Dalbavancin for Injection

Safety Data Sheet

According To Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules And Regulations And According To The Hazardous Products Regulation (December 15, 2022).

Revision Date: Date of Issue: 06/18/2025 Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Dalbavancin for Injection

1.2 Recommended Use and Restrictions on Use

Use Of The Substance/Mixture : Injection (I.V.)

Restrictions On Use : No additional information available

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/

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

Skin sensitization, Category 1B	H317
Reproductive toxicity, Category 2	H361
Reproductive toxicity, Additional category for effects on or via lactation	H362
Combustible Dust	

2.2. Label Elements

GHS-US/CA Labeling

Hazard Pictograms (GHS-US/CA) :

GHS07 GHS08

Signal Word (GHS-US/CA) : Warning

Hazard Statements (GHS-US/CA) : H Comb Dust - May form combustible dust concentrations in air.
H317 - May cause an allergic skin reaction.
H361 - Suspected of damaging fertility or the unborn child.
H362 - May cause harm to breast-fed children.

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 dust.
P263 - Avoid contact during pregnancy and while nursing.
P264 - Wash hands, forearms and face 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.
P280 - Wear protective gloves, protective clothing, eye protection.
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.
P308+P313 - IF exposed or concerned: Get medical advice or attention.
P321 - Specific treatment (Section 4 of this Safety Data Sheet).

P333+P313 - If skin irritation or rash occurs: Get medical advice or attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P405 - Store locked up.
P501 - Dispose of contents and/or container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulations.

Supplemental Information : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Proper grounding procedures to avoid static electricity should be followed. Prevent dust accumulation (to minimize explosion hazard). Avoid generating dust.

2.3 Hazards associated with known or reasonably anticipated uses

If this product is used in unforeseeable chemical processes and not used as intended or reasonable, the hazards listed in Section 2.3 cannot cover all chemistries. Therefore, a Process Hazard Analysis (PHA) or other hazard assessment for additional specific end uses should be performed to ensure that hazards are fully understood, and adequate safety measures are in place. See Section 10 for relevant reactivity and stability information

2.4. Other Hazards

It is strongly recommended that pregnant workers not be exposed to this product. 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
Dalbavancin Hydrochloride	2-deoxy-1-O-[(3S,15R,18R,34R,35S,38S,48R,50aR)-5,31-dichloro-38- {[3-(dimethylamino)propyl] carbamoyl}-6,11,34,40,44-pentahydroxy-42-(α-D-mannopyranosyloxy)-15-(methylamino)-2,16,36,50,51,59-hexaoxo-2,3,16,17,18,19,35,36,37,38,48,49,50,50a-tetradecahydro-1H,15H,34H-20,23:30, 33-dietheno-3,18:35,48-bis(iminomethano) 4,8:10,14:25,28:43,47-tetrametheno[1,14,6,22] dioxadiazacyclooctacosino[4,5-m][10,2,16] benzoxadiazacyclotetracosin-56-yl]-2-[(10-methylundecanoyl)amino]-βD-glucopyranuronic acid	(CAS-No.) 2227366-51-8	1 – 5	Skin Sens. 1B, H317 Repr. 2, H361 Lact., H362
D-Mannitol	1,2,3,4,5,6-Hexanehexol / Mannitol, D- / Hexanehexol / MANNITOL / Mannite / Mannitol	(CAS-No.) 69-65-8	0.5 – 1.5	Combustible Dust
Lactose, monohydrate	D-Glucose, 4-O-.beta.-D-galactopyranosyl-, monohydrate / Lactose monohydrate / D-Glucose. 4-.ortho.-.beta.-D-galactopyranosyl / 4-O-.beta.-D-Glucose monohydrate / D-Glucose. 4-.ortho.-.beta.-D-galactopyranosyl-, hydrate (1:1) / lactose monohydrate	(CAS-No.) 64044-51-5	0.5 – 1.5	Combustible Dust

Hydrochloric acid	Hydrogen chloride / Muriatic acid / HYDROCHLORIC ACID / Hydrochloric acid, anhydrous	(CAS-No.) 7647-01-0	≤ 1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 1, H370 Aquatic Acute 2, H401
Sodium hydroxide	Caustic soda / Sodium hydroxide (Na(OH)) / SODIUM HYDROXIDE / LYE / Lye solution	(CAS-No.) 1310-73-2	≤ 1	Met. Corr. 1, H290 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Skin Corr. 1, H314 Eye Dam. 1, H318 STOT SE 1, H370 Aquatic Acute 3, H402

