



Pfizer Ireland Pharmaceuticals
Ringaskiddy Active Pharmaceutical Ingredient Plant
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Pfizer Ireland Pharmaceuticals

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

03-June-2021

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

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

Dear Sir/Madam,

We wish to notify the Agency that it's planned to introduce the following new materials onsite for the manufacture of the final three steps (3,4,5) of COVID Solid Oral Dose (SOD)-a new treatment for COVID-19. We note our submission LR058373, in which we notified new materials associated with the manufacture of the first two steps of COVID SOD, was approved by the Agency on the 19-May-2021.

Given the extent and impact of the pandemic, the timeline for the introduction of this new treatment is aggressive and it's planned to commence manufacture of this product in the OSP4 manufacturing facility during early to mid-June. The manufacturing of the process steps 3-5 for which these new materials are being notified, is due to commence in mid-July.

We request Agency approval to introduce the following new materials on site.

- PF-07328614-01 Step 3 RSM
- 2-PYRIDINOL 1-OXIDE (HOPO)
- N-Ethyl-N'-(3-dimethylaminopropyl) carbodiimide hydrochloride (EDC HCl)
- TRIFLUOROACETIC ANHYDRIDE (TFAA)
- PF-07321332 MTBE Solvate
- PF-07321332 API

This product is a 5-step process. We reference LR058373 which was the notification of new materials associated with the first 2 steps. Combined step 3-4 and step 5 are being notified in this submission. PF-07328614-01 is the regulatory starting material in step 3-4 of the process and is transformed to PF-07321332 MTBE Solvate (Step 4 intermediate) which is the output of the fourth step of the product. This material is then subsequently used in the

fifth step of the process and is transformed to PF-07321332 API. 2-PYRIDINOL 1-OXIDE (HOPO), N-Ethyl-N'-(3-dimethylaminopropyl) carbodiimide hydrochloride (EDC HCl) and Trifluoroacetic Anhydride (TFAA) are reagents in the process. Reagents are typically used up in a process and any reagents added in stoichiometric excess are contained in the waste streams which are discussed later.

The SDS for the above materials are attached in Appendix 1.

The manufacture of Steps 3,4 and 5 is scheduled for the OSP4 manufacturing plant initially. The volumes manufactured will be determined based on the progress and extent of the global pandemic. Currently there are 3 campaigns of this product scheduled based on current market demand. The third and any subsequent campaigns are envisaged to be manufactured in OSP3. 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 COVID SOD are no different to manufacturing any of our existing products. Minimal engineering changes are required to expedite the manufacture of this product. Irrespective of the manufacturing plant and volume, there will be no environmental impact resulting from the manufacture of COVID SOD explained as follows:

We confirm that the solvents used in Step 3-4 are Methyl Ethyl Ketone, Methyl tert-butyl ether and Isopropyl acetate. Isopropyl acetate and n-Heptane will be used in Step 5. These solvents are routinely in use on site and the existing air abatement systems are capable of handling these emissions.

There will be no new emissions to air resulting from this process. 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, V13 which is continuously monitored. When these steps are manufactured in the OSP3 manufacturing facility, air emissions from this process and all processes in the OSP3 manufacturing facilities are managed by the existing OSP3 VOC Absorption system which is the main VOC emission abatement system for OSP3. Treated emissions from the OSP3 abatement system are directed to atmosphere via the licensed emission point, V5 which is continuously monitored.

H [Hazard] Phrases for the new materials are identified in the SDS attached as 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.

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 packed 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 COVID SOD 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 Plant serving OSP3, the licensed volumetric flowrate of the fans is 2,700 m³/hour. The operational volumetric flow range is variable and currently typically in the range 300-700 m³/hour (10-25% of design), showing that there is significant spare abatement capacity available. 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 COVID-SOD product will therefore take place fully within the existing design envelope of the VOC Absorption Plant, and solvents/VOCs will be efficiently removed as per design and continuously monitored by a CEMS.

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

Table 1: 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 [2020]	Ringaskiddy average 30-minute mean mg/m ³ [2019]
Volatile organic compounds (excluding Particulate matter) expressed as total organic carbon	20 mg/m³	0.33 mg/m³	0.34 mg/m³

Table 2: V3: ELV's for licensed emission point from OSP3 Production

Solvent	1997 TA Luft Class	Emission Limit Value [ELV]	Ringaskiddy average kg/hr [2020]	Ringaskiddy average kg/hr [2019]
Methyl Ethyl Ketone	TA Luft Organics Class III	150mg/m³ (at mass flows >3.0 kg/hr)	0.00067 kg/hr	0.00138kg/hr
Methyl tert-butyl ether	TA Luft Organics Class III	150mg/m³ (at mass flows >3.0 kg/hr)	0.00067 kg/hr	0.00138kg/hr
Isopropyl acetate	TA Luft Organics Class III	150mg/m³ (at mass flows >3.0 kg/hr)	0.00067 kg/hr	0.00138kg/hr

n-Heptane	TA Luft Organics Class III	150mg/m3 (at mass flows >3.0 kg/hr)	0.00067 kg/hr	0.00138kg/hr
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Tables 1 and 2 above provide a summary of the annual emissions data from V13 [licensed emission point for OSP4] and V5 [licensed emission point for OSP3] from 2019 and 2020 and all emissions from the OSP4 and OSP3 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. Waste streams deemed not suitable for treatment in the waste-water treatment plant will be removed from site for off-site disposal/treatment. We confirm that waste streams from Steps 3-5 of COVID SOD will be sent off site for treatment. In cases where ecotoxicity and sludge inhibition data isn't available for the output / product of process step, waste streams are sent for off-site treatment. There is no eco-toxicity data available for COVID-SOD currently, which is typical for new product launch. Emissions from the process will not impact the operation of the waste-water treatment plant or the quality of the final effluent discharged.

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

We note that following a meeting with the Agency the submission LR058373, notifying new materials associated with steps 1 and 2 of this product, was approved by the Agency on the 19-May-2021.

In summary, there will be no environmental impact resulting from the manufacture of COVID SOD, steps 3-5.

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

Ellen O'Driscoll

Ellen O'Driscoll

Environment, Health and Safety Department

Appendix 1:



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

1.1. Product identifier

Product Name PF-07328614-01

Product Code(s) PF00180

Trade Name: Not established

Chemical Family: Not determined

PF-07328614-01

CAS No

-

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

Recommended Use Pharmaceutical process intermediate

1.3. Details of the supplier of the safety data sheet

Pfizer 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

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

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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-07328614-01 -	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

- Not Assigned

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

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

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

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

Most important symptoms and effects No data available

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

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

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

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

5.3. Advice for firefighters

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

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

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

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

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

Methods for cleaning up 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)

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Specific use(s) Pharmaceutical process intermediate.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Pfizer OEB Statement:

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

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Pfizer Occupational Exposure Band (OEB):

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

8.2. Exposure controls

Engineering controls Engineering controls should be used as the primary means to control exposures.

Environmental exposure controls No information available.

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

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

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

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

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

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

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Solid
Color	White to light yellow
Odor	No information available.
Odor threshold	No information available
Molecular formula	C7 H14 Cl N3 O2
Molecular weight	207.8

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

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

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. As a precautionary measure, keep away from electrostatic discharge.

10.5. Incompatible materials

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

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

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Section 11: TOXICOLOGICAL INFORMATION

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

General Information: Toxicological properties have not been investigated.

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

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

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

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

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.

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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-07328614-01

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

European Union

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

Authorizations and/or restrictions on use:

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

Persistent Organic Pollutants

Not applicable

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

Not applicable

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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 24-Mar-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

AB 137083

Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II, as amended by Regulation (EU) No. 830/2015 - Europe

Date of revision 05.02.2021

Version 0.03

1. Identification of the Substance and the Company

1.1 Product identifier

Product name	2-Hydroxypyridine N-oxide; 98%
CAS number	13161-30-3
Product code	AB 137083
Synonym	2-Pyridinol, 1-oxide

1.2 Identified uses

Chemicals used in research and development, analysis and production

1.3 Details of the supplier of the safety data sheet

Company details	abcr GmbH Im Schlehert 10 76187 Karlsruhe Germany
Telephone	+49 (0)721 950 610
Email	sdb@abcr.de

1.4 Emergency telephone number

+49 (0) 6131/19240
www.giftinfo.uni-mainz.de

2. Hazards identification

2.1 Classification of the substance or mixture

Product definition Substance

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

H315	SKIN CORROSION/IRRITATION - Category 2
H319	SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2
H335	SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3

2.2 Label elements

Hazard pictograms



Signal word	Warning
Hazard statements	H319 - Causes serious eye irritation. H315 - Causes skin irritation. H335 - May cause respiratory irritation.

