

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Allopurinol for Injection

1.2. Intended Use of the Product

Allopurinol for Injection is indicated for the management of patients with leukemia, lymphoma, and solid tumor malignancies who are receiving cancer therapy which causes elevations of serum and urinary uric acid levels and who cannot tolerate oral therapy.

1.3. Name, Address, and Telephone of the Responsible Party

Distributor

Fresenius Kabi USA, LLC

Three Corporate Drive

Lake Zurich, IL 60047

General Phone Number: (847) 550-2300

Customer Service Phone Number: (888) 386-1300

Health Issues Information: (800) 551-7176

<http://www.fresenius-kabi.com/us/>

Manufacturer

Gland Pharma, Ltd.

143 – 148, 150 & 151, Near Gandimaisamma Cross Roads

D.P. Pally, Quthubullapur Mandal – Ranga Reddy District

Hyderabad, Andhra Pradesh 500 043

India

+91-40-30510999

+91-40-30510810

1.4. Emergency Telephone Number

Emergency Number : ChemTel LLC

(800)255-3924 (North America)

+1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US/CA Classification

Met. Corr. 1 H290

Acute Tox. 3 (Oral) H301

Skin Corr. 1A H314

Eye Dam. 1 H318

Skin Sens. 1 H317

Repr. 1B H360

STOT SE 3 H335

STOT RE 1 H372

Full text of hazard classes and H-statements : see section 16

2.2. Label Elements

GHS-US/CA Labeling

Hazard Pictograms (GHS-US/CA)



Signal Word (GHS-US/CA)

: Danger

Hazard Statements (GHS-US/CA)

: H290 - May be corrosive to metals.

H301 - Toxic if swallowed.

H314 - Causes severe skin burns and eye damage.

H317 - May cause an allergic skin reaction.

H318 - Causes serious eye damage.

H335 - May cause respiratory irritation.

H360 - May damage fertility or the unborn child.

H372 - Causes damage to organs through prolonged or repeated exposure (oral).

Precautionary Statements (GHS-US/CA) : P201 - Obtain special instructions before use.

P202 - Do not handle until all safety precautions have been read and understood.

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P234 - Keep only in original container.
P260 - Do not breathe dusts.
P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P271 - Use only outdoors or in a well-ventilated area.
P272 - Contaminated work clothing should not be allowed out of the workplace.
P280 - Wear protective gloves, protective clothing, and eye protection.
P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor.
P301+P330+P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water .
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P310 - Immediately call a POISON CENTER or doctor.
P314 - Get medical advice/attention if you feel unwell.
P321 - Specific treatment (see section 4 on this SDS).
P330 - Rinse mouth.
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P390 - Absorb spillage to prevent material-damage.
P403+P233 - Store in a well-ventilated place. Keep container tightly closed.
P405 - Store locked up.
P406 - Store in corrosive resistant container with a resistant inner liner.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US/CA)

No additional information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
4H-Pyrazolo[3,4-d]pyrimidin-4-one, 1,5-dihydro-	Allopurinol / NSC-1390 / H-Pyrazolo(3,4-d)pyrimidin-4-ol / Pyrimidine, 4-hydroxypyrazolo[3,4-d]- / allopurinol	(CAS-No.) 315-30-0	76.5	Acute Tox. 3 (Oral), H301 Skin Sens. 1, H317 Repr. 1B, H360 STOT RE 1, H372
Sodium hydroxide	Caustic soda / Sodium hydroxide (Na(OH)) / SODIUM HYDROXIDE / LYE	(CAS-No.) 1310-73-2	≥ 23.5	Met. Corr. 1, H290 Acute Tox. 4 (Oral), H302 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 3, H402 Aquatic Chronic 3, H412
Water	AQUA / water	(CAS-No.) 7732-18-5	≤ 0.1	Not classified

Full text of H-statements: see section 16

*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%).

