



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.

**26-October-2021**

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

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

Dear Sir/Madam,

We wish to notify the Agency that it's planned to introduce the following new materials onsite for the manufacture of Vupanorsen - a biotherapeutic for regulating protein production. It's being developed for potential indications in cardiovascular risk reduction and severe hypertriglyceridemia.

It's planned to commence manufacture in the New Products Technology Laboratory [NPTL] in February 2022.

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

- PF-07285948 (Oligo) - Intermediate
- PF-07296913 (THA8/GalNAc) - Regulatory Starting Material [RSM]
- Pentafluorophenyl Trifluoroacetate - PFP-FTA
- PF-07285557/Vupanorsen Crude Conjugate Solution

PF-07296913 (THA8/GalNAc) is the regulatory starting material in the process and is transformed to PF-07285948 (Oligo) Intermediate in the presence of acetonitrile, triethylamine and water using Pentafluorophenyl Trifluoroacetate as a reagent. The intermediate is subsequently transformed to

PF-07285557/Vupanorsen Crude Conjugate Solution which is the output of the process in triethylamine solvent and water and ammonium hydroxide is used as the reagent. Acetonitrile and triethylamine are the solvents used and PFP-FTA (Pentafluorophenyl Trifluoroacetate) and ammonium hydroxide are the reagents used in the process. The solvents and reagents are historically approved by the Agency. Reagents are typically used up in a process and any reagents added in stoichiometric excess are quenched / contained in the waste streams which are discussed later.

The manufacture of this product is scheduled for the New Product Technology Laboratory, NPTL. 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 Vupanorsen 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 Vupanorsen explained as follows:

We confirm that the solvents used are triethylamine and acetonitrile. These solvents are routinely used 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 NPTL will be managed by the existing OSP3 VOC Absorption system which is the main VOC emission abatement system for OSP3 manufacturing plant. Treated emissions from the OSP3 abatement system are directed to atmosphere via the licensed emission point, V5 [A2-4] which is continuously monitored.

The licensed volumetric flowrate of the fans is 2,700 m<sup>3</sup>/hour for the VOC Absorption Plant serving OSP3. The operational volumetric flow range is variable and currently typically in the range 300-700 m<sup>3</sup>/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 Vupanorsen 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 Continuous Emissions Monitoring System, CEMS.

Table 1 identifies the solvents used in the process and their associated ELV's for licensed emissions point for OSP3, V5, [A2-4]. The abatement system in OSP3 is governed by the TA Luft standard as specified in IE Licence P0013-05.

Table 1: ELV's for licensed emission point from OSP3 Manufacturing, V5, [A2-4] and annual emissions data for 2019 and 2020

<b>Solvent</b>	<b>1997 TA Luft Class</b>	<b>Emission Limit Value [ELV]</b>	<b>Ringaskiddy average kg/hr [2020]</b>	<b>Ringaskiddy average kg/hr [2019]</b>
<b>Triethylamine</b>	<b>TA Luft Organics Class I</b>	<b>20mg/m<sup>3</sup> (at mass flows &gt;0.1 kg/hr)</b>	<b>0.0003518 kg/hr</b>	<b>0.0011197kg/hr</b>
<b>Acetonitrile</b>	<b>TA Luft Organics Class II</b>	<b>100mg/m<sup>3</sup> (at mass flows &gt;2.0 kg/hr)</b>	<b>0.0004895 kg/hr</b>	<b>0.001305kg/hr</b>

Table 1 above provides the ELV's for the aforementioned solvents and a summary of the annual emissions data from V5, [A2-4] from 2019 and 2020. All emissions from the OSP3 air emissions abatement systems comply with the relevant ELV's. The solvents used in this process are typically used and historical data has proven 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 SDS for the above materials are attached in Appendix 1 which include the H [Hazard] Phrases for the new materials. We confirm that no new H Phrases are being added to the Site Inventory of Materials. We confirm there are no H-Phrases associated with the RSM and the intermediate material. The H-Phrases associated with Pentafluorophenyl Trifluoroacetate and PF-07285557/Vupanorsen Crude Conjugate Solution identified are routinely used on site.

The introduction of this new product will not impact on emissions to sewer. This new process is different to other processes in that there will be no liquid waste generated from the manufacture of Vupanorsen. The crude active pharmaceutical ingredient [API] will be drummed off with the process liquors and transported to another Pfizer facility for further processing.

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

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

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

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

Yours sincerely,

**Pfizer Ireland Pharmaceuticals**

Ringaskiddy Active Pharmaceutical Ingredient Plant

**Geraldine Rooney**

Geraldine Rooney

Environment, Health and Safety Department

# Appendix 1:



# SAFETY DATA SHEET

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

### 1.1. Product identifier

**Product Name** PF-07285948  
**Product Code(s)** PF00196  
**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 process intermediate

### 1.3. Details of the supplier of the safety data sheet

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

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

### 1.4. Emergency telephone number

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

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous

### 2.2. Label elements

**Signal word** Not classified

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

### 2.3. Other hazards

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

### **Note:**

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

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## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

**Substances** Not applicable

### 3.2 Mixtures

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)
Water 7732-18-5	*		231-791-2	No data available	Not Listed	No data available	No data available
PF-07285948 -	15 - 20		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

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
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available

### Additional information

- Not Assigned  
\* Proprietary  
Non-hazardous ingredients provided for completeness. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret. 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

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

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

**Most important symptoms and** No data available

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## effects

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

**Note to physicians** None.

## **Section 5: FIRE-FIGHTING MEASURES**

### 5.1. Extinguishing media

**Suitable Extinguishing Media** Dry chemical, CO<sub>2</sub>, 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 mists) may fuel fires/explosions.

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

### 5.3. Advice for firefighters

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

## **Section 6: ACCIDENTAL RELEASE MEASURES**

### 6.1. Personal precautions, protective equipment and emergency procedures

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

**For emergency responders** Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

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

### 6.3. Methods and material for containment and cleaning up

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

**Methods for cleaning up** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. 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**

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

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

## 7.2. Conditions for safe storage, including any incompatibilities

**Storage Conditions** Store at 2 - 8 °C in properly labeled containers. Keep away from heat, sparks, and flames.

## 7.3. Specific end use(s)

**Specific use(s)** Pharmaceutical process intermediate.

## **Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

### 8.1. Control parameters

**Exposure Limits**  
No exposure limits established.

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

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

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

**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

<b>Physical state</b>	Liquid
<b>Color</b>	Clear
<b>Odor</b>	No information available.
<b>Odor threshold</b>	No information available
<b>Molecular formula</b>	Mixture

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<b>Molecular weight</b>	Mixture
<b>Property</b>	<b>Values</b>
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 As a precautionary measure, keep away from electrostatic discharge. Fine particles (such as mists) may fuel fires/explosions.

### 10.5. Incompatible materials

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

### 10.6. Hazardous decomposition products

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**Hazardous decomposition products** No data available.

## Section 11: TOXICOLOGICAL INFORMATION

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

**General Information:** Toxicological properties have not been investigated.

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-

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

### 11.2. Information on other hazards

#### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

#### 11.2.2. Other information

**Other adverse effects** No information available.

## Section 12: ECOLOGICAL INFORMATION

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

### 12.1. Toxicity

**No information available**

### 12.2. Persistence and degradability

**Persistence and degradability** No information available.

### 12.3. Bioaccumulative potential

**Bioaccumulation** .

### 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.

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## 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

Water

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-791-2
<b>AICS</b>	Present

PF-07285948

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

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

Not applicable

### Legend:

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

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

**AICS** - Australian Inventory of Chemical Substances

### 15.2. Chemical safety assessment

**Chemical Safety Report** No information available

## **Section 16: OTHER INFORMATION**

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

**Data Sources:** Pfizer proprietary drug development information.

**Reason for revision** New data sheet.

**Revision date** 21-Apr-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

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

### 1.1. Product identifier

**Product Name** PF-07296913  
**Product Code(s)** PF00132  
**Trade Name:** Not established  
**Chemical Family:** Not determined  
**PF-07296913**  
**CAS No** 1637413-82-1

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

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

### 1.4. Emergency telephone number

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

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

Not classified as hazardous

#### OSHA Classification Physical Hazard

Combustible Dust

### 2.2. Label elements

#### Signal word

Warning

#### Hazard statements

May form combustible dust concentrations in air

#### Supplemental Hazard

Compound, not fully tested, hazards unknown.

### 2.3. Other hazards

#### Other hazards

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

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

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

NonHazardous

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
PF-07296913	Not Listed	1637413-82-1	100	Not Listed	

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

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

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

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

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

**Most important symptoms and effects** No data available

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

**Note to physicians** None.

## Section 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing media

**Suitable Extinguishing Media** Dry chemical, CO<sub>2</sub>, alcohol-resistant foam or water spray.

### 5.2. Special hazards arising from the substance or mixture

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<b>Specific hazards arising from the chemical</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Hazardous combustion products</b>	Formation of toxic gases is possible during heating or fire. May include oxides of carbon, nitrogen.

### 5.3. Advice for firefighters

<b>Special protective equipment for fire-fighters</b>	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

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

### 6.2. Environmental precautions

<b>Environmental precautions</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
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### 6.3. Methods and material for containment and cleaning up

<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so.
<b>Methods for cleaning up</b>	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.
<b>Prevention of secondary hazards</b>	Clean contaminated objects and areas thoroughly observing environmental regulations.

### 6.4. Reference to other sections

<b>Reference to other sections</b>	See section 8 for more information. See section 13 for more information.
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## **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

<b>Storage Conditions</b>	Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.
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### 7.3. Specific end use(s)

<b>Specific use(s)</b>	Pharmaceutical process intermediate.
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## **Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

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## 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.

### **PF-07296913**

Pfizer Occupational Exposure Band (OEB):

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

## 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**

Off-white to beige

**Molecular formula (MF):**

C78 H125 N7 O36

**Molecular weight**

1736.87

**Odor**

No data available.

**Odor threshold**

No data available

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<u>Property</u>	<u>Values</u>
<b>pH</b>	
<b>Melting point / freezing point</b>	No data available
<b>Boiling point / boiling range</b>	No data available
<b>Flash point</b>	No data available
<b>Evaporation rate</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Flammability Limit in Air</b>	
<b>Upper flammability limit:</b>	No data available
<b>Lower flammability limit:</b>	No data available
<b>Vapor pressure</b>	No data available
<b>Vapor density</b>	No data available
<b>Relative density</b>	No data available
<b>Water solubility</b>	No data available
<b>Solubility(ies)</b>	No data available
<b>Autoignition temperature</b>	No data available
<b>Decomposition temperature</b>	No data available
<b>Kinematic viscosity</b>	No data available
<b>Dynamic viscosity</b>	No data available
<b>Explosive properties</b>	No data available
<b>Oxidizing properties</b>	No data available
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>	
<b>PF-07296913</b>	
Predicted 7.4 Log D -1.234	

## 9.2. Other information

<b>Liquid Density</b>	No data available
<b>Bulk density</b>	No data 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** As a precautionary measure, keep away from electrostatic discharge. Fine particles (such as dust and mists) may fuel fires/explosions.

### 10.5. Incompatible materials

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

### 10.6. Hazardous decomposition products

**Hazardous decomposition products** No data available.

## **Section 11: TOXICOLOGICAL INFORMATION**

### 11.1. Information on toxicological effects

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**General Information:** Toxicological properties have not been investigated.

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

## Section 12: ECOLOGICAL INFORMATION

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

### 12.1. Toxicity

No information available

### 12.2. Persistence and degradability

**Persistence and degradability** No information available.

### 12.3. Bioaccumulative potential

#### Bioaccumulation

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

PF-07296913

Predicted 7.4 Log D -1.234

### 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. Other adverse effects

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

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## 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-07296913

CERCLA/SARA Section 313 de minimus %

Not Listed

California Proposition 65

Not Listed

EINECS

Not Listed

### 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

05-Nov-2020

#### Prepared By

Product Stewardship Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

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

## SAFETY DATA SHEET

Version 6.2  
Revision Date 11/06/2019  
Print Date 05/06/2020**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifiers**

Product name : Pentafluorophenyl trifluoroacetate

Product Number : 377074  
Brand : Aldrich  
CAS-No. : 14533-84-7**1.2 Relevant identified uses of the substance or mixture and uses advised against**

Identified uses : Laboratory chemicals, Synthesis of substances

**1.3 Details of the supplier of the safety data sheet**Company : S-A Co, LLC (STL)  
3050 Spruce Street  
SAINT LOUIS MO 63103  
UNITED STATESTelephone : +1 314 771 5765  
Fax : +1 800 325 5052**1.4 Emergency telephone number**

Emergency Phone # : +1-703-527-3887

**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)**Flammable liquids (Category 3), H226  
Skin irritation (Category 2), H315  
Eye irritation (Category 2A), H319  
Specific target organ toxicity - single exposure (Category 3), Respiratory system, H335  
For the full text of the H-Statements mentioned in this Section, see Section 16.**2.2 GHS Label elements, including precautionary statements**

Pictogram



Signal word : Warning

Hazard statement(s)  
H226 : Flammable liquid and vapour.  
H315 : Causes skin irritation.

H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
Precautionary statement(s)	
P210	Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P233	Keep container tightly closed.
P240	Ground/bond container and receiving equipment.
P241	Use explosion-proof electrical/ ventilating/ lighting equipment.
P242	Use only non-sparking tools.
P243	Take precautionary measures against static discharge.
P261	Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264	Wash skin thoroughly after handling.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves/ eye protection/ face protection.
P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304 + P340 + P312	IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332 + P313	If skin irritation occurs: Get medical advice/ attention.
P337 + P313	If eye irritation persists: Get medical advice/ attention.
P362	Take off contaminated clothing and wash before reuse.
P370 + P378	In case of fire: Use dry sand, dry chemical or alcohol-resistant foam to extinguish.
P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
P403 + P235	Store in a well-ventilated place. Keep cool.
P405	Store locked up.
P501	Dispose of contents/ container to an approved waste disposal plant.

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

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Synonyms	:	Trifluoroacetic acid pentafluorophenyl ester
Formula	:	C <sub>8</sub> F <sub>8</sub> O <sub>2</sub>
Molecular weight	:	280.07 g/mol
CAS-No.	:	14533-84-7

Component	Classification	Concentration
<b>Pentafluorophenyl trifluoroacetate</b>		
	Flam. Liq. 3; Skin Irrit. 2; Eye Irrit. 2A; STOT SE 3; H226, H315, H319, H335	<= 100 %

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

---

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

#### General advice

Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

#### If inhaled

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

#### In case of skin contact

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

#### In case of eye contact

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

#### If swallowed

Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

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

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

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

No data available

---

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

#### Suitable extinguishing media

Dry powder Dry sand

#### Unsuitable extinguishing media

Do NOT use water jet.

