

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Trade name or designation of the mixture	Milbemax 2.5/25
Registration number	-
Synonyms	CGA179246/CGA114326 TAB 2,5+25 * Milbemax 2,5/25 TAB
Item Code	CA5002

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	Veterinary Product
Uses advised against	None known.

### 1.3. Details of the supplier of the safety data sheet

#### National Supplier

Company name	Elanco Europe Ltd.
Address	Lilly House, Priestley Road Basingstoke RG24 9NL United Kingdom
Telephone	+44 1256 353131
e-mail	lilly_msds@lilly.com
Emergency telephone number	CHEMTREC International +1-703-527-3887
1.4. Information on operation hours	24 hours

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

#### Classification according to Regulation (EC) No 1272/2008 as amended

##### Environmental hazards

Hazardous to the aquatic environment, acute aquatic hazard	Category 1	H400 - Very toxic to aquatic life.
Hazardous to the aquatic environment, long-term aquatic hazard	Category 1	H410 - Very toxic to aquatic life with long lasting effects.

#### Label according to Regulation (EC) No. 1272/2008 as amended

##### Hazard pictograms



Signal word: Warning

##### Hazard statements

H410: Very toxic to aquatic life with long lasting effects.

#### Precautionary statements

##### Prevention

P273: Avoid release to the environment.

##### Response

P391: Collect spillage.

##### Storage

Not available.

##### Disposal

P501: Dispose of contents/container in accordance with local/regional/national/international regulations.

Supplemental label information: None.

2.3. Other hazards: None known.

### SECTION 3: Composition/information on ingredients

Chemical name General information	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
MILBEMYCIN OXIME	2	129496-10-2	-	-	M=10000
<b>Classification:</b>	Acute Tox. 4;H332, Aquatic Acute 1;H400, Aquatic Chronic 1;H410				
PRAZIQUANTEL	20	55268-74-1 259-559-6	-	-	
<b>Classification:</b>	Aquatic Chronic 3;H412				

#### List of abbreviations and symbols that may be used above

M: M-factor

**Composition comments** The full text for all H-statements is displayed in section 16.  
Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

### SECTION 4: First aid measures

**General information** Not available.

#### 4.1. Description of first aid measures

**Inhalation** Remove to fresh air. If breathing stops, provide artificial respiration. Get medical attention immediately.

**Skin contact** Wash off immediately with plenty of water. Continue to rinse for at least 15 minutes. Immediately take off all contaminated clothing. Get medical attention if irritation develops and persists.

**Eye contact** In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.

**Ingestion** Immediately give large quantities of water to drink. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician immediately.

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

**4.3. Indication of any immediate medical attention and special treatment needed** Not available.

### SECTION 5: Firefighting measures

**General fire hazards** Not available.

#### 5.1. Extinguishing media

**Suitable extinguishing media** Water fog. Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>).

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

**5.2. Special hazards arising from the substance or mixture** During fire, gases hazardous to health may be formed.

#### 5.3. Advice for firefighters

**Special protective equipment for firefighters** Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

**Special fire fighting procedures** Use water spray to cool unopened containers.

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

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

**For non-emergency personnel** Wear suitable protective clothing, gloves and eye/face protection. See Section 8 for personal protective equipment.

**For emergency responders** Not available.

**6.2. Environmental precautions** Avoid discharge into drains, water courses or onto the ground.

**6.3. Methods and material for containment and cleaning up** Do not sweep. Collect spill using a vacuum cleaner with a HEPA filter. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist/wet material and remove by mopping or wet wiping.

**6.4. Reference to other sections** For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.

## SECTION 7: Handling and storage

<b>7.1. Precautions for safe handling</b>	Avoid contact with eyes, skin, and clothing. Provide adequate ventilation. Wear appropriate personal protective equipment. Avoid release to the environment.
<b>7.2. Conditions for safe storage, including any incompatibilities</b>	Store in closed original container at temperatures between 2°C and 25°C. Protect from light. Protect from humidity.
<b>7.3. Specific end use(s)</b>	Not available.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

<b>Occupational exposure limits</b>	No exposure limits noted for ingredient(s).
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Recommended monitoring procedures</b>	Novartis Internal Exposure Limit (NPIEL): 0.12 mg/m <sup>3</sup> 8 hour TWA (milbemycin oxime) Elanco OEL: 3.0 mg/m <sup>3</sup> 8 hour TWA (praziquantel)
<b>Derived no effect levels (DNELs)</b>	Not available.
<b>Predicted no effect concentrations (PNECs)</b>	Not available.

