

Pfizer Ireland Pharmaceuticals Ringaskiddy Active Pharmaceutical Ingredient Plant P.O. Box 140, Ringaskiddy, Co. Cork, Ireland

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Pfizer Ireland Pharmaceuticals

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

25-Mar-2024

Co. Cork.

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 is available for operations. The RCMF will manufacture active pharmaceutical ingredients [API's] to support clinical trials for new products commencing in Q2 2024. It consists of production, laboratorie's 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 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.

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We request Agency approval to introduce the following new materials:

- PF-07952970-01, PF-07940041 and PF-07977435-01 for the manufacture of Sisunatovir, [PF-07923568] Step B
- 2. PF-07927020, Ethyl chloroacetate for the manufacture of Sisunatovir, [PF-07923568] Step D
- 3. PF-07328614-01, PF-07955843 and 2-Chloro-1-methylpyridinium p-toluenesulfonate [CMPT] for the manufacture of PF-07817883. Transfer of materials from Sandwich for storage only
- 4. PF-07231192 and PF-01309518 for the manufacture of **PF-07248144 Transfer of materials from**Sandwich for storage only

We request Agency approval to transfer the materials outlined in No. 3 and 4 from Sandwich. These are speciality materials to be initially stored in the dedicated warehouse area in the RCMF prior to use in their respective process steps. All of these materials are non-hazardous solids and the storage and use of these materials will have no environmental impact as outlined below.

The additional materials used to manufacture Sisunatovir, [PF-07923568] Step B are Acetonitrile, Pyridine, THF and 1-(3-Dimethylamino)propyl)-3-ethyl-carbodiimide hydrochloride [EDCI]. The additional materials used to manufacture Sisunatovir, [PF-07923568] Step D are Potassium tert butoxide, solution in THF, IPA, 30% sodium hydroxide, methanol and 36% hydrochloric acid. All these materials are pre-approved for use and in routine use. The SDS for the new materials are attached in Appendix 1. All the materials listed are non-hazardous, except ethyl chloroacetate which has H [Hazard] Phrases assigned. We note that materials with these H phrases are in routine use so no new Hazard phrases are being added to the inventory of materials.

The manufacture of the above steps [1 & 2] is scheduled for the RCMF. Depending on the success of the clinical trials, the product steps may move to OSP1, OSP3, OSP4 or OSP5 for larger scale manufacturing. The volumes manufactured will be dependent upon patient demand. As noted in previous submissions, Pfizer Ringaskiddy is a multi-product plant with numerous equipment trains to manufacture products. Depending on the product mix at any one time, products may move between equipment trains in the various production plants so manufacturing plant and batch size will vary during the course of a products lifetime depending on equipment availability and market demand. Equipment trains are regularly changed over and configured to the next scheduled product based on detailed production plans which forecast market demand over extended time periods. The unit operations to manufacture these products are no different to manufacturing any of our existing products.

It's planned that the manufacture of these products will commence within the RCMF facility, but they could be moved to other manufacturing areas for the reasons outlined above. Irrespective of the manufacturing plant and volume, there will be no environmental impact resulting from the manufacture of these steps explained as follows:

Impact on air emissions:

There will be no new emissions to air resulting from this 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. We confirm that the solvents used in the above steps are [Acetonitrile, Pyridine and THF in Step B] and Potassium tert butoxide, solution in THF, IPA and methanol are used in Step D] are previously approved by the Agency and routinely used on site. 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.

These steps will be initially manufactured in the RCMF so air emissions from this process 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 systems 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	Emission Limit Value [ELV]	Ringaskiddy	Ringaskiddy
	Class		average kg/hr	average kg/hr
			[2023]	[2022]
Pyridine	TA Luft	20mg/m3 (at mass flows >0.1	0.00021 kg/hr	0.00022 kg/hr
	Organics Class I	kg/hr)		
Acetonitrile, THF	TA Luft	100mg/m3 (at mass flows	0.00023 kg/hr	0.00016 kg/hr
	Organics Class	>2.0 kg/hr)		
Methanol, IPA	TA Luft	150mg/m3 (at mass flows	0.00036 kg/hr	0.00065 kg/hr
	Organics Class	>3.0 kg/hr)		

