416
Revision date 06-Apr-2023

Page 7 / 8
Version 2

Partition Coefficient: (Method, pH, Endpoint, Value)

PF-07212416

Predicted 7.4 Log D -0.186

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental Hazard(s):	Not applicable

Special precautions for user:	Not applicable
Additional Information	Transportation classification is based on data and/or procedures that may not be reflected on this document. The classification was conducted as per defining criteria in the international transportation regulations and the shipper's knowledge of the material.

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

SAFETY DATA SHEET

Product Name PF-07212416
Revision date 06-Apr-2023

Page 8 / 8
Version 2

PF-07212416

CERCLA/SARA Section 313 de minimus %
California Proposition 65
EINECS

Not Listed
Not Listed
Not Listed

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Data Sources: Pfizer proprietary drug development information.

Reason for revision Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 9 - Physical and Chemical Properties.

Revision date 06-Apr-2023

Prepared By Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

Safety Data Sheet

Divi's safety data sheet according to Regulation (EU) 2020/878.



Product Name: PF-07823177

Version: 000

Revision date: 08.08.2022

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name : PF-07823177

Chemical name : 3-(3-bromo-1-(tetrahydro-2H-pyran-2-yl)-1H-pyrazol-5-yl)cyclopent-2-en-1-one

CAS No. : Not assigned

Other means of identification:

None

1.2 Relevant identified uses of the substance or mixture and uses advised against

Pharmaceutical process intermediate

1.3 Details of the supplier of the safety data sheet

Name Divi's Laboratories Limited

Address 1-72/23(P)/Divi's/303,
Divi towers, Cyber Hills, Gachibowli,
Hyderabad – 500 032,
Telangana, India.

E-mail mail@divislaboratories.com

Web site: www.divislab.com

1.4 Emergency telephone number: +91-8922-248944

SECTION: 2 Hazards Identification

2.1 Classification of the substance or mixture:

Classification according to Regulation (EC) No 1272/2008

No need to classify as hazardous substance according to regulation

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

Hazard pictogram(s)

Not applicable

Signal word(s)

No signal word

Hazard statement(s)

Not applicable

Precautionary statement(s)

Not applicable

2.3 Other hazards

Combustible Dust. May form combustible dust concentrations in air

Endocrine disrupting properties:

No data available

090177e19c49f674\Approved\Approved On: 09-Jan-2023 11:28 (GMT)

Safety Data Sheet

Divi's safety data sheet according to Regulation (EU) 2020/878.



Product Name: PF-07823177

Version: 000

Revision date: 08.08.2022

Results of PBT and vPvB assessment

No data available

SECTION 3. Composition/information on ingredients

- 3.1 **Substances** : PF-07823177
Molecular Formula : C₁₃H₁₅BrN₂O₂
Molecular Weight : 311.18g/mol
- 3.2 **Mixtures** : Not applicable

Substance Name	CAS No	Ec No	Content ratio W/W %	M-Factor	Classification according Regulation (EC) No. 1272/2008 [CLP]
PF-07823177	--	---	NLT 99%	---	Not classified as hazardous substance

SECTION 4: First aid measures

4.1 Description of first aid measures

4.1.1 General information:

On inhalation:

If inhaled, remove from contaminated area to fresh air immediately. If breathing is difficult, give oxygen. Apply artificial respiration with a respiratory medical device if not breathing. Do not use mouth to mouth resuscitation. Immediately medical attention is required.

On skin contact:

Immediate medical attention is required. Immediately call a poison center or doctor. Effects of exposure (skin contact) to substance may be delayed. Remove and wash contaminated clothing before re-use. Remove and isolate contaminated clothing and shoes. In case of contact with substance, immediately flush skin with running water for at least 20 minutes.

On eye contact:

Immediately flush eyes with running water for at least 15 minutes, keeping eyelids open. Eye contact with vapours or substance may cause severe injury, burns, or death. Call emergency medical service. Move victim to fresh air. Check for and remove any contact lenses. Keep victim warm and quiet.

On ingestion

Harmful if swallowed. Do not induce vomiting without medical advice. Effects of exposure (ingestion) to substance may be delayed. Call a physician or Poison Control Center immediately. Do not use mouth-to-mouth method if victim ingested the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Loosen tight clothing such as a collar, tie, belt or waistband. If a person vomits place them in the recovery position so that vomit will not re-enter the mouth and throat. Rinse mouth. Keep victim warm and quiet.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/effects

No data available

090177e19c49f674\Approved\Approved On: 09-Jan-2023 11:28 (GMT)

Safety Data Sheet

Divi's safety data sheet according to Regulation (EU) 2020/878.



Product Name: PF-07823177

Version: 000

Revision date: 08.08.2022

4.3 Indication of any immediate medical attention and special treatment needed

Treatment:

No specific antidote. Treat symptomatically

SECTION 5: Fire fighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Dry chemical, CO₂, alcohol-resistant foam or water spray

Unsuitable extinguishing media:

High volume water jet

5.2 Special hazards arising from the substance or mixture:

Fine particles (such as dust and mists) may fuel fires/explosions.

Formation of toxic gases is possible during heating or fire.

Hazardous combustion products:

In combustion emits toxic fumes of carbon dioxide / carbon monoxide. Nitrogen oxides (NO_x). Sulphur oxides (SO_x).

5.3 Advice for fire-fighters:

Evacuate area and fight fire from a safe distance upwind of fire.

For large fires use regular foam or flood with fine water spray.

Do not get water inside containers. Use water spray to reduce vapors or divert vapor cloud drift. Avoid allowing water runoff to contact spilled material. Prevent entry into waterways, sewers, basements or confined areas.

Fire-men have to wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. Under fire conditions may emit toxic fumes.

Wear positive pressure self-contained breathing apparatus (SCBA). Structural fire fighters' protective clothing provides limited protection in fire situations ONLY; it may not be effective in spill situations. Wear chemical protective clothing which is specifically recommended by the manufacturer. It may provide little or no thermal protection.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel:

No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas.

Avoid breathing vapor or mist. Provide adequate ventilation. Eliminate all ignition sources (no smoking, flares, sparks, or flames)

Protective equipment:

Eye/face protection tight sealing safety goggles. Face protection shield.

Skin and Body Protection Wear protective gloves and protective clothing.

090177e19c49f674Approved\Approved On: 09-Jan-2023 11:28 (GMT)

Safety Data Sheet

Divi's safety data sheet according to Regulation (EU) 2020/878.



Product Name: PF-07823177

Version: 000

Revision date: 08.08.2022

Respiratory protection if exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations

Emergency procedures:

As an immediate precautionary measure, isolate spill or leak area for at least 50 meters (150 feet) in all directions. Eliminate all ignition sources (no smoking, flares, sparks or flames in immediate area) keep out of low areas. Keep unauthorized personnel away. Stay upwind. Ventilate closed spaces before entering.

6.1.2 For emergency responders:

As an immediate precautionary measure, isolate spill or leak area for at least 50 meters (150 feet) in all directions.

Evacuate unnecessary personnel. Mark out the contaminated area with signs and prevent access to unauthorized personnel. Do not touch or walk on the spilled product. Move containers from spill area. Approach release from upwind. Use personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid contact with skin, eyes and clothing. Keep upwind. Avoid creating or spreading dust. Ventilate the area thoroughly, especially low lying areas (basements, workpits etc).

Move containers from spill area. Approach release from upwind. Use personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

No action shall be taken involving any personal risk or without suitable training.

Ventilate spillage area. Mark the danger area.

Isolate area until gas has dispersed. Do not clean-up or dispose except under supervision of a specialist. In case of a spill and/or a leak, always shut off any sources of ignition, ventilate the area, and exercise caution. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Warn personnel to move away. Prevent entry into sewers, basements or confined areas; dike if needed.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3 Methods and material for containment and cleaning up

6.3.1 For containment:

Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. ELIMINATE all ignition sources (no smoking, flares, sparks, or flames in immediate area). Stop leak if without risk. Absorb with an inert material and put the spilled material in an appropriate waste disposal container.

For large amounts: Contain with dust binding material and dispose of. Avoid raising dust. Dispose of absorbed material in accordance with regulations

090177e19c49f674\Approved\Approved On: 09-Jan-2023 11:28 (GMT)

Safety Data Sheet

Divi's safety data sheet according to Regulation (EU) 2020/878.



Product Name: PF-07823177
Version: 000

Revision date: 08.08.2022

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent product from entering drains. Following product recovery, flush area with water.

6.3.2 For cleaning up:

Contain the source of the spill or leak. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean spill area thoroughly

6.3.3 Other information:

No data available

6.4 Reference to other sections

None

SECTION 7: Handling and storage

7.1 Precautions for safe handling

7.1.1 Protective measures:

Advice on safe handling

Restrict access to work area. Avoid open handling. Ground and bond all bulk transfer equipment. Minimize dust generation. Use process containment, local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eyes, and clothing. When handling, use appropriate personal protective equipment. Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation

Use personal protective equipment as required. Keep people away from and upwind of spill/leak. Evacuate personnel to safe areas.

Avoid dispersion as a dust cloud. Depending upon the scale of operation, use of appropriate exhaust ventilation is recommended to provide routine control of fire and explosion hazards during handling of this material. Bond and earth (ground) all plant and equipment to ensure that no isolated conductors are present. Isolated conductors can accumulate sufficient electrostatic charge to produce discharges of many hundreds of milli-Joules. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Minimise dust generation and accumulation. Provide appropriate exhaust ventilation at places where dust is formed. Avoid breathing dust. Avoid contact with skin and eyes.

090177e19c49f674\Approved\Approved On: 09-Jan-2023 11:28 (GMT)

Safety Data Sheet

Divi's safety data sheet according to Regulation (EU) 2020/878.



Product Name: PF-07823177

Version: 000

Revision date: 08.08.2022

Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Fire preventions:

Risk of self-ignition when a large surface area is produced due to fine dispersion. Prevent electrostatic. Potential ignition sources include: propagating brush, spark, bulking brush, and electrostatic discharges from operators, and hot surfaces.

charge - sources of ignition should be kept well clear - fire extinguishers should be kept handy.

Aerosol and dust generation preventions:

Completely enclosed plant should be used whenever practicable for handling dust. This will reduce or prevent significant dust clouds within the building. In a substantially closed system the oxygen content of the atmosphere within the plant can be controlled at a safe level reduce the exposure of employees to dust, which might have a health risk

Environmental precautions:

As in the workplace, the first priority is to prevent the generation of airborne dust, and, if generation cannot be prevented, then secondly, its removal. Measures that minimize waste generation should be given priority, and any inevitable waste disposal should be so planned as to avoid environmental damage. Do not discharge into drains/surface water/groundwater. Do not empty into drains

7.1.2 Advice on general occupational hygiene

Handle in accordance with good industrial hygiene and safety practice.

Wearing of closed work clothing is recommended.

Handle in accordance with good industrial hygiene and safety practice.

No eating, drinking, smoking or tobacco use at the place of work.

Hands and/or face should be washed before breaks and at the end of the shift.

Store work clothing separately.

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. An occupational/industrial hygiene monitoring method has been developed for this material. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. New or expectant mothers might be at greater risk from overexposure. Risk assessments must take this into consideration. Female employees anticipating pregnancy or with a confirmed pregnancy must be encouraged to notify an occupational health professional or their line manager. This will act as the trigger for individual re-assessment of the employee's work practices.

7.2 Conditions for safe storage, including any incompatibilities

Store in a dry well-ventilated area at ambient temperature. Keep away from heat, sparks and flames.

090177e19c49f674Approved\Approved On: 09-Jan-2023 11:28 (GMT)

Safety Data Sheet

Divi's safety data sheet according to Regulation (EU) 2020/878.



Product Name: PF-07823177

Version: 000

Revision date: 08.08.2022

7.3 Specific end use(s)

Recommendations: None

Specific end uses: As specified in section 1

SECTION 8: Exposure controls/ personal protection

8.1 Control parameters

8.1.1 Occupational exposure limits

Substance name	CAS No	Occupational exposure Limits.
PF-07823177	--	No exposure limits established

8.2 Exposure controls

Engineering controls should be used as the primary means to control exposures

8.2.1 Appropriate engineering controls

An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Provide eyewash station.

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

8.2.2 Individual protection measures, such as Personal protective equipment:

Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Eye / Face protection:

Wear safety glasses as minimum protection. (Safety glasses must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Skin protection:

Hand protection: Wear impervious gloves (e.g. Nitrile, etc.) if skin contact is possible. (Protective glove must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Body protection: Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

090177e19c49f674Approved\Approved On: 09-Jan-2023 11:28 (GMT)

Safety Data Sheet

Divi's safety data sheet according to Regulation (EU) 2020/878.



Product Name: PF-07823177
Version: 000

Revision date: 08.08.2022

Respiratory protection:

Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure. (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.).

Thermal hazards

No data available

8.2.3 Environmental exposure controls:

Measures that minimize waste generation should be given priority, and any inevitable waste disposal should be so planned as to avoid environmental damage. Do not discharge into drains/surface water/ground water.

Do not empty into drains

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	Solid
Colour	Yellow to brown color solid.
Odour	No data available
Odour threshold	No data available
Melting point / freezing point	133°C to 142°C
Initial boiling point / boiling range	No data available
Flammability	No data available
Upper explosive limits	No data available
Lower explosive limits	No data available
Flash point	No data available
Auto-ignition temperature (For gases and liquids)	No data available
Decomposition temperature	No data available
PH	~6.5
Viscosity (Kinematic)	No data available
Solubility(ies)	Soluble in chloroform, DMSO, Toluene
Partition- coefficient: n-Octanol/water	Predicted 7.4 Log D 1.891
Vapour Pressure	No data available
Density/Relative density	No data available
Relative vapour density	No data available
Evaporation rate	No data available
Particle characteristics (for solids)	No data available

090177e19c49f674Approved\Approved On: 09-Jan-2023 11:28 (GMT)

Safety Data Sheet

Divi's safety data sheet according to Regulation (EU) 2020/878.



Product Name: PF-07823177

Version: 000

Revision date: 08.08.2022

9.2 Other information:

9.2.1 Information with regard to physical hazard classes

No data available

9.2.2 Other Safety characteristics

DSC: Exotherm of -21 J/g at 193 °C and -580 J/g at 238 °C.

SECTION 10: Stability and Reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under normal conditions

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

Fine particles (such as dust and mists) may fuel fires/explosions.

10.5 Incompatible materials

As a precautionary measure, keep away from strong oxidizers.

10.6 Hazardous decomposition products

Carbon oxides, Nitrogen oxides and sulphur oxides.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD 50 Oral (Rat) - > 510 mg/kg

Skin corrosion/ irritation

No data available

Serious eye damage/irritation

No data available

Respiratory or skin sensitisation

No data available

Germ cell mutagenicity

No data available

Carcinogenicity

Not listed as a carcinogen by IARC, NTP or US OSHA.

Reproductive Toxicity

No data available

STOT-Single Exposure

No data available

090177e19c49f674Approved\Approved On: 09-Jan-2023 11:28 (GMT)

DocumentUltimate

Safety Data Sheet

Divi's safety data sheet according to Regulation (EU) 2020/878.



Product Name: PF-07823177
Version: 000

Revision date: 08.08.2022

STOT-repeated Exposure

No data available

Aspiration Hazard

No data available

11.1.2 Information on likely routes of exposure

Occupational exposure can occur through inhalation of dust, skin, eye contact and ingestion

11.1.3 Symptoms related to the physical, chemical and toxicological characteristics

No data available

11.1.4 Delayed and immediate effects as well as chronic effects from short and Long-term exposure

No data available

11.2 Information on other hazard classes

11.2.1 Endocrine disrupting properties

No data available

11.2.2 Other information

No data available

SECTION 12: Ecological information

12.1 Toxicity:

No data available

12.2 Persistence and degradability:

No data available

12.3 Bio accumulative potential:

No data available

12.4 Mobility in soil:

No data available

12.5 Results of PBT and VPvB assessment

No data available

12.6 Endocrine disrupting properties

No data available

12.7 Other adverse effects:

Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated

SECTION 13: Disposal considerations

13.1 Waste treatment methods:

Contact a licensed professional waste disposal service to Dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an after burner and scrubber. Observe all federal, state, and local environmental regulations.