### 8.2. Exposure controls

<b>Appropriate engineering controls</b>	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

<b>General information</b>	Use personal protective equipment as required.
<b>Eye/face protection</b>	If contact is likely, safety glasses with side shields are recommended.
<b>Skin protection</b>	
- Hand protection	Wear appropriate chemical resistant gloves.
- Other	Not available.
<b>Respiratory protection</b>	In case of insufficient ventilation, wear suitable respiratory equipment.
<b>Thermal hazards</b>	Not available.
<b>Hygiene measures</b>	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. Observe any medical surveillance requirements.
<b>Environmental exposure controls</b>	Inform appropriate managerial or supervisory personnel of all environmental releases.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

<b>Appearance</b>	Tablet.
<b>Physical state</b>	Solid.
<b>Form</b>	Tablet.
<b>Colour</b>	White
<b>Odour</b>	Odourless.
<b>Odour threshold</b>	Not available.
<b>pH</b>	Not applicable.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not applicable.
<b>Evaporation rate</b>	Not applicable.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not applicable.

Vapour density	Not applicable.
Relative density	Not available.
Solubility(ies)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not applicable.
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.
9.2. Other information	No relevant additional information available.

## SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Contact with incompatible materials.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	No hazardous decomposition products are known.

## SECTION 11: Toxicological information

General information	Not available.
---------------------	----------------

### 11.1. Information on toxicological effects

Components	Species	Test results
MILBEMYCIN OXIME (CAS 129496-10-2)		
<u>Acute</u>		
<b>Dermal</b>		
LD50	Rat	> 2000 mg/kg
<b>Inhalation</b>		
LC50	Rat	1220 mg/m3, 4 h
<b>Oral</b>		
LD	Rat	> 2000 mg/m3
PRAZIQUANTEL (CAS 55268-74-1)		
<u>Acute</u>		
<b>Dermal</b>		
LD50	Rat	> 2000 mg/kg
<b>Oral</b>		
LD50	Rat	2840 mg/kg
<b>Skin corrosion/irritation</b>	Rabbit: No skin irritation. (Active ingredient(s)) Based on available data, the classification criteria are not met.	
<b>Serious eye damage/eye irritation</b>	Rabbit: No irritation (Active ingredient(s)) Based on available data, the classification criteria are not met.	
<b>Respiratory sensitisation</b>	Due to lack of data the classification is not possible.	
<b>Skin sensitisation</b>	Guinea pig: Not a skin sensitiser. (Active ingredient(s)) Based on available data, the classification criteria are not met.	
<b>Germ cell mutagenicity</b>	In vitro and in vivo tests did not show mutagenic effects. (Active ingredient(s)) Based on available data, the classification criteria are not met.	
<b>Carcinogenicity</b>	Not listed by IARC, NTP, ACGIH or OSHA. (Active ingredient(s)) No effects identified in animal studies. (Milbemycin Oxime) No data available for remaining ingredients. Due to lack of data the classification is not possible.	
<b>Hungary. 26/2000 EüM Ordinance on protection against and preventing risk relating to exposure to carcinogens at work (as amended)</b>		
Not listed.		
<b>Reproductive toxicity</b>	No significant adverse effects reported. (Active ingredient(s)) Based on available data, the classification criteria are not met.	

<b>Specific target organ toxicity - single exposure</b>	No significant target organ toxicity reported. (Active ingredient(s)) Based on available data, the classification criteria are not met.
<b>Specific target organ toxicity - repeated exposure</b>	No significant target organ toxicity reported. (Active ingredient(s)) Based on available data, the classification criteria are not met.
<b>Aspiration hazard</b>	Not applicable.
<b>Mixture versus substance information</b>	Not applicable.
<b>Other information</b>	Not available.

