

## SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER

<b>Product name:</b>	<b>Eclipse E Injection with B12 &amp; Selenium</b>
<b>Product code:</b>	A011151
<b>Recommended use:</b>	For the control and treatment of parasites in cattle and aid in the treatment and prevention of Vitamin B12 (cobalt) and selenium deficiency
<b>Company details:</b>	Boehringer Ingelheim Animal Health New Zealand Limited
<b>Address:</b>	Level 3, Boehringer Ingelheim Building 2 Osterley Way Manukau City Auckland 2104 New Zealand
<b>Telephone number:</b>	Phone: +64 9 263 1400
<b>Emergency telephone number:</b>	Boehringer Ingelheim Freephone: 0800 800 822 National Poisons Centre : 0800 764 766 (0800 POISON) Fire Service, Ambulance : Dial 111
<b>Date of preparation:</b>	July 2017
<b>Date of review:</b>	9 February 2022

## SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

### Chemical characterization:

#### Product components:

Eprinomectin	123997-26-2	7
Levamisole phosphate	32093-35-9	223
BHT	128-37-0	1
Dimethylacetamide	127-19-5	50
Vitamin B12		1.4
Selenium		2.8
Other		To 1L

## SECTION 3: HAZARDS IDENTIFICATION

<b>Hazard classifications:</b>	Acute oral toxicity (Category 4), Skin sensitisation (Category 1), Germ cell mutagenicity (Category 2), Reproductive toxicity (Category 1), Reproductive toxicity - Effects on or via lactation (Additional category), Specific target organ toxicity - single exposure (Category 1), Specific target organ toxicity - repeated exposure (Category 1), Hazardous to the aquatic environment acute (Category 1), Hazardous to the aquatic environment chronic (Category 1), Hazardous to the terrestrial environment
<b>Priority and secondary identifiers:</b>	DANGER WARNING
<b>Risk and safety phrases:</b>	<b><u>Hazard Statements</u></b>  <b>Health Hazard – Acute toxicity (Category 4)</b> Warning. Oral: Harmful if swallowed  <b>Health Hazard – Respiratory or skin sensitisation (Category 1)</b> Warning. May cause an allergic skin reaction

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## **Health Hazard – Germ cell mutagenicity (Category 2)**

Warning. Suspected of causing genetic defects

## **Health Hazard – Reproductive toxicity (Category 1)**

Danger. May damage fertility or the unborn child

## **Health Hazard – Reproductive toxicity – Effects on or via lactation (Additional category)**

May cause harm to breast-fed children

## **Health Hazard - Specific target organ toxicity – single exposure (Category 1)**

Danger. Causes damage to organs

## **Health Hazard - Specific target organ toxicity – repeated exposure (Category 1)**

Danger. Causes damage to organs through prolonged or repeated exposure

## **Environmental hazards - Hazardous to the aquatic environment acute (Category 1)**

Warning. Very toxic to aquatic life

## **Environmental hazards - Hazardous to the aquatic environment chronic (Category 1)**

Warning. Very toxic to aquatic life with long lasting effects

## **Environmental hazards – Hazardous to the terrestrial environment**

Hazardous to soil organisms  
Hazardous to terrestrial vertebrates  
Hazardous to terrestrial invertebrates

## **Precautionary statements**

### **Precautionary statement - General**

P101 If medical advice is needed, have product container or label at hand  
P102 Keep out of reach of children  
P103 Read carefully and follow all instructions

### **Precautionary statement – Prevention**

P201 Obtain special instructions before use  
P202 Do not handle until all safety precautions have been read and understood  
P260 Do not breathe dust/fume/gas/mist/vapours/spray  
P261 Avoid breathing dust/fume/gas/mist/vapours/spray  
P263 Avoid contact during pregnancy and while nursing  
P264 Wash contaminated skin/eyes thoroughly after handling  
P270 Do not eat, drink or smoke when using this product  
P272 Contaminated clothing should not be allowed out of the workplace  
P273 Avoid release to the environment  
P280 Wear protective gloves/protective clothing/eye protection/face protection

### **Precautionary statement – Response**

P301 + P312 IF SWALLOWED: Call a POISON CENTRE/Doctor if you feel unwell  
P302 + P352 IF ON SKIN: Wash with plenty of water  
P308+P311 IF exposed or concerned: Call a POISON CENTRE/Doctor

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P308 + P313 IF exposed or concerned: Get medical advice/attention  
P314 Get medical advice/attention if you feel unwell  
P321 Specific treatment – see Section 4: First Aid Measures  
P330 Rinse mouth  
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention  
P362 + P364 Take off contaminated clothing and wash it before reuse  
P391 Collect spillage

## Precautionary statement – Storage

P405 Store locked up

## Precautionary statement – Disposal

P501 Dispose of contents/container according to the label description of one or more appropriate and achievable methods for the disposal of a substance in accordance with the Hazardous Substances (Disposal) Regulations 2001. This may also include any method of disposal that must be avoided. See Section 13 for disposal details.

