

SAFETY DATA SHEET



1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product identifier

LESINURAD AND ALLOPURINOL TABLETS

Details of the supplier of the safety data sheet : ASTRAZENECA
P.O. Box 15437
Wilmington, DE 19850-5437
USA

Phone (24 hr.) Medical :
(800) 236-9933
(24 hr.) Chemical / Spill Emergency:
INFOTRAC - (800) 535-5053

SafetyDataSheets.AlderleyPark@astrazeneca.com

Alternative Names

Lesinurad/Allopurinol tablets 200/200, 200/300, 400/200, 400/300 mg

CAS No. : Not applicable
Use : treatment of gout

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

| Classification UN GHS | | |
|-----------------------------|----------|---|
| Hazard class | Category | Hazard Statements |
| Acute toxicity | 4 | H302 |
| Effects on or via lactation | | H362 |
| Acute aquatic toxicity | 1 | H400 |
| Chronic aquatic toxicity | 1 | H410 |
| | | # Refer to Section 16 'Other Information' |

| Label elements | |
|---------------------------------|---|
| Signal Word Warning | |
| Hazard Statements | |
| H302 | : Harmful if swallowed. |
| H362 | : May cause harm to breast-fed children. |
| H410 | : Very toxic to aquatic life with long lasting effects. |
| Precautionary Statements | |
| P264 | Wash hands thoroughly after handling. |
| P273 | Avoid release to the environment. |

| | | |
|-------------|---|---|
| P301 + P312 | : | IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. |
| P308 + P313 | : | IF exposed or concerned: Get medical advice/attention. |
| P391 | : | Collect spillage. |
| P501 | : | Dispose of contents/ container to an approved incineration plant. |

Other hazards

May cause flu-like symptoms such as fever, chills and headache.

May in rare cases cause skin rash followed by severe skin reactions after systemic exposure. May form explosive dust-air mixture if dispersed. See Section 11.

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

| Component | % | CAS No. | | |
|--------------------------|-----------------------------|-----------------|----------------------------|--|
| Lesinurad | 24 - 42 | 878672-00-5 | | |
| | Hazard class # | Category | Hazard Statements # | |
| | Acute toxicity | 4 | H302 | |
| Component | % | CAS No. | | |
| Allopurinol | 20 - 37 | 315-30-0 | | |
| | Hazard class # | Category | Hazard Statements # | |
| | Acute toxicity | 4 | H302 | |
| | Effects on or via lactation | | H362 | |
| | Acute aquatic toxicity | 1 | H400 | |
| Chronic aquatic toxicity | 1 | H410 | | |

Refer to Section 16 'Other Information'

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

- Inhalation : Remove patient from exposure. Obtain medical attention if ill effects occur.
- Skin Contact : Wash skin with soap and water.
- Eye Contact : Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention if ill effects remain.
- Ingestion : Wash out mouth with water and give 200-300ml of water to drink. Obtain medical attention if ill effects occur. Do NOT induce vomiting as a First-Aid measure.

Most important symptoms and effects, both acute and delayed

Refer to sections 2 and 11

Indication of any immediate medical attention and special treatment needed

Symptomatic treatment and supportive therapy as indicated. Emergency medical treatment advice varies within different countries. For further information consult the Local National Poisons Information Services.

5. FIRE FIGHTING MEASURES

Extinguishing Media (suitable) : water spray, foam, dry chemical or CO₂.

- Extinguishing Media (unsuitable) : Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.
- Special hazards arising from the substance or mixture : If involved in a fire, it may burn and emit noxious and toxic fumes.
- Special protective actions for fire-fighters : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions. Prevent fire extinguishing water from contaminating surface water or the ground water system.

6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Ensure suitable personal protection during removal of spillages. See Section 8. Avoid dispersal of dust in the air.
- Environmental Precautions : Prevent entry into drains, sewers or watercourses. Collect spillage.
- Methods and material for containment and cleaning up : Avoid dust generation. Transfer spilled tablets to a suitable container for disposal. Wash the spillage area with water. Avoid release to the environment. See section 13.

7. HANDLING AND STORAGE

- Precautions for safe handling : Avoid contact with skin and eyes. Wash hands after use. Minimize dust generation and accumulation. The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate and if it is dispersed.
- Conditions for safe storage, including any incompatibilities : Keep container tightly closed. Store at room temperature.
- Specific end use(s) : Not applicable, refer to Section 1

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Occupational Exposure Limit Value

| Ingredients | Value | Control parameters | Comments |
|----------------------------------|-----------------------|--------------------|-----------|
| Lesinurad | 0.5 mg/m ³ | TWA | COM, PROV |
| Allopurinol | 0.3 mg/m ³ | TWA | COM, PROV |
| Cellulose (Total Inhalable Dust) | 10 mg/m ³ | TWA | WEL |
| Cellulose (Total Inhalable Dust) | 20 mg/m ³ | STEL/CEILING(C) | WEL |
| Cellulose (Respirable Dust) | 4 mg/m ³ | TWA | WEL |

Exposure Controls

The specific controls will depend on local circumstances and should be based on the risk assessment.

Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment.

Prevent entry into drains, sewers or watercourses. See Section 6 for environmental precautions.

Occupational exposure controls

Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc.

The information below should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis. The recommended personal protective equipment (PPE) is based on preventing the potential adverse health effects from exposure to the active pharmaceutical ingredient (API). The risk of exposure to the API in the formulation/product needs to be taken into consideration.

Respiratory protection

As necessary, use NIOSH approved respiratory protection device consistent with the work place risk assessment.

Consult a qualified safety and health professional for additional guidance, as needed.

