

SDS Title: Docetaxel Injection, USP Safety Data Sheet	SDS Number: SDS-000045	Page Number: Page 1 of 18
Function: Regulatory Affairs	Effective Date: January 05, 2024	Version number: 3.0

Section 1. Identification

GHS product identifier : Docetaxel Injection, USP

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: Anticancer

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
H318 SERIOUS EYE DAMAGE - Category 1
H360 TOXIC TO REPRODUCTION - Category 1B
H362 TOXIC TO REPRODUCTION - Effects on or via lactation
H373 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2

GHS label elements

Hazard pictograms :



Signal word : Danger



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

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Section 2. Hazards identification

Hazard statements : H225 - Highly flammable liquid and vapor.
H318 - Causes serious eye damage.
H360 - May damage fertility or the unborn child.
H362 - May cause harm to breast-fed children.
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.
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.
P233 - Keep container tightly closed.
P260 - Do not breathe vapor.
P263 - Avoid contact during pregnancy or while nursing.
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.
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P305 + P351 + P338, P310 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor.

Storage : P405 - Store locked up.
P403 + P235 - Store in a well-ventilated place. 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 : Mixture
Other means of identification : Not available.

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Section 3. Composition/information on ingredients

Ingredient name	Other names	%	CAS number
Poly(oxy-1,2-ethanediyl), α -hydro- ω -hydroxy-Ethane-1,2-diol, ethoxylated	PEG 300	$\geq 50 - \leq 70$	25322-68-3
Sorbitan monooleate, ethoxylated	Polysorbate 80	$\geq 10 - \leq 25$	9005-65-6
Ethanol	Ethyl alcohol	$\geq 10 - < 20$	64-17-5
Benzenepropanoic acid, β -[(1,1-dimethylethoxy) carbonyl]amino]- α -hydroxy-, (2aR,4S,4aS,6R, 9S,11S,12S,12aR, 12bS)-12b- (acetyloxy)-12 -(benzoyloxy)- 2a, 3,4,4a,5,6,9,10,11,12,12a,12b- dodecahydro-4,6,11- trihydroxy-4a,8,13, 13-tetramethyl-5-oxo-7,11-methano- 1H-cyclodeca[3, 4]benz [1,2-b] oxet-9-yl ester, (α R, β S)-	-	< 1	114977-28-5
citric acid	Citric acid	< 1	77-92-9
nitrogen	Nitrogen	≤ 0.1	7727-37-9

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

- : Get medical attention immediately. Call a poison center or physician. 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. Chemical burns must be treated promptly by a physician.

Inhalation

- : Get medical attention immediately. Call a poison center or physician. 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. 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

- : Get medical attention immediately. Call a poison center or physician. 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. Chemical burns must be treated promptly by a physician. Wash clothing before reuse. Clean shoes thoroughly before reuse.



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Section 4. First aid measures

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. Chemical burns must be treated promptly by a 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 damage.
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
watering
redness
Inhalation : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations
Skin contact : Adverse symptoms may include the following:
pain or irritation
redness
dryness
cracking
blistering may occur
reduced fetal weight
increase in fetal deaths
skeletal malformations
Ingestion : Adverse symptoms may include the following:
stomach pains
reduced fetal weight
increase in fetal deaths
skeletal malformations

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.

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Section 4. First aid measures

- 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, 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

- 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 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".

