

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER

Product name:	Eclipse E Injection
Product code:	A010640
Recommended use:	For the control and treatment of parasites in cattle.
Company details:	Boehringer Ingelheim Animal Health New Zealand Limited
Address:	Level 3, Boehringer Ingelheim Building 2 Osterley Way Manukau City Auckland 2104 New Zealand
Telephone number:	Phone: +64 9 980 1600 Fax: +64 9 980 1601
Emergency telephone number:	Boehringer Ingelheim Freephone: 0800 800 822 National Poisons Centre : 0800 764 766 (0800 POISON) Fire Service, Ambulance : Dial 111
Date of preparation:	March 2011

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization:

Product components:

<u>Name</u>	<u>CAS</u>	<u>Proportion</u>
Eprinomectin	123997-26-2	7
Levamisole phosphate	32093-35-9	223
BHT	128-37-0	1
Dimethylacetamide	127-19-5	50

SECTION 3: HAZARDS IDENTIFICATION

Hazard classifications:	6.1D Acute oral toxin 6.5B Contact sensitiser 6.6B Mutagen 6.8A Reproductive/developmental toxin 6.8C Reproductive/developmental toxin via lactation 6.9A Target organ toxin 9.1A Aquatic toxin 9.2C Soil toxin 9.3B Vertebrate toxin 9.4A Invertebrate toxin
Priority and secondary identifiers:	Warning KEEP OUT OF REACH OF CHILDREN Warning Dangerous to the environment
Risk and safety phrases:	6.1D May be harmful if swallowed. 6.5B Repeated exposure may cause skin allergy. 6.6B Levamisole may possibly cause damage to genetic material. 6.8A Eprinomectin and Dimethylacetamide can affect development and/or reproduction. 6.8C BHT may possibly have effects on or via lactation. 6.9A Levamisole (blood and haematopoietic system) may possibly cause organ damage. Wash hands and exposed skin before meals and after use. Avoid skin contact. Handle with care. 9.1A Very toxic to aquatic organisms. 9.2C Harmful to the soil environment. 9.3B Toxic to terrestrial vertebrates. 9.4 A Very toxic to terrestrial invertebrates. Avoid contamination of any water supply with product or empty container. Avoid release to the environment.

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SECTION 4: FIRST AID MEASURES

Necessary first aid measures:

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.

Workplace facilities:

No special facilities required.

Required instructions:

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 reuse.

Notes for medical personnel:

Apply symptomatic therapy (no specific antidote). Note the nature of the product (possible mutagen, reproductive/developmental toxin, sensitiser and irritant).

SECTION 5: FIRE FIGHTING MEASURES

Type of hazard:

Non flammable, Non combustible, Non explosive

Fire hazard properties:

Eprinomectin-Levamisole Injection is not classified as flammable, and will not support combustion. Hazardous fumes when heated to decomposition.

Regulatory requirements:

Not applicable

Extinguishing media and methods:

Treat the fire as for the other materials present. Do not allow water to enter drains.

Hazchem code:

2X

Recommended protective clothing:

When fighting a major fire wear full protective clothing including breathing apparatus

SECTION 6: ACCIDENTAL RELEASE MEASURES

Emergency procedures:

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 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.

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SECTION 7: HANDLING AND STORAGE

Precautions for safe handling:	Apply with well-maintained and calibrated equipment. Handle with care
Regulatory requirements:	N/A
Approved handlers:	Not required
Conditions for safe storage:	Store at 2-8°C. Protect from light. Keep out of reach of children.
Store site requirements:	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.
Packaging:	Packaging Schedule 3 (UN Packing Group III) for quantities >1L (Hazardous Substances Packaging Regulations 2001).

SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION

Workplace exposure standards:	2,6-Di-tert-butyl-p-cresol: TWA 10mg/m ³ Dimethylacetamide: TWA 10ppm (36mg/m ³)
Application in the workplace:	Prevent exposure by using engineering controls, personal protective equipment and work practices that prevent skin and eye contact.
Exposure standards outside the workplace:	TELS and EELs are not set at this time.
Engineering controls:	Use only in well ventilated areas.
Personal protection:	Clothing should consist of overalls with long sleeves, and impervious gloves. Wear eye protection (eg. glasses, goggles or face shield).
References:	N/A

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Specify product data:	<u>Formulation type</u> : Solution <u>Appearance</u> : Clear solution <u>Specific gravity</u> : 1.0-1.1 g/mL <u>Vapour Pressure</u> : NA <u>Solubility in Water</u> : Eprinomectin is insoluble in water
Required specifications:	
Further specifications:	
Specific advice:	

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SECTION 10: STABILITY AND REACTIVITY

Stability of the substance:	Stable under normal conditions of use and storage.
Conditions to avoid:	No specific conditions to avoid
Material to avoid:	No specific materials to avoid.
Hazardous decomposition products:	No hazardous decomposition products are expected, except when heated to decomposition.
Hazardous polymerization:	Components are not expected to form hazardous polymers.
Specific data:	N/A