Precautionary statements	P280 - Wear protective gloves. Wear eye or face protection. P261 - Avoid breathing dust. P304 + P340 + P312 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or physician if you feel unwell. P332 + P313 - If skin irritation occurs: Get medical attention. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Hazardous ingredients	2-hydroxypyridine 1-oxide
Supplemental label elements	Not applicable.
Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	Not applicable.

2.3 Other hazards

Other hazards which do not result in classification	None known.
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See Section 11 for more detailed information on health effects and symptoms.

3. Composition/information on ingredients

Substance/mixture Mono-constituent substance

Product/ingredient name	Identifiers	%	Classification Regulation (EC) No. 1272/2008 [CLP]	Type
2-Hydroxypyridine N-oxide	EC: 236-100-8 CAS: 13161-30-3	100	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 See Section 16 for the full text of the H statements declared above.	[A]

There are no additional ingredients present which, within the current knowledge of the supplier, are classified and contribute to the classification of the substance and hence require reporting in this section.

Type

[A] Constituent

[B] Impurity

[C] Stabilizing additive

Occupational exposure limits, if available, are listed in Section 8.

4. First aid measures

4.1 Description of first aid measures

Eye contact	Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.
Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If necessary, call a poison center or physician. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
Skin contact	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Continue to rinse for at least 10 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.
Ingestion	Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
Protection of first-aiders	No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

4.2 Most important symptoms and effects, both acute and delayed

Potential acute health effects

Eye contact	Causes serious eye irritation.
Inhalation	May cause respiratory irritation.
Skin contact	Causes skin irritation.

Over-exposure signs/symptoms

Eye contact	Adverse symptoms may include the following: pain or irritation watering redness
Inhalation	Adverse symptoms may include the following: respiratory tract irritation coughing
Skin contact	Adverse symptoms may include the following: irritation redness

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician	In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
Specific treatments	No specific treatment.

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media In case of fire, use water spray (fog), foam, dry chemical or CO₂.

Unsuitable extinguishing media None known.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture Combustible

Hazardous combustion products Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides

5.3 Advice for firefighters

Special precautions for fire-fighters Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

6.2 Environmental precautions

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3 Methods and materials for containment and cleaning up

Small spill	Move containers from spill area. Avoid dust generation. Using a vacuum with HEPA filter will reduce dust dispersal. Place spilled material in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.
Large spill	Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor.

6.4 Reference to other sections

See Section 1 for emergency contact information.

See Section 8 for information on appropriate personal protective equipment.

See Section 13 for additional waste treatment information.

7. Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

7.1 Precautions for safe handling

Protective measures	Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.
Advice on general occupational hygiene	Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

7.3 Specific end use(s)

Recommendations	Not available.
Industrial sector specific solutions	Not available.

8. Exposure controls/Personal protective equipment

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

8.1 Control parameters

Occupational exposure limits

No exposure limit value known.

Recommended monitoring procedures

If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

Derived effect levels

No DELs available.

Predicted effect concentrations

No PECs available.

8.2 Exposure controls

Appropriate engineering controls

Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

Individual protection measures

Hygiene measures

Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection

Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.

Skin protection

Hand protection

Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection

Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection	Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Respiratory protection	Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.
Environmental exposure controls	Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Physical state	Solid.
Color	Not available.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Burning time	Not available.
Burning rate	Not available.
Upper/lower flammability or explosive limits	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Density	Not available.
Solubility(ies)	Not available.
Partition coefficient: n-octanol/water	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.

9.2 Other information

No additional information.

10. Stability and reactivity

10.1 Reactivity

No specific test data related to reactivity available for this product or its ingredients.

10.2 Chemical stability

Stable under recommended storage and handling conditions (see Section 7).

10.3 Possibility of hazardous reactions

Under normal conditions of storage and use, hazardous reactions will not occur.

10.4 Conditions to avoid

exposure to heat and moisture

10.5 Incompatible materials

alkalis
acids
oxidizing agents

10.6 Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11. See toxicological information

11.1 Information on toxicological effects

Acute toxicity

Conclusion/Summary Not available.

Irritation/Corrosion

Conclusion/Summary Not available.

Sensitizer

Conclusion/Summary Not available.

Mutagenicity

Conclusion/Summary Not available.

Carcinogenicity

Conclusion/Summary Not available.

Reproductive toxicity

Conclusion/Summary Not available.

Teratogenicity

Conclusion/Summary Not available.

Information on the likely routes of exposure Not available.

Potential acute health effects

Inhalation	May cause respiratory irritation.
Skin contact	No known significant effects or critical hazards.
Ingestion	Causes skin irritation.
Eye contact	Causes serious eye irritation.

Symptoms related to the physical, chemical and toxicological characteristics

Inhalation	Adverse symptoms may include the following: respiratory tract irritation coughing
Ingestion	No specific data.
Skin contact	Adverse symptoms may include the following: irritation redness
Eye contact	Adverse symptoms may include the following: pain or irritation watering redness

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects Not available.

Potential delayed effects Not available.

Long term exposure

Potential immediate effects Not available.

Potential delayed effects Not available.

Potential chronic health effects

Not available.

Conclusion/Summary Not available.

General	No known significant effects or critical hazards.
Carcinogenicity	No known significant effects or critical hazards.
Mutagenicity	No known significant effects or critical hazards.
Teratogenicity	No known significant effects or critical hazards.
Developmental effects	No known significant effects or critical hazards.
Fertility effects	No known significant effects or critical hazards.

Other information Not available.

12. Ecological Information

12.1 Toxicity

Conclusion/Summary Not available.

12.2 Persistence and degradability

Conclusion/Summary Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Soil/water partition coefficient (K_{oc}) Not available.

Mobility Not available.

12.5 Results of PBT and vPvB assessment

PBT No.

vPvB Not available.

12.6 Other adverse effects

No known significant effects or critical hazards.

13. Disposal considerations

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

13.1 Waste treatment methods

Product

Methods of disposal The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

Hazardous waste The classification of the product may meet the criteria for a hazardous waste.

Packaging

Methods of disposal The generation of waste should be avoided or minimized wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

14. Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
14.2 UN proper shipping name	-	-	-	-
14.3 Transport hazard class(es)	-	-	-	-
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.
14.6 Special precautions for user	Not available.	Not available.	Not available.	Not available.
Additional information	-	-	-	-

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

Not available.

15. Regulatory information

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

EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorization

Substances of very high concern

None of the components are listed.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

Not applicable.

Other EU regulations

Europe inventory

This material is listed or exempted.

Black List Chemicals

Priority List Chemicals Not listed
Industrial emissions (integrated pollution prevention and control) - Air Not listed
Industrial emissions (integrated pollution prevention and control) - Water Not listed

Chemical Weapons Convention List Schedule I Chemicals Not applicable.

Chemical Weapons Convention List Schedule II Chemicals Not applicable.

Chemical Weapons Convention List Schedule III Chemicals Not applicable.

15.2 Chemical Safety Assessment

Not available.

16. Other information

▣ Indicates information that has changed from previously issued version.

Abbreviations and acronyms ATE = Acute Toxicity Estimate
 CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
 DNEL = Derived No Effect Level
 EUH statement = CLP-specific Hazard statement
 PNEC = Predicted No Effect Concentration
 RRN = REACH Registration Number

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Skin Irrit. 2, H315	Expert judgment
Eye Irrit. 2, H319	Expert judgment
STOT SE 3, H335	Expert judgment

Full text of abbreviated H statements H315 Causes skin irritation.
 H319 Causes serious eye irritation.
 H335 May cause respiratory irritation.

Full text of classifications [CLP/GHS] Eye Irrit. 2, H319 SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2
 Skin Irrit. 2, H315 SKIN CORROSION/IRRITATION - Category 2
 STOT SE 3, H335 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3

Full text of classifications [CLP/GHS]	Eye Irrit. 2, H319	SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2
	Skin Irrit. 2, H315 STOT SE 3, H335	SKIN CORROSION/IRRITATION - Category 2 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3
Date of issue/ Date of revision	05.02.2021	
Version	0.03	

Notice to reader

The above information is based on our present state of knowledge. It should not therefore be construed as guaranteeing specific properties of the products described or their suitability for a particular application.

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

1.1. Product identifier

Product name: **1-(3-Dimethylaminopropyl)-3-ethylcarbodiimide HCl**
 Trade name, synonyms: (Water Soluble Carbodiimide, EDAC HCl)
 IUPAC name: **3-(Ethyliminomethylideneamino)-N,N-dimethylpropan-1-amine;hydrochloride**
 CAS No.: 25952-53-8
 EC No.: 247-361-2
 REACH reg. No.: 01-2120762851-50-0001
 Product No.: 3803-KL

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

Identified uses: Chemical in syntheses. Laboratory reagent.

