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

Pfizer Ireland Pharmaceuticals

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

24-May-22

Ref. IE Licence Register Number P0013-05 (Pfizer Ringaskiddy)

Re: For Agency Approval: Update to site inventory of materials: Arry 797

Dear Sir/Madam,

We wish to notify the Agency that it's planned to introduce the following new materials onsite for the manufacture of Arry 797 for the treatment of dilated cardiomyopathy, DCM.

We request Agency approval to introduce the following new materials on site for the manufacture of Arry 797.

- PF-07328543-15 (Step 1 RSM)
- PF-07812051 (Arry-797 Step 1 Intermediate)
- PF-01663123 (2,4-Difluorophenol Step 2 RSM)
- PF-07327853 (Arry-797 Step 2 intermediate)
- Sodium tert-butoxide in THF (2.0M)
- Copper (I) Bromide
- PF-07327855-11 (Step 3 RSM)
- PF-07265803 (Arry-797 Step 3 Intermediate/Crude API)
- PF-07265803 API (Arry-797 step 3R)

This product is a 4-step process. PF-07328543-15 is the regulatory starting material in step 1 of the process and is transformed to PF-07812051 (Step 1 intermediate) which is the output of the first step of the product using acetonitrile as the solvent, sodium hydroxide, hydrochloric acid as reagents and water. This material is then subsequently used in the second step of the process and is transformed to PF-07327853 [Step 2 intermediate]

using PF-01663123 (2,4-Difluorophenol, Step 2 RSM), Copper (I) Bromide and Sodium tert-butoxide in THF (2.0M). In step 2 of the process, pre-notified solvents, toluene and tetrahydrofuran are used and pre-notified reagents, ammonium chloride, citric acid and sodium chloride are used.
The intermediate generated from Step 2 is combined with PF-07327855-11 (Step 3 RSM) to form PF-07265803 (Step 3 Intermediate/Crude API). Pre-notified solvents, THF, 2-propanol and Triethylamine are used in Step 3 and pre-notified reagents 1,1 carbonydiimidazole and potassium phosphate tribasic and water are used.
Step 3R involves combining PF-07265803 (Step 3 Intermediate/Crude API) with the PF-07265803 API (step 3R) in the presence of acetone and water to form the final active pharmaceutical ingredient. The step 3 crude and the final API step [Step 3R] are the same materials, therefore the one SDS covers both materials.

The SDS for the above materials are attached in Appendix 1. H [Hazard] Phrases for the new materials are identified in the SDS attached in appendix 1. We confirm that no new H Phrases are being added to the Site Inventory of Materials. The associated H-Phrases identified in appendix 1 are routinely used on site.

The manufacture of the above steps is scheduled for the OSP4 manufacturing plant initially, specifically the Small Equipment Group [SEG] for the launch campaign. 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 Arry 797 are no different to manufacturing any of our existing products. Minimal engineering changes are required to expedite the manufacture of this product.
It's planned that the manufacture of Arry 797 will commence within the OSP4 manufacturing facility, but it 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 Arry 797 explained as follows:

There will be no new emissions to air resulting from this process. Only the solvents used in the process may be routed to the vessel headspace and potentially onto the vent header system within each manufacturing plant. We confirm that the solvents used in the above steps are acetonitrile, toluene, tetrahydrofuran, 2-propanol, triethylamine and acetone and are routinely used on site. The tables below demonstrate that the existing air emission abatement systems are capable of handling these emissions.

Air emissions from this process and all processes in the OSP4 manufacturing facility are managed by the existing Thermal Oxidiser which is the main VOC emission abatement system for OSP4. Treated emissions from the OSP4 abatement system are directed to atmosphere via the licensed emission point, A2-5 [V13] which is continuously monitored. Should these steps be manufactured in the OSP3 or OSP1 manufacturing facilities, air emissions from this process and all processes in either OSP3 or OSP1 manufacturing facilities are managed by the existing OSP3 or OSP1 VOC Absorption systems which are the main VOC emission abatement systems for OSP3 and OSP1 respectively. Treated emissions from the OSP3 / OSP1 abatement systems are directed to

atmosphere via the licensed emission points, A2-4 [V5] and A2-2 [V3] respectively which are continuously monitored.

In the case of OSP4, abatement is provided by a flameless thermal oxidiser, and so the flowrate is much more constant by design. 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 the Arry 797 product 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.

In the case of the VOC Absorption Plants serving OSP3 and OSP1, 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 300-800 m3/hour (10-25% of design). All 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 the Arry 797 product 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.

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

Table 1: A2-5 [V13]: ELV for TOC for licensed emission point from OSP4 Production

Parameter	**Emission Limit Value [ELV] 30-minute mean (mg/m^3)**	**Ringaskiddy average 30-minute mean mg/m^3 [2021]**	**Ringaskiddy average 30-minute mean mg/m^3 [2020]**
Volatile organic compounds *(excluding Particulate matter)* expressed as total organic carbon	20 mg/m^3	0.42 mg/m3	0.33 mg/m3

Table 2: A2-4 [V5],: ELV's for licensed emission point from OSP3 Production

Solvent	**1997 TA Luft Class**	**Emission Limit Value [ELV]**	**Ringaskiddy average kg/hr [2021]**	**Ringaskiddy average kg/hr [2020]**

Triethylamine	TA Luft Organics Class I	150mg/m3 (at mass flows >3.0 kg/hr)	0.00028 kg/hr	0.00035 kg/hr
Acetonitrile Toluene, Tetrahydrofuran	TA Luft Organics Class II	100mg/m3 (at mass flows >2.0 kg/hr)	0.00041 kg/hr	0.00049 kg/hr
Acetone 2-propanol	TA Luft Organics Class III	150mg/m3 (at mass flows >3.0 kg/hr)	0.00071 kg/hr	0.00067 kg/hr

Table 3: A2-2 [V3]: ELV's for licensed emission point from OSP1 Production

Solvent	**1997 TA Luft Class**	**Emission Limit Value [ELV]**	**Ringaskiddy average kg/hr [2021]**	**Ringaskiddy average kg/hr [2020]**
Triethylamine	TA Luft Organics Class I	150mg/m3 (at mass flows >3.0 kg/hr)	0.00018 kg/hr	0.00026 kg/hr
Acetonitrile, Toluene, Tetrahydrofuran	TA Luft Organics Class II	100mg/m3 (at mass flows >2.0 kg/hr)	0.00015 kg/hr	0.00029 kg/hr
Acetone 2-propanol	TA Luft Organics Class III	150mg/m3 (at mass flows >3.0 kg/hr)	0.00022 kg/hr	0.00037 kg/hr

Tables 1, 2 and 3 above provide a summary of the annual emissions data from A2-5 [V13], licensed emission point for OSP4, A2-4 [V5], licensed emission point for OSP3 and A2-2 [V3] from 2020 and 2021 and all emissions from the OSP4, OSP3 and OSP1 air emissions abatement systems comply with the relevant ELV's. The solvents used in this process are typically used and historical data proves 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.

The introduction of this new product will not impact on emissions to sewer. We confirm that no waste stream containing Arry 797 or any of its intermediates will be routed to the wastewater treatment plant. Such waste streams will be segregated and sent off site for suitable treatment by the approved waste management broker. Solvent containing waste streams are typically either recovered on or off site or sent to high or low calorific value waste for off-site treatment. We confirm that no waste stream containing Arry 797 or any of its intermediates will be sent to the wastewater treatment plant preventing any impact on the quality of the final effluent discharged to sewer.

There will be no emissions to surface water resulting from the manufacture of this product.

In summary, there will be no environmental impact resulting from the manufacture of Arry 797.

