



# Melphalan Hydrochloride for Injection

## SAFETY DATA SHEET

North America GHS

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations & the Hazardous Products Regulation (February 11, 2015) & NORMA Oficial Mexicana NOM-018-STPS-2015

### 1. IDENTIFICATION

#### Product identifier

**Product Name:** Melphalan Hydrochloride for Injection

**Synonyms:** Melphalan Hydrochloride for Injection, 50 mg/vial; Melphalan HCl for Injection; Melphalan Hydrochloride for Injection Kit

#### Other means of identification

**Other Information:** No other information

#### Recommended use of the chemical and restrictions on use

**Recommended Use:** Pharmaceutical. Use only as directed.

The intent of this safety data sheet (SDS) is to provide safety information for occupational handling of this product. This information may not be relevant for medical use of this product. Patients/ consumers should consult the package insert/ product label/ physician/ pharmacist for information regarding the usage of this product. For information on the ingredients used in this product, refer to the appropriate SDS for each ingredient.

**Uses advised against:** No information available.

#### Details of the supplier of the safety data sheet

Mylan Inc.

Robert J. Coury Global Center

1000 Mylan Blvd.

Canonsburg, PA 15317, USA

+1.724.514.1800

**Contact e-mail:**

[SDScontact@mylan.com](mailto:SDScontact@mylan.com)

#### Emergency telephone number

**Emergency Telephone:**

24 hr. Emergency Contact ChemTel

**International:** +1-813-248-0585

**US & Canada:** 1-800-255-3924

**Mexico:** 800-099-0731

#### Other Contact Information

**FDA Adverse Events Reporting**

**Number:**

For reporting adverse health events call:

+1 877-446-3679

### 2. HAZARDS IDENTIFICATION

**Patients/Consumers:** Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions

#### Classification

Acute toxicity - Oral, Category 2

Respiratory sensitization, Category 1B

Skin sensitization, Category 1B

Germ cell mutagenicity, Category 1B

Carcinogenicity, Category 1A

Reproductive toxicity, Category 1B

Specific target organ toxicity (repeated exposure), Category 1 ( Bone marrow )

#### Label elements



**Signal word:**

Danger

**Hazard statements:**

H300 - Fatal if swallowed  
 H317 - May cause an allergic skin reaction  
 H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled  
 H340 - May cause genetic defects  
 H350 - May cause cancer  
 H360 - May damage fertility or the unborn child  
 H372 - Causes damage to organs through prolonged or repeated exposure

**Precautionary Statements - Prevention:**

Obtain special instructions before use  
 Do not handle until all safety precautions have been read and understood  
 Wear protective gloves/protective clothing/eye protection/face protection  
 Wash face, hands and any exposed skin thoroughly after handling  
 Do not eat, drink or smoke when using this product  
 In case of inadequate ventilation wear respiratory protection  
 Contaminated work clothing must not be allowed out of the workplace  
 Do not breathe dust/fume/gas/mist/vapors/spray

**Precautionary Statements - Response:**

IF exposed or concerned: Get medical advice/attention  
 Specific treatment (see supplemental first aid instructions on this label)

**Skin:**

IF ON SKIN: Wash with plenty of water and soap  
 If skin irritation or rash occurs: Get medical advice/attention  
 Wash contaminated clothing before reuse

**Inhalation:**

IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing  
 If experiencing respiratory symptoms: Call a POISON CENTER or doctor

**Ingestion:**

IF SWALLOWED: Immediately call a POISON CENTER or doctor  
 Rinse mouth

**Precautionary Statements - Storage:**

Store locked up

**Precautionary Statements - Disposal:**

Dispose of contents/container to an approved waste disposal plant

**Other Hazards**

CAUTION: Cytotoxic agent.

**Unknown acute toxicity**

No information available

**3. COMPOSITION/INFORMATION ON INGREDIENTS****Mixture**

Chemical name	CAS No	Weight-%	Hazard statements
Melphalan Hydrochloride	3223-07-2	60 - 80	H300 - Fatal if swallowed H317 - May cause an allergic skin reaction H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled H340 - May cause genetic defects H350 - May cause cancer H360 - May damage fertility or the unborn child H372 - Causes damage to organs through prolonged or repeated exposure

**4. FIRST AID MEASURES****Description of first aid measures**

**General advice:** Immediate medical attention is required. Show this safety data sheet to the doctor in attendance. IF exposed or concerned: Get medical advice/attention.

