

SECTION 1: IDENTIFICATION

Product Identifier

Product Form: Mixture

Product Name: Posaconazole Injection

Formula: C37H42F2N8O4

Anti-Fungal

Intended Use of the Product

Treatment of invasive aspergillosis and prophylaxis of invasive Aspergillus and Candida infections

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/>

Emergency Telephone Number

Emergency Number : VelocityEHS

(800)255-3924 (North America)

+1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS-US/CA Classification

Skin sensitization, Category 1	H317
Reproductive toxicity Category 2	H361
Specific target organ toxicity (repeated exposure) Category 1	H372
Hazardous to the aquatic environment – Acute Hazard Category 3	H402
Hazardous to the aquatic environment – Chronic Hazard Category 3	H412

Label Elements

GHS-US/CA Labeling

Hazard Pictograms (GHS-US/CA)



Signal Word (GHS-US/CA)

: Danger

Hazard Statements (GHS-US/CA)

: H317 - May cause an allergic skin reaction.
 H361 - Suspected of damaging fertility or the unborn child.
 H372 - Causes damage to organs (adrenal glands, liver) through prolonged or repeated exposure.
 H402 - Harmful to aquatic life.
 H412 - Harmful to aquatic life with long lasting effects.

Precautionary Statements (GHS-US/CA)

: P201 - Obtain special instructions before use.
 P202 - Do not handle until all safety precautions have been read and understood.
 P260 - Do not breathe vapors, mist, or spray.
 P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
 P270 - Do not eat, drink or smoke when using this product.
 P272 - Contaminated work clothing should not be allowed out of the workplace.
 P273 - Avoid release to the environment.

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P280 - Wear protective gloves, protective clothing, and eye protection.
 P302+P352 - IF ON SKIN: Wash with plenty of water.
 P308+P313 - If exposed or concerned: Get medical advice/attention.
 P321 - Specific treatment (see section 4 on this SDS).
 P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
 P362+P364 - Take off contaminated clothing and wash it before reuse.
 P405 - Store locked up.
 P501 - Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Other Hazards

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

Unknown Acute Toxicity (GHS-US/CA)

No additional information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
Water	water / AQUA	(CAS-No.) 7732-18-5	58	Not classified
Captisol	.beta.-Cyclodextrin, sulfobutyl ethers, sodium salts / Sulfobutylether .beta.-cyclodextrin / Sulfobutyl ether .beta.-cyclodextrin sodium / betadex sulfobutyl ether sodium / Betadex sulfobutyl ether sodium	(CAS-No.) 182410-00-0	40	Skin Sens. 1, H317 Comb. Dust
Posaconazole	-	(CAS-No.) 171228-49-2	1.8	Acute Tox. 4 (Oral), H302 Eye Irrit. 2, H319 Repr. 2, H361 STOT RE 1, H372 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Glycine, N,N'-1,2-ethanediybis[N-(carboxymethyl)-, disodium salt, dihydrate	Acetic acid, (ethylenedinitrilo)tetra-, disodium salt, dihydrate / Glycine, N,N'-1,2-ethanediybis(N-(carboxymethyl)-, disodium salt, dihydrate (9Cl) / Glycine, N,N'-1,2-ethanediybis[N-(carboxymethyl)-, disodium salt, dihydrate / Disodium dihydrate EDTA / Ethylenediaminetetraacetic acid, sodium salt, dihydrate / Ethylenediaminetetraacetic acid (EDTA), disodium salt, dihydrate / Disodium ethylenediamine tetraacetate / Ethylenediaminetetraacetic acid sodium salt dihydrate / Disodium edetate hydrate / Ethylenediaminetetraacetic acid (EDTA), disodium salt, dihydrate / Ethylenediaminetetraacetic acid sodium salt dihydrate / Ethylenediaminetetraacetic acid, disodium, dihydrate / Ethylenediaminetetraacetic acid disodium salt / Disodium ethylenediaminetetraacetate /	(CAS-No.) 6381-92-6	0.2	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation:dust,mist), H332 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335 STOT RE 2, H373 Aquatic Acute 3, H402 Aquatic Chronic 3, H412 Comb. Dust

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	Sodium edetate hydrate / Glycine, N,N'-1,2-ethanediybis[N-(carboxymethyl)-, sodium salt, hydrate (1:2:2)			
Hydrochloric acid	HYDROCHLORIC ACID / Hydrochloric acid, anhydrous / Muriatic acid / Hydrogen chloride / hydrochloric acid	(CAS-No.) 7647-01-0	< 0.1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 2, H401
Sodium hydroxide	SODIUM HYDROXIDE / Sodium hydroxide (Na(OH)) / Caustic soda / LYE	(CAS-No.) 1310-73-2	< 0.1	Met. Corr. 1, H290 Acute Tox. 4 (Oral), H302 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 1, H370 Aquatic Acute 3, H402

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%).

