

SAFETY DATA SHEET**1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING****Product identifier****LESINURAD****Details of the supplier of the safety data sheet**

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Alternative Names

2-[[5-bromo-4-(4-cyclopropyl-1-naphthyl)-1,2,4-triazol-3-yl]sulfanyl]acetic acid
 RDEA594

CAS No. : 878672-00-5
 Use : Pharmaceutical active: treatment of gout

2. HAZARDS IDENTIFICATION**Classification of the substance or mixture**

Classification UN GHS		
Hazard class	Category	Hazard Statements
Acute toxicity	4	H302

Label elements	
Signal Word Warning	
Hazard Statements	
H302	: Harmful if swallowed.
Precautionary Statements	
P264	Wash hands thoroughly after handling.
P301 + P312	: IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell.
P501	: Dispose of contents/ container to an approved incineration plant.

Other hazards

May form explosible dust-air mixture if dispersed. See Section 11.

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

Ingredients	%	CAS No.
Lesinurad		878672-00-5

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

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

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 emit noxious and toxic fumes. May form explosible dust clouds in air.
- Special protective actions for fire-fighters : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

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.
- Methods and material for containment and cleaning up : Moisten spillages with water. Transfer to a container for disposal. Wash the spillage area with water.

7. HANDLING AND STORAGE

- Precautions for safe handling : Avoid contact with skin and eyes. Avoid inhalation. Minimize dust generation and accumulation. The material may form explosible dust-air mixture if dispersed. Dust clouds are sensitive to ignition by electrostatic discharge or other ignition sources. Ensure good earthing of equipment and personnel.
- 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

Exposure Controls

Use appropriate controls (e.g. containment, ventilation) as specified in the workplace risk assessment to ensure that the defined occupational exposure limit is not exceeded. Prevent entry into drains, sewers or watercourses.

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.

Respiratory protection

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

Skin protection

Use protective clothing to protect against direct contact with the substance if the risk assessment does not support the selection of other protection. Use impervious protective gloves to protect against direct contact with the substance. If the substance 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 substance 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 : solid
- Color : off-white/beige
- Molecular Weight : 404.28 g/mol
- Molecular Formula : C₁₇H₁₄BrN₃O₂S
- Minimum Ignition Energy : 100 - 500 mJ

Solubility(Water) : very slightly soluble
 Solubility(Other) : sparingly soluble in.; acetonitrile soluble in.; dimethyl sulfoxide, methanol

Other information

Dissociation constant (pKa): : 3.2
 Minimum ignition temperature : > 410 °F

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

Inhalation : May cause adverse effects as described under long term.
 Skin Contact : Unlikely to be corrosive to the skin.
 Eye Contact : May cause eye irritation.
 Ingestion : Harmful if swallowed. Evident toxicity with mortality in rats at a dose of 1,000 mg/kg
 Specific Target Organ Toxicity (STOT) : **Single exposure**
 No specific effects reported.
Repeated exposure
 Routes of exposure: Oral
 Studies in animals have shown that repeated doses may produce adverse effects on kidneys and intestine.
 Sensitization : Unlikely to cause skin sensitization.
 Carcinogenicity : Animal testing did not show any carcinogenic effects.
 Mutagenicity : There is no evidence of genotoxic potential in in vitro and in vivo tests.
 Reproductive toxicity : The results from reproductive toxicity studies in animals do not indicate a reproductive risk to humans.

12. ECOLOGICAL INFORMATION

Toxicity	:	NOEC Pseudokirchneriella subcapitata (green algae) 72 H growth rate 30 mg/l ErC50 Pseudokirchneriella subcapitata (green algae) 72 H growth rate > 120 mg/l NOEC Daphnia magna 48 H > 120 mg/l EC50 Daphnia magna 48 H > 120 mg/l NOEC Daphnia magna 21 d 10 mg/l NOEC fathead minnow 28 d 2 mg/l
Effect on Effluent Treatment	:	Low toxicity to sewage micro-organisms.
Persistence and degradability	:	Not readily biodegradable.
Bioaccumulative potential	:	Unlikely to be bioaccumulative.
Mobility in soil	:	The substance has low mobility in soil.
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

NOT RESTRICTED FOR TRANSPORT

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.

The following sections contain revisions or new statements :

Minor changes: 2, 5, 6, 7, 12, 13

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.