1.3. Details of supplier of the safety data sheet

Supplier/Manufacturer: KEMILAB Organics Ltd.
 H-8200 Veszprém, Zrínyi street 13/B; Hungary
 Telephone: +36 30 226 4546;
 Fax: +88 412 559
 E-mail: kemilab@kemilab.hu

1.4. Emergency telephone number

Emergency telephone call number: See: <https://echa.europa.eu/support/helpdesks>
 Availability: 24 hours

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Acute Tox.	Category 4 – H302
Acute Tox.	Category 3 – H311
Skin Sens.	Category 1 – H317
Skin Irrit.	Category 2 – H315
Eye Irrit.	Category 2 – H319
STOT RE	Category 2 – H373
Aquatic Acute	Category 1 – H400
Aquatic Chronic	Category 1 – H410

Supplier:

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

2.2. Label elements

2.2.1 According to Regulation No. 1272/2008 (CLP)/EU

- Hazard pictograms:



- Signal word:

DANGER



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▪ Hazard statements:

- H302 Harmful if swallowed
- H311 Toxic in contact with skin
- H315 Causes skin irritation
- H317 May cause an allergic skin reaction
- H319 Causes serious eye irritation
- H373 May cause damage to stomach, intestine and trachea through prolonged or repeated exposure
- H410 Very toxic to aquatic life with long lasting effects

▪ Precautionary statements:

- P261 Avoid breathing dust/fume/gas/vapour/spray
- P273 Avoid release to the environment
- P280 Wear protective gloves/protective clothing/eye protection/face protection
- P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell
Rinse mouth
- P302+P352 IF ON SKIN: Wash with plenty of water and soap.
- P337+P313 If eye irritation persists: Get medical advice/attention
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P362+P364 Take off contaminated clothing and wash it before reuse
- P333+P313 If skin irritation or rash occurs: Get medical advice/attention

2.3. Other hazards

- Most important hazards: Harmful! Irritating to eyes, respiratory system and skin.
Specific hazards: In certain cases, it may cause sensitization by inhalation or contact with skin.

SECTION 3: Composition/information on ingredients

The name of the component	Formula/Molar mass	EC-No.	CAS No	Weight %
1-(3-Dimethylaminopropyl)-3-ethyl carbodiimide . HCl salt	$\text{CH}_3 \text{CH}_2 \text{N}=\text{C}=\text{N}(\text{CH}_2)_3 \text{N}(\text{CH}_3)_2 \cdot \text{HCl}$ salt Molar mass: 191,7 g/mol	247-361-2	25952-53-8	99+

SECTION 4: First aid measures

4.1. Description of first aid measures

- Protection of first aiders: Take appropriate steps to avoid every contact of the material. Instantly remove clothing soiled by the material.
- Inhalation: Move to fresh air. Keep patient warm. If rapid recovery does not occur, seek medical attention. Seek immediate medical advice in every case.
- Skin contact: Instantly wash affected skin with soap and plenty of water. Seek immediate medical advice.
- Eye contact: DO NOT DELAY. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If persistent irritation occurs, seek medical attention.
- Ingestion: DO NOT DELAY. Do not induce vomiting. Never give anything by mouth to an unconscious person. SEEK MEDICAL ATTENTION IMMEDIATELY.



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Note to physician: Treat symptomatically.

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

Damages to the eyes. Nausea, headache, vomiting. Causes severe corneal edema.

4.3. Indication of immediate medical attention and special treatment needed

No data available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

For small fires use media such as „alcohol” foam, dry chemical or carbon dioxide. For large fires apply water spray as far as possible.

5.2. Special hazards arising from the substance or mixture

Carbon oxides and nitrogen oxides, HCl.

5.3. Advice for firefighters

Wear self-contained breathing apparatus and chemical protective clothing.

Further information

Collect separately contaminated extinguishing water, do not allow to reach sewage or effluent system.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Do not breathe the powder of the material. Avoid contact with skin, eyes and clothing.

Wear protective equipment. Keep unprotected persons away. Emergency services may be called to assist in this operation.

6.2. Environmental precautions

Prevent contamination of soil and water. If materials enters drains, it should be separated and pumped out into an open vessel. Emergency services may be called to assist in this operation.

6.3. Methods and material for containment and cleaning up

Do not flush away residues with water. Contain spillage and then collect with an electrically protected vacuum cleaner or wet-brushing and place in a container for disposal according to local regulations (see Section 13).

6.4. Reference to other sections

For disposal see Section 13.

SECTION 7: Handling and storage

7.2. Precautions for safe handling

Do not eat, drink or smoke when using it! Avoid contact with skin, eyes and clothing. Do not breath its powder. Prevent spills and avoid all operations which contaminate clothing and work areas. Ensure good ventilation/exhausting at the workplace. Avoid generation of powdering! Observe label precautions!

7.3. Conditions for safe storage, including any incompatibilities

Segregate from acids and strong oxidants! Keep away from humidity and water!! Keep container tightly closed in a cool, well-ventilated place. Proposed storage temperature: 2-8 C⁰ Some days storage at ambient temperature (for example during transport, not higher than 30⁰C) does not cause any damage in material.

Containers which are opened must be carefully inertised by Nitrogen then resealed and kept it upright to prevent leakage!

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7.3. Specific end use(s)

No data available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits are not available. Apply it closed system!!!! Need a suitable ventilation!

8.2. Exposure controls

- **Eye/face protection:** Tightly fitting safety goggles. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
- **Skin protection:** Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose the contaminated gloves after use in accordance with applicable laws. Wash and dry hands. The selected protective gloves must satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.
- **Body protection:** Complete suit protecting against chemicals. Flame retardant antistatic protective clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
- **Respiratory protection:** Where risk assessment shows air purifying respirators are appropriate use a full-face respirator with multipurpose combination (US) or type ABEKP (EN 14387) 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).

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

a) Appearance	White to off white powder.
b) Odour	Characteristic
c) Odour threshold	No data available
d) pH	6,5 – 7 in water solution (5m/m%)
e) Melting point	108 – 118 °C
f) Initial boiling point and boiling range	No data available
g) Flash point	No data available
h) Evaporation rate	No data available
i) Flammability (solid, gas)	Combustible
j) Upper/lower flammability or explosive limits	No data available
k) Vapour pressure	< 1,3 hPa at 20 °C
l) Vapour density	No data available
m) Relative density	~ 0,4 kg/liter
n) Water solubility	Soluble, hygroscopic
o) Partition coefficient: n-octanol/water	Log Pow 0,21 (calculated data) Bioaccumulation is not feasible.
p) Autoignition temperature	Not data available
q) Decomposition temperature	Not data available
r) Viscosity	Not data available
s) Explosive properties	Not data available
t) Oxidizing properties	Not data available

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9.2. Other information

No data available.

SECTION 10: Stability and reactivity

10.1. Reactivity

It reacts with acids and acidic water!

10.2. Chemical stability

No data available

10.3. Possibility of hazardous reactions

No data available

10.4. Conditions to avoid

Humidity! Avoid heat!

10.5. Incompatible materials

Strong oxidizing materials, acids.

10.6. Hazardous decomposition products

No data available

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

- **Acute toxicity:**
LD50 intravenous 56 mg/kg on mouse
LD50 oral 500 mg/kg rat (OECD Test Guideline 423)
LD50 dermal >200 – 1.000 mg/kg rabbit, male and female (OECD Test Guideline 402)
- **Skin corrosion/irritation:**
Skin - Rabbit
Result: Severe skin irritation
(OECD Test Guideline 404)
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitization**
Local lymph node assay (LLNA) - Mouse
May cause allergic skin reaction.
(OECD Test Guideline 429)
- **Germ cell mutagenicity**
No data available
Ames test
S. typhimurium
Result: positive
Chromosome aberration test in vitro
mouse lymphoma cells
Result: positive
(OECD Test Guideline 489)
Rat - male
Result: negative
- **Carcinogenicity**
IARC: No component of this product present at levels greater than or equal to 0,1% is identified as probable, possible or confirmed human carcinogen by IARC.
- **Reproductive toxicity:**
No data available

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- **Specific target organ toxicity – single exposure**
Not classified.
- **Specific target organ toxicity – repeated exposure**
Oral - May cause damage to organs through prolonged or repeated exposure. - Stomach, large intestine, lymph node
- **Aspiration hazards**
No data available
- **Potential health effects**
Inhalation: may be harmful if inhaled. Material is extremely destructive to the tissue of the mucous membranes and upper respiratory tract.
Ingestion: may be harmful if swallowed. Causes burns.
Skin: may be harmful if absorbed through skin. Causes skin burns.
Eyes: Causes eye burns and serious eye damage
- **Signs and Symptoms of exposure**
Material is extremely destructive to the tissue of the mucous membranes and upper respiratory tract.
- **Additional information.** RTECS 2200000

SECTION 12: Ecological information

12.1. Toxicity

Toxicity to fish static test LC50 - Cyprinus carpio (Carp) - 4,6 mg/l - 96 h (OECD Test Guideline 203)

Toxicity to daphnia and other aquatic invertebrates

EC50 - Daphnia magna (Water flea) - 0,41 mg/l - 48 h (ISO 6341)

Toxicity to bacteria EC50 - activated sludge - > 347 - < 470 mg/l - 3 h (OECD Test Guideline 209)

H410 – Very toxic to aquatic life with long lasting effects

12.2. Persistence and degradability

Biodegradability aerobic Chemical oxygen demand - Exposure time 28 d

Result: < 5 % - Not readily biodegradable. (OECD Test Guideline 301F)

12.3. Bioaccumulative potential

Log Pow 0,21 (calculated data)

Bioaccumulation is not feasible.

