

SAFETY DATA SHEET

Zoetis New Zealand Limited
Level 3, 14 Normanby Road, Mt Eden, Auckland



Section 1: Identification of the Substance and Supplier

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| Trade Name: | DECTOMAX[®] |
| ACVM Registration No.: | A006199 |
| Classification: | Unrestricted |
| Recommended Use: | Injectable endectocide for treatment and control of doramectin-sensitive gastrointestinal roundworms (including inhibited larvae of <i>Ostertagia ostertagi</i>), lungworms, sucking lice and mange of cattle and internal and external parasites of sheep and pigs. |
| Company Details: | Zoetis New Zealand Limited |
| Address: | Level 3,14 Normanby Road Mt Eden Auckland 1024 New Zealand |
| Telephone No.: | 0800 650 277 (Business Hours) |
| Emergency Telephone No.: | National Poisons Centre: 0800 POISON (0800 764 766) Emergency Services: In an emergency dial 111 |
| Date of Preparation: | 13 February 2013 |

Section 2: Hazards Identification

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| Hazard Classification: | 6.1E, 6.8B, 6.8C, 6.9B, 9.1A, 9.2C, 9.4A |
| Priority Identifier(s): | WARNING – KEEP OUT OF REACH OF CHILDREN ECOTOXIC |
| Secondary Identifier(s): | 6.1E May be harmful if swallowed, inhaled or absorbed through the skin. 6.8B Suspected of damaging fertility or the unborn child from repeated oral exposure. 6.8C May cause harm to breast-fed children from repeated oral exposure. 6.9B May cause target organ damage from repeated oral exposure at high doses. 9.1A Very toxic to aquatic organisms. Avoid contamination of any water supply with product or empty container. 9.2C Harmful to the soil environment. 9.4A Very toxic to terrestrial invertebrates. |

Section 3: Composition / Information on Ingredients

Chemical Identity of Ingredients

| Ingredient | CAS No. | Concentration |
|---|-------------|---------------|
| Doramectin | 117704-25-3 | 10.0 g/L |
| Other ingredients determined not to be hazardous. | - | - |

This is a commercial product whose exact ratio of components may vary.
Trace quantities of impurities are also likely.

Section 4: First Aid Measures

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| Necessary First Aid Measures: | <p>For advice contact the National Poisons Centre at 0800 POISON (0800 764 766) or a doctor immediately. If the patient is not breathing begin artificial respiration and seek medical advice immediately. Never give fluids or induce vomiting if a patient is unconscious or convulsing, regardless of injury.</p> <p>Self-Injection: Immediate medical advice should be sought on the management of all instances of accidental self-injection, particularly those near a joint or associated with bruising. Allow the wound to bleed freely and avoid squeezing the injection site to avoid spread of the product. Clean the wound thoroughly with soap and water, then keep it clean and dry.</p> <p>Ingestion: DO NOT induce vomiting. If the patient is conscious wash mouth out with water. Do not give anything by mouth to an unconscious person. Seek medical advice immediately.</p> <p>Eye Contact: Flush the eye(s) out with running water for at least 15 minutes. Removal of contact lenses should be done with caution within 5 minutes of exposure. If symptoms develop seek medical advice immediately.</p> <p>Skin Contact: Remove any contaminated clothing and wash the affected area immediately with soap and water. If symptoms develop seek medical advice immediately.</p> <p>Inhalation: Move the patient to fresh air. If symptoms develop seek medical advice immediately.</p> |
| Poisoning Symptoms: | Signs and symptoms of exposure include respiratory depression, weakness, tremors and ataxia. |
| Workplace Facilities: | No specific facilities required. Standard emergency equipment must be available. |
| Hygiene Practices: | Avoid self-injection, ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while using this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use. |
| Notes for Medical Personnel: | This product contains sesame oil as a vehicle. Accidental self-injection may lead to an inflammatory response and deep injections, particularly those near a joint or associated with bruising should be treated medically or surgically. |

Section 5: Fire-Fighting Measures

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| Type of hazard: | This product is not flammable, however, irritating and possibly toxic gases may be generated by thermal decomposition or combustion. |
| Fire Hazard Properties: | Heat may cause violent rupture of containers. |
| Regulatory Requirements: | Not applicable. |
| Extinguishing Media & Methods: | Use dry chemical, foam, carbon dioxide or water to extinguish fires involving this product. |
| Hazchem Code: | Not allocated. |
| Recommended Protective Clothing: | During large-scale fire fighting operations wear approved positive pressure, self-contained breathing apparatus and full protective turn-out gear. |

Section 6: Accidental Release Measures

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| Personal Precautions: | Personnel involved in clean-up should wear appropriate personal protective equipment to minimise exposure. This may include eye protection, chemically resistant gloves, boots and overalls. |
| Environmental Precautions: | Prevent material from entering surface water drains or waterways. If a significant quantity of material enters drains, advise emergency services. |
| Procedure for Spills: | <ol style="list-style-type: none">1. Non-essential personnel should be evacuated from the affected area.2. Stop leak and contain the source of spill if it is safe to do so. Reposition any leaking containers to minimise further leakage.3. Absorb the spill with an absorbent material (e.g. sand).4. Collect the spilled material into labelled containers for disposal, minimising dust generation.5. Decontaminate the spill area thoroughly with detergent and water, preventing runoff from entering drains. |
| Procedure for Disposal: | Contaminated material must be disposed of at an approved landfill or other approved facility in accordance with local, regional and national requirements. Avoid contamination of any water supply with product or empty container. |

