

Product Name: **Doraject Injection**

## 1. IDENTIFICATION OF SUBSTANCE AND SUPPLIER

<b>Product name:</b>	<b>Doraject Injection</b>
<b>ACVM Approval No.</b>	<b>A10717</b>
<b>Recommended use:</b>	<b>For the treatment and control of doramectin-sensitive internal parasites of cattle.</b>
<b>Supplier:</b>	<b>HORIZON AGRESOURCES (NZ) LTD</b>
<b>Address:</b>	<b>Gloucester Court, 250 Gloucester St, Napier 4112.</b>
<b>Contact number:</b>	<b>0800 378 6300</b>
<b>Emergency contact number:</b>	<b>0800 734 607 (24 hours)</b>
<b>Document version and date:</b>	<b>1.0 27 December 2016</b>

## 2. DETAILS OF FORMULATION

<b>Product ingredients:</b>	<b>C.A.S Number</b>	<b>Concentration:</b>
Doramectin	117704-25-3	10 g/L
Benzyl alcohol	100-51-6	< 5%

Remaining ingredients are commercially sensitive and cannot be disclosed in a public document.

## 3. EPA HAZAR CLASSIFICATION

This product is an approved substance under the Hazardous Substances and New Organisms Act (HSNO). Approval code: HSR100442.

<b>Hazard Classification</b>	<b>Hazard statements</b>
6.8B Suspected of damaging fertility and/or the unborn child	WARNING: Doramectin is suspected of damaging fertility or the unborn child. Avoid using product immediately prior to; or during pregnancy.
6.8C May cause harm to breast-fed children.	Avoid use whilst breast-feeding.
9.1A Aquatic toxin (crustacean and algae)	WARNING: Very toxic to aquatic life.
9.2C Soil toxin	Harmful to the soil environment.
9.4A Invertebrate toxin	WARNING: Very toxic to terrestrial invertebrates.

**KEEP OUT OF REACH OF CHILDREN**

**Warning Dangerous to the environment**

Avoid contamination of any water supply with product or empty container. Avoid release to the environment.



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## 4. FIRST AID INSTRUCTIONS

<b>Necessary first aid measures:</b>	For advice contact the National Poisons Centre on 0800 POISON (0800 764 766), or a doctor immediately. INGESTION: If swallowed seek medical attention. Do NOT induce vomiting. EYES: If splashed in eyes wash out immediately with water. SKIN: If skin or hair contact occurs remove contaminated clothing and flush skin and hair with running water. INHALATION: Remove to fresh air. SELF-INJECTION: Seek medical attention.
<b>Workplace facilities:</b>	No special facilities required.
<b>Required instructions:</b>	Observe good work practices and avoid skin and eye contact. Wash hands and exposed skin before meals and after use. Do not eat or drink while using. Launder protective clothing separately from other clothing, and before each re-use.
<b>Notes for medical personnel:</b>	Apply symptomatic therapy (no specific antidote). Note the nature of the product (reproductive/developmental toxin, sensitizer and irritant).

## 5. FIRE FIGHTING MEASURES

<b>Fire and explosion hazards:</b>	Non flammable, Non combustible, Non explosive
<b>Suitable extinguishing substances:</b>	Carbon dioxide, extinguishing powder or water jet. Fight larger fires with water jet or alcohol resistant foam.
<b>Unsuitable extinguishing substances:</b>	Not known.
<b>Products of combustion:</b>	Carbon dioxide, and if combustion is incomplete, carbon monoxide and smoke. Water. May form toxic mixtures in air and may accumulate in sumps, pits and other low-lying spaces, forming potentially explosive mixtures.
<b>Protective equipment:</b>	Self-contained breathing apparatus. Safety boots, non-flammable overalls, gloves, hat and eye protection.
<b>Hazchem code:</b>	3Z

## 6. ACCIDENTAL RELEASE MEASURES

<b>Emergency procedures:</b>	Wear suitable protective clothing. Restrict access to contaminated area. Contain the spill and prevent further dispersion. Retrieve intact containers from site. Place damaged containers into containment devices. Absorb spills with inert material (e.g. sand or vermiculite), and place in waste containers. Wash the area with water and absorb with further inert material. Collect spilled material and place in sealable containers for subsequent disposal. Prevent contamination of water courses or sewers. Dispose of waste safely.
<b>Containment for bulk storage:</b>	If greater than 100L is stored in one location, secondary containment and emergency plans to manage any potential spills must be in place. <b>In all cases design storage to prevent discharge to storm-water drains. (If this occurs contact your regional council immediately).</b>

