

# **Melphalan Hydrochloride for Injection Safety Data Sheet**

## **Sterile Diluent for Melphalan Hydrochloride for Injection Safety Data Sheet**

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## Section 1. Identification

**GHS product identifier** : Melphalan Hydrochloride for Injection

**Other means of identification** : Not available.

**Product type** : Powder.

### Relevant identified uses of the substance or mixture and uses advised against

**Product use** : Pharmaceuticals. (For intended use only.)  
Observe technical data sheet/instructions for use.  
Specific Treatments: Cancer.

**Area of application** : Professional applications.

**Supplier's details** : Meitheal Pharmaceuticals, Inc.  
8700 W. Bryn Mawr, Suite 600S  
Chicago, IL 60631

Telephone: 224-443-4617  
www.meithealpharma.com

**e-mail address of person responsible for this SDS** : info@meithealpharma.com

**Emergency telephone number (with hours of operation)** : 844-824-8426 (Monday - Friday, 08:00 - 18:00 CST)

## Section 2. Hazards identification

**OSHA/HCS status** : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

**Classification of the substance or mixture** :

H300	COMBUSTIBLE DUSTS
H317	ACUTE TOXICITY (oral) - Category 2
H340	SKIN SENSITIZATION - Category 1
H350	GERM CELL MUTAGENICITY - Category 1
H361	CARCINOGENICITY - Category 1A
	TOXIC TO REPRODUCTION - Category 2

### GHS label elements

**Hazard pictograms** :



**Signal word** : Danger

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## Section 2. Hazards identification

<b>Hazard statements</b>	: H300 - Fatal if swallowed. H317 - May cause an allergic skin reaction. H340 - May cause genetic defects. H350 - May cause cancer. H361 - Suspected of damaging fertility or the unborn child. May form combustible dust concentrations in air.
<b>Precautionary statements</b>	
<b>Prevention</b>	: P201 - Obtain special instructions before use. P202 - Do not handle until all safety precautions have been read and understood. P280 - Wear protective gloves, protective clothing and eye or face protection. P261 - Avoid breathing dust or mist. P270 - Do not eat, drink or smoke when using this product. P264 - Wash thoroughly after handling. P272 - Contaminated work clothing must not be allowed out of the workplace.
<b>Response</b>	: P308 + P313 - IF exposed or concerned: Get medical advice or attention. P301 + P310, P330 - IF SWALLOWED: Immediately call a POISON CENTER or doctor. Rinse mouth. P363 - Wash contaminated clothing before reuse. P302 + P352 - IF ON SKIN: Wash with plenty of water. P333 + P313 - If skin irritation or rash occurs: Get medical advice or attention.
<b>Storage</b>	: P405 - Store locked up.
<b>Disposal</b>	: P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.
<b>Supplemental label elements</b>	: Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Prevent dust accumulation.
<b>Hazards not otherwise classified</b>	: None known.

## Section 3. Composition/information on ingredients

<b>Substance/mixture</b>	: Mixture
<b>Other means of identification</b>	: Not available.

Ingredient name	Other names	%	CAS number
Alanine, 3-(p-(bis(2-chloroethyl)amino)phenyl)-, monohydrochloride, L-	-	≥50 - ≤75	3223-07-2
2-Pyrrolidinone, 1-ethenyl-, homopolymer	Povidone	≥20 - ≤30	9003-39-8
Hydrochloric acid	-	≤0.1	7647-01-0

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

**There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.**



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## Section 4. First aid measures

### Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Skin contact** : Wash with plenty of soap and water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Get medical attention immediately. Call a poison center or physician. Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

### Most important symptoms/effects, acute and delayed

#### Potential acute health effects

- Eye contact** : Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the eyes.
- Inhalation** : Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the nose, throat and lungs.
- Skin contact** : May cause an allergic skin reaction.
- Ingestion** : Fatal if swallowed.

#### Over-exposure signs/symptoms

- Eye contact** : Adverse symptoms may include the following:  
irritation  
redness
- Inhalation** : Adverse symptoms may include the following:  
respiratory tract irritation  
coughing  
reduced fetal weight  
increase in fetal deaths  
skeletal malformations



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## Section 4. First aid measures

- Skin contact** : Adverse symptoms may include the following:  
irritation  
redness  
reduced fetal weight  
increase in fetal deaths  
skeletal malformations
- Ingestion** : Adverse symptoms may include the following:  
reduced fetal weight  
increase in fetal deaths  
skeletal malformations

### Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

See toxicological information (Section 11)

## Section 5. Fire-fighting measures

### Extinguishing media

- Suitable extinguishing media** : Use dry chemical powder.
- Unsuitable extinguishing media** : Do not use water jet.