Section 7: Handling and Storage

Handling

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| Precautions for Safe Handling: | No special technical protective measures required. No special handling advice required. |
| Regulatory Requirements: | Not required. |
| Handling Practices: | Avoid self-injection, ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while handling this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use. |
| Approved Handlers: | Approved handlers are not required for this product. |

Storage

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| Conditions for Safe Storage: | Store below 30°C (Room Temperature). Protect from light. Keep out of reach of children. Store in a well ventilated area in the original container, tightly closed, away from foodstuffs. |
| Store Site Requirements: | A requirement for an emergency management plan, secondary containment and signage is applicable when quantities of 100 L are stored. |
| Packaging: | Packaging Schedule 3 (UN Packing Group III) for quantities > 5 L (Hazardous Substances Packaging Regulations 2001). |

Section 8: Exposure Control / Personal Protection

Always Read and Follow the Label Instructions and Warnings

Workplace Exposure Guidelines

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| Workplace Exposure Standards: | A time weighted average (TWA) concentration for an 8-hour day and a 5-day week has not been established by NOHSC Australia for any of the major ingredients in this product. There is a blanket limit of 10 mg/m ³ for dusts or mists when limits have not otherwise been established. |
| Application in the Workplace: | The nature of this product makes it unlikely that this level will be approached during normal handling. |
| Exposure Standards Outside the Workplace: | None set. |
| Engineering Controls: | Engineering controls should be used as the primary means to control exposures. Use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. |
| Personal Protection: | <p>The following instructions are for those coming into frequent and / or lengthy contact with this product. For occasional handling employ precautions suitable for the conditions under which the product is being handled.</p> <p>Hands: Impervious gloves are recommended if skin contact is possible and for bulk processing operations.</p> <p>Eyes: It is always prudent to utilise protective eyewear.</p> <p>Skin: When prolonged or frequently repeated contact could occur, utilise chemically protective clothing. Selection of specific items such as a face shield, gloves, boots, or overalls will depend on the situation.</p> <p>Respiratory: Respiratory protection is not normally required; however, if necessary utilise an air-purifying respirator that complies with NZ standards.</p> |
| General Hygiene: | Change work clothes regularly. Avoid self-injection, ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while handling this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use. |

Section 9: Physical and Chemical Properties

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| Appearance: | Colourless to pale yellow clear liquid |
| Odour: | Odourless |
| Specific Gravity / Density: | 0.91 g/mL |
| Freezing / Melting Point: | Not applicable |
| Boiling Point: | No data available. Expected to decompose before boiling |
| pH: | Approximately 8.0 |
| Solubility in Water: | Virtually insoluble in water |
| Flashpoint: | Approximately 100°C |
| Oxidising Properties: | Not applicable. This product is not an oxidiser |
| Corrosive Properties: | Not applicable. This product is not corrosive |
| Vapour Pressure: | Less than 7 x 10 ⁻⁷ torr at 20°C (doramectin) |

Section 10: Stability and Reactivity

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| Stability of the Substance: | This product is stable under normal conditions of use. |
| Conditions to Avoid: | Store as recommended. No specific conditions to avoid. |
| Material to Avoid: | None known. |
| Hazardous Decomposition Products: | Thermal and photolytic decomposition of doramectin gives rise to a number of compounds from oxidation of radicals. None of these degradation by-products are considered more toxic than the parent compound. |
| Hazardous Polymerisation: | This product is unlikely to spontaneously polymerise. |
| Specific Data: | No specific data available. |

Section 11: Toxicological Information

HSNO Classifications

- 6.1E** May be harmful if swallowed, inhaled or absorbed through the skin.
- 6.8B** Suspected of damaging fertility or the unborn child from repeated oral exposure.
- 6.8C** May cause harm to breast-fed children from repeated oral exposure.
- 6.9B** May cause target organ damage from repeated oral exposure at high doses.

Acute Effects

Primary route of exposure is accidental self-injection or by skin exposure from breakage or leakage.

Should self-injection occur, it is most doubtful that the consequences would be life-threatening. While there is no data on human exposure to the compound, it is closely structurally and toxicologically related to ivermectin which has been extensively administered to humans for filarial disease in Africa for a number of years. In addition, doramectin has been shown to be almost identical in behaviour to mammalian toxicology assessment systems and in terms of acute toxicity it has been shown to be even safer than ivermectin.

The formulation constituents are non-toxic oils. Therefore, the nature and use of the product makes it unlikely that any ill effects will be sustained while using the product.

Self-Injection: Local injection site reactions in humans may occur from accidental self-injection through the skin.

Ingestion: Due to the method of application, this should not occur however data suggests that the product should be considered as slightly toxic by ingestion.