090177e19c49f674Approved\Approved On: 09-Jan-2023 11:28 (GMT)

DocumentUltimate

Safety Data Sheet

Divi's safety data sheet according to Regulation (EU) 2020/878.



Product Name: PF-07823177
Version: 000

Revision date: 08.08.2022

Section 14: Transport information

Regulation		Land transport (ADR/RID)	Inland waterway transport (ADN)	Sea transport (IMDG)	Air transport (IATA/ICAO)
14.1	UN No or ID number	Not regulated as dangerous goods	Not regulated as dangerous goods	Not regulated as dangerous goods	Not regulated as dangerous goods
14.2	UN Proper shipping name				
14.3	Transport hazard class(es)				
	Hazard label(s)				
14.4	Packing group				
14.5	Environmental hazards				

14.6 Special precautions for user

None

14.7 Maritime transport in bulk according to IMO instruments

No data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture.

EINECS Not Listed
European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants: Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009: Not applicable

15.2 Chemical Safety Assessment:

Chemical safety assessment has not been conducted on the substance/product

SECTION 16: Other information

Information on revision :

Product code : II/PF-07823177/01
Version : 000
Effective date : 08.08.2022
Previous effective date : ----
Prepared By : Divi's Laboratories Limited

090177e19c49f674\Approved\Approved On: 09-Jan-2023 11:28 (GMT)

Safety Data Sheet

Divi's safety data sheet according to Regulation (EU) 2020/878.



Product Name: PF-07823177
Version: 000

Revision date: 08.08.2022

Abbreviations and acronyms :

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

CLP: Regulation on Classification, labeling and packing of substance& mixture

EC No: European Community No.

STOT: Specific target organ toxicity

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

vPvB: very Persistent and very Bio accumulative

Key literature references and sources for data

Data Sources: Pfizer proprietary drug development information; Revision date 22-Mar-2022

Training advice

Consult your supervisor or local safety & health professional for required training appropriate for the safe handling, use of protective equipment, and Emergency response for this material

16.7 Further information

NOTICE: This Safety Data Sheet is based upon data considered to be accurate at the time of preparation. Despite our efforts, it may not be up to date or applicable to the circumstances of any particular case. We are not responsible for any damage or injury resulting from abnormal use, from any failure to follow appropriate practices or from hazards inherent in the nature of the product.

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

END OF SAFETY DATA SHEET.



SAFETY DATA SHEET

Revision date 15-Mar-2023

Version 2

Page 1 / 8

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name PF-07313698
Product Code(s) PF00337
Synonyms Step code HCD; Hydrocortisone dibromide intermediate
Trade Name: Not established
Chemical Family: Not determined
PF-07313698
CAS No -

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical process intermediate

1.3. Details of the supplier of the safety data sheet

Pfizer Inc
66 Hudson Boulevard East
New York, New York 10001
1-800-879-3477
E-mail address pfizer-MSDS@pfizer.com

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous according to Regulation (EC) 1272/2008 and/or other applicable regulations.

OSHA Classification
Physical Hazard Combustible Dust

2.2. Label elements
Signal word (OSHA) Warning

Hazard statements OSHA - May form combustible dust concentrations in air

2.3. Other hazards
Other hazards An Occupational Exposure Value has been established for this substance (see Section 8).

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

SAFETY DATA SHEET

Product Name PF-07313698
Revision date 15-Mar-2023

Page 2 / 8
Version 2

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
PF-07313698 (CAS #: -)	100		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate
No information available

Additional information

- Not Assigned
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. Non-hazardous ingredients provided for completeness.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects No data available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO2, alcohol-resistant foam or water spray.

SAFETY DATA SHEET

Product Name PF-07313698
Revision date 15-Mar-2023

Page 3 / 8
Version 2

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Formation of toxic gases is possible during heating or fire.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.
Methods for cleaning up Avoid use of a filtered vacuum to clean spills of dry solids. Contain the source of the spill or leak. Clean spill area thoroughly. Collect spilled material by a method that controls dust generation.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical process intermediate.

SAFETY DATA SHEET

Product Name PF-07313698
Revision date 15-Mar-2023

Page 4 / 8
Version 2

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

PF-07313698

Pfizer Occupational Exposure Band (OEB):

OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m³ to < 100ug/m³)

8.2. Exposure controls

Engineering controls

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels to below the OEB range.

Environmental exposure controls

No information available.

Personal protective equipment

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Eye/face protection

Wear safety goggles as minimum protection. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection

Wear 2 layers of impervious disposable gloves (e.g. Nitrile, etc.) to prevent skin contact. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection

Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection

Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state

Solid

Color

White to tan

Odor

No information available.

Odor threshold

No information available

Molecular formula

C7 H11 N3 O2

Molecular weight

169.18

SAFETY DATA SHEET

Product Name PF-07313698
Revision date 15-Mar-2023

Page 5 / 8
Version 2

<u>Property</u>	<u>Values</u>
pH	No data available
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

Partition Coefficient: (Method, pH, Endpoint, Value)

PF-07313698

Predicted 7.4 Log D -0.716

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

DSC:

Exotherm of >-430 J/g at 265 °C.

