

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Lorazepam Injection, USP

Anxiolytic - Sedative

1.2. Intended Use of the Product

Benzodiazepine indicated for the treatment of status epilepticus and in adult patients, as a preanesthetic medication

1.3. Name, Address, and Telephone of the Responsible Party

Distributor

Fresenius Kabi USA, LLC

Three Corporate Drive

Lake Zurich, IL 60047

General Phone Number: (847) 550-2300

Customer Service Phone Number: (888) 386-1300

Health Issues Information: (800) 551-7176

<http://www.fresenius-kabi.com/us/>

1.4. Emergency Telephone Number

Emergency Number : VelocityEHS

(800)255-3924 (North America)

+1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US/CA Classification

Reproductive toxicity Category 2 H361

Reproductive toxicity, Additional category, Effects on or via lactation H362

Specific target organ toxicity – Single exposure, Category 3, Narcosis H336

2.2. Label Elements

GHS-US/CA Labeling

Hazard Pictograms (GHS-US/CA)



Signal Word (GHS-US/CA)

: Warning

Hazard Statements (GHS-US/CA)

: H336 - May cause drowsiness or dizziness.

H361 - Suspected of damaging fertility or the unborn child.

H362 - May cause harm to breast-fed children.

Precautionary Statements (GHS-US/CA)

: P201 - Obtain special instructions before use.

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

P260 - Do not breathe vapors, mist, or spray.

P263 - Avoid contact during pregnancy/while nursing.

P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product.

P271 - Use only outdoors or in a well-ventilated area.

P280 - Wear protective gloves, protective clothing, and eye protection.

P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.

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

P312 - Call a POISON CENTER or doctor if you feel unwell.

P403+P233 - Store in a well-ventilated place. Keep container tightly closed.

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P405 - Store locked up.

P501 - Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US/CA)

No additional information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
1,2-Propanediol	1,2-Propylene glycol / 1,2-Dihydroxypropane / Propane-1,2-diol / Propylene glycol / PROPYLENE GLYCOL	(CAS-No.) 57-55-6	79.8	Not classified
Polyethylene glycol	Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy- / Polyethylene glycol 6000 / Polyethylene glycol ether / Polyethylene glycols / PEG-10 / Polyethylene glycol 400 / Polyethylene glycol 8000 / PEG / Macrogols / Ethylene oxide polymer / 1,2-Ethenediol, homopolymer / Macrogol / PEG-9 / .alpha.-Hydro-.omega.-hydroxypoly(oxyethylene) / PEG-14 / .alpha.-Hydro-.omega.-hydroxypoly(oxy-1,2-ethanediyl) / Ethoxylated 1,2-ethenediol / Polyethylene glycol 35 / Polyethylene glycol 115 / Poly(ethylene glycol) 400 / Polyethylene oxide / PEG-100 / PEG-115M / PEG-135 / PEG-14M / PEG-150 / PEG-16 / PEG-160M / PEG-18 / PEG-180 / PEG-180M / PEG-1M / PEG-20 / PEG-200 / PEG-20M / PEG-220 / PEG-23M / PEG-240 / PEG-25M / PEG-2M / PEG-32 / PEG-33 / PEG-350 / PEG-40 / PEG-400 / PEG-45 / PEG-450 / PEG-45M / PEG-500 / PEG-55 / PEG-5M / PEG-60 / PEG-65M / PEG-75 / PEG-7M / PEG-80 / PEG-800 / PEG-90 / PEG-90M / PEG-9M / polyethylene glycol 1600 / Ethylene glycol homopolymer	(CAS-No.) 25322-68-3	18	STOT SE 3, H335
Benzyl alcohol	Benzenecarbinol / Benzenemethanol / Methanol, phenyl- / Phenylmethanol / Phenylmethyl alcohol / BENZYL ALCOHOL / .alpha.-Hydroxytoluene / Benzylalcohol	(CAS-No.) 100-51-6	2	Flam. Liq. 4, H227 Acute Tox. 4 (Oral), H302 Eye Irrit. 2A, H319 Aquatic Acute 2, H401
Lorazepam	2H-1,4-Benzodiazepin-2-one, 7-chloro-5-(2-chlorophenyl)-1,3-dihydro-3-hydroxy- / 2H,1,4-Benzodiazepin-2-one,	(CAS-No.) 846-49-1	0.2	Repr. 2, H361 Lact, H362 STOT SE 3, H336

