



LEFAMULIN ACETATE SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006
GENERIC EU SDS - NO COUNTRY SPECIFIC OEL DATA

Date of Issue: 2022-04-01
Revision Number: A/0

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product Identifier : Lefamulin Acetate
Product Number : L060
CAS Number : [1350636-82-6]
EC Number : [695-920-8]
REACH Registration Number : A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration, or the registration is envisaged for a later registration deadline.

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified Uses : For research use only - restricted to professional users.
Uses Advised Against : Not for human or animal use

1.3 Details of the supplier of the safety data sheet

Company : TOKU-E Company
4112 Bakerview Spur
Bellingham, WA 98226
Phone Number : (360) 734-1789
E-mail Address : info@toku-e.com
Safety Data Sheet Issued by : TOKU-E Company (USA)

1.4 Emergency telephone number

Emergency Phone Number (Internat.) : +1 (352) 353-3500 (INFOTRAC, 24-Hour Number)
Emergency Phone Number (US Only) : 1 (800) 535-5053 (INFOTRAC, 24-Hour Number)

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008

Acute Toxicity-Inhalation (Category 4), H302
Hazardous to the Aquatic Environment-Chronic (Category 2), H411
Acute Toxicity-Oral (Category 2), H330
Serious Eye Damage (Category 1), H318
Damage to fertility or unborn child (Category 2), H361
Skin Irritation (Category 2), H315
Skin Sensitization (Category 1B), H317

For the full text of the H-Statements mentioned in this section, see Section 16.

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008

Hazard Pictogram(s):



Signal Word: Danger

Hazard Statement(s)

| | |
|------|---|
| H302 | Harmful if swallowed |
| H411 | Toxic to aquatic life with long lasting effects |
| H330 | Fatal if inhaled |
| H318 | Causes serious eye damage |
| H361 | Suspected of damaging fertility or the unborn child |
| H315 | Causes skin irritation |
| H317 | May cause an allergic skin reaction |

Precautionary Statement(s)

| | |
|------------|---|
| P260 | Do not breathe dust/fumes/gas/mist/vapors/spray. |
| P261 | Avoid breathing dust/fumes/gas/mist/vapors/spray. |
| P270 | Do not eat, drink, or smoke when using this product. |
| P301+P312 | IF SWALLOWED: Call a POISON CENTER or doctor/physician IF you feel unwell |
| P330 | Rinse mouth |
| P273 | Avoid release to the environment. |
| P391 | Collect spillage. |
| P501 | Dispose of contents/container in accordance with governmental regulation |
| P271 | Use only outdoors or in a well-ventilated area. |
| P272 | Contaminated work clothing should not be allowed out of the workplace. |
| P284 | [In case of inadequate ventilation] Wear respiratory protection. |
| P304+P340 | IF INHALED: Remove person to fresh air and keep comfortable for breathing. |
| P310 | Immediately call a POISON CENTER/doctor. |
| P320 | Specific treatment is urgent (see Section 4) |
| P403+P233 | Store in a well-ventilated place. Keep container tightly closed |
| P405 | Store locked up. |
| P280 | Wear protective gloves/protective clothing/eye protection/face protection. |
| P305+P351+ | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| P201 | Obtain special instructions before use |
| P202 | Do not handle until all safety precautions have been read and understood |
| P308+P313 | IF exposed or concerned: Get medical advice/attention. |
| P264 | Wash hands/skin thoroughly after handling. |
| P302+P352 | IF ON SKIN: Wash with plenty of water/soap |
| P321 | Specific treatment, see applicable response statements on this label |
| P332+P313 | IF SKIN irritation occurs: Get medical advice/attention. |
| P362+P364 | Take off contaminated clothing and wash it before reuse. |
| P333+P313 | IF SKIN irritation or rash occurs: Get medical advice/attention. |

