



# SAFETY DATA SHEET

Revision date: 02-Apr-2015

Version: 4.0

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

### Product Identifier

**Material Name:** Eletriptan Hydrobromide Film Coated Tablets

**Trade Name:** RELPAX; RELERT; ELETRIPTAN-PFIZER

**Chemical Family:** Mixture

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

**Intended Use:** Pharmaceutical product for the treatment of migraine headache

### 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

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

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

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

Acute Oral Toxicity: Category 4  
Serious Eye Damage/Eye Irritation: Category 1

#### EU Classification:

EU Indication of danger: Irritant

EU Risk Phrases:

R41 - Risk of serious damage to eyes.

### Label Elements

**Signal Word:** Danger

**Hazard Statements:** H302 - Harmful if swallowed  
H318 - Causes serious eye damage

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**Precautionary Statements:**

P264 - Wash hands thoroughly after handling  
P270 - Do not eat, drink or smoke when using this product  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician 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  
P310 - Immediately call a POISON CENTRE or doctor/physician  
P330 - Rinse mouth  
P501 - Dispose of contents/container in accordance with all local and national regulations



**Other Hazards**  
**Australian Hazard Classification (NOHSC):**

No data available  
Hazardous Substance. Non-Dangerous Goods.

**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 EINECS/ELINCS List	EU Classification	GHS Classification	%
Eletriptan hydrobromide	177834-92-3	Not Listed	R52/53 Xi;R41 Xn;R22	Acute Tox.4 (H302) Eye Dam. 1 (H318) Aquatic Acute 3 (H402) Aquatic Chronic 3 (H412)	23.42
Magnesium stearate	557-04-0	209-150-3	Not Listed	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	Not Listed	*
FD&C yellow No.6 aluminum lake	15790-07-5	239-888-1	Not Listed	Not Listed	*
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	Not Listed	*
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	Not Listed	*
Triacetin	102-76-1	203-051-9	Not Listed	Not Listed	*

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**Additional Information:** \* Proprietary  
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.

For the full text of the R phrases and 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.

**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 Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions Aggravated by Exposure:** None known

#### Indication of the Immediate Medical Attention and Special Treatment Needed

**Notes to Physician:** None

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

#### Special Hazards Arising from the Substance or Mixture

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

**Fire / 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.

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**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

If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Minimize dust generation and accumulation. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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

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

#### Eletriptan hydrobromide

Pfizer OEL TWA-8 Hr: 0.1 mg/m<sup>3</sup>

#### Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup>  
Lithuania OEL - TWA 5 mg/m<sup>3</sup>  
Sweden OEL - TWAs 5 mg/m<sup>3</sup>

#### Titanium dioxide

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup>  
ACGIH OELs - Notice of Intended Changes Listed  
Australia TWA 10 mg/m<sup>3</sup>  
Austria OEL - MAKs 5 mg/m<sup>3</sup>  
Belgium OEL - TWA 10 mg/m<sup>3</sup>  
Bulgaria OEL - TWA 10.0 mg/m<sup>3</sup>  
Denmark OEL - TWA 6 mg/m<sup>3</sup>  
Estonia OEL - TWA 5 mg/m<sup>3</sup>  
France OEL - TWA 10 mg/m<sup>3</sup>  
Greece OEL - TWA 10 mg/m<sup>3</sup>  
Ireland OEL - TWAs 5 mg/m<sup>3</sup>  
Ireland OEL - TWAs 10 mg/m<sup>3</sup>  
Latvia OEL - TWA 4 mg/m<sup>3</sup>  
Latvia OEL - TWA 10 mg/m<sup>3</sup>  
Lithuania OEL - TWA 5 mg/m<sup>3</sup>  
OSHA - Final PELs - TWAs: 15 mg/m<sup>3</sup>  
Poland OEL - TWA 10.0 mg/m<sup>3</sup>  
Portugal OEL - TWA 10 mg/m<sup>3</sup>  
Romania OEL - TWA 10 mg/m<sup>3</sup>  
Russia OEL - TWA 10 mg/m<sup>3</sup>  
Spain OEL - TWA 10 mg/m<sup>3</sup>  
Sweden OEL - TWAs 5 mg/m<sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Switzerland OEL -TWAs	3 mg/m <sup>3</sup>
Vietnam OEL - TWAs	6 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>

#### Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
Latvia OEL - TWA	2 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Romania OEL - TWA	10 mg/m <sup>3</sup>
Russia OEL - TWA	6 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL -TWAs	3 mg/m <sup>3</sup>
Vietnam OEL - TWAs	10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>

**Analytical Method:** Analytical method available for Eletriptan. Contact Pfizer Inc for further information.

#### Exposure Controls

**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.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands:** Wear impervious gloves to prevent skin contact.