- Specific hazards arising from the chemical** : May form explosible dust-air mixture if dispersed.

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:  
carbon dioxide  
carbon monoxide  
nitrogen oxides  
halogenated compounds  
Chlorine dioxide

- Special protective actions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.

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## Section 5. Fire-fighting measures

**Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

## Section 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

**For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Do not breathe dust. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

**For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

**Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

### Methods and materials for containment and cleaning up

**Small spill** : Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Place spilled material in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.

**Large spill** : Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Avoid creating dusty conditions and prevent wind dispersal. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

## Section 7. Handling and storage

### Precautions for safe handling

**Protective measures** : Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Avoid exposure - obtain special instructions before use. Avoid exposure during pregnancy. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not breathe dust. Do not ingest. Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Prevent dust accumulation. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Electrical equipment and lighting should be protected to appropriate standards to

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## Section 7. Handling and storage

prevent dust coming into contact with hot surfaces, sparks or other ignition sources. Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Empty containers retain product residue and can be hazardous. Do not reuse container.

### Advice on general occupational hygiene

: Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

### Conditions for safe storage, including any incompatibilities

: Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Eliminate all ignition sources. Separate from oxidizing materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

## Section 8. Exposure controls/personal protection

### Control parameters

#### Occupational exposure limits

Ingredient name	Exposure limits
Alanine, 3-(p-(bis(2-chloroethyl)amino)phenyl)-, monohydrochloride, L- 2-Pyrrolidinone, 1-ethenyl-, homopolymer Hydrochloric acid	None. None. <b>ACGIH TLV (United States, 1/2022).</b> C: 2 ppm <b>NIOSH REL (United States, 10/2020).</b> CEIL: 5 ppm CEIL: 7 mg/m <sup>3</sup> <b>OSHA PEL (United States, 5/2018).</b> CEIL: 5 ppm CEIL: 7 mg/m <sup>3</sup>

### Appropriate engineering controls

: Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.

### Environmental exposure controls

: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

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## Section 8. Exposure controls/personal protection

### Individual protection measures

- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields. If operating conditions cause high dust concentrations to be produced, use dust goggles.
- Skin protection**
- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

## Section 9. Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

### Appearance

- Physical state** : Solid. [Lyophilized/Powder.]
- Color** : White to off-white.
- Odor** : Not available.
- Odor threshold** : Not available.
- pH** : Not available.
- Melting point** : Not available.
- Boiling point, initial boiling point, and boiling range** : Not available.





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## Section 9. Physical and chemical properties

<b>Flash point</b>	: Not applicable.
<b>Evaporation rate</b>	: Not available.
<b>Flammability</b>	: Not available.
<b>Lower and upper explosion limit/flammability limit</b>	: Not applicable.
<b>Vapor pressure</b>	: Not available.
<b>Relative vapor density</b>	: Not applicable.
<b>Relative density</b>	: Not available.
<b>Density</b>	: Not available.
<b>Solubility(ies)</b>	: Not available.
<b>Partition coefficient: n-octanol/water</b>	: Not applicable.
<b>Auto-ignition temperature</b>	: Not applicable.
<b>Decomposition temperature</b>	: Not available.
<b>SADT</b>	: Not available.
<b>Viscosity</b>	: Not applicable.
<b>Flow time (ISO 2431)</b>	: Not available.
<b><u>Particle characteristics</u></b>	
<b>Median particle size</b>	: Not available.
<b><u>Other information</u></b>	
<b>Physical/chemical properties comments</b>	: No additional information.

## Section 10. Stability and reactivity

<b>Reactivity</b>	: No specific test data related to reactivity available for this product or its ingredients.
<b>Chemical stability</b>	: The product is stable.
<b>Possibility of hazardous reactions</b>	: Under normal conditions of storage and use, hazardous reactions will not occur. Under normal conditions of storage and use, hazardous polymerization will not occur.
<b>Conditions to avoid</b>	: Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Prevent dust accumulation. Extremes of temperature and direct sunlight.
<b>Incompatible materials</b>	: Reactive or incompatible with the following materials: oxidizing materials Reactive or incompatible with the following materials: acids and alkalis.

