



A Pfizer Company

SAFETY DATA SHEET

Revision date: 02-Aug-2017

Version: 1.0

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

Product Identifier

Material Name: Diazepam Injection (Hospira, Inc.)

Trade Name: Diazepam Injection, USP
Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used as antianxiety agent

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

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Serious Eye Damage/Eye Irritation: Category 1
Reproductive Toxicity: Category 2
Specific target organ systemic toxicity (repeated exposure): Category 1
Flammable liquids- Category 3

Label Elements

Signal Word: Danger
Hazard Statements: H226 - Flammable liquid and vapor
H318 - Causes serious eye damage
H372 - Causes damage to organs through prolonged or repeated exposure: respiratory system

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Precautionary Statements:

- P202 - Do not handle until all safety precautions have been read and understood
- P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
- P260 - Do not breathe dust/fume/gas/mist/vapors/spray
- 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
- P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower
- 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
- P308 + P313 - IF exposed or concerned: Get medical attention/advice
- P370 + P378 - In case of fire: Use .? for extinction
- 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



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 EINECS/ELINCS List	GHS Classification	%
Diazepam	439-14-5	207-122-5	Acute Tox. 4 (H302)2 (H361)	0.5
Benzyl Alcohol	100-51-6	202-859-9	Acute Tox.4 (H302) Acute Tox.4 (H332)	1.5
Ethanol	64-17-5	200-578-6	Flam. Liq. 2 (H225)	10
Propylene glycol	57-55-6	200-338-0	Not Listed	*
Benzoic acid	65-85-0	200-618-2	STOT RE 1 (H372) Skin Irrit. 2 (H315) Eye Dam. 1 (H318)	5

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water for Injection	7732-18-5	231-791-2	Not Listed	*
Sodium benzoate	532-32-1	208-534-8	Not Listed	*

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

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.

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: Dry chemical, carbon dioxide, water spray or alcohol-resistant foam

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire. May include oxides of carbon.

Fire / Explosion Hazards: Flammable liquid and vapor. Vapors will form flammable or explosive mixtures with air at room temperature.

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. Eliminate all sources of ignition and ventilate area using explosion-proof equipment.

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 spill with absorbent material. 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.

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7. HANDLING AND STORAGE

Precautions for Safe Handling

Keep away from heat, sparks, flame and all other sources of ignition. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Use with adequate ventilation. 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. Keep away from open flames, hot surfaces and sources of ignition

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.

Diazepam

Pfizer OEL TWA-8 Hr:	7µg/m ³
Bulgaria OEL - TWA	0.1 mg/m ³

Benzyl Alcohol

Bulgaria OEL - TWA	5.0 mg/m ³
Czech Republic OEL - TWA	40 mg/m ³
Finland OEL - TWA	10 ppm
	45 mg/m ³
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Poland OEL - TWA	240 mg/m ³

Ethanol

ACGIH Threshold Limit Value (STEL)	1000 ppm
Australia TWA	1000 ppm
	1880 mg/m ³
Austria OEL - MAKs	1000 ppm
	1900 mg/m ³
Belgium OEL - TWA	1000 ppm
	1907 mg/m ³
Bulgaria OEL - TWA	1000 mg/m ³
Czech Republic OEL - TWA	1000 mg/m ³
Denmark OEL - TWA	1000 ppm
	1900 mg/m ³
Estonia OEL - TWA	500 ppm
	1000 mg/m ³
Finland OEL - TWA	1000 ppm
	1900 mg/m ³
France OEL - TWA	1000 ppm
	1900 mg/m ³
Germany - TRGS 900 - TWAs	500 ppm
	960 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Germany (DFG) - MAK	500 ppm
	960 mg/m ³
Greece OEL - TWA	1000 ppm
	1900 mg/m ³
Hungary OEL - TWA	1900 mg/m ³
Latvia OEL - TWA	1000 mg/m ³
Lithuania OEL - TWA	500 ppm
	1000 mg/m ³
Netherlands OEL - TWA	260 mg/m ³
OSHA - Final PELs - TWAs:	1000 ppm
	1900 mg/m ³
Poland OEL - TWA	1900 mg/m ³
Portugal OEL - TWA	1000 ppm
Romania OEL - TWA	1000 ppm
	1900 mg/m ³
Russia OEL - TWA	1000 mg/m ³
Slovakia OEL - TWA	500 ppm
	960 mg/m ³
Slovenia OEL - TWA	1000 ppm
	1900 mg/m ³
Sweden OEL - TWAs	500 ppm
	1000 mg/m ³
Switzerland OEL - TWAs	500 ppm
	960 mg/m ³
Vietnam OEL - TWAs	1000 mg/m ³
Propylene glycol	
Australia TWA	150 ppm
	474 mg/m ³
	10 mg/m ³
Ireland OEL - TWAs	150 ppm
	470 mg/m ³
	10 mg/m ³
Latvia OEL - TWA	7 mg/m ³
Lithuania OEL - TWA	7 mg/m ³
Benzoic acid	
Latvia OEL - TWA	5 mg/m ³