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

No data available

12.6. Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product. Burn in a chemical incinerator equipped with an afterburner and scrubber in accordance with the requirements of local Waste Disposal Authority.

Contaminated packaging: Dispose of as unused product.

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SECTION 14: Transport information

14.1. UN number

UN No. (ADR/RID)	UN 2811
UN No. (IMDG)	UN 2811
UN No. (ICAO)	UN 2811
UN No. (ADN)	UN 2811

14.2. UN proper shipping name

Proper shipping name (ADR/RID)	TOXIC SOLID, ORGANIC, N.O.S. (1-(3-(Dimethylamino)propyl)-3-ethylcarbodiimide hydrochloride)
Proper shipping name (IMDG)	TOXIC SOLID, ORGANIC, N.O.S. (1-(3-(Dimethylamino)propyl)-3-ethylcarbodiimide hydrochloride)
Proper shipping name (ICAO)	Toxic solid, organic, n.o.s. (1-(3-(Dimethylamino)propyl)-3-ethylcarbodiimide hydrochloride)
Proper shipping name (ADN)	Toxic solid, organic, n.o.s. (1-(3-(Dimethylamino)propyl)-3-ethylcarbodiimide hydrochloride)

14.3. Transport hazard class(es)

ADR/RID class	6.1
IMDG class	6.1
ICAO class/division	6.1
ADN class	6.1

Transport labels:



14.4. Packing group

ADR/RID	III
IMDG	III
ICAO	III
ADN	III

14.5. Environmental hazards

ADR/RID	Yes
IMDG	Marine pollutant
ICAO	No
ADN	Yes

14.6. Special precautions for user

No data available

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SECTION 15: Regulatory information

This safety datasheet complies with the requirements of Regulations (EC) No.: 1907/2006 and 2015/830

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

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

16.1. Abbreviations and acronyms:

ACGIH	American Conference of Governmental Industrial Hygienists IARC - International Agency for Research on Cancer
ADN	The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	Accord europeen sur le transport des marchandises dangereuses par Route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CAS	Chemical abstract Service (division of the American Chemical Society)
CEN	European Committee for Standardization
CLP	Classification, Labelling and Packaging
EC50	Effective Concentration 50%
EINECS/ELINCS	European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
Ems	Emergency Response Procedures for Ships Carrying Dangerous Goods (EmS Guide)
GHS	Globally Harmonized System of Classification and Labelling of Chemicals.
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO/IMDG	International Maritime Organization/International Maritime Dangerous Goods Code
IUPAC	International Union of Pure and Applied Chemistry
LC50	Lethal Concentration 50%
LD50	Lethal Dose 50%
MARPOL	International Convention for the Prevention of Pollution from Ships
NIOSH	National Institute for Occupational Safety and Health
NOEC	No Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative
POW	Partition coefficient Octanol:Water
RID	Reglement interntional conRegulation Concerning the cemant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Dangerous Goods by Rail)
RPE	Respiratory Protective Equipment
RTECS	Registry of Toxic Effects of Chemical Substances
Toxic yPyB	very Persistent, very Bioaccumulative
TSCA	United States Toxic Substances Control Act Section 8(b) Inventory
TWA	Time Weighted Average
VOC	Volatile Organic Compounds
WEL	Workplace Exposure Limit



SAFETY DATA SHEET

according to Regulations (EU) No.1907/2006 & Commission Regulation (EU) No 2015/830

1-(3-Dimethylaminopropyl)-3-ethylcarbodiimide.HCl

05th November 2020
Version 9

16.2. Hazard statements in full:

- H302 Harmful if swallowed
- H311 Toxic in contact with skin
- H315 Causes skin irritation
- H317 May cause an allergic skin reaction
- H319 Causes serious eye irritation
- H373 May cause damage to stomach, intestine and trachea through prolonged or repeated exposure
- H400 Very toxic to aquatic life
- H410 Very toxic to aquatic life with long lasting effects

16.3. Version: This is the version 9 and valid from 06th of November 2020. Changes from the previous version by the reinvestigation version 8:

Some of new toxicological data were available which are introduced into 11.1 point of this SDS. As consequence of these the ADR classification changed from NOT DANGEROUS GOODS to DANGEROUS GOODS (see Section 14).

16.4. Further information: The information in this document should be available to all who may handle the product. The information contained herein based on the present state of our knowledge. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty, guarantee or representation is made to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use.

END OF DOCUMENT

TRIFLUOROACETIC ANHYDRIDE

Revision Date 25.09.2020

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

- | | |
|-------------------------------|------------------------------------|
| - Trade name | TRIFLUOROACETIC ANHYDRIDE |
| - Chemical name | Acetic acid, trifluoro-, anhydride |
| - CAS-No. | 407-25-0 |
| - REACH : Registration number | 01-2119960260-46 |

1.2 Relevant identified uses of the substance or mixture and uses advised against**Uses of the Substance/Mixture**

- Intermediate for synthesis
- Laboratory chemicals

1.3 Details of the supplier of the safety data sheet**Company**

SOLVAY CHEMICALS INTERNATIONAL SA
RUE DE RANSBEEK, 310
1120, BRUXELLES
BELGIUM
Tel: +32-2-2642111
Fax: +32-2-2641802

E-mail address

manager.sds@solvay.com

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

1.4 Emergency telephone number

+44(0)1235 239 670 [CareChem 24]

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

Acute toxicity, Category 4
Skin corrosion, Category 1
Serious eye damage, Category 1
Long-term (chronic) aquatic hazard, Category 3

H332: Harmful if inhaled.
H314: Causes severe skin burns and eye damage.
H318: Causes serious eye damage.
H412: Harmful to aquatic life with long lasting effects.

2.2 Label elements**Regulation (EC) No 1272/2008****Hazardous products which must be listed on the label**

- CAS-No. 407-25-0 trifluoroacetic anhydride

Pictogram**Signal word**

- Danger

P00000021946

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Hazard statements

- H314 Causes severe skin burns and eye damage.
- H332 Harmful if inhaled.
- H412 Harmful to aquatic life with long lasting effects.

Precautionary statementsPrevention

- P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response

- P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
- P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.
- P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.

Additional Labeling

- EUH014 Reacts violently with water.

2.3 Other hazards which do not result in classification

- In the presence of water, forms corrosive solutions.
- Reacts violently with water.

Results of PBT and vPvB assessment

- This substance is not considered to be persistent, bioaccumulating and toxic (PBT).
- This substance is not considered to be very persistent and very bioaccumulating (vPvB).

SECTION 3: Composition/information on ingredients**3.1 Substance**

- Chemical name Acetic acid, trifluoro-, anhydride
- Synonyms TFAH
- Formula (CF₃CO)₂O

Information on Components and Impurities

Chemical name	Identification number	Classification Regulation (EC) No 1272/2008	Concentration [%]
trifluoroacetic anhydride	CAS-No. : 407-25-0 EINECS-No. : 206-982-9	Acute toxicity, Category 4 ; H332 Skin corrosion, Category 1A ; H314 Serious eye damage, Category 1 ; H318 Long-term (chronic) aquatic hazard, Category 3 ; H412	>= 99 - <= 100
	Registration number: 01-2119960260-46-xxxx		
	self classification		

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

3.2 Mixture

- Not applicable, this product is a substance.

SECTION 4: First aid measures**4.1 Description of first aid measures****General advice**

- Show this safety data sheet to the doctor in attendance.
- First aider needs to protect himself.
- Place affected clothing in a sealed bag for subsequent decontamination.

In case of inhalation

- Move to fresh air.
- Oxygen or artificial respiration if needed.
- Victim to lie down in the recovery position, cover and keep him warm.
- Call a physician immediately.

In case of skin contact

- Take off contaminated clothing and shoes immediately.
- Wash immediately and thoroughly for a prolonged period (at least 15 minutes).
- Keep warm and in a quiet place.
- Call a physician or poison control centre immediately.
- Wash contaminated clothing before re-use.

