1. Identification of Substance & Company

Product	
Product name	Alpheus Anti-parasitic Capsules contains: Abamectin Cattle Capsules and Levamisole HCl/ Oxfendazole primer tablets
ACVM approval	pending
HSNO approval	HSR100758
Approval description	Veterinary Medicines (Non-dispersive Closed System Application) Group Standard 2012
UN number	2811
Proper Shipping Name	TOXIC SOLID, ORGANIC, NOS, (contains Abamectin)
DG class	6
Packaging group	III
Hazchem code	2X
Uses	Intraruminal anthelmintic controlled-release capsules with primer dose.

Company Details	
Company	**Sirona Animal Health Ltd**
Address	PO Box 4151 Mt Manganui South 3149 New Zealand
Telephone	0800 4SIRONA (0800 474 766)
Website	www.sironaanimalhealth.com

Emergency Telephone Number: 0800-474 766

2. Hazard Identification

Approval

This product has been approved under the Hazardous Substances and New Organisms Act (HSNO, Approval HSR100758, Veterinary Medicines (Non-dispersive Closed System Application) Group Standard 2012), and is classified as follows:

Classes	Hazard Statements
For Abamectin Cattle Capsules:	
6.1C (oral)	Toxic if swallowed.
6.8B	Suspected of damaging fertility or the unborn child
6.8C	May cause harm to breast-fed children.
6.9A	Causes damage to organs through prolonged or repeated exposure
9.1A	Very toxic to aquatic life.
9.2B	Toxic to the soil environment.
9.3B	Toxic to terrestrial vertebrates.
9.4A	Very toxic to terrestrial invertebrates.

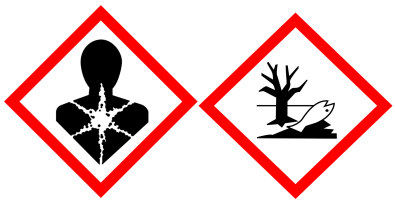
SYMBOLS

DANGER

Classes	Hazard Statements
For Levamisole HCl/ Oxfendazole primer tablets	
6.1D (oral)	Harmful if swallowed.
6.5B	May cause an allergic skin reaction.
6.6B	Suspected of causing genetic defects
6.8B	Suspected of damaging fertility or the unborn child
6.9A	Causes damage to organs through prolonged or repeated exposure
9.1B	Toxic to aquatic life with long lasting effects.
9.3B	Toxic to terrestrial vertebrates.

SYMBOLS

DANGER



Other Classifications

There are no other Classifications that are known to apply.

Precautionary Statements

Keep out of reach of children.
Read label before use.
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.

Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.
Do not breathe dust/vapours.
Avoid contact during pregnancy/while nursing.
Use personal protective equipment as required.

Avoid release to the environment.
Collect spillage.
Store locked up.

Further precautionary statements can be found in Section 4 – First Aid.

3. Composition / Information on Ingredients

Abamectin Cattle Capsules:

Component	CAS/ Identification	Class for ingredient(s)	Concentration
Abamectin	71751-41-2	6.1B (oral), 6.8B, 6.8C, 6.9A (oral), 9.1A, 9.2A, 9.3A, 9.4A	13-18%
Ingredients not contributing to HSNO classes	NA	NA	balance

Levamisole HCl/ Oxfendazole primer tablets:

Component	CAS/ Identification	Class for ingredient(s)	Concentration
Levamisole hydrochloride	16595-80-5	6.1C (oral), 6.5B, 6.6B, 6.9A, 9.3B	28-35%
Oxfendazole	53-716-50-0	6.8B, 6.9B (oral), 9.1A	16-21%
Ingredients not contributing to HSNO classes	NA	NA	balance

This is a commercial product whose exact ratio of components may vary. Trace quantities of impurities are also likely.

4. First Aid

General Information

If medical advice is needed, have product container or label at hand. You should call the National Poisons Centre if you feel that you may have been poisoned or harmed by this product. The number is 0800 764 766 (0800 POISON) (24 hr emergency service).
IF exposed or concerned: Get medical advice/ attention.

Recommended first aid facilities Ready access to running water is recommended. Accessible eyewash is recommended.

Exposure

Swallowed IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth.

Eye contact If product gets in eyes, wash material from them with running water for several minutes. If symptoms persist, seek medical advice.