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## Section 10. Stability and reactivity

**Hazardous decomposition products** : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## Section 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Alanine, 3-(p-(bis (2-chloroethyl)amino)phenyl)-, monohydrochloride, L-	LD50 Oral	Rat	11200 µg/kg	-
2-Pyrrolidinone, 1-ethenyl-, homopolymer	LD50 Oral	Rat	100 g/kg	-

#### Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Hydrochloric acid	Eyes - Mild irritant	Rabbit	-	0.5 minutes 5 mg	-

#### Sensitization

Not available.

#### Mutagenicity

**Conclusion/Summary** : Not available.

#### Carcinogenicity

**Conclusion/Summary** : Not available.

#### Classification

Product/ingredient name	OSHA	IARC	NTP
2-Pyrrolidinone, 1-ethenyl-, homopolymer	-	3	-
Hydrochloric acid	-	3	-

#### Reproductive toxicity

**Conclusion/Summary** : Not available.

#### Teratogenicity

**Conclusion/Summary** : Not available.

#### Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
Hydrochloric acid	Category 3	-	Respiratory tract irritation

#### Specific target organ toxicity (repeated exposure)



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## Section 11. Toxicological information

Not available.

### Aspiration hazard

Not available.

**Information on the likely routes of exposure** : Routes of entry anticipated: Oral, Dermal, Inhalation, Eyes.

### Potential acute health effects

- Eye contact** : Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the eyes.
- Inhalation** : Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the nose, throat and lungs.
- Skin contact** : May cause an allergic skin reaction.
- Ingestion** : Fatal if swallowed.

### Symptoms related to the physical, chemical and toxicological characteristics

- Eye contact** : Adverse symptoms may include the following:  
irritation  
redness
- Inhalation** : Adverse symptoms may include the following:  
respiratory tract irritation  
coughing  
reduced fetal weight  
increase in fetal deaths  
skeletal malformations
- Skin contact** : Adverse symptoms may include the following:  
irritation  
redness  
reduced fetal weight  
increase in fetal deaths  
skeletal malformations
- Ingestion** : Adverse symptoms may include the following:  
reduced fetal weight  
increase in fetal deaths  
skeletal malformations

### Delayed and immediate effects and also chronic effects from short and long term exposure

#### Short term exposure

**Potential immediate effects** : Not available.

**Potential delayed effects** : Not available.

#### Long term exposure



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## Section 11. Toxicological information

**Potential immediate effects** : Not available.

**Potential delayed effects** : Not available.

### Potential chronic health effects

**General** : Repeated or prolonged inhalation of dust may lead to chronic respiratory irritation. Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.

**Carcinogenicity** : May cause cancer. Risk of cancer depends on duration and level of exposure.

**Mutagenicity** : May cause genetic defects.

**Reproductive toxicity** : Suspected of damaging fertility or the unborn child.

### Numerical measures of toxicity

#### Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/l)
Melphalan Hydrochloride for Injection	15.2	N/A	N/A	N/A	N/A
Alanine, 3-(p-(bis(2-chloroethyl)amino)phenyl)-, monohydrochloride, L-	11.2	N/A	N/A	N/A	N/A
2-Pyrrolidinone, 1-ethenyl-, homopolymer	100000	N/A	N/A	N/A	N/A

## Section 12. Ecological information

### Toxicity

Product/ingredient name	Result	Species	Exposure
Hydrochloric acid	Acute LC50 240000 µg/l Marine water	Crustaceans - <i>Carcinus maenas</i> - Adult	48 hours
	Acute LC50 282 ppm Fresh water	Fish - <i>Gambusia affinis</i> - Adult	96 hours

**Conclusion/Summary** : Not available.

### Persistence and degradability

Not available.

### Bioaccumulative potential

Not available.

### Mobility in soil

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## Section 12. Ecological information




**Soil/water partition coefficient (K<sub>oc</sub>)** : Not available.

**Other adverse effects** : No known significant effects or critical hazards.

## Section 13. Disposal considerations

**Disposal methods** : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

## Section 14. Transport information

	<b>DOT Classification</b>	<b>IMDG</b>	<b>IATA</b>
<b>UN number</b>	UN3249	UN3249	UN3249
<b>UN proper shipping name</b>	Medicine, solid, toxic, n.o.s.	MEDICINE, SOLID, TOXIC, N.O. S.	Medicine, solid, toxic, n.o.s.
<b>Transport hazard class(es)</b>	6.1 	6.1 	6.1 
<b>Packing group</b>	II	II	II
<b>Environmental hazards</b>	No.	No.	No.