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

Solvent 1997 TA Luft		Emission Limit Value [ELV]	Ringaskiddy	Ringaskiddy	
	Class		average kg/hr	average kg/hr	
			[2023]	[2022]	
Pyridine	TA Luft	20mg/m3 (at mass flows >0.1	0.00064 kg/hr	0.00041 kg/hr	
	Organics Class I	kg/hr)			
Acetonitrile, THF	TA Luft	100mg/m3 (at mass flows	0.00102 kg/hr	0.00041 kg/hr	
	Organics Class II	>2.0 kg/hr)			
Methanol, IPA	TA Luft	150mg/m3 (at mass flows	0.00143 kg/hr	0.00050 kg/hr	
	Organics Class	>3.0 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/m³)	Ringaskiddy average 30-minute mean mg/m³ [2023]	Ringaskiddy average 30-minute mean mg/m ³ [2022]
Volatile organic compounds (excluding Particulate matter)	20 mg/m ³	0.62 mg/m3	0.47mg/m3

expressed as total organic		
carbon		

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 process steps 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 manufacture of these product steps. 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. 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 bunded 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 do not 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 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:



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

1.1. Product identifier

Product Name PF-07952970-01

Product Code(s) PF00788
Trade Name: Not established
Chemical Family: Not determined

PF-07952970-01

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 OSG Building

Groton, CT USA Ringaskiddy, Co. Cork.

1-800-879-3477 Ireland

+353 21 4378701

Pfizer Ireland Pharmaceuticals

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

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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	EC No	Classification	Specific	M-Factor	M-Factor
		Registration		according to	concentration		(long-term)
		Number		Regulation	limit (SCL)		
				(EC) No.			
				1272/2008			
				[CLP]			
PF-07952970-01	100		Not Listed	Not classified	Not Listed	No data	No data
(CAS #: -)				as hazardous		available	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

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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

Methods for cleaning up

Prevent further leakage or spillage if safe to do so.

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.

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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.

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Pfizer Occupational Exposure

Band (OEB): 8.2. Exposure controls OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m3 to <

100ug/m³)

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 Off-white

No information available. Odor Odor threshold No information available Molecular formula C11 H18 Cl2 F3 N3

Molecular weight 320.18

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Property Values

No data available pН Melting point / freezing point No data available

Boiling point / boiling range

Flash point No information available No data available

Evaporation rate Flammability (solid, gas) No data available

Flammability Limit in Air

Upper flammability limit: No data available

Lower flammability limit: No data available

No data available Vapor pressure 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 No information available **Explosive properties**

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 39 J/g at 137 °C. and 21 J/g at 360 °C. Exotherm of -115 J/g at 137 °C. and -167 J/g at 350 °C.

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stable under normal conditions. Stability

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

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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: Acute toxicity Serious eye damage/eye irritation Skin corrosion/irritation Respiratory or skin sensitization STOT - single exposure STOT - repeated exposure

Reproductive toxicity Germ cell mutagenicity Carcinogenicity **Aspiration hazard**

Toxicological properties have not been investigated. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met.

Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met.

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

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 No information available.

12.4. Mobility in soil

No information available. Mobility in soil

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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:
UN proper shipping name:
Transport hazard class(es):
Packing group:
Environmental Hazard(s):
Not applicable
Not applicable
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-07952970-01

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

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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-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.



Revision date 01-Jun-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-07940041

Product Code(s) PF00688
Trade Name: Not established
Chemical Family: Not determined

PF-07940041

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 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

Product Name PF-07940041 Revision date 01-Jun-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	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
				[CLP]			
PF-07940041 (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

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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

Product Name PF-07940041

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.

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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.