**Eyes:** Wear safety goggles as minimum protection.

**Skin:** Wear impervious protective clothing to prevent skin contact.

**Respiratory protection:** 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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Tablet	<b>Color:</b>	Orange
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

**Solvent Solubility:** No data available

**Water Solubility:** No data available

**pH:** No data available.

**Melting/Freezing Point (°C):** No data available

**Boiling Point (°C):** No data available.

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

**Eletriptan hydrobromide**

Measured Log P 3.45

**Magnesium stearate**

No data available

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Croscarmellose sodium**

No data available

**Lactose NF, monohydrate**

No data available

**Microcrystalline cellulose**

No data available

**Hydroxypropyl methylcellulose**

No data available

**Triacetin**

No data available

**Titanium dioxide**

No data available

**FD&C yellow No.6 aluminum lake**

No data available

**Decomposition Temperature (°C):** No data available.

**Evaporation Rate (Gram/s):** No data available

**Vapor Pressure (kPa):** No data available

**Vapor Density (g/ml):** No data available

**Relative Density:** No data available

**Viscosity:** No data available

**Flammability:**

**Autoignition Temperature (Solid) (°C):** No data available

**Flammability (Solids):** No data available

**Flash Point (Liquid) (°C):** No data available

**Upper Explosive Limits (Liquid) (% by Vol.):** No data available

**Lower Explosive Limits (Liquid) (% by Vol.):** No data available

**Polymerization:** Will not occur

### 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 Products:** No data available

### 11. TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects**

**General Information:** There are no data for this formulation. The information included in this section describes the potential hazards of eletriptan in hydrobromide and/or hemisulfate salt forms. The remaining information describes the potential hazards of the individual ingredients.

**Short Term:** Active ingredient may be harmful if swallowed. May cause respiratory tract irritation. (based on components) .

**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on liver, thyroid, heart.

**Known Clinical Effects:** Adverse effects most commonly reported in clinical use include weakness, sleepiness, nausea and dizziness

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### 11. TOXICOLOGICAL INFORMATION

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

##### **Eletriptan hydrobromide**

Rat Dermal LD50 2000mg/kg  
Rat/Mouse Oral LD50 100-1000mg/kg (hemisulfate)  
Rat/Mouse IV LDmin. 20mg/kg (hemisulfate)

##### **Magnesium stearate**

Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

##### **Microcrystalline cellulose**

Rat Oral LD50 > 5000 mg/kg  
Rabbit Dermal LD50 > 2000 mg/kg

##### **Hydroxypropyl methylcellulose**

Rat Oral LD50 > 10,000 mg/kg

##### **Triacetin**

Rat Oral LD 50 3000 mg/kg  
Mouse Oral LD 50 1100mg/kg

##### **Titanium dioxide**

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

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

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

##### **Eletriptan hydrobromide**

Eye Irritation Rabbit Very severe  
Skin Irritation Rabbit Non-irritating  
Antigenicity- Passive cutaneous anaphylaxis Guinea Pig Negative  
Antigenicity- Active anaphylaxis Guinea Pig Negative

##### **Microcrystalline cellulose**

Skin Irritation Rabbit Non-irritating  
Eye Irritation Rabbit Non-irritating

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

##### **Eletriptan hydrobromide**

1 Month(s) Rat Oral 5 mg/kg/day NOAEL Liver, Thyroid  
6 Month(s) Rat Oral 15 mg/kg/day NOAEL Liver  
6 Month(s) Dog Oral 1.25 mg/kg/day NOAEL Heart  
12 Month(s) Dog Oral 0.75 mg/kg/day NOAEL Heart  
24 Month(s) Mouse Oral 20 mg/kg/day NOAEL Liver, Thyroid

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

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### 11. TOXICOLOGICAL INFORMATION

#### Eletriptan hydrobromide

Reproductive & Fertility	Rat	Oral 50 mg/kg/day	NOAEL	No effects at maximum dose
Embryo / Fetal Development	Rat	Oral 10 mg/kg/day	NOAEL	Maternal Toxicity, Fetotoxicity
Embryo / Fetal Development	Rabbit	Oral 10 mg/kg/day	NOAEL	Maternal Toxicity, Not Teratogenic
Peri-/Postnatal Development	Rat	Oral 15 mg/kg/day	NOAEL	Maternal Toxicity, Neonatal toxicity

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

#### Eletriptan hydrobromide

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
Mammalian Cell Mutagenicity	Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Negative
<i>In Vivo</i> Micronucleus	Mouse Bone Marrow	Negative

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

#### Eletriptan hydrobromide

24 Month(s)	Mouse	Oral, in feed	400 mg/kg/day	NOAEL	Not carcinogenic
24 Month(s)	Rat	Oral	75 mg/kg/day	NOAEL	Not carcinogenic

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

#### Titanium dioxide

##### IARC:

Group 2B (Possibly Carcinogenic to Humans)

### 12. ECOLOGICAL INFORMATION

#### Environmental Overview:

In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater. Harmful effects to aquatic organisms could occur. Releases to the environment should be avoided.

#### Toxicity:

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

#### Eletriptan hydrobromide

<i>Daphnia magna</i> (Water Flea)	TAD OECD	LC50	48 Hours	29 mg/L
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#### Persistence and Degradability:

No data available

#### Bio-accumulative Potential:

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

#### Eletriptan hydrobromide

Measured	Log P	3.45
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#### Mobility in Soil:

No data available



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### 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.

### 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

#### Canada - WHMIS: Classifications

##### WHMIS hazard class:

Class D, Division 2, Subdivision B



#### Eletriptan hydrobromide

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

#### Croscarmellose sodium

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

#### FD&C yellow No.6 aluminum lake

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	239-888-1

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### 15. REGULATORY INFORMATION

#### Lactose NF, monohydrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	Not Listed

#### Magnesium 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	209-150-3

#### Hydroxypropyl methylcellulose

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 for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	Not Listed

#### Triacetin

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	203-051-9

#### Titanium dioxide

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen initial date 9/2/11 airborne, unbound particles of respirable size
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	236-675-5

#### Microcrystalline cellulose

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 XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 9[f]. powder
EU EINECS/ELINCS List	232-674-9

### 16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

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Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed  
Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage  
Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects

C - Corrosive  
Xn - Harmful

R22 - Harmful if swallowed.  
R41 - Risk of serious damage to eyes.  
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other 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**