

SAFETY DATA SHEET

Milbemax Tablets for Cats

Section 1. Identification

Product identifier	:	Milbemax Tablets for Cats
Product code	:	124000000433
Other means of identification	:	A-11302; CA5015; CGA179246/CGA1114326 FLAV TAL 16+40; Milbemax 16/40; MILBEMAX BROAD-SPECTRUM ALL WORMER TABLETS FOR CATS OVER 2 KG BODYWEIGHT; Milbemax FC 16/40 MG TAL; Milbemax Tablets for Cats; MilbeVet film-coated tablets

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

Identified uses : Veterinary product.

Uses advised against : None known.

Company Name : Elanco Australasia Pty Ltd
106 Wiri Station Road,
Manukau, Auckland 2104, New Zealand

Telephone number : +64 0800 352 626

0800 446 121 (Adverse Events Local Number)

Emergency telephone number : CHEMTREC International: 00 1 703-527-3887 (24 hours)
CHEMTREC: +64 9-801 0034 (Local)
CHEMTREC: 0800 425 459 (Freephone)

Email : elanco_sds@elancoah.com

Section 2. Hazards identification

HSNO Approval Number : HSR100757

HSNO Group Standard : Veterinary Medicines (Limited Pack Size, Finished Dose)

HSNO Classification : ACUTE TOXICITY (oral) - Category 4
SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1
LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1
HAZARDOUS TO SOIL ORGANISMS
HAZARDOUS TO TERRESTRIAL INVERTEBRATES

This material is classified as hazardous according to criteria in the Hazardous Substances (Hazard Classification) Notice 2020.

This material is classified as DANGEROUS GOODS according to criteria in New Zealand Standard 5433:2020 Transport of Dangerous Goods on Land.

GHS label elements

Signal word : Warning

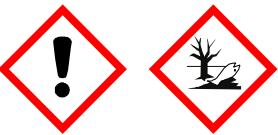
Hazard statements : H302 - Harmful if swallowed.
H410 - Very toxic to aquatic life with long lasting effects.

Precautionary statements

General : Do not apply directly into or onto water.
Take all reasonable steps to ensure that the substance does not cause any significant adverse effects to the environment beyond the application area.

Prevention : P273 - Avoid release to the environment.
P270 - Do not eat, drink or smoke when using this product.
P264 - Wash thoroughly after handling.
Do not apply substance to plants if - (a) Bees are foraging; or (b) The plants are in flower or part flower and are likely to be visited by non-target invertebrate pollinators (including bees).
Do not apply the substance to a plant if the plant is likely to flower within [***] days.

Section 2. Hazards identification

Response	: P391 - Collect spillage. P301 + P312, P330 - IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell. Rinse mouth.
Storage	: Not applicable.
Disposal	: P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.
Symbol	: 

Other hazards which do not result in classification : None known.

Section 3. Composition/information on ingredients

Substance/mixture	: Mixture	% (w/w)	CAS number
Praziquantel		≥30 - ≤60	55268-74-1
Cellulose		≥10 - ≤30	9004-34-6
Milbemycin, oxime		≥10 - ≤30	129496-10-2
silicon dioxide		≤3	7631-86-9
magnesium distearate		≤3	557-04-0
Talc , not containing asbestos fibers		≤3	14807-96-6

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

Inhalation	: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
Ingestion	: Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. If necessary, call a poison center or physician. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
Skin contact	: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. Wash clothing before reuse. Clean shoes thoroughly before reuse.
Eye contact	: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.

Most important symptoms/effects, acute and delayed

Section 4. First aid measures

Potential acute health effects

- Inhalation** : No known significant effects or critical hazards.
- Ingestion** : Harmful if swallowed.
- Skin contact** : No known significant effects or critical hazards.
- Eye contact** : No known significant effects or critical hazards.

Over-exposure signs/symptoms

- Inhalation** : No specific data.
- Ingestion** : No specific data.
- Skin** : No specific data.
- Eyes** : No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

- Specific treatments** : No specific treatment.
- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

See toxicological information (Section 11)

Section 5. Firefighting measures

Extinguishing media

- Suitable** : Use an extinguishing agent suitable for the surrounding fire.
- Not suitable** : None known.
- Specific hazards arising from the chemical** : This material is very toxic to aquatic life with long lasting effects. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.
- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
metal oxide/oxides
- Hazchem code** : 2Z
- Special precautions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
- For emergency responders** : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions

- Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Water polluting material. May be harmful to the environment if released in large quantities. Collect spillage.

Methods and material for containment and cleaning up

Section 6. Accidental release measures

Small spill : Move containers from spill area. Avoid dust generation. Using a vacuum with HEPA filter will reduce dust dispersal. Place spilled material in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.

