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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

**Product Identifier** 

**Material Name: Pantoprazole Tablets** 

Trade Name: PROTONIX; NOXANTOR

Synonyms: Pantoprazole Delayed-Release Tablets

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product for the treatment of gastrointestinal disorders

**Details of the Supplier of the Safety Data Sheet** 

Pfizer Inc Pfizer Pharmaceuticals Group 235 East 42nd Street

New York, New York 10017

1-800-879-3477

Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd

Ramsgate Road Sandwich, Kent CT13 9NJ

United Kingdom

+00 44 (0)1304 616161 Emergency telephone number:

International CHEMTREC (24 hours): +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

**GHS - Classification** 

Carcinogenicity: Category 1B

**Label Elements** 

Signal Word: Danger

Hazard Statements: H350 - May cause cancer

Precautionary Statements: P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

P281 - Use personal protective equipment as required

P308 + P313 - IF exposed or concerned: Get medical attention/advice

P405 - Store locked up

P501 - Dispose of contents/container in accordance with all local and national regulations



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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

requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases.

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

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

#### **Hazardous**

Ingredient	CAS Number	EU	GHS Classification	%
<b>g</b>		EINECS/ELINCS		, ,
		List		
Calcium stearate	1592-23-0	216-472-8	Not Listed	*
Pantoprazole Sodium Sesquihydrate	164579-32-2	Not Listed	Acute Tox.4 (H302) Carc.1B (H350)	22
			Aquatic Acute 3 (H402)	
Propylene glycol	57-55-6	200-338-0	Not Listed	*
Sodium lauryl sulfate	151-21-3	205-788-1	Not Listed	*
Sodium carbonate	498-19-8	Not Listed	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Crospovidone	9003-39-8	Not Listed	Not Listed	*
Ferric oxide yellow	51274-00-1	257-098-5	Not Listed	*
Methacrylic acid copolymer	25086-15-1	Not Listed	Not Listed	*
Mannitol	69-65-8	200-711-8	Not Listed	*
Polysorbate 80	9005-65-6	Not Listed	Not Listed	*
Triethyl Citrate	77-93-0	201-070-7	Not Listed	*
Povidone	9003-39-8	Not Listed	Not Listed	*
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	*

Additional Information: \* Proprietary

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

safetv.

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has

been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

**Description of First Aid Measures** 

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention

immediately.

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.

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**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of For information on potential signs and symptoms of exposure, See Section 2 - Hazards

**Exposure:** Identification and/or Section 11 - Toxicological Information.

Medical Conditions None known

Aggravated by Exposure:

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

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

**Products:** 

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

**Advice for Fire-Fighters** 

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

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

### **Environmental Precautions**

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

### Methods and Material for Containment and Cleaning Up

Measures for Cleaning /

Collecting:

Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of

dry solids. Clean spill area thoroughly.

**Additional Consideration for** 

Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

## **Precautions for Safe Handling**

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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.

Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### **Control Parameters**

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

**Calcium stearate** 

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Pantoprazole Sodium Sesquihydrate

Pfizer OEL TWA-8 Hr: 300µg/m<sup>3</sup>

Propylene glycol

 Australia TWA
 150 ppm

 474 mg/m³
 10 mg/m³

 Ireland OEL - TWAs
 150 ppm

470 mg/m<sup>3</sup> 10 mg/m<sup>3</sup> 7 mg/m<sup>3</sup>

Latvia OEL - TWA 7 mg/m³ Lithuania OEL - TWA 7 mg/m³

Sodium lauryl sulfate

Pfizer OEL TWA-8 Hr: 0.3 mg/m<sup>3</sup>

Titanium dioxide

**ACGIH Threshold Limit Value (TWA)** 10 mg/m<sup>3</sup> **Australia TWA** 10 mg/m<sup>3</sup>  $5 \text{ mg/m}^3$ **Austria OEL - MAKs** 10 mg/m<sup>3</sup> **Belgium OEL - TWA** 10.0 mg/m<sup>3</sup> **Bulgaria OEL - TWA** 6 mg/m<sup>3</sup> **Denmark OEL - TWA** 5 mg/m<sup>3</sup> Estonia OEL - TWA 10 mg/m<sup>3</sup> France OEL - TWA 10 mg/m<sup>3</sup> **Greece OEL - TWA** 5 mg/m<sup>3</sup> Ireland OEL - TWAs 10 mg/m<sup>3</sup>

 $4 \text{ mg/m}^3$ Latvia OEL - TWA 10 mg/m<sup>3</sup>  $5 \text{ mg/m}^3$ Lithuania OEL - TWA **OSHA - Final PELS - TWAs:** 15 mg/m<sup>3</sup> Poland OEL - TWA 10.0 mg/m<sup>3</sup> 10 mg/m<sup>3</sup> Portugal OEL - TWA Romania OEL - TWA 10 mg/m<sup>3</sup> 10 mg/m<sup>3</sup> **Russia OEL - TWA** 10 mg/m<sup>3</sup> Spain OEL - TWA 5 mg/m<sup>3</sup> **Sweden OEL - TWAs** 3 mg/m<sup>3</sup> **Switzerland OEL -TWAs** 

> 6 mg/m<sup>3</sup> 5 mg/m<sup>3</sup>

**Exposure Controls** 

Vietnam OEL - TWAs

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne

contamination levels below the exposure limits listed above in this section.

