SECTION 1 : CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

SECTION 1.1 : PRODUCT IDENTIFIER

PRODUCT NAME : TRICLABENDAZOLE Solution (5.0%)-All presentation Volumes
PRODUCT TYPE : MIXTURE
REACH REGISTRATION : Not Available

SECTION 1.2 : RELEVANT IDENTIFIED USES, & USES ADVISED AGAINST

IDENTIFIED USES : VETERINARY; Oral Drench Benzimidazole Anthelmintic/ Flukicide for **SHEEP**

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:
• **Reproductive Hazard**	**Category 2**	**H361d**	**WARNING**
• **Hazardous to the Aquatic Environment**	**Category 4**	**H413**	**WARNING**

SECTION 2.2 : LABEL ELEMENTS

LABELLING ACCORDING TO REGULATION 1272/2008/EC [CLP]

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WARNING

Hazard Statements	Precautionary Statements			
	Prevention	**Response**	**Storage**	**Disposal**
H361d: Suspected of Damaging the Unborn Child	P201: Obtain Special Instructions before Use	P308+P313: If Exposed or Concerned: Get Medical Advice/Attention	P405: Store Locked Up	P501: Dispose of Contents/Container in accordance with local/ regional/ national/ international regulations
H413: May Cause Long Lasting Harmful to Aquatic Life	P202: Do Not Handle until all Safety Precautions have been Read & Understood			
	P273: Avoid release to the environment			
	P281: Wear Personal Protective Equipment as Required			

SECTION 2.3 : OTHER HAZARDS

* 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	GHS & CLP LABEL (ingredient)
TRICLABENDAZOLE	API	5.0%	68786-66-3	Repr Tox. Cat 2 **WARNING**	 H361d: Suspected of Damaging Fertility or The Unborn Child
Methyl 4-Hydroxybenzoate	Excipient	0.20%	99-76-3	Aquatic Chronic Cat 3 **WARNING**	No Symbol H412: Harmful to Aquatic Life with Long Lasting Effects

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

SECTION 4 : FIRST AID MEASURES.

SECTION 4.1: **Description of First Aid Measures (First Aid Section Refers to the Finished Product Mixture)**

General: If unconscious, place person on their side in the recovery position; contact medical aid; give access to this SDS.

Inhalation: If coughing, dizziness, or irritation develops remove to Fresh Air; Keep Patient Warm; Seek Medical Assistance

Skin Contact: Wash affected area with mild soap & water; if irritation develops contact physician.

Eye Contact: Rinse open eye with water for several minutes; Remove Contact Lenses if present. Seek Medical Advice

Ingestion: Rinse Mouth with water; immediately 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):**
This product contains ingredients which may induce Gastrointestinal Disturbance and/or Possible Allergic Reaction

SECTION 4.3: **Indication of Any Immediate Medical Attention & Special Treatment Needed**
Notes to Physician: Treat Symptomatically.

SECTION 5 : FIREFIGHTING MEASURES.

SECTION 5.1: **EXTINGUISHING MEDIA**

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

Unsuitable Extinguishing Media: Full Water Jet deemed unsuitable as it may spread the flame.

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

Hazardous Thermal Decomposition Products: Possibility of Toxic or irritating Fumes

SECTION 5.3: **ADVICE FOR FIREFIGHTERS**

Wear self-contained respiratory protection; Wear Protective Clothing; Evacuate Area

ADDITIONAL INFORMATION

Collect contaminated Fire Fighting Media, Not to be discharged to drain.
Exposure to fire may cause container to rupture or if heated under confinement

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. No Smoking. Unnecessary personnel should be removed to safe area.

For Emergency Personnel:
Refer to section 8 for required PPE to contain spillage.
Ensure proper containment for disposal as detailed in Section 13.
Affected Area may then be cleaned with Water and Detergent.

SECTION 6.2: **ENVIRONMENTAL PRECAUTIONS**

Do NOT discharge 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. Absorb spilled material with a suitable absorptive agent
(E.g. Spill Kit/ Diatomaceous Earth). Label collected material appropriately and store for disposal
Referring to Section 13 for more information

SECTION 7 : HANDLING & STORAGE.

SECTION 7.1: **PRECAUTIONS FOR SAFE HANDLING: (Refer to section 4 for First Aid Protocols)**
Avoid contact with skin and eyes. Avoid breathing mist/vapours. DO NOT eat, drink or smoke during use of product. Wash Hands after use. Keep container tightly closed when not in use.

FINISHED PRODUCT: **For Persons administering the Product:** Keep all medicines away from children & pets; children are particularly at risk from product and may prove harmful. Pets can be susceptible to Toxicity therefore access to this product should be restricted. In all cases of accidental exposure via 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 children, pets and animals; Finished Product does not require any special storage conditions though it is recommended to store securely, under 30°C, dry, & well ventilated area. Avoid storing in 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; 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 itself requires no Respiratory Protection under Normal Conditions of Use and a well ventilated environment. A (minimum) Grade Mask **(EN 143)** in enclosed areas recommended especially if working with bulk volumes and as a back-up to engineering controls. Gloves are required **(EN 374)** when handling bulk product for extended periods, wash hands thoroughly after handling product. Eye protection normally required when handling the finished product, protective eyewear **(EN 166)** is recommended when working with large or bulk volumes where the incidence of exposure is increased.

Respiratory Protection	Eye Protection	Hand Protection	General Protection
			 
Quarter Mask Grade as per EN143	Safety Glasses Grade as per EN166	Protective Gloves Grade as per EN374	General Protective Garb and Safety Footwear appropriate to task

SECTION 9 : PHYSICAL & CHEMICAL PROPERTIES.