### 5.2 Special hazards arising from the substance or mixture

Carbon oxides, Hydrogen fluoride

### 5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

### 5.4 Further information

Use water spray to cool unopened containers.

---

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas.

For personal protection see section 8.

## **6.2 Environmental precautions**

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

## **6.3 Methods and materials for containment and cleaning up**

Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

## **6.4 Reference to other sections**

For disposal see section 13.

---

## **SECTION 7: Handling and storage**

### **7.1 Precautions for safe handling**

Avoid contact with skin and eyes. Avoid inhalation of vapour or mist.

Keep away from sources of ignition - No smoking. Take measures to prevent the build up of electrostatic charge.

For precautions see section 2.2.

### **7.2 Conditions for safe storage, including any incompatibilities**

Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage.

Moisture sensitive.

Storage class (TRGS 510): 3: Flammable liquids

### **7.3 Specific end use(s)**

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

---

## **SECTION 8: Exposure controls/personal protection**

### **8.1 Control parameters**

#### **Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

### **8.2 Exposure controls**

#### **Appropriate engineering controls**

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

#### **Personal protective equipment**

##### **Eye/face protection**

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

##### **Skin protection**

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

### Body Protection

Impervious clothing, 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 multi-purpose combination (US) or type ABEK (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).

### Control of environmental exposure

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

---

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

a) Appearance	Form: clear, liquid Colour: colourless
b) Odour	No data available
c) Odour Threshold	No data available
d) pH	No data available
e) Melting point/freezing point	No data available
f) Initial boiling point and boiling range	122 - 123 °C 252 - 253 °F - lit.
g) Flash point	52 °C (126 °F) - closed cup
h) Evaporation rate	No data available
i) Flammability (solid, gas)	No data available
j) Upper/lower flammability or explosive limits	No data available
k) Vapour pressure	No data available
l) Vapour density	No data available
m) Relative density	1.63 g/cm <sup>3</sup> at 25 °C (77 °F)
n) Water solubility	No data available
o) Partition coefficient: n-octanol/water	No data available
p) Auto-ignition temperature	No data available
q) Decomposition temperature	No data available
r) Viscosity	No data available
s) Explosive properties	No data available

t) Oxidizing properties No data available

## 9.2 Other safety information

No data available

---

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No data available

### 10.2 Chemical stability

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

No data available

### 10.4 Conditions to avoid

Heat, flames and sparks.

### 10.5 Incompatible materials

Strong oxidizing agents

### 10.6 Hazardous decomposition products

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

Other decomposition products - No data available

In the event of fire: see section 5

---

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### Acute toxicity

No data available

Dermal: No data available

No data available

#### Skin corrosion/irritation

No data available

#### Serious eye damage/eye irritation

No data available

#### Respiratory or skin sensitisation

No data available

#### Germ cell mutagenicity

No data available

#### Carcinogenicity

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.

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

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

**Reproductive toxicity**

No data available

No data available

**Specific target organ toxicity - single exposure**

Inhalation - May cause respiratory irritation.

**Specific target organ toxicity - repeated exposure**

No data available

**Aspiration hazard**

No data available

**Additional Information**

RTECS: Not available

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

---

**SECTION 12: Ecological information****12.1 Toxicity**

No data available

**12.2 Persistence and degradability**

No data available

**12.3 Bioaccumulative potential**

No data available

**12.4 Mobility in soil**

No data available

**12.5 Results of PBT and vPvB assessment**

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

**12.6 Other adverse effects**

No data available

---

**SECTION 13: Disposal considerations****13.1 Waste treatment methods****Product**

Offer surplus and non-recyclable solutions to a licensed disposal company. Burn in a chemical incinerator equipped with an afterburner and scrubber but exert extra care in igniting as this material is highly flammable. Contact a licensed professional waste disposal service to dispose of this material.

**Contaminated packaging**

Dispose of as unused product.