In accordance with Agency guidance, the Site Inventory of Materials 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:

Pfizer Ireland Pharmaceuticals
Registered in Ireland – Company Number: 490938 – VAT Number: IE 9767830C
Registered Office: Operations Support Group, Ringaskiddy, Co. Cork
Directors: Colm Higgins, Paul Duffy
Company Secretary: Colm Higgins

PADMANABH MAFATLAL GROUP	NAVIN FLUORINE INTERNATIONAL LIMITED,DEWAS
	SAFETY DATA SHEET

MSDS No: NFIL/SDS/FG/40	**Creation Date: 03/07/14**	**Revision date : 15/12/21**	**Revision: 02**

SECTION 1 – IDENTIFICATION:

Product Identifier	2,4-Difluorophenol
Trade Names/Synonyms	2,4-Difluorophenol
Chemical Formula	$C_6H_4F_2O$
Recommended Use	Laboratory chemicals, Manufacture of substances
Manufacturer Information	NAVIN FLUORINE INTERNATIONAL LIMITED
Mailing & Email Address	NEW INDUSTRIAL AREA NO-2, A.B.ROAD DEWAS, MADHYA PRADESH, INDIA. msds@nfil.in
Emergency telephone	+91 75097 44625, +91-7272-666786 Fax (+91-7272-666776)

SECTION 2 - HAZARDS IDENTIFICATION:

2.1 Classification of the substance or mixture

H302 Acute toxicity, Oral (Category 4)

H315 Skin irritation (Category 2)

H312 Harmful in contact with skin

H332 Harmful if inhaled

H318 Serious eye damage (Category 1)

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

2.2 Label elements

Pictogram

Signal word Danger

Hazard statement(s)

H302 + H312 + H332 Harmful if swallowed, in contact with skin or if inhaled.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H335 May cause respiratory irritation.

Precautionary statement(s

P261 Avoid breathing dust/fume/gas/mist/vapors/spray.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301 + P312 IF SWALLOWED: call a POISON CENTER or doctor/physician IF you feel unwell.
P302 + P352 IF ON SKIN: wash with plenty of soap and water
P304 + P340 IF INHALED: Remove victim to fresh air and Keep at rest in a position comfortable for breathing.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P403 + P233 Store in a well-ventilated place. Keep container tightly closed.

2.3 Other hazards

Not applicable

SECTION 3 - COMPOSITION / INFORMATION ON INGREDIENTS:

3.1 Substances

Molecular Formula**:** $C_6H_4F_2O$

Molecular weight **:** 130.09 g/mol

Hazardous ingredients according to Regulation (EC) No 1272/2008

CAS No.	Component	Classification	Concentration
CAS no. 367-27-1 EC-No. 206-688-0	2,4-Difluorophenol	Acute Tox. 4; Skin Irrit. 2; Eye Dam. 1; STOT SE 3; H332, H312, H302, H315, H318, H335	>98%

SECTION 4 - FIRST AID MEASURES:

4.1 Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

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

In case of skin contact

Wash off with soap and plenty of water. Consult a physician

In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed

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

4.2 Most important symptoms and effects, both acute and delayed

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

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5 - FIRE FIGHTING MEASURES:

Extinguishing media

Suitable extinguishing media

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

Special hazards arising from the substance or mixture

Carbon oxides, hydrogen fluoride.

Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6 - ACCIDENTAL RELEASE MEASURES:6.1 Personal precautions, protective equipment and emergency procedures

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure

Adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

For personal protection see section 8.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7 - HANDLING AND STORAGE:

7.1 Precautions for safe handling

Avoid formation of dust and aerosols.

Provide appropriate exhaust ventilation at places where dust is formed.

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed, under an inert atmosphere, in a dry and well-ventilated place.

7.3 Specific end use(s)

NA

8. Exposure controls/personal protection:

8.1 Control parameters

Components with workplace control parameters

8.2 Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Occupational exposure controls	Provide exhaust ventilation or other engineering controls to keep the air borne concentrations of vapours below their respective occupational exposure limits. Ensure that eye wash stations and safety showers are proximal to the work station location.
Respiratory protection	Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N99 (US) or type P2 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Hand protection	The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. Handle with gloves.
Eye protection	Safety eye wear complying with an approved standard such as NIOSH (US) or EN 166(EU) should be use when a risk assessment indicates this is necessary to avoid exposure to mists or dusts.
Skin and body protection	Personal protective equipment for the body should be selected based on the tasks being performed and the risk involved and should be approved by a specialist before handling this product. Body : Recommended : chemical resistant protective suit
Hygiene measures	Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES:

9.1 Information on basic physical and chemical properties

1	Appearance	Solid or liquid
2	Colour	White to Yellow or Gray Solid
3	Odour	Phenol like
4	pH of 1% solution water	6-7
5	Melting Range/freezing point	22.4 °C
6	Initial boiling point and boiling range	52 – 53 °C @ 19 mmHg
7	Flash point	57 ºC
8	Flammability (solid, gas)	No data available
9	Upper/lower flammability or explosive limits	No data available
10	Density	1.36 g/cm3 (Predicted)
11	Water solubility	Insoluble
12	Partition coefficient: nocturnal/water	No data available
13	Auto-ignition temperature	No data available
14	Decomposition temperature	No data available
15	Viscosity	No data available
16	Explosive properties	No data available
17	Oxidizing properties	No data available

9.2 Other safety information
No data available.

SECTION 10 - STABILITY AND REACTIVITY:

10.1 Reactivity

No data available.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

No data available.

10.5 Incompatible materials

Strong oxidizing agents, Strong bases

10.6 Hazardous decomposition products

Other decomposition products - No data available

Hazardous decomposition products formed under fire conditions. - Carbon oxides, Hydrogen fluoride

SECTION 11 - TOXICOLOGICAL INFORMATION:

11.1 Information on toxicological effects

Acute toxicity

No data available
LD50 Oral - 500,1 mg/kg
LC50 Inhalation - 4 h - 1,5 mg/l
(Acute toxicity estimate)
LD50 Dermal - 1.100 mg/kg

Skin corrosion/irritation
No data available
Serious eye damage/eye irritation
No data available
Respiratory or skin sensitisation
No data available
Germ cell mutagenicity
No data available
Carcinogenicity
No data available
Reproductive toxicity
No data available
Specific target organ toxicity - single exposure
Inhalation - May cause respiratory irritation.
Specific target organ toxicity - repeated exposure
No data available
Aspiration hazard
No data available
Additional Information
Not available.

SECTION 12 - ECOLOGICAL INFORMATION:
12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bio accumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment
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 Other adverse effects

No data available

SECTION 13 - DISPOSAL CONSIDERATIONS:
13.1 Waste treatment methods

Product

No data available

Contaminated packaging

Dispose of as unused product.

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SECTION 14 - TRANSPORT INFORMATION:

14.1 UN number

ADR/RID: Hazardous Substance	IMDG: Hazardous Substance	IATA: Hazardous Substance

14.2 UN proper shipping name

ADR/RID: 1325	IMDG: 1325	IATA: 1325

14.3 Transport hazard class(es)

ADR/RID: 8	IMDG: 8	IATA: 8

14.4 Packaging group

ADR/RID: III	IMDG: III	IATA: III

14.5 Environmental hazards

ADR/RID: no	IMDG: no	IATA: no

14.6 Dangerous Goods Code

ADR/RID: Hazardous Substance	IMDG: Hazardous Substance	IATA: Hazardous Substance

14.7 Special precautions for user

No data available.

SECTION 15 - REGULATORY INFORMATION:

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

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

No data available

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out.

SECTION 16 - OTHER INFORMATION:

H302 Harmful if swallowed.

