SECTION 1 : CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

SECTION 1.1 : PRODUCT IDENTIFIER

PRODUCT NAME : Oxfendazole 2.265% Oral Suspension
PRODUCT TYPE : MIXTURE
REACH REGISTRATION : Not Available

SECTION 1.2 : RELEVANT IDENTIFIED USES, & USES ADVISED AGAINST

IDENTIFIED USES : **VETERINARY ONLY**; Anthelminthic Agent for treatment of parasitic infection

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

Hazard Type:	Category:	H-Statement:	SIGNAL:
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			
		Prevention	Response	Storage	Disposal
None	None	None	None	None	None
SIGNAL					
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 11 for Toxicological Data
* Refer to Section 5 regarding Thermal Decomposition
* 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	SIGNAL
Oxfendazole	API	<2.50%	53716-50-0	Aquatic Acute Cat. 1 H400: Very Toxic to Aquatic Life 	WARNING
Citric acid monohydrate	Excipient	<1.00%	77-92-9	Eye Irritant. Cat 2 H319: Causes Serious Eye Irritation 	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 (if conscious) 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 **EXTINGUISHING MEDIA**

Suitable Extinguishing Media: Dry Chemical Powder; Carbon Dioxide; Foam; Water Spray;

SECTION 5.2 **SPECIAL HAZARDS (arising from substance/mixture)**

Hazardous Thermal Decomposition Products: Possibility of: Carbon Oxides (COx); Nitrogen Oxides (NOx); Sulphur Oxides (SOx)

SECTION 5.3 **ADVICE FOR FIREFIGHTERS**

Wear self-contained respiratory protection; Wear Protective Clothing.

ADDITIONAL INFORMATION

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 **Personal Precautions, Protective Equipment & Emergency Procedures**

For Non-Emergency Personnel 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.

For Emergency Personnel 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.

SECTION 6.2 **ENVIRONMENTAL PRECAUTIONS**

Do NOT discharge large volumes of spilled material to soil, sewers, waterways, surface or ground waters. Contact relevant authorities if contamination occurs.

SECTION 6.3 **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 **PRECAUTIONS FOR SAFE HANDLING: (Refer to section 4 for First Aid Protocols)**

FINISHED PRODUCT: **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.

SECTION 7.2 **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 30°C, dry & ventilated area and away from direct sunlight.

SECTION 7.3 **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 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 Solid	A smooth, white to off-white coloured suspension Re-suspends easily after gentle shaking.
Odour	Not Available	Faint Characteristic Odour
Odour Threshold	Not Available	Not Available
.pH	Not Available	4.8 ± 0.5 (Room Temp)
Melting/Freezing Point	Melting : 245-265ºC	Not Available
Boiling Point (Range)	Not Available	Not Available
Flash Point	Not Available	Not Available (Not Flammable)
Evaporation Rate	Not Available	Not Available
Flammability	Not Available	Not Flammable Product
Upper/Lower Explosive Limits	Not listed as Explosive Hazard	Not Available
Vapour Pressure	Not Available	Not Available
Vapour Density	Not Available	Not Available
Relative Density	Not Available	Density: 1.03 g/ml ± 0.01 g/ml
Solubility	Practically Insoluble in Water (<1mg/L)	Aqueous Suspension
Partition Coefficient n-octanol/water	Not Available	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.

SECTION 10.1	**: REACTIVITY**	: Considered Stable
SECTION 10.2	**: CHEMICAL STABILITY**	: Stable under Normal Conditions
SECTION 10.3	**: POSSIBILITY OF HAZARDOUS REACTIONS**	: None Listed or Known
SECTION 10.4	**: CONDITIONS TO AVOID**	: No Specific Data
SECTION 10.5	**: INCOMPATIBLE MATERIALS**	: Strong Oxidising Agents
SECTION 10.6	**: HAZARDOUS DECOMPOSITION PRODUCTS**	: 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
Oxfendazole	Oral	Mouse	>6,400.00 mg/kg
		Rat	>6,400.00 mg/kg
Citric acid monohydrate			11,700.00 mg/kg

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 accordingly, classification of the Finished Product within **Section 2** is based on the GHS-CLP guidance on this calculated figure. Based on the available data the ATE for the Finished Product is > 220,000 mg/kg. Ingredients not listed in **Section 3.2** which were classified as non-hazardous according to Regulation EC 1272/2008 are exempt from inclusion in the ATE calculation.

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. Certain Ingredients May Cause Irritation.** Refer to Sections 4 & 8.

11.1.3 : Eye Irritation/Damage Data — No Available Data for Finished Product: **Finished Product not considered to be an Eye irritant. Certain Ingredients May Cause Irritation.** Refer to Sections 4 & 8.

