



SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Lapizole® 20 mg/ml suspension for oral administration
Synonyms:	Not Available
Proper Shipping name:	Not Available
Other means of identification:	None
1.2 Relevant identified uses of the substances or mixture and uses advised against	
Recommended uses:	Broad spectrum de-wormer/antiparasiticide. For oral administration in the prevention and treatment of infections caused by internal parasites, including <i>Encephalitozoon cuniculi</i> .
Uses advised against:	<p>Not for human use. Do not use in animals intended for human consumption. Do not eat the eggs of treated birds.</p> <p>Lapizole is only for use in rabbits, birds, reptiles and ferrets. Do not use in animals other than those indicated. Do not use in pregnant animals. Do not overdose.</p> <p>In birds, fenbendazole can cause intestinal problems and inhibit bone marrow production. Do not use in nestlings/ growing birds or those in moult. In some mammalian species, high doses of fenbendazole can lead to bone marrow suppression, gastrointestinal tract irritation and problems in pregnancy.</p> <p>As with all veterinary medicines, occasional instances of allergic response due to prior sensitisation, drug intolerance and idiosyncratic reactions may occur.</p>
1.3 Details of the supplier of the substance or mixture	
Registered company name:	Dechra Ltd
Address:	Snaygill Industrial Estate Keighley Road Skipton North Yorkshire BD23 2RW UK
Telephone:	+44 (0) 1756 791311



Fax:	+44 (0) 1756 798604
Email:	Not available
1.4 Emergency Telephone Numbers	
	+44 (0) 1756 791311

SECTION 2: HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
DSD Classification (EU):	Not Available
DPD Classification (EU)¹:	Not Available
Classification according to regulation (EC) No 1272/2008 [CLP] (EU)¹:	Not Available
2.2 Label Elements	
Signal Word:	Not Available
Hazard Statement(s)	
Not Available	
Additional Statement(s)	
Not Available	
Precautionary Statement(s) Prevention:	
Not Available	
Precautionary Statement(s) Response:	
Not Available	
Precautionary Statement(s) Storage:	
Not Available	
Precautionary Statement(s) Disposal:	
Not Available	
2.3 Other Hazard Information	
Not Available	

SECTION 3: INFORMATION ON THE INGREDIENTS			
3.1 Substances			
See section below for composition of mixtures			
3.2 Mixtures			
1.CAS No 2.EC Number 3.Index Number 4.REACH Number	% weight	Name	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
1. 43210-67-9 2. 256-145-7 3. Not Available 4. Not Available	2	Fenbendazole	Carcinogenicity Category 2; H351 ¹
Not Applicable	Proprietary	Other ingredients are non-hazardous	N/a
Legend: 1. Classified by Chemwatch			

SECTION 4: FIRST AID MEASURES	
4.1 Description of first aid measures	
Eye contact:	In case of accidental contact of the product with the eyes rinse abundantly with fresh water. Seek medical attention if irritation persists, showing the package leaflet or the label to the medical practitioner.
Skin contact:	In case of accidental contact of the product with the skin rinse abundantly with fresh water. Seek medical attention if irritation persists, showing the package leaflet or the label to the medical practitioner.
Inhalation:	Not considered to be a hazard. If inhaled, remove to fresh air and encourage to rest.
Ingestion:	Following accidental ingestion, seek medical advice, showing the package leaflet to the medical practitioner.
4.2 Most important symptoms and effects, both acute and delayed	
See Section 11	
4.3 Indication of immediate medical attention and special treatment needed	
N/a	

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media	
Suitable:	All systems may be used.
Unsuitable:	None.
5.2 Special hazards arising from the substance or mixture	
Fire incompatibility:	None known.
5.3 Special protective actions for fire-fighters:	
Firefighting:	Alert Fire Brigade and tell them location and nature of hazard. Wear full breathing apparatus and self-contained breathing apparatus.
Fire / explosion hazard:	None.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures	
For information on protective equipment, see section 8.	
6.2 Environmental Precautions	
Do not allow product to reach sewage system or any water course. Inform respective authorities in case of seepage into water course or sewage system. Do not allow to enter sewers/surface or ground water.	
6.3 Methods and material for containment and cleaning up	
Minor Spills:	Clean affected area with water.
Major Spills:	Clean up all spills immediately. Clean affected area with water. For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems. Control personal contact with the substance, by using protective equipment. Avoid contact with skin and eyes.



SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Safe Handling:	Wear suitable protection gloves and clothing when handling the product. Wash hands after use. When handling, DO NOT eat, drink or smoke. Observe manufacturer's storage and handling recommendations.
Other Information:	Keep out of the reach and sight of children. Store in a cool, dry, well-ventilated place.

7.2 Conditions for safe storage, including any incompatibilities

Suitable Container:	Do not store above 25°C. Do not freeze. Protect from direct sunlight. No in-use shelf life studies have been undertaken on this product.
Storage incompatibility:	No major incompatibilities known.

7.3 Specific end uses

Not available

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

DERIVED NO EFFECT LEVEL - DNEL

Not Available

PREDICTED NO EFFECT LEVEL - PNEC

Not Available


OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA:

Not Available

EMERGENCY LIMITS:

Ingredient	Material Name	TEEL-1	TEEL-2	TEEL-3
Not Available				

Ingredient	Original IDLH	Revised IDLH
Not Available		
8.2 Exposure controls		
Appropriate engineering controls:	The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the particular risk.	
Personal protection:		
Eye and face protection:	Safety glasses with side shields / chemical goggles	
Skin protection:	See hand protection below	
Hands/ feet protection:	No special equipment needed when handling small quantities. OTHERWISE: Wear chemical protective gloves	
Body protection:	Wear appropriate clothing	
Other protection:	No special equipment needed when handling small quantities	
Thermal hazards:	Not applicable	
Respiratory protection:	Not applicable	
8.3 Environmental exposure controls		
See Section 12		

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Lapizole®: Light green liquid
 Fenbendazole: a white, or almost white, powder
Container: Polypropylene container containing 100 ml of suspension and a dosing syringe.
Physical state: Lapizole®: Liquid
Odour: Not available
Odour Threshold: Not available
pH (as supplied): Not available
Melting point / freezing point (degrees C): Not available
Initial boiling point and boiling range: Not available
Flash Point: Not available
Evaporation rate: Not available
Flammability: Not available
Upper/lower flammability or explosive limits: Not available
Vapour pressure: Not available
Relative Density (at degrees C): Not available
Solubility in water and solvents (mg/l): Fenbendazole: practically insoluble
Vapour density: Not available
Auto ignition temperature (degrees C): Not available
Decomposition temperature (degrees C): Not available
Viscosity: (degrees C): Not available
Explosive properties: Not available
Oxidising properties: Not available
Partition Coefficient: Not available
Molecular weight: Fenbendazole: 299.37
Taste: Not available
Surface tension: Not available
Volative component: Not available
Gas group: Not available
pH as a solution: Not available
VOC g/L: Not available

9.2 Other information
 Not Available

10: REACTIVITY AND STABILITY

10.1 Reactivity:	See Section 7
10.2 Chemical stability:	Product is considered stable.
10.3 Possibility of hazardous reactions:	Stable under normal temperatures and conditions.
10.4 Conditions to avoid:	Protect from direct sunlight.
10.5 Incompatible materials:	See section 7.



10.6 Hazardous decomposition:	See Section 5.
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SECTION 11: TOXICOLOGICAL INFORMATION

Inhalation:	Not considered to be a hazard.	
Ingestion:	Only hazardous if swallowed in large amounts.	
Skin contact:	The material is not thought to produce adverse health effects or skin irritation following contact	
Eye contact:	Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result.	
Chronic:	<i>Encephalitozoon cuniculi</i> is a protozoal parasite of rabbits which affects the nervous and urinary systems and can cause a number of clinical signs. These include, but are not limited to, head tilt, hind limb paralysis or weakness, eye problems and death. It is a common parasite which is frequently sub-clinical, but in one study over 50% of rabbits in the UK were shown to have been infected. <i>Encephalitozoon cuniculi</i> may be passed on to humans and presents a potential risk to individuals who may have deficiencies to the immune system.	
Lignol®:	Acute toxicity	Irritation
	Not Available	Not Available
Lidocaine hydrochloride:	Acute toxicity	Irritation
	Oral (rat) LD ₅₀ : >10000 mg/kg ¹	Not Available

1. * Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted from RTECS - Register of Toxic Effect of chemical Substances

Skin corrosion/ irritation:
Not available
Serious eye damage/ irritation:
Not available
Respiratory or skin sensitization:
Not available
Germ cell mutagenicity:
Not available
Carcinogenicity:
No data available