H302 + H312 + H332 Harmful if swallowed, in contact with skin or if inhaled.

H312 Harmful in contact with skin.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

DISCLAIMER

Information contained in this Material Safety Data Sheet is believed to be reliable but no representation; guarantee or warranties of any kind are made as to its accuracy, suitability for a particular application or results to be obtained from them. It is up to the user / distributor to ensure that the information contained in the material safety data sheet is relevant to the product manufactured / handled or sold by him as the case may be. There would be no warranties expressed or implied in the respect of the adequacy of this document for any particular purpose.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Version 7.0
Revision Date 19.10.2021
Print Date 20.04.2022
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	:	Copper(I) bromide
Product Number	:	212865
Brand	:	SIGALD
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.	:	7787-70-4

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

Identified uses	:	Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company	:	Merck Life Science N.V. Haarlerbergweg 21 A 1101 CH AMSTERDAM NETHERLANDS
Telephone	:	+31 078 620-5411
Fax	:	+31 078 620-5421
E-mail address	:	technischeservicebenelux@merckgroup.com

1.4 Emergency telephone

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

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008
Acute toxicity, Oral (Category 4), H302
Acute toxicity, Dermal (Category 4), H312
Skin irritation (Category 2), H315
Serious eye damage (Category 1), H318
Short-term (acute) aquatic hazard (Category 1), H400
Long-term (chronic) aquatic hazard (Category 1), H410

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)	
H302 + H312	Harmful if swallowed or in contact with skin.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H410	Very toxic to aquatic life with long lasting effects.
Precautionary statement(s)	
P264	Wash skin thoroughly after handling.
P273	Avoid release to the environment.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.
P301 + P312	IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell.
P302 + P352 + P312	IF ON SKIN: Wash with plenty of water.Call a POISON CENTER/ doctor if you feel unwell.
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)	
H318	Causes serious eye damage.
Precautionary statement(s)	
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

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.

SECTION 3: Composition/information on ingredients

3.1 Substances

Synonyms	:	Cuprous bromide
Formula	:	BrCu

Molecular weight : 143,45 g/mol
CAS-No. : 7787-70-4
EC-No. : 232-131-6

Component		Classification	Concentration
copper(I) bromide; cuprous bromide			
CAS-No. EC-No.	7787-70-4 232-131-6	Acute Tox. 4; Skin Irrit. 2; Eye Dam. 1; Aquatic Acute 1; Aquatic Chronic 1; H302, H312, H315, H318, H400, H410 M-Factor - Aquatic Acute: 10 - Aquatic Chronic: 10	<= 100 %

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

SECTION 4: First aid measures

4.1 Description of first-aid measures

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

If inhaled
After inhalation: fresh air.

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

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

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

4.2 Most important symptoms and effects, both acute and delayed
The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed
No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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

5.2 Special hazards arising from the substance or mixture

Hydrogen bromide gas
Copper oxides
Not combustible.
Ambient fire may liberate hazardous vapours.

5.3 Advice for firefighters

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

5.4 Further information

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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Avoid inhalation of dusts. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.
For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

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

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling
Work under hood. Do not inhale substance/mixture.

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
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). Tightly fitting safety goggles

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

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

Full contact
Material: Nitrile rubber
Minimum layer thickness: 0,11 mm
Break through time: 480 min
Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact
Material: Nitrile rubber
Minimum layer thickness: 0,11 mm
Break through time: 480 min
Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de, test method: EN374
If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the EC approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body Protection
protective clothing

Respiratory protection
required when dusts are generated.
Our recommendations on filtering respiratory protection are based on the following standards: DIN EN 143, DIN 14387 and other accompanying standards relating to the used respiratory protection system.
Recommended Filter type: Filter type P2

The 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)	Appearance	Form: powder
b)	Odor	No data available
c)	Odor Threshold	No data available
d)	pH	No data available
e)	Melting point/freezing point	Melting point/range: 504 °C - lit.
f)	Initial boiling point and boiling range	No data available
g)	Flash point	Not applicable
h)	Evaporation rate	No data available
i)	Flammability (solid, gas)	No data available
j)	Upper/lower flammability or explosive limits	No data available
k)	Vapor pressure	No data available
l)	Vapor density	No data available
m)	Density	4,71 g/mL at 25 °C - lit.
	Relative density	No data available
n)	Water solubility	insoluble
o)	Partition coefficient: n-octanol/water	Not applicable for inorganic substances
p)	Autoignition temperature	No data available
q)	Decomposition temperature	No data available
r)	Viscosity	Viscosity, kinematic: No data available Viscosity, dynamic: No data available
s)	Explosive properties	No data available
t)	Oxidizing properties	No data available

9.2 Other safety information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
No data available

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

10.3 Possibility of hazardous reactions
No data available

10.4 Conditions to avoid
Air Light.
no information available

10.5 Incompatible materials
Alkali metals

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 - male and female - 336 mg/kg
Remarks: (in analogy to similar products)
The value is given in analogy to the following substances: Copper (I)-chloride
Inhalation: No data available
LD50 Dermal - Rat - female - 1.224 mg/kg
(OECD Test Guideline 402)
Remarks: (in analogy to similar products)
The value is given in analogy to the following substances: Copper (I)-chloride

Skin corrosion/irritation
Skin - Rabbit
Result: Skin irritation
Remarks: (in analogy to similar products)
The value is given in analogy to the following substances: Copper (I)-chloride

Serious eye damage/eye irritation
Eyes - Rabbit
Result: Risk of serious damage to eyes.
Remarks: (in analogy to similar products)
The value is given in analogy to the following substances: Copper (I)-chloride

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.

Symptoms of systemic copper poisoning may include: capillary damage, headache, cold sweat, weak pulse, and kidney and liver damage, central nervous system excitation followed by depression, jaundice, convulsions, paralysis, and coma. Death may occur from shock or renal failure. Chronic copper poisoning is typified by hepatic cirrhosis, brain damage and demyelination, kidney defects, and copper deposition in the cornea as exemplified by humans with Wilson's disease. It has also been reported that copper poisoning has lead to hemolytic anemia and accelerates arteriosclerosis., Gastrointestinal disturbance, Blood disorders, Liver injury may occur., Damage to the lungs., To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to daphnia and other aquatic invertebrates	static test EC50 - Daphnia magna (Water flea) - 0,024 mg/l - 48 h (OECD Test Guideline 202) Remarks: (in analogy to similar products) The value is given in analogy to the following substances: Copper (I)-chloride

12.2 Persistence and degradability
The methods for determining biodegradability are not applicable to inorganic substances.

12.3 Bioaccumulative potential
No data available

12.4 Mobility in soil
No data available

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

12.6 Endocrine disrupting properties

Product:

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

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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: 3077 IMDG: 3077 IATA: 3077

14.2 UN proper shipping name

ADR/RID: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (copper(I) bromide; cuprous bromide)

IMDG: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (copper(I) bromide; cuprous bromide)

IATA: Environmentally hazardous substance, solid, n.o.s. (copper(I) bromide; cuprous bromide)

14.3 Transport hazard class(es)

ADR/RID: 9 IMDG: 9 IATA: 9

14.4 Packaging group

ADR/RID: III IMDG: III IATA: III

14.5 Environmental hazards

ADR/RID: yes IMDG Marine pollutant: yes IATA: yes

14.6 Special precautions for user

Further information

EHS-Mark required (ADR 2.2.9.1.10, IMDG code 2.10.3) for single packagings and combination packagings containing inner packagings with Dangerous Goods > 5L for liquids or > 5kg for solids.Packages smaller than or equal to 5 kg / L , not dangerous goods of Class 9

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.

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.	: ENVIRONMENTAL HAZARDS

Other regulations

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

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.

