



# ADALIMUMAB (adalimumab-aacf) Injection For Subcutaneous Use

## Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Date of Issue: 10/26/2023

Version: 1.0

### SECTION 1: IDENTIFICATION

#### 1.1. Product Identifier

**Product Form:** Mixture

**Product Name:** ADALIMUMAB (adalimumab-aacf) Injection For Subcutaneous Use

#### 1.2. Intended Use of the Product

ADALIMUMAB is indicated for Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Crohn's Disease, Ulcerative Colitis (adults only), and Plaque Psoriasis

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

##### Manufacturer

Fresenius Kabi USA, LLC

Three Corporate Drive

Lake Zurich, IL 60047 USA

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/>

##### USA Distributor

Fresenius Kabi USA, LLC

Three Corporate Drive

Lake Zurich, IL 60047 USA

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/>

#### 1.4. Emergency Telephone Number

**Emergency Number** : VelocityEHS

(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

Not classified

#### 2.2. Label Elements

##### GHS-US/CA Labeling

No labeling applicable according to 29 CFR 1910.1200 and the Hazardous Products Regulations (HPR) SOR/2015-17.

#### 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
Water	water / AQUA	(CAS-No.) 7732-18-5	87.7	Not classified
Trehalose dihydrate	trehalose dihydrate / D-(+)-Trehalose dihydrate / Trehalose, dihydrate / .alpha.-D-Glucopyranosyl .alpha.-D-glucopyranoside dihydrate / .alpha.-D-Glucopyranoside, .alpha.-D-glucopyranosyl, dihydrate	(CAS-No.) 6138-23-4	6.85	Combustible Dust
Adalimumab-aacf	Immunoglobulin G1, anti-(human tumor necrosis factor) (human monoclonal D2E7 heavy chain), disulfide with human monoclonal D2E7 light chain, dimer / adalimumab	(CAS-No.) 331731-18-1	5	Not classified

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Sodium chloride	Salt / SEA SALT / Sodium salt of hydrochloric acid / SODIUM CHLORIDE / Sodium chloride (NaCl) / Sea salt	(CAS-No.) 7647-14-5	0.29	Not classified
Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives	Sorbitan monooleate, ethoxylated (1-6.5 moles ethoxylated) / POLYSORBATE 80 / POLYSORBATE 81 / PEG-6 sorbitan oleate / PEG-40 sorbitan oleate / PEG-20 sorbitan oleate / PEG-40 SORBITAN OLEATE / PEG-6 SORBITAN OLEATE / PEG sorbitan oleate / PEG-20 SORBITAN OLEATE / Polyethylene glycol sorbitan monooleate / Polyoxyethylene (20) sorbitan monooleate / PEG-3 SORBITAN OLEATE / Polyoxyethylene (5) sorbitan monooleate / Sorbitan, mono-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives, (Z)- / Sorbitan monooleate, ethoxylated / Polysorbate 80 / Polyoxyethylene sorbitan monooleate	(CAS-No.) 9005-65-6	0.1	Not classified
Acetic acid	ACETIC ACID / Acetic acid solution / Vinegar acid / Ethylic acid / Ethanoic acid / Acetic acid, glacial / Acetic acid ...%	(CAS-No.) 64-19-7	0.06	Flam. Liq. 3, H226 Met. Corr. 1, H290 Acute Tox. 4 (Inhalation:vapor), H332 Skin Corr. 1A, H314 Eye Dam. 1, H318 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

### 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). 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. Drench affected area with water for at least 5 minutes. Obtain medical attention if irritation develops or persists.

**Eye Contact:** Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

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

### 4.2. Most Important Symptoms and Effects Both Acute and Delayed

**General:** Not expected to present a significant hazard under anticipated conditions of normal use.

**Inhalation:** Prolonged exposure may cause irritation.

**Skin Contact:** Prolonged exposure may cause skin irritation.

**Eye Contact:** May cause slight irritation to eyes.

**Ingestion:** Ingestion may cause adverse effects.

**Chronic Symptoms:** None expected under normal conditions of use.

### 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:** Use extinguishing media suitable for surrounding type of fire.

**Unsuitable Extinguishing Media:** None known.

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### 5.2. Special Hazards Arising From the Substance or Mixture

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

**Explosion Hazard:** Product is not explosive.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

### 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, CO<sub>2</sub>).

### 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:** Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

#### 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.

### 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.

**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.

### 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:** Materials used during injections may be biologically contaminated with pathogenic organisms. Accidental injection may cause pain and swelling at the injection site. Sharps should be handled appropriately to minimize risk of accidents.

**Precautions for Safe Handling:** Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

**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.

**Incompatible Materials:** Strong acids, strong bases, strong oxidizers.

**Storage Temperature:** 2-8 °C (36-46 °F). Do not freeze. Can be stored at room temperature up to a maximum of 77°F (25°C) for a period of up to 28 days.