**Inhalation:** May cause allergic respiratory reaction. If breathing has stopped, give artificial respiration. Get medical attention immediately. Remove to fresh air. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Get immediate medical advice/attention.

**Skin contact:** Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a physician.

**Eye contact:** In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

**Ingestion:** Get immediate medical advice/attention. Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. May produce an allergic reaction.

**Self-protection of the first aider:** Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Avoid contact with skin, eyes or clothing. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Use personal protective equipment as required. See section 8 for more information.

**Most important symptoms and effects, both acute and delayed**

**Symptoms:** May cause adverse effects on the bone marrow and blood-forming system. Leukopenia (reduced blood leukocytes). Anemia. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Coughing and/ or wheezing. Itching. Rashes. Hives. Erythema (skin redness). Edema. Dyspnea (breathing difficulty).

**Chronic symptoms:** May cause adverse reproductive effects - such as birth defect, miscarriages, or infertility. Contains a known or suspected carcinogen. Contains a known or suspected mutagen. May cause damage to the following organs through prolonged or repeated exposure: Bone marrow.

**Indication of any immediate medical attention and special treatment needed**

May cause sensitization in susceptible persons. Treat symptomatically.

## **5. FIRE-FIGHTING MEASURES**

### **Extinguishing media**

**Suitable Extinguishing Media:** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Unsuitable extinguishing media:** None known.

### **Specific hazards arising from the chemical**

**Fire hazard:** Not flammable.

**Explosive hazard:** Not an explosive. Dust can form an explosive mixture with air.

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

**Hazardous combustion products:** Carbon oxides. Nitrogen oxides.

### **Advice for firefighters**

**Precautionary measures in case of fire:** Standard procedure for chemical fires.

**Firefighting instructions:** Use water spray or fog; do not use straight streams.

**Protection of Firefighters:** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

**Other Information:** Refer to Section 9 for flammability properties.

## **6. ACCIDENTAL RELEASE MEASURES**

### **Personal precautions, protective equipment and emergency procedures**

**Personal precautions:** Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

### **For non-emergency personnel**

**Personal Protective Equipment:** Use personal protective equipment as required.

**Emergency procedures:** Evacuate personnel to safe areas.

### **For emergency responders**

**Personal Protective Equipment:** Use personal protective equipment as required.

**Emergency procedures:** Evacuate personnel to safe areas. Ventilate the area. Eliminate all ignition sources if safe to do so.

**Other Information:** Refer to protective measures listed in Sections 7 and 8.

### **Environmental precautions**

Prevent further leakage or spillage if safe to do so.

### **Methods and material for containment and cleaning up**

**Methods for containment:** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up:** Use appropriate personal protective equipment (PPE). Carefully shovel or sweep up spilled material and place in suitable container. Avoid generating dust. For spills: Soak up with inert absorbent material. Use clean non-sparking tools to collect absorbed material. Avoid breathing dust or spray mist.

**Prevention of secondary hazards:** Clean contaminated objects and areas thoroughly observing environmental regulations.

### **Reference to other sections**

See section 8 for more information. See section 13 for more information.

## **7. HANDLING AND STORAGE**

### **Precautions for safe handling**

**Patients/Consumers:** Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

**Advice on safe handling:** Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Provide extract ventilation to points where emissions occur. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Take off contaminated clothing and wash before reuse.

### **Conditions for safe storage, including any incompatibilities**

**Storage Conditions:** Keep at temperatures between 20 and 25 °C (68 and 77 °F). Protect from light. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of reach of children. Store locked up. Do not re-use. Once opened, discard.

**Specific end use(s):** Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information.

## **8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### **Control parameters**

**Exposure Limits:** No information available

### **Exposure controls**

**Appropriate engineering controls:** Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below

recommended exposure limits.

**Individual protection measures, such as personal protective equipment**

**Hand protection:** Wear suitable gloves.

**Eye/face protection:** Wear safety glasses with side shields (or goggles).

**Skin and body protection:** Skin sensitizer. Avoid contact with skin. Wear suitable protective clothing. Wash thoroughly after handling.