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	7-chloro-5-(o-chlorophenyl)- 1,3-dihydro-3-hydroxy- / 7- Chloro-5-(o-chlorophenyl)-1,3- dihydro-3-hydroxy-2H-1,4- benzodiazepin-2-one / lorazepam			
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Full text of H-statements: see section 16

*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%).

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

Skin Contact: Immediately remove contaminated clothing. Drench affected area with water for at least 15 minutes. If exposed or concerned: Get medical advice/attention.

Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: May cause drowsiness and dizziness. Suspected of damaging fertility or the unborn child. May cause harm to breast-fed children.

Inhalation: High concentrations may cause central nervous system depression such as dizziness, vomiting, numbness, drowsiness, headache, and similar narcotic symptoms.

Skin Contact: Prolonged exposure may cause skin irritation.

Eye Contact: May cause slight irritation to eyes.

Ingestion: Ingestion may cause adverse effects. Drowsiness.

Chronic Symptoms: Suspected of damaging fertility or the unborn child.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides, Nitrogen oxides. Chlorides.

5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not get in eyes, on skin, or on clothing. Do not breathe vapor, mist or spray. If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

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6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Accidental injection may cause pain and swelling at the injection site. Sharps should be handled appropriately to minimize risk of accidents. . Material may be biologically contaminated with pathogenic organisms during use.

Precautions for Safe Handling: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe vapors, mist, spray. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not get in eyes, on skin, or on clothing. Avoid contact during pregnancy/while nursing.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store in refrigerator 2° to 8°C (35.6 - 46.4 °F). Protect from light. Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store locked up/in a secure area. Use carton to protect contents from light.

Incompatible Materials: Peroxides. Strong acids, strong bases, strong oxidizers.

Storage Temperature: 2 – 8 °C (35.6 - 46.4 °F)

7.3. Specific End Use(s)

Benzodiazepine indicated for the treatment of status epilepticus and in adult patients, as a preanesthetic medication

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

Polyethylene glycol (25322-68-3)		
USA AIHA	WEEL TWA	10 mg/m ³ (molecular weight>200-aerosol)
Benzyl alcohol (100-51-6)		
USA AIHA	WEEL TWA [ppm]	10 ppm
1,2-Propanediol (57-55-6)		
USA AIHA	WEEL TWA	10 mg/m ³
Ontario	OEL TWA	10 mg/m ³ (for assessing the visibility in a work environment where 1,2-Propylene glycol aerosol is present-aerosol only) 155 mg/m ³ (aerosol and vapor)
Ontario	OEL TWA [ppm]	50 ppm (aerosol and vapor)

8.2. Exposure Controls

Appropriate Engineering Controls: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

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Personal Protective Equipment: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical safety goggles.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Consumer Exposure Controls: Avoid contact during pregnancy/while nursing

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: No data available
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: Not applicable
Lower Flammable Limit	: No data available
Upper Flammable Limit	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Specific Gravity	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability:

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

10.4. Conditions to Avoid:

Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible Materials:

Peroxides. Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products:

Thermal decomposition may produce: Carbon oxides, Nitrogen oxides. Chlorides.

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Acute Toxicity (Oral): Not classified

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

LD50 and LC50 Data:

No additional information available

Skin Corrosion/Irritation: Not classified

Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Suspected of damaging fertility or the unborn child. May cause harm to breast-fed children.

Specific Target Organ Toxicity (Single Exposure): May cause drowsiness or dizziness.

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: High concentrations may cause central nervous system depression such as dizziness, vomiting, numbness, drowsiness, headache, and similar narcotic symptoms.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects. Drowsiness.