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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-07940041

Pfizer Occupational Exposure

Band (OEB): 8.2. Exposure controls OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m3 to <

100ug/m³)

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

No information available. Odor No information available Odor threshold C12 H10 F N O3 Molecular formula

Molecular weight 235.21

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<u>Property</u> <u>Values</u>

pHNo data availableMelting point / freezing pointNo data available

Boiling point / boiling range

Product Name PF-07940041

Flash point No information available

Evaporation rateFlammability (solid, gas)
No data available
No data available

Flammability Limit in Air

Upper flammability limit: No data available

Lower flammability limit: No data available

No data available Vapor pressure 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)

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Predicted 7.4 Log D -2.333

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 119 J/g at 247 °C Exotherm of -82 J/g at 247 °C

and -196 J/g at 322 °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

Product Name PF-07940041 Revision date 01-Jun-2023

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

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. Based on available data, the classification criteria are not met. **Acute toxicity** 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. 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**

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

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

No information available. **Endocrine disrupting properties**

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

No information available. Persistence and degradability

12.3. Bioaccumulative potential

Bioaccumulation

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

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Predicted 7.4 Log D -2.333

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version date 01-Jun-2023

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessmentNo 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:
UN proper shipping name:
Transport hazard class(es):
Packing group:
Environmental Hazard(s):
Not applicable
Not applicable
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-07940041

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

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EINECS Not Listed

European Union

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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

<u>Legend:</u>

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 01-Jun-2023

Prepared By Pfizer Global Environment, Health, and Safety

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Revision date 13-Nov-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-07977435-01

Product Code(s) PF00832
Trade Name: Not established
Chemical Family: Not determined

PF-07977435-01

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

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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	EC No	Classification	Specific	M-Factor	M-Factor
		Registration		according to	concentration		(long-term)
		Number		Regulation	limit (SCL)		
				(EC) No.			
				1272/2008			
				[CLP]			
PF-07977435-01	100		Not Listed	Not classified	Not Listed	No data	No data
(CAS #: -)				as hazardous		available	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

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

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5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

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

chemical

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.

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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.

Revision date 13-Nov-2023 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.

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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 interactional again plant.)

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

OdorNo information available.Odor thresholdNo information availableMolecular formulaC23 H25 CI F4 N4 O2

Molecular weight 500.92

Revision date 13-Nov-2023 Version

<u>Property</u> <u>Values</u>

pH No data available
Melting point / freezing point No data available

Boiling point / boiling range

Product Name PF-07977435-01

Flash point

Evaporation rate

Flammability (solid, gas)

No information available
No data available
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 No data available **Decomposition temperature** Kinematic viscosity No data available **Dynamic viscosity** No data available

Particle characteristics

Particle Size
Particle Size Distribution
No information available
Explosive properties
No information available
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 96 J/g at 147 °C. Exotherm of -373 J/g at 147 °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.

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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. Based on available data, the classification criteria are not met. Reproductive toxicity 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

<u>Bioaccumulation</u> No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

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Product Name PF-07977435-01 Revision date 13-Nov-2023

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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.

Contact Pfizer Global Dangerous Goods Compliance (DGCompliance@pfizer.com) for guidance on transport classification.

UN number:
UN proper shipping name:
Transport hazard class(es):
Packing group:
Environmental Hazard(s):

To be determined
To be determined
To be determined
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-07977435-01

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

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Revision date 13-Nov-2023 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

Product Name PF-07977435-01

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 13-Nov-2023

Prepared By Pfizer Global Environment, Health, and Safety

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Revision date 15-Jun-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-07927020

Product Code(s)
Synonyms
RV-00015114
Trade Name:
Chemical Family:
Not determined

PF-07927020

CAS No 1378834-16-2

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

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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.

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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	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
PF-07927020 (CAS #: 1378834-16-2)	100		Not Listed	[CLP] 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

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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

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

chemical

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

5.3. Advice for firefighters

Special protective equipment for fire-fighters

r Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

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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.

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)

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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.

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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 Brown

Odor No information available. **Odor threshold** No information available

Molecular formula C10 H8 F N O

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Molecular weight 177.18

Property Values

pHMelting point / freezing pointNo data availableNo data available

Boiling point / boiling range

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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 SizeNo information availableParticle Size DistributionNo information availableExplosive propertiesNo information available

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

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Predicted 7.4 Log D 1.928

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 -14 J/g at 234 °C and -436 J/g at 277 °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

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

10.6. Hazardous decomposition products

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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. Based on available data, the classification criteria are not met. **Acute toxicity** 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. 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**

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)

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Predicted 7.4 Log D 1.928

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12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessmentNo 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:
UN proper shipping name:
Transport hazard class(es):
Packing group:
Environmental Hazard(s):
Not applicable
Not applicable
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-07927020

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

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EINECS Not Listed

European Union

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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

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 12 - Ecological Information.

