



SAFETY DATA SHEET

Revision date 19-Dec-2022

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

1.1. Product identifier

Product Name Lorazepam Injection (Hospira, Inc)
Product Code(s) PZ03156
Synonyms PNU-33030
Trade Name: Not applicable
Chemical Family: Benzodiazepine

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

Recommended Use Pharmaceutical product used as antianxiety agent

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

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

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: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

Reproductive toxicity Category 1B
Effects on or via lactation - (H360D, H362)

2.2. Label elements

Signal word Danger

Hazard statements H360D - May damage the unborn child
H362 - May cause harm to breast-fed children

Precautionary Statements P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P263 - Avoid contact during pregnancy/while nursing
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P280 - Wear protective gloves and protective clothing
P308 + P313 - IF exposed or concerned: Get medical attention/advice

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P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations



2.3. 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 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	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Propylene glycol (CAS #: 57-55-6)	*		200-338-0	Not classified as hazardous	Not Listed	No data available	No data available
Polyethylene glycol (CAS #: 25322-68-3)	*		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available
BENZYL ALCOHOL (CAS #: 100-51-6)	2		202-859-9	Acute Tox. 4 (H302) Acute Tox. 4 (H332)	Not Listed	No data available	No data available
Lorazepam (CAS #: 846-49-1)	<0.4		212-687-6	Repr.1B (H360D) Lact. (H362)	Not Listed	No data available	No data available

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

Acute Toxicity Estimate

No information available

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Propylene glycol 57-55-6	20000	20800	No data available	No data available	No data available

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Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Polyethylene glycol 25322-68-3	22000	20000	No data available	No data available	No data available
BENZYL ALCOHOL 100-51-6	1230	2000	4.178	No data available	No data available
Lorazepam 846-49-1	4500	No data available	No data available	No data available	No data available

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. Non-hazardous ingredients provided for completeness.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

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

Most important symptoms and effects For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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 Use extinguishing agent suitable for type of surrounding fire.

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.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

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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 vapor or mist. 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.

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 drug product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

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

BENZYL ALCOHOL

Pfizer OEL TWA-8 Hr: 10 ppm

Lorazepam

Pfizer OEL TWA-8 Hr: 5 µg/m³

Propylene glycol

Ireland

10 mg/m³

150 ppm

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	470 mg/m ³
	STEL: 1410 mg/m ³
	STEL: 30 mg/m ³
	STEL: 450 ppm
Latvia	7 mg/m ³
Poland	100 mg/m ³
Russia	MAC: 7 mg/m ³
United Kingdom	TWA: 150 ppm
	TWA: 474 mg/m ³
	TWA: 10 mg/m ³
	STEL: 450 ppm
	STEL: 1422 mg/m ³
	STEL: 30 mg/m ³
Polyethylene glycol	
Austria	1000 mg/m ³
	STEL 4000 mg/m ³
Denmark	1000 mg/m ³
Germany	250 mg/m ³ average molecular weight 200-600;because formation of a mist is possible, exposure should be minimized for reasons of occupational safety and hygiene
	Ceiling / Peak: 500 mg/m ³
Germany	200 mg/m ³
Russia	MAC: 10 mg/m ³
Slovakia	1000 mg/m ³
Switzerland	500 mg/m ³
BENZYL ALCOHOL	
Bulgaria	5.0 mg/m ³
Czech Republic	40 mg/m ³
	Ceiling: 80 mg/m ³
Finland	10 ppm
	45 mg/m ³
Germany	22 mg/m ³ can occur as vapor and aerosol at the same time
	5 ppm can occur as vapor and aerosol at the same time
	Ceiling / Peak: 44 mg/m ³
	Ceiling / Peak: 10 ppm
	Skin
Germany	5 ppm
	22 mg/m ³
	H*
Ceiling Limit Value	25 mg/m ³
Latvia	5 mg/m ³
Poland	240 mg/m ³
Russia	MAC: 5 mg/m ³
	Skin
Switzerland	5 ppm
	22 mg/m ³
	H*

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

Environmental exposure controls

No information available.

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

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the workplace and specific operational processes.

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 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.).

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 full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Liquid
Color	Clear, colorless
Odor	No information available.
Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture
Property	Values
pH	No data available
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	Practically insoluble
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

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9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable at normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

Hazardous polymerization Will not occur.