H302	Harmful if swallowed.
H302 + H312	Harmful if swallowed or in contact with skin.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Relevant changes since previous version

2. Hazards identification

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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Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

Na-tert.-Butoxide sol. 20% in tetrahydrofuran

Version number: GHS 2.0
Replaces version of: 2020-06-17 (GHS 1)

Revision: 2021-01-20

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

1.1 Product identifier

Trade name	**Na-tert.-Butoxide sol. 20% in tetrahydrofuran**
CAS number	Mixture
Alternative name(s)	Na-tert.-Butylate sol. 20% in tetrahydrofuran STB, 20 wt% in THF
Product number	300019

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

Relevant identified uses	Industrial use Professional use
Uses advised against	Do not use for squirting or spraying. Do not use for products which come into direct contact with the skin. Do not use for products which come into contact with foodstuffs. Do not use for private purposes (household).

1.3 Details of the supplier of the safety data sheet

Ascensus Specialties Callery LLC
1424 Mars-Evans City Road
Evans City PA 16033
United States

Telephone: +1 724-538-1200
Telefax: +1 724-538-1265
e-mail: Customer.Care@ascensusspecialties.com
Website: www.ascensusspecialties.com

Supplier:
CAMIDA SOURCE • SUPPLY • SOLUTION
Camida Ltd
New Quay
Clonmel
Co.Tipperary
Ireland
Tel No: +353 (0)52 6125455 (Office Hrs)
Fax No: +353 (0)52 6125466
Email: info@camida.com
Emergency Tel No: +44 (0) 1865 407333 (Carechem24)
Information provided is advisory only

e-mail (competent person): ProdReg@ascensusspecialties.com (Product Regulatory)

1.4 Emergency telephone number

Emergency information service: Chemtrec (USA): +1-800-424-9300 (collect calls accepted), Chemtrec (International): +1-703-741-5970 (collect calls accepted)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)

Section	Hazard class	Category	Hazard class and category	Hazard statement
2.6	flammable liquid	2	Flam. Liq. 2	H225
3.1O	acute toxicity (oral)	4	Acute Tox. 4	H302
3.2	skin corrosion/irritation	1B	Skin Corr. 1B	H314
3.3	serious eye damage/eye irritation	1	Eye Dam. 1	H318
3.6	carcinogenicity	2	Carc. 2	H351
3.8R	specific target organ toxicity - single exposure (respiratory tract irritation)	3	STOT SE 3	H335

Section	Hazard class	Category	Hazard class and category	Hazard statement
3.8D	specific target organ toxicity - single exposure (narcotic effects, drowsiness)	3	STOT SE 3	H336

For full text of abbreviations: see SECTION 16.

The most important adverse physicochemical, human health and environmental effects

Skin corrosion produces an irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis. The product is combustible and can be ignited by potential ignition sources.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP)

- Signal word danger

- Pictograms

GHS02, GHS05, GHS07, GHS08

- Hazard statements

H225	Highly flammable liquid and vapour.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H351	Suspected of causing cancer.

- Precautionary statements

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
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 or shower.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor.
P370+P378	In case of fire: Use sand, carbon dioxide or powder extinguisher to extinguish.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P403+P235	Store in a well-ventilated place. Keep cool.

- Supplemental hazard information

EUH019	May form explosive peroxides.

- Hazardous ingredients for labelling Tetrahydrofuran, Na-tert.-Butoxide

2.3 Other hazards

of no significance

SECTION 3: Composition/information on ingredients

3.1 Substances

Not relevant (mixture)

Identifiers

CAS No Mixture

3.2 Mixtures

Description of the mixture

Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms
Tetrahydrofuran	CAS No 109-99-9 EC No 203-726-8 Index No 603-025-00-0 REACH Reg. No 01-2119444314-46-xxxx	75 – < 90	Flam. Liq. 2 / H225 Acute Tox. 4 / H302 Eye Irrit. 2 / H319 Carc. 2 / H351 STOT SE 3 / H335 STOT SE 3 / H336	
Na-tert.-Butoxide	CAS No 865-48-5 EC No 212-741-9 REACH Reg. No 01-2119971576-24-xxxx	10 – < 25	Flam. Sol. 1 / H228 Self-heat. 1 / H251 Acute Tox. 4 / H302 Skin Corr. 1B / H314 Eye Dam. 1 / H318	

Name of substance	Specific Conc. Limits	M-Factors	ATE	Exposure route
Tetrahydrofuran	Eye Irrit. 2; H319: C ≥ 25 % STOT SE 3; H335: C ≥ 25 %	-	-	
Na-tert.-Butoxide	-	-	690 $^{mg}/_{kg}$	oral

For full text of abbreviations: see SECTION 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes

Do not leave affected person unattended. Remove victim out of the danger area. Keep affected person warm, still and covered. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice. In case of unconsciousness place person in the recovery position. Never give anything by mouth.

Following inhalation

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. In case of respiratory tract irritation, consult a physician. Provide fresh air.

Following skin contact

Gently wash with plenty of soap and water. Take off contaminated clothing. After contact with skin, take off immediately all contaminated clothing, and wash immediately with acetic acid 3 % and plenty of water.

Following eye contact

Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart.

Following ingestion

Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting.

If swallowed immediately drink

Water, Milk

4.2 Most important symptoms and effects, both acute and delayed

Narcotic effects. Pulmonary irritation. Headaches and dizziness may occur. Production of tissue damage in the eye. Pulmonary oedema.

4.3 Indication of any immediate medical attention and special treatment needed

none

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Excess of water, Alcohol resistant foam, BC-powder, Carbon dioxide (CO_2), Sand, Dry sand

Unsuitable extinguishing media

Chlorinated hydrocarbons

5.2 Special hazards arising from the substance or mixture

In case of insufficient ventilation and/or in use, may form flammable/explosive vapour-air mixture. Solvent vapours are heavier than air and may spread along floors. Places which are not ventilated, e.g. unventilated below ground level areas such as trenches, conduits and shafts, are particularly prone to the presence of flammable substances or mixtures.

Hazardous combustion products

Nitrogen oxides (NO_x), Carbon monoxide (CO), Carbon dioxide (CO_2), Sodium and potassium hydroxide

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Firefighting water forms corrosive alkaline solutions - slip hazard. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

Special protective equipment for firefighters

Footwear protecting against chemicals, Protective clothing against liquid and gaseous chemicals, including liquid aerosols and solid particles, Self-contained breathing apparatus (SCBA)

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Follow emergency procedures such as the need to evacuate the danger area or to consult an expert. Prevent skin contact. Avoid inhaling sprayed product.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Bunding, Covering of drains, Take up mechanically

Advice on how to clean up a spill

Wipe up with absorbent material (e.g. cloth, fleece). Take up mechanically. Collect spillage: Sawdust, Kieselgur (diatomite), Sand, Universal binder, Absorbent material (e.g. sand, diatomaceous earth, acid binder, universal binder, sawdust, etc.)

Appropriate containment techniques

Use of adsorbent materials.

Suitable material for cleaning/taking up

Kieselgur (diatomite), Sawdust, Sand, Dry sand

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Recommendations

- Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Avoidance of ignition sources. Keep away from sources of ignition - No smoking. Take precautionary measures against static discharge. Use only in well-ventilated areas. Due to danger of explosion, prevent leakage of vapours into cellars, flues and ditches. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting/equipment. Use only non-sparking tools.

- Specific notes/details

Places which are not ventilated, e.g. unventilated below ground level areas such as trenches, conduits and shafts, are particularly prone to the presence of flammable substances or mixtures. Vapours are heavier than air, spread along floors and form explosive mixtures with air. Vapours may form explosive mixtures with air.