## SECTION 12: Ecological information

**12.1. Toxicity** 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)

**12.2. Persistence and degradability** No data is available on the degradability of this product.

**12.3. Bioaccumulative potential** No data available.

**Partition coefficient  
n-octanol/water (log Kow)**

MILBEMYCIN OXIME 6,5, (at 20 °C, pH 7)  
7, (at 20 °C, pH 7)

**Bioconcentration factor (BCF)** Not available.

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

**12.5. Results of PBT and vPvB assessment** No Chemical Safety Assessment has been carried out.

**12.6. Other adverse effects** Not available.

## SECTION 13: Disposal considerations

**Disposal methods/information** Dispose of contents/container in accordance with local/regional/national/international regulations.

## SECTION 14: Transport information

**General information** Effective January 1, 2015 by Special Provision, UN3077 and UN3082 when packaged in inner packages of 5L / 5 KG or less are not subject to the dangerous goods regulations.

### ADR

**14.1. UN number** UN3077  
**14.2. UN proper shipping name** Environmentally hazardous substance, solid, n.o.s. (MILBEMYCIN OXIME)  
**14.3. Transport hazard class(es)**  
**Class** 9  
**Subsidiary risk** -  
**Label(s)** 9  
**Hazard No. (ADR)** 90  
**Tunnel restriction code** E  
**14.4. Packing group** III  
**14.5. Environmental hazards** Yes  
**14.6. Special precautions for user** Read safety instructions, SDS and emergency procedures before handling.

### RID

**14.1. UN number** UN3077  
**14.2. UN proper shipping name** Environmentally hazardous substance, solid, n.o.s. (MILBEMYCIN OXIME)  
**14.3. Transport hazard class(es)**  
**Class** 9

Subsidiary risk	-
Label(s)	9
14.4. Packing group	III
14.5. Environmental hazards	Yes
14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

#### ADN

14.1. UN number	UN3077
14.2. UN proper shipping name	Environmentally Hazardous Solid, N.o.s. (MILBEMYCIN OXIME)
14.3. Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
14.4. Packing group	III
14.5. Environmental hazards	Yes
14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

#### IATA

14.1. UN number	UN3077
14.2. UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (MILBEMYCIN OXIME)
14.3. Transport hazard class(es)	
Class	9
Subsidiary risk	-
14.4. Packing group	III
14.5. Environmental hazards	Yes
ERG Code	9L
14.6. 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.

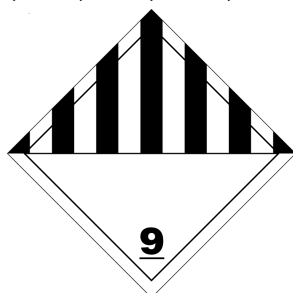
#### IMDG

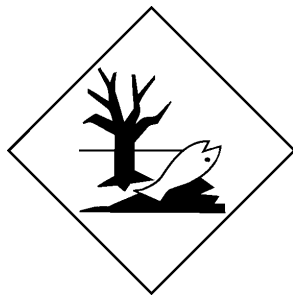
14.1. UN number	UN3077
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (MILBEMYCIN OXIME)
14.3. Transport hazard class(es)	
Class	9
Subsidiary risk	-
14.4. Packing group	III
14.5. Environmental hazards	
Marine pollutant	Yes
EmS	F-A, S-F
14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable.

ADN; ADR; IATA; IMDG; RID





## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Not listed.

#### Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

#### Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

#### Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances, as amended

Not listed.

#### National regulations

The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended and respective national laws implementing EC directives.

#### 15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

## SECTION 16: Other information

#### List of abbreviations

TWA: Time Weighted Average

Elanco OEL: Elanco Occupational Exposure Limit

Not available.

#### References

##### Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

##### Full text of any H-statements not written out in full under Sections 2 to 15

H332 Harmful if inhaled.

H410 Very toxic to aquatic life with long lasting effects.

H412 Harmful to aquatic life with long lasting effects.

#### Lilly Lab Code

Health: 1

Fire: 1

Reactivity: 0

#### Revision information

None.

## 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 MATERIAL 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