

## SECTION 1 : CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

### SECTION 1.1 : PRODUCT IDENTIFIER

PRODUCT NAME : Fenbendazole 2.5% Oral Suspension  
 PRODUCT TYPE : MIXTURE  
 REACH REGISTRATION : Not Available

### SECTION 1.2 : RELEVANT IDENTIFIED USES, & USES ADVISED AGAINST

IDENTIFIED USES : **VETERINARY ONLY**; Anthelmintic Agent for treatment of parasitic infection (Sheep & Cattle)

### SECTION 1.3 : DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

COMPANY NAME : Chanelle Pharmaceuticals Manufacturing Ltd  
 COMPANY ADDRESS : Dublin Road, Loughrea, Co. Galway, Rep. of Ireland  
 HOURS OF BUSINESS : 8.30 AM -5.00 PM (GMT)

### SECTION 1.4 : EMERGENCY CONTACT INFORMATION

COMPANY TELEPHONE : +353-(0)-91-841-788 (Reception -during office hours)  
 COMPANY FAX : +353-(0)-91-841-303  
 COMPANY WEBSITE : <http://www.chanellegroup.ie/>

## SECTION 2 : HAZARDS IDENTIFICATION

### SECTION 2.1 CLASSIFICATION OF THE SUBSTANCE/MIXTURE

CLASSIFICATION ACCORDING TO REGULATION 1272/2008/EC

<b>Hazard Type:</b>	<b>Category:</b>	<b>H-Statement:</b>	<b>SIGNAL:</b>
Not Classified	Not Applicable	Not Applicable	None

### SECTION 2.2 LABEL ELEMENTS

LABELLING ACCORDING TO REGULATION 1272/2008/EC [CLP]					
LABEL	Hazard Statements	Precautionary Statements			
None	None	Prevention	Response	Storage	Disposal
		None	None	None	None
SIGNAL	None	None	None	None	None
None					
Finished Product does not meet the criteria to be classified as hazardous under the applicable regulation.					

### SECTION 2.3 : OTHER HAZARDS

**Please Note:** Product has been classified in Section 2 based on information on ingredients as a **MIXTURE**. **FINISHED PRODUCT** does not meet the criteria under the applicable regulation to be classified as hazardous. However, as a veterinary medicinal product, care must be taken during normal applications of use. Your attention is drawn to the following sections in particular, but all data presented in this SDS should be reviewed.

- \* Refer to Section 4 for First Aid Measures
- \* Refer to Section 5 regarding Thermal Decomposition
- \* Refer to Section 11 for Toxicological Data
- \* Refer to Section 12 for Environmental Toxicity Data

## SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS.

**SECTION 3.1** : **SUBSTANCE** : NOT APPLICABLE  
**SECTION 3.2** : **MIXTURE** : INGREDIENTS ACCORDING TO 1272/2008/EC

COMPONENT	TYPE	CONC.	CAS	CLASSIFICATION	SYMBOL	SIGNAL
Fenbendazole	API	2.5%	43210-67-9	Aquatic Acute Cat. 1 H400: Very Toxic to Aquatic Life Aquatic Chronic Cat 1 H410 Very Toxic to Aquatic Life with Long Lasting Effects		WARNING

Note: All other ingredients, not listed above, are either below reportable levels, or are not classified as hazardous according to GHS-CLP regulation.

## SECTION 4 : FIRST AID MEASURES.

**General** If unconscious, place person on their side in the recovery position; ensure breathing; contact medical aid-give access to SDS.  
**Inhalation** **Finished Product Not Considered Irritating by Inhalation**, however if coughing dizziness or irritation develops remove to Fresh Air; Keep Patient Warm; Seek Medical Assistance and Treatment.  
**Skin Contact** **Finished Product Not Considered Irritating**; Wash affected area with mild soap & water; if irritation develops contact physician.  
**Eye Contact** **Finished Product Not Considered Irritating to Eyes**; Rinse open eye with water for several minutes; Remove Contact Lenses if present. Seek medical advice if irritation develops or persists  
**Ingestion** Rinse Mouth with water; if a large volume is ingested contact medical physician/assistance showing the pack information or this SDS; Keep patient in resting position; Allow patient to drink water; Never administer anything to patient in an unconscious state; DO NOT INDUCE VOMITING unless directed to do so by a medical physician; if patient loses consciousness, place in recovery position.  
**SECTION 4.2** **Most Important Symptoms and Effects (Acute & Delayed)**: Overdose by Ingestion may include, and are not limited to: gastro-intestinal disturbances or allergic reaction  
**SECTION 4.3** **Indication of Any Immediate Medical Attention & Special Treatment Needed**  
**Notes to Physician**: In cases of overdose: Treat Symptomatically.