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## 7. HANDLING AND STORAGE

<b>Precautions for safe handling:</b>	Apply with well-maintained and calibrated equipment. Handle with care.
<b>Regulatory requirements:</b>	N/A
<b>Approved handler requirements</b>	N/A
<b>Conditions for safe storage:</b>	Store below 25°C. Protect from light. Store locked up and out of reach of children
<b>Store site requirements:</b>	This substance is subject to a requirement for an emergency management plan, secondary containment and signage, whenever it is held in quantities of 100L or more. See Hazardous Substances (Emergency management) regulations 25 to 42.
<b>Packaging:</b>	Packaging Schedule 3 (UN Packing Group III) for quantities >1L (Hazardous Substances Packaging Regulations 2001).

## 8. EXPOSURE CONTROL/PERSONAL PROTECTION

<b>Work place exposure standards:</b>	N/A
<b>Application in the workplace</b>	Prevent exposure by using engineering controls, personal protective equipment and work practices that prevent skin and eye contact, and prevent release to the environment.
<b>Exposure standards outside the workplace:</b>	TELs and EELs are not set at this time.
<b>Engineering controls:</b>	N/A
<b>Personal protection:</b>	Clothing should consist of overalls with long sleeves, eye protection and impervious gloves.
<b>References:</b>	N/A

## 9. PHYSICAL AND CHEMICAL CHARACTERISTICS

<b>Formulation Type:</b>	Liquid
<b>Appearance:</b>	Clear yellow tinted solution
<b>Specific gravity:</b>	0.92 – 0.98 g/mL
<b>Vapour pressure:</b>	N/A
<b>Solubility in water:</b>	Doramectin is insoluble in water; excipients are also insoluble in water.
<b>Auto ignition temperature:</b>	Not known
<b>Hazards:</b>	Non-flammable; non-corrosive; non-oxidizing; non-explosive.

## 10. STABILITY AND REACTIVITY

<b>Stability of the substance:</b>	Stable under normal conditions of use and storage.
<b>Conditions to avoid:</b>	No specific conditions to avoid
<b>Material to avoid:</b>	No specific materials to avoid.
<b>Hazardous decomposition products:</b>	Hazardous decomposition products are expected when heated to decomposition temperatures. Use appropriate PPE when fighting fires.
<b>Hazardous polymerization:</b>	Components are not expected to form hazardous polymers.
<b>Specific data:</b>	N/A

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<b>11. TOXICOLOGICAL INFORMATION</b>	
<b>Data and interpretation:</b>	Harmful if swallowed. Repeated exposure may cause skin allergy. Doramectin can affect development of the unborn child and/or reproduction. May cause harm to breast-fed children.
<b>Summary data:</b>	<p><b><i>Doramectin</i></b></p> <p>Refer to EPA website for full details of toxicity classifications: <a href="http://www.epa.govt.nz/search-databases/Pages/ccid-details.aspx?SubstanceID=747">http://www.epa.govt.nz/search-databases/Pages/ccid-details.aspx?SubstanceID=747</a></p> <p>Highest classification data included below:</p> <p>6.4A SPECIES: Rabbit RESULT: Moderate REFERENCE SOURCE: Fischer J. E. (1990i). Eye irritation study in albino rabbits with AC 301, 423. Unpublished report No. A90-22. Submitted to WHO by American Cyanamid Company, Princeton, NJ, USA. Doramectin (WHO Food Series 36), Dr K. Woodward, Veterinary Medicines Directorate, Ministry of Agriculture, Fisheries and Food, Addlestone, Surrey, England [INCHEM]</p> <p>6.9A (oral) EndPoint: LOEC Primary Organ: Neurotoxicity (nervous system) In a 90-day study, groups of pure-bred beagle dogs (4/sex/group) were fed diets containing 0, 10, 30 or 60 mg Doramectin/kg of feed, equal to 0, 0.3, 0.9 or 1.6 mg/kg bw/day, for 90 days At the highest dose, lacrimation, tremors, salivation, slight ataxia and a languid appearance were noted. Dose-dependent reductions in absolute body weights and food consumption were noted in dogs given the two highest doses. No other signs were noted and there were no deaths during the test period. No abnormalities in haematological parameters, ophthalmoscopic examinations or urinalyses were seen. Organ weights were comparable with controls except in the high-dose females (decrease in absolute heart weights) and high-dose males (slight decreases in absolute pituitary and pituitary to brain weight ratios). No microscopic abnormalities were seen. The NOEL in this study was 0.3 mg/kg bw/day (Schulze, 1989b). Groups of pure-bred beagle dogs (6/sex/dose) were given diets containing 0, 10, 20 or 45 mg Doramectin/kg of feed, equivalent to 0, 0.26, 0.52 or 1.15 mg/kg bw/day, for 52 weeks. No signs of toxicity occurred and body weights remained comparable to controls throughout the study. There were no abnormalities in haematological parameters, clinical chemistry or urinalyses, and ophthalmoscopic examinations were normal. No gross or microscopic abnormalities were seen at necropsy. The NOEL in this study was 1.15 mg/kg bw/day (Schulze, 1991). Doramectin (WHO Food Series 36), Dr K. Woodward, Veterinary Medicines Directorate, Ministry of Agriculture, Fisheries and Food, Addlestone, Surrey, England [INCHEM]</p>