**Respiratory protection:** Use appropriate respiratory protection.

**General hygiene considerations:** Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Remove and wash contaminated clothing and gloves, including the inside, before re-use.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**Information on basic physical and chemical properties**

<b>Physical state:</b>	Solid
<b>Appearance:</b>	Powder
<b>Color:</b>	No information available
<b>Odor:</b>	No data available
<b>Odor threshold:</b>	No data available
<b>pH:</b>	No data available
<b>Melting point / freezing point:</b>	No data available
<b>Boiling point / boiling range:</b>	No data available
<b>Flash point:</b>	No data available
<b>Evaporation rate:</b>	No data available
<b>Flammability (solid, gas):</b>	No data available
<b>Upper flammability limit:</b>	No data available
<b>Lower flammability limit:</b>	No data available
<b>Vapor pressure:</b>	No data available
<b>Vapor density:</b>	No data available
<b>Relative density:</b>	No data available
<b>Water solubility:</b>	No data available
<b>Solubility in other solvents:</b>	No data available
<b>Partition coefficient:</b>	No data available
<b>Autoignition temperature:</b>	No data available
<b>Decomposition temperature:</b>	No data available
<b>Kinematic viscosity:</b>	No data available
<b>Dynamic viscosity:</b>	No data available
<b>Explosive properties:</b>	No data available
<b>Oxidizing properties:</b>	No data available
<b><u>Other Information</u></b>	
<b>VOC Content (%):</b>	No data available

**10. STABILITY AND REACTIVITY**

**Reactivity**

Hazardous reactions will not occur under normal conditions.

**Chemical stability**

Stable under normal conditions.

**Possibility of hazardous reactions**

None under normal processing.

**Conditions to avoid**

Extremes of temperature and direct sunlight.

**Incompatible materials**

Strong oxidizing agents, strong acids, and strong bases.

**Hazardous decomposition products**

Decomposition will not occur under normal conditions.

**11. TOXICOLOGICAL INFORMATION**

**Information on toxicological effects**

**Information on likely routes of exposure**

**Inhalation:** May cause sensitization in susceptible persons.

**Ingestion:** Fatal if swallowed. May cause additional effects as listed under "Inhalation".

**Eye contact:** Specific test data for the substance or mixture is not available.

**Skin contact:** Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. May cause sensitization by skin contact.

**Symptoms related to the physical, chemical and toxicological characteristics**

**Symptoms:** May cause adverse effects on the bone marrow and blood-forming system. Leukopenia (reduced blood leukocytes). Anemia. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Coughing and/ or wheezing. Itching. Rashes. Hives. Erythema (skin redness). Edema. Dyspnea (breathing difficulty).

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

**Skin corrosion/irritation:** Based on available data, the classification criteria are not met.

**Serious eye damage/eye irritation:** Based on available data, the classification criteria are not met.

**Respiratory or skin sensitization:** May cause sensitization by inhalation. May cause sensitization by skin contact.

**Germ cell mutagenicity:** Contains a known or suspected mutagen.

**Carcinogenicity:** Contains a known or suspected carcinogen.

Chemical name	Weight-%	OSHA	IARC	NTP	ACGIH
Melphalan Hydrochloride 3223-07-2	60 - 80	X	Group 1	-	-

**Reproductive toxicity:** Contains a known or suspected reproductive toxin.

**STOT - single exposure:** Based on available data, the classification criteria are not met.

**STOT - repeated exposure:** Causes damage to organs through prolonged or repeated exposure ( Bone marrow ).

**Aspiration hazard:** Based on available data, the classification criteria are not met.

**Numerical measures of toxicity**

**Acute toxicity:** No information available

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

No information available.

### Persistence and degradability

No information available.

### Bioaccumulation

No information available.

### Mobility

No information available.

### Other adverse effects

No information available.

## 13. DISPOSAL CONSIDERATIONS

### Waste treatment methods

Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable. Dispose of waste in accordance with environmental legislation. Do not flush into surface water or sanitary sewer system.

## 14. TRANSPORT INFORMATION

Transportation requirements can vary based on numerous factors such as regional regulations and shipment volume. It is the responsibility of the transporting organization to ensure compliance with all applicable laws and regulations regarding the transportation of this product.

**In accordance with DOT / ICAO / IATA / TDG**

### UN Number

UN 3249

### UN proper shipping name

Medicine, solid, toxic, n.o.s. (Melphalan Hydrochloride)

### Transport hazard class(es)

Hazard Class: 6.1



### Packing group

II

### Environmental hazards

No

### Special precautions for user

No information available

### Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

### **Special Provisions**

Shipper, please take note that in addition to limited and/or excepted quantity exemptions, the following Special Provisions may apply to this product.