Full text of H-statements: see section 16

*The actual concentration of ingredient(s) is withheld as a trade secret in accordance with the Hazardous Products Regulations (HPR) SOR/2022-272 and 29 CFR 1910.1200. 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: If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens. Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

Inhalation: Using proper respiratory protection, immediately move the exposed person to fresh air. Encourage exposed person to cough, spit out, and blow nose to remove dust. 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.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: Suspected of damaging fertility or the unborn child. Skin sensitization. May cause harm to breast-fed children.

Inhalation: Prolonged exposure may cause irritation.

Skin Contact: May cause an allergic skin reaction.

Eye Contact: Eye contact with dust may cause mechanical irritation.

Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Suspected of damaging fertility or the unborn child. Repeated and prolonged exposure may cause an allergic skin reaction.

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 appropriate for surrounding fire.

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: Combustible Dust.

Explosion Hazard: Dust explosion hazard in air.

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_2). Hydrogen chloride. Nitrogen oxides. Unidentified hydrocarbons.

Other Information: Risk of dust explosion.

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: If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens. Remove ignition sources. Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking. Do not get in eyes, on skin, or on clothing. Do not breathe dust. Avoid generating dust.

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: Remove ignition sources. Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams. Avoid generation of dust during clean-up of spills.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Vacuum clean-up is preferred. If sweeping is required use water mist as a dust suppressant. Use explosion proof vacuum during cleanup, with appropriate filter. Do not mix with other materials. Use only non-sparking tools. 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: Accidental injection may cause pain and swelling at the injection site. Sharps should be handled appropriately to minimize risk of accidents. Materials used during injections may be biologically contaminated with pathogenic organisms. Accumulation and dispersion of dust with an ignition source can cause a combustible dust explosion. Keep dust levels to a minimum and follow applicable regulations.

Precautions for Safe Handling: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get in eyes, on skin, or on clothing. Do not breathe dust. Avoid contact during pregnancy/while nursing. Avoid creating or spreading dust. Keep away from heat, sparks, open flames, and hot surfaces. No smoking. Contaminated sharps should be handled with care and discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a syringe disposal program. In hospital and workplace settings, contaminated sharps are to be handled in accordance with established protocols. 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. Avoid creating or spreading dust. Use explosion-proof electrical, ventilating, lighting equipment. Proper grounding procedures to avoid static electricity should be followed.

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: Strong acids, strong bases, strong oxidizers.

Storage Temperature: 25 °C (77 °F); Excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

7.3. Specific End Use(s)

Injection (I.V.)

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.

Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH® TLV® C	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA OSHA	OSHA PEL C	7 mg/m³
USA OSHA	OSHA PEL C	5 ppm
USA NIOSH	NIOSH REL C	7 mg/m³
USA NIOSH	NIOSH REL C	5 ppm
USA IDLH	IDLH	50 ppm
Alberta	OEL C	3 mg/m³
Alberta	OEL C	2 ppm
British Columbia	OEL C	2 ppm
Manitoba	OEL C	2 ppm
New Brunswick	OEL C	2 ppm
Newfoundland & Labrador	OEL C	2 ppm
Nova Scotia	OEL C	2 ppm
Nunavut	OEL C	2 ppm
Northwest Territories	OEL C	2 ppm
Ontario	OEL C	2 ppm
Prince Edward Island	OEL C	2 ppm
Québec	Plafond (OEL C)	2 ppm
Saskatchewan	OEL C	2 ppm
Yukon	OEL C	7 mg/m³
Yukon	OEL C	5 ppm

Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH® TLV® C	2 mg/m³
USA OSHA	OSHA PEL TWA	2 mg/m³
USA NIOSH	NIOSH REL C	2 mg/m³
USA IDLH	IDLH	10 mg/m³
Alberta	OEL C	2 mg/m³
British Columbia	OEL C	2 mg/m³
Manitoba	OEL C	2 mg/m³
New Brunswick	OEL C	2 mg/m³
Newfoundland & Labrador	OEL C	2 mg/m³
Nova Scotia	OEL C	2 mg/m³
Nunavut	OEL C	2 mg/m³
Northwest Territories	OEL C	2 mg/m³
Ontario	OEL C	2 mg/m³
Prince Edward Island	OEL C	2 mg/m³
Québec	Plafond (OEL C)	2 mg/m³
Saskatchewan	OEL C	2 mg/m³
Yukon	OEL C	2 mg/m³