Doramectin:

- Rat (M) Oral LD50 1000-2000 mg/kg (aqueous suspension)
- Rat (F) Oral LD50 500-1000 mg/kg (aqueous suspension)
- Rat(M) Oral LD50 50-100 mg/kg (in sesame oil)
- Rat (F) Oral LD50 100-200 mg/kg (in sesame oil)

Eye Contact: Data suggests that this product should be classified as a minimal eye irritant.

Doramectin:

- Irritation Ocular (Rabbit) Negative

Skin Contact: Data suggests that the product presents minimal hazard via skin contact.

Doramectin:

- Irritation Dermal (Rabbit) Negative

Inhalation: There is no data available relating to inhalation however the mode of use of the product would make this highly unlikely.

Chronic / Long Term Effects

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| Subchronic Effects: | Doramectin was tested in both rats and dogs. In a 3-month rat study, the only treatment related effect noted was an increase in liver weight. In dogs a 1-month study resulted in mydriasis, decreased food consumption and decreased body weight. Animals receiving the high dose (4 mg/kg/day) also exhibited tremors, salivation, ataxia, and emesis. A 3-month study in dogs produced only dose-dependent mydriasis. |
| Carcinogenicity: | No carcinogenic data available. However, the carcinogenic potential of a structurally related avermectin, abamectin, has been investigated in rodents. No evidence of carcinogenicity was seen in these studies. None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. |
| Mutagenicity: | No evidence of mutagenicity was observed for doramectin when tested in vitro and in vivo in the following assays: the Ames test, the mouse lymphoma assay, and the unscheduled DNA synthesis (UDS) assay. |
| At Increased Risk from Exposure: | This material has been shown in rats to be excreted in milk and, as a result, to cause toxicity in young pups; nursing mothers should exercise caution regarding exposure. |

Section 12: Ecotoxicity Information

HSNO Classifications

- 9.1A** Very toxic to aquatic organisms. Avoid contamination of any water supply with product or empty container.
- 9.2C** Harmful to the soil environment.
- 9.4A** Very toxic to terrestrial invertebrates.

The environmental characteristics of this material have not been fully evaluated.
Avoid contamination of any water supply with product or empty container.

Ecotoxicity Effects

| Aquatic Toxicity: | <u>Type:</u> | <u>Species:</u> | <u>Result:</u> |
|---|---------------------------|-------------------------|----------------|
| | EC ₅₀ /48h | Daphnia magna | 0.1 ppb |
| | LC ₅₀ /96h | Bluegill Sunfish | 11 ppb |
| | LC ₅₀ /96h | Rainbow Trout | 5.1 ppb |
| | MIC/24-48h | Aspergillus niger | 600 mg/l |
| | MIC/24-48h | Clostridium perfringens | 40 mg/l |
| | MIC/14days | Green Algae | <1 mg/l |
| | MIC/24-72h | Nostoc | 60 mg/l |
| Toxicity to Birds: | Not applicable. | | |
| Toxicity to Soil Dwelling Organisms: | No information available. | | |
| Acute Toxicity to Bees: | Not applicable. | | |

Environmental Fate

In the environment, the active ingredient in this formulation is expected to bind tightly to soil or sediment and readily desorb. It is unlikely to reach groundwater and is also biodegradable by soil microflora. Harmful effects to aquatic organisms could occur.

Section 13: Disposal Considerations

Product Disposal: Preferably dispose of product by use in accordance with label directions. Otherwise dispose of product at an approved landfill, or other approved facility in accordance with local, regional and national regulations. Avoid contamination of any water supply with product.

Container Disposal: Dispose of empty containers by wrapping in paper and putting in garbage for disposal at an approved landfill, or other approved facility in accordance with local, regional and national regulations. Avoid contamination of any water supply with empty container. Used needles and syringes should immediately be placed in a designated and appropriately labelled "sharps" container.

Section 14: Transport Information

Dangerous Goods Classification

UN No.: 3082

Class: 9

Packing Group: III

Proper Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID or N.O.S

Section 15: Regulatory Information

HSNO Approval No.: HSR001908

HSNO Controls: See www.epa.govt.nz for controls

ACVM Registration No.: A006199

ACVM Controls: See www.foodsafety.govt.nz for registration conditions

Section 16: Other Information

Note: This product is a veterinary medicine and must therefore be used in accordance with the container label directions. A comprehensive package of toxicological and environmental data for the active ingredients of this product has been submitted to the Government health and environment authorities and has been evaluated by expert toxicologists and environmental scientists.

CONTACT POINT: **Zoetis New Zealand Limited:** 0800 650 277 (Business Hours)
 National Poisons Centre: 0800 POISON (0800 764 766)
 Emergency Services: Dial 111

This Safety Data Sheet summarises our best knowledge of the health and safety hazard information of the product and how to safely handle and use the product in the workplace. Each user should read this SDS and consider the information in the context of how the product will be handled and used in the workplace including in conjunction with other products.

PLEASE READ ALL LABELS CAREFULLY BEFORE USING PRODUCT.

If clarification of further information is needed to ensure that an appropriate risk assessment can be made, the user should contact this company.

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