Large spill : Move containers from spill area. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Protective measures

Protective measures : Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Avoid release to the environment. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities : Store between the following temperatures: 2 to 25°C (35.6 to 77°F). Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
praziquantel	Elanco OEL (ELANCO). TWA: 3 mg/m ³ 8 hours.
Cellulose	HSWA 2015 - HSW (GRWM) 2016. Workplace exposure standards (WES) (New Zealand, 11/2020). WES-TWA: 10 mg/m ³ 8 hours. EH40/2005 WELs (United Kingdom (UK), 1/2020). TWA: 4 mg/m ³ 8 hours. Form: respirable dust STEL: 20 mg/m ³ 15 minutes. Form: inhalable dust TWA: 10 mg/m ³ 8 hours. Form: inhalable dust Safe Work Australia (Australia, 12/2019). TWA: 10 mg/m ³ 8 hours. Form: fibres
Milbemycin, oxime	Elanco OEL (ELANCO). TWA: 0.12 mg/m ³ 8 hours.
silicon dioxide	HSWA 2015 - HSW (GRWM) 2016. Workplace exposure standards (WES) (New Zealand, 11/2020). [Silica-Amorphous: Silica gel] WES-TWA: 10 mg/m ³ 8 hours. EH40/2005 WELs (United Kingdom (UK), 1/2020). [silica, amorphous] TWA: 2.4 mg/m ³ 8 hours. Form: respirable dust TWA: 6 mg/m ³ 8 hours. Form: inhalable dust Safe Work Australia (Australia, 12/2019). TWA: 2 mg/m ³ 8 hours. Form: Respirable dust and fumes

Section 8. Exposure controls/personal protection

magnesium distearate	HSWA 2015 - HSW (GRWM) 2016. Workplace exposure standards (WES) (New Zealand, 11/2020). [Stearates] WES-TWA: 10 mg/m ³ 8 hours. Safe Work Australia (Australia, 12/2019). [Stearates] TWA: 10 mg/m ³ 8 hours. EH40/2005 WELs (United Kingdom (UK), 1/2020). TWA: 1 mg/m ³ 8 hours. Form: respirable dust Safe Work Australia (Australia, 12/2019). TWA: 2.5 mg/m ³ 8 hours.
Talc , not containing asbestiform fibres	

Biological exposure indices

No exposure indices known.

Appropriate engineering controls : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties and safety characteristics

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

Appearance

Physical state : Solid. [tablets]

Colour : Brownish-red. [Light]

Odour : meat

Odour threshold : Not available.

Section 9. Physical and chemical properties and safety characteristics

pH	: Not available.
Melting point/freezing point	: Not available.
Boiling point, initial boiling point, and boiling range	: Not available.
Flash point	: Not applicable.
Evaporation rate	: Not available.
Flammability	: Not available.
Lower and upper explosion limit/flammability limit	: Not applicable.
Vapour pressure	: Not available.
Relative vapour density	: Not applicable.
Relative density	: Not available.
Solubility(ies)	: Not available.
Solubility in water	: Not available.
Partition coefficient: n-octanol/water	: Not applicable.
Auto-ignition temperature	: Not applicable.
Decomposition temperature	: Not available.
Viscosity	: Not applicable.
Flow time (ISO 2431)	: Not available.
Particle characteristics	
Median particle size	: Not available.

Section 10. Stability and reactivity

Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	: The product is stable.
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to avoid	: No specific data.
Incompatible materials	: No specific data.
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on likely routes of exposure

Inhalation	: No known significant effects or critical hazards.
Ingestion	: Harmful if swallowed.
Skin contact	: No known significant effects or critical hazards.
Eye contact	: No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Inhalation	: No specific data.
Ingestion	: No specific data.
Skin contact	: No specific data.
Eye contact	: No specific data.

Section 11. Toxicological information

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Praziquantel	LD50 Dermal LD50 Oral	Rat Rat	>2000 mg/kg 2249 mg/kg	-
Cellulose	LD50 Oral	Rat	>5 g/kg	-
Milbemycin, oxime	LC50 Inhalation Vapour	Rat	1220 mg/m ³	4 hours
	LD50 Dermal	Rat	2000 mg/kg	-
silicon dioxide	LD50 Oral LC50 Inhalation Dusts and mists	Rat Rabbit	456 to 762 mg/kg >58.8 mg/l	- 4 hours
	LD50 Dermal	Rabbit	>5000 mg/kg	-
magnesium distearate	LD50 Oral LC50 Inhalation Vapour	Rat	>5000 mg/kg >2000 mg/m ³	- 1 hours
	LD50 Oral	Rat	>10000 mg/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
silicon dioxide	Eyes - Mild irritant	Rabbit	-	24 hours 25 mg	-
Talc , not containing asbestos fibres	Skin - Mild irritant	Human	-	72 hours 300 ug l	-

Sensitisation

Not available.