Particulates not otherwise classified (PNOC)		
USA ACGIH	ACGIH® TLV® TWA	3 mg/m³ Respirable fraction 10 mg/m³ Total Dust
USA OSHA	OSHA PEL TWA	5 mg/m³ Respirable fraction 15 mg/m³ Total Dust
USA OSHA	OSHA PEL TWA	15 mppcf Respirable fraction 50 mppcf Total dust See 29 CFR 1910.1000 Table Z-3

Alberta	OEL TWA	10 mg/m³ (total) 3 mg/m³ (respirable)
British Columbia	OEL TWA	10 mg/m³ (including nuisance dusts-total dust) 3 mg/m³ (including nuisance dusts-respirable fraction)
Manitoba	OEL TWA	10 mg/m³ (inhalable particles, recommended) 3 mg/m³ (respirable particles, recommended)
New Brunswick	OEL TWA	10 mg/m³ (recommended-inhalable particles) 3 mg/m³ (recommended-respirable particles)
Newfoundland & Labrador	OEL TWA	10 mg/m³ (inhalable particles, recommended) 3 mg/m³ (respirable particles, recommended)
Nova Scotia	OEL TWA	10 mg/m³ (inhalable particles, recommended) 3 mg/m³ (respirable particles, recommended)
Nunavut	OEL STEL	20 mg/m³ (insoluble or poorly soluble-inhalable fraction) 6 mg/m³ (insoluble or poorly soluble-respirable fraction)
Nunavut	OEL TWA	10 mg/m³ (insoluble or poorly soluble-inhalable fraction) 3 mg/m³ (insoluble or poorly soluble-respirable fraction)
Northwest Territories	OEL STEL	20 mg/m³ (insoluble or poorly soluble-inhalable fraction) 6 mg/m³ (insoluble or poorly soluble-respirable fraction)
Northwest Territories	OEL TWA	10 mg/m³ (insoluble or poorly soluble-inhalable fraction) 3 mg/m³ (insoluble or poorly soluble-respirable fraction)
Ontario	OEL TWAEV	10 mg/m³ (inhalable fraction) 3 mg/m³ (respirable fraction)
Prince Edward Island	OEL TWA	10 mg/m³ (inhalable particles, recommended) 3 mg/m³ (respirable particles, recommended)
Québec	VEMP (OEL TWAEV)	10 mg/m³ (including dust, inert or nuisance particulates-inhalable particulates) 3 mg/m³ (including dust, inert or nuisance particulates-respirable particulates)
Saskatchewan	OEL STEL	20 mg/m³ (insoluble or poorly soluble-inhalable fraction) 6 mg/m³ (insoluble or poorly soluble-respirable fraction)
Saskatchewan	OEL TWA	10 mg/m³ (insoluble or poorly soluble-inhalable fraction) 3 mg/m³ (insoluble or poorly soluble-respirable fraction)

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. Proper grounding procedures to avoid static electricity should be followed. Use explosion-proof equipment. Use local exhaust or general dilution ventilation or other suppression methods to maintain dust levels below exposure limits. Power equipment should be equipped with proper dust collection devices. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment.

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 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.

Consumer Exposure Controls: Avoid contact during pregnancy/while nursing

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
Color	:	White to tan
Odor	:	Odorless
Odor Threshold	:	No data available
pH	:	No data available
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)	:	No data available
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, Kinematic	:	No data available
Particle characteristics	:	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, Including those Associated with Foreseeable Emergencies:

Hazardous polymerization will not occur.

10.4. Conditions to Avoid:

Direct sunlight, extremely high or low temperatures, and incompatible materials. Avoid creating or spreading dust. Sparks, heat, open flame and other sources of ignition. Dust accumulation (to minimize explosion hazard).

10.5. Incompatible Materials:

Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products:

Thermal decomposition may produce: Carbon oxides (CO, CO_2). Hydrogen chloride. Nitrogen oxides. Hydrocarbons.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Likely routes of exposure: Dermal, Eye Contact, Inhalation, Oral.

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.

Eye Damage/Irritation: Not classified.

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

Germ Cell Mutagenicity: Not classified.

Carcinogenicity: Not classified.

