

SAFETY DATA SHEETS

This SDS packet was issued with item:

078912317

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078558855

Novartis Animal Health US, Inc.
3200 Northline Avenue, Suite 300
Greensboro, North Carolina 27408

In Case of Emergency, Call:
Novartis Animal Health US, Inc. (800)637-0281
CHEMTREC (800)424-9300

1. CHEMICAL IDENTIFICATION

<u>Technical Name</u>	Milbemycin Oxime	Product No: 86026
<u>Trade Name(s)</u>	MilbeMite™ OTIC Solution	
<u>Active Ingredient(%)</u>	0.1 %	CAS No: Not Applicable (mixture)
<u>Chemical Name</u>	A3 and A4 Oxime	
<u>Chemical Class</u>	Macrolide Derivative Canine Anthelmintic	

2. COMPOSITION/INFORMATION ON INGREDIENTS

	OSHA	ACGIH		NTP/IARC/OSHA
Materials	PEL	TLV	Other	Carcinogen
Milbemycin Oxime	None	None		Not Listed
Inert Ingredients	None	None		Not Listed

3. HAZARDS IDENTIFICATION

Notes to Physician:

There is no specific antidote if ingested. Induce emesis or lavage stomach. Treat symptomatically based on judgement of the physician, in response to reactions of the patient.

Symptoms of Acute Exposure:

Eye irritation may occur if eye contact is made.

Hazardous Decomposition Products:

None known

Physical Properties:

Appearance: Clear and Viscous
Odor: Odorless

Unusual Fire, Explosion and Reactivity Hazards:

Under normal conditions of use this material does not present a significant fire or explosion hazard.

4. FIRST AID MEASURES

If human exposure is suspected, immediately contact a physician, the nearest hospital, or nearest Poison Control Center. Tell the person contacted the complete product name, chemical class, and type and amount of exposure. Describe any symptoms and follow the advice given.

Ingestion:

If victim is fully conscious, immediately give 1 or 2 glasses of water with medicinal charcoal to drink repeatedly. Never give anything by mouth to an unconscious person.

Eye Contact:

Immediately rinse eyes with a large amount of running water. Hold eyelids apart to rinse the entire surface of the eye and lids. Do not apply any medicating agents except on the advice of a physician.

Skin Contact:

Wash with plenty of soap and water, including hair and under fingernails. Do not apply any medicating agents except on the advice of a physician. Remove contaminated clothing and wash before reuse.

Inhalation:

Move victim from contaminated area to fresh air. Apply artificial respiration if necessary.

Notes to Physician:

There is no specific antidote if ingested. Induce emesis or lavage stomach. Treat symptomatically based on judgement of the physician, in response to reactions of the patient.

Medical Conditions Likely to be Aggravated by Exposure:

None

5. FIRE FIGHTING MEASURES**Fire and Explosion:**

Flash Point (Test Method) Not Available

Flammable Limits (% in Air) Not Available

Autoignition Temperature Not Available

Flammability Not Available

Unusual Fire, Explosion and Reactivity Hazards:

None Known

In Case of Fire:

Under normal conditions of use this material does not present a significant fire or explosion hazard. Use dry chemical, foam, or CO₂ extinguishing media. Wear full protective clothing and self-contained breathing apparatus. Evacuate non-essential personnel from the area to prevent human exposure to fire, smoke, fumes, or products of combustion. Prevent use of buildings, area, and equipment until decontaminated.

6. ACCIDENTAL RELEASE MEASURES**In Case of Spill or Leak:**

For Clinic use: Cover spill with an absorbent material such as pet litter, sweep up and place in an approved chemical waste container. Wash the area with water containing a strong detergent, absorb with absorbent material, sweep up and place in chemical container. Flush the area with water to remove any residue.

For Bulk product: Wear chemical safety glasses or goggles, rubber gloves, rubber boots, long-sleeved

shirt, long pants, and head covering. Cover with an absorbent material such as pet litter, sweep up and place in an approved chemical waste container. Wash the area with water containing a strong detergent, absorb with absorbent material, sweep up and place in chemical container. Flush the area with water to remove any residue. Do not allow wash water to contaminate water supplies.

7. HANDLING AND STORAGE

Store at room temperature between 59 and 86° F (15-30° C).
Shelf-life is 24 months.

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Ingestion: Not required under normal conditions of therapeutic administration and use.
Eye Contact: Not required under normal conditions of therapeutic administration and use.
Skin Contact: Not required under normal conditions of therapeutic administration and use.
Inhalation: Not required under normal conditions of therapeutic administration and use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear and Viscous
Odor: Odorless
Melting Point: Not Available
Boiling Point: Not Available
Specific Gravity/Density: Not Available
pH: Not Available
Evaporation Rate: Not Available
Solubility in H2O: Not Available
Vapor Pressure: Not Available

10. STABILITY AND REACTIVITY

Reactivity:
Stability: Stable under normal handling and storage conditions.
Hazardous Polymerization: Not available.
Conditions to Avoid: Oxidizing agents

Hazardous Decomposition Products: None Known

11. TOXICOLOGICAL INFORMATION

Acute Toxicity/Irritation Studies:

<u>Acute Oral Toxicity:</u>		
LD50:	532-863 mg/kg (rat)	Data based on technical material
<u>Acute Dermal Toxicity:</u>		
LD50	>2000 mg/kg (rat)	Data based on technical material
<u>Acute Inhalation Toxicity:</u>		
LC50	1220 mg/m3 (rat; 4h)	Data based on technical material
<u>Acute Eye Irritation:</u>	Non irritant (rabbit)	Data based on technical material
<u>Acute Skin Irritation:</u>	Non irritant (rabbit)	Data based on technical material
<u>Skin Sensitization:</u>	Not sensitizing (guinea pig)	Data based on technical material

<u>Mutagenic Potential in Vitro:</u>	Negative	Data based on technical material
<u>Reproductive Hazard Potential:</u>	Not Available	Data based on technical material
<u>Chronic/Subchronic Toxicity Studies:</u> A study was conducted to evaluate the safety of a 0.1% milbemycin oxime solution in adult cats. Topical doses at 1x, 3x and 5x the recommended dose applied in one ear did not produce adverse effects. A study at 1x, 3x or 5x of the recommended 0.1% milbemycin oxime solution administered once weekly for six applications conducted in kittens 4 weeks of age at initiation did not produce adverse systemic or local effects. One kitten treated with a .5% solution (5x) was lethargic 8 hours after the second treatment. In this kitten, lethargy was not observed after subsequent treatments.		
<u>Carcinogenic Potential:</u>	Not Available	
<u>Teratogenicity:</u>	Not teratogenic (rabbit, rat)	Data based on technical material
<u>Toxicity of Other Components:</u>	Not Available	
<u>Target Organs:</u>		
<u>Active Ingredients:</u>	None Known	
<u>Inert Ingredients:</u>	None Known	

12. ECOLOGICAL INFORMATION

<u>Summary of Effects:</u>	Not Available
<u>Eco-Acute Toxicity:</u>	Not Available
<u>Eco-Chronic Toxicity:</u>	Not Available
<u>Environmental Fate:</u>	Not Available

13. DISPOSAL CONSIDERATION

Disposal: Dispose of product containers, waste containers, and residues according to local, state, and federal health and environmental regulations.

<u>Characteristic Waste:</u>	Not Available
<u>Listed Waste:</u>	Not Available

14. TRANSPORT INFORMATION

<u>DOT Classification:</u>	Not applicable, No label or placard required
<u>B/L Freight Classification:</u>	Pharmaceutical Chemical, N.O.S.
<u>International Transportation:</u>	Not Available

15. REGULATORY INFORMATION

SARA Title III Classification:

Section 311/312:	None
Section 313 chemical(s):	None

Proposition 65: No component listed on California Prop. 65 List.
CERCLA Reportable Quantity (RO): Not Available

RCRA Classification: Not Applicable

TSCA Status: Not Available

16. OTHER INFORMATION

NFPA Hazard Ratings:

Health: 0

Flammability: 0

Reactivity: 0

0	Least
1	Slight
2	Moderate
3	High
4	Severe

Questions concerning the safe handling of this product should be referred to:

Novartis Animal Health US, Inc.
1-800-637-0281

Issued Date: October 1, 2001

Revised Date: January 16, 2002

Supersedes: October 1, 2001

The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein.



SAFETY DATA SHEET

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

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

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	Water spray. Alcohol resistant foam. Powder. Carbon dioxide (CO ₂).
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. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
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/m ³ 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	
Hand protection	Wear appropriate chemical resistant gloves.
Other	Wear suitable protective clothing.
Respiratory protection	In case of insufficient ventilation, wear suitable respiratory equipment.

Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	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.
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Components	Species	Test Results
Milbemycin Oxime (CAS 129496-10-2)		
<u>Acute</u>		
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.		
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)		
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.		
Components	Species		Test Results
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

Disposal instructions Dispose of contents/container in accordance with local/regional/national/international regulations.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

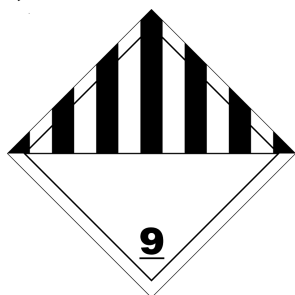
UN number	UN3082
UN proper shipping name	Environmentally hazardous substance, liquid, n.o.s. (MILBEMYCIN OXIME)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Environmental hazards	Yes
ERG Code	9L
Special precautions for user	Read safety instructions, SDS and emergency procedures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

IMDG

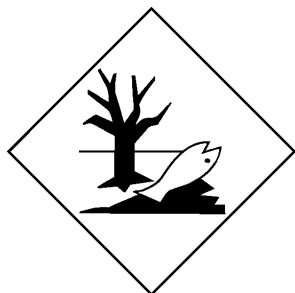
UN number	UN3082
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (MILBEMYCIN OXIME)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Environmental hazards	
Marine pollutant	Yes
EmS	F-A, S-F
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established. Not applicable.

IATA; IMDG



Marine pollutant



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

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*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 MERCHANT ABILITY 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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