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

SAFETY DATA SHEET

Product Name PF-07313698
Revision date 15-Mar-2023

Page 6 / 8
Version 2

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information:	Toxicological properties have not been investigated.
Acute toxicity	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

Carcinogenicity Not listed as a carcinogen by IARC, NTP or US OSHA.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated.

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Partition Coefficient: (Method, pH, Endpoint, Value)

PF-07313698

Predicted 7.4 Log D -0.716

SAFETY DATA SHEET

Product Name PF-07313698
Revision date 15-Mar-2023

Page 7 / 8
Version 2

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental Hazard(s):	Not applicable

Special precautions for user:	Not applicable
Additional Information	Transportation classification is based on data and/or procedures that may not be reflected on this document. The classification was conducted as per defining criteria in the international transportation regulations and the shipper's knowledge of the material.

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

PF-07313698	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed

SAFETY DATA SHEET

Product Name PF-07313698
Revision date 15-Mar-2023

Page 8 / 8
Version 2

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Data Sources:	Pfizer proprietary drug development information.
Reason for revision	Updated Section 8 - Exposure Controls / Personal Protection.
Revision date	15-Mar-2023
Prepared By	Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.



SAFETY DATA SHEET

Revision date 16-Dec-2023

Version 3.02

Page 1 / 9

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name PF-07104091
Product Code(s) PZ03848
Trade Name: Not established
Compound Number VC-000991865
Chemical Family: Not determined

PF-07104091
CAS No NOT ASSIGNED

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical active

1.3. Details of the supplier of the safety data sheet

Pfizer Research and Development
445 Eastern Point Road
Groton, CT USA
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

Germ cell mutagenicity Category 2 - (H341)

OSHA Classification
Physical Hazard Combustible Dust

2.2. Label elements

Signal word Warning

Hazard statements H341 - Suspected of causing genetic defects
OSHA - May form combustible dust concentrations in air

Precautionary Statements P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P280 - Wear protective gloves and protective clothing
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P405 - Store locked up

SAFETY DATA SHEET

Product Name PF-07104091
Revision date 16-Dec-2023

Page 2 / 9
Version 3.02

Supplemental Hazard

P501 - Dispose of contents/container in accordance with all local and national regulations
Compound, not fully tested, hazards unknown.



2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for this substance (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
PF-07104091 (CAS #: NOT ASSIGNED)	100		Not Listed	Muta 2 (H341)	Not Listed	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

No information available

Additional information

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation

Remove to fresh air. Seek immediate medical attention/advice.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

Skin contact

Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

SAFETY DATA SHEET

Product Name PF-07104091
Revision date 16-Dec-2023

Page 3 / 9
Version 3.02

Ingestion

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects No data available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO₂, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Dust can form an explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Formation of toxic gases is possible during heating or fire. May include oxides of carbon and nitrogen

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Remove all sources of ignition. Contain the source of the spill if it is safe to do so. Collect spilled material by a method that controls dust generation. Clean spill area thoroughly. Avoid use of a filtered vacuum to clean spills of dry solids.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

SAFETY DATA SHEET

Product Name PF-07104091
Revision date 16-Dec-2023

Page 4 / 9
Version 3.02

Advice on safe handling

Restrict access to work area. Avoid open handling. Ground and bond all bulk transfer equipment. Minimize dust generation. Use process containment, local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eyes, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical active.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

PF-07104091

Pfizer Occupational Exposure Band (OEB):

Default (control exposure to the range of $1\mu\text{g}/\text{m}^3$ to $<10\mu\text{g}/\text{m}^3$)

8.2. Exposure controls

Engineering controls

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

Environmental exposure controls

No information available.

Personal protective equipment

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Eye/face protection

Wear safety glasses as minimum protection (goggles recommended). (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection

Wear impervious disposable gloves (e.g. Nitrile, etc.) as minimum protection (double recommended). (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection

Wear impervious disposable protective clothing when handling this compound. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

SAFETY DATA SHEET

Product Name PF-07104091
Revision date 16-Dec-2023

Page 5 / 9
Version 3.02

Respiratory protection

Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	solid
Color	White
Odor	No information available.
Odor threshold	No information available
Molecular formula	C ₁₉ H ₂₈ N ₆ O ₄
Molecular weight	404.471

Property

Values

pH	No data available
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

Partition Coefficient: (Method, pH, Endpoint, Value)

PF-07104091

Predicted 7.4 Log D 0.963

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

SAFETY DATA SHEET

Product Name PF-07104091
Revision date 16-Dec-2023

Page 6 / 9
Version 3.02

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information:	Toxicological properties have not been thoroughly investigated.
Acute toxicity	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Suspected of causing genetic defects.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

Acute Toxicity: (Species, Route, End Point, Dose)

PF-07104091

Dog Oral LOAEL 20 (10 BID) mg/kg

Mouse Oral NOAEL 1000 (500 BID) mg/kg

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

PF-07104091

14 Day(s) Mouse Oral 150 (75 BID) mg/kg/day LOAEL Gastrointestinal System, Male reproductive system, Bone marrow, Blood

1 Month(s) Mouse Oral 150 (75 BID) mg/kg/day NOAEL Lymphatic system, Gastrointestinal system, Bone, Female reproductive system, Male reproductive system

1 Month(s) Dog Oral 30 (15 BID) mg/kg/day NOAEL Gastrointestinal system, Male reproductive system

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

PF-07104091

Bacterial Mutagenicity (Ames) *Salmonella* Negative

SAFETY DATA SHEET

Product Name PF-07104091
Revision date 16-Dec-2023

Page 7 / 9
Version 3.02

In Vitro Micronucleus TK6 Cells Positive

In Vivo Micronucleus Mouse Bone marrow Positive

Genetic Toxicity Comments: **PF-07104091:** The above genetic toxicity studies (Ames and *In vitro* Micronucleus) were preliminary assays.

