SAFETY DATA SHEET

Section 1: Identification	
Material **Recommended use**	**Allopurinol Tablets USP, 100 mg and 300 mg** Medicinal Product.
Manufacturer	Hetero Labs Limited, Unit V, Polepally, Jadcherla Mahaboob Nagar-509301, India.
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Classified hazards	Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device
Label elements	Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.
Hazard(s) not otherwise classified (HNOC)	Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.
Section 3: Composition/Information on Ingredients	
Ingredients	**CAS**
Allopurinol	315-30-0
Corn Starch	9005-25-8
Lactose monohydrate	644044-51-5
Magnesium Stearate	557-04-0
Crospovidone USP-NF	9003-39-8
Povidone	9003-39-8
Section 4: First-Aid Measures	
Inhalation	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
Eye contact	Rinse thoroughly with plenty of water for at least 15

	minutes and consult a physician
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center
Most important symptoms/effects, acute and delayed	May cause an allergic skin reaction. Prolonged exposure may cause chronic effects.
Indication of immediate medical attention and special treatment needed	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.
General information	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves
Section 5: Fire-Fighting Measures	
Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials
General fire hazards	No unusual fire or explosion hazards noted.
Section 6: Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	This material is classified as a water pollutant under the Clean Water Act and should be prevented from contaminating soil or from entering sewage and drainage systems which lead to waterways. Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in

	vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground
Section 7: Handling and Storage	
Precautions for safe handling	Avoid prolonged exposure. Avoid contact with eyes. Avoid release to the environment. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).
Section 8: Exposure Controls/Personal Protection	
Eye/face protection	Not normally needed. If contact is likely, safety glasses with side shields are recommended.
Skin protection **Hand protection** **Other**	 Not normally needed. For prolonged or repeated skin contact use suitable protective gloves. Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.
Respiratory protection	No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional

Section 9: Physical and Chemical Properties	
Physical Form	Solid
Colour	White to off-white
Description	Allopurinol tablets, USP 100 mg -White to off-white colored, round tablets debossed with "U" and "5" on one side and functional scored line with "H" on the other side. Bottles of 90 with child-resistant closure NDC 31722-252-90 Bottles of 100 with child-resistant closure NDC 31722-252-01 Bottles of 500 with child-resistant closure NDC 31722-252-05 Bottles of 1000 with child-resistant closure NDC 31722-252-10 Allopurinol tablets, USP 300 mg -White to off-white colored, round tablets debossed with "U" and "6" on one side and functional scored line with "H" on the other side. Bottles of 90 with child-resistant closure NDC 31722-253-90 Bottles of 100 with child-resistant closure NDC 31722-253-01 Bottles of 500 with child-resistant closure NDC 31722-253-05 Bottles of 1000 with child-resistant closure NDC 31722-253-10 Store at 20°C to 25°C (68°F to 77°F) (see USP Controlled Room Temperature), in a dry place. Dispense in a tight container as defined in the USP.
Section 10: Stability and Reactivity	
Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Contact with incompatible materials
Incompatible materials	Acids. Peroxides. Phenols
Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

Section 11: Toxicological Information	
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard
Skin contact	May cause an allergic skin reaction
Eye contact	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
Ingestion	Health injuries are not known or expected under normal use. May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Symptoms related to the physical, chemical and toxicological characteristics	May cause an allergic skin reaction. Prolonged exposure may cause chronic effects.
Acute toxicity	Expected to be a low hazard for usual industrial or commercial handling by trained personnel. May cause an allergic skin reaction.

Components	**Species**	**Test Results**
Allopurinol	(CAS 315-30-0)	
Acute		
Oral		
LD50	Rat	> 7500 mg/kg
Chronic		
Oral		
LOAEL	Rat	30 mg/kg/day, 60 weeks Kidney
NOAEL	Rat	12 mg/kg/day, 60 weeks

Skin corrosion/irritation	Health injuries are not known or expected under normal use.
Irritation Corrosion - Skin	
Allopurinol	Acute dermal irritation; OECD 404, Primary Irritation Index: 0 Result: Non-irritant Species: Rabbit

Serious eye damage/eye irritation	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation
Eye	
Allopurinol	Acute ocular irritation; OECD 405, Kay and Calandra score =3; maximum group mean score = 4 Result: Minimal Irritant Species: Rabbit IRE Assay Result: Negative; not likely to be a severe irritant

Respiratory or skin sensitization	
Respiratory sensitization	No studies have been conducted.
Skin sensitization Sensitization	May cause an allergic skin reaction.
Allopurinol	SAR / QSAR, DEREK, Lhasa, UK Result: Negative