### Additional information

**DOT Classification** : **Reportable quantity** 38.008 lbs / 17.256 kg. Package sizes shipped in quantities less than the product reportable quantity are not subject to the RQ (reportable quantity) transportation requirements.  
**Limited quantity** Yes.  
**Packaging instruction** Exceptions: 153. Non-bulk: 212. Bulk: 242.  
**Quantity limitation** Passenger aircraft/rail: 25 kg. Cargo aircraft: 100 kg.  
**Special provisions** T3, TP33



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## Section 14. Transport information

- IMDG** : **Emergency schedules** F-A, S-A  
**Special provisions** 221
- IATA** : **Quantity limitation** Passenger and Cargo Aircraft: 25 kg. Packaging instructions: 669.  
Cargo Aircraft Only: 100 kg. Packaging instructions: 676. Limited Quantities - Passenger Aircraft: 1 kg. Packaging instructions: Y644.  
**Special provisions** A3
- Special precautions for user** : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**Transport in bulk according to IMO instruments** : Not available.

## Section 15. Regulatory information

**U.S. Federal regulations** : **TSCA 8(a) CDR Exempt/Partial exemption:** Not determined  
**United States inventory (TSCA 8b):** Not determined.  
**Clean Water Act (CWA) 311:** Hydrochloric acid

**Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs)** : Listed

**Clean Air Act Section 602 Class I Substances** : Not listed

**Clean Air Act Section 602 Class II Substances** : Not listed

**DEA List I Chemicals (Precursor Chemicals)** : Not listed

**DEA List II Chemicals (Essential Chemicals)** : Not listed

**SARA 302/304**

**Composition/information on ingredients**

Name	%	EHS	SARA 302 TPQ		SARA 304 RQ	
			(lbs)	(gallons)	(lbs)	(gallons)
Hydrochloric acid	≤0.1	Yes.	500	50.6	5000	506.5

**SARA 304 RQ** : 16666666.7 lbs / 7566666.7 kg

**SARA 311/312**



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## Section 15. Regulatory information

**Classification** : COMBUSTIBLE DUSTS  
ACUTE TOXICITY (oral) - Category 2  
SKIN SENSITIZATION - Category 1  
GERM CELL MUTAGENICITY - Category 1  
CARCINOGENICITY - Category 1A  
TOXIC TO REPRODUCTION - Category 2

### Composition/information on ingredients

Name	%	Classification
Alanine, 3-(p-(bis(2-chloroethyl) amino)phenyl)-, monohydrochloride, L-	≥50 - ≤75	ACUTE TOXICITY (oral) - Category 2 SKIN SENSITIZATION - Category 1 GERM CELL MUTAGENICITY - Category 1B CARCINOGENICITY - Category 1A TOXIC TO REPRODUCTION - Category 2
Hydrochloric acid	≤0.1	SKIN CORROSION - Category 1B SERIOUS EYE DAMAGE - Category 1 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3 HNOC - Corrosive to digestive tract

### SARA 313

Not applicable.

### State regulations

**Massachusetts** : None of the components are listed.  
**New York** : None of the components are listed.  
**New Jersey** : None of the components are listed.  
**Pennsylvania** : None of the components are listed.

### California Prop. 65

This product does not require a Safe Harbor warning under California Prop. 65.

### International regulations

#### Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

#### Montreal Protocol

Not listed.

#### Stockholm Convention on Persistent Organic Pollutants

Not listed.

#### Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

#### UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

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## Section 16. Other information

### Hazardous Material Information System (U.S.A.)

Health	*	3
Flammability		3
Physical hazards		0

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings and the associated label are not required on SDSs or products leaving a facility under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered trademark and service mark of the American Coatings Association, Inc.

The customer is responsible for determining the PPE code for this material. For more information on HMIS® Personal Protective Equipment (PPE) codes, consult the HMIS® Implementation Manual.

