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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

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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 OSG Building

New York, New York 10017 Ringaskiddy, Co. Cork.

1-800-879-3477 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	EC No	Classification according to	Specific concentration	M-Factor	M-Factor (long-term)
			J					(long term)
			Number		Regulation	limit (SCL)		
					(EC) No.			
					1272/2008			
					[CLP]			
ĺ	PF-07321332	100		Not Listed	No data	Not Listed	No data	No data
	-				available		available	available

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

Acute Toxicity Estimate
No information available

Additional information

Not Assigned

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

safetv.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

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

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

Consult a physician.

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

medical attention.

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

not induce vomiting unless directed by medical personnel. Seek medical attention

immediately.

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

Most important symptoms and

effects

No data available

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

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

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

chemical

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

nitrogen and products of fluorine.

5.3. Advice for firefighters

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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

Personnel involved in clean-up should wear appropriate personal protective equipment (see Personal precautions

Section 8). Minimize exposure.

Use personal protection recommended in Section 8. For emergency responders

6.2. Environmental precautions

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

taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment

Prevent further leakage or spillage if safe to do so. 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

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

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

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

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

7.2. Conditions for safe storage, including any incompatibilities

Store at room temperature in properly labeled containers. Protect from light. Keep away **Storage Conditions**

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 $10ug/m^3$ 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

OdorNo information available.Odor thresholdNo information available

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C23 H32 F3 N5 O4 Molecular formula

Molecular weight 499.5265

Property Values

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

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 No information available **Particle Size Distribution**

No information available **Explosive properties**

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

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Predicted 7.4 Log D 1.591

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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

Stable under normal conditions. Stability

Explosion data

Sensitivity to Mechanical Impact No data available. Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

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

PF-07321332: Neurofunction: not significant. Pulmonary: increased respiratory rate, Safety Pharmacology:

(1000 mg/kg). In vivo Cardiovascular: decreased heart rate, increase blood pressure,

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(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

No information available. Other adverse effects

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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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 % Not Listed **California Proposition 65** Not Listed **EINECS** Not Listed

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European Union

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

Authorizations and/or restrictions on use:

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

Persistent Organic Pollutants

Not applicable

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

Not applicable

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

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