**US DOT:** [DOT - ORM-D]: CFR Title 49 §173.153 - (c) *Consumer commodities*. Until December 31, 2020, a limited quantity package of poisonous material in Packing Group III or a drug or medicine in Packing Group II or III that is also a “consumer commodity” as defined in §171.8 of this subchapter, may be renamed “Consumer commodity” and reclassified as ORM-D

**TDG:** TDG - 16; TDG - 38

**IMDG:** [IMDG - 221]: Substances included under this entry shall not be of packing group I; [IMDG - 223]: If the chemical or physical properties of a substance covered by this description are such that, when tested, it does not meet the established defining criteria for the class or division listed in column 3, or any other class or division, it is not subject to the provisions of this Code except in the case of a marine pollutant where 2.10.3 applies

**IATA:** IATA - A3

## **15. REGULATORY INFORMATION**

### **Safety, health and environmental regulations/legislation specific for the substance or mixture**

#### **International Regulations**

**Ozone-depleting substances (ODS):** Not applicable

**Persistent Organic Pollutants:** Not applicable

**The Rotterdam Convention:** Not applicable

#### **US Federal Regulations**

**SARA 313:** Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

#### **CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

#### **CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

#### **U.S. State Right-to-Know Regulations**

**US State Regulations:** This product does not contain any substances regulated by state right-to-know regulations

#### **Canada**

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all the information required by the CPR.

## **16. OTHER INFORMATION**

**Revision Date:** 12-August-2020

**Other Information:** This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warning included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

### **Key or legend to abbreviations and acronyms used in the safety data sheet:**

#### **Legend, Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA: TWA (time-weighted average)

STEL: STEL (Short Term Exposure Limit)

#### **Party responsible for the preparation of this document:**

Mylan Global Environmental, Health, and Safety Department - Occupational Toxicology

Phone number: +1 304-559-2595

*This SDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product.*

*Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.*



# Melphalan Hydrochloride for Injection Diluent

## SAFETY DATA SHEET

North America GHS

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations & the Hazardous Products Regulation (February 11, 2015) & NORMA Oficial Mexicana NOM-018-STPS-2015

### 1. IDENTIFICATION

#### **Product identifier**

**Product Name:** Melphalan Hydrochloride for Injection Diluent

**Synonyms:** Sterile Diluent for Melphalan Hydrochloride Injection; Melphalan Hydrochloride for Injection Kit (Diluent)

#### **Other means of identification**

**Other Information:** No other information

#### **Recommended use of the chemical and restrictions on use**

**Recommended Use:** Pharmaceutical. Use only as directed.

The intent of this safety data sheet (SDS) is to provide safety information for occupational handling of this product. This information may not be relevant for medical use of this product. Patients/ consumers should consult the package insert/ product label/ physician/ pharmacist for information regarding the usage of this product. For information on the ingredients used in this product, refer to the appropriate SDS for each ingredient.

**Uses advised against:** No information available.

#### **Details of the supplier of the safety data sheet**

Mylan Inc.

Robert J. Coury Global Center

1000 Mylan Blvd.

Canonsburg, PA 15317, USA

+1.724.514.1800

**Contact e-mail:**

[SDScontact@mylan.com](mailto:SDScontact@mylan.com)

#### **Emergency telephone number**

**Emergency Telephone:**

24 hr. Emergency Contact ChemTel

**International:** +1-813-248-0585

**US & Canada:** 1-800-255-3924

**Mexico:** 800-099-0731

#### **Other Contact Information**

**FDA Adverse Events Reporting**

**Number:**

For reporting adverse health events call:

+1 877-446-3679

### 2. HAZARDS IDENTIFICATION

**Patients/Consumers:** Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions

#### **Classification**

Not classified

#### **Label elements**

Not classified

#### **Other Hazards**

No information available.

#### **Unknown acute toxicity**

No information available

**3. COMPOSITION/INFORMATION ON INGREDIENTS****Mixture**

Chemical name	CAS No	Weight-%	Hazard statements
Propylene Glycol	57-55-6	50 - 70	Not classified
Ethanol	64-17-5	2 - 10	H225 - Highly flammable liquid and vapor H319 - Causes serious eye irritation

**4. FIRST AID MEASURES****Description of first aid measures**

**General advice:** Never give anything by mouth to an unconscious person. IF exposed or concerned: Get medical advice/attention. Show this safety data sheet to the doctor in attendance.