## 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 with B12 and Selenium 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

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<b>Recommended protective clothing:</b>	When fighting a major fire wear full protective clothing including breathing apparatus
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## SECTION 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 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

<b>Precautions for safe handling:</b>	Apply with well-maintained and calibrated equipment. Handle with care
<b>Regulatory requirements:</b>	N/A
<b>Approved handlers:</b>	Not required
<b>Conditions for safe storage:</b>	Store at 2-8°C. Protect from light. Keep 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).

## SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION

<b>Workplace exposure standards:</b>	2,6-Di-tert-butyl-p-cresol: TWA 10mg/m <sup>3</sup> Dimethylacetamide: TWA 10ppm (36mg/m <sup>3</sup> ) Selenium compounds, as Se: TWA (0.1mg/m <sup>3</sup> )
<b>Application in the workplace:</b>	Prevent exposure by using engineering controls, personal protective equipment and work practices that prevent skin and eye contact.
<b>Exposure standards outside the workplace:</b>	TELs and EELs are not set at this time.
<b>Engineering controls:</b>	Use only in well ventilated areas.
<b>Personal protection:</b>	Clothing should consist of overalls with long sleeves, and impervious gloves. Wear eye protection (eg. glasses, goggles or face shield).
<b>References:</b>	N/A

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<b>Specify product data:</b>	<u>Formulation type:</u> Solution <u>Appearance:</u> Clear red solution <u>Specific gravity:</u> 1.0-1.2 g/mL
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<b>Required specifications:</b>	<u>Vapour Pressure:</u> NA
<b>Further specifications:</b>	<u>Solubility in Water:</u> Eprinomectin is insoluble in water
<b>Specific advice:</b>	

## SECTION 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>	No hazardous decomposition products are expected, except when heated to decomposition.
<b>Hazardous polymerization:</b>	Components are not expected to form hazardous polymers.
<b>Specific data:</b>	N/A

## SECTION 11: TOXICOLOGICAL INFORMATION

<b>Data and interpretation:</b>	<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.
<b>Summaries data:</b>	INGREDIENTS  <u>Eprinomectin</u> Rat (F) LD50 55 mg/kg bw Ref. [EMEA Summary report 1, 1996]  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]  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]  <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

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(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.

#### 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.

#### Sodium selenate

Sodium selenate is acutely toxic [LD50 (oral) 25mg/kg]. Dusts are toxic if inhaled and irritant to eyes. Acute poisoning exhibits as dyspnea, spasms and death from respiratory failure. Selenium poisoning in humans has been described and gastrointestinal and neurological symptoms predominated. Potential mutagen. Repeated dose testing in laboratory species identified a lowest NOAEL of 0.37mg/kg/day (liver toxicity).

## 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>]

Biocummulative: 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 [LD<sub>50</sub> (oral, rats & mice) = 200-500mg/kg]. Not toxic to fish or honey bees. Levamisole does not

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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.

## Sodium selenate

Very toxic to fish [LC<sub>50</sub> (96hr, Flathead minnow) 690ug/L], to crustacea [LC<sub>50</sub> (48hr, *Grammarus pseudolimnaeus*) 83ug/L] and algae [EC<sub>50</sub> (96hr, green algae) 0.2mg/L]. Toxic to plants [EC<sub>20</sub> (22d) 0.1mg/kg soil]. Toxic to terrestrial vertebrates based on an acute oral LD<sub>50</sub>(rats) of 25 mg/kg. Selenium is bioaccumulative and persists.

## 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.

## 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. A011151  
See [www.foodsafety.govt.nz](http://www.foodsafety.govt.nz) for registration conditions

Approved pursuant to the HSNO Act, Approval Code HSR100758.  
See [www.epa.govt.nz](http://www.epa.govt.nz) for approval conditions

Classified as Hazardous according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

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](http://www.boehringer-ingelheim.co.nz)

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