Germ cell mutagenicity **Mutagenicity** Allopurinol	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic. Ames Assay, GLP assay Result: Negative
Mutagenicity Allopurinol	Chromosomal Aberration Assay In Vitro, human lymphocytes Result: Negative Mouse Lymphoma Cell (L5178Y) Mutation Assay Result: Negative
Carcinogenicity Allopurinol	Not classifiable as to carcinogenicity to humans. Carcinogenic effects are not expected as a result of occupational exposure. 2 year bioassay, Maximum dose = 20 mg/kg/day Result: Negative Species: Mouse 2 year bioassay, Maximum dose = 20 mg/kg/day Result: Negative Species: Rat
Specific target organ toxicity - single exposure	Due to partial or complete lack of data the classification is not possible.
Specific target organ toxicity - repeated exposure	May cause damage to organs through prolonged or repeated exposure
Aspiration hazard	Not likely, due to the form of the product
Chronic effects	Prolonged inhalation may be harmful.
Further information	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

Section 12: Ecological Information

Components		**Species**	**Test Results**
ALLOPURINOL (CAS 315-30-0)			
Acute Activated Sludge Respiration	IC50	Residential sludge	1100 mg/l, 3 hours OECD 209
Algae	EC50	Green algae (Scenedesmus subspicatus)	0.45 mg/l,72 hours Measured. OECD201
	NOEC	Green algae (Scenedesmus	0.157 mg/l, 72 hours Measured
Crustacea	EC50	Water flea (Daphnia magna)	130 mg/l, 48 hours Measured, OECD202
	NOEC	Water flea (Daphnia magna)	32 mg/l, 48 hours Measured
Fish	EC50	Rainbow trout (Juvenile Oncorhyncus mykiss)	> 100 mg/l, 96 hours Static renewal test, OECD 203
	NOEC	Rainbow trout (Juvenile Oncorhyncus mykiss)	100 mg/l, 96 hours Static renewal test

	NOEC	Rainbow trout (Juvenile Oncorhyncus mykiss)	100 mg/l, 96 hours Static renewal test

Biodegradability
Percent degradation (Aerobic biodegradation-inherent)

ALLOPURINOL	2 %, 28 days Modified Zahn-Wellens, Activated sludge
MAGNESIUM STEARATE	77 %, 28 days BOD
POLYVINYLPYRROLIDONE	0 %, 28 days Modified MITI test, Activated sludge

Bioaccumulative potential
Partition coefficient n-octanol / water (log Kow)
ALLOPURINOL 0.33

Mobility in soil
Adsorption
Soil/sediment sorption - log Koc

ALLOPURINOL	< 1.25 OECD 121
MAGNESIUM STEARATE	5.86 Estimated

Mobility in general
Volatility
Henry's law
ALLOPURINOL 0 atm m^3/mol Estimated
Other adverse effects Not available.

Section 13: Disposal Considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

Section 14: Transport Information

DOT
UN number UN3077
UN proper shipping name Environmentally hazardous substances, solid, n.o.s. (ALLOPURINOL), MARINE POLLUTANT
Class 9
Transport hazard class(es)

Class 9
Subsidiary risk -
Label(s) 9
Packing group III
Marine pollutant Yes
Special precautions for user Read safety instructions, SDS and emergency procedures before handling.
Special provisions 8, 146, 335, A112, B54, IB8, IP3, N20, T1, TP33
Packaging exceptions 155
Packaging non bulk 213
Packaging bulk 240

Read safety instructions, SDS and emergency procedures before handling

IATA
UN number UN3077
UN proper shipping name Environmentally hazardous substance, solid, n.o.s. (ALLOPURINOL)
Transport hazard class(es) 9
Subsidiary class(es) -
Packaging group III
Labels required Not available.
Environmental hazards No.
ERG Code 9L
Special precautions for user Read safety instructions, SDS and emergency procedures before handling.
Cargo aircraft only Allowed with restrictions.
Other information
Cargo aircraft only Allowed with restrictions

Passenger & cargo Allowed with restrictions

IMDG
UN number : UN3077
UN proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ALLOPURINOL), MARINE POLLUTANT
Transport hazard class(es)
Class : 9
Subsidiary risk : -
Packing group : III
Environmental hazards
Marine pollutant : Yes
EmS : F-A, S-F
Special precautions for user :Read safety instructions, SDS and emergency procedures before handling.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:

MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.
DOT; IATA; IMDG

Section 15: Regulatory Information

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard – No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous No chemical

SARA 313 (TRI reporting) Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

STARCH (CAS 9005-25-8)

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

STARCH (CAS 9005-25-8)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain
any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes

Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines (PICCS)	Philippine Inventory of Chemicals and Chemical Substances	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

Section 16: Other Information

Issue Date : 12-01-2024

Version : 00

Further information

Revision date: New issue

Revision note: New issue

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Hetero Labs Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero Labs Limited reserves the right to revise this SDS.