

Carmustine for Injection

Safety Data Sheet

Dehydrated Alcohol Injection

Safety Data Sheet

SDS Title: Carmustine for Injection Safety Data Sheet	SDS Number: SDS-000036	Page Number: Page 1 of 15
Function: Regulatory Affairs	Effective Date: November 08, 2023	Version number: 4.0

Section 1. Identification

GHS product identifier : Carmustine for Injection

Other means of identification : 1,3-Bis-(2-chloroethyl)-1-nitrosourea / N,N'-Bis-(2-chloroethyl)-N-nitroso-urea

Product type : Solid.

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 ACUTE TOXICITY (oral) - Category 2
H350 CARCINOGENICITY - Category 1B
H360 TOXIC TO REPRODUCTION - Category 1B
H373 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2

GHS label elements

Hazard pictograms :



Signal word : Danger

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Section 2. Hazards identification

Hazard statements	: H300 - Fatal if swallowed. H350 - May cause cancer. H360 - May damage fertility or the unborn child. H373 - May cause damage to organs through prolonged or repeated exposure. (liver)
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. P260 - Do not breathe dust. P270 - Do not eat, drink or smoke when using this product. P264 - Wash thoroughly after handling.
Response	: 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.
Storage	: P405 - Store locked up.
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	: 1,3-Bis-(2-chloroethyl)-1-nitroso-urea / N,N'-Bis-(2-chloroethyl)-N-nitroso-urea

Ingredient name	Other names	%	CAS number
carmustine	-	≥90	154-93-8
Ethanol	Ethyl alcohol	<10	64-17-5

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. 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. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. 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** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : Defatting to the skin. May cause skin dryness and irritation.
- Ingestion** : Fatal if swallowed.

Over-exposure signs/symptoms

- Eye contact** : No specific data.
- Inhalation** : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations
- Skin contact** : Adverse symptoms may include the following:
irritation
dryness
cracking
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

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Section 4. First aid measures

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, CO₂, alcohol-resistant foam or water spray (fog).
- Unsuitable extinguishing media** : Do not use water jet.

- Specific hazards arising from the chemical** : No specific fire or explosion hazard.

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
halogenated compounds
Hydrogen chloride (HCl).

- 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. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

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Section 6. Accidental release measures

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. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor.

Large spill : Move containers from spill area. 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. 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). 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 ingest. If during normal use the material presents a respiratory hazard, use only with adequate ventilation or wear appropriate respirator. 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 between the following temperatures: 2 to 8°C (35.6 to 46.4°F). 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. Store locked up. 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.

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Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
carmustine Ethanol	None. ACGIH TLV (United States, 1/2023). STEL: 1000 ppm 15 minutes. NIOSH REL (United States, 10/2020). TWA: 1000 ppm 10 hours. TWA: 1900 mg/m ³ 10 hours. OSHA PEL (United States, 5/2018). TWA: 1000 ppm 8 hours. TWA: 1900 mg/m ³ 8 hours.

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: safety glasses with side-shields.

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.

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Section 8. Exposure controls/personal protection

- 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.
- Color** : Pale yellow.
- Odor** : Not available.
- Odor threshold** : Not available.
- pH** : 4 to 6.8 (reconstitution solution)
- Melting point** : Not available.
- Boiling point, 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

- Miscible with water** : No.
- Partition coefficient: n-octanol/water** : Not applicable.
- Auto-ignition temperature** : Not applicable.
- Decomposition temperature** : Not available.
- SADT** : Not available.
- Viscosity** : Not applicable.
- Flow time (ISO 2431)** : Not available.
- Particle characteristics**
- Median particle size** : Not available.

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Section 9. Physical and chemical properties

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 : Protect from light.

Incompatible materials : No specific data.

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
carmustine	LD50 Oral	Rat	20 mg/kg	-
Ethanol	LC50 Inhalation Vapor	Rat	124700 mg/m ³	4 hours
	LD50 Oral	Rat	7 g/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
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.

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Section 11. Toxicological information

Mutagenicity

Conclusion/Summary : Not available.

Carcinogenicity

Conclusion/Summary : Not available.

Classification

Product/ingredient name	OSHA	IARC	NTP
carmustine	-	2A	Reasonably anticipated to be a human carcinogen.

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

Not available.

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

Potential acute health effects

Eye contact : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Skin contact : Defatting to the skin. May cause skin dryness and irritation.
Ingestion : Fatal if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No specific data.
Inhalation : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

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Section 11. Toxicological information

- Skin contact** : Adverse symptoms may include the following:
irritation
dryness
cracking
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** : 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** : May cause cancer. Risk of cancer depends on duration and level of exposure.
- Mutagenicity** : No known significant effects or critical hazards.
- Reproductive toxicity** : May damage 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)
Carmustine for Injection	21.1	N/A	N/A	N/A	N/A
carmustine	20	N/A	N/A	N/A	N/A
Ethanol	7000	N/A	N/A	124.7	N/A

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Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
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 ul/L Fresh water	Daphnia - <i>Daphnia magna</i> - Neonate	21 days
	Chronic NOEC 0.375 ul/L Fresh water	Fish - <i>Gambusia holbrooki</i> - Larvae	12 weeks

Conclusion/Summary : Not available.