## SECTION 5 : FIREFIGHTING MEASURES.

**SECTION 5.1** Suitable Extinguishing Media  
**SECTION 5.2** Hazardous Thermal Decomposition Products  
**SECTION 5.3**  
**ADDITIONAL INFORMATION**

**EXTINGUISHING MEDIA**  
Dry Chemical Powder; Carbon Dioxide; Foam; Extinguishing Blanket; Water Spray  
**SPECIAL HAZARDS (arising from substance/mixture)**  
Possibility of Toxic or Irritating Fumes including NOx & SOx  
**ADVICE FOR FIREFIGHTERS**  
Wear self-contained respiratory protection; Wear Protective Clothing.  
Cool endangered receptacles with water spray.  
Collect contaminated Fire Fighting Media, Not to be discharged to drain.

## SECTION 6 : ACCIDENTAL RELEASE MEASURES.

**SECTION 6.1** **For Non-Emergency Personnel**  
**For Emergency Personnel**

**SECTION 6.2**

**SECTION 6.3**

**Personal Precautions, Protective Equipment & Emergency Procedures**  
No action should be taken without appropriate training; PPE or if danger of personal risk exists. Do not walk through, touch or attempt to contain spilled material without PPE. Refer to Section 8 for PPE requirements.  
Refer to section 8 for required PPE to contain spillage. Ensure proper containment for disposal as detailed in Section 13. Absorb/Contain/Collect spilled volumes with appropriate physical methods - Large Volumes may use spill containment to be removed for disposal. Affected Area may be cleaned with Water and Detergent, preventing excessive Run-Off from entering drains.  
**ENVIRONMENTAL PRECAUTIONS**  
Do NOT discharge large volumes of spilled material to soil, sewers, waterways, surface or ground waters. Contact relevant authorities if contamination occurs.  
**MATERIALS/METHODS (for containment and clean-up)**  
Approach release from up-wind. Label collected material appropriately and store for disposal referring to Section 13 for further information regarding Disposal Considerations.

## SECTION 7 : HANDLING & STORAGE.

**SECTION 7.1** **FINISHED PRODUCT:**  
**SECTION 7.2**  
**SECTION 7.3**

**PRECAUTIONS FOR SAFE HANDLING: (Refer to section 4 for First Aid Protocols)**  
**For Persons administering the Product:** Keep all medicines away from children & pets as it may prove harmful. In all cases of accidental exposure through ingestion, contact medical physician immediately. Avoid contact with Skin/ Eyes.  
**CONDITIONS FOR SAFE STORAGE Including Incompatibilities:** Keep all medicines stored away from pets and animals; Veterinary Medicinal Product does not require any special storage conditions though it is recommended to store securely, under 25°C, dry & ventilated area and away from direct sunlight.  
**SPECIFIC END USE(s); Use ONLY as detailed in Section 1.2.**

## SECTION 8 : EXPOSURE CONTROLS/ PERSONAL PROTECTION.

**SECTION 8.1** : **EXPOSURE CONTROLS:** None specified; No existing Data regarding OEL for finished product; appropriate engineering controls Should be in place where individuals are exposed to dust, vapours; mist; airborne particles/mist to ensure worker exposure are Within/below any recommended limits.

**ENVIRONMENTAL EXPOSURE CONTROLS:** None specified; Emissions from ventilation or work processes should meet Requirements of environmental protection legislation

**SECTION 8.2** : **CONTROL PARAMETERS:** Ensure good ventilation and/or exhaust measures within the workplace;

**List of PPE is as follows:** Finished Product requires no Respiratory Protection under Normal Conditions of Use. A (minimum) P1 Grade Mask/ FFP1 Grade Mask in enclosed areas recommended especially if working with bulk. Gloves are required when handling bulk product for extended periods, Wash hands thoroughly after handling product. Eye protection not normally required when handling the finished product, however Protective-Eyewear is recommended when working with larger or bulk volumes.

## SECTION 9 : PHYSICAL & CHEMICAL PROPERTIES.

**SECTION 9.1** : **INFORMATION ON BASIC PHYSICAL & CHEMICAL PROPERTIES**

	Active Ingredient	FINISHED PRODUCT
APPEARANCE: Form/Colour	White/Off White Crystalline Powder	Pale Pink Smooth Suspension
Odour	None	"Characteristic"
Odour Threshold	Not Available	Not Available
pH	Not Available	6.0 (+0.5) at RT
Melting/Freezing Point	Melting : 233°C	Not Available
Boiling Point (Range)	Not Available	Not Available
Flash Point	Not Available	Not Available
Evaporation Rate	Not Available	Not Available
Flammability	Not Available	Not Available
Upper/Lower Explosive Limits	Not listed as Explosive Hazard	Not Available
Vapour Pressure	<0.0000001kPa @ 25°C	Not Available
Vapour Density	Not Available	Not Available
Relative Density	Not Available	Not Available
Solubility	Practically Insoluble in Water (<1mg/L) Soluble in Methanol	Not Available -
Partition Coefficient n-octanol/water	Log Pow 3.85 @20°C	Not Available
Auto-Ignition Temperature	Not Available	Not Available
Decomposition Temperature	Not Available	Not Available
Viscosity	Not Available	Not Available
Explosive properties	Not Available	Not Available
Oxidising Properties	Not Available	Not Available