10.4. Conditions to avoid

Conditions to avoid Keep away from heat and other sources of ignition, including electrostatic discharge.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

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

General Information:	The information included in this section describes the potential hazards of the individual ingredients
Short term	May be harmful if swallowed. May cause irritation (based on components).
Long Term:	Repeat-dose studies in animals have shown a potential to cause adverse effects on developing fetus. May cause harm to breastfed babies.
Known Clinical Effects:	Adverse effects most commonly reported in clinical use include sedation, dizziness, weakness, clumsy motion of limbs/trunk (ataxia), incoordination, tiredness, drowsiness, amnesia, confusion, state of intense good feeling (euphoria), suicidal behavior. Benzodiazepines may cause fetal damage when administered during pregnancy. Secreted in human breast milk.
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	May damage the unborn child.
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.

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

Propylene glycol

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

BENZYL ALCOHOL

Rat Oral LD 50 1230 mg/kg
Mouse Oral LD 50 1360 mg/kg
Rabbit Dermal LD 50 2 gm/kg

Lorazepam

Mouse Oral LD 50 1850 mg/kg
Rat IV LD50 20(M) 25 (F) mg/kg
Dog IV LD50 50 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Propylene glycol	= 20 g/kg (Rat)	= 20800 mg/kg (Rabbit)	-
Polyethylene glycol	= 22 g/kg (Rat)	> 20 g/kg (Rabbit)	-
BENZYL ALCOHOL	= 1230 mg/kg (Rat)	= 2 g/kg (Rabbit)	> 4178 mg/m ³ (Rat) 4 h
Lorazepam	= 4500 mg/kg (Rat)	-	-

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
Eye irritation Rabbit Mild

Polyethylene glycol

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

BENZYL ALCOHOL

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

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

Lorazepam

1 Month(s) Rat Intravenous 10 mg/kg/day NOAEL Blood, Spleen

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

Lorazepam

Fertility and Embryonic Development Rabbit Intravenous 40 mg/kg/day LOAEL Fetotoxicity
Embryo / Fetal Development Rat Intravenous 2 mg/kg/day LOAEL Maternal Toxicity, Not Teratogenic
Embryo / Fetal Development Rabbit Intravenous 1 mg/kg/day LOAEL Maternal Toxicity, Not Teratogenic

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

Lorazepam

18 Month(s) Rat Oral Not carcinogenic
18 Month(s) Mouse Oral Not carcinogenic

Carcinogenicity

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

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11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

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

12.1. Toxicity

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

BENZYL ALCOHOL

Pimephales promelas (Fathead Minnow) EPA LC50 96 hours 460 - 770 mg/L

Daphnia magna (Water Flea) NPDES OECD EC50 48 Hours 230 mg/L

Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 hours 500 mg/L

12.2. Persistence and degradability

Persistence and degradability

Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

BENZYL ALCOHOL

OECD Activated sludge Ready 92 % After 28 Day(s) Ready

12.3. Bioaccumulative potential

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

No information available.

Chemical name	PBT and vPvB assessment
Propylene glycol	The substance is not PBT / vPvB PBT assessment does not apply
Polyethylene glycol	The substance is not PBT / vPvB
BENZYL ALCOHOL	The substance is not PBT / vPvB

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

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13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

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

Special precautions for user: Not applicable

Section 15: REGULATORY INFORMATION

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

Propylene glycol	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-338-0
AICS	Present
Polyethylene glycol	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	Not Listed
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 3 Schedule 2
BENZYL ALCOHOL	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	202-859-9
AICS	Present
Lorazepam	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	developmental toxicity 7/1/1990 developmental toxicity 10/1/1992
U.S. - DEA (Drug Enforcement Administration)	Schedule IV Controlled Substance
EINECS	212-687-6
Standard for Uniform Scheduling of Medicines and	Schedule 4

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Poisons (SUSMP)

Chemical name	French RG number	Title
Propylene glycol 57-55-6	RG 84	-
BENZYL ALCOHOL 100-51-6	RG 84	-

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

Persistent Organic Pollutants

Not applicable

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

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

Reproductive toxicity-Cat.1B; H360D - May damage the unborn child Reproductive toxicity, effects on or via lactation; H362 - May cause harm to breast-fed children Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled

Data Sources: Publicly available toxicity information. Pfizer proprietary drug development information.

Reason for revision Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

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Prepared By Pfizer Global Environment, Health, and Safety

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is no known information at this time.