### National Fire Protection Association (U.S.A.)



### Procedure used to derive the classification

Classification	Justification
COMBUSTIBLE DUSTS ACUTE TOXICITY (oral) - Category 2 SKIN SENSITIZATION - Category 1 GERM CELL MUTAGENICITY - Category 1 CARCINOGENICITY - Category 1A TOXIC TO REPRODUCTION - Category 2	On basis of test data Calculation method Calculation method Calculation method Calculation method Calculation method

### History

<b>Date of issue/Date of revision</b>	: 06/19/2023
<b>Date of previous issue</b>	: 09/15/2022
<b>Version</b>	: 4.0
<b>Prepared by</b>	: Sphera Solutions
<b>Key to abbreviations</b>	: ATE = Acute Toxicity Estimate AMP = Acceptable maximum peak above the acceptable ceiling concentration for an 8-hr shift BCF = Bioconcentration Factor GHS = Globally Harmonized System of Classification and Labelling of Chemicals IATA = International Air Transport Association IBC = Intermediate Bulk Container IMDG = International Maritime Dangerous Goods LogPow = logarithm of the octanol/water partition coefficient MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)





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## Section 16. Other information

N/A = Not available

UN = United Nations

### References

: HCS (U.S.A.)- Hazard Communication Standard  
International transport regulations

Indicates information that has changed from previously issued version.

### Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

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## Section 1. Identification

**GHS product identifier** : Sterile Diluent for Melphalan Hydrochloride for Injection (Meitheal)

**Other means of identification** : Not available.

**Product type** : Liquid.

### Relevant identified uses of the substance or mixture and uses advised against

**Product use** : Pharmaceuticals. (For intended use only.)  
Observe technical data sheet/instructions for use.  
Specific Treatments: Diluent.

**Area of application** : Professional applications.

**Supplier's details** : Meitheal Pharmaceuticals, Inc.  
8700 W. Bryn Mawr, Suite 600S  
Chicago, IL 60631

Telephone: 224-443-4617  
www.meithealpharma.com

**e-mail address of person responsible for this SDS** : info@meithealpharma.com

**Emergency telephone number (with hours of operation)** : 844-824-8426 (Monday - Friday, 08:00 - 18:00 CST)

## Section 2. Hazards identification

**OSHA/HCS status** : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

**Classification of the substance or mixture** : H319 EYE IRRITATION - Category 2A  
H373 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2

### GHS label elements

**Hazard pictograms** :



**Signal word** : Warning

**Hazard statements** : H319 - Causes serious eye irritation.  
H373 - May cause damage to organs through prolonged or repeated exposure. (liver)



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## Section 2. Hazards identification

### Precautionary statements

#### Prevention

- : P280 - Wear eye or face protection.
- : P260 - Do not breathe vapor.
- : P264 - Wash thoroughly after handling.

#### Response

- : P314 - Get medical advice or attention if you feel unwell.
- : P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- : P337 + P313 - If eye irritation persists: Get medical advice or attention.

#### Storage

- : Not applicable.

#### Disposal

- : P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.

#### Supplemental label elements

- : Avoid contact with skin and clothing. Wash thoroughly after handling.

#### Hazards not otherwise classified

- : Prolonged or repeated contact may dry skin and cause irritation.

## Section 3. Composition/information on ingredients

#### Substance/mixture

- : Mixture

#### Other means of identification

- : Not available.

<b>Ingredient name</b>	<b>Other names</b>	<b>%</b>	<b>CAS number</b>
propane-1,2-diol	Propylene Glycol	≥50 - ≤75	57-55-6
water	-	≥25 - ≤50	7732-18-5
Ethanol	Ethyl alcohol	≤5	64-17-5
trisodium citrate	-	≤3	68-04-2

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

## Section 4. First aid measures

### Description of necessary first aid measures

#### Eye contact

- : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.



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## Section 4. First aid measures

- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention following exposure or if feeling unwell. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Skin contact** : Wash skin thoroughly with soap and water or use recognized skin cleanser. Remove contaminated clothing and shoes. Continue to rinse for at least 10 minutes. Get medical attention following exposure or if feeling unwell. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention following exposure or if feeling unwell. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

### Most important symptoms/effects, acute and delayed

#### Potential acute health effects

- Eye contact** : Causes serious eye irritation.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : Defatting to the skin. May cause skin dryness and irritation.
- Ingestion** : No known significant effects or critical hazards.

#### Over-exposure signs/symptoms

- Eye contact** : Adverse symptoms may include the following:  
pain or irritation  
watering  
redness
- Inhalation** : No specific data.
- Skin contact** : Adverse symptoms may include the following:  
irritation  
dryness  
cracking
- Ingestion** : No specific data.

### Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

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## Section 4. First aid measures

- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

See toxicological information (Section 11)

## Section 5. Fire-fighting measures

### Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : Do not use water jet.