---

**SECTION 14: Transport information****DOT (US)**

UN number: 3272 Class: 3 Packing group: III  
Proper shipping name: Esters, n.o.s.  
Reportable Quantity (RQ):  
Poison Inhalation Hazard: No

**IMDG**

UN number: 3272 Class: 3 Packing group: III EMS-No: F-E, S-D  
Proper shipping name: ESTERS, N.O.S. (Pentafluorophenyl trifluoroacetate)

**IATA**

UN number: 3272 Class: 3 Packing group: III  
Proper shipping name: Esters, n.o.s. (Pentafluorophenyl trifluoroacetate)

---

**SECTION 15: Regulatory information****SARA 302 Components**

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

**SARA 313 Components**

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

**SARA 311/312 Hazards**

Fire Hazard, Acute Health Hazard

**Massachusetts Right To Know Components**

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

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

**Pennsylvania Right To Know Components**

Pentafluorophenyl trifluoroacetate	CAS-No. 14533-84-7	Revision Date
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Pentafluorophenyl trifluoroacetate	CAS-No. 14533-84-7	Revision Date
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**New Jersey Right To Know Components**

Pentafluorophenyl trifluoroacetate	CAS-No. 14533-84-7	Revision Date
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## **SECTION 16: Other information**

### **Further information**

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

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Print Date: 05/06/2020



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

### 1.1. Product identifier

**Product Name** Vupanorsen Crude Conjugate Solution  
**Product Code(s)** PF00261  
**Trade Name:** Not applicable  
**Compound Number** PF-07285557; ISIS 703802  
**Chemical Family:** Not determined

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

**Recommended Use** Pharmaceutically active formulation

### 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

**Specific target organ toxicity (single exposure)** Category 3 - (H335)  
**Acute aquatic toxicity** Category 2 - (H401)  
**Physical Hazards** Flammable liquids Category 2 - (H225)

### 2.2. Label elements

**Signal word** Danger

**Hazard statements** H225 - Highly flammable liquid and vapor  
H335 - May cause respiratory irritation  
H401 - Toxic to aquatic life

**Precautionary Statements** P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking  
P273 - Avoid release to the environment  
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
P312 - Call a POISON CENTER or doctor/physician if you feel unwell  
P303 + P361 + P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower

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P403 + P235 - Store in a well-ventilated place. Keep cool  
P405 - Store locked up  
P501 - Dispose of contents/container in accordance with all local and national regulations  
Compound, not fully tested, additional hazards may exist.

## Supplemental Hazard



## 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)
+ Acetonitrile 75-05-8	< 10		200-835-2	Acute Tox. 4 (H302) Acute Tox. 4 (H312) Acute Tox. 4 (H332) Eye Irrit. 2 (H319) Flam. Liq. 2 (H225)	Not Listed	No data available	No data available
Ammonium hydroxide 1336-21-6	1 - 5		215-647-6	Skin Corr. 1B (H314) Aquatic Acute 1 (H400)	STOT SE 3 :: C>=5%	1	No data available
+ TRIETHYLAMINE 121-44-8	1		204-469-4	Acute Tox. 4 (H302) Acute Tox. 4 (H312) Acute Tox. 4	STOT SE 3 :: C>=1%	No data available	No data available

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				(H332) Skin Corr. 1A (H314) Flam. Liq. 2 (H225)			
--	--	--	--	---	--	--	--

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)
Water 7732-18-5	80 - 85		231-791-2	No data available	Not Listed	No data available	No data available
Vupanorsen 2097587-62-5	1 - 5		Not Listed	No data available	Not Listed	No data available	No data available
PF-07296913 1637413-82-1	< 1		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

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
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
+ Acetonitrile 75-05-8	617	> 2000	26.8	No data available	No data available
Ammonium hydroxide 1336-21-6	350	No data available	No data available	No data available	No data available
+ TRIETHYLAMINE 121-44-8	460	415	3.625	No data available	No data available

**Additional information**

+ Substance with a Union workplace exposure limit  
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

<b>Inhalation</b>	Remove to fresh air. Seek immediate medical attention/advice.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	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

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immediately.

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

**Most important symptoms and effects** No data available

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

**Note to physicians** None.

## **Section 5: FIRE-FIGHTING MEASURES**

### 5.1. Extinguishing media

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

### 5.2. Special hazards arising from the substance or mixture

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

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

### 5.3. Advice for firefighters

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

## **Section 6: ACCIDENTAL RELEASE MEASURES**

### 6.1. Personal precautions, protective equipment and emergency procedures

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

**For emergency responders** Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

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

### 6.3. Methods and material for containment and cleaning up

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

**Methods for cleaning up** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. 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**

Restrict access to work area. Avoid open handling. Minimize generating airborne mists and vapors. Use appropriate engineering controls to maintain exposures below the B-OEB taking all applicable routes of exposure into consideration. A change area to

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facilitate 'good laboratory/manufacturing' decontamination practices is recommended. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

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

## 7.2. Conditions for safe storage, including any incompatibilities

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

## 7.3. Specific end use(s)

**Specific use(s)** Pharmaceutically active formulation.

## **Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

### 8.1. Control parameters

#### **Exposure Limits**

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

#### **+ Acetonitrile**

ACGIH - Skin Absorbers	Skin - potential significant contribution to overall exposure by the cutaneous route
ACGIH TLV	20 ppm S*
Austria	40 ppm 70 mg/m <sup>3</sup> STEL 160 ppm STEL 280 mg/m <sup>3</sup> H*
Bulgaria	40 ppm 70 mg/m <sup>3</sup> K*
Czech Republic	70 mg/m <sup>3</sup> 3 mg/m <sup>3</sup> Ceiling: 100 mg/m <sup>3</sup> Ceiling: 10 mg/m <sup>3</sup> D*
Denmark	40 ppm 70 mg/m <sup>3</sup> H*
Estonia	40 ppm 70 mg/m <sup>3</sup> STEL: 60 ppm STEL: 100 mg/m <sup>3</sup> A*
European Union	TWA: 40 ppm TWA: 70 mg/m <sup>3</sup> *
Finland	20 ppm 34 mg/m <sup>3</sup> 1 mg/m <sup>3</sup> STEL: 40 ppm STEL: 68 mg/m <sup>3</sup> STEL: 5 mg/m <sup>3</sup> iho*