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## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Personal Protective Refer to applicable national standards and regulations in the selection and use of personal

**Equipment:** protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an

assessment of the workplace conditions, other chemicals used or present in the workplace and

specific operational processes.

Hands: Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is

possible and for bulk processing operations. (Protective gloves must meet the standards in

accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the

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

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and

for bulk processing operations. (Protective clothing must meet the standards in accordance

with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is

exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international

Mixture

equivalent.)

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Tablet Color: Yellow

Odor: No data available. Odor Threshold: No data available.

Molecular Formula: Mixture Molecular Weight:

Solvent Solubility:
Water Solubility:
PH:
No data available
No data available
No data available.
No data available.
No data available
No data available
No data available

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

**Pantoprazole** 

Predicted 7.4 Log P 2.05

Pantoprazole Sodium
No data available
Calcium stearate
No data available
Ferric oxide yellow

No data available

Hydroxypropyl methylcellulose

No data available
Polysorbate 80
No data available
Propylene glycol
No data available

Titanium dioxide

No data available

**Triethyl Citrate**No data available

**Povidone** 

No data available

Methacrylic acid copolymer

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## 9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Sodium lauryl sulfate

No data available

Crospovidone

No data available

**Mannitol** 

No data available

Sodium carbonate

No data available

Pantoprazole Sodium Sesquihydrate

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s):

Vapor Pressure (kPa):

Vapor Density (g/ml):

Relative Density:

No data available

Flammablity:

Autoignition Temperature (Solid) (°C):No data availableFlammability (Solids):No data availableFlash Point (Liquid) (°C):No data availableUpper Explosive Limits (Liquid) (% by Vol.):No data availableLower Explosive Limits (Liquid) (% by Vol.):No data available

## 10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

**Possibility of Hazardous Reactions** 

Oxidizing Properties: No data available

**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions. **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition No data available

Products:

## 11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

**General Information:** The information included in this section describes the potential hazards of various forms of the

active ingredients. The remaining information describes the potential hazards of the individual

ingredients.

Short Term: May be harmful if swallowed. (based on animal data) . Accidental ingestion may cause effects

similar to those seen in clinical use.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include headache, diarrhea, nausea,

and flatulence. May cause mild skin rash.

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

**Pantoprazole Sodium** 

Rat Oral LD 50 747 mg/kg

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### 11. TOXICOLOGICAL INFORMATION

Mouse Oral LD 50 > 1000mg/kg Rat Intravenous LD 50 256mg/kg

### Hydroxypropyl methylcellulose

Rat Oral LD50 > 10,000 mg/kg

### Polysorbate 80

Rat Oral LD50 25 g/kg

### Propylene glycol

Oral LD 50 22,000 mg/kg Mouse Oral LD 50 24,900mg/kg Rabbit Dermal LD 50 20,800mg/kg

#### Titanium dioxide

Rat Oral LD50 > 7500 mg/kg Subcutaneous LD50 50 mg/kg Rat

#### **Povidone**

Rat Oral LD50 100 g/kg

#### Sodium lauryl sulfate

Rat Oral LD50 1288 mg/kg

#### Mannitol

Rat Oral LD 50 13500 mg/kg Mouse Oral LD 50 22 g/kg

### Pantoprazole Sodium Sesquihydrate

Rat Oral LD50 ~ 900 mg/kg Mouse Oral LD50 > 700mg/kg Rat Intravenous LD50 240mg/kg ~ 370mg/kg Mouse Intravenous LD50

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

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

### Propylene glycol

Skin Irritation Rabbit Mild Eve Irritation Rabbit Mild

### Sodium lauryl sulfate

Eve Irritation Rabbit Moderate Skin Irritation Rabbit Mild Moderate Skin Sensitization - GPMT Guinea Pig Negative Skin Sensitization - LLNA Mouse Negative

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

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## 11. TOXICOLOGICAL INFORMATION

### Pantoprazole Sodium Sesquihydrate

1 Year(s) Rat Oral 300 mg/kg/day LOEL Thyroid 1 Year(s) Dog Oral 60 mg/kg/day LOEL Thyroid

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

#### **Pantoprazole**

Reproductive & Fertility-Males Rat Oral 500 mg/kg/day NOEL No effects at maximum dose Reproductive & Fertility - Females Rat Oral 450 mg/kg/day NOEL No effects at maximum dose Fertility and Embryonic Development 450 mg/kg/day Not Teratogenic Rat Oral NOEL Fertility and Embryonic Development 40 mg/kg/day Not Teratogenic Rabbit Oral NOEL