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12. ECOLOGICAL INFORMATION	
<b>Data and interpretation:</b>	Very toxic to aquatic organisms. Harmful to the soil environment. Harmful to terrestrial vertebrates. Harmful to terrestrial invertebrates.
<b>Summary data:</b>	<p><b>Doramectin</b>                      Ecotoxicity to:</p> <p>9.1A (fish)    SPECIES: Rainbow trout TYPE OF EXPOSURE: DURATION: 96 hr ENDPOINT: LC50 VALUE: 0.16 ppb (= 0.00016 mg/l) REFERENCE SOURCE: [Company data]</p> <p>Biocumulative: Yes Log Kow = 4.766 [American Cyanamid MSDS No AG09136-3]</p> <p>Rapidly Degradable: ND 9.1A (crustacean)    SPECIES: Daphnia magna TYPE OF EXPOSURE: DURATION: 48 hr ENDPOINT: EC50 VALUE: 30 ppt (= 0.00003 mg/l) REFERENCE SOURCE: [Company data]</p> <p>Biocumulative: Yes Log Kow = 4.766 [American Cyanamid MSDS No AG09136-3]</p> <p>Rapidly Degradable: ND 9.2A    REMARK: Classification based on Company data.</p> <p>Soil DT 50 &gt; 30 days: yes BIOSIS COPYRIGHT: BIOL ABS. Avermectins and their metabolites are excreted mainly in the faeces; they do not readily move from the site of dung deposition because of their low solubility in water and their tight binding to organic matter. Avermectins degrade in the environment through photodegradation and aerobic breakdown by soil organisms. Environmental assessment of veterinary avermectins in temperate pastoral ecosystems. Authors: WRATTEN SD FORBES AB Author Address: Dep. Entomol. Anim. Ecol., Lincoln Univ., Canterbury, New Zealand. Source: ANNALS OF APPLIED BIOLOGY; 128 (2). 1996. 329-348. [TOXLINE]</p> <p>9.3A    SPECIES: Mouse (F) ENDPOINT: LD50 VALUE: 42 mg/kg bw REFERENCE SOURCE: Fischer J. E. (1990a). Oral LD50 study in the albino mouse with AC 301, 423. Unpublished report No. A90-45. Submitted to WHO by American Cyanamid Company, Princeton, NJ, USA. [INCHEM]</p> <p>9.4A    Data for Milbemectin (a milbemycin insecticide):</p> <p>SPECIES: ENDPOINT: LD50 VALUE: (contact) 0.025 ug/bee REFERENCE SOURCE: [Pesticides Manual] [MF = 10]</p>

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## 13. DISPOSAL CONSIDERATIONS