SECTION 4: FIRST AID MEASURES

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). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

Skin Contact: Remove contaminated clothing. Wash affected area with soap and water for at least 15 minutes. If exposed or concerned: Get medical advice/attention.

Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

Most Important Symptoms and Effects Both Acute and Delayed

General: Suspected of damaging fertility or the unborn child. Causes damage to organs (adrenal glands, liver) through prolonged or repeated exposure. Skin sensitization.

Inhalation: Prolonged exposure may cause irritation.

Skin Contact: May cause an allergic skin reaction.

Eye Contact: May cause slight irritation to eyes.

Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Suspected of damaging fertility or the unborn child. Causes damage to organs (adrenal glands) through prolonged or repeated exposure. Repeated and prolonged exposure may cause an allergic skin reaction.

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

Extinguishing Media

Suitable Extinguishing Media: Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: None known.

Special Hazards Arising From the Substance or Mixture

Fire Hazard: This material may present a combustible dust hazard in its dried form.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

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). Chlorides. Sodium oxides. Fluorine compounds. Nitrogen oxides.

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Other Information: Do not allow run-off from fire fighting to enter drains or water courses.

Reference to Other Sections

Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not get in eyes, on skin, or on clothing. Do not breathe vapor, mist or spray. If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

For Non-Emergency Personnel

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

Emergency Procedures: Evacuate unnecessary personnel.

For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Ventilate area. 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.

Environmental Precautions

Prevent entry to sewers and public waters. Avoid release to the environment.

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.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

Reference to Other Sections

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

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling

Additional Hazards When Processed: Accidental injection may cause pain and swelling at the injection site. Sharps should be handled appropriately to minimize risk of accidents. Material may be biologically contaminated with pathogenic organisms during use.

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. Do not get in eyes, on skin, or on clothing. Do not breathe vapors, mist, spray.

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

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 locked up/in a secure area.

Incompatible Materials: Explosives. Peroxides. Strong acids, strong bases, strong oxidizers. Self-reactive substances.

Storage Temperature: 2 – 8 °C (35.6 - 46.4 °F)

Specific End Use(s)

Treatment of invasive aspergillosis and prophylaxis of invasive Aspergillus and Candida infections

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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.

Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH OEL Ceiling [ppm]	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA OSHA	OSHA PEL (Ceiling)	7 mg/m ³
USA OSHA	OSHA PEL C [ppm]	5 ppm
USA NIOSH	NIOSH REL (Ceiling)	7 mg/m ³
USA NIOSH	NIOSH REL C [ppm]	5 ppm

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USA IDLH	IDLH [ppm]	50 ppm
Alberta	OEL C	3 mg/m ³
Alberta	OEL Ceiling [ppm]	2 ppm
British Columbia	OEL Ceiling [ppm]	2 ppm
Manitoba	OEL Ceiling [ppm]	2 ppm
New Brunswick	OEL C	7.5 mg/m ³
New Brunswick	OEL Ceiling [ppm]	5 ppm
Newfoundland & Labrador	OEL Ceiling [ppm]	2 ppm
Nova Scotia	OEL Ceiling [ppm]	2 ppm
Nunavut	OEL Ceiling [ppm]	2 ppm
Northwest Territories	OEL Ceiling [ppm]	2 ppm
Ontario	OEL Ceiling [ppm]	2 ppm
Prince Edward Island	OEL Ceiling [ppm]	2 ppm
Québec	Plafond (OEL Ceiling) [ppm]	2 ppm
Saskatchewan	OEL Ceiling [ppm]	2 ppm
Yukon	OEL C	7 mg/m ³
Yukon	OEL Ceiling [ppm]	5 ppm
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

Exposure Controls

Appropriate Engineering Controls: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

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



Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical safety goggles.

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.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: No data available
Odor	: No data available
Odor Threshold	: No data available
pH	: 2.6
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	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

SECTION 10: STABILITY AND REACTIVITY

Reactivity:

Hazardous reactions will not occur under normal conditions.