SECTION 11: TOXICOLOGICAL INFORMATION

Data and interpretation:	<p><u>Eclipse E Injection</u> May be harmful if swallowed. Repeated exposure may cause skin allergy. Levamisole may possibly cause damage to genetic material. Eprinomectin and Dimethylacetamide can affect development and/or reproduction. BHT may possibly have effects on or via lactation. Levamisole (blood and haematopoietic system) may possibly cause organ damage.</p>
Summaries data:	<p>INGREDIENTS</p> <p><u>Eprinomectin</u> Rat (F) LD50 55 mg/kg bw Ref. [EMEA Summary report 1, 1996]</p> <p>2-generation repro study with 1 litter for the first generation and 2 litters for the second generation was performed in rats, doses of 1, 2.5-3 and 6 mg/kg bw/day. Maternal toxicity characterised by a diminution of the mating/ reproductive performance was observed at the highest level especially in adult F1. An increase in pup mortality, a marked reduction in pup growth and body tremors among all pups were noted at the highest level. Treatment related body tremors were also noted at 2.5-3 mg/kg bw/day in 4 out of 26 litters of the F2 generations. 1 mg/kg was retained as the NOEL for growth and reproductive performance of the rat. [EMEA Summary report 1, 1996]</p> <p>Target organ toxicity EndPoint: LOAEL Primary Organ: Neurotoxicity (nervous system) 53 week oral toxicity study in dogs, doses of 0. 0.5, 1 and 2 mg/kg bw/day. At the highest level mydriasis (pupil dilation) was reported. Histopathological examination showed a slight focal degeneration in the pons area and/or the cerebellar nuclei in 3/8 dogs. This degenerative change was characterised by neuronal enlargement that resulted from increased eosinophilic vacuolated cytoplasm with nuclear displacement. Although this change affected 1 -3 neurons per dog it was attributed to treatment because other compounds in this class have caused neuronal degeneration in dogs in this area of the brain. NOEL = 1 mg/kg bw/day. [EMEA Summary report 1, 1996]</p> <p><u>Levamisole</u> Levamisole is a broad-spectrum anthelmintic with a long history of use in cattle and sheep. It has moderate to high acute toxicity [LD50 (oral, rats & mice) = 200-500 mg/kg]. A potential mutagen [levamisole] induced chromosome gaps and breaks in human lymphocytes in vitro and in vivo and levamisole hydrochloride induced an increase in the mitotic index, numerical chromosomal changes (aneuploidy, polyploidy) and structural chromosomal changes]. Haemolytic anaemic was the main toxic effect demonstrated in repeated dose animal studies (LOAEL 1.25mg/kg/day). In humans, levamisole has been associated with various non-specific effects (nausea, vomiting, rashes). Levamisole has induced leucopenia and agranulocytosis (idiosyncratic) at low doses.</p>

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BHT

Maternal LOAEL = 200 mg/kg bw/day in Wistar rats. No LOAEL could be determined for the F1 generation (IUCLID, 2000).

In a range finding study in designed to assess the tolerance of rats to BHT, the body weight of F1 pups from BHT-treated dams at weaning were less than those from the control groups. In the main experiment, pups from BHT treated dams were found to lose weight during the lactation period (DART). In a further study, pups from dams treated with BHT were reported to show stunted growth, with poor fur condition and were less active.

Dimethylacetamide

Known or presumed human reproductive or developmental toxicants.

SECTION 12: ENVIRONMENTAL INFORMATION

Eclipse E Injection

Very toxic to aquatic organisms. Harmful to the soil environment. Toxic to terrestrial vertebrates. Very toxic to terrestrial invertebrates.

INGREDIENTS

Eprinomectin

Ecotoxicity to:

Crustacean: Daphia EC50 0.45 ug/L (= 0.00045 mg/l) Ref. NRA report Australia Dec 1997;

Bioaccumulative: Yes; Rapidly Degradable: No

Algae

Lemna minor, 168 hr EC50 0.42 mg/L

Ref. [<http://www.envirpharma.org/presentation/poster/tarazona3.pdf>]

Bioaccumulative: Yes; Rapidly Degradable: No

Soil DT 50 > 30 days: yes

Terrestrial vertebrates: Mallard duck LD50 24 mg/kg Ref. [NRA report Australia Dec 1997]

Terrestrial invertebrates: Bee LD50 (contact) 0.002 ug/bee; Ref.

[Evaluation on Abamectin. July 1992. DEFRA, Pesticides Safety Directorate, UK]

Levamisole

Levamisole is potentially toxic to terrestrial vertebrates based on laboratory animal toxicity data [LD₅₀ (oral, rats & mice) = 200-500mg/kg]. Not toxic to fish or honey bees. Levamisole does not bioaccumulate in biological systems. In soil, levamisole has a half-life of five to seventy five days depending on sunlight, soil type and climatic conditions. Levamisole binds strongly to soil particles and organic matter. It does not leach in soils and is readily degraded by hydrolysis and microbial action.

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SECTION 13: DISPOSAL CONSIDERATIONS

Disposal information :	Preferably dispose of the product by use. Otherwise dispose of product and packaging at an approved landfill or other approved facility. Avoid contamination of any water source. Burn empty container in an appropriate incinerator, if circumstances such as wind direction permit. Otherwise crush or puncture and bury in a suitable landfill. Do NOT use container for any other purpose.
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SECTION 14: TRANSPORT INFORMATION

Relevant information:	Dangerous Goods for transport. ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Eprinomectin 0.7%) UN Number: 3082 Dangerous Goods Class: 9 The maximum quantity per package of this substance allowed for carriage on public transport is 1L.
Other requirements:	N/A

SECTION 15: REGULATORY INFORMATION

Regulatory status:	Registered pursuant to the ACVM Act 1997, No. A010640 See www.foodsafety.govt.nz for registration conditions Approved pursuant to the HSNO Act, Approval Code HSR100394. See www.epa.govt.nz for approval conditions SDS is required for quantities greater than or equal to 0.1L
HSNO and ACVM controls:	Refer to Section 3
List exposure limits:	N/A

SECTION 16: OTHER INFORMATION

Additional information:	For product information visit the Boehringer Ingelheim website www.boehringer-ingelheim.co.nz While the information set forth is believed to be accurate as of the date hereof, BOEHRINGER INGELHEIM makes no warranty with respect hereto and disclaims all liability from reliance thereon.
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