Carcinogenicity Not listed as a carcinogen by IARC, NTP or US OSHA.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated.

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Partition Coefficient: (Method, pH, Endpoint, Value)

PF-07104091

Predicted 7.4 Log D 0.963

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

SAFETY DATA SHEET

Product Name PF-07104091
Revision date 16-Dec-2023

Page 8 / 9
Version 3.02

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental Hazard(s):	Not applicable
Special precautions for user:	Not applicable

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

PF-07104091

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

SAFETY DATA SHEET

Product Name PF-07104091
Revision date 16-Dec-2023

Page 9 / 9
Version 3.02

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects.

Data Sources: Pfizer proprietary drug development information.

Reason for revision Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients.

Revision date 16-Dec-2023

Prepared By Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

SAFETY DATA SHEET

ER043-026F

Page: 1

Compilation date: 07/09/2022

Revision No: 1

Section 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product Identifier

Product name: ER043-026F

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.3. Details of the supplier of the safety data sheet

Company name: Biocatalysts Ltd

Cefn Coed

Parc Nantgarw

Cardiff

CF15 7QQ

UK

Tel: +44 (0)1443 843712

Fax: +44 (0)1443 846500

Email: sales@biocats.com

1.4. Emergency telephone number

Emergency tel: +44 (0)1443 843712

Section 2: Hazards identification

2.1. Classification of the substance or mixture

Classification under CLP: Resp. Sens. 1A: H334

Most important adverse effects: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

2.2. Label elements

Label elements:

Hazard statements: H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Hazard pictograms: GHS08: Health hazard



Signal words: Danger

Precautionary statements: P261: Avoid breathing dust/fume/gas/mist/vapours/spray.

P284: In case of inadequate ventilation wear respiratory protection.

P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P342+P311: If experiencing respiratory symptoms: Call a POISON CENTER or doctor.

P501: Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

[cont...]

SAFETY DATA SHEET

ER043-026F

Page: 2

2.3. Other hazards

PBT: This product is not identified as a PBT/vPvB substance.

Section 3: Composition/information on ingredients

3.1. Substances

Chemical identity: NON-PROTEASE ENZYME

Section 4: First aid measures

4.1. Description of first aid measures

Skin contact: Rinse with plenty of running water. Remove contaminated clothing and shoes. Obtain medical attention if symptoms occur.

Eye contact: Rinse eye thoroughly with eye wash or running water. Obtain medical attention if symptoms occur.

Ingestion: If swallowed, rinse mouth with water (only if the person is conscious). Obtain medical attention if symptoms occur.

Inhalation: Supply fresh air. Obtain medical attention if symptoms occur.

4.2. Most important symptoms and effects, both acute and delayed

Skin contact: Irritation. Redness.

Eye contact: Irritation. Redness.

Ingestion: Irritation.

Inhalation: Shortness of breath, wheezing and coughing. The effect of inhalation may be delayed.

Delayed / Immediate effects: Delayed effects can be expected after long-term exposure.

4.3. Indication of any immediate medical attention and special treatment needed

Immediate / special treatment: Not applicable.

Section 5: Fire-fighting measures

5.1. Extinguishing media

Extinguishing media: Suitable extinguishing media for the surrounding fire should be used. Avoid creating inhalable dust or aerosols from the product.

5.2. Special hazards arising from the substance or mixture

Exposure hazards: May cause allergic respiratory reaction.

5.3. Advice for fire-fighters

Advice for fire-fighters: Wear respiratory protection to prevent inhalation of dust or aerosols (section 8). Wear protective clothing to prevent contact with skin and eyes.

Section 6: Accidental release measures

090177e19b85581bApprovedApproved Approved On: 12-Oct-2022 15:31 (GMT+7)

[cont...]

SAFETY DATA SHEET

ER043-026F

Page: 3

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Refer to section 8 of SDS for personal protection details.

6.2. Environmental precautions

Environmental precautions: Spilt material should be removed promptly to avoid formation of inhalable dust. Avoid discharge of water used for cleaning to surface water drainage (storm drains).

6.3. Methods and material for containment and cleaning up

Clean-up procedures: Take up, preferably by mechanical means. Clean up residues with large amounts of water (discharge to foul sewer only).

6.4. Reference to other sections

Reference to other sections: Refer to section 8 of SDS.

Section 7: Handling and storage

7.1. Precautions for safe handling

Handling requirements: Ensure there is exhaust ventilation of the area.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Keep cool. See label or product literature for recommended storage temperature.

Suitable packaging: It is recommended that the product is stored in the original packaging.

7.3. Specific end use(s)

Specific end use(s): No data available.

