

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER

Product name:	Iver Matrix Calf Hi Mineral Minidose Drench
Product code:	A011065
Recommended use:	For the treatment and control internal parasites in sheep and cattle and tapeworm in sheep, including those with single or dual resistance to Avermectin/Milbemycin, Benzimidazole or Levamisole/Morantel families.
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:	November 2014

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization:	Suspension	
Product components:		
<u>Name</u>	<u>CAS</u>	<u>Proportion</u>
Ivermectin	70288-86-7	2.0
Levamisole HCl	16595-80-5	min. 80
Oxfendazole	53716-50-0	45.4
Selenium (as sodium selenate)	as 13410-01-0	1 (selenium)
Disodium cobalt EDTA	15137-09-4	33.6 (cobalt=4.4)
Other		to 1L

SECTION 3: HAZARDS IDENTIFICATION

Hazard classifications:	6.1D Acute oral toxin 6.5B Contact sensitiser 6.6B Mutagen 6.8B Reproductive/developmental toxin 6.9A Target organ toxin 9.1A Aquatic toxin 9.2C Soil toxin 9.3C 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. Wash hands and exposed skin before meals and after use. 6.5B Repeated exposure may cause skin allergy. Avoid skin contact. 6.6B Levamisole HCl possibly may cause damage to genetic material. Handle with care. 6.8B Ivermectin and Oxfendazole may affect development and/or reproduction. Handle with care. 6.9A Oxfendazole (liver and alimentary system) and Levamisole HCl (blood and haematopoietic system) possibly may cause organ damage. Handle with care.

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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. Avoid release to the environment.
9.3C Harmful to terrestrial vertebrates. Avoid release to the environment.
9.4A Very toxic to terrestrial invertebrates. Avoid release to the environment.

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.

Workplace facilities:

No special facilities required.

Required instructions:

Observe good work practices and avoid skin 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 and sensitiser).

SECTION 5: FIRE FIGHTING MEASURES

Type of hazard:

Non flammable, Non combustible, Non explosive

Fire hazard properties:

Iver Matrix Calf Hi Mineral Minidose Drench 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. Avoid 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
Handling practices:	N/A
Approved handlers:	Not required
Conditions for safe storage:	Store in a cool place below 25°C with top secured. Keep out of reach of children.
Store site requirements:	This substance is subject to a requirement for an emergency management plan, 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:	Selenium compounds, as Se TWA 0.1mg/m ³ Cobalt metal dust and fume, as Co TWA 0.05mg/m ³ Dusts 10mg/m ³
Application in the workplace:	Prevent exposure by using engineering controls, personal protective equipment and work practices that prevent skin contact.
Exposure standards outside the workplace:	TELs and EELs are not set at this time.
Engineering controls:	Ensure that ventilation maintains dust levels below WES.
Personal protection:	Clothing should consist of overalls with long sleeves and impervious gloves.
References:	N/A

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Specify product data:	<u>Formulation type:</u> Suspension <u>Appearance:</u> Pink liquid <u>Specific gravity:</u> 1-1.12g / mL <u>Boiling Point:</u> ca. 100° C <u>pH:</u> ~4 <u>Vapour Pressure:</u> NA <u>Solubility in Water:</u> (active ingredient) insoluble
Required specifications:	N/A
Further specifications:	N/A
Specific advice:	N/A

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 products are expected, except when heated to decomposition.
Hazardous polymerization:	Components are not expected to form hazardous polymers.
Specific data:	N/A

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SECTION 11: TOXICOLOGICAL INFORMATION

Data and interpretation:

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May be harmful if swallowed. Repeated exposure may cause skin allergy. Levamisole HCl possibly may cause damage to genetic material.

Ivermectin and Oxfendazole may affect development and/or reproduction. Ivermectin may have effects on or via lactation. Oxfendazole (liver and alimentary system) and Levamisole HCl (blood and haematopoietic system) possibly may cause organ damage.