Chemical Stability:

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

Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

Conditions to Avoid:

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

Incompatible Materials:

Explosives. Peroxides. Strong acids, strong bases, strong oxidizers. Self-reactive substances.

Hazardous Decomposition Products:

Thermal decomposition may produce: Carbon oxides (CO, CO₂). Chlorides. Sodium oxides. Fluorine compounds. Nitrogen oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Toxicological Effects - Product

Acute Toxicity (Oral): Not classified

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

LD50 and LC50 Data:

No additional information available

Skin Corrosion/Irritation: Not classified

pH: 2.6

Eye Damage/Irritation: Not classified

pH: 2.6

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 (adrenal glands, liver) through prolonged or repeated exposure.

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Reproductive Toxicity: Suspected of damaging fertility or the unborn child.

Specific Target Organ Toxicity (Single Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Suspected of damaging fertility or the unborn child. Causes damage to organs (adrenal glands) through prolonged or repeated exposure. Repeated and prolonged exposure may cause an allergic skin reaction.

Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Posaconazole (171228-49-2)	
LD50 Oral Rat	> 300 mg/kg
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate (6381-92-6)	
LD50 Oral Rat	2000 mg/kg
Hydrochloric acid (7647-01-0)	
LD50 Oral Rat	238 – 277 mg/kg
LD50 Dermal Rabbit	> 5010 mg/kg
LC50 Inhalation Rat	1.68 mg/l (Exposure time: 1 h)
Sodium hydroxide (1310-73-2)	
LD50 Oral Rat	325 mg/kg
Hydrochloric acid (7647-01-0)	
IARC Group	3

SECTION 12: ECOLOGICAL INFORMATION

Toxicity

Ecology - General: Harmful to aquatic life with long lasting effects.

Hydrochloric acid (7647-01-0)	
LC50 Fish 1	7.45 mg/l (Species: Oncorhynchus mykiss - Exposure time: 96h)
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

Persistence and Degradability

Posaconazole Injection	
Persistence and Degradability	May cause long-term adverse effects in the environment.

Bioaccumulative Potential

Posaconazole Injection	
Bioaccumulative Potential	Not established.

Mobility in Soil

No additional information available

Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

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. This material is hazardous to the aquatic environment. Keep out of sewers and waterways.

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.

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In Accordance with DOT

Not regulated for transport

In Accordance with IMDG

Not regulated for transport

In Accordance with IATA

Not regulated for transport

In Accordance with TDG

Not regulated for transport

SECTION 15: REGULATORY INFORMATION

US Federal Regulations

Posaconazole Injection	
SARA Section 311/312 Hazard Classes	Health hazard - Reproductive toxicity Health hazard - Specific target organ toxicity (single or repeated exposure) Health hazard - Respiratory or skin sensitization
Hydrochloric acid (7647-01-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active Listed on the United States SARA Section 302 Subject to reporting requirements of United States SARA Section 313	
CERCLA RQ	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
SARA Section 313 - Emission Reporting	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)
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	

US State Regulations

Hydrochloric acid (7647-01-0)
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
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

Canadian Regulations

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate (6381-92-6)
Listed on the Canadian DSL (Domestic Substances List)
Hydrochloric acid (7647-01-0)
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)

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

Date of Preparation or Latest Revision : 10/05/2023

Revision

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.

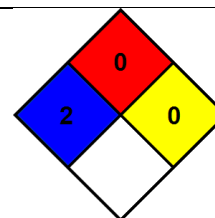
GHS Full Text Phrases:

H290	May be corrosive to metals
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H319	Causes serious eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation
H361	Suspected of damaging fertility or the unborn child
H370	Causes damage to organs
H372	Causes damage to organs through prolonged or repeated exposure
H373	May cause damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life
H401	Toxic to aquatic life
H402	Harmful to aquatic life
H410	Very toxic to aquatic life with long lasting effects
H412	Harmful to aquatic life with long lasting effects

NFPA Health Hazard : 2 - Materials that, under emergency conditions, can cause temporary incapacitation or residual injury.

NFPA Fire Hazard : 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.

NFPA Reactivity Hazard : 0 - Material that in themselves are normally stable, even under fire conditions.



HMIS III Rating

Health : 2 Moderate Hazard - Temporary or minor injury may occur
* Chronic - Chronic (long-term) health effects may result from repeated overexposure

Flammability : 0 Minimal Hazard

Physical : 0 Minimal 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)