<b>Disposal information:</b>	<p>Preferably dispose of the product by its intended use (as a drench). If this isn't possible, dispose of product and packaging at an approved landfill or other approved hazardous waste disposal facility. Avoid contamination of any water source. Preferably recycle empty container using a suitable drench container recovery program (e.g. AgRecovery: for details visit the site <a href="http://www.agrecovery.co.nz/programmes/container-recycling">http://www.agrecovery.co.nz/programmes/container-recycling</a>) If this isn't possible then burn empty container in an appropriate incinerator, providing circumstances permit; i.e. suitable wind direction. Otherwise crush or puncture and bury in a suitable landfill. Do NOT re-use container for any other purpose.</p>
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## 14. TRANSPORT INFORMATION

<b>Relevant information:</b>	<p>Dangerous Goods for transport. ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Doramectin 1.0%) UN Number: 3082 Dangerous Goods Class: 9</p> <p>The maximum quantity per package of this substance allowed for carriage on public transport is 1000L.</p>
<b>Other requirements:</b>	N/A

## 15. REGULATORY INFORMATION

<b>Regulatory status:</b>	<p>Registered pursuant to the ACVM Act 1997, No. A10717 See <a href="http://www.foodsafety.govt.nz">www.foodsafety.govt.nz</a> for registration conditions</p> <p>This product is an approved substance under the Hazardous Substances and New Organisms Act (HSNO). Approval code: HSR100442.</p> <p>SDS is required for quantities greater than or equal to 0.1L</p>
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<b>16. OTHER INFORMATION</b>	
<b>Abbreviations:</b>	<p>ACVM Agricultural Compounds and Veterinary Medicines            ARTG Australian Register of Therapeutic Goods            CAS Number Unique Chemical Abstracts Service Registry Number            Ceiling Exposure Value: The maximum airborne concentration of a biological or chemical agent to which a worker may be exposed at any time.            Controls Matrix List of default controls linking regulation numbers to Matrix code (e.g. T1, I16).            EC50 Ecotoxic Concentration 50% – concentration in water which is fatal to 50% of a test population (e.g. daphnia, fish species)            ERMA Environmental Risk Management Authority (now EPA)            EPA Environmental Protection Agency (previously known as ERMA)            HAZCHEM Code Emergency action code of numbers and letters that provide information to emergency services, especially fire fighters            HSNO Hazardous Substances and New Organisms (Act and Regulations)            IARC International Agency for Research on Cancer            LEL Lower Explosive Limit            LD50 Lethal Dose 50% – dose which is fatal to 50% of a test population (usually rats).            LC50 Lethal Concentration 50% – concentration in air which is fatal to 50% of a test population (usually rats)            MSDS Material Safety Data Sheet (or Safety Data Sheet)            STEL Short Term Exposure Limit - The maximum airborne concentration of a chemical or biological agent to which a worker may be exposed in any 15-minute period, provided the TWA is not exceeded            TWA Time Weighted Average – generally referred to WES averaged over typical work day (usually 8 hours)            UEL Upper Explosive Limit            UN Number United Nations Number            WES Workplace Exposure Standard - The airborne</p>
<b>References:</b>	<p>Unless otherwise stated, toxicity information has been obtained from the EPA HSNO chemical classification information database (CCID) <a href="http://www.epa.govt.nz/hs/compliance/chemicals.html">http://www.epa.govt.nz/hs/compliance/chemicals.html</a> for specific chemicals.            EPA Transfer Gazettes Classifications and controls assigned for specific ingredients (consolidated gazette, 2004)            Controls Matrix Part of the EPA New Zealand User Guide to the HSNO Control Regulations            WES 2013 The NZ Workplace Exposure Standards Effective from 2013, published by WorkSafe NZ and available on their web site – <a href="http://www.worksafe.govt.nz">www.worksafe.govt.nz</a>.            Other References: Suppliers MSDSs</p>
<b>Disclaimer:</b>	<p>This MSDS was prepared by Horizon AgResources Ltd., and is based on our current state of knowledge, including information obtained from suppliers. This SDS is written in good faith and constitutes a guideline (not a guarantee of safety). The level of risk each substance poses is relevant to its properties (as summarised in the MSDS) AND HOW THE SUBSTANCE IS USED. While guidelines are given for personal protective equipment, such precautions must be relevant to the use. The likely HSNO classifications, are based on experience, EPA Guidelines and international classifications. This MSDS is copyright Horizon AgResources Ltd, and must not be edited without the permission of the copyright holder or used for other than intended purpose.</p>