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SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

Inhalation: Remove to fresh air and keep at rest in a position comfortable for breathing. Immediately call a poison center or doctor/physician.

Skin Contact: Immediately remove contaminated clothing. Drench affected area with water for at least 60 minutes. Immediately flush skin with plenty of water for at least 30 minutes. Get immediate medical advice/attention.

Eye Contact: Immediately rinse with water for at least 30 minutes. Immediately rinse with water for at least 60 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get immediate medical advice/attention.

Ingestion: Do NOT induce vomiting. Rinse mouth. Immediately call a POISON CENTER or doctor. Obtain emergency medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: Causes damage to organs through prolonged or repeated exposure (oral). May cause respiratory irritation. Skin sensitization. May damage fertility. May damage the unborn child. Toxic if swallowed. Causes severe skin burns and eye damage.

Inhalation: Irritation of the respiratory tract and the other mucous membranes. May be corrosive to the respiratory tract.

Skin Contact: May cause an allergic skin reaction. Causes severe irritation which will progress to chemical burns.

Eye Contact: Causes permanent damage to the cornea, iris, or conjunctiva.

Ingestion: This material is toxic in small amounts orally, and can cause adverse health effects or death. . May cause burns or irritation of the linings of the mouth, throat, and gastrointestinal tract.

Chronic Symptoms: Causes damage to organs through prolonged or repeated exposure (oral). May damage fertility or the unborn child.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Contact with metallic substances may release flammable hydrogen gas.

Reactivity: May be corrosive to metals. Contact with metals may evolve flammable hydrogen gas. May react exothermically with water releasing heat. Adding an acid to a base or base to an acid may cause a violent reaction. Product may react with strong reducing agents to generate hydrogen gas, which may be flammable or explosive.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Sodium oxides. Nitrogen oxides. Nitrous fumes.

5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not breathe dusts. Do not get in eyes, on skin, or on clothing.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

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6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. As an immediate precautionary measure, isolate spill or leak area in all directions.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill. Absorb spillage to prevent material damage. Cautiously neutralize spilled liquid.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: May be corrosive to metals. May release corrosive vapors.

Precautions for Safe Handling: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid contact with eyes, skin and clothing. Do not breathe dusts. Handle empty containers with care because they may still present a hazard.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store in corrosive resistant container with a resistant inner liner. Store locked up/in a secure area. Store in original container or corrosive resistant and/or lined container.

Storage temperature: 20 – 25 °C (68 – 77 °F) [See USP Controlled Room Temperature]

Incompatible Materials: Acids. Bases. Oxidizers. Metals. May be corrosive to metals. Organic halogen compounds. Acid halides. Epoxides. Strong reducing agents.

7.3. Specific End Use(s)

Allopurinol for Injection is indicated for the management of patients with leukemia, lymphoma, and solid tumor malignancies who are receiving cancer therapy which causes elevations of serum and urinary uric acid levels and who cannot tolerate oral therapy.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH OEL Ceiling	2 mg/m ³
USA OSHA	OSHA PEL (TWA) [1]	2 mg/m ³
USA NIOSH	NIOSH REL (Ceiling)	2 mg/m ³
USA IDLH	IDLH	10 mg/m ³
Alberta	OEL C	2 mg/m ³
British Columbia	OEL C	2 mg/m ³
Manitoba	OEL C	2 mg/m ³
New Brunswick	OEL C	2 mg/m ³
Newfoundland & Labrador	OEL C	2 mg/m ³
Nova Scotia	OEL C	2 mg/m ³
Nunavut	OEL C	2 mg/m ³
Northwest Territories	OEL C	2 mg/m ³
Ontario	OEL C	2 mg/m ³
Prince Edward Island	OEL C	2 mg/m ³
Québec	Plafond (OEL Ceiling)	2 mg/m ³
Saskatchewan	OEL C	2 mg/m ³
Yukon	OEL C	2 mg/m ³

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8.2. Exposure Controls

Appropriate Engineering Controls: Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

Personal Protective Equipment: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection. Face shield.



