

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

<u>Disposal:</u>	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

<u>SARA Title III Classification:</u>	
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	0	Least
Flammability:	0	1	Slight
Reactivity:	0	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

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