Revision date 15-Jun-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.



according to Regulation (EC) No. 1907/2006

Version 6.7 Revision Date 26.08.2023 Print Date 01.09.2023

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 : Ethyl chloroacetate

Product Number : E16856 Brand : Aldrich

Index-No. : 607-070-00-7

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. : 105-39-5

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

Flammable liquids (Category 3), H226
Acute toxicity, Oral (Category 3), H301
Acute toxicity, Inhalation (Category 1), H330
Acute toxicity, Dermal (Category 2), H310

Skin irritation (Category 2), H315

Serious eye damage (Category 1), H318

Short-term (acute) aquatic hazard (Category 1), H400

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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 Danger

Hazard statement(s)

H226 Flammable liquid and vapor.

H301 Toxic if swallowed.

H310 + H330 Fatal in contact with skin or if inhaled.

H315 Causes skin irritation.

H318 Causes serious eye damage. H400 Very toxic to aquatic life.

Precautionary statement(s)

P210 Keep away from heat, hot surfaces, sparks, open flames and

other ignition sources. No smoking.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protection/ face

protection.

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated

clothing. Rinse skin with water.

P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable

for breathing. Immediately call a POISON CENTER/ doctor.

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 Danger

Hazard statement(s)

H301 Toxic if swallowed.

H318 Causes serious eye damage.

H310 + H330 Fatal in contact with skin or if inhaled.

Precautionary statement(s)

P280 Wear protective gloves/ protective clothing/ eye protection/ face

protection.

P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable

for breathing. Immediately call a POISON CENTER/ doctor.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue

rinsing.

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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.

Lachrymator.

SECTION 3: Composition/information on ingredients

3.1 Substances

Component		Classification	Concentration
ethyl chloroacetate			
CAS-No. EC-No. Index-No.	105-39-5 203-294-0 607-070-00-7	Flam. Liq. 3; Acute Tox. 3; Acute Tox. 1; Acute Tox. 2; Skin Irrit. 2; Eye Dam. 1; Aquatic Acute 1; H226, H301, H330, H310, H315, H318, H400	<= 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

First aiders need to protect themselves. Show this material safety data sheet to the doctor in attendance.

If inhaled

After inhalation: fresh air. Immediately call in physician. If breathing stops: immediately apply artificial respiration, if necessary also oxygen.

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In case of skin contact

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

In case of eye contact

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

If swallowed

If swallowed: give water to drink (two glasses at most). Seek medical advice immediately. In exceptional cases only, if medical care is not available within one hour, induce vomiting (only in persons who are wide awake and fully conscious), administer activated charcoal (20 - 40 g in a 10% slurry) and consult a doctor as quickly as possible.

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) Dry powder

Unsuitable extinguishing media

Foam Water

5.2 Special hazards arising from the substance or mixture

Carbon oxides

Hydrogen chloride gas

Combustible.

Vapors are heavier than air and may spread along floors.

Forms explosive mixtures with air at elevated temperatures.

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

Remove container from danger zone and cool with water. 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. Keep away from heat and sources of ignition. Evacuate the danger area, observe emergency procedures, consult an expert.

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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 carefully 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

Advice on safe handling

Work under hood. Do not inhale substance/mixture. Avoid generation of vapours/aerosols.

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

Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face 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. Keep locked up or in an area accessible only to qualified or authorized persons.

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

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). Tightly fitting safety goggles

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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: Nitrile rubber

Minimum layer thickness: 0,4 mm Break through time: 30 min

Material tested: Camatril® (KCL 730 / Aldrich Z677442, Size M)

Body Protection

Flame retardant antistatic protective clothing.

Respiratory protection

Recommended Filter type: Filter A (acc. to DIN 3181) for vapours of organic

compounds

The entrepeneur 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. Risk of explosion.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Physical state clear, liquidb) Color colorless

c) Odor No data available

d) Melting Melting point/range: -26 °C - lit.

point/freezing point

Flammability (solid,

e) Initial boiling point 143 °C - lit.

and boiling range

No data available

gas)

f)

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q) Upper/lower Lower explosion limit: 2,6 %(V)

flammability or explosive limits

h) Flash point 54 °C - closed cup Autoignition No data available i)

temperature

Decomposition No data available temperature

k) рΗ No data available

Viscosity, kinematic: No data available I) Viscosity

Viscosity, dynamic: No data available

20 g/l at 19,8 °C m) Water solubility No data available n) Partition coefficient:

n-octanol/water

13 hPa at 38 °C o) Vapor pressure

p) Density 1,145 g/cm3 at 25 °C - lit.