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Section 6. Accidental release measures

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). Avoid exposure - obtain special instructions before use. Avoid contact during pregnancy or while nursing. 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 vapor or mist. Do not ingest. 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 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 between the following temperatures: 20 to 25°C (68 to 77°F). 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

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Section 7. Handling and storage

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
Poly(oxy-1,2-ethanediyl), α -hydro- ω -hydroxy- Ethane-1,2-diol, ethoxylated Sorbitan monooleate, ethoxylated Ethanol	OARS WEEL (United States, 4/2022). TWA: 10 mg/m ³ 8 hours. 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. None.
Benzenepropanoic acid, β -[[[(1,1-dimethylethoxy) carbonyl] amino]- α - hydroxy-, (2aR,4S,4aS,6R, 9S,11S,12S,12aR,12bS) -12b- (acetyloxy)-12 -(benzoyloxy)- 2a,3,4,4a, 5,6,9,10,11,12,12a,12b- dodecahydro-4,6,11- trihydroxy-4a,8,13, 13-tetramethyl- 5-oxo-7,11-methano- 1H-cyclodeca[3, 4]benz [1,2-b] oxet-9-yl ester, (α R, β S)- citric acid nitrogen	None. ACGIH TLV (United States, 1/2023). Oxygen Depletion [Asphyxiant].

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

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.



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Section 8. Exposure controls/personal protection

- 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 and/or face shield. If inhalation hazards exist, a full-face respirator may be required instead.
- 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 to light yellow.
- Odor** : Alcohol-like.
- Odor threshold** : Not available.
- pH** : 3.5 to 5.5
- Melting point** : Not available.
- Boiling point, initial boiling point, and boiling range** : Not available.
- Flash point** : Closed cup: 22 to 25°C (71.6 to 77°F)
- 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
Ethanol	42.94865	5.7				

Relative vapor density : Not available.

Relative density : Not available.

Density : Not available.

Solubility(ies) : Not available.

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

Auto-ignition temperature	:	Ingredient name	°C	°F	Method
		Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy- Ethane-1,2-diol, ethoxylated	360	680	

Decomposition temperature : Not available.

SADT : Not available.

Viscosity : Not available.

Flow time (ISO 2431) : Not available.

Particle characteristics

Median particle size : Not applicable.

Other information

Physical/chemical properties comments : No additional information.

Section 10. Stability and reactivity

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

Chemical stability : The product is stable.

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

Conditions to avoid : 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. Protect from light. Keep away from heat, sparks and flame. Do not freeze.

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
Poly(oxy-1,2-ethanediyl), α -hydro- ω -hydroxy- Ethane-1,2-diol, ethoxylated	LD50 Dermal	Rat - Male, Female	>2000 mg/kg	-
Sorbitan monooleate, ethoxylated	LD50 Oral	Rat - Female	>2000 mg/kg	-
Ethanol	LD50 Oral	Rat	34500 uL/kg	-
citric acid	LC50 Inhalation Vapor	Rat	124700 mg/m ³	4 hours
	LD50 Oral	Rat	7 g/kg	-
	LD50 Dermal	Rat - Male, Female	>2000 mg/kg	-
	LD50 Oral	Rat	3 g/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Poly(oxy-1,2-ethanediyl), α -hydro- ω -hydroxy- Ethane-1,2-diol, ethoxylated	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
	Eyes - Mild irritant	Rabbit	-	500 mg	-
	Skin - Mild irritant	Rabbit	-	24 hours 500 mg	-
Sorbitan monooleate, ethoxylated	Skin - Mild irritant	Rabbit	-	500 mg	-
Ethanol	Eyes - Mild irritant	Rabbit	-	150 mg	-
	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
	Eyes - Moderate irritant	Rabbit	-	0.06666667 minutes 100 mg	-
citric acid	Eyes - Moderate irritant	Rabbit	-	100 uL	-
	Eyes - Severe irritant	Rabbit	-	500 mg	-
	Eyes - Severe irritant	Rabbit	-	24 hours 750 ug	-
	Skin - Mild irritant	Rabbit	-	24 hours 500 mg	-
	Skin - Moderate irritant	Rabbit	-	0.5 MI	-

Sensitization

Not available.

