

Melphalan Hydrochloride for Injection Safety Data Sheet

Sterile Diluent for Melphalan Hydrochloride for Injection Safety Data Sheet



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

SDS Title: Melphalan Hydrochloride for Injection (Meitheal) Safety Data Sheet	SDS Number: SDS-000060	Page Number: Page 1 of 17
Function: Regulatory Affairs	Effective Date: February 06, 2025	Version number: 4.0

Section 1. Identification

GHS product identifier : Melphalan Hydrochloride for Injection (Meitheal)

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
H315	ACUTE TOXICITY (oral) - Category 2
H319	SKIN IRRITATION - Category 2
H317	EYE IRRITATION - Category 2A
H340	SKIN SENSITIZATION - Category 1
H350	GERM CELL MUTAGENICITY - Category 1
H361	CARCINOGENICITY - Category 1A
H335	TOXIC TO REPRODUCTION - Category 2
	SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3

Percentage of the mixture consisting of ingredient(s) of unknown acute oral toxicity: 10%

GHS label elements

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Section 2. Hazards identification

Hazard pictograms



Signal word

: Danger

Hazard statements

: H300 - Fatal if swallowed.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.
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.

Precautionary statements

Prevention

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

Response

: P308 + P313 - IF exposed or concerned: Get medical advice or attention.
P304 + P340, P312 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor if you feel unwell.
P301 + P310, P330 - IF SWALLOWED: Immediately call a POISON CENTER or doctor. Rinse mouth.
P302 + P352 - IF ON SKIN: Wash with plenty of water.
P333 + P313 - If skin irritation or rash occurs: Get medical advice or attention.
P362 + P364 - Take off contaminated clothing and wash it before reuse.
P363 - Wash contaminated clothing before reuse.
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

: P405 - Store locked up.
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed.

Disposal

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

Supplemental label elements

: Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Prevent dust accumulation.

Hazards not otherwise classified

: None known.

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Section 3. Composition/information on ingredients

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

Ingredient name	Other names	%	Identifiers
Alanine, 3-(p-(bis(2-chloroethyl)amino)phenyl)-, monohydrochloride, L-	-	≥50 - ≤75	CAS: 3223-07-2
2-Pyrrolidinone, 1-ethenyl-, homopolymer	Povidone	≥20 - ≤30	CAS: 9003-39-8
Hydrochloric acid	-	≤10	CAS: 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.

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 it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. 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 necessary, call a poison center or physician. 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

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Section 4. First aid measures

Potential acute health effects

- Eye contact** : Causes serious eye irritation.
- Inhalation** : May cause respiratory irritation.
- Skin contact** : Causes skin irritation. May cause an allergic skin reaction.
- Ingestion** : Fatal if swallowed.

Over-exposure signs/symptoms

- Eye contact** : Adverse symptoms may include the following:
 - pain or irritation
 - watering
 - 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

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)



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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
Emits toxic fumes when heated to decomposition.

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.

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.

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Section 6. Accidental release measures

- 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.

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 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

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Section 8. Exposure controls/personal protection

Ingredient name	Exposure limits
Alanine, 3-(p-(bis(2-chloroethyl)amino)phenyl)-, monohydrochloride, L- 2-Pyrrolidinone, 1-ethenyl-, homopolymer Hydrochloric acid	None. None. ACGIH TLV (United States, 1/2024) A4. C: 2 ppm. NIOSH REL (United States, 10/2020) CEIL: 5 ppm. CEIL: 7 mg/m ³ . OSHA PEL (United States, 5/2018) CEIL: 5 ppm. CEIL: 7 mg/m ³ . CAL OSHA PEL (United States, 5/2018) C: 2 ppm. TWA 8 hours: 0.45 mg/m ³ . TWA 8 hours: 0.3 ppm.

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.

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: chemical splash goggles. If operating conditions cause high dust concentrations to be produced, use dust goggles.