### 7.3. Specific End Use(s)

ADALIMUMAB is indicated for Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Crohn's Disease, Ulcerative Colitis (adults only), and Plaque Psoriasis

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters

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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.

<b>Acetic acid (64-19-7)</b>		
<b>USA ACGIH</b>	ACGIH OEL TWA [ppm]	10 ppm
<b>USA ACGIH</b>	ACGIH OEL STEL [ppm]	15 ppm
<b>USA OSHA</b>	OSHA PEL (TWA) [1]	25 mg/m <sup>3</sup>
<b>USA OSHA</b>	OSHA PEL (TWA) [2]	10 ppm
<b>USA NIOSH</b>	NIOSH REL (TWA)	25 mg/m <sup>3</sup>
<b>USA NIOSH</b>	NIOSH REL TWA [ppm]	10 ppm
<b>USA NIOSH</b>	NIOSH REL (STEL)	37 mg/m <sup>3</sup>
<b>USA NIOSH</b>	NIOSH REL STEL [ppm]	15 ppm
<b>USA IDLH</b>	IDLH [ppm]	50 ppm
<b>Alberta</b>	OEL STEL	37 mg/m <sup>3</sup>
<b>Alberta</b>	OEL STEL [ppm]	15 ppm
<b>Alberta</b>	OEL TWA	25 mg/m <sup>3</sup>
<b>Alberta</b>	OEL TWA [ppm]	10 ppm
<b>British Columbia</b>	OEL STEL [ppm]	15 ppm
<b>British Columbia</b>	OEL TWA [ppm]	10 ppm
<b>Manitoba</b>	OEL STEL [ppm]	15 ppm
<b>Manitoba</b>	OEL TWA [ppm]	10 ppm
<b>New Brunswick</b>	OEL STEL	37 mg/m <sup>3</sup>
<b>New Brunswick</b>	OEL STEL [ppm]	15 ppm
<b>New Brunswick</b>	OEL TWA	25 mg/m <sup>3</sup>
<b>New Brunswick</b>	OEL TWA [ppm]	10 ppm
<b>Newfoundland &amp; Labrador</b>	OEL STEL [ppm]	15 ppm
<b>Newfoundland &amp; Labrador</b>	OEL TWA [ppm]	10 ppm
<b>Nova Scotia</b>	OEL STEL [ppm]	15 ppm
<b>Nova Scotia</b>	OEL TWA [ppm]	10 ppm
<b>Nunavut</b>	OEL STEL [ppm]	15 ppm
<b>Nunavut</b>	OEL TWA [ppm]	10 ppm
<b>Northwest Territories</b>	OEL STEL [ppm]	15 ppm
<b>Northwest Territories</b>	OEL TWA [ppm]	10 ppm
<b>Ontario</b>	OEL STEL [ppm]	15 ppm
<b>Ontario</b>	OEL TWA [ppm]	10 ppm
<b>Prince Edward Island</b>	OEL STEL [ppm]	15 ppm
<b>Prince Edward Island</b>	OEL TWA [ppm]	10 ppm
<b>Québec</b>	VECD (OEL STEL)	37 mg/m <sup>3</sup>
<b>Québec</b>	VECD (OEL STEL) [ppm]	15 ppm
<b>Québec</b>	VEMP (OEL TWA)	25 mg/m <sup>3</sup>
<b>Québec</b>	VEMP (OEL TWA) [ppm]	10 ppm
<b>Saskatchewan</b>	OEL STEL [ppm]	15 ppm
<b>Saskatchewan</b>	OEL TWA [ppm]	10 ppm
<b>Yukon</b>	OEL STEL	43 mg/m <sup>3</sup>
<b>Yukon</b>	OEL STEL [ppm]	25 ppm
<b>Yukon</b>	OEL TWA	25 mg/m <sup>3</sup>
<b>Yukon</b>	OEL TWA [ppm]	10 ppm

## 8.2. 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.

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**Personal Protective Equipment:** Gloves. Protective clothing. Protective goggles or glasses.



**Materials for Protective Clothing:** Chemically resistant materials and fabrics.

**Hand Protection:** Wear protective gloves.

**Eye and Face Protection:** Chemical safety goggles or safety glasses with side shields.

**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	: Liquid
Appearance	: Not specified
Odor	: Not specified
Odor Threshold	: No data available
pH	: 5.2
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: 0 °C (32 °F)
Boiling Point	: 100 °C (212 °F)
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

### 10.1. Reactivity:

Hazardous reactions will not occur under normal conditions.

### 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.

### 10.5. Incompatible Materials:

Strong acids, strong bases, strong oxidizers.