**Inhalation:** IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention immediately if symptoms occur.

**Skin contact:** Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention.

**Eye contact:** In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

**Ingestion:** Do not induce vomiting without medical advice. Rinse mouth thoroughly with water. Get medical attention if symptoms occur.

**Self-protection of the first aider:** First aider: Pay attention to self-protection. Do not breathe dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.

**Most important symptoms and effects, both acute and delayed**

**Symptoms:** No information available.

**Indication of any immediate medical attention and special treatment needed**

Treat symptomatically. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

**5. FIRE-FIGHTING MEASURES****Extinguishing media**

**Suitable Extinguishing Media:** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Unsuitable extinguishing media:** None known.

**Specific hazards arising from the chemical**

**Fire hazard:** Not flammable.

**Explosive hazard:** Not an explosive.

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

**Hazardous combustion products:** Carbon oxides.

**Advice for firefighters**

**Precautionary measures in case of fire:** Standard procedure for chemical fires.

**Firefighting instructions:** Use water spray or fog; do not use straight streams.

**Protection of Firefighters:** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

**Other Information:** Refer to Section 9 for flammability properties.

**6. ACCIDENTAL RELEASE MEASURES****Personal precautions, protective equipment and emergency procedures**

**Personal precautions:** Avoid contact with skin, eyes or clothing. Do not breathe dust/fume/gas/mist/vapors/spray. Use personal protective equipment as required.

**For non-emergency personnel**

**Personal Protective Equipment:** Use personal protective equipment as required.

**Emergency procedures:** Evacuate personnel to safe areas.

**For emergency responders**

**Personal Protective Equipment:** Use personal protective equipment as required.

**Emergency procedures:** Evacuate personnel to safe areas. Ventilate the area. Eliminate all ignition sources if safe to do so.

**Environmental precautions**

Do not flush into surface water or sanitary sewer system. Should not be released into the environment. See Section 12 for additional Ecological Information.

**Methods and material for containment and cleaning up**

**Methods for containment:** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up:** Use appropriate personal protective equipment (PPE). Carefully shovel or sweep up spilled material and place in suitable container. Avoid generating dust. For spills: Soak up with inert absorbent material. Use clean non-sparking tools to collect absorbed material. Avoid breathing dust or spray mist.

**Prevention of secondary hazards:** Clean contaminated objects and areas thoroughly observing environmental regulations.

**Reference to other sections**

See section 8 for more information. See section 13 for more information.

**7. HANDLING AND STORAGE**



**Precautions for safe handling**

**Patients/Consumers:** Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

**Conditions for safe storage, including any incompatibilities**

**Storage Conditions:** Keep at temperatures between 20 and 25 °C (68 and 77 °F). Keep containers tightly closed in a dry, cool and well-ventilated place. Protect from light. Do not re-use. Once opened, discard.

**Specific end use(s):** Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Control parameters**

**Exposure Limits:** No information available

**Exposure controls**

**Appropriate engineering controls:** Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

**Individual protection measures, such as personal protective equipment**

**Hand protection:** Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.

**Eye/face protection:** Safety glasses with side shields are recommended for medical or industrial exposures.

**Skin and body protection:** Wear suitable protective clothing.

**Respiratory protection:** Use appropriate respiratory protection.

**9. PHYSICAL AND CHEMICAL PROPERTIES****Information on basic physical and chemical properties**

<b>Physical state:</b>	Liquid
<b>Appearance:</b>	Solution
<b>Color:</b>	No information available
<b>Odor:</b>	No data available
<b>Odor threshold:</b>	No data available
<b>pH:</b>	No data available
<b>Melting point / freezing point:</b>	No data available
<b>Boiling point / boiling range:</b>	No data available
<b>Flash point:</b>	No data available
<b>Evaporation rate:</b>	No data available
<b>Flammability (solid, gas):</b>	No data available
<b>Upper flammability limit:</b>	No data available
<b>Lower flammability limit:</b>	No data available
<b>Vapor pressure:</b>	No data available
<b>Vapor density:</b>	No data available
<b>Relative density:</b>	No data available
<b>Water solubility:</b>	No data available
<b>Solubility in other solvents:</b>	No data available
<b>Partition coefficient:</b>	No data available
<b>Autoignition temperature:</b>	No data available
<b>Decomposition temperature:</b>	No data available
<b>Kinematic viscosity:</b>	No data available
<b>Dynamic viscosity:</b>	No data available
<b>Explosive properties:</b>	No data available
<b>Oxidizing properties:</b>	No data available
<b><u>Other Information</u></b>	
<b>VOC Content (%):</b>	No data available

**10. STABILITY AND REACTIVITY****Reactivity**

Hazardous reactions will not occur under normal conditions.

