

Page 1 of 5

Product Name: BIONIC Hi-Mineral Combination Sheep Capsules Reviewed on: 23 July 2015

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER

Product name: Bionic Hi Mineral Combination Sheep Capsules

Product code: A9646

Recommended use: Intra-ruminal capsule for the treatment and 100 day control of

internal parasites

Company details: Merial New Zealand Ltd Address: Level 3, Merial Building

Osterley Way Manukau City New Zealand

Telephone number: Phone: +64 9 980 1600 Fax: +64 9 980 1601

Emergency telephone Merial Ancare Freephone: 0800 800 822

number: 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 15137-09-4 Cobalt chelate 6.4-6.6 Butylated hydroxytoluene 128-37-0 1.0 - 1.10Other 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

environment.

Page 2 of 5

Product Name: BIONIC Hi-Mineral Combination Sheep Capsules Reviewed on: 23 July 2015

SECTION 4: FIRST AID MEASURES

For advice contact the National Poisons Centre on 0800 POISON Necessary first aid

(0800 764 766), or a doctor immediately. measures:

Ingestion: If swallowed seek medical attention. Do NOT induce

vomitina.

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: 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:

Recommended protective

clothing:

When fighting a major fire wear full protective clothing including

breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Wear suitable protective clothing. Restrict access to contaminated **Emergency procedures:**

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.

SECTION 7: HANDLING AND STORAGE

Precautions for safe Apply with well-maintained and calibrated equipment. Handle with

handling: care

Regulatory requirements:

Not required Not required

Handling practices: Approved handlers: Not required

Store below 30°C (room temperature). Store in original packaging Conditions for safe storage:

> 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

100kg or more. See Hazardous Substances (Emergency

Page 3 of 5

Product Name: BIONIC Hi-Mineral Combination Sheep Capsules Reviewed on: 23 July 2015

management) regulations 25 to 42.

Packaging: Packaging Schedule 3 (UN Packing Group III) for quantities > 3kg

(Hazardous Substances Packaging Regulations 2001).

SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION

Workplace exposure Selenium compounds, as Se TWA 0.1mg/m³

standards: Cobalt metal dust and fume, as Co TWA 0.05mg/m³

Dusts 10mg/m³

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: Formulation type: Tableted formulation within a plastic capsule.

Appearance: Whitish capsule with taped wings, sealed except for a

small orifice at one end.
Specific gravity: NA
Boiling Point: NA
Vapour Pressure: NA

Solubility in Water: 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: Albendazole: Benzimidazoles prevent tubulin polymerisation or

spindle movement and their administration can result in aneuploidy. They are weak mutagens. Albendazole has low to moderate acute

Page 4 of 5

Product Name: BIONIC Hi-Mineral Combination Sheep Capsules Reviewed on: 23 July 2015

oral toxicity [LD $_{50}$ (oral, rabbit) 500-1250mg/kg; LD $_{50}$ (oral, rat) 1320-2400mg/kg; LD $_{50}$ (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).

<u>Abamectin</u>: Abamectin is an acute oral toxin [LD $_{50}$ (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. LD_{50} (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:

Data organisation:

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

Albendazole: Albendazole may be toxic to terrestrial vertebrates based on LD_{50} data [LD_{50} (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 Streptomycetes 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 $[LD_{50}$ (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]. Selenium chelate: Selenium accumulates in living tissues and

Page 5 of 5

Product Name: BIONIC Hi-Mineral Combination Sheep Capsules Reviewed on: 23 July 2015

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.

<u>Disodium cobalt EDTA</u>: Cobalt is toxic to fish and other aquatic life $[LC_{50}$ (96hr, Trout) 1.406mg/L; EC_{50} (48hr, *Daphnia magna*)

1.11mg/L]. Not readily biodegradable, cobalt persists.

Environmental risk and safety phrases:

TOXIC SOLID, ORGANIC, N.O.S.

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. A9646

See www.foodsafety.govt.nz for registration conditions

Approved pursuant to the HSNO Act, Approval Code HSR001651

See www.epa.govt.nz for approval conditions

HSNO and ACVM controls: Refer to Section 3

List exposure limits: N/A

SECTION 16: OTHER INFORMATION

Additional information: For product information visit the Merial website <u>www.merial.co.nz</u>

While the information set forth is believed to be accurate as of the date hereof, MERIAL NZ LTD. makes no warranty with respect

hereto and disclaims all liability from reliance thereon.