Skin contact This product is non-irritating to skin. No further measures should be required.

Inhaled Generally, inhalation of fumes/dust is unlikely to result in adverse health effects. If coughing, dizziness or shortness of breath is experienced, remove the patient to fresh air immediately. If patient is unconscious, place in the recovery position (on the side) for transport and contact a doctor.

Advice to Doctor

Treat symptomatically

5. Firefighting Measures

Fire and explosion hazards: There are no specific risks for fire/explosion for this chemical. It is not classed as flammable.

Suitable extinguishing substances: Carbon dioxide, extinguishing powder, foam, fog sprays.

Unsuitable extinguishing substances: Unknown.

Products of combustion: Carbon dioxide, and if combustion is incomplete, carbon monoxide, oxides of nitrogen and silicon and smoke. Water. May form toxic mixtures in air and may accumulate in sumps, pits and other low-lying spaces, forming potentially explosive mixtures.

Protective equipment: Self-contained breathing apparatus. Safety boots, non-flammable overalls, gloves, hat and eye protection.

Hazchem code: 2X

6. Accidental Release Measures

Containment If greater than 100kg Alpheus Anti-parasitic Capsules, or greater than 100kg of Abamectin Cattle Capsules and/or greater than 1000kg of the Levamisole HCl/ Oxfendazole primer tablets are stored, secondary containment and emergency plans to manage any potential spills must be in place.In all cases design storage to prevent discharge to stormwater.

Emergency procedures	The container size will limit a major spill. In the event of a large spillage (>100kg) alert the fire brigade to location and give brief description of hazard. Stop the source of the leak, if safe to do so. Wear protective equipment to prevent skin, eye and respiratory exposure. Clear area of any unprotected personnel. Contain using sand, earth or vermiculite. Prevent by whatever means possible any spillage from entering drains, sewers, or water courses. (If this occurs contact your regional council immediately).
Clean-up method	Sweep up spill, collect and seal in properly labelled containers or drums for disposal. If contamination of crops, sewers or waterways has occurred advise local emergency services.
Disposal	Collect recoverable material into labelled containers for recycling or salvage. Recycle containers wherever possible. This material may be suitable for approved landfill. Dispose of only in accord with all regulations.
Precautions	Avoid the creation of dust during clean up. Wear protective equipment to prevent skin and eye contamination and the inhalation of vapours. Work up wind or increase ventilation.

7. Storage & Handling

Storage	Avoid storage of harmful substances with food. Store out of reach of children. Containers should be kept closed in order to minimise contamination. Keep from extreme heat and open flames.
Handling	Keep exposure to a minimum, and minimise the quantities kept in work areas. See section 8 with regard to personal protective equipment requirements. Avoid skin and eye contact and inhalation of vapour, or dusts.

8. Exposure Controls / Personal Protective Equipment

Workplace Exposure Standards

A workplace exposure standard (WES) has not been established by WorkSafe NZ for this product. There is a general limit of 10mg/m^3 for dusts and mists when limits have not otherwise been established.

NZ Workplace Exposure Stds (2013)	Ingredient	WES-TWA	WES-STEL
	Excipients may contain traces of crystalline silica:		
	Quartz (respirable dust)	0.2mg/m^3	data unavailable
	Cristobalite, respirable dust	0.1mg/m^3	data unavailable

Engineering Controls

In industrial situations, it is expected that employee exposure to hazardous substances will be controlled to a level as far below the WES as practicable by applying the hierarchy of control required by the Health and Safety in Employment Act 1992 (HSE). Exposure can be reduced by process modification, use of local exhaust ventilation, capturing substances at the source, or other methods. If you believe air borne concentrations of mists, dusts or vapours are high, you are advised to modify processes or increase ventilation.

Personal Protective Equipment

Eyes	Protective eyewear is not normally necessary when using this product.
Skin	Avoid repeated or prolonged skin contact. Wear impervious gloves if handling tablets. Rubber or nitrile gloves are recommended. Replace frequently. Gloves should be checked for tears or holes before use. Remove protective clothing and wash exposed areas with soap and water prior to eating, drinking or smoking.
Respiratory	Respirator is not required under normal use. Ensure adequate natural ventilation. If product is being used in confined conditions or if the plastic capsule is damaged, the use of a mask or respirator with a particulate filter (dust/mists) may be preferred.

