

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER

Product name:	Bionic Hi Mineral Combination Sheep Capsules
Product code:	A009646
Recommended use:	Intra-ruminal capsule for the treatment and 100 day control of internal parasites
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:	25 May 2006

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization:	Polypropylene capsule containing albendazole and abamectin tablets	
Product components:		
Name	CAS	Proportion
Albendazole	54965-21-8	35.0-37.4
Abamectin	71751-41-2	1.0-1.36
Selenium chelate	-	1.3-1.5
Cobalt chelate	15137-09-4	6.4-6.6
Butylated hydroxytoluene	128-37-0	1.0-1.10
Other		to 100%

SECTION 3: HAZARDS IDENTIFICATION

Hazard classifications:	6.1C, 6.5B, 6.6B, 6.8A, 6.8C, 6.9B, 9.1A, 9.2C, 9.3B, 9.4A
Priority and secondary identifiers:	DANGER KEEP OUT OF REACH OF CHILDREN WARNING Dangerous to the environment
Risk and safety phrases:	6.1C This material may be dangerous if swallowed. Do not eat, drink or smoke while using. Remove protective clothing and wash hands and face before meals and after work. 6.5B Repeated exposure may cause skin allergy. Avoid skin contact. 6.6B Albendazole and Selenium possibly may cause damage to genetic material. Handle with care. 6.8A Albendazole may affect development and/or reproduction. Abamectin and Cobalt possibly may affect development and/or reproduction. Handle with care. 6.8C Abamectin and Butylated hydroxytoluene may have effects on or via lactation. Handle with care. 6.9B Albendazole, Abamectin (nervous system), Selenium (hepatotoxicity/alimentary system), Cobalt (cardiovascular) and Butylated hydroxytoluene (weight loss) possibly may cause organ damage from repeated oral exposure at high doses. Handle with care. 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. 9.3B Toxic to terrestrial vertebrates. Avoid release to the environment. 9.4A Very toxic to terrestrial invertebrates. Avoid release to the

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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. <u>Ingestion:</u> If swallowed seek medical attention. Do NOT induce vomiting. <u>Eyes:</u> If splashed in eyes wash out immediately with water. <u>Skin:</u> If skin or hair contact occurs remove contaminated clothing and flush skin and hair with running water. <u>Inhalation:</u> 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:	Bionic Hi Mineral Combination Sheep Capsules are 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:	2XE
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 and capsules from site. Place damaged containers and capsules 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:	Not required
Handling practices:	Not required
Approved handlers:	Not required
Conditions for safe storage:	Store below 30°C (room temperature). Store in original packaging in a dry place. Protect from light. After opening, ensure aluminium foil bags are re-sealed properly to protect capsules. Keep out of reach of children.
Store site requirements:	This substance is subject to a requirement for an emergency management plan and signage, whenever it is held in quantities of

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Packaging:	100kg or more. See Hazardous Substances (Emergency management) regulations 25 to 42. Packaging Schedule 3 (UN Packing Group III) for quantities >3kg (Hazardous Substances Packaging Regulations 2001).
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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:	Applicable to manufacturing. 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> : Tableted formulation within a plastic capsule. <u>Appearance</u> : Whitish capsule with taped wings, sealed except for a small orifice at one end. <u>Specific gravity</u> : NA <u>Boiling Point</u> : NA <u>Vapour Pressure</u> : NA <u>Solubility in Water</u> : Tablets break down in water.
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

SECTION 11: TOXICOLOGICAL INFORMATION

Data and interpretation:	This material may be dangerous if swallowed. Repeated exposure may cause skin allergy. Danger of serious damage to health by prolonged exposure if swallowed. Albendazole and Selenium possibly may cause damage to genetic material. Albendazole may affect development and/or reproduction. Abamectin and Cobalt possibly may affect development and/or reproduction. Abamectin and Butylated hydroxytoluene may have effects on or via lactation. Albendazole, Abamectin (nervous system), Selenium (hepatotoxicity/alimentary system), Cobalt (cardiovascular) and Butylated hydroxytoluene (weight loss) possibly may cause organ damage from repeated oral exposure at high doses.
Summaries data:	<u>Albendazole</u> : Benzimidazoles prevent tubulin polymerisation or spindle movement and their administration can result in aneuploidy.

