



Product Name: SENTINEL[®] SPECTRUM Tasty Chews for Small Dogs

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Date issued : 31st of March 2009

MATERIAL SAFETY DATA SHEET

Section 1 - Identification of Chemical Product and Company

COMPANY DETAILS:

Novartis Animal Health Australasia Pty Limited
54 Waterloo Road
North Ryde NSW 2113

Phone: (02) 9805 3555

Fax: (02) 9888 8387

Product Name : SENTINEL[®] Spectrum Tasty Chews for Small Dogs
Active Ingredients: Milbemycin oxime (macrolide derivative), praziquantel (acylated pyrazino- isoquinoline derivative), lufenuron (benzoyl urea)
Ciba-Geigy Code : Milbemycin oxime (CGA 179246), lufenuron (CGA 184699)
Product Use : Monthly treatment to prevent heartworm (*Dirofilaria immitis*) infection, control adult roundworm (*Toxocara canis*, *Toxascaris leonina*), immature roundworm (*Toxocara canis*), adult whipworm (*Trichuris vulpis*), adult hookworm (*Ancylostoma caninum*), adult tapeworm (*Echinococcus granulosus*, *Taenia pisiformis*, *Dipylidium caninum*), aid in the control of adult hookworm (*Uncinaria stenocephala*) infection, long term protection and control of flea (*Ctenocephalides felis*) infestations, and control of flea allergy dermatitis in dogs.
Creation Date: March 2009
Revision Date: March 2014

Section 2 Hazards Identification

Hazard classification: NON-HAZARDOUS SUBSTANCE
NON-DANGEROUS GOODS
Risk Phrases: None
Safety Phrases: None
SUSDP Classification: S5
UN Number: None allocated

Section 3 Composition / Information on ingredients

| Ingredients (mg/m ³) | CAS No | Content | TWA (mg/m ³) | STEL |
|----------------------------------|---------------------------|--------------------|--------------------------|---------|
| Milbemycin oxime | 150702-33-3 & 150702-32-2 | 5.75 mg per tablet | not set | not set |
| Praziquantel | 55268-74-1 | 57 mg per tablet | not set | not set |
| Lufenuron | 103055-07-8 | 115 mg per tablet | not set | not set |
| Other non hazardous ingredients | | to 1.5 g | not set | not set |

Novartis Animal Health Australasia Pty Ltd

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This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non hazardous ingredients are also possible.

The TWA exposure value is the average airborne concentration of a particular substance when calculated over a normal 8 hour working day for a 5 day working week. The STEL (Short Term Exposure Limit) is an exposure value that should not be exceeded for more than 15 minutes and should not be repeated for more than 4 times per day. There should be at least 60 minutes between successive exposures at the STEL. The term "peak "is used when the TWA limit, because of the rapid action of the substance, should never be exceeded, even briefly.

Section 4 First Aid Measures**Label Regulated First****Aid Statement:**

If poisoning is suspected, immediately contact a doctor, the nearest hospital, or **Poisons Information Centre (Phone 131126)**. Tell the person contacted the complete product name, and the type and amount of exposure. Describe any symptoms and follow the advice given.

General

Remove the victim from contaminated area. If there is a risk of unconsciousness, position and transport in a stable lateral position. Remove soiled or soaked clothing immediately.

Scheduled Poisons :

Product is a S5 scheduled poison. Poisons Information Centres in each State capital city can provide additional assistance for scheduled poisons (Phone 131126).

Inhalation:

Inhalation of this product will not occur.

Skin Contact:

Wash affected area immediately with soap and water. Seek medical advice if required.

Eye Contact:

Flush eye immediately with large amounts of water, occasionally lifting eyelids, until no evidence of chemical remains. Seek medical advice if eye irritation persists.

Ingestion :

If vomiting occurs due to ingestion, keep the head lower than the hips to help prevent aspiration.

Advice to Doctor:

No specific antidote is known. If poisoning is suspected, treat symptomatically. Lavage stomach only if very large quantities are ingested.