- Measures to protect the environment

Avoid release to the environment. Dispose of contents/container to industrial combustion plant. Dispose of contents/container to recovery or disposal facilities. Dispose of this material and its container to hazardous or special waste collection point. This material and its container must be disposed of as hazardous waste. Do not empty into drains; dispose of this material and its container at hazardous or special waste collection point.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Managing of associated risks

- Explosive atmospheres

Keep container tightly closed. Store in a closed container. Keep container tightly closed and in a well-ventilated place. Use local and general ventilation. Use only in well-ventilated areas. Protect from sunlight.

- Flammability hazards

Keep away from sources of ignition - No smoking. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use only non-sparking tools. Take precautionary measures against static discharge. Ground/bond container and receiving equipment. Protect from sunlight.

- Incompatible substances or mixtures

Observe hints for combined storage. Store away from other materials.

- Do not mix with

Acids, Strong oxidisers, Oxidisers

- Evaporative conditions

Keep container tightly closed and in a well-ventilated place. Keep under inert gas.

- Ventilation requirements

Use local and general ventilation. Ground/bond container and receiving equipment.

- Packaging compatibilities

Only packagings which are approved (e.g. acc. to ADR) may be used. Metallic packaging. Glass packaging.

- Shelf-life production date + 48 months

7.3 Specific end use(s)

See section 16 for a general overview.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values (Workplace Exposure Limits)

Country	Name of agent	CAS No	Identifier	TWA [ppm]	TWA [mg/m³]	STEL [ppm]	STEL [mg/m³]	Ceiling-C [ppm]	Ceiling-C [mg/m³]	Notation	Source
EU	tetrahydrofuran	109-99-9	IOELV	50	150	100	300				2000/39/EC
GB	tetrahydrofuran	109-99-9	WEL	50	150	100	300				EH40/2005

Notation
Ceiling-C ceiling value is a limit value above which exposure should not occur
STEL short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)
TWA time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average (unless otherwise specified)

Relevant DNELs of components of the mixture

Name of substance	CAS No	End-point	Threshold level	Protection goal, route of exposure	Used in	Exposure time
Tetrahydrofuran	109-99-9	DNEL	150 mg/m³	human, inhalatory	worker (industry)	chronic - systemic effects
Tetrahydrofuran	109-99-9	DNEL	300 mg/m³	human, inhalatory	worker (industry)	acute - systemic effects
Tetrahydrofuran	109-99-9	DNEL	150 mg/m³	human, inhalatory	worker (industry)	chronic - local effects

Relevant DNELs of components of the mixture

Name of substance	CAS No	End-point	Threshold level	Protection goal, route of exposure	Used in	Exposure time
Tetrahydrofuran	109-99-9	DNEL	300 mg/m³	human, inhalatory	worker (industry)	acute - local effects
Tetrahydrofuran	109-99-9	DNEL	25 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
Na-tert.-Butoxide	865-48-5	DNEL	1 mg/m³	human, inhalatory	worker (industry)	chronic - systemic effects
Na-tert.-Butoxide	865-48-5	DNEL	1 mg/m³	human, inhalatory	worker (industry)	acute - systemic effects
Na-tert.-Butoxide	865-48-5	DNEL	1 mg/m³	human, inhalatory	worker (industry)	chronic - local effects
Na-tert.-Butoxide	865-48-5	DNEL	1 mg/m³	human, inhalatory	worker (industry)	acute - local effects

Relevant PNECs of components of the mixture

Name of substance	CAS No	End-point	Threshold level	Organism	Environmental compartment	Exposure time
Tetrahydrofuran	109-99-9	PNEC	4.32 mg/l	aquatic organisms	freshwater	short-term (single instance)
Tetrahydrofuran	109-99-9	PNEC	0.432 mg/l	aquatic organisms	marine water	short-term (single instance)
Tetrahydrofuran	109-99-9	PNEC	4.6 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
Tetrahydrofuran	109-99-9	PNEC	23.3 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
Tetrahydrofuran	109-99-9	PNEC	2.33 mg/kg	aquatic organisms	marine sediment	short-term (single instance)
Tetrahydrofuran	109-99-9	PNEC	2.13 mg/kg	terrestrial organisms	soil	short-term (single instance)
Na-tert.-Butoxide	865-48-5	PNEC	0.11 mg/l	aquatic organisms	freshwater	short-term (single instance)
Na-tert.-Butoxide	865-48-5	PNEC	0.011 mg/l	aquatic organisms	marine water	short-term (single instance)
Na-tert.-Butoxide	865-48-5	PNEC	10 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
Na-tert.-Butoxide	865-48-5	PNEC	0.419 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
Na-tert.-Butoxide	865-48-5	PNEC	0.042 mg/kg	aquatic organisms	marine sediment	short-term (single instance)
Na-tert.-Butoxide	865-48-5	PNEC	0.019 mg/kg	terrestrial organisms	soil	short-term (single instance)

8.2 Exposure controls

Appropriate engineering controls

Exhaust ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection

Wear eye/face protection. Use safety goggle with side protection. Wear face-shield. Use protective eyewear to guard against splash of liquids.

Skin protection

- Hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. Check leak-tightness/impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

- Type of material

NBR: acrylonitrile-butadiene rubber, IIR: isobutene-isoprene (butyl) rubber, FKM: fluoro-elastomer, Nitrile

- Protective gloves - Splash protection

Type of material	NBR: acrylonitrile-butadiene rubber IIR: isobutene-isoprene (butyl) rubber FKM: fluoro-elastomer nitrile

- Other protection measures

Wash hands thoroughly after handling. Protective clothing against liquid chemicals. Footwear protecting against chemicals.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

Environmental exposure controls

Use appropriate container to avoid environmental contamination. Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	liquid
Colour	colourless - amber
Odour	like ether
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	65 °C
Flammability	flammable liquid in accordance with GHS criteria
Lower and upper explosion limit	not determined
Flash point	-18.3 °C at 1 atm
Auto-ignition temperature	not determined
Decomposition temperature	not relevant
pH (value)	not determined

Kinematic viscosity	1.1 cSt at 20 °C
Solubility(ies)	not determined

Partition coefficient

Partition coefficient n-octanol/water (log value)	this information is not available

Vapour pressure	17 kPa at 20 °C

Density and/or relative density

Density	0.902 $^{g}/_{cm^3}$ at 21.5 °C 0.865 $^{g}/_{cm^3}$ at 55 °C

Particle characteristics	no data available

9.2 Other information

Information with regard to physical hazard classes	there is no additional information
Other safety characteristics	there is no additional information

SECTION 10: Stability and reactivity

10.1 Reactivity

Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials". The mixture contains reactive substance(s). Risk of ignition.

If heated:

Risk of ignition

10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

10.3 Possibility of hazardous reactions

Reacts with water, releasing excess pressure or heat.

10.4 Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Hints to prevent fire or explosion

Use explosion-proof electrical/ventilating/lighting/equipment. Use only non-sparking tools. Take precautionary measures against static discharge.

10.5 Incompatible materials

Water, Acids, Oxidisers

10.6 Hazardous decomposition products

Sodium and potassium hydroxide. Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

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

Test data are not available for the complete mixture.

Classification procedure

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

Classification according to GHS (1272/2008/EC, CLP)

Acute toxicity

Harmful if swallowed.

- Acute toxicity estimate (ATE)

Oral 500 $^{mg}/_{kg}$

Acute toxicity estimate (ATE) of components of the mixture

Name of substance	CAS No	Exposure route	ATE
Na-tert.-Butoxide	865-48-5	oral	690 $^{mg}/_{kg}$

Skin corrosion/irritation

Causes severe skin burns and eye damage.

Serious eye damage/eye irritation

Causes serious eye damage.

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Suspected of causing cancer.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

May cause respiratory irritation. May cause drowsiness or dizziness.

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

11.2 Information on other hazards

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

12.2 Persistence and degradability

Data are not available.

12.3 Bioaccumulative potential

Data are not available.

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

Data are not available.

12.6 Endocrine disrupting properties

None of the ingredients are listed.

12.7 Other adverse effects

Ozone depletion potential

No data available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Dispose of contents/container to industrial combustion plant. Dispose of contents/container to recovery or disposal facilities. Dispose of this material and its container to hazardous or special waste collection point. This material and its container must be disposed of as hazardous waste.

Waste treatment-relevant information

Incineration. Physico-chemical treatment.

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

Waste treatment of containers/packagings

It is a dangerous waste; only packagings which are approved (e.g. acc. to ADR) may be used. Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

Remarks

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

SECTION 14: Transport information

14.1 UN number or ID number

ADR/RID/ADN	UN 2924
IMDG-Code	UN 2924
ICAO-TI	UN 2924

14.2 UN proper shipping name

ADR/RID/ADN	FLAMMABLE LIQUID, CORROSIVE, N.O.S.
IMDG-Code	FLAMMABLE LIQUID, CORROSIVE, N.O.S.

ICAO-TI	Flammable liquid, corrosive, n.o.s.
Technical name (hazardous ingredients)	Tetrahydrofuran, Sodium-Tert-Butylate

14.3 Transport hazard class(es)

ADR/RID/ADN	3 (8)
IMDG-Code	3 (8)
ICAO-TI	3 (8)

14.4 Packing group

ADR/RID/ADN	II
IMDG-Code	II
ICAO-TI	II

14.5 Environmental hazards non-environmentally hazardous acc. to the dangerous goods regulations

14.6 Special precautions for user

Provisions for dangerous goods (ADR) should be complied within the premises.

14.7

Information for each of the UN Model Regulations

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN)

Classification code	FC
Danger label(s)	3+8

Special provisions (SP)	274
Excepted quantities (EQ)	E2
Limited quantities (LQ)	1 L
Transport category (TC)	2
Tunnel restriction code (TRC)	D/E
Hazard identification No	338
Emergency Action Code	3WE

International Maritime Dangerous Goods Code (IMDG) - Additional information

Marine pollutant	-
Danger label(s)	3+8

Special provisions (SP)	274
Excepted quantities (EQ)	E2
Limited quantities (LQ)	1 L
EmS	F-E, S-C
Stowage category	B
Stowage codes	SW2

International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information

Danger label(s)	3+8

Special provisions (SP)	A3
Excepted quantities (EQ)	E2
Limited quantities (LQ)	0,5 L

SECTION 15: Regulatory information

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

Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

Dangerous substances with restrictions (REACH, Annex XVII)

Name of substance	Name acc. to inventory	CAS No	Restriction	No
Na-tert.-Butoxide sol. 20% in tetrahydrofuran	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC		R3	3
Tetrahydrofuran	flammable / pyrophoric		R40	40
Na-tert.-Butoxide	flammable / pyrophoric		R40	40

Legend

R3 1. Shall not be used in:
- ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays,
- tricks and jokes,
- games for one or more participants, or any article intended to be used as such, even with ornamental aspects,
2. Articles not complying with paragraph 1 shall not be placed on the market.
3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they:
- can be used as fuel in decorative oil lamps for supply to the general public, and,
- present an aspiration hazard and are labelled with R65 or H304,
4. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation (CEN).
5. Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of dangerous substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met:
(a) lamp oils, labelled with R65 or H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: 'Keep lamps filled with this liquid out of the reach of children'; and, by 1 December 2010, 'Just a sip of lamp oil - or even sucking the wick of lamps - may lead to life-threatening lung damage';
(b) grill lighter fluids, labelled with R65 or H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: 'Just a sip of grill lighter may lead to life threatening lung damage';
(c) lamp oils and grill lighters, labelled with R65 or H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010.
6. No later than 1 June 2014, the Commission shall request the European Chemicals Agency to prepare a dossier, in accordance with Article 69 of the present Regulation with a view to ban, if appropriate, grill lighter fluids and fuel for decorative lamps, labelled R65 or H304, intended for supply to the general public.
7. Natural or legal persons placing on the market for the first time lamp oils and grill lighter fluids, labelled with R65 or H304, shall by 1 December 2011, and annually thereafter, provide data on alternatives to lamp oils and grill lighter fluids labelled R65 or H304 to the competent authority in the Member State concerned. Member States shall make those data available to the Commission.

Legend

R40 1. Shall not be used, as substance or as mixtures in aerosol dispensers where these aerosol dispensers are intended for supply to the general public for entertainment and decorative purposes such as the following:
- metallic glitter intended mainly for decoration,
- artificial snow and frost,
- 'whoopee' cushions,
- silly string aerosols,
- imitation excrement,
- horns for parties,
- decorative flakes and foams,
- artificial cobwebs,
- stink bombs.

2. Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances, suppliers shall ensure before the placing on the market that the packaging of aerosol dispensers referred to above is marked visibly, legibly and indelibly with:
'For professional users only'.

3. By way of derogation, paragraphs 1 and 2 shall not apply to the aerosol dispensers referred to Article 8 (1a) of Council Directive 75/324/EEC (2).

4. The aerosol dispensers referred to in paragraphs 1 and 2 shall not be placed on the market unless they conform to the requirements indicated.

List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list

none of the ingredients are listed

Deco-Paint Directive (2004/42/EC)

VOC content	80 %

Directive on industrial emissions (VOCs, 2010/75/EU)

VOC content	80 %

Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) - Annex II

none of the ingredients are listed

Regulation 166/2006/EC concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

none of the ingredients are listed

Water Framework Directive (WFD)

none of the ingredients are listed

National inventories

Country	Inventory	Status
EU	REACH Reg.	all ingredients are listed
CA	DSL	all ingredients are listed
US	TSCA	all ingredients are listed

Legend

DSL	Domestic Substances List (DSL)
REACH Reg.	REACH registered substances
TSCA	Toxic Substance Control Act

15.3 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)	Safety-relevant
2.3	Other hazards	Other hazards: of no significance	yes
2.3	Results of PBT and vPvB assessment: This mixture does not contain any substances that are assessed to be a PBT or a vPvB.		yes
3.2		Description of the mixture: change in the listing (table)	yes
3.2		Description of the mixture: change in the listing (table)	yes
7.2	- Shelf-life: production date + 12 months	- Shelf-life: production date + 48 months	yes
9.1	Appearance		yes
9.1	Other safety parameters		yes
9.1	Flammability (solid, gas): not relevant, (fluid)	Flammability: flammable liquid in accordance with GHS criteria	yes
9.1	Evaporation rate: not determined		yes
9.1		Decomposition temperature: not relevant	yes
9.1		Density and/or relative density	yes
9.1	Vapour density: this information is not available		yes
9.1	Viscosity		yes
9.1	Explosive properties: explosive		yes
9.1	Oxidising properties: none		yes
9.1		Particle characteristics: no data available	yes
9.2	other information: there is no additional information	Other information	yes
9.2		Information with regard to physical hazard classes: there is no additional information	yes
9.2		Other safety characteristics: there is no additional information	yes
11.2		Information on other hazards: There is no additional information.	yes
14.1	UN number: 2924	UN number or ID number	yes
14.1		ADR/RID/ADN: UN 2924	yes

