1. Identification

Product identifier: MilbeMite™

Other means of identification:
- Item Code: CA4800
- Synonyms: Milbemite Otic Solution

Recommended use: Veterinary Product

Recommended restrictions: None known.

Manufacturer/Importer/Supplier/Distributor information

Company Name: Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140
US

Phone: 1-877-Elanco1 (1-877-352-6261)

Emergency Telephone: Elanco Product Technical Support / Human or Animal Exposure Reporting:
1-888-545-5973

Email: elanco_sds@elanco.com

Transportation Emergency Telephone: CHEMTREC: 1-800-424-9300
(Outside U.S. 1-703-527-3887)

2. Hazard(s) identification

Physical hazards: Not classified.

Health hazards: Not classified.

OSHA defined hazards: Not classified.

Label elements

- Hazard symbol: None.
- Signal word: None.
- Hazard statement: The mixture does not meet the criteria for classification.
- Precautionary statement
  - Prevention: Not available.
  - Response: Not available.
  - Storage: Not available.
  - Disposal: Not available.

Hazard(s) not otherwise classified (HNOC): None known.

Supplemental information: None.

3. Composition/information on ingredients

Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milbemycin Oxime</td>
<td>(6R, 25R)-5-demethoxy-28-deoxy-6, 28-epoxy-5-hydroxyimino-25-ethyl/methyl milbemycin B</td>
<td>129496-10-2</td>
<td>0.1</td>
</tr>
</tbody>
</table>

Composition comments: Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

4. First-aid measures

Inhalation: Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact: Wash off with soap and water. Get medical attention if irritation develops and persists.
**Eye contact**
Rinse with water. Get medical attention if irritation develops and persists.

**Ingestion**
Rinse mouth. Get medical attention if symptoms occur.

**Most important symptoms/effects, acute and delayed**
None known.

**Indication of immediate medical attention and special treatment needed**
Treat symptomatically.

**General information**
Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

### 5. Fire-fighting measures

**Suitable extinguishing media**

**Unsuitable extinguishing media**
Do not use water jet as an extinguisher, as this will spread the fire.

**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**
Use water spray to cool unopened containers.

**Specific methods**
Use standard firefighting procedures and consider the hazards of other involved materials.

**General fire hazards**
No unusual fire or explosion hazards noted.

### 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**
Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. 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**
Prevent product from entering drains.

**Large Spills:** Stop the flow of material, if this is without risk. 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.

**Environmental precautions**
Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Inform appropriate managerial or supervisory personnel of all environmental releases. Avoid discharge into drains, water courses or onto the ground.

### 7. Handling and storage

**Precautions for safe handling**
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).

### 8. Exposure controls/personal protection

**Biological limit values**
No biological exposure limits noted for the ingredient(s).

**Exposure guidelines**
Novartis Internal Exposure Limit (NPIEL): 0.12 mg/m3 8 hour TWA (milbemycin oxime)

**Appropriate engineering controls**
Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection**
Wear safety glasses with side shields (or goggles).

**Skin protection**
Wear appropriate chemical resistant gloves.

**Hand protection**
Wear suitable protective clothing.

**Respiratory protection**
In case of insufficient ventilation, wear suitable respiratory equipment.
Wear appropriate thermal protective clothing, when necessary.

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.

9. Physical and chemical properties

Appearance

Viscous.

Physical state

Liquid.

Form

Liquid.

Color

Colorless.

Odor

Odorless

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

Not available.

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

Not available.

Flammability limit - upper (%)

Not available.

Explosive limit - lower (%)

Not available.

Explosive limit - upper (%)

Not available.

Vapor pressure

Not available.

Vapor density

Not available.

Relative density

Not available.

Solubility(ies)

Solubility (water)

Not available.

Partition coefficient (n-octanol/water)

Not available.

Auto-ignition temperature

Not available.

Decomposition temperature

Not available.

Viscosity

Not available.

Other information

Explosive properties

Not explosive.

Oxidizing properties

Not oxidizing.

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

No dangerous reaction known under conditions of normal use.

Conditions to avoid

Contact with incompatible materials.

Incompatible materials

Strong oxidizing agents.

Hazardous decomposition products

No hazardous decomposition products are known.