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Section 11. Toxicological information

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 citric acid	Category 3 Category 3	- -	Narcotic effects Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

Name	Category	Route of exposure	Target organs
Ethanol Benzenepropanoic acid, β -[[[(1,1-dimethylethoxy) carbonyl] amino]- α - hydroxy-, (2aR,4S,4aS,6R, 9S,11S,12S,12aR, 12bS)-12b- (acetyloxy)-12 -(benzoyloxy)- 2a,3,4,4a, 5,6,9,10,11,12,12a,12b- dodecahydro-4,6,11- trihydroxy-4a, 8,13, 13-tetramethyl- 5-oxo-7,11-methano- 1H-cyclodeca[3, 4]benz[1,2-b] oxet-9-yl ester, (α R, β S)-	Category 2 Category 1	- -	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 : Causes serious eye damage.
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
 watering
 redness

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Section 11. Toxicological information

Inhalation : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

Skin contact : Adverse symptoms may include the following:
pain or irritation
redness
dryness
cracking
blistering may occur
reduced fetal weight
increase in fetal deaths
skeletal malformations

Ingestion : Adverse symptoms may include the following:
stomach pains
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 : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Reproductive toxicity : May damage fertility or the unborn child.
May cause harm to breast-fed children.

Numerical measures of toxicity

Acute toxicity estimates

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Section 11. Toxicological information

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/l)
Docetaxel Injection, USP	3338.8	2563.6	N/A	N/A	N/A
Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy- Ethane-1,2-diol, ethoxylated	2500	2500	N/A	N/A	N/A
Ethanol	7000	N/A	N/A	124.7	N/A
citric acid	3000	2500	N/A	N/A	N/A

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy- Ethane-1,2-diol, ethoxylated	Acute EC50 >100 mg/l Fresh water	Daphnia - <i>Daphnia magna</i>	48 hours
Ethanol	Acute LC50 >1000000 µg/l Fresh water	Fish - <i>Salmo salar</i> - Parr	96 hours
	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
citric acid	Acute LC50 160000 µg/l Marine water	Crustaceans - <i>Carcinus maenas</i> - Adult	48 hours

Conclusion/Summary : Not available.

Persistence and degradability

Product/ingredient name	Test	Result	Dose	Inoculum
Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy- Ethane-1,2-diol, ethoxylated	OECD 301D Ready Biodegradability - Closed Bottle Test	74.85 % - Readily - 28 days	4 mg/l	-

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Section 12. Ecological information

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
Poly(oxy-1,2-ethanediyl), α -hydro- ω -hydroxy- Ethane-1,2-diol, ethoxylated	-	-	Readily
Ethanol	-	-	Readily
citric acid	-	-	Readily

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
Poly(oxy-1,2-ethanediyl), α -hydro- ω -hydroxy- Ethane-1,2-diol, ethoxylated	0.2	3.2	Low
Ethanol	-0.35	-	Low
citric acid	-1.8	-	Low
nitrogen	0.67	-	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. 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.

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Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	UN1170	UN1170	UN1170
UN proper shipping name	Ethanol solutions	ETHANOL SOLUTION	Ethanol solution
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

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

Transport in bulk according to IMO instruments : Not available.

Section 15. Regulatory information

U.S. Federal regulations : **TSCA 8(a) CDR Exempt/Partial exemption:** Not determined
United States inventory (TSCA 8b): Not determined.

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

Clean Air Act Section 602 Class I Substances : Not listed



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Safety Data Sheet

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Section 15. Regulatory information

nitrogen	≤0.1	SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3 GASES UNDER PRESSURE - Compressed gas SIMPLE ASPHYXIANTS
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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	*	4
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.

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Section 16. Other information

[National Fire Protection Association \(U.S.A.\)](#)



[Procedure used to derive the classification](#)

Classification	Justification
FLAMMABLE LIQUIDS - Category 2 SERIOUS EYE DAMAGE - Category 1 TOXIC TO REPRODUCTION - Category 1B TOXIC TO REPRODUCTION - Effects on or via lactation SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2	Expert judgment Calculation method Calculation method Calculation method Calculation method

[History](#)

Date of issue/Date of revision	: 01/05/2024
Date of previous issue	: 01/07/2022
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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