Skin protection



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Section 8. Exposure controls/personal 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 or Cake.]
- Color** : White to pale yellow.
- Odor** : Not available.
- Odor threshold** : Not available.
- pH** : 6.3 to 7.0 [Conc. (% w/w): 0.5%] [Reconstitution solution]
- Melting point** : 180°C (356°F)
- Boiling point or initial boiling point and boiling range** : Not available.
- Flash point** : Not applicable.
- Evaporation rate** : Not available.
- Flammability** : Not available.
- Lower and upper explosion limit/flammability limit** : Not applicable.
- Vapor pressure** : Not available.
- Relative vapor density** : Not applicable.
- Relative density** : Not available.
- Density** : Not available.
- Solubility(ies)** :

Media	Result
water	Very slightly soluble



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Section 9. Physical and chemical properties

Partition coefficient: n-octanol/water	: Not applicable.
Auto-ignition temperature	: Not applicable.
Decomposition temperature	: Not available.
SADT	: Not available.
Viscosity	: Dynamic (room temperature): Not available. Kinematic (room temperature): Not available. Kinematic (40°C (104°F)): Not available.
Flow time (ISO 2431)	: Not available.
<u>Particle characteristics</u>	
Median particle size	: Not available.
<u>Other information</u>	
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	: 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.
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
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)

Not available.

Aspiration hazard

Not available.



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Section 11. Toxicological information

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** : May cause respiratory irritation.
- Skin contact** : Causes skin irritation. 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:
pain or irritation
watering
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

- 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.

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Section 11. Toxicological information

- 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 (Meitheal)	17.0	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 240 mg/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

Product/ingredient name	LogP _{ow}	BCF	Potential
2-Pyrrolidinone, 1-ethenyl-, homopolymer	0.37	-	Low

Mobility in soil

- Soil/Water partition coefficient** : Not available.

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

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

Additional information

DOT Classification : **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

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.



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Section 14. Transport information

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 (CAA) 112 regulated toxic substances: 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	≤10	Yes.	500	-	5000	-

SARA 304 RQ : 50000 lbs / 22700 kg

SARA 311/312

Classification : COMBUSTIBLE DUSTS
ACUTE TOXICITY (oral) - Category 2
SKIN IRRITATION - Category 2
EYE IRRITATION - Category 2A
SKIN SENSITIZATION - Category 1
GERM CELL MUTAGENICITY - Category 1
CARCINOGENICITY - Category 1A
TOXIC TO REPRODUCTION - Category 2
SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3

Composition/information on ingredients



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Section 15. Regulatory information

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	≤10	CORROSIVE TO METALS - Category 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

	Product name	CAS number	%
Form R - Reporting requirements	Hydrochloric acid	7647-01-0	≤10
Supplier notification	Hydrochloric acid	7647-01-0	≤10

SARA 313 notifications must not be detached from the SDS and any copying and redistribution of the SDS shall include copying and redistribution of the notice attached to copies of the SDS subsequently redistributed.

State regulations

- Massachusetts** : The following components are listed: HYDROGEN CHLORIDE
New York : The following components are listed: Hydrochloric acid
New Jersey : The following components are listed: HYDROGEN CHLORIDE
Pennsylvania : The following components are listed: HYDROCHLORIC ACID

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 IRRITATION - Category 2 EYE IRRITATION - Category 2A SKIN SENSITIZATION - Category 1 GERM CELL MUTAGENICITY - Category 1 CARCINOGENICITY - Category 1A TOXIC TO REPRODUCTION - Category 2 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3	On basis of test data Calculation method Calculation method Calculation method Calculation method Calculation method Calculation method Calculation method Calculation method

History

Date of issue/Date of revision	: 02/06/2025
Date of previous issue	: 03/13/2023
Version	: 4.0
Prepared by	: Sphera Solutions
Key to abbreviations	: - 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



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Section 16. Other information

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

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.
- Hazards identified when used** : No known significant effects or critical hazards.

Section 3. Composition/information on ingredients

- Substance/mixture** : Mixture
- Other means of identification** : Not available.