Skin protection

Use protective clothing to protect against direct contact with the product if the risk assessment does not support the selection of other protection. Use impervious protective gloves to protect against direct contact with the product.

If the product is dissolved or wetted use a glove material that is resistant to the solvent/liquid.

Eye protection

Use safety glasses to protect against direct contact with the product if the risk assessment does not support the selection of other protection.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Form : coated tablets

Other information

No other data available

10. STABILITY AND REACTIVITY

Reactivity : No known reactivity hazard under normal conditions.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : None known.

Conditions to avoid : No conditions producing hazardous situations known.

- Incompatible materials : None known.
- Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

This health hazard assessment is based on a consideration of the composition of this product.

- Inhalation : May cause effects as described under single exposure.(STOT)
- Skin Contact : No information available.
- Eye Contact : No information available.
- Ingestion : Harmful if swallowed.
May cause effects as described under single exposure.(STOT)
- Specific Target Organ Toxicity (STOT) : **Single exposure**
Routes of exposure: Inhalation, Ingestion
May cause flu-like symptoms such as fever, chills and headache.
,May in rare cases cause skin rash followed by severe skin reactions after systemic exposure.,Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.
- Repeated exposure**
May cause alterations of the liver function and acute attacks of gout.,
Studies in animals have shown that repeated doses may produce adverse effects on kidneys and intestine.
- Sensitization : No information available.
- Carcinogenicity : No evidence of carcinogenicity in animal studies.
- Mutagenicity : There is no evidence of genotoxic potential in in vitro and in vivo tests.
- Reproductive toxicity : The material is not considered to be a reproductive risk to human.The substance passes into breast milkMay cause harm to breast-fed children.

12. ECOLOGICAL INFORMATION

Very toxic to aquatic life with long lasting effects. No information on this formulation. The following information refers to Allopurinol :

- Toxicity : EC50 green algae 72 H 0.45 mg/l
NOEC green algae 72 H 0.157 mg/l
EC50 Daphnia magna 48 H 130 mg/l
NOEC Daphnia magna 48 H 32 mg/l
EC50 Rainbow trout 72 H > 100 mg/l
NOEC Rainbow trout 72 H 100 mg/l
- Effect on Effluent Treatment : No information available.
- Persistence and degradability : Not rapidly degradable.

- Bioaccumulative potential : No information available.
- Mobility in soil : The substance has no potential for bioaccumulation.
- Other adverse effects : No information available.

13. DISPOSAL CONSIDERATIONS

- Waste treatment methods : Disposal should be in accordance with local, state or national legislation. Waste, even small quantities, should never be poured down drains, sewers or water courses. Normal waste disposal is via incineration operated by an accredited disposal contractor.
- Contaminated Packaging : Empty container will retain product residue. Observe all hazard precautions.

14. TRANSPORT INFORMATION

ICAO/IATA

- UN No. : 3077
- Proper Shipping Name : Environmentally hazardous substance, solid, n.o.s. (ALLOPURINOL)
- Class : 9
- Packing Group : III
- Environmental hazards : Environmentally hazardous

IMO/MDG

- UN No. : 3077
- Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ALLOPURINOL)
- Class : 9
- Marine pollutant : Marine pollutant
- Packing Group : III

DOT (Department of Transport)

- UN No. : 3077
- Proper Shipping Name : Environmentally hazardous substances, solid, n.o.s. (ALLOPURINOL)
- Class : 9
- Packing Group : III

This material is not regulated for domestic transportation within the US when shipped in non-bulk packages by air, highway or rail.

15. REGULATORY INFORMATION

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

TSCA (Toxic Substances Control Act) Regulations, 40 CFR 710: This product is a drug and is exempt from TSCA regulation when manufactured, processed or distributed in commerce for use as a drug. CERCLA and SARA Regulations (40 CFR 302,355,370 and 372): This product does not contain any chemicals subject to applicable reporting requirements. Other Determined Regulations: California Proposition 65: This product does not contain a listed chemical. Discarded product is not considered a "hazardous waste" under RCRA, 40 CFR 261.

16. OTHER INFORMATION

Hazard Statements H302 : Harmful if swallowed.
 H362 : May cause harm to breast-fed children.
 H400 : Very toxic to aquatic life.
 H410 : Very toxic to aquatic life with long lasting effects.

The following sections contain revisions or new statements :

The Safety Data Sheet has been updated to adhere to Globally Harmonized System of Classification and Labelling of Chemicals (GHS)., This update affects most Sections of the Safety Data Sheet.

This Safety Data Sheet was prepared in accordance with Hazard Communication Standard (HCS) (29 CFR 1910.1200(g)).

GLOSSARY

COM : In-house occupational exposure limit
LTEL : Long-term exposure limit (8 hour TWA (time-weighted average))
STEL : Short-term exposure limit (15-minute TWA (time-weighted average))
TLV : Threshold Limit Value (ACGIH)
TLV-C : Threshold Limit Value - Ceiling limit (ACGIH)
HYG : An in-house analytical method for occupational exposure monitoring is available
Sk : Can be absorbed through skin, thus contributing to systemic effects
Sen : Capable of causing respiratory sensitization

This Glossary is applicable to Substances for which Hazardous Ingredients/Occupational Exposure Limits are assigned.

The information contained herein is based on data considered accurate and is offered solely for information, consideration and investigation. Company extends no warranties, makes no representations and assumes no responsibility as to the accuracy, completeness or suitability of this data for any third party use. The data on this Safety Data Sheet relates only to this product and does not relate to use with any other material or in any process. All chemical products should only be used by, or under the direction of, technically qualified personnel who are aware of the hazards involved and the necessity for reasonable care in handling. Hazard communication regulations require that employees must be trained on how to use a Safety Data Sheet as a source of hazard information.