Section	Former entry (text/value)	Actual entry (text/value)	Safety-relevant
14.1		IMDG-Code: UN 2924	yes
14.1		ICAO-TI: UN 2924	yes
14.2	UN proper shipping name: FLAMMABLE LIQUID, CORROSIVE, N.O.S.	UN proper shipping name	yes
14.2		ADR/RID/ADN: FLAMMABLE LIQUID, CORROSIVE, N.O.S.	yes
14.2		IMDG-Code: FLAMMABLE LIQUID, CORROSIVE, N.O.S.	yes
14.2		ICAO-TI: Flammable liquid, corrosive, n.o.s.	yes
14.3	Class: 3 (flammable liquids)		yes
14.3	Subsidiary risk(s): 8 (corrosive effects)		yes
14.3		ADR/RID/ADN: 3 (8)	yes
14.3		IMDG-Code: 3 (8)	yes
14.3		ICAO-TI: 3 (8)	yes
14.4	Packing group: II (substance presenting medium danger)	Packing group	yes
14.4		ADR/RID/ADN: II	yes
14.4		IMDG-Code: II	yes
14.4		ICAO-TI: II	yes
14.7	UN number: 2924		yes
14.7	Proper shipping name: FLAMMABLE LIQUID, CORROSIVE, N.O.S.		yes
14.7	Class: 3		yes
14.7	Packing group: II		yes
14.7	UN number: 2924		yes
14.7	Proper shipping name: FLAMMABLE LIQUID, CORROSIVE, N.O.S.		yes
14.7	Class: 3		yes
14.7	Subsidiary risk(s): 8		yes

Section	Former entry (text/value)	Actual entry (text/value)	Safety-relevant
14.7	Packing group: II		yes
14.7	UN number: 2924		yes
14.7	Proper shipping name: Flammable liquid, corrosive, n.o.s.		yes
14.7	Class: 3		yes
14.7	Subsidiary risk(s): 8		yes
14.7	Packing group: II		yes
16		Abbreviations and acronyms: change in the listing (table)	yes
16	Key literature references and sources for data: Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2015/830/EU.Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).	Key literature references and sources for data: Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).	yes

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
2000/39/EC	Commission Directive establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC
Acute Tox.	Acute toxicity
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord européen relatif au transport international des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
ADR/RID/ADN	European Agreements concerning the International Carriage of Dangerous Goods by Road/Rail/Inland Waterways (ADR/RID/ADN)
ATE	Acute Toxicity Estimate
Carc.	Carcinogenicity
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
Ceiling-C	Ceiling value
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)

Abbr.	Descriptions of used abbreviations
EH40/2005	EH40/2005 Workplace exposure limits (http://www.nationalarchives.gov.uk/doc/open-government-licence/)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye
Flam. Liq.	Flammable liquid
Flam. Sol.	Flammable solid
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical instructions for the safe transport of dangerous goods by air
IMDG	International Maritime Dangerous Goods Code
IMDG-Code	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
IOELV	Indicative occupational exposure limit value
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
Self-heat.	Self-heating material
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
STEL	Short-term exposure limit
STOT SE	Specific target organ toxicity - single exposure
SVHC	Substance of Very High Concern
TWA	Time-weighted average
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative
WEL	Workplace exposure limit

Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

Classification procedure

Physical and chemical properties: The classification is based on tested mixture.
Health hazards, Environmental hazards: The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

List of relevant phrases (code and full text as stated in chapter 2 and 3)

Code	Text
H225	Highly flammable liquid and vapour.
H228	Flammable solid.
H251	Self-heating: may catch fire.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H351	Suspected of causing cancer.

Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

SAFETY DATA SHEET

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

1.1. Product identifier

Product Name PF-07265803

Product Code(s) PF00058
Synonyms ARRY-797, ARRY-371797
Trade Name: Not established
Chemical Family: Not determined

PF-07265803
CAS No PROPRIETARY

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

Recommended Use Pharmaceutical intermediate

1.3. Details of the supplier of the safety data sheet

Pfizer Inc
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887
E-mail address pfizer-MSDS@pfizer.com

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Reproductive toxicity Category 2

OSHA Classification
Physical Hazard Combustible Dust

2.2. Label elements

Signal word Warning

Hazard statements
May form combustible dust concentrations in air
H361 - Suspected of damaging fertility or the unborn child

Precautionary Statements
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P280 - Wear protective gloves and eye/face protection
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P405 - Store locked up
P501 - Dispose of contents/ container to an approved waste disposal plant

2.3. Other hazards

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

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

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

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-07265803 PROPRIETARY	100		Not Listed	Repr 2 (H361)	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 For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

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

Hazardous combustion products Carbon monoxide, carbon dioxide, nitrogen oxides and fluorine-containing compounds

5.3. Advice for firefighters

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

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

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

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

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

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

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

6.4. Reference to other sections

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

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under hood/fume cupboard. Avoid inhalation and contact with skin, eyes, and clothing. When handling, use

appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

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

7.2. Conditions for safe storage, including any incompatibilities

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

7.3. Specific end use(s)

Specific use(s) Pharmaceutical intermediate.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

PF-07265803

Pfizer OEL TWA-8 Hr: 40 µg/m^3 Contact Hazards Unknown

8.2. Exposure controls

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

Environmental exposure controls No information available.

Personal protective equipment 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 Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a 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 to tan
Odor	No information available.
Odor threshold	No information available
Molecular formula	C24H29F2N5O3
Molecular weight	473.5

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

Partition Coefficient: (Method, pH, Endpoint, Value)
PF-07265803
Predicted 7.4 Log D 1.317

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.

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

Known Clinical Effects: Based on clinical trials in humans, possible adverse effects following exposure to this compound may include: headache, nausea, diarrhea, dizziness, constipation, sleepiness (somnolence), insomnia, mouth sores, acne.

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

PF-07265803

Rat Oral NOEL > 600 (300 BID) mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

PF-07265803

28 Day(s) Rat Oral 60 (30 BID) mg/kg/day NOAEL Liver, Skeletal muscle
26 Week(s) Rat Oral 20 (10 BID) mg/kg/day NOAEL Liver
28 Day(s) Monkey Oral 60 (30 BID) mg/kg/day LOAEL Skeletal muscle
9 Month(s) Monkey Oral 60 (30 BID) mg/kg/day NOAEL Skeletal muscle

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

PF-07265803

Embryo / Fetal Development Rat Oral 20 (10 BID) mg/kg/day NOAEL Fetotoxicity, Not teratogenic
Embryo / Fetal Development Rabbit Oral 60 (30 BID) mg/kg/day NOAEL Fetotoxicity, Not Teratogenic

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

PF-07265803

In Vitro Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative
In Vitro Mammalian Cell Mutagenicity Mouse Lymphoma Negative
In Vivo Micronucleus Mouse Negative

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

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

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

be avoided.

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-07265803
Predicted 7.4 Log D 1.317

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects
No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

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

Section 14: TRANSPORT INFORMATION

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

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

Section 15: REGULATORY INFORMATION

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

PF-07265803

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

European Union

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

Authorizations and/or restrictions on use:

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

Persistent Organic Pollutants

Not applicable

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

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

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

Full text of H-Statements referred to under section 3

Reproductive toxicity-Cat.2; H361 - Suspected of damaging fertility or the unborn child

Data Sources:	Pfizer proprietary drug development information.
Reason for revision	New data sheet.
Revision date	05-Dec-2021
Prepared By	Pfizer Global Environment, Health, and Safety

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

SAFETY DATA SHEET

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

1.1. Product identifier

Product Name PF-07327853

Product Code(s) PF00275
Synonyms AR00344864
Trade Name: Not established
Chemical Family: Not determined

PF-07327853
CAS No 765914-40-7

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

Recommended Use Pharmaceutical process intermediate

1.3. Details of the supplier of the safety data sheet

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

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

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887
E-mail address pfizer-MSDS@pfizer.com

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous

OSHA Classification
Physical Hazard Combustible Dust

2.2. Label elements

Signal word Warning

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

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
PF-07327853 765914-40-7	100		Not Listed	No data available	Not Listed	No data available	No data available

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

Acute Toxicity Estimate
No information available

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

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

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

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

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

Ingestion Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

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

Most important symptoms and effects No data available

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

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

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

Hazardous combustion products Carbon monoxide, carbon dioxide, nitrogen oxides and fluorine-containing compounds

5.3. Advice for firefighters

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

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

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

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

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

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

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

6.4. Reference to other sections

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

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

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

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

7.2. Conditions for safe storage, including any incompatibilities

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

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-07327853

Pfizer Occupational Exposure Band (OEB): OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m^3 to < 100ug/m^3)

8.2. Exposure controls

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

Environmental exposure controls No information available.