### 10.6. Hazardous Decomposition Products:

Thermal decomposition may produce: Carbon oxides (CO, CO<sub>2</sub>).

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on Toxicological Effects - Product

**Acute Toxicity (Oral):** Not classified

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**Acute Toxicity (Dermal):** Not classified

**Acute Toxicity (Inhalation):** Not classified

### LD50 and LC50 Data:

No additional information available

**Skin Corrosion/Irritation:** Not classified

**pH:** 5.2

**Eye Damage/Irritation:** Not classified

**pH:** 5.2

**Respiratory or Skin Sensitization:** Not classified

**Germ Cell Mutagenicity:** Not classified

**Carcinogenicity:** Not classified

**Specific Target Organ Toxicity (Repeated Exposure):** Not classified

**Reproductive Toxicity:** Not classified

**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:** Prolonged exposure may cause skin irritation.

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

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

**Chronic Symptoms:** None expected under normal conditions of use.

**Potential Adverse human health effects and symptoms:** Based on available data, the classification criteria are not met.

## 11.2. Information on Toxicological Effects - Ingredient(s)

### LD50 and LC50 Data:

<b>Acetic acid (64-19-7)</b>	
LD50 Oral Rat	3310 mg/kg
LC50 Inhalation Rat	11.4 mg/l/4h
<b>Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives (9005-65-6)</b>	
LD50 Oral Rat	37.605 g/kg
<b>Sodium chloride (7647-14-5)</b>	
LD50 Oral Rat	3550 mg/kg (Species: Wistar)
LD50 Dermal Rabbit	> 10000 mg/kg (Species: New Zealand White)
LC50 Inhalation Rat	> 42 mg/l (Exposure time: 1 h)

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

**Ecology - General:** Not classified.

<b>Acetic acid (64-19-7)</b>	
LC50 Fish 1	79 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 - Crustacea [1]	65 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
LC50 Fish 2	75 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
<b>Sodium chloride (7647-14-5)</b>	
LC50 Fish 1	5560 (5560 – 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 - Crustacea [1]	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 Fish 2	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 - Crustacea [2]	340.7 (340.7 – 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
NOEC Chronic Fish	252 mg/l (Species: Pimephales promelas)

### 12.2. Persistence and Degradability

**ADALIMUMAB (adalimumab-aacf) Injection For Subcutaneous Use**

**Persistence and Degradability** Not established.

### 12.3. Bioaccumulative Potential

**ADALIMUMAB (adalimumab-aacf) Injection For Subcutaneous Use**

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<b>Bioaccumulative Potential</b>	Not established.
<b>Acetic acid (64-19-7)</b>	
<b>Partition coefficient n-octanol/water (Log Pow)</b>	-0.17 at 25 °C (at pH 7)
<b>Sodium chloride (7647-14-5)</b>	
<b>BCF Fish 1</b>	(no bioaccumulation)

### 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 Treatment Methods:** Product contaminated with biological materials should preferably be incinerated.

**Sewage Disposal Recommendations:** Do not dispose of waste into sewer.

**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

Not regulated for transport

### 14.2. In Accordance with IMDG

Not regulated for transport

### 14.3. In Accordance with IATA

Not regulated for transport

### 14.4. In Accordance with TDG

Not regulated for transport

## SECTION 15: REGULATORY INFORMATION

### 15.1. US Federal Regulations

<b>Acetic acid (64-19-7)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
<b>CERCLA RQ</b>	5000 lb
<b>Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives (9005-65-6)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
<b>EPA TSCA Regulatory Flag</b>	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).
<b>Sodium chloride (7647-14-5)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
<b>Water (7732-18-5)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	

### 15.2. US State Regulations

<b>Acetic acid (64-19-7)</b>
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

<b>Acetic acid (64-19-7)</b>
Listed on the Canadian DSL (Domestic Substances List)

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### Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives (9005-65-6)

Listed on the Canadian DSL (Domestic Substances List)

### Sodium chloride (7647-14-5)

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** : 10/26/2023

**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:

H226	Flammable liquid and vapor
H290	May be corrosive to metals
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H332	Harmful if inhaled
H402	Harmful to aquatic life

**NFPA Health Hazard** : 0 - Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials.

**NFPA Fire Hazard** : 1 - Materials that must be preheated before ignition can occur.

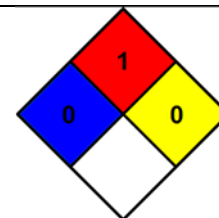
**NFPA Reactivity Hazard** : 0 - Material that in themselves are normally stable, even under fire conditions.

HMIS III Rating

**Health** : 0 Minimal Hazard - No significant risk to health

**Flammability** : 1 Slight 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)