In case of eye contact

- Call a physician or poison control centre immediately.
- Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
- In the case of difficulty of opening the lids, administer an analgesic eye wash (oxybuprocaine).
- Take victim immediately to hospital.

In case of ingestion

- Call a physician or poison control centre immediately.
- Take victim immediately to hospital.
- If swallowed, rinse mouth with water (only if the person is conscious).
- Do not give anything to drink.
- Do NOT induce vomiting.
- Artificial respiration and/or oxygen may be necessary.

4.2 Most important symptoms and effects, both acute and delayed**Effects**

- Skin contact may aggravate existing skin disease
- Inhalation of product may aggravate existing chronic respiratory problems such as asthma, emphysema or bronchitis

In case of inhalation**Symptoms**

- Breathing difficulties
- Cough
- Chemical pneumonitis
- pulmonary oedema

Effects

- Corrosive to respiratory system.

Repeated or prolonged exposure

- Nose bleeding
- Risk of chronic bronchitis

In case of skin contact**Symptoms**

- Redness
- Swelling of tissue

Effects

- Corrosive
- Causes severe burns.

In case of eye contact**Symptoms**

- Redness
- Lachrymation
- Swelling of tissue

Effects

- Corrosive
- Causes severe burns.
- May cause irreversible eye damage.
- May cause blindness.

In case of ingestion**Symptoms**

- Nausea
- Abdominal pain
- Bloody vomiting
- Diarrhoea
- Suffocation
- Cough
- Severe shortness of breath

Effects

- If ingested, severe burns of the mouth and throat, as well as a danger of perforation of the oesophagus and the stomach.
- Risk of shock.
- Risk of throat (o)edema and suffocation.
- Risk of chemical pneumonitis
- Risk of pulmonary oedema.

4.3 Indication of any immediate medical attention and special treatment needed**Notes to physician**

- Treat symptomatically.
- There is no specific antidote available.
- Take victim immediately to hospital.
- Immediate medical attention is required.
- Consult with an ophthalmologist immediately in all cases.
- Burns must be treated by a physician.
- If swallowed
- Avoid gastric lavage (risk of perforation).
- Keep under medical supervision for at least 48 hours.

SECTION 5: Firefighting measures**5.1 Extinguishing media****Suitable extinguishing media**

- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Carbon dioxide (CO₂)
- powder

Unsuitable extinguishing media

- Never use water.

5.2 Special hazards arising from the substance or mixture

- The product is not flammable.
- Reacts violently with water.
- In the presence of water, forms corrosive solutions.
- On combustion, toxic gases are released.
- Gives off hydrogen by reaction with metals.

5.3 Advice for firefighters

Special protective equipment for firefighters

- Use personal protective equipment.
- Wear chemical resistant oversuit
- Boots
- Gloves
- Goggles
- Self-contained breathing apparatus (EN 133)
- Cool containers/tanks with water spray.
- Keep from any possible contact with water.

Specific fire fighting methods

- Evacuate personnel to safe areas.
- Cool containers/tanks with water spray.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- Avoid contact with the skin and the eyes.
- Do not breathe vapour.
- Personal protective equipment

Advice for non-emergency personnel

- Prevent further leakage or spillage if safe to do so.
- Keep away from incompatible products

Advice for emergency responders

- Evacuate personnel to safe areas.
- Keep people away from and upwind of spill/leak.
- Ventilate the area.
- Wear suitable protective clothing.
- Wear self-contained breathing apparatus in confined spaces, in cases where the oxygen level is depleted, or in case of significant emissions.
- Suppress (knock down) gases/vapours/mists with a water spray jet.
- Avoid spraying the leak source.

6.2 Environmental precautions

- Dam up.
- Discharge into the environment must be avoided.
- Do not flush into surface water or sanitary sewer system.
- If the product contaminates rivers and lakes or drains inform respective authorities.

6.3 Methods and materials for containment and cleaning up

- Prevent product from entering sewage system.
- Contact with water may produce heat release and presents risks of splashing.

Recovery

- Pump up the product into a spare container :- suitably labelled.
- Acid resistant materials.
- Keep container tightly closed.

Neutralization

- If recovery is impossible, or if the pools are too small:
- Absorb spillage with:
 - Dry sodium carbonate
- Decontaminate and wash the floor with:
 - Wash with sodium carbonate solution (5% Na₂CO₃).

Disposal

- Dispose of contents/ container to an approved waste disposal plant.

Additional advice

- Only qualified personnel equipped with suitable protective equipment may intervene.
- Stop the leak. Turn leaking containers leak-side up to prevent the escape of liquid.
- Mark the contaminated area with signs and prevent access to unauthorized personnel.

6.4 Reference to other sections

- Refer to protective measures listed in sections 7 and 8.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

- Keep in a bunded area.
- acid resisting floor

- Do not allow contact with air.
- Avoid inhalation, ingestion and contact with skin and eyes.
- All pipes used to transfer the product must be sealed at both ends when not in use.
- Clean and dry piping circuits and equipment before any operations.
- Keep away from water.
- Provide adequate ventilation.
- Store away from heat.
- To avoid thermal decomposition, do not overheat.
- Preferably transfer by pump or gravity.
- Keep away from incompatible products

Hygiene measures

- Emergency equipment immediately accessible, with instructions for use.
- Ensure that eyewash stations and safety showers are close to the workstation location.
- Regular cleaning of equipment, work area and clothing.
- Use clean, well-maintained personal protection equipment.
- Store personal protection equipment in a clean location away from the work area.
- Contaminated work clothing should not be allowed out of the workplace.
- Take off contaminated clothing and shoes immediately.
- Wash contaminated clothing before re-use.
- Before reuse, thoroughly clean personal protection equipment

- Wash hands before breaks and immediately after handling the product.
- When using do not eat, drink or smoke.
- Handle in accordance with good industrial hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

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Technical measures/Storage conditions

- The floor of the depot should be impermeable and designed to form a water-tight basin.
 - Keep only in the original container.
 - Keep container tightly closed and dry.
 - Keep in a well-ventilated place.
 - Keep away from open flames, hot surfaces and sources of ignition.
 - Store in cool place.
 - Keep under inert gas.
- Keep away from: Alkalis and caustic products.

Packaging material**Suitable material**

- Polyethylene
- Stainless steel

Unsuitable material

- With most metals.

Requirements for storage rooms and vessels

- The product may become coloured over a period of time. This does not affect its properties.

7.3 Specific end use(s)

- Contact your supplier for additional information

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Components with workplace occupational exposure limits**

Components	Value type	Value	Basis
trifluoroacetic anhydride	STEL	3.4 ppm 16.0 mg/m ³	Solvay Acceptable Exposure Limit

Predicted No Effect Concentration (PNEC)

Product name	Compartment	Value	Remarks
trifluoroacetic anhydride	Fresh water	1 mg/l	
	Marine water	0.1 mg/l	
	Intermittent use/release	0.1 mg/l	
	Sewage treatment plant	83.2 mg/l	
	Fresh water sediment	4.6 mg/kg	
	Marine sediment	0.46 mg/kg	
	Soil	0.0083 mg/kg	

8.2 Exposure controls

- This Safety Data Sheet is consistent with the specific conditions relied on to justify the registration in accordance with

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Article 17 or 18 of REACH Regulation No 1907/2006 (EC)

Control measures

Engineering measures

- Avoid splashes.
- Handle only in a place equipped with local exhaust (or other appropriate exhaust).

Individual protection measures

Respiratory protection

- Use a respirator with an approved filter if a risk assessment indicates this is necessary.
- Self-contained breathing apparatus in case of: 1) large uncontrolled emissions, 2) insufficient oxygen, 3) the mask and cartridge do not give adequate protection.

Hand protection

- Where there is a risk of contact with hands, use appropriate gloves
- The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.
- Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time.
- Gloves must be inspected prior to use.
- Gloves should be discarded and replaced if there is any indication of degradation or chemical breakthrough.

Suitable material

- PVC

Eye protection

- Tightly fitting safety goggles
- In case of contact through splashing:
- Wear face-shield and protective suit.

Skin and body protection

- Choose body protection according to the amount and concentration of the dangerous substance at the work place.
- Remove and wash contaminated clothing.

- Light overall made of PVC.
- Acid-resistant boots.

- If splashes are likely to occur, wear:
 - Apron
 - Boots
 - Neoprene

Hygiene measures

- Emergency equipment immediately accessible, with instructions for use.
- Ensure that eyewash stations and safety showers are close to the workstation location.
- Regular cleaning of equipment, work area and clothing.
- Use clean, well-maintained personal protection equipment.
- Store personal protection equipment in a clean location away from the work area.
- Contaminated work clothing should not be allowed out of the workplace.
- Take off contaminated clothing and shoes immediately.
- Wash contaminated clothing before re-use.
- Before reuse, thoroughly clean personal protection equipment

- Wash hands before breaks and immediately after handling the product.
- When using do not eat, drink or smoke.
- Handle in accordance with good industrial hygiene and safety practice.

