SAFETY DATA SHEETS

This SDS packet was issued with item:

078948569

N/A

Safety Data Sheet

SECTION 1. IDENTIFICATION

Common/Trade Name: Allopurinol Tablets

Chemical Name: 1H-pyrazolo[3,4-d] pyrimidin-4-ol

Synonyms: Allopurinol

Molecular Formula: $C_5H_4N_4O$

Molecular Weight: 136.11

CAS No: 315-30-0

Manufacturer's Name	Unichem Laboratories Limited
Address	Unichem Laboratories Limited, C-31&32, Industrial Area, Meerut Road, Ghaziabad, INDIA
Marketed by	Unichem Pharmaceuticals (USA), Inc. Hasbrouck Heights, NJ 07604
Phone Number	201-226-0240 (**Fax :** 201-368-0407)
Emergency Phone No.	1-866-562-4616

Recommended Use: Management of primary or secondary gout; patients with leukemia, lymphoma and malignancies; patients with recurrent calcium oxalate calculi

Restriction on Use: Prescription Only.

SECTION 2. HAZARD(s) IDENTIFICATION

Emergency Overview	**Physical State:** 100 mg: White to off-white, round flat, beveled, uncoated tablets debossed with "349" above breakline, "U" below breakline on one side and plain on the other side. 300 mg: White to off-white, round flat, beveled, uncoated tablets debossed with "350" above breakline, "U" below breakline on one side and plain on the other side. **Odor:** Not available. **WARNING!** May be harmful if swallowed. Accidental ingestion of large amounts may be harmful.
Primary Route(s) of Entry	Ingestion
Potential Health Effects:	**Eyes** May Cause eye irritation **Skin** Slightly hazardous in case of skin contact. **Inhalation** Not expected to be an inhalation hazard in final pharmaceutical form. **Ingestion** Ingestion of this material may cause effects similar to those seen in clinical use including fever, headache, pharyngitis, cough, abdominal pain, diarrhea, otitis media, influenza, rhinorrhea, sinusitis, otitis. Please see Patient Package Insert for further information
Toxicity Data:	See 'WARNINGS' and 'PRECAUTIONS'

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS

Composition	**CAS #**	**Quantity**
Allopurinol, USP (active ingredient)	315-30-0	100 mg and 300 mg.

REFER to PHYSICIAN'S DESK REFERENCE for common components

Effects of Overexposure:	Overdose may cause abdominal pain, somnolence, thirst, headache, vomiting and psychomotor hyperactivity.
Target Organs:	Human kidneys.

SECTION 4. FIRST AID MEASURES	
Eye Contact	In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.
Skin Exposure	Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
Ingestion	If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.
Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
SECTION 5. FIRE-FIGHTING MEASURES	
Flammability	Presumed to be a combustible particulate solid.
Flash Point	Not available.
Extinguishing Media	Use carbon dioxide, dry chemical, foam or water spray.
Special Fire Fighting Procedures	In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters. Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. Do NOT use water jet. In the event of fire and/or explosion do not breathe fumes.
Unusual Fire/Explosion Hazards	Not Applicable.
Hazardous Combustion Products	Hazardous combustion or decomposition products are expected when the product is exposed to fire.
SECTION 6. ACCIDENTAL RELEASE MEASURES	
STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES ARE SPILLED: Use appropriate personal protective equipment (see Section 8). Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained. Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.	
SECTION 7. HANDLING AND STORAGE	
Precautions **General Handling:**	Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.
Storage	Store at 20^0 to 25^0C (68^0 to 77^0F) in a dry place [see USP Controlled Room Temperature].
SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION	
Engineering Controls	Apply technical measures to comply with the occupational exposure guideline. Local exhaust ventilation is needed for limited open handling or where aerosols may be generated
Respiratory Protection	Base respirator selection on a risk assessment.
Personal Protection	**Eye/face Protection** Provide eye protection based on risk assessment. **Skin Protection** Wear nitrile or latex gloves. Wear protective garment **General Hygiene Considerations** When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday. **Other** Limit access to only personnel trained in the safe handling of this material Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance
Recommended Facilities	Eye wash, washing facilities

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES					
Appearance	White to off-white, round beveled-edge, flat tablets	Melting point	Not available	Solubility in water	Not available
Odor	odorless	Boiling point	Not available	Specific Gravity	Not available
Taste	Not available	Vapor Pressure	Not available	Flashpoint	Not available
pH	Not available	Density	Not available	Flammability Limits	Not available

SECTION 10. STABILITY AND REACTIVITY	
Stability	Stable at room temperature.
Incompatibility	None known
Hazardous Decomposition	None under normal use
Conditions to Avoid	No data available
Hazardous Polymerization	None under normal use.

SECTION 11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Allopurinol

Oral Rat : LD50 – > 750 mg/kg IP (intraperitoneal)/ 6000 mg/kg IP (orally).
Oral Mice : LD50 – > 160 mg/kg IP (intraperitoneal)/ 700 mg/kg IP (orally).
Corrosivity : No data available.

Allopurinol:

Carcinogenicity	Enhanced bone marrow suppression by cyclophosphamide and other cytotoxic agents has been reported among patients with neoplastic disease, except leukemia, in the presence of allopurinol. However, in a well-controlled study of patients with lymphoma on combination therapy, allopurinol did not increase the marrow toxicity of patients treated with cyclophosphamide, doxorubicin, bleomycin, procarbazine, and/or mechlorethamine.
Genetic Toxicity	No data available
Reproductive Toxicity & Developmental Toxicity	Reproductive studies have been performed in rats and rabbits at doses up to twenty times the usual human dose (5 mg/kg per day), and it was concluded that there was no impaired fertility or harm to the fetus due to allopurinol. There is a published report of a study in pregnant mice given 50 or 100 mg/kg allopurinol intraperitoneally on gestation days 10 or 13. There were increased numbers of dead fetuses in dams given 100 mg/kg allopurinol but not in those given 50 mg/kg. There were increased numbers of external malformations in fetuses at both doses of allopurinol on gestation day 10 and increased numbers of skeletal malformations in fetuses at both doses on gestation day 13. It cannot be determined whether this represented a fetal effect or an effect secondary to maternal toxicity. There are, however, no adequate or well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

SECTION 12. ECOLOGICAL INFORMATION

The environmental characteristics of this mixture have not been fully evaluated. The active ingredient in this formulation may be harmful to aquatic organisms. Releases to the environment should be avoided.

SECTION 13. DISPOSAL CONSIDERATIONS

Waste Disposal Method Dispose of in accordance with local and national regulations

SECTION 14. TRANSPORT INFORMATION
The Material Safety Data Sheet (MSDS) should accompany all shipments for reference in the event of spillage or accidental release. Transportation and shipping of this product is not restricted. It has no known significant hazards requiring special packaging or labeling for air, maritime or ground transport purpose. Not regulated for transport under USDOT, EUADR, IATA or IMDG regulations.
SECTION 15. REGULATORY INFORMATION
Use appropriate containment to avoid environmental contamination. DEA: Allopurinol is not a controlled substance. FDA: Allopurinol Tablet is an approved prescription medication.
SECTION 16. OTHER INFORMATION
ABBEVIATIONS: N/A – not applicable
Prepared by: Unichem Laboratories Limited
References: 1. Drug Bank 2. PDR – Physicians Desk Reference 3. Allopurinol Tablets, Package Insert, Unichem Laboratories Limited
Date: March 27, 2019 - Version: 000
SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION