



SAFETY DATA SHEET

Revision date 17-Jun-2025

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

1.1. Product identifier

Product Name Magnesium Sulfate in 5% Dextrose Injection, USP (Hospira Inc.)
Product Code(s) PZ03096
Trade Name: Magnesium Sulfate in 5% Dextrose Injection, USP
Chemical Family: Not determined

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

Recommended Use Pharmaceutical product used as anticonvulsant

1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

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

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP].

OSHA Classification

Hazards not otherwise classified (HNOC)
Not applicable

Hazards classified under paragraph (d)(1)(ii) of 1910.1200
Not applicable

2.2. Label elements

Signal word Not classified

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

Supplemental Hazard Compound, not fully tested, additional hazards may exist.

2.3. Other hazards **Other hazards**

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

PBT & vPvB The product does not contain any substance(s) classified as PBT or vPvB.

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.

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 (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5 (011-002-00-6)	Skin Corr. 1A (H314)	Eye Irrit. 2 :: 0.5%≤C<2% Skin Corr. 1A :: C≥5% Skin Corr. 1B :: 2%≤C<5% Skin Irrit. 2 :: 0.5%≤C<2%	No data available	No data available
+ SULPHURIC ACID ... % (CAS #: 7664-93-9)	**		231-639-5 (016-020-00-8)	Skin Corr. 1A (H314)	Eye Irrit. 2 :: 5%≤C<15% Skin Corr. 1A :: C≥15% Skin Irrit. 2 :: 5%≤C<15%	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
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Water (CAS #: 7732-18-5)	93	-	231-791-2	Not classified	Not classified	No data available	No data available
Dextrose, monohydrate (CAS #: 5996-10-1)	5		Not Listed	Not classified	Not classified	No data available	No data available
Magnesium sulfate heptahydrate (CAS #: 10034-99-8)	1-2		Not Listed	Not classified	Not classified	No data available	No data available

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

Acute Toxicity Estimate

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	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
Magnesium sulfate heptahydrate 10034-99-8	>5000	No data available	No data available	No data available	No data available
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
+ SULPHURIC ACID ... % 7664-93-9	2140	No data available	0.375	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59).

Additional information

+ Substance with a Union workplace exposure limit

** to adjust pH

Non-hazardous ingredients provided for completeness. Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Move victim to fresh air.
Eye contact	If symptoms persist, call a physician.
Skin contact	Wash skin with soap and water. If skin irritation persists, call a physician.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

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

Most important symptoms and effects	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
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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 Not applicable.

Hazardous combustion products Formation of toxic gases is possible during heating or fire. Emits oxides of sulfur under combustion.

Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

5.3. Advice for firefighters

Special protective equipment and precautions 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 Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing.

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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.

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 as directed by product packaging.

7.3. Specific end use(s)

Specific use(s)

Pharmaceutical product used as. anticonvulsant.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

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

Sodium hydroxide

ACGIH OEL (Ceiling)	2 mg/m ³
ACGIH TLV	Ceiling: 2 mg/m ³
Austria	TWA-TMW: 2 mg/m ³ ; inhalable fraction
	STEL-KZGW: 4 mg/m ³ (8 X 5 min); inhalable fraction
Bulgaria	TWA: 2.0 mg/m ³ ; alkaline aerosols
Czech Republic	1 mg/m ³
	Ceiling: 2 mg/m ³
Denmark	Ceiling: 2 mg/m ³ ;
Estonia	TWA: 1 mg/m ³ ;
	STEL: 2 mg/m ³ ;
Finland	Ceiling: 2 mg/m ³ ;
France	2 mg/m ³
Hungary	TWA-AK: 1 mg/m ³ ;
	STEL-CK: 2 mg/m ³ ;
Ireland	STEL: 2 mg/m ³ ;
Ceiling Limit Value	2 mg/m ³
Latvia	TWA: 0.5 mg/m ³ ;
Poland	TWA-NDS: 0.5 mg/m ³ ;
	STEL-NDSch: 1 mg/m ³ ;
Romania	TWA: 1 mg/m ³ ;
	STEL: 3 mg/m ³ ;
Slovakia	TWA: 2 mg/m ³ ;
Spain	STEL (VLA-EC): 2 mg/m ³ ;
Switzerland	TWA-MAK: 2 mg/m ³ ; inhalable dust
	STEL-KZGW: 2 mg/m ³ ; inhalable dust
OSHA PEL	TWA: 2 mg/m ³
	(vacated) Ceiling: 2 mg/m ³
United Kingdom	STEL: 2 mg/m ³ ;