Relative density No data available No data available q) Relative vapor

density

r) Particle

No data available

characteristics

s) Explosive properties No data available No data available Oxidizing properties

9.2 Other safety information

Surface tension 0,038 at -26 °C

SECTION 10: Stability and reactivity

10.1 Reactivity

Vapor/air-mixtures are explosive at intense warming.

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:

Risk of ignition or formation of inflammable gases or vapours with:

bases

Alkali metals

Alkaline earth metals

Cyanides

Oxidizing agents

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Generates dangerous gases or fumes in contact with: Water

10.4 Conditions to avoid

Heating.

10.5 Incompatible materials

no information 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 - 180 mg/kg

Remarks: (ECHA)

LC50 Inhalation - Rat - 4 h - 3,33 mg/m3 - vapor

Remarks: (ECHA)

LD50 Dermal - Rat - female - 161 mg/kg

Remarks: (ECHA)

Skin corrosion/irritation

Skin - Rabbit

Result: Skin irritation (OECD Test Guideline 404)

Serious eye damage/eye irritation

Eyes - Rabbit

Result: Severe eye irritation

Remarks: (RTECS)

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

No data available Test Type: Ames test

Test system: S. typhimurium

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 471

Result: negative

Carcinogenicity

No data available

Reproductive toxicity

No data available

Specific target organ toxicity - single exposure

No data available

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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.

RTECS: AF9110000

Cough, Shortness of breath, Headache, Nausea, Vomiting

After absorption:

somnolence

ataxia (impaired locomotor coordination)

Tremors

Further data:

Handle in accordance with good industrial hygiene and safety practice.

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish LC50 - Fish - 1,48 mg/l - 96 h

Remarks: (External MSDS)

Toxicity to daphnia and other aquatic

invertebrates

static test EC50 - Daphnia magna (Water flea) - 1,6 mg/l - 48 h

Remarks: (ECHA)

12.2 Persistence and degradability

Biodegradability aerobic - Exposure time 28 d

Result: 75 % - Readily biodegradable.

(OECD Test Guideline 301F)

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

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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

Discharge into the environment must be avoided.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

No data available

SECTION 14: Transport information

14.1 UN number

ADR/RID: 1181 IMDG: 1181 IATA: 1181

14.2 UN proper shipping name

ADR/RID: ETHYL CHLOROACETATE IMDG: ETHYL CHLOROACETATE IATA: Ethyl chloroacetate

14.3 Transport hazard class(es)

ADR/RID: 6.1 (3) IMDG: 6.1 (3) IATA: 6.1 (3)

14.4 Packaging group

ADR/RID: II IMDG: II IATA: II

14.5 Environmental hazards

ADR/RID: yes IMDG Marine pollutant: yes IATA: no

14.6 Special precautions for user

Tunnel restriction code : (D/E)

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.

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National legislation

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

ACUTE TOXIC

E1 ENVIRONMENTAL HAZARDS

P5c FLAMMABLE LIQUIDS

Other regulations

Observe work restrictions regarding maternity protection in accordance to Dir 92/85/EEC or stricter national regulations where applicable.

H1

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.

H226	Flammable liquid and vapor.
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H310 + H330	Fatal in contact with skin or if inhaled.
H315	Causes skin irritation.
H318	Flammable liquid and vapor.
H330	Toxic if swallowed.
H400	Fatal in contact with skin or if inhaled.

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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.

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

1.1. Product identifier

Product Name PF-07328614-01

Product Code(s) PF00180
Trade Name: Not established
Chemical Family: Not determined

PF-07328614-01

CAS No 2628280-48-6

REACH Registration Number 01-2120910644-59-0000

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 Pfizer Ireland Pharmaceuticals

66 Hudson Boulevard East OSG Building

New York, New York 10001 Ringaskiddy, Co. Cork.