Based on the oral LD₅₀ of the actives in rodents, ingestion of a fatal dose by an adult human is unlikely to occur

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| Extinguishing Media: | Sprayed water jet, foam, dry powder, sand, CO ₂ |
| Fire and Explosion Hazards: | Non-flammable, Non-explosive material. Outer packaging may burn. |
| Fire Fighting: | Fight fire in the early stages if safe to do so. Wear respiratory protection. In a well ventilated areas wear full mask with a combination filter. In enclosed areas wear respirator with independent air supply. Contain fire-fighting water. Do not allow the fire-water to enter drains |

Section 6 Accidental Release Measures

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| Accidental Release: | Use any protective equipment listed in Section 8 Due to the nature of the packaging, open spillage of the product is highly unlikely. Spilled product should be shovelled and placed in sealed containers for disposal. Do not empty into drains. Avoid breathing any dust and contact with the skin. On completion of clean up, scrub the area with detergent and water and rinse with water. Do not eat, drink or smoke during the clean-up operation. |
|----------------------------|--|

Section 7 Handling and Storage

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| Safe Handling: | No specific recommendations |
| Storage: | Keep out of reach of children Store in original containers out of reach of children. Store below 25°C (Air conditioning), away from direct sunlight. Store away from food, drink and food preparation areas. |

Section 8 Exposure Controls / Personal Protection

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| Exposure Limits: | No exposure allocated for milbemycin oxime No exposure allocated for praziquantel No exposure allocated for lufenuron No exposure allocated for other ingredients |
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| Ventilation: | No ventilation is required under normal conditions of use. |
| Eye Protection | No eye protection is required under normal conditions of use. |
| Skin protection: | No skin protection is required under normal conditions of use. |
| Respirator: | No respirator is required under normal conditions of use. |
| Protective material types: | Rubber latex |
| General advice | None |

Section 9 - Physical and Chemical Properties

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| Physical State: | Cushion-shaped soft chewies in foil strips |
| Colour | Slightly brown |
| Odour: | Beef/Bacon |
| Corrosiveness: | Non-corrosive |
| Flammability: | Non-flammable |

Section 10 - Stability and Reactivity

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| Chemical Stability: | Product is stable. No hazardous reactions |
| Incompatible Materials: | None |

Section 11 - Toxicological Information**Acute Toxicity :**

| | |
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| Oral: | Milbemycin oxime is non-toxic: Oral LD ₅₀ in rats > 2000 mg/kg bodyweight. Praziquantel is practically non-toxic by oral administration: LD ₅₀ in rats >2000 mg/kg. Lufenuron is of low toxicity: LD ₅₀ in rats > 2000 mg/kg |
| Dermal: | Milbemycin oxime - toxicity unknown, although subcutaneous LD ₅₀ in rats > 2000 mg/kg bodyweight. Praziquantel - LD ₅₀ in rats > 2000 mg/kg Lufenuron is of low toxicity: LD ₅₀ in rats > 2000 mg/kg bodyweight (estimated) |
| Inhalation: | Milbemycin oxime - LC ₅₀ (4hrs) in rats is 1220 mg/m ³ Praziquantel – toxicity unknown, but highly unlikely route of exposure. Lufenuron is of low toxicity: LC ₅₀ (4hrs) in rats >2350 mg/kg bodyweight. |

Local Effects:

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| Irritation - | (Based on studies with Rabbits) |
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Eye: Milbemycin oxime is a non-irritant. Praziquantel is a non-irritant. Lufenuron is a non-irritant.

Skin: Milbemycin oxime is a non-irritant. Praziquantel is a non-irritant. Lufenuron is a non-irritant.

Sensitisation - (Based on results on guinea-pigs)

Skin: Milbemycin oxime is a non-sensitiser. Praziquantel is a non-sensitiser. Lufenuron is a moderate potential sensitiser.

Chronic Toxicity - Milbemycin oxime: In subchronic and chronic feeding studies in dogs, no compound-related signs of toxicity were observed at 1.5 mg/kg (3 times the monthly use level). Mild, transient ataxia and/or trembling was observed in puppies dosed at 9 mg/kg and 15 mg/kg daily for three days. No adverse effects on reproduction or pup development occurred in dogs dosed at three times the recommended monthly dose level, given daily throughout pregnancy.