### Specific hazards arising from the chemical

- Hazardous thermal decomposition products** : In a fire or if heated, a pressure increase will occur and the container may burst.
- Decomposition products may include the following materials:  
carbon dioxide  
carbon monoxide  
nitrogen oxides  
metal oxide/oxides

### Special protective actions for fire-fighters

### Special protective equipment for fire-fighters

- : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
- : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

## Section 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
- For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

### Environmental precautions

- : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

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## Section 6. Accidental release measures

### Methods and materials for containment and cleaning up

- Small spill** : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
- Large spill** : Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

## Section 7. Handling and storage

### Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Do not breathe vapor or mist. Do not ingest. Avoid contact with eyes, skin and clothing. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

## Section 8. Exposure controls/personal protection

### Control parameters

#### Occupational exposure limits





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## Section 8. Exposure controls/personal protection

<b>Ingredient name</b>	<b>Exposure limits</b>
propane-1,2-diol	<b>OARS WEEL (United States, 4/2022).</b> TWA: 10 mg/m <sup>3</sup> 8 hours.
water	None.
Ethanol	<b>ACGIH TLV (United States, 1/2023).</b> STEL: 1000 ppm 15 minutes.
	<b>NIOSH REL (United States, 10/2020).</b> TWA: 1000 ppm 10 hours. TWA: 1900 mg/m <sup>3</sup> 10 hours.
	<b>OSHA PEL (United States, 5/2018).</b> TWA: 1000 ppm 8 hours. TWA: 1900 mg/m <sup>3</sup> 8 hours.
	<b>CAL OSHA PEL (United States, 5/2018).</b> TWA: 1900 mg/m <sup>3</sup> 8 hours. TWA: 1000 ppm 8 hours.
trisodium citrate	None.

### Appropriate engineering controls

- : If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

### Environmental exposure controls

- : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

### Individual protection measures

#### Hygiene measures

- : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

#### Eye/face protection

- : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.

#### Skin protection

##### Hand protection

- : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.



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## Section 8. Exposure controls/personal protection

- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

## Section 9. Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

### Appearance

- Physical state** : Liquid. [Clear solution.]
- Color** : Colorless.
- Odor** : Not available.
- Odor threshold** : Not available.
- pH** : 8 to 9.5
- Melting point** : Not available.
- Boiling point, initial boiling point, and boiling range** : Not available.
- Flash point** :

Ingredient name	Closed cup			Open cup		
	°C	°F	Method	°C	°F	Method
propane-1,2-diol	99	210.2				

- Evaporation rate** : Not available.
- Flammability** : Not available.
- Lower and upper explosion limit/flammability limit** : Not available.
- Vapor pressure** :

Ingredient name	Vapor Pressure at 20°C			Vapor pressure at 50°C		
	mm Hg	kPa	Method	mm Hg	kPa	Method
water	17.5	2.3		92.258	12.3	

- Relative vapor density** : Not available.
- Relative density** : Not available.
- Density** : 1.009 to 1.071 g/cm<sup>3</sup> [20°C (68°F)]





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## Section 9. Physical and chemical properties

<b>Solubility(ies)</b>	<b>Media</b>	<b>Result</b>
	water	Soluble

**Miscible with water** : Yes.

**Partition coefficient: n-octanol/water** : Not applicable.

<b>Auto-ignition temperature</b>	<b>Ingredient name</b>	<b>°C</b>	<b>°F</b>	<b>Method</b>
	propane-1,2-diol	371	699.8	

**Decomposition temperature** : Not available.

**SADT** : Not available.

**Viscosity** : Not available.

**Flow time (ISO 2431)** : Not available.

### Particle characteristics

**Median particle size** : Not applicable.

### Other information

**Physical/chemical properties comments** : No additional information.

## Section 10. Stability and reactivity

**Reactivity** : No specific test data related to reactivity available for this product or its ingredients.

**Chemical stability** : The product is stable.

**Possibility of hazardous reactions** : Under normal conditions of storage and use, hazardous reactions will not occur.  
Under normal conditions of storage and use, hazardous polymerization will not occur.

**Conditions to avoid** : No specific data.

**Incompatible materials** : Reactive or incompatible with the following materials: oxidizing materials.

**Hazardous decomposition products** : Under normal conditions of storage and use, hazardous decomposition products should not be produced.