**SECTION 9.2** : **OTHER INFORMATION;** No other information available; Refer to Section 10

## SECTION 10 : STABILITY & REACTIVITY DATA.

<b>SECTION 10.1</b>	: <b>REACTIVITY</b>	: Considered Stable
<b>SECTION 10.2</b>	: <b>CHEMICAL STABILITY</b>	: Stable under Normal Conditions
<b>SECTION 10.3</b>	: <b>POSSIBILITY OF HAZARDOUS REACTIONS</b>	: None Listed or Known
<b>SECTION 10.4</b>	: <b>CONDITIONS TO AVOID</b>	: No Specific Data
<b>SECTION 10.5</b>	: <b>INCOMPATIBLE MATERIALS</b>	: Strong Oxidising Agents
<b>SECTION 10.6</b>	: <b>HAZARDOUS DECOMPOSITION PRODUCTS</b>	: Normal Conditions NONE Known: Refer to Section 5 (fire conditions)

## SECTION 11 : TOXICOLOGICAL INFORMATION.

**SECTION 11.1** : **INFORMATION ON TOXICOLOGICAL EFFECTS**

**11.1.1** : **Acute Toxicity**

Ingredient	LD50	Species	Result
Fenbendazole	Oral	Mouse	>10,000.00 mg/kg (>10g)
		Rat	>10,000.00 mg/kg (>10g)

**Supplementary Information:** The Information provided in this Table is for individual components for which Acute Toxicity Data is available at 100% concentration of that specific ingredient. Single Active component (listed above) is present in the Finished Product at the concentrations listed in SECTION 3.2. Usually for the purposes of SDS information, the Acute Toxicity Estimate (ATE) for the Finished Product is calculated for mixtures for which data is available. Classification of the Finished Product within Section 2 is then based on the GHS-CLP guidance on this calculated figure. Based on the available data for the Finished Product is not considered to be Acutely Toxic and does not meet criteria.

Section 11: Toxicological Information continues overleaf →

**Section 11: Toxicological Information continued:**

**11.1.2 : Skin Irritation/Corrosion Data**

No Available Data for Finished Product:  
Finished Product not considered to be a Skin irritant.  
No Ingredient listed as Irritating to Skin: Refer to Sections 4 & 9.

**11.1.3 : Eye Irritation/Damage Data**

No Available Data for Finished Product:  
Finished Product not considered to be an Eye irritant. Refer to Sections 4 & 9.

**11.1.4 : Respiratory &/or Skin Sensitisation Data**

No Available Data for Finished Product:  
Finished Product not considered to be a Respiratory/Skin Sensitizing Agent.

**11.1.5 : Germ Cell Mutagenicity**

**Finished Product Not Classified: No Data Available for Ingredients or Not Classified**

**11.1.6 : Carcinogenicity**

**Finished Product Not Classified: No Ingredient Classified as Carcinogenic.**

Ingredient	Dose Regimen	Species	Result
Fenbendazole	0-405mg/kg/day (2 years)	Mouse	No Observed Effects or Incidence
	135mg/kg/day	Rat	Slight increases of cyst formation and hepatocellular foci (45 mg/kg/day)

Based on the available data, the criteria for classification of the Active Ingredient is not met.

**11.1.7 : Reproductive Toxicity**

**Finished Product Not Classified: No Ingredient Classified as Reproductive Toxin.**

Ingredient	Dose Regimen	Species	Result
Fenbendazole	0-1000 mg/kg (reproductive study)	Rat	No significant adverse effects noted
	0-135 mg/kg/day (reproductive study)		NOAEL 15mg/kg (decrease body weight)
	60-120 mg/kg/day (reproductive study)		NEGATIVE for teratogenicity or embryotoxicity

Based on the available data, the criteria for classification of the Active Ingredient is not met.

**11.1.8 : STOT- Single Exposure**

No Available Data for Finished Product.

**11.1.9 : STOT- Repeated Exposure**

No Available Data for Finished Product.

**11.1.10 : Aspiration Hazard**

No Available Data for Finished Product.