Persistence and degradability

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
Ethanol	-	-	Readily

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
carmustine	1.53	-	Low
Ethanol	-0.35	-	Low

Mobility in soil

Soil/water partition coefficient (K_{oc}) : 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

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Section 13. Disposal considerations

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.
Transport in bulk according to IMO instruments	Not available.



Meitheal Pharmaceuticals, Inc.

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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 Air Act Section 112 : Not listed

(b) Hazardous Air Pollutants (HAPs)

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 : ACUTE TOXICITY (oral) - Category 2
CARCINOGENICITY - Category 1B
TOXIC TO REPRODUCTION - Category 1B
SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2
HNOC - Defatting irritant

Composition/information on ingredients

Name	%	Classification
carmustine	≥90	ACUTE TOXICITY (oral) - Category 2 CARCINOGENICITY - Category 1B TOXIC TO REPRODUCTION - Category 1B
Ethanol	<10	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

SARA 313

Not applicable.

State regulations

Massachusetts : The following components are listed: BISCHLOROETHYL NITROSOUREA; ETHYL ALCOHOL

New York : The following components are listed: Bischloroethyl nitrosourea

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Meitheal Pharmaceuticals, Inc.

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Section 15. Regulatory information

New Jersey : The following components are listed: ETHYL ALCOHOL
Pennsylvania : The following components are listed: BISCHLOROETHYL NITROSOUREA; ETHANOL
California Prop. 65

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

Ingredient name	No significant risk level	Maximum acceptable dosage level
Bischloroethyl nitrosoarea	-	-

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	*	3
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
ACUTE TOXICITY (oral) - Category 2	Calculation method
CARCINOGENICITY - Category 1B	Calculation method
TOXIC TO REPRODUCTION - Category 1B	Calculation method
SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2	Calculation method

History

Date of issue/Date of revision	: 11/08/2023
Date of previous issue	: 11/22/2021
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 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 : Dehydrated Alcohol Injection

Other means of identification : Ethyl Alcohol

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 : H225 FLAMMABLE LIQUIDS - Category 2
H319 EYE IRRITATION - Category 2A
H336 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Narcotic effects) - Category 3
H373 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2

GHS label elements

Hazard pictograms :



Signal word : Danger

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Section 2. Hazards identification

Hazard statements : H225 - Highly flammable liquid and vapor.
H319 - Causes serious eye irritation.
H336 - May cause drowsiness or dizziness.
H373 - May cause damage to organs through prolonged or repeated exposure. (liver)

Precautionary statements

Prevention : P280 - Wear protective gloves, protective clothing and eye or face protection.
P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P241 - Use explosion-proof electrical, ventilating or lighting equipment.
P242 - Use non-sparking tools.
P243 - Take action to prevent static discharges.
P271 - Use only outdoors or in a well-ventilated area.
P260 - Do not breathe vapor.
P264 - Wash thoroughly after handling.

Response : P314 - Get medical advice or attention if you feel unwell.
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.
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
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.
P403 + P235 - Keep cool.

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 : Substance
Other means of identification : Ethyl Alcohol

CAS number/other identifiers

CAS number : 64-17-5

Ingredient name	Other names	%	CAS number
Ethanol	Ethyl alcohol	≤100	64-17-5

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

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Section 3. Composition/information on ingredients

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.
- 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. If necessary, call a poison center or physician. 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** : Can cause central nervous system (CNS) depression. May cause drowsiness or dizziness.
- Skin contact** : Defatting to the skin. May cause skin dryness and irritation.
- Ingestion** : Can cause central nervous system (CNS) depression.

Over-exposure signs/symptoms

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

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Section 4. First aid measures

- Inhalation** : Adverse symptoms may include the following:
nausea or vomiting
headache
drowsiness/fatigue
dizziness/vertigo
unconsciousness
- 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** : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
- 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.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

- Suitable extinguishing media** : Use dry chemical, CO₂, water spray (fog) or foam.
- Unsuitable extinguishing media** : Do not use water jet.

- Specific hazards arising from the chemical** : Highly flammable liquid and vapor. Runoff to sewer may create fire or explosion hazard. In a fire or if heated, a pressure increase will occur and the container may burst, with the risk of a subsequent explosion.

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
Thermal decomposition can lead to release of irritating gases and vapors.

- 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. 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).

Methods and materials for containment and cleaning up

Small spill : Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. 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. Use spark-proof tools and explosion-proof equipment. 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. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Do not enter storage areas and confined spaces unless adequately ventilated. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Store and use away from heat, sparks, open flame or any other ignition source. Use explosion-proof electrical (ventilating, lighting and material handling) equipment. Use only non-sparking tools. Take precautionary measures

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Section 7. Handling and storage

against electrostatic discharges. 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
Ethanol	ACGIH TLV (United States, 1/2023). STEL: 1000 ppm 15 minutes. NIOSH REL (United States, 10/2020). TWA: 1000 ppm 10 hours. TWA: 1900 mg/m ³ 10 hours. OSHA PEL (United States, 5/2018). TWA: 1000 ppm 8 hours. TWA: 1900 mg/m ³ 8 hours.