Protective measures

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- The protective equipment must be selected in accordance with current CEN standards and in cooperation with the supplier of the protective equipment.
- Selection of appropriate personal protective equipment should be based on an evaluation of the performance characteristics of the protective equipment relative to the task(s) to be performed, conditions present, duration of use, and the potential hazards and/or risks that may occur during use.

Environmental exposure controls

- Dam up.
- Discharge into the environment must be avoided.
- Dispose of rinse water in accordance with local and national regulations.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

<u>Appearance</u>	<u>Form:</u> strongly hygroscopic, fumes on contact with air
	<u>Physical state:</u> liquid (20 °C) (1,013 hPa)
<u>Odour</u>	<u>Colour:</u> colourless to pale yellow pungent
<u>Odour Threshold</u>	No data available
<u>Molecular weight</u>	210.03 g/mol
<u>pH</u>	Not applicable reacts with water < 1.0 <u>pKa:</u> 0.3 - 0.4 hydrolyses
<u>Melting point/freezing point</u>	<u>Melting point/freezing point:</u> -64.2 °C Method: EU Test Guideline A1
<u>Initial boiling point and boiling range</u>	<u>Boiling point/boiling range:</u> 39.15 °C (1,013 hPa) Method: EU Test Guideline A2
<u>Flash point</u>	No data available
<u>Evaporation rate (Butylacetate = 1)</u>	No data available
<u>Flammability (solid, gas)</u>	Not applicable
<u>Flammability (liquids)</u>	The product is not flammable.
<u>Flammability/Explosive limit</u>	<u>Explosiveness:</u> With certain materials (see section 10).
<u>Auto-ignition temperature</u>	Not applicable
<u>Vapour pressure</u>	433 hPa (20 °C) Method: EU Test Guideline A4
<u>Vapour density</u>	3.9 (20 °C) TRIFLUOROACETIC ACID
<u>Density</u>	<u>Bulk density:</u> Not applicable
<u>Relative density</u>	1.49 (25 °C) Method: EU Test Guideline A3

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Solubility

Water solubility:
hydrolyses, Reacts violently with water.
completely miscible

Solubility in other solvents:

Acetone : soluble

Acetic acid : soluble

Ether : soluble

Hydrocarbons : practically insoluble

Partition coefficient: n-octanol/water

log Pow: 0.79
Hydrolysis products

Decomposition temperature

No data available

Viscosity

Viscosity, 1.8 mPa.s (20 °C)
dynamic : Method: OECD Test Guideline 114
TRIFLUOROACETIC ACID

Viscosity, 1.21 mm²/s (20 °C)
kinematic : Method: OECD Test Guideline 114

Explosive properties

Not explosive
Structure-activity relationship (SAR)

Oxidizing properties

Not considered as oxidizing, Structure-activity relationship (SAR)

9.2 Other information**Surface tension**

72.5 mN/m (20 °C)
Hydrolysis products, Structure-activity relationship (SAR), Not considered as surface-active

Hygroscopicity

strongly hygroscopic

SECTION 10: Stability and reactivity**10.1 Reactivity**

- Reacts violently with water.
- Potential for exothermic hazard

10.2 Chemical stability

- strongly hygroscopic
- Hydrolyses at room temperature on contact with humidity.

10.3 Possibility of hazardous reactions

- Reacts violently with water., Corrosive to many metals when in contact with water or humidity., Gives off hydrogen by reaction with metals., Keep away from strong bases., Risk of violent reaction., Risk of explosion.

10.4 Conditions to avoid

- Exposure to air.
- Exposure to moisture
- Avoid excessive heat for prolonged periods of time.
- freezing

10.5 Incompatible materials

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- Reacts suddenly with water, giving the corresponding acid.
- Reacts with the following substances:
- Aqueous solution
- Alcohols
- Metals
- Oxidizing agents
- Strong bases
- Alkalis

10.6 Hazardous decomposition products

- On thermal decomposition (pyrolysis) releases:
- highly toxic gases.
- hydrofluoric acid
- Carbon monoxide

SECTION 11: Toxicological information**11.1 Information on toxicological effects****Acute toxicity****Acute oral toxicity**

The product itself has not been tested.

According to the available data on the constituents
Harmful if swallowed.**Acute inhalation toxicity**
trifluoroacetic anhydride

By analogy

NOAEC - 4 h (vapour) : 0.3 mg/l - Rat
Method: OECD Test Guideline 403
This product is classified as acute toxicity, category 4
Unpublished internal reports**Acute dermal toxicity**

The product itself has not been tested.

According to the available data on the constituents
Harmful in contact with skin.**Acute toxicity (other routes of administration)**

No data available

Skin corrosion/irritation

trifluoroacetic anhydride

human skin
Corrosive
Method: In Vitro Membrane Barrier Test Method for Skin Corrosion -
CORROSITEX
Unpublished reports**Serious eye damage/eye irritation**

trifluoroacetic anhydride

Corrosive

Irreversible effects on the eye

Respiratory or skin sensitisation

trifluoroacetic anhydride

Corrosive
The product itself has not been tested.**Mutagenicity****Genotoxicity in vitro**

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trifluoroacetic anhydride

By analogy
In vitro tests did not show mutagenic effects
Unpublished reports

Genotoxicity in vivo

No data available

Carcinogenicity

No data available

Toxicity for reproduction and development**Toxicity to reproduction/Fertility**

No data available

Developmental Toxicity/Teratogenicity

No data available

STOT**STOT - single exposure**

trifluoroacetic anhydride

The substance or mixture is not classified as specific target organ toxicant, single exposure according to GHS criteria.

STOT - repeated exposure

No data available

Experience with human exposure

No data available

Aspiration toxicity

No data available

SECTION 12: Ecological information**12.1 Toxicity****Aquatic Compartment****Acute toxicity to fish**

trifluoroacetic anhydride

static test

semi-static test

flow-through test

LC50 - 96 h : ≥ 999 mg/l - Danio rerio (zebra fish)

Method: OECD Test Guideline 203

Hydrolysis products

Not harmful to fish (LC/LL50 > 100 mg/L)

Unpublished internal reports

Acute toxicity to daphnia and other aquatic invertebrates

trifluoroacetic anhydride

EC50 - 48 h : ≥ 999 mg/l - Daphnia magna (Water flea)

Method: OECD Test Guideline 202

Hydrolysis products

Not harmful to aquatic invertebrates. (EC/EL50 > 100 mg/L)

Unpublished internal reports

Toxicity to aquatic plants

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trifluoroacetic anhydride ErC50 - 72 h : 8.5 mg/l - Pseudokirchneriella subcapitata (microalgae)
 Method: OECD Test Guideline 201
 Growth rate
 Harmful to algae.
 Hydrolysis products
 Unpublished reports

EC10 - 72 h : 0.2 mg/l - Pseudokirchneriella subcapitata (microalgae)
 Method: OECD Test Guideline 201
 Growth rate
 Hydrolysis products
 Unpublished reports

Toxicity to microorganisms

trifluoroacetic anhydride

activated sludge
 Method: OECD Test Guideline 209

EC50 - 3 h : > 1,000 mg/l

NOEC - 3 h : > 832 mg/l

Hydrolysis products
 Unpublished internal reports

Chronic toxicity to fish

No data available

Chronic toxicity to daphnia and other aquatic invertebrates

trifluoroacetic anhydride

NOEC: \geq 25 mg/l - 21 Days - Daphnia magna (Water flea)
 Method: OECD Test Guideline 211
 No adverse chronic effect observed up to and including the threshold of 1 mg/L.
 Hydrolysis products
 Unpublished internal reports

Terrestrial Compartment**Toxicity to terrestrial plants**

trifluoroacetic anhydride

- Triticum aestivum (wheat)

EC50: 4.7 - 10 mg/kg - 28 Days

NOEC: 0.83 mg/kg - 28 Days

Hydrolysis products
 Unpublished reports

12.2 Persistence and degradability**Abiotic degradation****Stability in water**

trifluoroacetic anhydride

Hydrolyses on contact with water.

Photodegradation

trifluoroacetic anhydride

Photolysis
 Test substance: TRIFLUOROACETIC ACID
 non-significant photolysis
 Air

hydrolyses
 Test substance: TRIFLUOROACETIC ACID
 instantaneous degradation

TRIFLUOROACETIC ANHYDRIDE

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Degradation products:
Water

**Physical- and photo-chemical
elimination**

No data available

Biodegradation

Biodegradability

trifluoroacetic anhydride

Ready biodegradability study:
Method: OECD Test Guideline 301
The substance does not fulfill the criteria for ready biodegradability and ultimate aerobic biodegradability
Hydrolysis products
Unpublished internal reports

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water

trifluoroacetic anhydride

Not potentially bioaccumulable
internal evaluation

Bioconcentration factor (BCF)

trifluoroacetic anhydride

Test substance: TRIFLUOROACETIC ACID
Bioaccumulation is unlikely.