Supplemental Hazard Information

No data available

2.3 Other hazards

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**3.1 Substances**

| | |
|------------------|--|
| Synonym(s) | : 14-O-([1R,2R,4R)-4-Amino-2-hydroxy-cyclohexylsulfanyl]-acetyl}-mutilin acetate |
| Formula | : C ₃₀ H ₄₉ NO ₇ S |
| Molecular weight | : 567.78 g/mol |

Hazardous ingredients according to Regulation (EC) No. 1272/2008

| Component | Classification | Concentration |
|---------------------------|---|---------------|
| Lefamulin Acetate | | |
| CAS Number [1350636-82-6] | Acute Tox. 4 H302 Skin Irrit. 2 H315 Skin Sens. 1B H317 | ≤ 100% |
| EC Number [695-920-8] | Eye Dam. 1 H318 Acute Tox. 2 H330 | |

For the full text of the H-Statements mentioned in this section, see Section 16.

SECTION 4: FIRST-AID MEASURES**4.1 Description of first-aid measures****General information**

Consult a doctor/physician if exposed - additional medical care may be required. Show this safety data sheet to the medical provider.

If inhaled

If inhaled, move to fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Wash skin thoroughly with soap and water. Remove any contaminated clothing. Consult a physician.

In case of eye contact

Flush eye with water. After initial flush, remove any contact lenses and continue flushing for at least 15 minutes.

If swallowed

Rinse mouth with water. Immediately call a doctor, physician, or poison control center. Never give anything by mouth to an unconscious person.

Self-protection of the first aider

Use personal protective equipment as required. Avoid contact with skin, eyes or clothing. Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent the spread of

4.2 Most important symptoms/effects, acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: FIRE-FIGHTING MEASURES**5.1 Extinguishing media****Suitable extinguishing media**

Water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable extinguishing media

No data available

5.2 Special hazards arising from the substance or mixture**Hazardous Combustion Products**

Carbon and nitrogen oxides, sulfur oxides, hydrogen fluoride

5.3 Advice for firefighters

Wear self-contained breathing apparatus if necessary.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed in Section 7 and 8. Use personal protective equipment. Avoid breathing dust, vapors, mist or gas. Avoid direct contact with spilled substances. Ensure adequate ventilation. Avoid dust formation.

For personal protection see Section 8.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel.

6.4 Reference to other sections

Refer to section 8 for exposure control and personal protection. Refer to section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Handle in a well ventilated place. Wear suitable protective clothing. Avoid formation of dust and aerosols. Use non-sparking tools. Provide appropriate exhaust ventilation at places where dust is formed. Avoid contact with skin and eyes.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place. Protect from humidity. Recommended storage temperature: -20 °C

Incompatibilities:

Strong oxidizing agents

7.3 Specific end use(s)

Refer to section 1.2

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters:

No OEL data available

8.2 Exposure controls

Appropriate engineering controls:

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling this product.

Personal Protective Equipment (PPE):

Respiratory protection

Wear respiratory protection. Use type N95 (US) or type P1 (EN 143) dust masks as a backup to engineering controls. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal techniques to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the selected EN 374 derived from it.

Eye/Face protection

Wear eye protection. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

Body protection

Wear protective clothing. The type of protective equipment must be selected according to the concentration of the dangerous substance at the specific work place.

Environmental exposure controls

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**9.1 Information on basic physical and chemical properties**

| | | |
|--|---|---------------------------------|
| Appearance | : | White powder |
| Odor | : | No data available |
| Odor Threshold | : | No data available |
| pH | : | No data available |
| Melting Point/Freezing Point | : | No data available |
| Initial Boiling Point and Range | : | No data available |
| Flash Point | : | No data available |
| Evaporation rate | : | No data available |
| Flammability (solid, gas) | : | No data available |
| Upper/Lower Flammability or | | |
| Explosive Limits | : | No data available |
| Vapor Pressure | : | No data available |
| Vapor Density | : | No data available |
| Relative Density | : | No data available |
| Water Solubility (pH 1-6.8) | : | Freely soluble |
| Other Solubilities | | Freely soluble in ethanol, DMSO |
| Partition Coefficient: n-octanol/water | : | No data available |
| Auto-Ignition Temperature | : | No data available |
| Decomposition Temperature | : | No data available |
| Viscosity | : | No data available |
| Explosive Properties | : | No data available |
| Oxidizing Properties | : | No data available |

9.2 Other information

No additional information relevant to safe use of the substance.