Appropriate engineering controls

: Use only with adequate ventilation. 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

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Section 8. Exposure controls/personal protection

- 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.
- 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. When there is a risk of ignition from static electricity, wear anti-static protective clothing. For the greatest protection from static discharges, clothing should include anti-static overalls, boots and gloves.
- 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.]
- Color** : Colorless.
- Odor** : Not available.
- Odor threshold** : Not available.
- pH** : 8.3 to 9.8
- Melting point** : -114.1°C (-173.4°F)
- Boiling point, initial boiling point, and boiling range** : 78.5°C (173.3°F)
- Flash point** : Closed cup: 12.8°C (55°F)
- Evaporation rate** : 1.4 (n-Butyl Acetate = 1)

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Section 9. Physical and chemical properties

Flammability	: Not available.
Lower and upper explosion limit/flammability limit	: Lower: 3.3% Upper: 19%
Vapor pressure	: Not available.
Relative vapor density	: Not available.
Relative density	: 0.79 [Water = 1] [15°C (59°F)]
Density	: 0.78 g/cm ³ [25°C (77°F)]

Solubility(ies)	: <table border="1"> <thead> <tr> <th>Media</th><th>Result</th></tr> </thead> <tbody> <tr> <td>water</td><td>Easily soluble</td></tr> </tbody> </table>	Media	Result	water	Easily soluble
Media	Result				
water	Easily soluble				

Miscible with water	: Yes.
Partition coefficient: n-octanol/water	: Not applicable.
Auto-ignition temperature	: 362.8°C (685°F)
Decomposition temperature	: 363°C (685.4°F)
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	: Volatility: 100%

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 all possible sources of ignition (spark or flame). Do not pressurize, cut, weld, braze, solder, drill, grind or expose containers to heat or sources of ignition.
Incompatible materials	: Reactive or incompatible with the following materials: oxidizing materials

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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
Ethanol	LC50 Inhalation Vapor LD50 Oral	Rat Rat	124700 mg/m ³ 7 g/kg	4 hours -

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
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

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** : Can cause central nervous system (CNS) depression. May cause drowsiness or dizziness.
- Skin contact** : Defatting to the skin. May cause skin dryness and irritation.
- Ingestion** : Can cause central nervous system (CNS) depression.

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:
nausea or vomiting
headache
drowsiness/fatigue
dizziness/vertigo
unconsciousness
- 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.

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Section 11. Toxicological information

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)
Ethanol	7000	N/A	N/A	124.7	N/A

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Ethanol	Acute EC50 17.921 mg/l Marine water	Algae - <i>Ulva pertusa</i>	96 hours
	Acute EC50 2000 µg/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

Conclusion/Summary : Not available.

Persistence and degradability

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
Ethanol	-	-	Readily

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
Ethanol	-0.35	-	Low

Mobility in soil

Soil/water partition coefficient (K_{oc}) : 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. Vapor from product residues may create a highly flammable or explosive atmosphere inside the container. Do not cut, weld or grind used containers unless they have been cleaned thoroughly internally. 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	UN1170	UN1170	UN1170
UN proper shipping name	Ethanol	ETHANOL	Ethanol
Transport hazard class(es)	3 	3 	3 
Packing group	II	II	II
Environmental hazards	No.	No.	No.

Additional information

DOT Classification

: **Limited quantity** Yes.
Packaging instruction Exceptions: 4b, 150. Non-bulk: 202. Bulk: 242.
Quantity limitation Passenger aircraft/rail: 5 L. Cargo aircraft: 60 L.
Special provisions 24, IB2, T4, TP1

IMDG

: **Emergency schedules** F-E, S-D
Special provisions 144

IATA

: **Quantity limitation** Passenger and Cargo Aircraft: 5 L. Packaging instructions: 353. Cargo Aircraft Only: 60 L. Packaging instructions: 364. Limited Quantities - Passenger Aircraft: 1 L. Packaging instructions: Y341.
Special provisions A3, A58, A180



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Section 14. Transport 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 : 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

Composition/information on ingredients

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Section 15. Regulatory information

Name	%	Classification
Ethanol	≤100	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

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: ETHYL ALCOHOL
Pennsylvania	: The following components are listed: 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.

Section 16. Other information

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

Health	*	2
Flammability		3
Physical hazards		0

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Section 16. Other information

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
FLAMMABLE LIQUIDS - Category 2	On basis of test data
EYE IRRITATION - Category 2A	Calculation method
SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Narcotic effects) - Category 3	Calculation method
SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2	Calculation method

[History](#)

Date of issue/Date of revision	: 07/24/2023
Date of previous issue	: 07/26/2021
Version	: 3.0
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 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.

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Section 16. Other information

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.

Effective