

SAFETY DATA SHEET

Pitolisant Hydrochloride Tablets



Section 1. Identification

GHS product identifier : Pitolisant Hydrochloride Tablets
Product code : Not available.
Other means of identification : Ciproxidine; Pitolisant Hydrochloride; Tiprolisant; Wakix ®
Product type : Solid. (Coated Tablet)

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

Product use : Use in treatment of excessive daytime sleepiness in adult patients with narcolepsy.
Area of application : Industrial applications.

Supplier/Manufacturer : Harmony Biosciences, LLC
630 West Germantown Pike,
Plymouth Meeting, PA 19462

Telephone no.: 1-(484) 539-9800

e-mail address of person responsible for this SDS : sds@harmonybiosciences.com

Emergency telephone number (with hours of operation) : CHEMTREC, U.S. : 1-800-424-9300 International: +1-703-527-3887 (24 hours)

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 : H315 SKIN IRRITATION - Category 2
H319 EYE IRRITATION - Category 2A
H372 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 1

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H372 - Causes damage to organs through prolonged or repeated exposure. (lungs)

Precautionary statements

Prevention : P280 - Wear protective gloves. Wear 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.

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Section 2. Hazards identification

Response	: P314 - Get medical advice or attention if you feel unwell. P362 + P364 - Take off contaminated clothing and wash it before reuse. P302 + P352 - IF ON SKIN: Wash with plenty of water. P332 + P313 - If skin irritation occurs: Get medical advice or attention. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 - If eye irritation persists: Get medical advice or attention.
Storage	: Not applicable.
Disposal	: P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.
Hazards not otherwise classified	: None known.

Section 3. Composition/information on ingredients

Substance/mixture	: Mixture
Other means of identification	: Ciproxidine; Pitolisant Hydrochloride; Tiprolisant; Wakix ®

Ingredient name	Other names	%	CAS number
Cellulose	Microcrystalline cellulose	≥50 - ≤75	9004-34-6
pitolisant hydrochloride	-	≥10 - <20	903576-44-3
2-Pyrrolidinone, 1-ethenyl-, homopolymer	-	≤10	9003-39-8
Talc , not containing asbestiform fibres	-	≤10	14807-96-6
Acetic acid ethenyl ester, polymer with ethenol	-	≤5	25213-24-5
Magnesium stearate	-	≤3	557-04-0
titanium dioxide	-	≤3	13463-67-7
Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-Ethane-1,2-diol, ethoxylated	-	≤3	25322-68-3
silicon dioxide	Silicon Dioxide	<1	7631-86-9

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 as hazardous to health 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 not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention following exposure or if feeling unwell. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
Skin contact	: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Continue to rinse for at least 10 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Section 4. First aid measures

- Ingestion** : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention following exposure or if feeling unwell. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

- Eye contact** : Causes serious eye irritation.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : Causes skin irritation.
- Ingestion** : No known significant effects or critical hazards.

Over-exposure signs/symptoms

- Eye contact** : Adverse symptoms may include the following:
pain or irritation
watering
redness
- Inhalation** : No specific data.
- Skin contact** : Adverse symptoms may include the following:
irritation
redness
- Ingestion** : Adverse symptoms may include the following:
abdominal cramps and pain
anxiety
delirium/hallucinations
headache
heartbeat increase
disturbed sleep
musculoskeletal pain
skin rash or hives
upper respiratory infection

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. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

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

Specific hazards arising from the chemical : 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
metal oxide/oxides

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

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

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

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

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

Methods and materials for containment and cleaning up

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

Large spill : Move containers from spill area. 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). Do not ingest. Avoid contact with eyes, skin and clothing. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.
- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