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France	70 mg/m <sup>3</sup> 5 mg/m <sup>3</sup>
Germany	10 ppm 17 mg/m <sup>3</sup> 2 mg/m <sup>3</sup> Ceiling / Peak: 20 ppm Ceiling / Peak: 34 mg/m <sup>3</sup> Ceiling / Peak: 2 mg/m <sup>3</sup> Skin
Germany	10 ppm 17 mg/m <sup>3</sup>
Hungary	H* 70 mg/m <sup>3</sup> 1 mg/m <sup>3</sup> STEL: 5 mg/m <sup>3</sup> b*
Ireland	40 ppm 70 mg/m <sup>3</sup> 5 mg/m <sup>3</sup> STEL: 120 ppm STEL: 310 mg/m <sup>3</sup> STEL: 15 mg/m <sup>3</sup> Sk*
Italy	20 ppm 35 mg/m <sup>3</sup> pelle*
Latvia	40 ppm 70 mg/m <sup>3</sup> *
Netherlands	34 mg/m <sup>3</sup> 1 mg/m <sup>3</sup> STEL: 5 mg/m <sup>3</sup> H*
Poland	STEL: 140 mg/m <sup>3</sup> 70 mg/m <sup>3</sup>
Romania	40 ppm 70 mg/m <sup>3</sup> 0.5 mg/m <sup>3</sup> STEL: 1 mg/m <sup>3</sup> P*
Russia	MAC: 10 mg/m <sup>3</sup>
Slovakia	40 ppm 70 mg/m <sup>3</sup> 1 mg/m <sup>3</sup> K*
Spain	40 ppm 68 mg/m <sup>3</sup> vía dérmica*
Switzerland	20 ppm 34 mg/m <sup>3</sup> STEL: 40 ppm STEL: 68 mg/m <sup>3</sup> H*
OSHA - Final PELs - Skin Notations: OSHA PEL	prevent or reduce skin absorption 40 ppm 70 mg/m <sup>3</sup> 5 mg/m <sup>3</sup> (vacated) TWA: 40 ppm (vacated) TWA: 70 mg/m <sup>3</sup> (vacated) TWA: 5 mg/m <sup>3</sup>

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United Kingdom	(vacated) STEL: 60 ppm (vacated) STEL: 105 mg/m <sup>3</sup> S* as CN TWA: 40 ppm TWA: 68 mg/m <sup>3</sup> TWA: 5 mg/m <sup>3</sup> STEL: 60 ppm STEL: 102 mg/m <sup>3</sup> Sk*
<b>Ammonium hydroxide</b>	
Finland	20 ppm 14 mg/m <sup>3</sup> STEL: 50 ppm STEL: 36 mg/m <sup>3</sup>
<b>+ TRIETHYLAMINE</b>	
ACGIH - Skin Absorbers	Skin - potential significant contribution to overall exposure by the cutaneous route
ACGIH TLV	STEL: 1 ppm 0.5 ppm S*
Austria	2 ppm 8.4 mg/m <sup>3</sup> STEL 3 ppm STEL 12.6 mg/m <sup>3</sup>
Bulgaria	STEL: 3 ppm STEL: 12.6 mg/m <sup>3</sup> 2 ppm 8.4 mg/m <sup>3</sup> K*
Czech Republic	8 mg/m <sup>3</sup> Ceiling: 12 mg/m <sup>3</sup> D*
Denmark	1 ppm 4.1 mg/m <sup>3</sup> H*
Estonia	2 ppm 8.4 mg/m <sup>3</sup> STEL: 3 ppm STEL: 12.6 mg/m <sup>3</sup> A*
European Union	TWA: 2 ppm TWA: 8.4 mg/m <sup>3</sup> STEL: 3 ppm STEL: 12.6 mg/m <sup>3</sup> *
Finland	STEL: 1 ppm STEL: 4.2 mg/m <sup>3</sup> iho*
France	4.2 mg/m <sup>3</sup>
Germany	1 ppm 4.2 mg/m <sup>3</sup> Ceiling / Peak: 2 ppm Ceiling / Peak: 8.4 mg/m <sup>3</sup>
Germany	1 ppm 4.2 mg/m <sup>3</sup> H*
Hungary	8.4 mg/m <sup>3</sup> STEL: 12.6 mg/m <sup>3</sup>
Ireland	b* 2 ppm