Section 8: Exposure controls/personal protection

8.1. Control parameters

Workplace exposure limits: No data available.

DNEL/PNEC Values

DNEL / PNEC No data available.

8.2. Exposure controls

Engineering measures: Ensure there is exhaust ventilation of the area.

Respiratory protection: Particle filter class P3SL (EN143).

Hand protection: Protective gloves.

Eye protection: If eye-protection is not an integral part of the respiratory protection being worn, then wear tightly fitting safety goggles.

Skin protection: Protective clothing.

Section 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Odour: Characteristic odour

090177e19b85581b\Approved\Approved On: 12-Oct-2022 15:31 (GMT)

[cont...]

SAFETY DATA SHEET

ER043-026F

Page: 4

9.2. Other information

Other information: No data available.

Section 10: Stability and reactivity

10.1. Reactivity

Reactivity: Stable under recommended transport or storage conditions.

10.2. Chemical stability

Chemical stability: Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous reactions: Hazardous reactions will not occur under normal transport or storage conditions.

10.4. Conditions to avoid

Conditions to avoid: None known.

10.5. Incompatible materials

Materials to avoid: None known.

10.6. Hazardous decomposition products

Haz. decomp. products: None known.

Section 11: Toxicological information

11.1. Information on toxicological effects

Relevant hazards for product:

Hazard	Route	Basis
Respiratory/skin sensitisation	-	Hazardous: calculated

Symptoms / routes of exposure

Skin contact: Irritation. Redness.

Eye contact: Irritation. Redness.

Ingestion: Irritation.

Inhalation: Shortness of breath, wheezing and coughing. The effect of inhalation may be delayed.

Delayed / Immediate effects: Delayed effects can be expected after long-term exposure.

Section 12: Ecological information

12.1. Toxicity

Ecotoxicity values: No data available.

12.2. Persistence and degradability

Persistence and degradability: Biodegradable.

090177e19b85581b\Approved\Approved On: 12-Oct-2022 15:31 (GMT)

[cont...]

SAFETY DATA SHEET

ER043-026F

Page: 5

12.3. Bioaccumulative potential

Bioaccumulative potential: No bioaccumulation potential.

12.4. Mobility in soil

12.5. Results of PBT and vPvB assessment

PBT Identification: This product is not identified as a PBT/vPvB substance.

12.6. Other adverse effects

Section 13: Disposal considerations

13.1. Waste treatment methods

NB: The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

Section 14: Transport information

14.1. UN number

UN number: Not Regulated

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

14.5. Environmental hazards

Environmentally hazardous: No

Marine pollutant: No

14.6. Special precautions for user

Special precautions: No special precautions.

Section 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Specific regulations: Not applicable.

15.2. Chemical Safety Assessment

Chemical safety assessment: A chemical safety assessment has not been carried out for the substance or the mixture by the supplier.

Section 16: Other information

Other Information

Other information: according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

* indicates text in the SDS which has changed since the last revision.

Phrases used in s.2 and s.3: H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

090177e19b85584bApproved\Approved On: 12-Oct-2022 15:31 (GMT)

[cont...]

SAFETY DATA SHEET

ER043-026F

Page: 6

Legal disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.

SAFETY DATA SHEET

PDN C161

Page: 1

Compilation date: 09/01/2023

Revision No: 1

Section 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name: PDN C161

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of substance / mixture: For Research Use Only

1.3. Details of the supplier of the safety data sheet

Company name: Biocatalysts Ltd

Cefn Coed

Parc Nantgarw

Cardiff

CF15 7QQ

UK

Tel: +44 (0)1443 843712

Fax: +44 (0)1443 846500

Email: sales@biocats.com

1.4. Emergency telephone number

Emergency tel: +44 (0)1443 843712

Section 2: Hazards identification

2.1. Classification of the substance or mixture

Classification under CLP: Resp. Sens. 1A: H334

Most important adverse effects: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

2.2. Label elements

Label elements:

Hazard statements: H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Hazard pictograms: GHS08: Health hazard



Signal words: Danger

Precautionary statements: P261: Avoid breathing dust/fume/gas/mist/vapours/spray.

P284: In case of inadequate ventilation wear respiratory protection.

P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P342+P311: If experiencing respiratory symptoms: Call a POISON CENTER or doctor.

[cont...]

SAFETY DATA SHEET

PDN C161

Page: 2

P501: Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

PBT: This product is not identified as a PBT/vPvB substance.

Section 3: Composition/information on ingredients

3.1. Substances

Chemical identity: NON-PROTEASE ENZYME

Section 4: First aid measures

4.1. Description of first aid measures

Skin contact: Wash immediately with plenty of soap and water.

Eye contact: Bathe the eye with running water for 15 minutes.

Ingestion: Wash out mouth with water. Consult a doctor.

Inhalation: Remove casualty from exposure ensuring one's own safety whilst doing so. If conscious, ensure the casualty sits or lies down. If unconscious and breathing is OK, place in the recovery position. If breathing becomes bubbly, have the casualty sit and provide oxygen if available. Transfer to hospital as soon as possible.

4.2. Most important symptoms and effects, both acute and delayed

Skin contact: There may be mild irritation at the site of contact.

Eye contact: There may be irritation and redness.

Ingestion: There may be irritation of the throat. There may be shortness of breath due to congestion of the lungs.

Inhalation: Exposure may cause coughing or wheezing. There may be congestion of the lungs causing severe shortness of breath.