+ SULPHURIC ACID ... %

ACGIH TLV	TWA: 0.2 mg/m ³ thoracic particulate matter
Austria	TWA-TMW: 0.1 mg/m ³ ; inhalable fraction
	STEL-KZGW: 0.2 mg/m ³ (); inhalable fraction
Bulgaria	TWA: 0.05 mg/m ³ ; respirable aerosol

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Czech Republic	1 mg/m ³ 0.05 mg/m ³ Ceiling: 2 mg/m ³
Denmark	TWA: 0.05 mg/m ³ ; mist STEL: 0.1 mg/m ³ ; mist
Estonia	TWA: 0.05 mg/m ³ ; particles that reach the upper respiratory tract
European Union	TWA: 0.05 mg/m ³ ; mist (thoracic fraction)
Finland	TWA: 0.05 mg/m ³ ; thoracic fraction STEL: 0.1 mg/m ³ ; thoracic fraction
France	0.05 mg/m ³
Germany DFG	TWA-MAK: 0.1 mg/m ³ ; I(1);inhalable fraction Peak: 0.1 mg/m ³ ; inhalable fraction
Germany TRGS	TWA-AGW; 0.1 mg/m ³ (exposure factor 1); inhalable fraction
Hungary	TWA-AK: 0.05 mg/m ³ ;
Ireland	TWA: 0.05 ppm; STEL: 0.15 ppm (calculated);
Italy MDLPS	TWA: 0.05 mg/m ³ ; thoracic fraction, mist
Ceiling Limit Value	1 mg/m ³
Latvia	TWA: 0.05 mg/m ³ ; fog, which is defined as the thoracic fraction
Netherlands	TWA: 0.05 mg/m ³ ; mist, thoracic fraction
Poland	TWA-NDS: 0.05 mg/m ³ ; thoracic fraction
Romania	TWA: 0.05 mg/m ³ ; thoracic fraction
Russia	MAC: 1 mg/m ³ Skin
Slovakia	TWA: 0.05 mg/m ³ ;
Spain	TWA-(VLA-ED): 0.05 mg/m ³ ; mist
Switzerland	TWA-MAK: 0.1 mg/m ³ ; inhalable dust STEL-KZGW: 0.2 mg/m ³ ; inhalable dust
OSHA PEL	TWA: 1 mg/m ³ (vacated) TWA: 1 mg/m ³
United Kingdom	TWA: 0.05 mg/m ³ ; mist STEL: 0.15 mg/m ³ ; mist

8.2. 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.

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 or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection

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.).

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Skin and body protection	Impervious disposable 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 equivalent.).
Thermal hazards	No information available.
Environmental exposure controls	No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Liquid
Color	Colourless
Odor	No information available.
Odor threshold	No information available

<u>Property</u>	<u>Values</u>
Melting point / freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
Flammability (solid, gas)	No data available
Lower and upper explosion limit/flammability limit	
Lower explosion limit	No data available
Upper explosion limit	No data available
Flash point	No data available
Autoignition temperature	No data available
Decomposition temperature	
SADT (°C)	No data available
pH	3.5-6.5
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	No data available
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

9.2. Other information

Molecular formula	Mixture
Molecular weight	Mixture

9.2.1. Information with regard to physical hazard classes

Oxidizing properties	None
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9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid None known.

10.5. Incompatible materials

Incompatible materials None known.

10.6. Hazardous decomposition products

Hazardous decomposition products Thermal decomposition products include. oxides of sulfur.