**Chemical stability**

Stable under normal conditions.

**Possibility of hazardous reactions**

None under normal processing.

**Conditions to avoid**

Extremes of temperature and direct sunlight.

**Incompatible materials**

Strong oxidizing agents, strong acids, and strong bases.

**Hazardous decomposition products**

Decomposition will not occur under normal conditions.

**11. TOXICOLOGICAL INFORMATION****Information on toxicological effects****Information on likely routes of exposure**

**Inhalation:** Specific test data for the substance or mixture is not available.

**Ingestion:** Based on available data, the classification criteria are not met.

**Eye contact:** Specific test data for the substance or mixture is not available.

**Skin contact:** Specific test data for the substance or mixture is not available.

**Symptoms related to the physical, chemical and toxicological characteristics**

**Symptoms:** No information available.

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

**Skin corrosion/irritation:** Based on available data, the classification criteria are not met.

**Serious eye damage/eye irritation:** Based on available data, the classification criteria are not met.

**Respiratory or skin sensitization:** Based on available data, the classification criteria are not met.

**Germ cell mutagenicity:** Based on available data, the classification criteria are not met.

**Carcinogenicity:** Based on available data, the classification criteria are not met.

**Reproductive toxicity:** Based on available data, the classification criteria are not met.

**STOT - single exposure:** Based on available data, the classification criteria are not met.

**STOT - repeated exposure:** Based on available data, the classification criteria are not met.

**Aspiration hazard:** Based on available data, the classification criteria are not met.

**Numerical measures of toxicity**

**Acute toxicity:** No information available

**12. ECOLOGICAL INFORMATION****Ecotoxicity**

No information available.

**Persistence and degradability**

No information available.

**Bioaccumulation**

No information available.

**Mobility**

No information available.

**Other adverse effects**

No information available.

**13. DISPOSAL CONSIDERATIONS****Waste treatment methods**

Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable. Dispose of waste in accordance with environmental legislation. Do not flush into surface water or sanitary sewer system.

**California Hazardous Waste Status**

This product contains one or more substances that are listed with the State of California as a hazardous waste.

Chemical name	Weight-%	California Hazardous Waste Status
Ethanol (CAS #: 64-17-5)	2 - 10	Toxic Ignitable

**14. TRANSPORT INFORMATION**

Transportation requirements can vary based on numerous factors such as regional regulations and shipment volume. It is the responsibility of the transporting organization to ensure compliance with all applicable laws and regulations regarding the transportation of this product.

**In accordance with DOT / ICAO / IATA / TDG**

**UN Number**

Not regulated

**UN proper shipping name**

Not regulated

**Transport hazard class(es)**

Hazard Class: Not regulated

**Packing group**

Not regulated

**Environmental hazards**

No

**Special precautions for user**

No information available

**Transport in bulk according to Annex II of MARPOL and the IBC Code**

Not applicable

**15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture****International Regulations****Ozone-depleting substances (ODS):** Not applicable**Persistent Organic Pollutants:** Not applicable**The Rotterdam Convention:** Not applicable**US Federal Regulations****SARA 313:** Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.**CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

**CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

**U.S. State Right-to-Know Regulations****US State Regulations:**

Chemical name	New Jersey	Massachusetts	Pennsylvania
Propylene Glycol 57-55-6	X	-	X
Ethanol 64-17-5	X	X	X

**Canada**

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all the information required by the CPR.

**16. OTHER INFORMATION****Revision Date:**

05-August-2020

**Other Information:**

This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warning included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

**Key or legend to abbreviations and acronyms used in the safety data sheet:****Legend, Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA: TWA (time-weighted average)

STEL: STEL (Short Term Exposure Limit)

**Party responsible for the preparation of this document:**

Mylan Global Environmental, Health, and Safety Department - Occupational Toxicology

Phone number: +1 304-559-2595

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*This SDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product.*

*Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.*