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	8.4 mg/m <sup>3</sup> STEL: 3 ppm STEL: 12.6 mg/m <sup>3</sup> Sk*
Italy	2 ppm 8.4 mg/m <sup>3</sup> STEL: 3 ppm STEL: 12.6 mg/m <sup>3</sup>
Latvia	pelle* 2 ppm 8.4 mg/m <sup>3</sup> STEL: 3 ppm STEL: 12.6 mg/m <sup>3</sup>
Netherlands	4.2 mg/m <sup>3</sup> STEL: 12.6 mg/m <sup>3</sup> H*
Poland	STEL: 9 mg/m <sup>3</sup> 3 mg/m <sup>3</sup>
Romania	2 ppm 8.4 mg/m <sup>3</sup> STEL: 3 ppm STEL: 12.6 mg/m <sup>3</sup>
Russia	P* MAC: 10 mg/m <sup>3</sup>
Slovakia	Skin 2 ppm 8.4 mg/m <sup>3</sup>
Spain	K* 2 ppm 8.4 mg/m <sup>3</sup> STEL: 3 ppm STEL: 12.6 mg/m <sup>3</sup>
Switzerland	vía dérmica* 1 ppm 4.2 mg/m <sup>3</sup> STEL: 2 ppm STEL: 8.4 mg/m <sup>3</sup>
OSHA PEL	25 ppm 100 mg/m <sup>3</sup> (vacated) TWA: 10 ppm (vacated) TWA: 40 mg/m <sup>3</sup> (vacated) STEL: 15 ppm (vacated) STEL: 60 mg/m <sup>3</sup>
United Kingdom	TWA: 2 ppm TWA: 8 mg/m <sup>3</sup> STEL: 4 ppm STEL: 17 mg/m <sup>3</sup> Sk*

## Pfizer OEB Statement:

The Biotherapeutic Occupational Exposure Band (B-OEB) is an acceptable daily intake (ADI) range, based on available hazard data with appropriate safety factors applied. Engineering control measures should be utilized to bring exposures into the relevant B-OEB; supplementary administrative controls and personal protective equipment are to be used to achieve exposure control to the bottom of the band. 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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## Vupanorsen

Pfizer Occupational Exposure Band (OEB): B-OEB 4 (control exposure to the range of 10 µg/day to <100 µg/day)

## PF-07296913

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

## 8.2. Exposure controls

### Engineering controls

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, biosafety cabinet, or other engineering controls to maintain airborne levels within the B-OEB range. It is recommended that all large scale operations should be fully enclosed. Air recirculation is not recommended.

### Environmental exposure controls

No information available.

### Personal protective equipment

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

### Eye/face protection

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

### Hand protection

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

### Skin and body protection

Wear impervious disposable protective clothing when handling this compound. Full body protection is recommended (scale dependent). Wear impervious protective clothing when handling this compound. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

### Respiratory protection

Under normal conditions of use, if the applicable Biotherapeutic Occupational Exposure Band (B-OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the B-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

Solution

#### Color

Clear

#### Odor

No information available.

#### Odor threshold

No information available

#### Molecular formula

Mixture

#### Molecular weight

Mixture

#### Property

#### Values

#### pH

No data available

#### Melting point / freezing point

No data available

#### Boiling point / boiling range

#### Flash point

< 23 °C

#### Evaporation rate

No data available

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<b>Flammability (solid, gas)</b>	No data available
<b>Flammability Limit in Air</b>	
<b>Upper flammability limit:</b>	No data available
<b>Lower flammability limit:</b>	No data available
<b>Vapor pressure</b>	No data available
<b>Vapor density</b>	No data available
<b>Relative density</b>	No data available
<b>Water solubility</b>	No data available
<b>Solubility(ies)</b>	No data available
<b>Partition coefficient</b>	No data available
<b>Autoignition temperature</b>	No data available
<b>Decomposition temperature</b>	No data available
<b>Kinematic viscosity</b>	No data available
<b>Dynamic viscosity</b>	No data available
<b>Particle characteristics</b>	
<b>Particle Size</b>	No information available
<b>Particle Size Distribution</b>	No information available
<b>Explosive properties</b>	No information available

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

PF-07296913

Predicted 7.4 Log D -1.234

## **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 mists) may fuel fires/explosions. As a precautionary measure, keep away from electrostatic discharge.

### **10.5. Incompatible materials**

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

### **10.6. Hazardous decomposition products**

**Hazardous decomposition products** No data available.

## **Section 11: TOXICOLOGICAL INFORMATION**

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

**General Information:** Toxicological properties have not been thoroughly investigated.  
**Known Clinical Effects:** No serious adverse events have been reported.