Summaries data:

Ivermectin

Ivermectin (a macrocyclic lactone class endectocide) is an acute oral toxin

[LD₅₀ (oral, mouse) 11.6mg/kg; LD₅₀ (oral, dog) >10 mg/kg; LD₅₀ (dermal, rabbit) ~ 406 mg/kg]. Clinical signs in repeated dose laboratory animal studies included ataxia, tremors, mydriasis, emesis and coma. High doses produced respiratory failure and deaths. Neonates were affected via milk (neurotoxicity and reduced body weights, LOAEL 0.4mg/kg/d). Foetal malformations were observed at doses that caused maternal toxicity. Ivermectin is widely used in humans for the treatment of onchocerciasis at single doses of 0.2 mg/kg and adverse effects are usually mild and transient.

Levamisole HCL

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.

Oxfendazole

Oxfendazole has low acute oral toxicity [LD₅₀ (oral) > 6400mg/kg]. In repeated oral dose studies hepatocellular lipid vacuolation was identified as an early toxic effect (lowest NOEL was 0.7 mg/kg/day). Teratogenicity and foetal toxicity has been demonstrated in laboratory animal studies (lowest NOEL was 0.9mg/kg/day).

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).

Disodium cobalt EDTA

Cobalt and cobalt compounds are possible carcinogens. In repeated dose studies, cobalt salts have been implicated in cardiac disease (oral doses, LOAEL 0.02mg/kg/d) and cobalt metal dust caused pulmonary toxicity when inhaled (LOAEL 0.02mg/L/d). Cobalt is a known skin and respiratory sensitiser. Cobalt metal fume and dust irritates the respiratory tract. Cobalt metal is irritant to eyes and skin. In a reproductive study in rats, cobalt was embryotoxic when

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fed at 0.05mg/kg/d throughout the gestation (decreased foetal weight).

SECTION 12: ENVIRONMENTAL INFORMATION

Potential environmental interactions:

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

Data organisation :

Ivermectin

Ivermectin is highly toxic to invertebrates in the aquatic, soil and terrestrial environments. Ivermectin is considered to be highly toxic to fish and bees due to similarity to abamectin [Abamectin data: LC₅₀ rainbow trout 0.0032mg/L; LC₅₀ bluegill sunfish 0.0096mg/L and extremely toxic to aquatic invertebrates: EC₅₀ Mysid shrimp 0.022ppb; EC₅₀ crustacea 0.00036mg/L; toxicity to bees LD₅₀ (contact) 0.002ug/bee]. Ivermectin is neither persistent nor bioaccumulative, but is ecotoxic.

Levamisole HCl

Levamisole is potentially toxic to terrestrial vertebrates based on LD₅₀ data [LD₅₀ (oral, rats & mice) = 200-500 mg/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.

Oxfendazole

Benzimidazoles are not toxic to birds or honey bees, but are moderately toxic to aquatic life [LC₅₀ *Daphnia magna* 0.52mg/L (48hrs)]. The potential for bioaccumulation is low and benzimidazoles are degraded in soil and probably also in water.

Sodium selenate

Very toxic to fish [LC₅₀ (96hr, Flathead minnow) 690ug/L], to crustacea [LC₅₀ (48hr, *Grammarus pseudolimnaeus*) 83ug/L] and algae [EC₅₀ (96hr, green algae) 0.2mg/L]. Toxic to plants [EC20 (22d) 0.1mg/kg soil]. Toxic to terrestrial vertebrates based on an acute oral LD₅₀(rats) of 25 mg/kg. Selenium is bioaccumulative and persists.

Disodium cobalt EDTA

Cobalt is toxic to fish and other aquatic life [LC₅₀ (96hr, Trout) 1.406mg/L; EC₅₀ (48hr, *Daphnia magna*) 1.11mg/L]. Not readily biodegradable, cobalt persists.

Environmental risk and safety phrases:

Not classified as dangerous for rail, road, air or sea transport.

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. 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. (Ivermectin 0.2%) UN Number: 3082 Dangerous Goods Class: 9
Other requirements:	The maximum quantity per package of this substance allowed for carriage on public transport is 1L. For tank wagon and transportable containers there is a need to comply with Reg. 4-43 where applicable.

SECTION 15: REGULATORY INFORMATION

Regulatory status:	Registered pursuant to the ACVM Act 1997, No. A011065 See www.foodsafety.govt.nz for registration conditions
	Approved pursuant to the HSNO Act, Approval Code HSR100758 See www.epa.govt.nz for approval conditions
HSNO and ACVM controls:	SDS is required for quantities greater than or equal to 1L Refer to Section 3
List exposure limits:	None set

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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