SECTION 11: TOXICOLOGICAL INFORMATION

Reproductive toxicity:
Not available
STOT – single exposure:
Not available
STOT–repeated exposure:
Not available
Aspiration hazard:
Not available

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity
Not Available
12.2 Persistence and degradability
Not Available
12.3 Bioaccumulative potential
Not Available
12.4 Mobility in Soil
Not Available
12.5 Results of PBT and vPvB assessment
Not Available
12.6 Other adverse effects
Not Available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	
Product / packaging disposal:	Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements. Legislation addressing waste disposal requirements may differ by



	country, state and/ or territory. Each user must refer to laws operating in their area. Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001.
Waste Treatment Options:	Not Available
Sewage Disposal Options:	Not Available

SECTION 14: TRANSPORT INFORMATION

Labels required:	None
Marine pollutant:	NO
Hazchem:	Not Applicable

Land transport (ADR):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	Class	N/a
	Sub risk	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	Special provisions	N/a
	Classification code	N/a
	Hazard Label	N/a
	Special provisions	N/a
	Limited quantity	N/a



14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
Air transport (ICAO-IATA / DGR):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	ICAO/IATA Class	N/a
	ICAO / IATA Sub risk	N/a
	ERG Code	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	Special provisions	N/a
	Cargo only packing instructions	N/a
	Cargo only maximum qty/pack	N/a
	Passenger and cargo packaging instructions	N/a
	Passenger and cargo maximum qty/pack	N/a
	Passenger and cargo limited quantity packing instructions	N/a
	Passenger and cargo limited maximum qty/pack	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
Sea transport (IMDG-Code / GGVSee):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	



14.3 Transport hazard class(es)	IMDG Class	N/a	
	IMDG Sub risk	N/a	
14.4 Packing group	N/a		
14.5 Environmental hazards	N/a		
14.6 Special precautions for user	EMS Number	N/a	
	Special provisions	N/a	
	Limited quantities	N/a	
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a		
Inland waterways transport (ADN):			
14.1 UN Number	N/a		
14.2 UN Proper Shipping Name	N/a		
14.3 Transport hazard class(es)	N/a		N/a
14.4 Packing group	N/a		
14.5 Environmental hazard	N/a		
14.6 Special precautions for user	Classification Code	N/a	
	Special provisions	N/a	
	Limited quantity	N/a	
	Equipment required	N/a	
	Fire cones number	N/a	
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a		

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture

FENBENDAZOLE (43210-67-9) IS FOUND ON THE FOLLOWING REGULATORY LISTS:

- European Customs Inventory of Chemical Substances ECICS (English)
- European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)

15.2 Chemical Safety Assessment

ECHA SUMMARY

Ingredient	CAS number	Index Number	ECHA Dossier
Fenbendazole	73-78-9	Not Available	Not Available

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Repr. 2, Aquatic Acute 1, Aquatic Chronic 1	GHS09, GHS08, Wng	H361, H410
2	Repr. 2, Aquatic Acute 1, Aquatic Chronic 1, Aquatic Chronic 3, STOT RE 2, Carc. 2, Not Classified	GHS09, GHS08, Dgr	H361, H410, H373, H400, H351, H341

Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification

Australia - AICS	Y
Canada - DSL	Y
Canada - NDSL	N (fenbendazole)
China - IECSC	N (fenbendazole)
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (fenbendazole)
Korea - KECI	Y
New Zealand - NZIoC	Y
Philippines - PICCS	N (fenbendazole)



USA - TSCA	N (fenbendazole)
Legend:	<i>Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)</i>

SECTION 16: OTHER INFORMATION

The SDS is written in accordance to guidelines specified by REACH, GHS and ECHA.

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

- EN 166 Personal eye-protection
- EN 340 Protective clothing
- EN 374 Protective gloves against chemicals and micro-organisms
- EN 13832 Footwear protecting against chemicals
- EN 133 Respiratory protective devices

Definitions and abbreviations

- PC—TWA: Permissible Concentration-Time Weighted Average
- PC—STEL: Permissible Concentration-Short Term Exposure Limit
- STEL: Short Term Exposure Limit
- TEEL: Temporary Emergency Exposure Limit
- IDLH: Immediately Dangerous to Life or Health Concentrations

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