WES Additional Information

Not applicable

9. Physical & Chemical Properties

Appearance	Abamectin Cattle Capsules: tablet stack contained in a winged plastic capsule Levamisole HCl/Oxfendazole primer tablets: off white circular tablets with bevelled edges
Odour	no odour
pH	no data
Vapour pressure	no data
Viscosity	no data
Boiling point	no data
Volatile materials	no data
Freezing / melting point	no data
Solubility	soluble in water
Specific gravity / density	no data
Flash point	non flammable
Danger of explosion	not explosive
Auto-ignition temperature	no data
Upper & lower flammable limits	non flammable
Corrosiveness	non corrosive

10. Stability & Reactivity

Stability	Stable
Conditions to be avoided	Containers should be kept closed in order to avoid contamination. Keep from extreme heat and open flames.
Incompatible groups	None known
Substance Specific Incompatibility	None known
Hazardous decomposition products	None known
Hazardous reactions	None known

11. Toxicological Information

Summary

For Abamectin Cattle Capsules:

IF SWALLOWED: may be fatal or cause serious damage to health. Ingestion can cause nausea, stomach pains, vomiting. Fever, rash and swelling of the lymph nodes may occur. Tremors, convulsions, coma and death.

IF ON SKIN: unlikely to cause an effect.
IF IN EYES: unlikely to cause an effect due to the nature of the capsule. Dust may cause irritation.
IF INHALED: unlikely to cause an effect, however if large amounts of dust of the substance are inhaled, similar effects to ingestion are expected.

CHRONIC EFFECTS: Long term exposure may result in health effects such as lung damage. Abamectin is suspected of being toxic to the unborn child and may affect a breast fed child via lactation.

For Levamisole HCl/ Oxfendazole primer tablets
IF SWALLOWED: Harmful if swallowed

IF ON SKIN: This mixture is considered a contact sensitiser. Susceptible individual may experience an allergic response, e.g. dermatitis.
IF IN EYES: unlikely to cause an effect as the formulation is tableted. Dust may cause irritation.
IF INHALED: unlikely to cause an effect, however if large amounts of dust of the substance are inhaled, similar effects to ingestion are expected.

CHRONIC EFFECTS: Long term exposure may result in health effect on the liver. Oxfendazole may show reproductive effects and developmental effects. Levamisole hydrochloride may affect blood, bone marrow and lymph nodes.

Supporting Data for Abamectin Cattle Capsules		
Acute	**Oral**	Using LD_{50}'s for ingredients, the calculated LD_{50} (oral, rat) for the mixture is between 50 and 300 mg/kg. Data considered includes: Abamectin 8.7-12.8 mg/kg (rat).
	Dermal	No evidence of dermal toxicity.
	Inhaled	No evidence of inhalation toxicity.
	Eye	The mixture is not considered to be an eye irritant.
	Skin	The mixture is not considered to be a skin irritant.
Chronic	**Sensitisation**	No ingredient present at concentrations > 0.1% is considered a sensitizer.
	Mutagenicity	No ingredient present at concentrations > 0.1% is considered a mutagen.
	Carcinogenicity	No ingredient present at concentrations > 0.1% is considered a carcinogen.
	Reproductive / Developmental	The mixture is considered to be a reproductive or developmental toxicant. Abamectin is suspected of causing fetotoxicity and teratogenic effects. Abamectin is also suspected to have an effect on or via lactation.
	Systemic	The mixture is considered to be a known or presumed target organ toxicant, because at least one of the ingredients present in greater than 1% is known or presumed to be a target organ toxicant. Abamectin may affect the lungs.
	Aggravation of existing conditions	None known.