<u>Ingredient name</u>	<u>Exposure limits</u>
Cellulose	ACGIH TLV (United States, 3/2020). TWA: 10 mg/m ³ 8 hours.
	NIOSH REL (United States, 10/2016). TWA: 5 mg/m ³ 10 hours. Form: Respirable fraction TWA: 10 mg/m ³ 10 hours. Form: Total
	OSHA PEL (United States, 5/2018). TWA: 5 mg/m ³ 8 hours. Form: Respirable fraction TWA: 15 mg/m ³ 8 hours. Form: Total dust
pitolisant hydrochloride	None.
2-Pyrrolidinone, 1-ethenyl-, homopolymer	None.
Talc , not containing asbestiform fibres	ACGIH TLV (United States, 3/2020). TWA: 2 mg/m ³ 8 hours. Form: Respirable fraction
	NIOSH REL (United States, 10/2016). TWA: 2 mg/m ³ 10 hours. Form: Respirable fraction
Acetic acid ethenyl ester, polymer with ethenol	None.
Magnesium stearate	ACGIH TLV (United States, 3/2020). TWA: 10 mg/m ³ 8 hours. Form: Inhalable fraction TWA: 3 mg/m ³ 8 hours. Form: Respirable fraction
titanium dioxide	ACGIH TLV (United States, 3/2020). TWA: 10 mg/m ³ 8 hours.
	OSHA PEL (United States, 5/2018). TWA: 15 mg/m ³ 8 hours. Form: Total dust
Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy- Ethane-1,2-diol, ethoxylated	AIHA WEEL (United States, 7/2018). TWA: 10 mg/m ³ 8 hours.
silicon dioxide	NIOSH REL (United States, 10/2016). TWA: 6 mg/m ³ 10 hours.

Section 8. Exposure controls/personal protection

- Appropriate engineering controls** : If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.
- Individual protection measures**
- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.
- Skin protection**
- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

Appearance

- Physical state** : Solid. [Coated Tablet]
- Color** : White.
- Odor** : Not available.
- Odor threshold** : Not available.
- pH** : Not available.
- Melting point** : Not available.
- Boiling point** : Not available.
- Flash point** : Not available.
- Evaporation rate** : Not available.
- Flammability (solid, gas)** : Not available.

Section 9. Physical and chemical properties

Lower and upper explosive (flammable) limits	: Not available.
Vapor pressure	: Not available.
Vapor density	: Not available.
Relative density	: Not available.
Density	: Not available.
Solubility	: Not available.
Partition coefficient: n-octanol/water	: Not available.
Auto-ignition temperature	: Not available.
Decomposition temperature	: Not available.
SADT	: Not available.
Viscosity	: Not available.
Flow time (ISO 2431)	: Not available.

Section 10. Stability and reactivity

Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	: The product is stable.
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur. Under normal conditions of storage and use, hazardous polymerization will not occur.
Conditions to avoid	: No specific data.
Incompatible materials	: 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
Cellulose	LD50 Oral	Rat	>5 g/kg	-
2-Pyrrolidinone, 1-ethenyl-, homopolymer	LD50 Oral	Rat	100 g/kg	-
Magnesium stearate	LD50 Oral	Rat	>10000 mg/kg	-
Poly(oxy-1,2-ethanediyl), α -hydro- ω -hydroxy-	LD50 Dermal	Rat - Male, Female	>2000 mg/kg	-
Ethane-1,2-diol, ethoxylated	LD50 Oral	Rat - Female	>2000 mg/kg	-
silicon dioxide	LC50 Inhalation Dusts and mists	Rat - Male, Female	>58.8 mg/l	4 hours
	LD50 Oral	Rat - Male, Female	>5000 mg/kg	-

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Section 11. Toxicological information

Female

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	-
silicon dioxide	Skin - Mild irritant	Rabbit	-	500 mg	-
	Eyes - Mild irritant	Rabbit	-	24 hours 25 mg	-

Sensitization

Not available.

Mutagenicity

Conclusion/Summary : Not available.

Carcinogenicity

Conclusion/Summary : Not available.

Classification

Product/ingredient name	OSHA	IARC	NTP
2-Pyrrolidinone, 1-ethenyl-, homopolymer	-	3	-
Talc , not containing asbestiform fibres	-	3	-
titanium dioxide	-	2B	-
silicon dioxide	-	3	-

Reproductive toxicity

Conclusion/Summary : Not available.

Teratogenicity

Conclusion/Summary : Not available.

Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
pitolisant hydrochloride	Category 3	-	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

Name	Category	Route of exposure	Target organs
Talc , not containing asbestiform fibres	Category 1	-	lungs

Aspiration hazard

Not available.

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

Potential acute health effects

Section 11. Toxicological information

Eye contact	: Causes serious eye irritation.
Inhalation	: No known significant effects or critical hazards.
Skin contact	: Causes skin irritation.
Ingestion	: No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact	: Adverse symptoms may include the following: pain or irritation watering redness
Inhalation	: No specific data.
Skin contact	: Adverse symptoms may include the following: irritation redness
Ingestion	: Adverse symptoms may include the following: abdominal cramps and pain anxiety delirium/hallucinations headache heartbeat increase disturbed sleep musculoskeletal pain skin rash or hives upper respiratory infection

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	: Causes damage to organs through prolonged or repeated exposure.
Carcinogenicity	: No known significant effects or critical hazards.
Mutagenicity	: No known significant effects or critical hazards.
Reproductive toxicity	: No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

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)
Pitolisant Hydrochloride Tablets 2-Pyrrolidinone, 1-ethenyl-, homopolymer Poly(oxy-1,2-ethanediyl), α -hydro- ω -hydroxy- Ethane-1,2-diol, ethoxylated	121666.7 100000 2500	118000 N/A 2500	N/A N/A N/A	N/A N/A N/A	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 LC50 3 mg/l Fresh water	Crustaceans - Ceriodaphnia dubia - Neonate	48 hours
	Acute LC50 6.5 mg/l Fresh water	Daphnia - Daphnia pulex - Neonate	48 hours
	Acute LC50 >1000000 μ g/l Marine water	Fish - Fundulus heteroclitus	96 hours
	Acute LC50 >1000000 μ g/l Fresh water	Fish - Salmo salar - Parr	96 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	-

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

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
Poly(oxy-1,2-ethanediyl), α -hydro- ω -hydroxy- Ethane-1,2-diol, ethoxylated	-	3.2	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 sewers.

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.

Additional information

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

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

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

Section 15. Regulatory information

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 : SKIN IRRITATION - Category 2
EYE IRRITATION - Category 2A
SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 1

Composition/information on ingredients

Name	%	Classification
pitolisant hydrochloride	≥10 - <20	SKIN IRRITATION - Category 2 EYE IRRITATION - Category 2A SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3
Talc , not containing asbestiform fibres	≤10	COMBUSTIBLE DUSTS SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 1
Acetic acid ethenyl ester, polymer with ethenol	≤5	EYE IRRITATION - Category 2A
Magnesium stearate	≤3	COMBUSTIBLE DUSTS
titanium dioxide	≤3	CARCINOGENICITY - Category 2
Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-	≤3	EYE IRRITATION - Category 2B
Ethane-1,2-diol, ethoxylated		
silicon dioxide	<1	EYE IRRITATION - Category 2B

SARA 313

Not applicable.

State regulations

Massachusetts : The following components are listed: CELLULOSE; TALC; SOAPSTONE; TITANIUM DIOXIDE; TIN DIOXIDE DUST

New York : None of the components are listed.

New Jersey : The following components are listed: CELLULOSE; SOAPSTONE; TITANIUM DIOXIDE; TITANIUM OXIDE (TiO₂)

Pennsylvania : The following components are listed: CELLULOSE; TALC; SOAPSTONE DUST; TITANIUM OXIDE

California Prop. 65

 **WARNING:** This product can expose you to Titanium dioxide, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

Ingredient name	No significant risk level	Maximum acceptable dosage level
Titanium dioxide	-	-

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol

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Section 15. Regulatory information

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 \(U.S.A.\)](#)



[Procedure used to derive the classification](#)

Classification	Justification
SKIN IRRITATION - Category 2	Calculation method
EYE IRRITATION - Category 2A	Calculation method
SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 1	Calculation method

[History](#)

Date of issue/Date of revision	: 12/20/2020
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Version	: 1
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

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Section 16. Other information

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.