1-800-879-3477 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.

2.2. Label elements

Signal word Not classified

Hazard statements Not classified in accordance with international standards for workplace safety.

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

Product Name PF-07328614-01 Revision date 24-Jun-2022 Page 2/9 Version 2.01

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	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
PF-07328614-01 (CAS #: 2628280-48-6)	100	01-212091064 4-59-0000	Not Listed	[CLP] 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 - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
PF-07328614-01 2628280-48-6	> 2000	No data available	No data available	No data available	No data 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

ffects

No data available

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

Product Name PF-07328614-01 Revision date 24-Jun-2022

VCISION 4410 24 3411 2022

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

Hazardous combustion products

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

chemical

Formation of toxic gases is possible during heating or fire. May include oxides of carbon,

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.

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

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Page 3/9 Version 2.01 Product Name PF-07328614-01 Revision date 24-Jun-2022

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.

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-07328614-01

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.

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).

Wear safety goggles as minimum protection. (Eye protection must meet the standards in Eye/face protection

accordance with EN166, ANSI Z87.1 or international equivalent.).

Wear 2 layers of impervious disposable gloves (e.g. Nitrile, etc.) to prevent skin contact. Hand protection

(Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or

international equivalent.).

Wear impervious protective clothing to prevent skin contact - consider use of disposable Skin and body protection

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.)

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

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state Solid

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Product Name PF-07328614-01 Revision date 24-Jun-2022

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ColorWhite to light yellowOdorNo information available.Odor thresholdNo information available

Odor thresholdNo information availableMolecular formulaC7 H14 Cl N3 O2

Molecular weight 207.8

<u>Property</u> <u>Values</u>

pH No data available
Melting point / freezing point 205.1 °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 pressureNo data availableVapor densityNo data availableRelative densityNo data available

Water solubility 637.7 g/L (20 °C) (pH 3.5)

Solubility(ies)

Partition coefficient

Autoignition temperature

Decomposition temperature

Kinematic viscosity

No data available

Dynamic viscosity

No data availab

Particle characteristics

 Particle Size
 D10 - 0.942 μm

 D50 - 40.16 μm
 D90 - 68.85 μm

Particle Size DistributionNo information availableExplosive propertiesNo information available

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

PF-07328614-01

Measured 6.5 Log P -3.63

9.2. Other information

Bulk density 1.1437 g/cm3

9.2.1. Information with regard to physical hazard classes

Flammable solids Not a Division 4.1 material

9.2.2. Other safety characteristics

Formation of explosible dust/air mixtures

Minimum Ignition Energy (mJ) 100 - 300 Minimum Ignition Temperature (°C) **550-560**

DSC: Exotherm of -18 J/g at 248 °C

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

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Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge This material has low 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 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 eve 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. 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 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-07328614-01

Rat Oral LD50 > 2000 mg/kg

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

PF-07328614-01

28 Day(s) Rat Oral (M) 100 / (F) 300 mg/kg/day NOAEL Central nervous system

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

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

investigated.

12.1. Toxicity

Product Name PF-07328614-01

<u>Aquatic Toxicity: (Species, Method, End Point, Duration, Result)</u> PF-07328614-01

Pseudokirchneriella subcapitata (Green Alga) OECD ErC50 72 hours 121.7 mg/L
Pseudokirchneriella subcapitata (Green Alga) OECD NOEC 72 hours 10 mg/L
Daphnia Magna (Water Flea) OECD EC50 48 hours > 100 mg/L
Gobiocypris rarus Rare Minnow OECD LC50 96 hours > 100 mg/L

12.2. Persistence and degradability

Persistence and degradability

Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

PF-07328614-01

OECD Activated sludge Ready 8.9 % in 28 Day(s) Not readily biodegradable

12.3. Bioaccumulative potential

Bioaccumulation No information available.

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

PF-07328614-01

Measured 6.5 Log P -3.63

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

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

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

UN number:
UN proper shipping name:
Transport hazard class(es):
Packing group:
Environmental Hazard(s):
Not applicable
Not applicable
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-07328614-01

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

Product Name PF-07328614-01 Revision date 24-Jun-2022

Revision date 24-Jun-2022 Version 2.01

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. Updated Section 9 - Physical and Chemical Properties. Updated Section 11 - Toxicology

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Information. Updated Section 12 - Ecological Information.