Supporting Data for Levamisole HCl/ Oxfendazole primer tablets		
Acute	**Oral**	Using LD_{50}'s for ingredients, the calculated LD_{50} (oral, rat) for the mixture is between 200 and 2000 mg/kg. Data considered includes: Levamisole hydrochloride 200mg/kg (mouse), Oxfendazole 1600 mg/kg (dog), 6400mg/kg (rat, mouse).
	Dermal	No evidence of dermal toxicity.
	Inhaled	No evidence of inhalation toxicity.
	Eye	The mixture is not considered to be an eye irritant.
	Skin	The mixture is not considered to be a skin irritant.
Chronic	**Sensitisation**	The mixture is considered to be a contact sensitizer, because at least one of the ingredients present in greater than 0.1% is known to be a contact sensitizer. (Levamisole Hydrochloride)
	Mutagenicity	Levamisole Hydrochloride is classed by EPA as a suspected mutagen. The mixture is classed 6.6B
	Carcinogenicity	No ingredient present at concentrations > 0.1% is considered a carcinogen.
	Reproductive / Developmental	The mixture is considered to be a reproductive or developmental toxicant. Oxfendazole is considered a suspected reproductive toxicant. Oxfendazole has shown reproductive effects in animal studies (rats), e.g. high pup mortality.
	Systemic	The mixture is considered to be a known or presumed target organ toxicant by ingestion, because at least one of the ingredients present in greater than 1% is known or presumed to be a target organ toxicant. Levamisole is classed 6.9A (oral) and may affect blood, bone and lymph nodes. Oxfendazole is classed 6.9B (oral)and is suspected of causing toxic effect of the liver in animal studies..
	Aggravation of existing conditions	None known.

12. Ecological Data

Summary

Abamectin Cattle capsules are considered extremely toxic in the aquatic environment and towards terrestrial invertebrates, toxic towards the soil environment and terrestrial vertebrates.
Levamisole HCl/ Oxfendazole primer tablets are considered toxic in the aquatic environment and towards terrestrial vertebrates.

Supporting Data For Abamectin Cattle Capsules	
Aquatic	Using EC_{50}'s for ingredients, the calculated EC_{50} for the mixture is <1 mg/L. Data considered includes: Abamectin 0.430g/L (48hr, Eastern Oyster (Crassostrea virginica)), 0.0036 mg/l (96hr, Rainbow trout), 0.00034 mg/l (48hr, Daphnia magna).
Bioaccumulation	No data
Degradability	No data
Soil	The capsules are classified as ecotoxic to the soil environment, with a soil ecotoxicity value between 1 and 10 mg/kg. Abamectin is classed 9.2A.
Terrestrial vertebrate	The capsules have been classified as ecotoxic to terrestrial vertebrates. Using the LD_{50}'s for ingredients, the calculated LD_{50} (oral, rat) for the mixture is between 50 and 500 mg/kg. See acute toxicity.
Terrestrial invertebrate	The capsules have been classified as very ecotoxic to terrestrial invertebrates. The calculated invertebrate ecotoxicity value for the mixture is < 2 µg/bee. Data considered includes: Abamectin LD_{50} (bee): 0.002 µg/bee.
Biocidal	no data

Supporting Data For Levamisole HCl/Oxfendazole Primer tablets	
Aquatic	Using EC_{50}'s for ingredients, the calculated EC_{50} for the mixture is between 1 mg/L and 10 mg/L and at least one of the components is either bioaccumulative or persistent in the aquatic environment. Data considered includes: Oxfendazole 0.52mg/L (48hr, Daphnia magna).
Bioaccumulation	No data
Degradability	No data
Soil	No evidence of soil toxicity.
Terrestrial vertebrate	The mixture has been classified as ecotoxic to terrestrial vertebrates. Using the LD_{50}'s for ingredients, the calculated LD_{50} (oral, rat) for the mixture is between 50 and 500 mg/kg. See acute toxicity.
Terrestrial invertebrate	No evidence of toxicity towards terrestrial invertebrates.
Biocidal	no data
Environmental effect levels	No EELs are available for this mixture or ingredients

13. Disposal Considerations

Restrictions	There are no product-specific restrictions, however, local council and resource consent conditions may apply, including requirements of trade waste consents.
Disposal method	Disposal of this product must comply with the requirements of the Resource Management Act for which approval should be sought from the Regional Authority. The substance must be treated and therefore rendered non-hazardous before discharge to the environment.
Contaminated packaging	Rinse containers with water before disposal. Preferably re-cycle container, otherwise send to landfill or similar.

14. Transport Information

Transport according to NZS 5433 (Transport of Hazardous Substances on Land). Considered a dangerous good for transport.