Materials for Protective Clothing: Chemically resistant materials and fabrics. Corrosion-proof clothing.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical safety goggles and face shield.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Solid
Appearance	: White to off white powder
Odor	: No data available
Odor Threshold	: No data available
pH	: 11 – 12
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: Not applicable
Lower Flammable Limit	: No data available
Upper Flammable Limit	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Specific Gravity	: No data available
Solubility	: Water: Soluble
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

May be corrosive to metals. Contact with metals may evolve flammable hydrogen gas. May react exothermically with water releasing heat. Adding an acid to a base or base to an acid may cause a violent reaction. Product may react with strong reducing agents to generate hydrogen gas, which may be flammable or explosive.

10.2. Chemical Stability:

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

10.4. Conditions to Avoid:

Direct sunlight, extremely high or low temperatures, and incompatible materials.

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10.5. Incompatible Materials:

Acids. Bases. Oxidizers. Metals. May be corrosive to metals. Organic halogen compounds. Acid halides. Epoxides. Strong reducing agents.

10.6. Hazardous Decomposition Products:

Thermal decomposition generates : Corrosive vapors. Carbon oxides (CO, CO₂). Sodium oxides. Nitrogen oxides. Nitrous fumes.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Acute Toxicity (Oral): Toxic if swallowed.

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

LD50 and LC50 Data:

Allopurinol for Injection	
ATE US/CA (oral)	119.43 mg/kg body weight

Skin Corrosion/Irritation: Causes severe skin burns.

pH: 11 – 12

Eye Damage/Irritation: Causes serious eye damage.

pH: 11 – 12

Respiratory or Skin Sensitization: May cause an allergic skin reaction.

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Specific Target Organ Toxicity (Repeated Exposure): Causes damage to organs through prolonged or repeated exposure.

Reproductive Toxicity: May damage fertility or the unborn child.

Specific Target Organ Toxicity (Single Exposure): May cause respiratory irritation.

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Irritation of the respiratory tract and the other mucous membranes. May be corrosive to the respiratory tract.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction. Causes severe irritation which will progress to chemical burns.

Symptoms/Injuries After Eye Contact: Causes permanent damage to the cornea, iris, or conjunctiva.

Symptoms/Injuries After Ingestion: This material is toxic in small amounts orally, and can cause adverse health effects or death. . May cause burns or irritation of the linings of the mouth, throat, and gastrointestinal tract.

Chronic Symptoms: Causes damage to organs through prolonged or repeated exposure (oral). May damage fertility or the unborn child.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

4H-Pyrazolo[3,4-d]pyrimidin-4-one, 1,5-dihydro- (315-30-0)	
LD50 Oral Rat	> 88 mg/kg
Sodium hydroxide (1310-73-2)	
LD50 Oral Rat	325 mg/kg

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

Sodium hydroxide (1310-73-2)	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 - Crustacea [1]	40 mg/l

12.2. Persistence and Degradability

Allopurinol for Injection	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Allopurinol for Injection	
Bioaccumulative Potential	Not established.

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12.4. Mobility in Soil

No additional information available

12.5. Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Proper Shipping Name : CORROSIVE SOLID, TOXIC, N.O.S. (Sodium Hydroxide; 4H-Pyrazolo[3,4-d]pyrimidin-4-one, 1,5-dihydro-)

Hazard Class : 8

Identification Number : UN2923

Label Codes : 8, 6.1

Packing Group : II

ERG Number : 154



14.2. In Accordance with IMDG

Proper Shipping Name : CORROSIVE SOLID, TOXIC, N.O.S. (Sodium Hydroxide; 4H-Pyrazolo[3,4-d]pyrimidin-4-one, 1,5-dihydro-)

Hazard Class : 8 (6.1)