Section 11: TOXICOLOGICAL INFORMATION

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

General Information: The information included in this section describes the potential hazards of the active ingredient(s).

Known Clinical Effects: Adverse effects associated with therapeutic use include flushing, sweating, decrease in blood pressure (hypotension), circulatory failure, central nervous system, depression.

Acute toxicity	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

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

Magnesium sulfate heptahydrate

Rat Oral LDmin. 5000 mg/kg

Mouse Oral LDmin. 3000 mg/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

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

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Sodium hydroxide	= 325 mg/kg (Rat)	= 1350 mg/kg (Rabbit)	-
+ SULPHURIC ACID ... %	= 2140 mg/kg (Rat)	-	= 0.375 mg/L (Rat) 4 h

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

Sodium hydroxide

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

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

Magnesium sulfate heptahydrate

Fertility and Embryonic Development Rat Oral 450 mg/kg/day NOEL No evidence of impaired fertility or harm to the fetus

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

Magnesium sulfate heptahydrate

Bacterial Mutagenicity (Ames) *Salmonella* Negative

Carcinogenicity

See below The International Agency for Research on Cancer (IARC) and the United States National Toxicology Program (NTP) have classified 'occupational exposure to strong inorganic acid mists containing sulfuric acid' as a known human carcinogen. This classification applies only to sulfuric acid when generated as a mist. This classification is debated within the scientific community and there is disagreement as to whether or not a cause and effect relationship between cancer and 'occupational exposure to strong inorganic acid mists containing sulfuric acid' exists.

+ SULPHURIC ACID ... %

IARC

NTP

Group 1

Known

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview:

Environmental properties have not been investigated. Releases to the environment should be avoided. Based on available data, the classification criteria are not met.

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

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Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
Sodium hydroxide	Not PBT/vPvB PBT assessment does not apply
+ SULPHURIC ACID ... %	Not PBT/vPvB PBT assessment does not apply

12.6. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

12.7. Other adverse effects

Other adverse effects No information available.

PMT or vPvM properties Based on available data, the classification criteria are not met.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products

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.

UN number: Not applicable
UN proper shipping name: Not applicable
Transport hazard class(es): Not applicable
Packing group: Not applicable
Environmental Hazard(s): Not applicable

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Section 15: REGULATORY INFORMATION

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

Water

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

Dextrose, monohydrate

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

Magnesium sulfate heptahydrate

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

Sodium hydroxide

CERCLA/SARA Section 313 de minimus %	Not Listed
Hazardous Substances RQs	1000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	215-185-5
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6

+ SULPHURIC ACID ... %

CERCLA/SARA Section 313 de minimus %	1.0 %
Hazardous Substances RQs	1000 lb
California Proposition 65	Carcinogen
TSCA	Present
EINECS	231-639-5
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 6

National regulations

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

TRGS 905

Not applicable

Chemical name	Netherlands - List of Carcinogens	Netherlands - List of Mutagens	Netherlands - List of Reproductive Toxins
+ SULPHURIC ACID ... % 7664-93-9	Present	-	-

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Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable
Storage of Hazardous Material Not applicable
WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20 Not applicable
Major Accidents Ordinance SR 814.012 Not applicable

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
Sodium hydroxide 1310-73-2	75	-
+ SULPHURIC ACID ... % 7664-93-9	75	-

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable.

Explosives Precursors Marketing and Use (2019/1148)

Not applicable

Chemical name	Limit value	Upper limit value for the purpose of licensing under article 5(3)	Reportable explosives precursors
+ SULPHURIC ACID ... % 7664-93-9	15 %w/w	40 %w/w	-

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing Chemicals Inventory
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances
NZIoC - New Zealand Inventory of Chemicals
TCSI - Taiwan Chemical Substance Inventory

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 any hazard and/or precautionary statements referred to under Sections 2-15

H314 - Causes severe skin burns and eye damage

Data Sources: Publicly available toxicity information.

Reason for revision Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.

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Prepared By Pfizer Global Environment, Health, and Safety

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