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). 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 disposable gloves (e.g. Nitrile, etc.) (double 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 goggles if eye contact is possible (face shield recommended if splashing is possible). (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Skin: Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly after handling this product. 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 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 full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	Color:	Clear, colorless to pale yellow
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Solvent Solubility:	No data available
Water Solubility:	Soluble
pH:	6.2-6.9
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	98

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

Diazepam

No data available

Benzyl Alcohol

No data available

Ethanol

No data available

Benzoic acid

No data available

Water for Injection

No data available

Propylene glycol

No data available

Sodium benzoate

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: 1.0349

Viscosity: No data available

Flammability:

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

Flammability (Solids): No data available

Flash Point (Liquid) (°C): 50

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

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

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10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: None
Conditions to Avoid: Keep away from heat, spark, flames and all other sources of ignition.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: May form toxic materials such as carbon monoxide and carbon dioxide.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: There are no data for this formulation. The remaining information describes the potential hazards of the individual ingredients.
Short Term: Harmful if swallowed (based on animal data)
Long Term: Animal studies have shown a potential to cause adverse effects on the fetus. Use of this drug is habit forming. Addiction may occur.
Known Clinical Effects: Therapeutic use of this substance has resulted in weakness, dizziness, drowsiness, ataxia, confusion, tremors, headache, and gastrointestinal disturbances.

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

Diazepam

Rat Oral LD 50 710 mg/kg
Rat Para-periosteal LD 50 32mg/kg
Rat Intraperitoneal LD 50 46.5mg/kg
Mouse Oral LD 50 48mg/kg
Mouse Intravenous LD 50 25mg/kg

Benzyl Alcohol

Rat Oral LD50 1230 mg/kg
Rat Para-periosteal LD50 53mg/kg
Rat Inhalation LC50 >4.178mg/L

Ethanol

Mouse Oral LD50 3,450 g/m³
Rat Oral LD50 7,060mg/kg
Mouse Inhalation LC50 4h 39g/m³
Rat Inhalation LC50 10h 20,000ppm

Benzoic acid

Rat Oral LD 50 1700 mg/kg
Mouse Oral LD 50 1940mg/kg
Rabbit Dermal LD50 > 5000mg/kg
Rat Inhalation LC50 > 0.026mg/L

Propylene glycol

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

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Sodium benzoate

Rat Oral LD50 4,070 mg/kg
Mouse Oral LD50 1600mg/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)

Benzyl Alcohol

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Minimal
Skin Irritation Guinea Pig Moderate

Ethanol

Eye Irritation Rabbit Severe

Benzoic acid

Skin Sensitization - GPMT Guinea Pig Negative
Skin Sensitization - Beuhler Guinea Pig Negative
Eye Irritation Rabbit Severe

Propylene glycol

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

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

Diazepam

6 Week(s) Mouse Oral 0.5 mg/kg LOAEL Male reproductive system
3 Month(s) Rat Oral 100 mg/kg/day NOAEL None identified
3 Month(s) Non-human Primate Oral 5 mg/kg/day LOAEL None identified
6 Month(s) Dog Oral 20 mg/kg/day LOAEL Liver
6 Month(s) Rat Oral 162 mg/kg/day LOAEL Kidney

Benzoic acid

250 Day(s) Dog Oral 1000 mg/kg/day NOAEL None identified
18 Month(s) Mouse Oral 80 mg/kg/day NOAEL None identified
18 Month(s) Rat Oral 80 mg/kg/day NOAEL

Sodium benzoate

10 Day(s) Rat Oral 27370 mg/kg LOAEL Liver, Blood
10 Day(s) Mouse Oral 45 g/kg LOAEL Liver, Kidney, Blood, Ureter, Bladder