SECTION 10: STABILITY AND REACTIVITY**10.1 Reactivity**

No data available

10.2 Chemical stability

Stable under recommended storage conditions

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

Strong oxidizing agents

10.6 Hazardous decomposition products

No data available

See Section 5 for hazardous combustion products.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute Toxicity

No data available

Skin Corrosion/Irritation

No data available

Serious Eye Damage/ Eye Irritation

No data available

Respiratory or Skin Sensitization

No data available

Germ Cell Mutagenicity

No data available

Carcinogenicity

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible, or confirmed human carcinogen by the International Agency for Research on Cancer Monograph.

Reproductive Toxicity

No data available

Specific Target Organ Toxicity: Single Exposure

No data available

Specific Target Organ Toxicity: Repeated Exposure

No data available

Aspiration Hazard

No data available

Additional Information

RTECS: Not available

Only select Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See actual entry in RTECS for complete information.

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects

Toxic/harmful to aquatic life (with long lasting effects)

In the absence of complete ecological information, treat product as environmentally hazardous.
Use proper storage, handling, and disposal to prevent unintentional release into the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Offer surplus and non-recyclable products to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Avoid disposal of material in drains or sewers. Waste material must be disposed of in accordance with the Directive on Waste 2008/98/EC as well as other national and local regulations.

Contaminated Packaging

Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

| | | ADR/RID | IMDG | IATA |
|------|----------------------------|---------------------|----------------------|---------------------|
| 14.1 | UN Number | - | - | - |
| 14.2 | UN Proper Shipping Name | Not Dangerous Goods | Not Dangerous Goods | Not Dangerous Goods |
| 14.3 | Transport Hazard Class(es) | - | - | - |
| 14.4 | Packing Group | - | - | - |
| 14.5 | Environmental Hazards | No | Marine Pollutant: No | No |

14.6 Special precautions for user

Further Information

No data available

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

SECTION 15: REGULATORY INFORMATION

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

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Authorizations and/or restrictions on use

Restricted to professional users.

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out.

SECTION 16: OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3

H302 Harmful if swallowed
H411 Toxic to aquatic life with long lasting effects
H330 Fatal if inhaled

H318 Causes serious eye damage
H361 Suspected of damaging fertility or the unborn child
H315 Causes skin irritation

Abbreviations and acronyms

ADR/RID: European Agreements Concerning the International Carriage of Dangerous Goods by Road (ADR) and Rail (RID)
CAS No: Chemical Abstracts Service number
EC: European Commission
EC No: European Commission number
EHS: Environmentally Hazardous Substance
EU: European Union
H-Statement: Hazard Statement
IARC: International Agency for Research on Cancer
IATA: International Air Transport Association
IBC: International Bulk Chemical
IMDG: International Maritime Dangerous Goods Code
LC50: Lethal concentration, 50%
LD50: Median Lethal dose
MARPOL 73/78: International Convention for the Prevention of Pollution from Ships
NIOSH: National Institute for Occupation Safety and Health
OEL: Occupational Exposure Limit
PBT: Persistent, Bioaccumulative and Toxic
REACH: Registration, Evaluation, Authorisation and restrictions of Chemicals
RTECS: Registry of Toxic Effects of Chemical Substances
SDS: Safety Data Sheet
UN: United Nations
vPvB: Very Persistent and Very Bioaccumulative

Further information

Revision Date: 2022-04-01

The above information is based upon the present state of our knowledge and is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information is believed to be correct but does not purport to be all inclusive. It does not represent any guarantees of the properties of the product. TOKU-E Company shall not be held liable for damage or injury resulting from contact, handling, or storage of the above product.