In a 3-month oral gavage study with rats, no signs of toxicity were observed at 3 mg/kg/day (equivalent to almost 200-times the recommended monthly dose for dogs). Effects at 15 and 100 mg/kg/day, given daily for 3 months, included a decrease in extramedullary haematopoietic foci in the spleen at both dose levels, with mild anaemia and fatty changes in the liver occurring at the high dose only.

Praziquantel: Praziquantel was reported to be non-tumorigenic in non-standard lifetime carcinogenicity assays in hamsters and rats. There is no direct evidence that praziquantel is carcinogenic, and no cause for concern based on decades of use in millions of humans.

Lufenuron: Lufenuron has been tested on laboratory mammals and in test tube systems. No evidence of mutagenic, carcinogenic, teratogenic or reproductive effects was obtained.

Section 12 - Ecological Information

Ecological Data for Praziquantel:

Fish:

LC₀ (96hrs) 31.6 mg/L Zebra barbel (*Brachydanio rerio*)

LC₁₀₀ (96hrs) 100mg/L Zebra barbel (*Brachydanio rerio*)

LC₀ (96hrs) > 10mg/L *Lepomis macrochirus*

Daphnia:

EC₀ (48hrs) 35mg/L Water flea (*Daphnia magna*)

EC₁₀₀ (48hrs) 35mg/L Water flea (*Daphnia magna*)

Bacteria

EC₅₀ > 10,000mg/L Activated sludge

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Ecological Data for Milbemycin oxime:

LC₅₀ (48hrs) 59 ng/L, Carp

LC₅₀ (3hrs) > 300 mg/L, Water flea (*Daphnia magna*)

Ecological Data for Lufenuron:

Toxicity to Fish: LC₅₀ (96hrs) > 29 mg/L, Bluegill sunfish

Toxicity to Daphnia: EC₅₀ (48hrs) 0.0011 – 0.0013 mg/L, Water flea (*Daphnia magna*)

Toxicity to Algae: EC₅₀ (3days) 10 mg/L, Green Algae (*Scenedesmus subspicatus*)

Toxicity to Microorganisms: EC₅₀ (3hrs) > 100 mg/L, Sewage sludge

Toxicity to Soil Organisms: EC₅₀ (14days) 1000 mg/L, Earthworm (*Eisenia foetida*)

Toxicity to Birds: LD₅₀ > 2000 mg/kg, Bobwhite Quail

Toxicity to Bees: LD₅₀ (48hrs) > 100 µg/bee, Honey bees (*Apis mellifera L.*)

Biodegradability: 0%. Not readily biodegradable. Test type: Carbondioxide Evolution (28days), Waste water bacteria

Section 13 - Disposal Considerations

After Intended Use: Dispose of empty packaging by wrapping in paper and putting in garbage

After Spill or Accident: Spilled product should be shovelled and placed in sealed containers for disposal. This can be disposed at an approved local waste disposal site.

Section 14 - Transport Information

UN Number: None allocated

UN proper shipping name: None allocated

Class & Subsidiary Risk : None allocated

Packaging Group: None allocated

HAZCHEM Code: None allocated

Section 15 - Regulatory Information

Australia : Product registered with the APVMA



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Section 16 - Other Information

This MSDS contains only safety-related information. For other data see product literature.

Acronyms:

| | |
|-------------------|---|
| ADG Code | Australian Code for the Transport of Dangerous Goods by Road and Rail |
| APVMA | Australian Pesticides and Veterinary Medicines Authority |
| CAS Number | Chemical Abstracts Service Registry Number |
| NOHSC | National Occupational Health and Safety Commission |
| R-Phrase | Risk Phrase |
| SUSDP | Standard for the Uniform Scheduling of Drugs & Poisons |
| UN Number | United Nations Number |

Note: This product is a registered veterinary chemical and therefore must be used in accordance with the container label directions. A comprehensive package of toxicological and environmental data has been submitted to the Federal health and environmental authorities and has been evaluated by expert toxicologists and environmental scientists.

CONTACT POINT: Regulatory Affairs Manager (02) 9805 3555