Species: Terrestrial plants, various species
Bioconcentration factor (BCF): 27 - 43
Exposure time: 35 Days
Test substance: Sodium trifluoroacetate
not significant

12.4 Mobility in soil

Adsorption potential (Koc)

trifluoroacetic anhydride

By analogy

Adsorption/Soil
Method: OECD Test Guideline 106
Not expected to adsorb on soil.
Unpublished internal reports

**Known distribution to environmental
compartments**

No data available

12.5 Results of PBT and vPvB assessment

This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

This substance is not considered to be very persistent and very bioaccumulating (vPvB).

12.6 Other adverse effects

Ecotoxicity assessment

Short-term (acute) aquatic hazard

trifluoroacetic anhydride

Harmful to aquatic life.

Long-term (chronic) aquatic hazard

trifluoroacetic anhydride

Harmful to aquatic life with long lasting effects.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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Product Disposal**Prohibition**

- Avoid release to the environment.
- In accordance with local and national regulations.
- Refer to manufacturer/supplier for information on recovery/recycling.
- Solutions with low pH-value must be neutralized before discharge.
- Must be incinerated in a suitable incineration plant holding a permit delivered by the competent authorities.

Advice on cleaning and disposal of packaging

- Allow it to drain thoroughly.
- Wash with caustic soda solution (2 to 5% NaOH).
- Dispose of in accordance with local regulations.
- To avoid treatments, as far as possible, use dedicated containers.
- The empty and clean containers are to be reused in conformity with regulations.

Measure for waste avoidance or recovery

- Land-fill is forbidden.
- Do not dispose of the product at a rubbish tip.
- Do NOT dispose of the packaging without first carrying out the necessary neutralization.

SECTION 14: Transport information**ADN**

14.1 UN number	UN 3265
14.2 Proper shipping name	CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (Trifluoroacetic anhydride)
14.3 Transport hazard class	8
Label(s):	8
14.4 Packing group	I
Packing group	
Classification Code	C3
14.5 Environmental hazards	NO
14.6 Special precautions for user	
Hazard Identification Number:	88

For personal protection see section 8.

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ADR

14.1 UN number	UN 3265
14.2 Proper shipping name	CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (Trifluoroacetic anhydride)
14.3 Transport hazard class	8
Label(s):	8
14.4 Packing group	
Packing group	I
Classification Code	C3
14.5 Environmental hazards	NO
14.6 Special precautions for user	
Hazard Identification Number:	88
Tunnel restriction code	(E)

For personal protection see section 8.

RID

14.1 UN number	UN 3265
14.2 Proper shipping name	CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (Trifluoroacetic anhydride)
14.3 Transport hazard class	8
Label(s):	8
14.4 Packing group	
Packing group	I
Classification Code	C3
14.5 Environmental hazards	NO
14.6 Special precautions for user	
Hazard Identification Number:	88

For personal protection see section 8.

TRIFLUOROACETIC ANHYDRIDE

Revision Date 25.09.2020

IMDG

14.1 UN number	UN 3265
14.2 Proper shipping name IMDG Code segregation group	CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (Trifluoroacetic anhydride) Acids (SGG1)
14.3 Transport hazard class Label(s):	8 8
14.4 Packing group Packing group	I
14.5 Environmental hazards Marine pollutant	NO
14.6 Special precautions for user EmS	F-A , S-B

For personal protection see section 8.

14.7 Transport in bulk vessels according to IMO instruments
No data available

IATA

14.1 UN number	UN 3265
14.2 Proper shipping name	CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (Trifluoroacetic anhydride)
14.3 Transport hazard class Label(s):	8 8
14.4 Packing group Packing group	I
14.5 Environmental hazards	NO
14.6 Special precautions for user Packing instruction (cargo aircraft) Max net qty/pkg Packing instruction (passenger aircraft) Max net qty/pkg	854 2.50 L 850 0.50 L

For personal protection see section 8.

Note: The above regulatory prescriptions are those valid on the date of publication of this sheet. Given the possible evolution of transport regulations for hazardous materials, it would be advisable to check their validity with your sales office.

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****Other regulations**

- Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), as amended
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, as amended
- Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work, as amended

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Major Accident Hazard 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.

Annex I: O1, O1

Notification status

Inventory Information	Status
United States TSCA Inventory	- Listed on Inventory
Mexico INSQ (INSQ)	- In compliance with the inventory
Canadian Domestic Substances List (DSL)	- Listed on Inventory
New Zealand. Inventory of Chemical Substances	- In compliance with the inventory
Australia Inventory of Chemical Substances (AICS)	- Listed on Inventory
Japan. CSCL - Inventory of Existing and New Chemical Substances	- Listed on Inventory
Korea. Korean Existing Chemicals Inventory (KECI)	- Listed on Inventory
China. Inventory of Existing Chemical Substances in China (IECSC)	- Listed on Inventory
Taiwan Chemical Substance Inventory (TCSI)	- Listed on Inventory
Philippines Inventory of Chemicals and Chemical Substances (PICCS)	- Listed on Inventory
EU. European Registration, Evaluation, Authorisation and Restriction of Chemical (REACH)	- "When purchased from a Solvay legal entity based in the EEA ("European Economic Area"), this product is compliant with the registration provisions of the REACH Regulation (EC) No. 1907/2006 as all its components are either excluded, exempt, and/or registered. When purchased from a legal entity outside of the EEA, please contact your local representative for additional information.

15.2 Chemical safety assessment

- Not applicable

SECTION 16: Other information

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

- H314: Causes severe skin burns and eye damage.
- H318: Causes serious eye damage.
- H332: Harmful if inhaled.
- H412: Harmful to aquatic life with long lasting effects.

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

- ADR: European Agreement on International Carriage of Dangerous Goods by Road.
- ADN: European Agreement on the International Carriage of Dangerous Goods by Inland Waterways.
- RID: European Agreement concerning the International Carriage of Dangerous Goods by Rail.
- IATA: International Air Transport Association.
- ICAO-TI: Technical Instructions for Safe Transport of Dangerous Goods by Air.
- IMDG: International Maritime Dangerous Goods.
- TWA: Time weighted average
- ATE: Estimated value of acute toxicity

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- EC: European Community number
- CAS: Chemical Abstracts Service.
- LD50: Substance that causes 50% (half) death in the test animals group (Median Fatal Dose).
- LC50: Substance concentration causing 50% (half) death in the test animals group.
- EC50: Effective Concentration of the substance causing the maximum of 50%.
- PBT: Persistent, Bioaccumulative and Toxic substance.
- vPvB: Very Persistent and Very Bioaccumulative.
- GHS/CLP/SEA: Classification, labeling, packaging regulation
- DNEL: Derived No Effect Level
- PNEC: Predicted No Effect Concentration
- STOT: Specific Target Organ Toxicity

Not all acronyms listed above are referenced in this SDS.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. Such information is only given as a guidance to help the user handle, use, process, store, transport, dispose and release the product in satisfactory safety conditions and is not to be considered as a warranty or quality specification. It should be used in conjunction with technical sheets but do not replace them. Thus, the information only relates to the designated specific product and may not be applicable if such product is used in combination with other materials or in any other manufacturing process, unless otherwise specifically indicated. It does not release the user from ensuring he is in conformity with all regulations linked to its activity.



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

1.1. Product identifier

Product Name PF-07321332 MTBE solvate
Product Code(s) PF00184
Trade Name: Not applicable
Chemical Family: Not determined

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

Recommended Use Pharmaceutical active

1.3. Details of the supplier of the safety data sheet

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

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

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

Skin corrosion/irritation
Physical Hazards

Category 2 - (H315)
Flammable solids Category 2 - (H228)

OSHA Classification
Physical Hazard

Combustible Dust

2.2. Label elements

Signal word

Warning

Hazard statements

H315 - Causes skin irritation
H228 - Flammable solid

Precautionary Statements

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.
No smoking
P240 - Ground and bond container and receiving equipment
P241 - Use explosion-proof electrical/ ventilating/ lighting/ equipment
P264 - Wash face, hands and any exposed skin thoroughly after handling
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

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P362 - Take off contaminated clothing and wash before reuse
P370 + P378 - In case of fire: Use dry chemical, CO2, water spray or alcohol-resistant foam to extinguish



2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients (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

Substances

Not applicable

3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
+ Tert-butyl methyl ether 1634-04-4	10 - 15		216-653-1	Skin Irrit. 2 (H315) Flam. Liq. 2 (H225)	Not Listed	No data available	No data available

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-07321332 -	*		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

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Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
+ Tert-butyl methyl ether 1634-04-4	2963	10000	85	No data available	No data available

Additional information

+ Substance with a Union workplace exposure limit

- Not Assigned

* Proprietary

Non-hazardous ingredients provided for completeness. Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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

Hazardous combustion products Formation of toxic gases is possible during heating or fire. May include oxides of carbon, nitrogen, phosphorous.