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

	ACTIVE PHARMACEUTICAL	FINISHED PRODUCT
APPEARANCE: Form/Colour	White/Off-White-Beige Powder	Blue Uniform Suspension (re-suspends on shaking)
Odour	Not Available	Characteristic Scent
Odour Threshold	Not Available	Not Available
.pH	6-7 (1% Water Solution)	5.5-7.5
Melting/Freezing Point	Melting : 174-178°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	Not Available	Not Available
Vapour Density	Not Available	Not Available
Relative Density	Not Available	Not Available
Solubility	Not Miscible with Water	Not Available
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 (Refer to Section 7.2) Avoid Extremes of Light & Heat
SECTION 10.5	: INCOMPATIBLE MATERIALS	: No Information or NONE Known
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
TRICLABENDAZOLE	Oral	Rat	>8000.00 mg/kg
	Dermal		>4000.00 mg/kg
Methyl 4- Hydroxybenzoate	Oral		2,100.00 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. Each component listed above is present in the **Finished Product** at the concentrations listed in **SECTION 3.2**. For the purposes of this SDS, the Acute Toxicity Estimate (ATE) for the Finished Product is estimated using the Rat LD50 data (most potent) and is estimated at >5,000.00mg/kg by calculation and accordingly, the finished product does not meet classification for Acute Toxicity. Finished Product is considered to be **NOT ACUTELY TOXIC.**
Ingredients not listed in **Section 3.2** are classified as non-hazardous according to Regulation EC 1272/2008 and are exempt from inclusion in the ATE calculation.

11.1.2	: Skin Irritation/Corrosion Data	: No Available Data for Finished Product: **Specific Ingredients May Cause Slight Skin Irritation.**
11.1.3	: Eye Irritation/Damage Data	: No Available Data for Finished Product: **Specific Ingredients May Cause Slight Eye Irritation.**
11.1.4	: Respiratory &/or Skin Sensitisation Data	: No Available Data for Finished Product: **No Specific Data for Ingredients**
11.1.5	: Germ Cell Mutagenicity	: Finished Product Not Classified. **Contains no Ingredient classified as Mutagenic** **Active Ingredient Classified as NEGATIVE in both *in-vivo* & *in-vitro* test battery**
11.1.6	: Carcinogenicity	: Finished Product Not Classified. **Contains no Ingredient classified as Carcinogenic** **Active Ingredient Classified as NEGATIVE in 2 year animal study at doses up to 300 mg/kg**
11.1.7	: Reproductive Toxicity	***: Note: TRICLABENDAZOLE is classified as Reproductive Hazard Cat 2 "suspect" [Source EDQM]***

- **Animal studies (rats) at doses up to 100 mg/kg TRICLABENDAZOLE API on days 6-16 of gestation resulted in low foetal bodyweight and a delay in ossification and was associated with maternal toxicity. No evidence of teratogenicity was observed. NOEL 3mg/kg BW.**
- **Oral administration to pregnant ewes at doses (single & multiple) of 10-50 mg/kg of TRICLABENDAZOLE API had NO REPRODUCTIVE IMPACT ON EWE OR OFFSPRING, however a 1:1 administration with FENBENDAZOLE in high doses of 150mg/kg BW did result in some incidents of kidney and skeletal abnormalities in some of the Offspring (ewes exposed on days 12 or 21)**
- **Finished Product is classified in Section 2, in this regard, as the Final Concentration of TRICLABENDAZOLE within the Finished Product is > 3.0% as defined under GHS-CLP guidance literature.**

11.1.8	: STOT- Single Exposure	: No Available Data for Finished Product. **NOT CLASSIFIED**
11.1.9	: STOT- Repeated Exposure	: No Available Data for Finished Product. **NOT CLASSIFIED**
11.1.10	: Aspiration Hazard	: No Available Data for Finished Product. **NOT CLASSIFIED**

SECTION 12 : ECOLOGICAL INFORMATION.

SECTION 12.1	: TOXICITY	: No Available Data for Finished Product: No Available Data for Ingredients
SECTION 12.2	: PERSISTANCE AND DEGRADEABILITY	: No Available Data
SECTION 12.3	: BIOACCUMULATIVE POTENTIAL	: No Available Data
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:

Due to the low water solubility of the Active Ingredient, it is not thought this Finished Product would have a direct impact to the environment when used as directed. Excipient classification as detailed within Section 3, is present in the Finished Product at concentration <1% and not thought to have an impact.

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 drain.

SECTION 14 : TRANSPORT INFORMATION.

Please Note: Section 14 applies to the Finished Product

SECTION 14.1	: UN NUMBER	: N/A
SECTION 14.2	: UN PROPER SHIPPING NAME	: Not Classified as Hazardous Material for transport
SECTION 14.3	: TRANSPORT HAZARD CLASS (ES)	: N/A
SECTION 14.4	: PACKING GROUP	: N/A
SECTION 14.5	: ENVIRONMENTAL HAZARDS	: None
SECTION 14.6	: SPECIAL PRECAUTIONS FOR USER	: No Data
SECTION 14.7	: TRANSPORT IN BULK	: Not Applicable

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 4th-October-2016)

Revised Sections : N/A

Prepared by : Materials Safety Data Officer, Chanelle Pharmaceuticals Ltd.

References : **Data is sourced from Supplied SDS, Sourced SDS, and recognised toxicological databases**

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

Prepared by: _____ **Date of Approval:** 04-10-2016

Material Safety Data Officer

END OF SDS