Potential chronic health effects

General	: No known significant effects or critical hazards.
Inhalation	: No known significant effects or critical hazards.
Ingestion	: No known significant effects or critical hazards.
Skin contact	: No known significant effects or critical hazards.
Eye contact	: No known significant effects or critical hazards.
Carcinogenicity	: No known significant effects or critical hazards.
Mutagenicity	: No known significant effects or critical hazards.
Teratogenicity	: No known significant effects or critical hazards.
Developmental effects	: No known significant effects or critical hazards.
Fertility effects	: No known significant effects or critical hazards.

Chronic toxicity

Not available.

Carcinogenicity

Not available.

Mutagenicity

Not available.

Teratogenicity

Not available.

Reproductive toxicity

Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Section 11. Toxicological information

Not available.

Numerical measures of toxicity

Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapours) (mg/l)	Inhalation (dusts and mists) (mg/l)
Milbemax 16/40	1646.9	N/A	N/A	63.1	N/A
Praziquantel	500	N/A	N/A	N/A	N/A
Milbemycin, oxime	2500	N/A	N/A	11	N/A

Section 12. Ecological information

Ecotoxicity : This material is very toxic to aquatic life with long lasting effects.

Aquatic and terrestrial toxicity

Product/ingredient name	Result	Species	Exposure
praziquantel	Acute EC50 77 mg/l Acute EC50 35 mg/l	Algae Crustaceans	72 hours 48 hours
Milbemycin, oxime	Acute LC50 29.22 mg/l Fresh water Acute EC50 0.011 mg/l (similar material) Chronic NOEC 0.0001 mg/l (similar material)	Fish - Carassius auratus Crustaceans	96 hours 48 hours
silicon dioxide	Acute EC50 2.2 g/L Fresh water Chronic NOEC 12.5 mg/l Fresh water	Crustaceans Daphnia - Daphnia magna - Neonate Daphnia - Daphnia magna - Neonate	21 days 48 hours 21 days

Persistence/degradability

Not available.

Bioaccumulative potential

Not available.

Mobility in soil

Soil/water partition coefficient (K_{oc})	: Not available.
Other adverse effects	: No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods	: The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.
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Section 14. Transport information

	New Zealand - Land - road/railway	IMDG	IATA
UN number	UN3077	UN3077	UN3077
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Milbemycin Oxime)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Milbemycin Oxime)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Milbemycin Oxime)
Transport hazard class(es)	9  	9  	9  
Packing group	III	III	III
Environmental hazards	Yes.	Yes.	Yes.

Additional information

New Zealand

: **Hazchem code** 2Z

IMDG

: This product is not regulated as a dangerous good when transported in sizes of ≤5 L or ≤5 kg, provided the packagings meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8.

IATA

: This product is not regulated as a dangerous good when transported in sizes of ≤5 L or ≤5 kg, provided the packagings meet the general provisions of 5.0.2.4.1, 5.0.2.6.1.1 and 5.0.2.8.

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to IMO instruments : Not available.

Section 15. Regulatory information

HSNO Approval Number	: HSR100757
HSNO Group Standard	: Veterinary Medicines (Limited Pack Size, Finished Dose)
HSNO Classification	: ACUTE TOXICITY (oral) - Category 4 SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1 LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1 HAZARDOUS TO SOIL ORGANISMS HAZARDOUS TO TERRESTRIAL INVERTEBRATES
Certified handler	: Not required
Tracking	: Not required
ACVM No.	: A008316
<u>Inventory list</u>	
New Zealand	: Not determined.

Section 16. Other information

History

Date of issue/Date of revision : 11/23/2023

Date of previous issue : 7/19/2023

Version : 0.04

Section 16. Other information

Key to abbreviations

- : ADG = Australian Dangerous Goods
- ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road
- ATE = Acute Toxicity Estimate
- BCF = Bioconcentration Factor
- GHS = Globally Harmonized System of Classification and Labelling of Chemicals
- IATA = International Air Transport Association
- IBC = Intermediate Bulk Container
- IMDG = International Maritime Dangerous Goods
- LogPow = logarithm of the octanol/water partition coefficient
- MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
- RID = The Regulations concerning the International Carriage of Dangerous Goods by Rail
- SGG = Segregation Group
- UN = United Nations

References

- : Not available.

 Indicates information that has changed from previously issued version.

Notice to reader

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:

Elanco Animal Health

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