Revision date 24-Jun-2022

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.



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

1.1. Product identifier

Product Name PF-07955843

Product Code(s) PF00618
Trade Name: Not established
Chemical Family: Not determined

PF-07955843

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 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

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

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Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No.	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
				1272/2008 [CLP]			
PF-07955843 (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

Revision date 15-Jun-2023 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

Product Name PF-07955843

Special protective equipment for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

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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

Methods for cleaning up

Prevent further leakage or spillage if safe to do so.

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.

Product Name PF-07955843

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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-07955843

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).

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

Wear 2 layers of impervious disposable gloves (e.g. Nitrile, etc.) to prevent skin contact. Hand protection

(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.).

Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is Respiratory protection

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 C18 H29 F3 N2 O5

Molecular weight 410.43

Product Name PF-07955843 Revision date 15-Jun-2023

Version date 13-3dil-2023

<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

No data available Vapor pressure 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
Particle Size Distribution
No information available
No information available

Explosive properties No information available

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

PF-07955843

Predicted 7.4 Log D 3.368

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.

10.5. Incompatible materials

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

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Page 5/8 Version 2 Product Name PF-07955843 Revision date 15-Jun-2023

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.

Based on available data, the classification criteria are not met. **Acute toxicity** 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. Based on available data, the classification criteria are not met. STOT - single exposure 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. Based on available data, the classification criteria are not met. **Aspiration hazard**

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

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. May persist in the aquatic environment.

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-07955843

Predicted 7.4 Log D 3.368

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12.4. Mobility in soil

Product Name PF-07955843

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessmentNo 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:
UN proper shipping name:
Transport hazard class(es):
Packing group:
Environmental Hazard(s):
Not applicable
Not applicable
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-07955843

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

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European Union

Product Name PF-07955843

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 15-Jun-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.



according to Regulation (EC) No. 1907/2006

Version 7.0 Revision Date 21.06.2022 Print Date 11.08.2022

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-Chloro-1-methylpyridinium p-

toluenesulfonate

2-Chloro-1-methylpyridinium-p-toluenesulfonate

Product Number : CDS021472 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. : 7403-46-5

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

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

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.

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SECTION 3: Composition/information on ingredients

3.1 Substances

Formula : C13H14CINO3S Molecular weight : 299,77 g/mol 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.

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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

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 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

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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. Recommended Filter type: Filter type P1

The entrepeneur 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

No data available b) Color c) Odor No data available d) Melting No data available

point/freezing point

e) Initial boiling point No data available and boiling range

Flammability (solid, No data available f)

gas)

g) Upper/lower

explosive limits

No data available flammability or

h) Flash point Not applicable Autoignition No data available

temperature

No data available Decomposition temperature

No data available k) pH

Viscosity, kinematic: No data available Viscosity Viscosity, dynamic: No data available

m) Water solubility No data available No data available n) Partition coefficient:

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n-octanol/water

o) Vapor pressure No data available p) Density No data available Relative density No data available q) Relative vapor No data available

density

r) Particle No data available

characteristics

s) Explosive properties No data available

t) Oxidizing properties none

Other safety information 9.2

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



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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

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

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12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

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

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.

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

SECTION 16: Other information

Relevant changes since previous version

2. Hazards identification



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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.

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

1.1. Product identifier

Product Name PF-07231192

Product Code(s) PF00815
Trade Name: Not established
Chemical Family: Not determined

PF-07231192

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

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.

Product Name PF-07231192 Revision date 01-Nov-2023 Page 2/8 Version 1

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

NonHazardous

	Chemical name	Weight-%	REACH	EC No	Classification	Specific	M-Factor	M-Factor
			Registration		according to	concentration		(long-term)
			Number		Regulation	limit (SCL)		
					(EC) No.			
1					1272/2008			
					[CLP]			
1	PF-07231192	100		Not Listed	Not classified	Not Listed	No data	No data
	(CAS #: -)				as hazardous		available	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

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

SAFFTY DATA SHFFT

Revision date 01-Nov-2023 Version 1

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

Product Name PF-07231192

Special protective equipment for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

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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

Place waste in an appropriately labeled, sealed container for disposal. Care should be **Environmental precautions**

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.