UN number:	2811	**Proper shipping name:**	TOXIC SOLID, ORGANIC, NOS, (contains Abamectin)
Class(es)	6.1	**Packing group:**	III
Precautions:	Toxic Ecotoxic (Marine Pollutant)	**Hazchem code:**	2X

NOTE: Passenger vehicle restrictions:
When a person carries a substance on a passenger service vehicle, the substance must be packaged in a sealed container and must not exceed 3kg per package.

15. Regulatory Information

This product is an approved substance under the Hazardous Substances and New Organisms Act (HSNO). Approval code: HSR100758, Veterinary Medicines (Non-dispersive Closed System Application) Group Standard 2012.

Specific Workplace Controls (as per HSNO approval referenced to Controls Matrix)

Key workplace requirements for Abamectin Cattle Capsules are:

SDS	To be available within 10 minutes in workplaces storing any quantity.
Labelling	No removal of labels and/or decanting of product into other containers can occur.
Emergency plan	Required if > 100kg is stored.
Approved handler	Not required. However the substance must be secured while not in use so that an unauthorised person cannot gain access to the substance.
Tracking	Not required.
Bunding & secondary containment	Required if > 100kg is stored.
Signage	Required if > 100kg is stored.
Location test certificate	Not required.
Flammable zone	Not required.
Fire extinguisher	Not required.

Key workplace requirements for Levamisole HCl/Oxfendazole Primer tablers are:

SDS	To be available within 10 minutes in workplaces storing any quantity.
Labelling	No removal of labels and/or decanting of product into other containers can occur.
Emergency plan	Required if > 1000kg is stored.
Approved handler	Not required. However the substance must be secured while not in use so that an unauthorised person cannot gain access to the substance.
Tracking	Not required.
Bunding & secondary containment	Required if > 1000kg is stored.
Signage	Required if > 1000kg is stored.
Location test certificate	Not required.
Flammable zone	Not required.
Fire extinguisher	Not required.

Note: The above workplace requirements apply if only this particular substance is present. The complete set of controls for a location will depend on the classification and total quantities of other substances present in that location.

Other Legislation

In New Zealand, the use of this product may come under the Resource Management Act and Regulations, the Health, Safety in Employment Act and Regulations, local Council Rules and Regional Council Plans.

16. Other Information

Abbreviations

Approval Code	Approval HSR100758, Veterinary Medicines (Non-dispersive Closed System Application) Group Standard 2012 Controls, EPA. www.epa.govt.nz
CAS Number	Unique Chemical Abstracts Service Registry Number
EC_{50}	Ecotoxic Concentration 50% – concentration in water which is fatal to 50% of a test population (e.g. daphnia, fish species)
EPA	Environmental Protection Agency.
HAZCHEM Code	Emergency action code of numbers and letters that provide information to emergency services, especially fire fighters
HSNO	Hazardous Substances and New Organisms (Act and Regulations)
LD_{50}	Lethal Dose 50% – dose which is fatal to 50% of a test population (usually rats).
LC_{50}	Lethal Concentration 50% – concentration in air which is fatal to 50% of a test population (usually rats)
MSDS (SDS)	Material Safety Data Sheet (or Safety Data Sheet)
STEL	Short Term Exposure Limit - The maximum airborne concentration of a chemical or biological agent to which a worker may be exposed in any 15 minute period, provided the TWA is not exceeded
TWA	Time Weighted Average – generally referred to WES averaged over typical work day (usually 8 hours)
UN Number	United Nations Number
WES	Workplace Exposure Standard - The airborne concentration of a biological or chemical agent to which a worker may be exposed.

References

Data	Unless otherwise stated comes from the EPA HSNO chemical classification information database (CCID) http://www.epa.govt.nz/search-databases/Pages/HSNO-CCID.aspx, for specific chemicals.
EPA Transfer Gazettes	Classifications and controls assigned for specific ingredients (consolidated gazette, 2004)
Controls Matrix	Part of the EPA New Zealand User Guide to the HSNO Control Regulations
WES 2013	The NZ Workplace Exposure Standards Effective from 2013, published by Worksafe NZ and available on their web site – www.worksafe.govt.nz.
Other References:	GESTIS http://www.dguv.de/ifa/index.jsp ECHA – GHS. http://echa.europa.eu/web/guest/information-on-chemicals/

Review

Date	**Reason for review**
October 2014	Not applicable – new SDS

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