**SECTION 12 : ECOLOGICAL INFORMATION.**

**SECTION 12.1 : TOXICITY**

**Finished Product Not Classified: Information on Active as follows**

Product/Ingredient	LC50/EC50/IC50	Species	Result
Fenbendazole	Aquatic Toxicity 96hr	Fish(Not Specified)	>500.0 mg/L
	Aquatic Toxicity 48hr	Daphnia magna	0.012 mg/L

Active Ingredient is of the Benzimidazole Class which are not considered toxic to bird or bee species. Active is considered moderately toxic to aquatic life (based on Daphnia magna data); the log POW data indicates a strong potential for bioaccumulation. Based on interpretation of dilution data, Finished Product does not meet the classification requirements to be designated as environmentally hazardous. Benzimidazoles degrade in soil and are expected to degrade in water.

<b>SECTION 12.2</b>	<b>: PERSISTANCE AND DEGRADEABILITY</b>	: No Available Data	
<b>SECTION 12.3</b>	<b>: BIOACCUMULATIVE POTENTIAL</b>	: Fenbendazole API:	Log POW; 3.85 @20°C
<b>SECTION 12.4</b>	<b>: MOBILITY IN SOIL</b>	: No Available Data	
<b>SECTION 12.5</b>	<b>: RESULTS OF PBT &amp; vPvB ASSESSMENT</b>	: No Available Data	
<b>SECTION 12.6</b>	<b>: OTHER ADVERSE EFFECTS</b>	: No Available Data	

**SECTION 13 : DISPOSAL CONSIDERATIONS.**

**SECTION 13.1 : WASTE TREATMENT METHODS:** It is recommended that the product be considered hazardous waste and disposed of in accordance with Local Authority Requirements & Regulations. Waste Products should not be disposed of untreated to sewer or drain. Incineration Methods are recommended for Substances & Contaminated Packaging.

**SECTION 14 : TRANSPORT INFORMATION.**

*: Please Note: Section 14 applies to the Finished Product: Not Classed as Dangerous Goods under Transport Regulation*

<b>SECTION 14.1</b>	<b>: UN NUMBER</b>	: N/A
<b>SECTION 14.2</b>	<b>: UN PROPER SHIPPING NAME</b>	: N/A
<b>SECTION 14.3</b>	<b>: TRANSPORT HAZARD CLASS (ES)</b>	: N/A
<b>SECTION 14.4</b>	<b>: PACKING GROUP</b>	: N/A
<b>SECTION 14.5</b>	<b>: ENVIRONMENTAL HAZARDS</b>	: Refer to Section 12
<b>SECTION 14.6</b>	<b>: SPECIAL PRECAUTIONS FOR USER</b>	: No Data
<b>SECTION 14.7</b>	<b>: TRANSPORT IN BULK</b>	: No Data

**SECTION 15 : OTHER REGULATORY INFORMATION.**


- SECTION 15.1 : SAFETY, HEALTH & ENVIRONMENTAL REGULATIONS/ LEGISLATION**  
(Specific for the substance/mixture) : Data Not Available
- SECTION 15.2 : CHEMICAL SAFETY ASSESSMENT** : Data Not Available

**SECTION 16 : OTHER INFORMATION.**

- Document History** : Version 1 (Created 27-January-2017)
- Revised Sections** : N/A
- Prepared by** : Materials Safety Data Officer, Chanelle Pharmaceuticals Ltd.
- Abbreviations Legend** : Listed in alphabetical order.

• <b>ADR</b> : "Accord-Dangereuses-Route" Dangerous Goods by Road; European Agree	• <b>IBC</b> : Intermediate Bulk Container
• <b>ATE</b> : Acute Toxicity Estimate	• <b>IMDG</b> : International Maritime code for Dangerous Goods
• <b>API</b> : Active Pharmaceutical Ingredient	• <b>LCS0</b> : Lethal Concentration 50 %
• <b>BCF</b> : Bio-concentration Factor	• <b>LDS0</b> : Lethal Dose, 50%
• <b>CAS</b> : Chemical Abstracts Service	• <b>LQ</b> : Limited Quantity (stated in ADR-LQ)
• <b>EINECS</b> : European Inventory of Existing Chemical Substances	• <b>MARPOL 73/78</b> : International Convention for the Prevention of Pollution from Ships
• <b>EmS</b> : Emergency Schedule (Code of Emergency Labelling)	• <b>NOEC</b> : No Observable Effect Concentration
• <b>GHS</b> : Globally Harmonised System (of Classification and Labelling of Chemicals)	• <b>N.O.S</b> : "Not Otherwise Specified"
• <b>IATA</b> : International Air Transport Association	• <b>UN</b> : United Nations

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Prepared by:  Date of Approval: 30-01-2017  
 Material Safety Data Officer **END OF SDS**