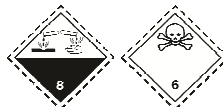
Identification Number : UN2923

Label Codes : 8, 6.1

Packing Group : II

EmS-No. (Fire) : F-A

EmS-No. (Spillage) : S-B



14.3. In Accordance with IATA

Proper Shipping Name : CORROSIVE SOLID, TOXIC, N.O.S. (Sodium Hydroxide; 4H-Pyrazolo[3,4-d]pyrimidin-4-one, 1,5-dihydro-)

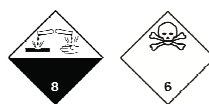
Hazard Class : 8 (6.1)

Identification Number : UN2923

Label Codes : 8, 6.1

Packing Group : II

ERG Code (IATA) : 8P



14.4. In Accordance with TDG

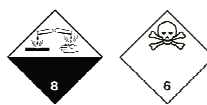
Proper Shipping Name : CORROSIVE SOLID, TOXIC, N.O.S. (Sodium Hydroxide; 4H-Pyrazolo[3,4-d]pyrimidin-4-one, 1,5-dihydro-).

Hazard Class : 8

Identification Number : UN2923

Label Codes : 8, 6.1

Packing Group : II



SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Allopurinol for Injection	
SARA Section 311/312 Hazard Classes	Physical hazard - Corrosive to metals Health hazard - Specific target organ toxicity (single or repeated exposure) Health hazard - Respiratory or skin sensitization

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	Health hazard - Reproductive toxicity Health hazard - Acute toxicity (any route of exposure) Health hazard - Serious eye damage or eye irritation Health hazard - Skin corrosion or Irritation
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4H-Pyrazolo[3,4-d]pyrimidin-4-one, 1,5-dihydro- (315-30-0)
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Sodium hydroxide (1310-73-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
CERCLA RQ	1000 lb

Water (7732-18-5)
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

15.2. US State Regulations

Allopurinol for Injection()
State or local regulations
Sodium hydroxide (1310-73-2)
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List
U.S. - Massachusetts - Right To Know List
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

15.3. Canadian Regulations

4H-Pyrazolo[3,4-d]pyrimidin-4-one, 1,5-dihydro- (315-30-0)
Listed on the Canadian DSL (Domestic Substances List)
Sodium hydroxide (1310-73-2)
Listed on the Canadian DSL (Domestic Substances List)
Water (7732-18-5)
Listed on the Canadian DSL (Domestic Substances List)

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 02/08/2022

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

GHS Full Text Phrases:

Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Met. Corr. 1	Corrosive to metals Category 1
Repr. 1B	Reproductive toxicity Category 1B
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Sens. 1	Skin sensitization, Category 1
STOT RE 1	Specific target organ toxicity (repeated exposure) Category 1
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H290	May be corrosive to metals
H301	Toxic if swallowed
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction

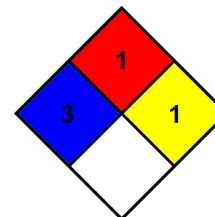
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H318	Causes serious eye damage
H335	May cause respiratory irritation
H360	May damage fertility or the unborn child
H372	Causes damage to organs through prolonged or repeated exposure
H402	Harmful to aquatic life
H412	Harmful to aquatic life with long lasting effects

- NFPA Health Hazard** : 3 - Materials that, under emergency conditions, can cause serious or permanent injury.
- NFPA Fire Hazard** : 1 - Materials that must be preheated before ignition can occur.
- NFPA Reactivity Hazard** : 1 - Materials that in themselves are normally stable but can become unstable at elevated temperatures and pressures.



HMIS III Rating

- Health** : 3 Serious Hazard - Major injury likely unless prompt action is taken and medical treatment is given
* Chronic - Chronic (long-term) health effects may result from repeated overexposure

Flammability : 1 Slight Hazard

Physical : 1 Slight Hazard

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

NA GHS SDS 2015 (Can, US)