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

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

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

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

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

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

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

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

Molecular formula	C18H16F2N2O3
Molecular weight	346.33

Property	**Values**
pH	No data available
Melting point / freezing point	150 °C
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Solvent Solubility:	Soluble: Acetone Acetonitrile Methanol Tetrahydrofuran
Explosive properties	No information available

Partition Coefficient: (Method, pH, Endpoint, Value)
PF-07327853
Predicted 7.4 Log D 1.684

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.

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: The toxicological properties of this chemical have not been thoroughly investigated.

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-07327853
Predicted 7.4 Log D 1.684

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects
No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

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

Section 14: TRANSPORT INFORMATION

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

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

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-07327853

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

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

Authorizations and/or restrictions on use:
This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants
Not applicable

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

Not applicable

Legend:
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

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

Data Sources:	Pfizer proprietary drug development information.
Reason for revision	New data sheet.
Revision date	06-Dec-2021
Prepared By	Pfizer Global Environment, Health, and Safety

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

SAFETY DATA SHEET

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

1.1. Product identifier

Product Name PF-07327855-11

Product Code(s) PF00345
Trade Name: Not established
Chemical Family: Not determined

PF-07327855-11
CAS No PROPRIETARY

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

Recommended Use Pharmaceutical intermediate

1.3. Details of the supplier of the safety data sheet

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

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

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887
E-mail address pfizer-MSDS@pfizer.com

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Not classified as hazardous

OSHA Classification
Physical Hazard Combustible Dust

2.2. Label elements

Signal word Warning

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

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
PF-07327855-11 PROPRIETARY	100		Not Listed	No data available	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

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

5.2. Special hazards arising from the substance or mixture

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

Hazardous combustion products Carbon monoxide, carbon dioxide, and oxides of nitrogen may be generated in a fire.

5.3. Advice for firefighters

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

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

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

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

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

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

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

6.4. Reference to other sections

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

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under hood/fume cupboard. Avoid inhalation and contact with skin, eyes, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Restrict access to work area. 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)

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-07327855-11

Pfizer Occupational Exposure Band (OEB): OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m^3 to < 100ug/m^3)

8.2. Exposure controls

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

Environmental exposure controls No information available.

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

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

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

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

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

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

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Solid
Color	White
Odor	No information available.
Odor threshold	No information available
Molecular formula	C6H15N3O.2C4H4O4
Molecular weight	377.35

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

9.2. Other information
No information available

9.2.1. Information with regard to physical hazard classes
No information available

9.2.2. Other safety characteristics
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.

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.

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

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

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.

Section 15: REGULATORY INFORMATION

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

European Union

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

Authorizations and/or restrictions on use:
This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants
Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009
Not applicable

Legend:
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

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

Data Sources:	Pfizer proprietary drug development information.
Reason for revision	New data sheet.
Revision date	26-Feb-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.

SAFETY DATA SHEET

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

1.1. Product identifier

Product Name PF-07328543-15

Product Code(s) PF00344
Trade Name: Not established
Chemical Family: Not determined

PF-07328543-15
CAS No PROPRIETARY

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

Recommended Use Pharmaceutical intermediate

1.3. Details of the supplier of the safety data sheet

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

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

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887
E-mail address pfizer-MSDS@pfizer.com

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Not classified as hazardous

OSHA Classification
Physical Hazard Combustible Dust

2.2. Label elements

Signal word Warning

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

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
PF-07328543-15 PROPRIETARY	100		Not Listed	No data available	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

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

5.2. Special hazards arising from the substance or mixture

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

Hazardous combustion products Carbon monoxide, carbon dioxide, oxides of nitrogen, sulfur oxides, and other sulfur- and bromine-containing compounds

5.3. Advice for firefighters

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

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

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

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

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

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

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

6.4. Reference to other sections

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

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under hood/fume cupboard. Avoid inhalation and contact with skin, eyes, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Restrict access to work area. 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)

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-07328543-15

Pfizer Occupational Exposure Band (OEB): OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m^3 to < 100ug/m^3)

8.2. Exposure controls

Engineering controls Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels 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	Light brown
Odor	No information available.
Odor threshold	No information available
Molecular formula	C13H15BrN2O2.C7H8O3S
Molecular weight	483.38

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

9.2. Other information
No information available

9.2.1. Information with regard to physical hazard classes
No information available

9.2.2. Other safety characteristics
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.

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.

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

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

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.

Section 15: REGULATORY INFORMATION

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

European Union

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

Authorizations and/or restrictions on use:

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

Persistent Organic Pollutants

Not applicable

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

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

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

Data Sources:	Pfizer proprietary drug development information.
Reason for revision	New data sheet.
Revision date	26-Feb-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.

SAFETY DATA SHEET

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

1.1. Product identifier

Product Name PF-07812051

Product Code(s) PF00302
Synonyms Array-797 Step 1 Intermediate
Trade Name: Not established
Chemical Family: Not determined

PF-07812051
CAS No PROPRIETARY

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

Not classified as hazardous

OSHA Classification
Physical Hazard Combustible Dust

2.2. Label elements

Signal word Warning

Hazard statements 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.

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-07812051 PROPRIETARY	100		Not Listed	No data available	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

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

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	Dust can form an explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions.
Hazardous combustion products	Formation of toxic gases is possible during heating or fire. Emits toxic fumes of carbon monoxide, carbon dioxide, oxides of nitrogen and bromine-containing compounds

5.3. Advice for firefighters

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

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
For emergency responders	Use personal protection recommended in Section 8.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Contain the source of the spill or leak. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean spill area thoroughly.
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

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

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

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

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

7.2. Conditions for safe storage, including any incompatibilities

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

7.3. Specific end use(s)

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-07812051

Pfizer Occupational Exposure Band (OEB): OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m^3 to < 100ug/m^3)

8.2. Exposure controls

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

Environmental exposure controls No information available.

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

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

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

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

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

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

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Solid
Color	White
Odor	No information available.
Odor threshold	No information available
Molecular formula	C12H13BrN2O2
Molecular weight	297.15

Property	Values
pH	No data available
Melting point / freezing point	203.1
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	Soluble: methanol, Acetone, Isopropyl alcohol
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-07812051
Predicted 7.4 Log D 0.173

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 100 J/g at 193 °C and -74 J/g at 234 °C and -120 J/g at 332 °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.

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.

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-07812051
Predicted 7.4 Log D 0.173

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

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

Section 14: TRANSPORT INFORMATION

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

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

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-07812051

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

European Union

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

Authorizations and/or restrictions on use:

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

Persistent Organic Pollutants

Not applicable

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

Not applicable

Legend:
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

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

Data Sources:	Pfizer proprietary drug development information.
Reason for revision	New data sheet.
Revision date	28-Apr-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.