Ingredient name	Synonyms	%	Identifiers
propane-1,2-diol	Propylene Glycol	≥45 - ≤70	CAS: 57-55-6
Water	-	≥15 - ≤40	CAS: 7732-18-5
Ethanol	Ethyl alcohol	≥1 - ≤5	CAS: 64-17-5
trisodium citrate	-	≥1 - ≤5	CAS: 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 : In a fire or if heated, a pressure increase will occur and the container may burst.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
metal oxide/oxides

- 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.
- 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. 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. Absorb with an inert 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. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. 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.

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

Ingredient name	Exposure limits
propane-1,2-diol	OARS WEEL (United States, 9/2024) TWA 8 hours: 10 mg/m ³ .
Water	None.
Ethanol	ACGIH TLV (United States, 1/2025) A3. STEL 15 minutes: 1000 ppm.
	NIOSH REL (United States, 10/2020) TWA 10 hours: 1000 ppm. TWA 10 hours: 1900 mg/m ³ .
	OSHA PEL (United States, 5/2018) TWA 8 hours: 1000 ppm. TWA 8 hours: 1900 mg/m ³ .
	CAL OSHA PEL (United States, 1/2025) TWA 8 hours: 1900 mg/m ³ . TWA 8 hours: 1000 ppm.
trisodium citrate	None.

Biological exposure indices

None known.

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



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Section 8. Exposure controls/personal 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** : Liquid. [Clear solution.]
- Color** : Colorless.
- Odor** : Not available.
- Odor threshold** : Not available.
- pH** : 8 to 9.5
- Melting point** : Not available.
- Boiling point or 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** :



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Section 9. Physical and chemical properties

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/cm³ [20°C (68°F)]

Solubility(ies) :

Media	Result
water	Soluble

Miscible with water : Yes.

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

Auto-ignition temperature :

Ingredient name	°C	°F	Method
propane-1,2-diol	371	699.8	

Decomposition temperature : Not available.

SADT : Not available.

Viscosity : Dynamic (room temperature): Not available.
Kinematic (room temperature): Not available.
Kinematic (40°C (104°F)): 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.



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Section 10. Stability and reactivity

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.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name

propane-1,2-diol

Result

Rat - Oral - LD50

20 g/kg

Rabbit - Dermal - LD50

20800 mg/kg

Ethanol

Rat - Oral - LD50

7 g/kg

Rat - Inhalation - LC50 Vapor

124700 mg/m³ [4 hours]

Toxic effects: Behavioral - Ataxia
Behavioral - Tetany Lung, Thorax, or
Respiration - Respiratory depression

Conclusion/Summary [Product]

: Not available.

Skin corrosion/irritation

Conclusion/Summary [Product]

: Not available.

Serious eye damage/eye irritation

Product/ingredient name

propane-1,2-diol

Result

Rabbit - Eyes - Mild irritant

Duration of treatment/exposure: 24
hours

Amount/concentration applied: 500 mg

Rabbit - Eyes - Mild irritant

Amount/concentration applied: 100 mg

Ethanol

Rabbit - Eyes - Mild irritant

Duration of treatment/exposure: 24
hours

Amount/concentration applied: 500 mg

Rabbit - Eyes - Moderate irritant

Duration of treatment/exposure:

0.066666667 minutes

Amount/concentration applied: 100 mg



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Section 11. Toxicological information

Rabbit - Eyes - Moderate irritant

Amount/concentration applied: 100 uL

Rabbit - Eyes - Severe irritant

Amount/concentration applied: 500 mg

Rabbit - Eyes - Mild irritant

Duration of treatment/exposure: 1 hours

Amount/concentration applied: 50 pph

Conclusion/Summary [Product] : Not available.

Respiratory corrosion/irritation

Conclusion/Summary [Product] : Not available.

Respiratory or skin sensitization

Skin

Conclusion/Summary [Product] : Not available.

Respiratory

Conclusion/Summary [Product] : Not available.

Germ cell mutagenicity

Conclusion/Summary [Product] : Not available.

Carcinogenicity

Conclusion/Summary [Product] : Not available.

Reproductive toxicity

Conclusion/Summary [Product] : Not available.

Specific target organ toxicity (single exposure)

Product/ingredient name

Ethanol

Result

SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE)
(Narcotic effects) - Category 3



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Section 11. Toxicological information

Specific target organ toxicity (repeated exposure)

Product/ingredient name

Ethanol

Result

SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE)
(liver) - Category 2

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** : 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.



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Section 11. Toxicological information

Potential chronic health effects

Conclusion/Summary [Product] : Not available.

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

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	
propane-1,2-diol	Acute - LC50 - Fresh water Crustaceans - Water flea - <i>Ceriodaphnia dubia</i> Age: <24 hours 1020 mg/l [48 hours]	<u>Effect</u> : Mortality
	Acute - LC50 - Fresh water Fish - Fathead minnow - <i>Pimephales promelas</i> Age: ≤7 days 710 mg/l [96 hours]	<u>Effect</u> : Mortality
	Acute - EC50 - Fresh water Algae 24200 mg/l [72 hours]	OECD [Alga, Growth Inhibition Test]
Ethanol	Acute - LC50 - Fresh water Fish - Rainbow trout, donaldson trout - <i>Oncorhynchus mykiss</i> 42 mg/l [4 days]	<u>Effect</u> : Mortality
	Acute - EC50 - Marine water Algae - Green algae - <i>Ulva pertusa</i>	<u>Effect</u> : Reproduction

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Section 12. Ecological information

17.921 mg/l [96 hours]

Chronic - NOEC - Marine water
Effect: Reproduction

Algae - Green algae - *Ulva pertusa*

4.995 mg/l [96 hours]

Chronic - NOEC - Fresh water
Effect: Mortality

Daphnia - Water flea - *Daphnia magna* -
Neonate

Age: <24 hours

100 µl/l [21 days]

Chronic - NOEC - Fresh water
Effect: Morphology

Fish - Eastern mosquitofish - *Gambusia
holbrooki* - Larvae

Age: 3 days

0.375 µl/l [12 weeks]

Acute - EC50 - Fresh water
Effect: Intoxication

Daphnia - Water flea - *Daphnia magna*

2 mg/l [48 hours]

Acute - EC50 - Fresh water
Effect: Intoxication

Crustaceans - Water flea -
Ceriodaphnia dubia - Neonate

Age: <24 hours

735.54 mg/l [48 hours]

trisodium citrate

Conclusion/Summary [Product]

: Not available.

Persistence and degradability

Product/ingredient name

Result

propane-1,2-diol

100 mg/l - DOC

98.3% [28 days] - Readily

OECD [Ready Biodegradability -
Manometric Respirometry Test]

Conclusion/Summary [Product]

: Not available.

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

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
propane-1,2-diol	-1.07	-	Low
Water	-1.38	-	Low
Ethanol	-0.35	-	Low



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Section 12. Ecological information

Mobility in soil

Soil/Water partition coefficient : 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
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	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.



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Safety Data Sheet

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Section 14. Transport information

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.

TSCA 12(b) - Chemical export notification

Not applicable.

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

Composition/information on ingredients

Name	%	Classification
propane-1,2-diol Ethanol	≥45 - ≤70 ≥1 - ≤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
trisodium citrate	≥1 - ≤5	COMBUSTIBLE DUSTS

SARA 313

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Section 15. Regulatory information

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
<u>California Prop. 65</u>	

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.

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.)



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Section 16. Other information



Procedure used to derive the classification

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

History

Date of issue/Date of revision	: 02/27/2026
Date of previous issue	: 03/01/2024
Version	: 3.0
Prepared by	: Sphera Solutions
Key to abbreviations	: ATE = Acute Toxicity Estimate 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 IMO = International Maritime Organization 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 SGG = Segregation Group TDG = Transportation of Dangerous Goods UN = United Nations
References	: HCS (U.S.A.)- Hazard Communication Standard International transport regulations

Indicates information that has changed from previously issued version.

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