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

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.

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

7.2. Conditions for safe storage, including any incompatibilities

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

and flames.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical process intermediate.

Product Name PF-07231192 Revision date 01-Nov-2023

version date of New 2023

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-07231192

Pfizer Occupational Exposure

Band (OEB): 8.2. Exposure controls OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m^3 to <

100ug/m³)

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 Off-white

OdorNo information available.Odor thresholdNo information available

Molecular formulaC9 H8 F N O2Molecular weight181.1637

PF00815

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<u>Property</u> <u>Values</u>

pH No data available
Melting point / freezing point No data available

Boiling point / heezing point

Boiling point / boiling range

Flash point

Evaporation rate

Flammability (solid, gas)

No information available
No data available
No data available

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 No data available **Decomposition temperature** Kinematic viscosity No data available **Dynamic viscosity** No data available

Particle characteristics

Product Name PF-07231192

Flammability Limit in Air

Particle SizeNo information availableParticle Size DistributionNo information availableExplosive propertiesNo information available

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

PF-07231192

Predicted 7.4 Log D 1.007

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 150 J/g at 117 °C. Exotherm of -651 J/g at 330 °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.

Product Name PF-07231192 Revision date 01-Nov-2023

Revision date 01-Nov-2025

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.

Based on available data, the classification criteria are not met. **Acute toxicity** 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. Based on available data, the classification criteria are not met. STOT - single exposure 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. Based on available data, the classification criteria are not met. **Aspiration hazard**

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-07231192

Predicted 7.4 Log D 1.007

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12.4. Mobility in soil

Product Name PF-07231192

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessmentNo 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:
UN proper shipping name:
Transport hazard class(es):
Packing group:
Environmental Hazard(s):
Not applicable
Not applicable
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-07231192

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

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European Union

Product Name PF-07231192

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 01-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.



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

1.1. Product identifier

Product Name PF-01309518

Product Code(s) PF00816

Synonyms 0614248; CAT-528845; CL-146283; MN-027085; UK-530180; VC-001651812; WL-136042

Trade Name: Not established Chemical Family: Not determined

PF-01309518

CAS No 10130-87-7

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 Ringaskiddy, Co. Cork.

1-800-879-3477 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

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.

Pfizer Ireland Pharmaceuticals

OSG Building

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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-01309518 (CAS #: 10130-87-7)	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 - 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

Remove to fresh air. Seek immediate medical attention/advice. Inhalation

Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Eye contact

Consult a physician.

Skin contact Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek

medical attention.

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do Ingestion

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

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

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

Product Name PF-01309518

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.

Use personal protection recommended in Section 8. For emergency responders

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.

Avoid use of a filtered vacuum to clean spills of dry solids. Contain the source of the spill or Methods for cleaning up

leak. Clean spill area thoroughly. Collect spilled material by a method that controls dust

generation.

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

6.4. Reference to other sections

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

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.

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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-01309518

Pfizer Occupational Exposure

Band (OEB): 8.2. Exposure controls OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m3 to <

100ug/m³)

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 Colorless

No information available. Odor Odor threshold No information available

Molecular formula C7 H7 CI O3 S 206.64

Molecular weight

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<u>Property</u> <u>Values</u>

pHMelting point / freezing pointNo data availableNo data available

Boiling point / boiling range

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Flash point

No information available

Evaporation rate

No data 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

No data available Vapor pressure 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-01309518

Predicted 7.4 Log D 1.868

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 116.18 J/g at 42.66 °C and 81.14 J/g at 289.43 °C. Exotherm of -418.75 J/g at 192.74 °C and -342.63 J/g at

320.95 °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.

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Version date 02 1407 2020

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.

Based on available data, the classification criteria are not met. **Acute toxicity** 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. 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 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. Based on available data, the classification criteria are not met. Carcinogenicity Based on available data, the classification criteria are not met. **Aspiration hazard**

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-01309518

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Predicted 7.4 Log D 1.868

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Not applicable
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California Proposition 65

EINECS

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Not Listed

European Union

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Reason for revision New data sheet.

Revision date 02-Nov-2023

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