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

#### + Acetonitrile

Mouse Oral LD50 617 mg/kg  
Mouse Inhalation LC50 3587 ppm  
Rabbit Dermal LD50 > 2000 mg/kg

#### Ammonium hydroxide

Rat Oral LD50 350 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
+ Acetonitrile	= 617 mg/kg ( Mouse )	> 2000 mg/kg ( Rabbit )	= 26.8 mg/L ( Rat ) 4 h
Ammonium hydroxide	= 350 mg/kg ( Rat )	-	-
+ TRIETHYLAMINE	= 460 mg/kg ( Rat )	= 415 mg/kg ( Rabbit )	= 14.5 mg/L ( Rat ) 1 h

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

#### + Acetonitrile

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Mild

#### Ammonium hydroxide

Eye Irritation Rabbit Severe

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

#### Vupanorsen

16 Week(s) Mouse Subcutaneous 3 mg/kg/week NOAEL Liver, Kidney, Spleen  
26 Week(s) Mouse Subcutaneous 24 mg/kg/week NOAEL None identified  
16 Week(s) Monkey Subcutaneous 8 mg/kg/week NOAEL Kidney, Liver, Lymphatic system  
39 Week(s) Monkey Subcutaneous 12 mg/kg/week NOAEL None identified

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

#### Vupanorsen

Fertility & Embryonic Development (Male/Female) Mouse Subcutaneous 10.5 mg/kg/week NOAEL No effects at maximum dose  
Embryo / Fetal Development Rabbit Subcutaneous 105 mg/kg/week NOAEL No effects at maximum dose

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

#### + Acetonitrile

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
Chromosome Aberration Mouse Bone Marrow Negative

#### Vupanorsen

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative  
*In Vitro* Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative  
*In Vivo* Micronucleus Mouse Bone marrow Negative

### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

#### + Acetonitrile

2 Year(s) Rat Inhalation 400 ppm NOAEL Not carcinogenic  
2 Year(s) Mouse Inhalation 200 ppm NOAEL Not carcinogenic

#### Vupanorsen

26 Week(s) Rat Subcutaneous > 15 mg/kg/day LOAEL Kidneys, Liver

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

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## 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

#### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

##### Ammonium hydroxide

*Daphnia magna* (Water Flea) LC50 48 hours 0.66 mg/L  
*Lepomis macrochirus* (Bluegill Sunfish) LC50 48 hours 0.024 mg/L  
*Pimephales promelas* (Fathead Minnow) LC50 96 hours 8.2 mg/L

### 12.2. Persistence and degradability

**Persistence and degradability** No information available.

### 12.3. Bioaccumulative potential

#### Bioaccumulation

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

##### PF-07296913

Predicted 7.4 Log D -1.234

### 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
+ Acetonitrile	The substance is not PBT / vPvB PBT assessment does not apply
+ TRIETHYLAMINE	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
+ Acetonitrile	Group III Chemical	-

### 12.7. Other adverse effects

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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.

Chemical name	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
+ Acetonitrile	-	-	-	Present
+ TRIETHYLAMINE	-	-	-	Present

## 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 1993  
**UN proper shipping name:** Flammable Liquid, n.o.s. (Acetonitrile, Triethylamine)  
**Transport hazard class(es):** 3  
**Packing group:** II

## Section 15: REGULATORY INFORMATION

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

Water

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-791-2
<b>AICS</b>	Present

+ Acetonitrile

<b>CERCLA/SARA Section 313 de minimus %</b>	1.0 %
<b>Hazardous Substances RQs</b>	5000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	200-835-2
<b>AICS</b>	Present

Ammonium hydroxide

<b>CERCLA/SARA Section 313 de minimus %</b>	1.0 %
<b>Hazardous Substances RQs</b>	1000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	215-647-6
<b>AICS</b>	Present

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<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5 Schedule 6
Vupanorsen	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
+ TRIETHYLAMINE	
<b>CERCLA/SARA Section 313 de minimus %</b>	1.0 %
<b>Hazardous Substances RQs</b>	5000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	204-469-4
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5
PF-07296913	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed

## France

### Occupational Illnesses (R-463-3, France)

Chemical name	French RG number	Title
+ Acetonitrile 75-05-8	RG 84	-
+ TRIETHYLAMINE 121-44-8	RG 49, RG 49bis	-

## 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 contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
+ Acetonitrile - 75-05-8	Use restricted. See item 75.	
Ammonium hydroxide - 1336-21-6	Use restricted. See item 75.	
+ TRIETHYLAMINE - 121-44-8	Use restricted. See item 75.	

### 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

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## 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**

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed. Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled. Acute toxicity, dermal-Cat.4; H312 - Harmful in contact with skin. Serious eye damage/eye irritation-Cat. 2; H319 - Causes serious eye irritation. Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage. Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life. Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects. Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor.

<b>Data Sources:</b>	Pfizer proprietary drug development information. Publicly available toxicity information.
<b>Reason for revision</b>	New data sheet.
<b>Revision date</b>	15-Sep-2021
<b>Prepared By</b>	Pfizer Global Environment, Health, and Safety

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