



Allopurinol Sodium for Injection (Aloprim®)

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: Allopurinol Sodium for Injection (Aloprim®)

Synonyms: Allopurinol Sodium for Injection, 500 mg; ALOPRIM®; ALOPRIM® (allopurinol sodium) for Injection, 500 mg

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

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

Skin corrosion/irritation, Category 1

Serious eye damage/eye irritation, Category 1

Skin sensitization, Category 1B

Acute aquatic toxicity, Category 3

Chronic aquatic toxicity, Category 2

Label elements



Signal word:	Danger
Hazard statements:	H314 - Causes severe skin burns and eye damage H317 - May cause an allergic skin reaction H402 - Harmful to aquatic life H411 - Toxic to aquatic life with long lasting effects
Precautionary Statements - Prevention:	Do not breathe dusts or mists Wash face, hands and any exposed skin thoroughly after handling Wear protective gloves/protective clothing/eye protection/face protection Contaminated work clothing must not be allowed out of the workplace Avoid release to the environment
Precautionary Statements - Response:	Immediately call a POISON CENTER or doctor Collect spillage Specific treatment (see supplemental first aid instructions on this label)
Eyes:	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing Immediately call a POISON CENTER or doctor
Skin:	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower Wash contaminated clothing before reuse If skin irritation or rash occurs: Get medical advice/attention
Inhalation:	IF INHALED: Remove person to fresh air and keep comfortable for breathing Immediately call a POISON CENTER or doctor
Ingestion:	IF SWALLOWED: Rinse mouth. DO NOT induce vomiting
Precautionary Statements - Storage:	Store locked up
Precautionary Statements - Disposal:	Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

Other Hazards

No information available.

Unknown acute toxicity

No information available

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

Chemical name	CAS No	Weight-%	Hazard statements
Allopurinol Sodium	17795-21-0	> 70	H317 - May cause an allergic skin reaction H402 - Harmful to aquatic life H411 - Toxic to aquatic life with long lasting effects
Sodium Hydroxide	1310-73-2	pH	H302 - Harmful if swallowed H314 - Causes severe skin burns and eye damage H412 - Harmful to aquatic life with long lasting effects

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

Overdose: Refer to information on package labeling and packaging. In case of overdose, get medical help or contact a Poison Control Center right away.

General advice: Immediate medical attention is required. Show this safety data sheet to the doctor in attendance.

Inhalation: Remove to fresh air. If breathing has stopped, give artificial respiration. Get medical attention immediately. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If breathing is difficult, (trained personnel should) give oxygen. Delayed pulmonary edema may occur. Get immediate medical advice/attention.

Skin contact: Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Get immediate medical advice/attention. May cause an allergic skin reaction.

Eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Do not rub affected area. Remove contact lenses, if present and easy to do. Continue rinsing. Get immediate medical advice/attention.

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

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. Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Symptoms: Nausea. Vomiting. Burning sensation. Itching. Rashes. Hives.

Indication of any immediate medical attention and special treatment needed

Product is a corrosive material. Use of gastric lavage or emesis is contraindicated. Possible perforation of stomach or esophagus should be investigated. Do not give chemical antidotes. Asphyxia from glottal edema may occur. Marked decrease in blood pressure may occur with moist rales, frothy sputum, and high pulse pressure. 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: Attention! Corrosive material. 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. Should not be released into the environment. Do not allow to enter into soil/subsoil. Prevent product from entering drains.

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. In case of insufficient ventilation, wear suitable respiratory equipment. Handle product only in closed system or provide appropriate exhaust ventilation. Do not eat, drink or smoke when using this product. 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). Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of reach of children. Store locked up.

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. Impervious gloves.

Eye/face protection: Tight sealing safety 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: Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

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

Exposure to air or moisture over prolonged periods.

Incompatible materials

Acids. Bases. Oxidizing agent.

Hazardous decomposition products

Decomposition will not occur under normal conditions.

11. TOXICOLOGICAL INFORMATION

Information on toxicological effects

Information on likely routes of exposure

Inhalation: Corrosive by inhalation. (based on components). Inhaled corrosive substances can lead to a toxic edema of the lungs. Pulmonary edema can be fatal.

Ingestion: Causes burns. (based on components). Ingestion causes burns of the upper digestive and respiratory tracts. May cause severe

burning pain in the mouth and stomach with vomiting and diarrhea of dark blood. Blood pressure may decrease. Brownish or yellowish stains may be seen around the mouth. Swelling of the throat may cause shortness of breath and choking. May cause lung damage if swallowed. May be fatal if swallowed and enters airways.

Eye contact: Causes burns. (based on components). Corrosive to the eyes and may cause severe damage including blindness. Causes serious eye damage. May cause irreversible damage to eyes.

Skin contact: May cause irritation. May cause sensitization by skin contact. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms: Nausea. Vomiting. Burning sensation. Itching. Rashes. Hives.

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

Skin corrosion/irritation: Causes burns.

Serious eye damage/eye irritation: Classification based on data available for ingredients. Causes burns. Risk of serious damage to eyes.

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

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

Harmful to aquatic life. Toxic to aquatic life with long lasting effects.

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

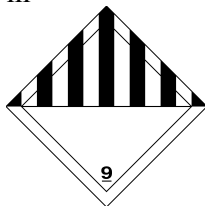
Transportation requirements can vary based on numerous factors such as regional regulations and shipment volume. It is the responsibility of the transporting organization to ensure compliance with all applicable laws and regulations regarding the transportation of this product.

DOT Not regulated

TDG

Marine pollutants exemption may apply. See 1.45.1 of the TRANSPORTATION OF DANGEROUS GOODS REGULATIONS code.

UN/ID no	UN 3077
Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains Allopurinol Sodium)
Hazard Class	9
Packing Group	III



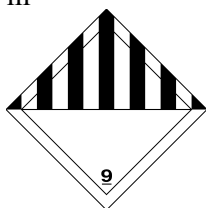
Special Provisions TDG - 16; TDG - 99

IATA

UN/ID no	UN 3077
Proper shipping name	Environmentally hazardous substances, solid, n.o.s. (contains Allopurinol Sodium)

Hazard Class
Packing Group

9
III



Special Provisions
IMDG

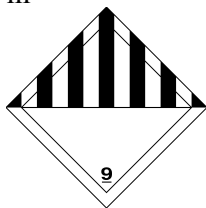
IATA - A97; IATA - A158; IATA - A179; IATA - 197

UN/ID no
Proper shipping name

UN 3077
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains Allopurinol Sodium)

Hazard Class
Packing Group

9
III



Special Provisions
Marine pollutant

IMDG - 274; IMDG - 335; IMDG - 966; IMDG - 967; IMDG - 969
This material meets the definition of a marine pollutant

	DOT	TDG	IATA	IMDG
Limited Quantity **	Not Regulated	5 kg	30 kg G	5 kg

**Limited quantities provide the maximum quantity per inner packaging or article for carrying dangerous goods as limited quantities in accordance with the regulations.

	DOT	TDG	IATA	IMDG
Excepted Quantity - Inner Packaging #	Not Regulated	30 g	30 g	30 g
Excepted Quantity - Outer Packaging #	Not Regulated	1000 g	1000 g	1000 g

Dangerous goods regulations may not be applicable to a shipment that satisfies the quantity limits and other excepted quantity regulations.

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: 31-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.

Mylan GEHS NA GHS SDS 2017