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

#### **Pantoprazole**

Chromosome Aberration Human Lymphocytes Positive

Micronucleus Mouse Positive

Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells Positive

In Vivo DNA Binding Assay Rat Equivocal

In Vivo Chromosome Aberration Rat Bone Marrow Negative

### Sodium lauryl sulfate

Bacterial Mutagenicity (Ames) Salmonella Negative

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

### **Pantoprazole**

24 Month(s) Rat Oral 0.5 mg/kg/day LOEL Tumors, Gastrointestinal system, Liver 24 Month(s) Rat Oral 5 mg/kg/day LOEL Tumors, Gastrointestinal system 24 Month(s) Mouse Oral 150 mg/kg/day LOEL Tumors, Liver

24 Month(s) Rat Oral 200 mg/kg/day LOEL Tumors, Thyroid

Carcinogen Status: See below

Titanium dioxide

IARC: Group 2B (Possibly Carcinogenic to Humans)

**Povidone** 

IARC: Group 3 (Not Classifiable)

Crospovidone

IARC: Group 3 (Not Classifiable)

## 12. ECOLOGICAL INFORMATION

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

avoided.

**Toxicity:** 

PZ00404

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

**Pantoprazole** 

Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 Hours 48 mg/L

Daphnia magna (Water Flea) OECD EC50 48 Hours >95 mg/L

Pimephales promelas (Fathead Minnow) OECD LC50 96 Hours >95 mg/L

Activated sludge OECD EC50 3 Hours > 1000 mg/L

Sodium lauryl sulfate

Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours 3.6 mg/L

Persistence and Degradability: No data available

**Bio-accumulative Potential:** 

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

**Pantoprazole** 

Predicted 7.4 Log P 2.05

Mobility in Soil: No data available

### 13. DISPOSAL CONSIDERATIONS

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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### 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.

## 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Crospovidone

CERCLA/SARA 313 Emission reporting Not Listed

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15. REGULATORY INFORMATION	
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
Calcium stearate	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	216-472-8
Ferric oxide yellow	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	257-098-5
Methacrylic acid copolymer	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
Mannitol	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the	Present
obligations of Register:	
EU EINECS/ELINCS List	200-711-8
Pantoprazole Sodium Sesquihydrate	Mark Danasa
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
Polysorbate 80	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
Post for the last	
Propylene glycol	Not Listed
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed Present
myemory - united States (SLA - Sect XID)	r JESEU

Present

Present

Australia (AICS):

Inventory - United States TSCA - Sect. 8(b)

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<b>GULATORY INFO</b>	RMATION
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**EU EINECS/ELINCS List** 200-338-0

Sodium lauryl sulfate

**CERCLA/SARA 313 Emission reporting** Not Listed **California Proposition 65** Not Listed Inventory - United States TSCA - Sect. 8(b) Present Australia (AICS): Present Standard for the Uniform Scheduling Schedule 6 for Drugs and Poisons:

**EU EINECS/ELINCS List** 205-788-1

Sodium carbonate

**CERCLA/SARA 313 Emission reporting** Not Listed **California Proposition 65** Not Listed **EU EINECS/ELINCS List** Not Listed

**Triethyl Citrate** 

**CERCLA/SARA 313 Emission reporting** Not Listed **California Proposition 65** Not Listed Inventory - United States TSCA - Sect. 8(b) Present Present Australia (AICS): **EU EINECS/ELINCS List** 201-070-7

**Povidone** 

Not Listed **CERCLA/SARA 313 Emission reporting California Proposition 65** Not Listed Inventory - United States TSCA - Sect. 8(b) Present Australia (AICS): Present Not Listed **EU EINECS/ELINCS List** 

Hydroxypropyl methylcellulose

Not Listed **CERCLA/SARA 313 Emission reporting** Not Listed **California Proposition 65** Inventory - United States TSCA - Sect. 8(b) Present Australia (AICS): Present Standard for the Uniform Scheduling Schedule 4 for Drugs and Poisons: **EU EINECS/ELINCS List** Not Listed

Titanium dioxide

**CERCLA/SARA 313 Emission reporting** Not Listed

**California Proposition 65** carcinogen 9/2/2011 airborne, unbound particles of respirable size

Inventory - United States TSCA - Sect. 8(b) Present Present Australia (AICS): **EU EINECS/ELINCS List** 236-675-5

## 16. OTHER INFORMATION

### Text of CLP/GHS Classification abbreviations mentioned in Section 3

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Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed Carcinogenicity-Cat.1B; H350 - May cause cancer

Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life

**Data Sources:** Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal

Protection. Updated Section 11 - Toxicology Information.

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Prepared by:

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

Pfizer Inc believes that the information contained in this Material 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.

**End of Safety Data Sheet**