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

Reproductive Toxicity: Suspected of damaging fertility or the unborn child. May cause harm to breast-fed children.

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: Eye contact with dust may cause mechanical irritation.

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

Chronic Symptoms: Suspected of damaging fertility or the unborn child. Repeated and prolonged exposure may cause an allergic skin reaction.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

D-Mannitol (69-65-8)	
LD50 Oral Rat	13500 mg/kg

Hydrochloric acid (7647-01-0)	
LD50 Oral Rat	238 – 277 mg/kg (Source: JAPAN_GHS)
LD50 Dermal Rabbit	> 5010 mg/kg (Source: JAPAN_GHS)
LC50 Inhalation Rat	1.68 mg/l (Exposure time: 1 h Source: JAPAN_GHS)

Sodium hydroxide (1310-73-2)	
LD50 Oral Rat	325 mg/kg
LD50 Dermal Rabbit	1350 mg/kg (Source: NLM_HSDB)

Hydrochloric acid (7647-01-0)	
IARC Group	3

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

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

12.2. Persistence and Degradability

Dalbavancin for Injection	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Dalbavancin for Injection	
Bioaccumulative Potential	Not established.

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

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

Dalbavancin for Injection	
SARA Section 311/312 Hazard Classes	Health hazard - Reproductive toxicity Health hazard - Respiratory or skin sensitization Physical hazard - Combustible dust

D-Mannitol (69-65-8)
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

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

15.2. 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

15.3. Canadian Regulations

D-Mannitol (69-65-8)
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)

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

Date of Preparation or Latest Revision : 06/18/2025

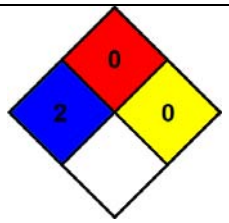
Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2022-272.

GHS Full Text Phrases:	
H290	May be corrosive to metals
H302	Harmful if swallowed
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H361	Suspected of damaging fertility or the unborn child
H362	May cause harm to breast-fed children
H370	Causes damage to organs.
H401	Toxic to aquatic life
H402	Harmful to aquatic life

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

Glossary of Data Source Abbreviations

ATSDR: Agency for Toxic Substances and Disease Registry (U.S. Department of Health and Human Services)
AU_WES: Australia WES
CHEMVIEW: ChemView (U.S. Environmental Protection Agency)
EC_RAR: European Commission Renewal Assessment Report
EC_SCOEL: European Commission Scientific Committee on Occupational Exposure Limits
ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals Reports
ECHA_API: European Chemicals Agency API
ECHA_RAC: ECHA Committee for Risk Assessment
EFSA: European Food Safety Authority
EPA: U.S. Environmental Protection Agency
EPA_AEGL: Acute Exposure Guideline Levels (U.S. Environmental Protection Agency)
EPA_FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act Reregistration Eligibility Decision (U.S. Environmental Protection Agency)
EPA_HPV: High Production Volume Chemicals (U.S. Environmental Protection Agency)
EPA_TRED: Risk Assessment for Tolerance Reassessment Eligibility Decision (U.S. Environmental Protection Agency)
EU_CLH: European Union Harmonised Classification and Labelling Proposal
EU_RAR: European Union Risk Assessment Report
FOOD_JOURN: Food Research Journal (1956)
IARC: The International Agency for Research on Cancer
IDLH: National Institute for Occupational Health and Safety Immediately Dangerous to Life or Health Value Profiles
IUCLID: International Uniform Chemical Information Database
JAPAN_GHS: Japan GHS Basis for Classification Data
JP_J-CHECK: Japan J-Check
KR_NIER: South Korea National Institute of Environmental Research Evaluations
NICNAS: Australia National Industrial Chemicals Notification and Assessment Scheme
NIOSH: National Institute for Occupational Health and Safety (U.S. Department of Health and Human Services)
NLM_CIP: National Library of Medicine ChemID plus database
NLM_HSDB: National Library of Medicine Hazardous Substance Data Bank
NLM_PUBMED: National Library of Medicine PubMed database
NTP: National Toxicology Program
NZ_CCID: New Zealand Chemical Classification and Information Database
OECD_EHSP: Environment, Health, and Safety Publication (Organisation for Economic Co-operation and Development)
OECD_SIDS: Screening Information Data Sets (Organisation for Economic Co-operation and Development)
WHO: World Health Organization

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.

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