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## Section 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
propane-1,2-diol	LD50 Dermal	Rabbit	20800 mg/kg	-
	LD50 Oral	Rat	20 g/kg	-
Ethanol	LC50 Inhalation Vapor	Rat	124700 mg/m <sup>3</sup>	4 hours
	LD50 Oral	Rat	7 g/kg	-

#### Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
propane-1,2-diol	Eyes - Mild irritant	Rabbit	-	100 mg	-
	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
Ethanol	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
	Eyes - Moderate irritant	Rabbit	-	0.066666667 minutes 100 mg	-
	Eyes - Moderate irritant	Rabbit	-	100 uL	-
	Eyes - Severe irritant	Rabbit	-	500 mg	-

#### Sensitization

Not available.

#### Mutagenicity

**Conclusion/Summary** : Not available.

#### Carcinogenicity

**Conclusion/Summary** : Not available.

#### Reproductive toxicity

**Conclusion/Summary** : Not available.

#### Teratogenicity

**Conclusion/Summary** : Not available.

#### Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
Ethanol	Category 3	-	Narcotic effects

#### Specific target organ toxicity (repeated exposure)

Name	Category	Route of exposure	Target organs
Ethanol	Category 2	-	liver

#### Aspiration hazard

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## Section 11. Toxicological information

Not available.

**Information on the likely routes of exposure** : Routes of entry anticipated: Oral, Dermal, Inhalation, Eyes.

### Potential acute health effects

- Eye contact** : Causes serious eye irritation.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : Defatting to the skin. May cause skin dryness and irritation.
- Ingestion** : No known significant effects or critical hazards.

### Symptoms related to the physical, chemical and toxicological characteristics

- Eye contact** : Adverse symptoms may include the following:
  - pain or irritation
  - watering
  - redness
- Inhalation** : No specific data.
- Skin contact** : Adverse symptoms may include the following:
  - irritation
  - dryness
  - cracking
- Ingestion** : No specific data.

### Delayed and immediate effects and also chronic effects from short and long term exposure

#### Short term exposure

- Potential immediate effects** : Not available.
- Potential delayed effects** : Not available.

#### Long term exposure

- Potential immediate effects** : Not available.
- Potential delayed effects** : Not available.

### Potential chronic health effects

- General** : May cause damage to organs through prolonged or repeated exposure. Prolonged or repeated contact can defat the skin and lead to irritation, cracking and/or dermatitis.
- Carcinogenicity** : No known significant effects or critical hazards.
- Mutagenicity** : No known significant effects or critical hazards.
- Reproductive toxicity** : No known significant effects or critical hazards.

### Numerical measures of toxicity

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## Section 11. Toxicological information

### Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/l)
propane-1,2-diol	20000	20800	N/A	N/A	N/A
Ethanol	7000	N/A	N/A	124.7	N/A

## Section 12. Ecological information

### Toxicity

Product/ingredient name	Result	Species	Exposure
propane-1,2-diol	Acute EC50 24200 mg/l Fresh water	Algae	72 hours
	Acute EC50 >110 ppm Fresh water	Daphnia - <i>Daphnia magna</i>	48 hours
	Acute LC50 1020000 µg/l Fresh water	Crustaceans - <i>Ceriodaphnia dubia</i>	48 hours
	Acute LC50 710000 µg/l Fresh water	Fish - <i>Pimephales promelas</i>	96 hours
Ethanol	Acute EC50 17.921 mg/l Marine water	Algae - <i>Ulva pertusa</i>	96 hours
	Acute EC50 2 mg/l Fresh water	Daphnia - <i>Daphnia magna</i>	48 hours
	Acute LC50 25500 µg/l Marine water	Crustaceans - <i>Artemia franciscana</i> - Larvae	48 hours
	Acute LC50 42000 µg/l Fresh water	Fish - <i>Oncorhynchus mykiss</i>	4 days
	Chronic NOEC 4.995 mg/l Marine water	Algae - <i>Ulva pertusa</i>	96 hours
	Chronic NOEC 100 µl/L Fresh water	Daphnia - <i>Daphnia magna</i> - Neonate	21 days
	Chronic NOEC 0.375 µl/L Fresh water	Fish - <i>Gambusia holbrooki</i> - Larvae	12 weeks
trisodium citrate	Acute EC50 735.54 mg/l Fresh water	Crustaceans - <i>Ceriodaphnia dubia</i> - Neonate	48 hours

**Conclusion/Summary** : Not available.

### Persistence and degradability

Product/ingredient name	Test	Result	Dose	Inoculum
propane-1,2-diol	OECD 301F Ready Biodegradability - Manometric Respirometry Test	98.3 % - Readily - 28 days	100 mg/l DOC	-



