

SAFETY DATA SHEET

Milbemax Tablets for Dogs

Section 1. Identification

Product identifier	: Milbemax Tablets for Dogs
Product code	: 12400000432
Other means of identification	: CA5007; CGA179246/CGA114326 TAB 12,5+125; Milbemax 12,5/125 TAB; MILBEMAX BROAD-SPECTRUM ALLWORMER TABLETS FOR DOGS OVER 5KG; Milbemax Tablets for Dogs; MILBEMAX 12.5/125MG X2BLCD IN
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
Emergency telephone number	0800 446 121 (Adverse Events Local 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	: SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1 LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1

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.

arning
10 - Very toxic to aquatic life with long lasting effects.
not apply directly into or onto water. ke all reasonable steps to ensure that the substance does not cause any nificant adverse effects to the environment beyond the application area.
73 - Avoid release to the environment.
91 - Collect spillage.
t applicable.
01 - Dispose of contents and container in accordance with all local, regional, tional and international regulations.
¥2

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

Section 3. Composition/information on ingredients

Substance/mixture : Mixture		
Ingredient name	% (w/w)	CAS number
Praziquantel	≥10 - <25	55268-74-1
Cellulose	≥10 - ≤30	9004-34-6
Milbemycin, oxime	≤3	129496-10-2
silicon dioxide	≤3	7631-86-9
magnesium distearate	≤3	557-04-0

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 firs	<u>st ald measures</u>
Inhalation	: Remove victim to fresh air and keep at rest in a position comfortable for breathing. 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. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel.
Skin contact	 Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
Eye contact	: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
Most important symptoms/e	ffects, acute and delayed
Potential acute health effect	<u>:ts</u>
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.
Over-exposure signs/symp	<u>toms</u>
Inhalation	: No specific data.
Ingestion	: No specific data.
Skin	: No specific data.
Eyes	: No specific data.
Indication of immediate med	lical 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.
See toxicological informatio	n (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.

Section 5. Firefighting measures

Hazardous thermal decomposition products	:	Decomposition products may include the following materials: carbon dioxide carbon monoxide nitrogen oxides metal oxide/oxides
Hazchem code	1	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, protec	tiv	e 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. 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 cor	<u>ita</u>	inment and cleaning up
Small spill	:	Move containers from spill area. Vacuum or sweep up material and place in a designated, labelled 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. Vacuum or sweep up

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 materia 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.
Broduct name : Milbemay	Tablete for Dogs N7 · ENGL

material and place in a designated, labelled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
praziquantel	Elanco OEL (ELANCO).
Cellulose	TWA: 3 mg/m ³ 8 hours. 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).
silicon dioxide	TWA: 0.12 mg/m ³ 8 hours. HSWA 2015 - HSW (GRWM) 2016. Workplace
	exposure standards (WES) (New Zealand, 11/2020).
	[Silica-Amorphous: Silica gel]
	WES-TWA: 10 mg/m³ 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
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.

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 measure	<u>es</u>	
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		

Section 8. Exposure controls/personal 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 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.	•	· · ·
Definitionbeing 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	Hand protection	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
 Respiratory protection Respiratory protection Selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. 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 	Body protection	being performed and the risks involved and should be approved by a specialist
appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important	Other skin protection	selected based on the task being performed and the risks involved and should be
	Respiratory protection	appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important

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	:	White.
Odour	:	Odourless.
Odour threshold	:	Not available.
рН	:	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	4	Not available.
Viscosity	1	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	: 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.

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.

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	Rat	>2000 mg/kg	-
	LD50 Oral	Rat	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	-
	LD50 Oral	Rat	456 to 762 mg/kg	-
silicon dioxide	LC50 Inhalation Dusts and mists	Rat	>58.8 mg/l	4 hours
	LD50 Dermal	Rabbit	>5000 mg/kg	-
	LD50 Oral	Rat	>5000 mg/kg	-
magnesium distearate	LC50 Inhalation Vapour	Rat	>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	-

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.
Product name :	Milbemax Tablets for Dogs

Pr Version :0.04

Section 11. Toxicological information

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

Not available.

Numerical measures of toxicity

Acute toxicity estimates

Product/ingredient name	Oral (mg/ kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	· · /	Inhalation (dusts and mists) (mg/l)
Milbemax 12.5/125	2500	N/A	N/A	N/A	N/A
Praziquantel	500	N/A	N/A		N/A
Milbemycin, oxime	2500	N/A	N/A		N/A

Section 12. Ecological information

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

Aquatic and terrestrial toxicity

Ecotoxicity

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

Persistence/degradability

Section 12. Ecological information

Not available.

Bioaccumulative potential

Not available.

Mobility in soil Soil/water partition : Not available. coefficient (Koc) : 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
	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.

Section 14. Transport information

	-		
	New Zealand - Land - road/ railway	IMDG	ΙΑΤΑ
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	Ш	III
Environmental hazards	Yes.	Yes.	Yes.
Additional information	tion		
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.		
ΙΑΤΑ	or ≤5 kg, provided t	 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 : Not available. to IMO instruments

Section 15. Regulatory information

HSNO Approval Number	: HSR100757
HSNO Group Standard	: Veterinary Medicines (Limited Pack Size, Finished Dose)
HSNO Classification	: SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1 LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1
ACVM No.	: A008273
Inventory list	
New Zealand	: All components are listed or exempted.

Section 16. Other information

<u>History</u>	
Date of issue/Date of revision	: 11/23/2023
Date of previous issue	: 7/19/2023
Version	: 0.04
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 = International Air Transport Association IBC = 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 0011+1-877-352-6261 0011+1-800-428-4441