Delayed / immediate effects: Delayed effects can be expected after long-term exposure.

4.3. Indication of any immediate medical attention and special treatment needed

Immediate / special treatment: Not applicable.

Section 5: Fire-fighting measures

5.1. Extinguishing media

Extinguishing media: Suitable extinguishing media for the surrounding fire should be used. Use water spray to cool containers.

5.2. Special hazards arising from the substance or mixture

Exposure hazards: In combustion emits toxic fumes.

5.3. Advice for fire-fighters

Advice for fire-fighters: Wear self-contained breathing apparatus. Wear protective clothing to prevent contact with skin and eyes.

090177e19d1b5004Approved\Approved On: 11-Apr-2023 15:29 (GMT)

[cont...]

SAFETY DATA SHEET

PDN C161

Page: 3

Section 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: If outside do not approach from downwind. Notify the police and fire brigade immediately. If outside keep bystanders upwind and away from danger point. Mark out the contaminated area with signs and prevent access to unauthorised personnel. Do not attempt to take action without suitable protective clothing - see section 8 of SDS. Do not create dust.

6.2. Environmental precautions

Environmental precautions: Do not discharge into drains or rivers. Alert the neighbourhood to the presence of fumes or gas.

6.3. Methods and material for containment and cleaning up

Clean-up procedures: Clean-up should be dealt with only by qualified personnel familiar with the specific substance. Transfer to a closable, labelled salvage container for disposal by an appropriate method.

6.4. Reference to other sections

Reference to other sections: Refer to section 8 of SDS.

Section 7: Handling and storage

7.1. Precautions for safe handling

Handling requirements: Ensure there is exhaust ventilation of the area. Avoid the formation or spread of dust in the air.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Store in a cool, well ventilated area. Keep container tightly closed.

7.3. Specific end use(s)

Specific end use(s): No data available.

Section 8: Exposure controls/personal protection

8.1. Control parameters

Workplace exposure limits: No data available.

DNEL/PNEC Values

DNEL / PNEC No data available.

8.2. Exposure controls

Engineering measures: Ensure there is exhaust ventilation of the area.

Respiratory protection: Self-contained breathing apparatus must be used in handling. Respiratory protective device with particle filter.

Hand protection: Protective gloves.

[cont...]

090177e19d1b5004\Approved\Approved On: 11-Apr-2023 15:29 (GMT)

SAFETY DATA SHEET

PDN C161

Page: 4

Eye protection: Safety glasses. Ensure eye bath is to hand.

Skin protection: Protective clothing.

Section 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Colour: Off-white

9.2. Other information

Other information: No data available.

Section 10: Stability and reactivity

10.1. Reactivity

Reactivity: Stable under recommended transport or storage conditions.

10.2. Chemical stability

Chemical stability: Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous reactions: Hazardous reactions will not occur under normal transport or storage conditions.
Decomposition may occur on exposure to conditions or materials listed below.

10.4. Conditions to avoid

Conditions to avoid: Heat.

10.5. Incompatible materials

Materials to avoid: Strong oxidising agents. Strong acids.

10.6. Hazardous decomposition products

Haz. decomp. products: In combustion emits toxic fumes.

Section 11: Toxicological information

11.1. Information on toxicological effects

Relevant hazards for product:

Hazard	Route	Basis
Respiratory/skin sensitisation	-	Hazardous: calculated

Symptoms / routes of exposure

Skin contact: There may be mild irritation at the site of contact.

Eye contact: There may be irritation and redness.

Ingestion: There may be irritation of the throat. There may be shortness of breath due to congestion of the lungs.

Inhalation: Exposure may cause coughing or wheezing. There may be congestion of the lungs causing severe shortness of breath.

090177e19d1b5004\Approved\Approved On: 11-Apr-2023 15:29 (GMT)

[cont...]

SAFETY DATA SHEET

PDN C161

Page: 5

Delayed / immediate effects: Delayed effects can be expected after long-term exposure.

Section 12: Ecological information

12.1. Toxicity

Ecotoxicity values: No data available.

12.2. Persistence and degradability

Persistence and degradability: Biodegradable.

12.3. Bioaccumulative potential

Bioaccumulative potential: No bioaccumulation potential.

12.4. Mobility in soil

Mobility: Readily absorbed into soil.

12.5. Results of PBT and vPvB assessment

PBT identification: This product is not identified as a PBT/vPvB substance.

12.6. Other adverse effects

Other adverse effects: Negligible ecotoxicity.

Section 13: Disposal considerations

13.1. Waste treatment methods

Disposal operations: Transfer to a suitable container and arrange for collection by specialised disposal company.

NB: The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

Section 14: Transport information

14.1. UN number

UN number: Not Applicable

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

14.5. Environmental hazards

Environmentally hazardous: No

Marine pollutant: No

14.6. Special precautions for user

Special precautions: No special precautions.

Section 15: Regulatory information

090177e19d1b5004\Approved\Approved On: 11-Apr-2023 15:29 (GMT)

[cont...]

SAFETY DATA SHEET

PDN C161

Page: 6

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Specific regulations: Not applicable.

15.2. Chemical Safety Assessment

Chemical safety assessment: A chemical safety assessment has not been carried out for the substance or the mixture by the supplier.

Section 16: Other information

Other information

Other information: according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

* indicates text in the SDS which has changed since the last revision.

Phrases used in s.2 and s.3: H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Legal disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.