11. Toxicological information

Information on toxicological effects

Acute toxicity

Based on available data, the classification criteria are not met.
Components | Species | Test Results
---|---|---
Milbemycin Oxime (CAS 129496-10-2)

**Acute**
- **Dermal**
  - LD50 Rat > 2000 mg/kg

- **Inhalation**
  - LC50 Rat 1220 mg/m³, 4 h

- **Oral**
  - LD Rat > 2000 mg/m³

**Skin corrosion/irritation**
- Rabbit: No irritation. (milbemycin oxime)
  - Based on available data, the classification criteria are not met.

**Serious eye damage/eye irritation**
- Rabbit: No irritation (milbemycin oxime)
  - Based on available data, the classification criteria are not met.

**Respiratory or skin sensitization**
- **Respiratory sensitization**
  - Due to lack of data the classification is not possible.

- **Skin sensitization**
  - Guinea pig: Not a skin sensitizer. (milbemycin oxime)
  - Based on available data, the classification criteria are not met.

**Germ cell mutagenicity**
- Result in genetic toxicity assays (in vitro and in vivo): Negative (milbemycin oxime)
  - Based on available data, the classification criteria are not met.

**Carcinogenicity**
- Due to lack of data the classification is not possible.

  - IARC Monographs. Overall Evaluation of Carcinogenicity
    - Not listed.

    - Not regulated.

  - US. National Toxicology Program (NTP) Report on Carcinogens
    - Not listed.

**Reproductive toxicity**
- No effects identified in animal studies. (milbemycin oxime)
  - Based on available data, the classification criteria are not met.

**Specific target organ toxicity - single exposure**
- No significant target organ toxicity reported. (milbemycin oxime)
  - Based on available data, the classification criteria are not met.

**Specific target organ toxicity - repeated exposure**
- No significant target organ toxicity reported. (milbemycin oxime)
  - Based on available data, the classification criteria are not met.

**Aspiration hazard**
- Not an aspiration hazard.

**12. Ecological information**

**Ecotoxicity**
- Very toxic to aquatic life with long lasting effects.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
</table>
| Milbemycin Oxime (CAS 129496-10-2)

**Aquatic**
- **Acute**
  - Crustacea: EC50 Daphnia 0.011 mg/l, 48 hr (similar substance)
  - 0 mg/l, 48 hr (similar substance)

  - Fish: LC50 Carp (Cyprinus carpio communis) 0.059 ppm, 48 hr

**Chronic**
- Crustacea: NOEC Daphnia 0.0001 mg/l, 21 d (similar substance)

**Persistence and degradability**
- No data is available on the degradability of any ingredients in the mixture.

**Bioaccumulative potential**
- **Partition coefficient n-octanol / water (log Kow)**
  - Milbemycin Oxime 6.5, (at 20 °C, pH 7)
  - 7, (at 20 °C, pH 7)

**Mobility in soil**
- No data available.

**Other adverse effects**
- Not available.
13. Disposal considerations
Dispose of contents/container in accordance with local/regional/national/international regulations.

14. Transport information

DOT
Not regulated as dangerous goods.

IATA
| UN number | UN3082 |
| UN proper shipping name | Environmentally hazardous substance, liquid, n.o.s. (MILBEMYCIN OXIME) |
| Transport hazard class(es) | 9 |
| Class | 9 |
| Subsidiary risk | - |
| Packing group | III |
| Environmental hazards | Yes |
| ERG Code | 9L |
| Special precautions for user | Read safety instructions, SDS and emergency procedures before handling. |
| Other information | Allowed with restrictions. |
| Passenger and cargo aircraft | Allowed with restrictions. |
| Cargo aircraft only | |

IMDG
| UN number | UN3082 |
| UN proper shipping name | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (MILBEMYCIN OXIME) |
| Transport hazard class(es) | 9 |
| Class | 9 |
| Subsidiary risk | - |
| Packing group | III |
| Environmental hazards | Yes |
| 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 | Not established. Not applicable. |

15. Regulatory information

US federal regulations
This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
Toxic Substances Control Act (TSCA)
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 1910.1001-1052)
Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)
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.

US state regulations
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

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*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).

16. Other information, including date of preparation or last revision

Issue date: 08-16-2017
Revision date: 03-18-2019
Version #: 02

List of abbreviations
TWA: Time Weighted Average

Disclaimer
As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:
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