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

Diazepam

Embryo / Fetal Development Mouse Oral 100 mg/kg/day NOAEL Teratogenic, Fetotoxicity
Embryo / Fetal Development Rat Oral 100 mg/kg LOAEL Embryotoxicity

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Embryo / Fetal Development	Dog	Oral	5 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Hamster	Intraperitoneal	280 mg/kg	LOAEL	Teratogenic
Embryo / Fetal Development	Rabbit	Oral	8 mg/kg	NOAEL	Not Teratogenic

Benzoic acid

Reproductive & Fertility	Rat	Oral	5 mg/kg/day	NOEL	Fertility, Not teratogenic
Fertility and Embryonic Development	Rat	Oral	500 mg/kg/day	NOAEL	No effects at maximum dose

Sodium benzoate

Embryo / Fetal Development	Rat	Oral	44 g/kg	LOEL	Developmental toxicity
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Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Diazepam

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vitro</i> Micronucleus	Mouse	Positive
<i>In Vivo</i> Chromosome Aberration	Mouse	Negative
<i>In Vivo</i> Micronucleus	Mouse	Negative
<i>In Vivo</i> Direct DNA Damage	Rat	Negative

Benzoic acid

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative
Sister Chromatid Exchange	Human Lymphocytes	Negative

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

Diazepam

2 Year(s)	Rat	Liver, Tumors
2 Year(s)	Mouse	Not carcinogenic
2 Year(s)	Hamster	Not carcinogenic
80 Week(s)	Male Mouse	Oral 75 mg/kg/day LOAEL Malignant tumors

Carcinogen Status:

Carcinogenicity of the mixture has not been determined. Consumption of alcoholic beverages is considered carcinogenic to humans (Group 1) by IARC, though ethanol itself has not been classified by this agency. No other components are listed as carcinogens by IARC, US OSHA or NTP.

Diazepam

IARC: Group 3 (Not Classifiable)

Ethanol

IARC: Group 1 (Carcinogenic to Humans)

At increase risk from exposure:

This material has been shown to be secreted in low concentrations in human breast milk. Adverse effects on nursing infants have been seen.

12. ECOLOGICAL INFORMATION

Environmental Overview:

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

Toxicity:

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

Benzyl Alcohol

Pimephales promelas (Fathead Minnow) EPA LC50 96 Hours 460 mg/L
Daphnia magna (Water Flea) OECD EC50 48 Hours 230 mg/L
Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 Hours 500 mg/L

Ethanol

Fingerling Trout NPDES LC50 24 Hours 11,200 mg/L
Oncorhynchus mykiss (Rainbow Trout) NPDES LC50 96 Hours 12,900 mg/L
Pimephales promelas (Fathead Minnow) NPDES LC50 96 Hours 14,200 mg/L

Benzoic acid

Daphnia magna (Water Flea) EC-50 24 Hours 500 mg/L
Fish LC50 96 Hours 180 mg/L

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Benzyl Alcohol

Daphnia magna (Water Flea) OECD 21 Day(s) EC50 66 mg/L Reproduction

Persistence and Degradability:

Benzyl Alcohol

OECD Activated sludge Ready 92% After 14 Day(s) Ready

Bio-accumulative Potential: No data available

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.

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.

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15. REGULATORY INFORMATION

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

Diazepam

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	developmental toxicity 1/1/1992
U.S. Drug Enforcement Administration: Inventory - United States TSCA - Sect. 8(b)	Schedule IV Controlled Substance
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS/ELINCS List	Schedule 4
	207-122-5

Benzyl Alcohol

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	202-859-9

Water for Injection

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 obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

Ethanol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen 4/29/2011 in alcoholic beverages developmental toxicity 10/1/1987 in alcoholic beverages
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-578-6

Propylene glycol

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	200-338-0

Sodium benzoate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present

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Australia (AICS):	Present
EU EINECS/ELINCS List	208-534-8

Benzoic acid

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-618-2

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled
Reproductive toxicity-Cat.2; H361 - Suspected of damaging fertility or the unborn child
Specific target organ toxicity, repeated exposure-Cat.1; H372 - Causes damage to organs through prolonged or repeated exposure
Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage
Skin corrosion/irritation-Cat.2; H315 - Causes skin irritation

Data Sources: The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: New data sheet.

Revision date: 02-Aug-2017

Product Stewardship Hazard Communication

Prepared by: 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