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. Certain Ingredients May Cause Respiratory Irritation if Inhaled.**

11.1.5 : Germ Cell Mutagenicity — **Finished Product Not Classified: No Ingredient Classified As Mutagenic.**

Ingredient	Dose Regimen	Species	Result
Oxfendazole	Ames Assay ± S9 0.5-5000µg/ml	*Salmonella typhimurium TA97a, TA98, TA100, TA102*	**NEGATIVE**

11.1.6 : Carcinogenicity — **Finished Product Not Classified: No Ingredient Classified as Carcinogenic.**

Ingredient	Dose Regimen	Species	Result
Oxfendazole	Up to 150 mg/kg bw/day	*Rats & Mice (78 weeks)*	**NEGATIVE for carcinogenicity NOEL 300mg/kg (45 mg/kg/day)**
	M-Up to 7 mg/kg bw/day F-Up to 8.8 mg/kg bw/day	*Rat (M & F)-(2 years)*	**NEGATIVE for carcinogenicity NOEL (Male-0.7 mg/kg/day) (Female-0.9 mg/kg/day)**
At the higher doses, hepatocellular vacuolation and hepatic discolouration were the main observations during these protocols			

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

Ingredient	Dose Regimen	Species	Result
Oxfendazole	Up to 100 mg/kg - 14 days	***Rat***	**Decreased Testicular Weight/ Spermatogenesis; NOEL 33 mg/kg**
	Up to 54 mg/kg - 3 months		**Testicular Atrophy; NOEL 17 mg/kg**
	10-60 mg/kg - on Days 6-15 gest. 5-20mg/kg - on Days 7-16 gest.		**Fetotoxicity Observed at doses >10mg/kg - NO Teratogenic Effects**
	360 mg/kg bw – on Days 6-15 gest.	***Mouse***	**Fetotoxicity Observed at dose listed. NO Teratogenic Effects at 108mg/kg (NOEL)**
Review of literature available indicates that no effects on the foetus were observed in trials conducted with pigs, rabbits, cattle & horse.			

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
Oxfendazole	Aquatic Toxicity 24hr	Fish-(Not Specified)	**>2.7 mg/L**
	Aquatic Toxicity 48hr	*Daphnia magna*	**0.52 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) but the log POW data indicates a low 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.			

SECTION 12.2 : PERSISTANCE AND DEGRADEABILITY : No Available Data

SECTION 12.3 : BIOACCUMULATIVE POTENTIAL : Oxfendazole API: Log Pow; 1.95 @20°C

SECTION 12.4 : MOBILITY IN SOIL : No Available Data

SECTION 12.5 : RESULTS OF PBT & vPvB ASSESSMENT : No Available Data

SECTION 12.6 : OTHER ADVERSE EFFECTS : 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

SECTION 14.1	**: UN NUMBER**	: N/A
SECTION 14.2	**: UN PROPER SHIPPING NAME**	: N/A
SECTION 14.3	**: TRANSPORT HAZARD CLASS (ES)**	: N/A
SECTION 14.4	**: PACKING GROUP**	: N/A
SECTION 14.5	**: ENVIRONMENTAL HAZARDS**	: Refer to Section 12
SECTION 14.6	**: SPECIAL PRECAUTIONS FOR USER**	: No Data
SECTION 14.7	**: TRANSPORT IN BULK**	: 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 29-November-2016)
Revised Sections	: N/A
Prepared by	: Materials Safety Data Officer, Chanelle Pharmaceuticals Ltd.
Abbreviations Legend	: Listed in alphabetical order.

ADR	**: "Accord-Dangereuses-Route" Dangerous Goods by Road; European Agree**	**IBC**	**: Intermediate Bulk Container**
ATE	**: Acute Toxicity Estimate**	**IMDG**	**: International Maritime code for Dangerous Goods**
API	**: Active Pharmaceutical Ingredient**	**LC50**	**: Lethal Concentration 50 %**
BCF	**: Bio-concentration Factor**	**LD50**	**: Lethal Dose, 50%**
CAS	**: Chemical Abstracts Service**	**LQ**	**: Limited Quantity (stated in ADR-LQ)**
EINECS	**: European Inventory of Existing Chemical Substances**	**MARPOL 73/78**	**: International Convention for the Prevention of Pollution from Ships**
EmS	**: Emergency Schedule (Code of Emergency Labelling)**	**NOEC**	**: No Observable Effect Concentration**
GHS	**: Globally Harmonised System (of Classification and Labelling of Chemicals)**	**N.O.S**	**: "Not Otherwise Specified"**
IATA	**: International Air Transport Association**	**UN**	**: United Nations**

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Prepared by: _____ **Date of Approval:** 29-11-2016

Material Safety Data Officer

END OF SDS