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## Section 12. Ecological information

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
propane-1,2-diol	-	-	Readily
Ethanol	-	-	Readily
trisodium citrate	-	-	Readily

### Bioaccumulative potential

Product/ingredient name	LogP <sub>ow</sub>	BCF	Potential
propane-1,2-diol	-1.07	-	Low
water	-1.38	-	Low
Ethanol	-0.35	-	Low

### Mobility in soil

**Soil/water partition coefficient (K<sub>oc</sub>)** : Not available.

**Other adverse effects** : No known significant effects or critical hazards.

## Section 13. Disposal considerations

**Disposal methods** : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

## Section 14. Transport information

	DOT Classification	IMDG	IATA
<b>UN number</b>	Not regulated.	Not regulated.	Not regulated.
<b>UN proper shipping name</b>	-	-	-

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## Section 14. Transport information

<b>Transport hazard class(es)</b>	-	-	-
<b>Packing group</b>	-	-	-
<b>Environmental hazards</b>	No.	No.	No.

### Additional information

**Special precautions for user** : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**Transport in bulk according to IMO instruments** : Not available.

## Section 15. Regulatory information

**U.S. Federal regulations** : **TSCA 8(a) CDR Exempt/Partial exemption:** Not determined  
**United States inventory (TSCA 8b):** All components are active or exempted.

**Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs)** : Not listed

**Clean Air Act Section 602 Class I Substances** : Not listed

**Clean Air Act Section 602 Class II Substances** : Not listed

**DEA List I Chemicals (Precursor Chemicals)** : Not listed

**DEA List II Chemicals (Essential Chemicals)** : Not listed

### SARA 302/304

#### Composition/information on ingredients

No products were found.

**SARA 304 RQ** : Not applicable.

### SARA 311/312

**Classification** : EYE IRRITATION - Category 2A  
SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2  
HNOC - Defatting irritant



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## Section 15. Regulatory information

### Composition/information on ingredients

Name	%	Classification
propane-1,2-diol Ethanol	≥50 - ≤75 ≤5	EYE IRRITATION - Category 2B FLAMMABLE LIQUIDS - Category 2 EYE IRRITATION - Category 2A SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Narcotic effects) - Category 3 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2 HNOC - Defatting irritant COMBUSTIBLE DUSTS
trisodium citrate	≤3	

### SARA 313

Not applicable.

### State regulations

#### Massachusetts

: The following components are listed: ETHYL ALCOHOL

#### New York

: None of the components are listed.

#### New Jersey

: The following components are listed: PROPYLENE GLYCOL; ETHYL ALCOHOL

#### Pennsylvania

: The following components are listed: 1,2-PROPANEDIOL; ETHANOL

### California Prop. 65

This product does not require a Safe Harbor warning under California Prop. 65.

### International regulations

#### Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

#### Montreal Protocol

Not listed.

#### Stockholm Convention on Persistent Organic Pollutants

Not listed.

#### Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

#### UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

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## Section 16. Other information

### Hazardous Material Information System (U.S.A.)

Health	*	2
Flammability		0
Physical hazards		0

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings and the associated label are not required on SDSs or products leaving a facility under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered trademark and service mark of the American Coatings Association, Inc.

The customer is responsible for determining the PPE code for this material. For more information on HMIS® Personal Protective Equipment (PPE) codes, consult the HMIS® Implementation Manual.

### National Fire Protection Association (U.S.A.)



### Procedure used to derive the classification

Classification	Justification
EYE IRRITATION - Category 2A	Calculation method
SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2	Calculation method

### History

<b>Date of issue/Date of revision</b>	: 03/01/2024
<b>Date of previous issue</b>	: 03/03/2022
<b>Version</b>	: 2.0
<b>Prepared by</b>	: Sphera Solutions
<b>Key to abbreviations</b>	: ATE = Acute Toxicity Estimate AMP = Acceptable maximum peak above the acceptable ceiling concentration for an 8-hr shift BCF = Bioconcentration Factor GHS = Globally Harmonized System of Classification and Labelling of Chemicals IATA = International Air Transport Association IBC = Intermediate Bulk Container IMDG = International Maritime Dangerous Goods LogPow = logarithm of the octanol/water partition coefficient MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution) N/A = Not available UN = United Nations





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## Section 16. Other information

**References** : HCS (U.S.A.)- Hazard Communication Standard  
International transport regulations

Indicates information that has changed from previously issued version.

### Notice to reader

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Effective