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They are weak mutagens. Albendazole has low to moderate acute oral toxicity [LD₅₀ (oral, rabbit) 500-1250mg/kg; LD₅₀ (oral, rat) 1320-2400mg/kg; LD₅₀ (oral, mice) >3000 mg/kg]. Identified as a potential skin sensitiser by a positive result in a guinea pig maximisation test. In repeated oral dose studies toxic effects included reduced weight gain, reduced erythrocyte and leucocyte counts, decreased testes and uterine weights, slight increases in relative liver and kidney weights, and sternal bone marrow hypocellularity (lowest NOAEL 5mg/kg/day). Teratogenicity (visceral, craniofacial and bone defects) has been demonstrated in animal studies (lowest NOEL was 5 mg/kg/day).

Abamectin: Abamectin is an acute oral toxin [LD₅₀ (oral) 8.7-12.8mg/kg]. Ingestion of a single large dose of abamectin by humans (~ 100mg/kg) was associated with coma, hypotension and respiratory failure. Clinical signs in repeated-dose laboratory animal studies included ataxia, tremor, mydriasis, emesis, pupil dilation and coma. High doses produced respiratory failure and deaths. The critical adverse effects in multigenerational reproductive studies were mortality and reduced weight gain of pups in early lactation (NOAEL 0.12mg/kg/d).

Selenium chelate: Selenium is an essential trace element. LD₅₀ ranges between 1 and 7mg/kg for many selenium compounds and animal species. 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 oral dose testing of selenium compounds in laboratory species identified a lowest NOAEL of 0.03mg Se/kg/day (weight loss and liver toxicity).

Disodium cobalt EDTA: Cobalt and cobalt compounds are possible carcinogens. In repeated does 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 fed at 0.05mg/kg/d throughout the gestation (decreased foetal weight).

Butylated hydroxytoluene: An antioxidant used in human foods, pharmaceuticals and cosmetics which is known to cause allergic dermatitis in sensitive individuals. LD₅₀ (oral, mouse) 650 mg/kg. High repeated doses in laboratory species reduced growth rates and were associated with reproductive abnormalities.

SECTION 12: ENVIRONMENTAL INFORMATION

Potential environmental interactions:

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

Data organisation :

Albendazole: Albendazole may be toxic to terrestrial vertebrates based on LD₅₀ data [LD₅₀ (oral, rabbit) 500-1250mg/kg]. Not toxic to fish or honey bees. The potential for bioaccumulation is low and benzimidazoles are degraded in soil and probably also in water.

Abamectin: Abamectin is a highly effective insecticide and acaricide produced by the soil microbe *Streptomyces avermitilis*. It acts by stimulating the release of gamma-aminobutyric acid, an inhibitory neurotransmitter, causing paralysis of the parasite. It is highly toxic to invertebrates in the aquatic, soil and terrestrial environments. Aquatic organisms: Abamectin is highly toxic to fish and extremely toxic to aquatic invertebrates [LC₅₀ Rainbow trout is 3.6 ppb (96hrs); EC₅₀ *Daphnia magna* 0.34 ppb (48hrs)]. Persist: yes. Soil organisms: Dung beetle Terrestrial fate value 20-40. Abamectin is toxic to mammals [LD₅₀ (oral, rats) 8.7 mg/kg], but is less toxic to birds [LC₅₀ Bobwhite quail >2000 mg/kg]. Abamectin is highly toxic to bees [LD₅₀ (oral) 0.0094 ug/bee; LD₅₀ (contact) 0.002 ug/bee].

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Environmental risk and safety phrases:

Selenium chelate: Selenium accumulates in living tissues and bioconcentration in aquatic organisms will be moderate to very high. Very toxic to aquatic organisms; may cause long term adverse effects in the aquatic environment. Toxic to terrestrial vertebrates based on laboratory animal toxicity data.

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.

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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. 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.
TOXIC SOLID, ORGANIC, N.O.S.
UN Number: 2811
Dangerous Goods Class: 6.1
The maximum quantity per package of this substance allowed for carriage on public transport is 0.5kg.

Other requirements:

N/A

SECTION 15: REGULATORY INFORMATION

Regulatory status:

Registered pursuant to the ACVM Act 1997, No. A009646
See www.foodsafety.govt.nz for registration conditions

HSNO and ACVM controls:

Approved pursuant to the HSNO Act, Approval Code HSR001651
See www.epa.govt.nz for approval conditions

List exposure limits:

Refer to Section 3

N/A

SECTION 16: OTHER INFORMATION

Additional information:

For product information visit the Boehringer Ingelheim website
www.boehringer-ingelheim.co.nz

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