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.

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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 Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Contain the source of the spill if it is safe to do so. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean spill area thoroughly.
Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

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

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

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

7.3. Specific end use(s)

Specific use(s) Pharmaceutical active.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits
Refer to available public information for specific member state Occupational Exposure Limits.

+ Tert-butyl methyl ether

ACGIH TLV	50 ppm
Austria	50 ppm
	180 mg/m ³

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Bulgaria	STEL 100 ppm STEL 360 mg/m ³ STEL: 100 ppm STEL: 367 mg/m ³ 50 ppm 183.5 mg/m ³
Czech Republic	100 mg/m ³ Ceiling: 200 mg/m ³
Denmark	40 ppm 144 mg/m ³
Estonia	50 ppm 183.5 mg/m ³ STEL: 100 ppm STEL: 367 mg/m ³
European Union	TWA: 50 ppm TWA: 183.5 mg/m ³ STEL: 100 ppm STEL: 367 mg/m ³
Finland	50 ppm 180 mg/m ³ STEL: 100 ppm STEL: 360 mg/m ³
France	183.5 mg/m ³
Germany	50 ppm 180 mg/m ³ Ceiling / Peak: 75 ppm Ceiling / Peak: 270 mg/m ³
Germany	50 ppm 180 mg/m ³
Hungary	183.5 mg/m ³ STEL: 367 mg/m ³
Ireland	50 ppm 183.5 mg/m ³ STEL: 100 ppm STEL: 367 mg/m ³
Italy	50 ppm 183.5 mg/m ³ STEL: 100 ppm STEL: 367 mg/m ³
Latvia	50 ppm 183.5 mg/m ³ STEL: 100 ppm STEL: 367 mg/m ³
Netherlands	180 mg/m ³ STEL: 360 mg/m ³ STEL: 270 mg/m ³ 180 mg/m ³
Poland	50 ppm 183.5 mg/m ³
Romania	50 ppm 183.5 mg/m ³ STEL: 100 ppm STEL: 367 mg/m ³
Russia	TWA: 100 mg/m ³ STEL: 300 mg/m ³
Slovakia	50 ppm 183.5 mg/m ³
Spain	50 ppm 183.5 mg/m ³ STEL: 100 ppm STEL: 367 mg/m ³
Switzerland	50 ppm

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United Kingdom

180 mg/m³
STEL: 75 ppm
STEL: 270 mg/m³
TWA: 50 ppm
TWA: 183.5 mg/m³
STEL: 100 ppm
STEL: 367 mg/m³

Pfizer 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-07321332

Pfizer Occupational Exposure Band (OEB):

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

8.2. Exposure controls

Engineering controls

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

Environmental exposure controls

No information available.

Personal protective equipment

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

Eye/face protection

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

Hand protection

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

Skin and body protection

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

Respiratory protection

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

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state

Solid

Color

White to off-white

Odor

No information available.

Odor threshold

No information available

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

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

PF-07321332
Predicted 7.4 Log D 1.591

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 Heat, sparks, flame, and electrostatic discharge.

10.5. Incompatible materials

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

10.6. Hazardous decomposition products
Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

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

General Information: Toxicological properties have not been thoroughly investigated.

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

+ Tert-butyl methyl ether

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50/4h 41000 mg/m³
Rat Dermal LD50 > 2000 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
+ Tert-butyl methyl ether	= 2963 mg/kg (Rat)	= 10000 mg/kg (Rabbit)	= 85 mg/L (Rat) 4 h

Safety Pharmacology: **PF-07321332:** Neurofunction: not significant. Pulmonary: increased respiratory rate, (1000 mg/kg). *In vivo* Cardiovascular: decreased heart rate, increase blood pressure, (150 (75 BID) mg/kg).

Irritation / Sensitization: (Study Type, Species, Severity)

+ Tert-butyl methyl ether

Skin irritation Rabbit Moderate to Severe
Eye irritation Rabbit Slight
Skin Sensitization - M & K Guinea Pig Negative

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

PF-07321332

14 Day(s) Rat Oral 1000 mg/kg/day NOAEL None identified
14 Day(s) Monkey Oral 600 (300 BID) mg/kg/day NOAEL None identified

+ Tert-butyl methyl ether

28 Day(s) Rat Oral 90 mg/kg/day NOAEL Kidney
13 Week(s) Rat Inhalation 500 ppm NOAEL Lungs
90 Day(s) Rat Oral 200 mg/kg/day LOAEL Liver

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

PF-07321332

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

+ Tert-butyl methyl ether

In Vitro Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative
In Vitro Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Negative
In Vivo Unscheduled DNA Synthesis Mouse Negative
In Vivo Micronucleus Mouse Negative

Carcinogenicity See below

+ Tert-butyl methyl ether

IARC Group 3 (Not Classifiable)

11.2. Information on other hazards

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11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

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

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation .

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

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Predicted 7.4 Log D 1.591

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment .

Chemical name	PBT and vPvB assessment
+ Tert-butyl methyl ether	The substance is not PBT / vPvB

12.6. Endocrine disrupting properties

Endocrine disrupting properties .

Chemical name	EU - Endocrine Disruptors Candidate List	EU - Endocrine Disruptors - Evaluated Substances
+ Tert-butyl methyl ether	Group III Chemical	-

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

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and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

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

This material is regulated for transportation as a hazardous material/dangerous good.

UN number: UN 3175
UN proper shipping name: Solids containing flammable liquid, n.o.s. (Tert-butyl methyl ether)
TDG 4.1
Packing group: II

Section 15: REGULATORY INFORMATION

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

PF-07321332

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

+ Tert-butyl methyl ether

CERCLA/SARA Section 313 de minimus % 1.0 %
Hazardous Substances RQs 1000 lb
California Proposition 65 Not Listed
TSCA Present
EINECS 216-653-1
AICS Present

France

Occupational Illnesses (R-463-3, France)

Chemical name	French RG number	Title
+ Tert-butyl methyl ether 1634-04-4	RG 84	-

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

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Legend:

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

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

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

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

Full text of H-Statements referred to under section 3

Skin corrosion/irritation-Cat.2; H315 - Causes skin irritation. Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reason for revision New data sheet.

Revision date 29-Mar-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.



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

1.1. Product identifier

Product Name PF-07321332
Product Code(s) PF00179
Trade Name: Not established
Chemical Family: Not determined

PF-07321332
CAS No -

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

Recommended Use Pharmaceutical active

1.3. Details of the supplier of the safety data sheet

Pfizer 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

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

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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-07321332 -	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

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

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

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

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

Most important symptoms and effects No data available

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

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

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

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

5.3. Advice for firefighters

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

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

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

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

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

Methods for cleaning up 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. Protect from light. Keep away from heat, sparks, and flames.

7.3. Specific end use(s)

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Specific use(s) Pharmaceutical active.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Pfizer OEB Statement:

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

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Pfizer Occupational Exposure Band (OEB):

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

8.2. Exposure controls

Engineering controls

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

Environmental exposure controls

No information available.

Personal protective equipment

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

Eye/face protection

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

Hand protection

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

Skin and body protection

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

Respiratory protection

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

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state

Powder

Color

White

Odor

No information available.

Odor threshold

No information available

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Molecular formula C23 H32 F3 N5 O4
Molecular weight 499.5265

<u>Property</u>	<u>Values</u>
pH	No data available
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	Unbuffered water (1.15 mg/mL), Ethanol, 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)
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Predicted 7.4 Log D 1.591

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. As a precautionary measure, keep away from electrostatic discharge.

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10.5. Incompatible materials

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

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

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

General Information: Toxicological properties have not been thoroughly investigated.

Safety Pharmacology: **PF-07321332:** Neurofunction: not significant. Pulmonary: increased respiratory rate, (1000 mg/kg). *In vivo* Cardiovascular: decreased heart rate, increase blood pressure, (150 (75 BID) mg/kg).

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

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14 Day(s) Rat Oral 1000 mg/kg/day NOAEL None identified

14 Day(s) Monkey Oral 600 (300 BID) mg/kg/day NOAEL None identified

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

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

In Vitro Cytogenetics TK6 cells Negative

In Vivo Micronucleus Rat Bone marrow Negative

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

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

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

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation .

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

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Predicted 7.4 Log D 1.591

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

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

Not Listed
Not Listed
Not Listed

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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. Publicly available toxicity information.

Reason for revision Updated Section 9 - Physical and Chemical Properties.

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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.