Chronic Symptoms: Suspected of damaging fertility or the unborn child.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Lorazepam (846-49-1)	
LD50 Oral Rat	4500 mg/kg
Polyethylene glycol (25322-68-3)	
LD50 Oral Rat	22 g/kg
LD50 Dermal Rabbit	> 20 g/kg
Benzyl alcohol (100-51-6)	
LD50 Oral Rat	1230 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
LD50 Intravenous Rat	53 mg/kg
LC50 Inhalation Rat	> 4178 mg/m ³ (Exposure time: 4 h)
1,2-Propanediol (57-55-6)	
LD50 Oral Rat	20 g/kg
LD50 Dermal Rabbit	20800 mg/kg

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

Benzyl alcohol (100-51-6)	
LC50 Fish 1	460 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 - Crustacea [1]	23 mg/l (Exposure time: 48 h - Species: water flea)
LC50 Fish 2	10 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
NOEC Chronic Crustacea	51 mg/l
1,2-Propanediol (57-55-6)	
LC50 Fish 1	51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 - Crustacea [1]	10000 mg/l (Exposure time: 24 h - Species: Daphnia magna)
LC50 Fish 2	41 – 47 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 - Crustacea [2]	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
NOEC Chronic Crustacea	1000 mg/l

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NOEC Chronic Algae	1000 mg/l
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12.2. Persistence and Degradability

Lorazepam Injection, USP	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Lorazepam Injection, USP	
Bioaccumulative Potential	Not established.

Benzyl alcohol (100-51-6)	
Partition coefficient n-octanol/water (Log Pow)	1.05

1,2-Propanediol (57-55-6)	
BCF Fish 1	(1)
Partition coefficient n-octanol/water (Log Pow)	-0.92

12.4. Mobility in Soil

No additional information available

12.5. Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Not regulated for transport

14.2. In Accordance with IMDG

Not regulated for transport

14.3. In Accordance with IATA

Not regulated for transport

14.4. In Accordance with TDG

Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

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SARA Section 311/312 Hazard Classes	Health hazard - Specific target organ toxicity (single or repeated exposure) Health hazard - Reproductive toxicity
Polyethylene glycol (25322-68-3)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).
Benzyl alcohol (100-51-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
1,2-Propanediol (57-55-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	

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15.2. US State Regulations

California Proposition 65

 **WARNING:** This product can expose you to Lorazepam, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

Chemical Name (CAS No.)	Carcinogenicity	Developmental Toxicity	Female Reproductive Toxicity	Male Reproductive Toxicity
Lorazepam (846-49-1)		X		

Benzyl alcohol (100-51-6)

U.S. - Pennsylvania - RTK (Right to Know) List

U.S. - Massachusetts - Right To Know List

1,2-Propanediol (57-55-6)

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

15.3. Canadian Regulations

Lorazepam (846-49-1)

Listed on the Canadian DSL (Domestic Substances List)

Polyethylene glycol (25322-68-3)

Listed on the Canadian DSL (Domestic Substances List)

Benzyl alcohol (100-51-6)

Listed on the Canadian DSL (Domestic Substances List)

1,2-Propanediol (57-55-6)

Listed on the Canadian DSL (Domestic Substances List)

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 10/17/2023

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

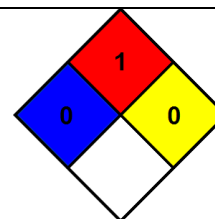
GHS Full Text Phrases:

H227	Combustible liquid
H302	Harmful if swallowed
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H336	May cause drowsiness or dizziness
H361	Suspected of damaging fertility or the unborn child
H362	May cause harm to breast-fed children
H401	Toxic to aquatic life

NFPA Health Hazard : 0 - Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials.

NFPA Fire Hazard : 1 - Materials that must be preheated before ignition can occur.

NFPA Reactivity Hazard : 0 - Material that in themselves are normally stable, even under fire conditions.



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HMIS III Rating

Health : 3 Serious Hazard - Major injury likely unless prompt action is taken and medical treatment is given

* Chronic - Chronic (long-term) health effects may result from repeated overexposure

Flammability : 0 Minimal Hazard

Physical : 0 Minimal Hazard

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

NA GHS SDS 2015 (Can, US)