SECTION 1 : CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

SECTION 1.1 : PRODUCT IDENTIFIER

PRODUCT NAME : IVERMECTIN Injection (1.0%)-All presentation Volumes
PRODUCT TYPE : MIXTURE
REACH REGISTRATION : Not Available

SECTION 1.2 : RELEVANT IDENTIFIED USES, & USES ADVISED AGAINST

IDENTIFIED USES : VETERINARY; Injectable Parasiticide with Anthelmintic Properties (for Bovine & Porcine Animals)

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 Toxicity	**Category 2**	**H361**	**Signal: WARNING**
Hazardous to the Aquatic Environment	**Category 3**	**H402**	**Signal: WARNING**

SECTION 2.2 : LABEL ELEMENTS

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

WARNING

Hazard Statements	Precautionary Statements			
	Prevention	Response	Storage	Disposal
H361: Suspected of damaging Fertility or the Unborn Child	P201	P308+P313	P405	P501
	P202			
H402: Harmful to Aquatic Life	P273			
	P280			

Please Refer to* Section 16: Other Information *for Full Explanation of Applicable Precautionary Statements

SECTION 2.3 : OTHER HAZARDS

* 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	GHS & CLP LABEL (ingredient)
IVERMECTIN	API	1.0%	70288-86-7	Acute Tox Cat 1 (ORAL) **DANGER** Acute Tox Cat 3 (DERMAL) **DANGER** Repr Tox Cat 2 **WARNING** Aquatic Acute Cat 1 **WARNING**	 H300: Fatal if Swallowed; H311: Toxic in contact with Skin; H361: Suspected of Damaging Fertility or The Unborn Child; H400: Very Toxic to Aquatic Life
GLYCERIN FORMAL	SOLVENT	<90%	N/A Refer to *	Repr Tox Cat 2 **WARNING**	 H361: Suspected of Damaging Fertility or The Unborn Child
*NOTE	Glycerin Formal is a mixture composed of two isomers (A) *5-HIDROXY-1,3-DIOXANE* & (B) *4-HIDROXYMETHYL-1,3-DIOXALANE* details of which are described below. The concentration values for each refer to the concentration of (A) & (B) in Glycerin Formal (above)				
5-HIDROXY-1,3-DIOXANE	Solvent Component	~55%	4740-78-7		
4-HIDROXYMETHYL-1,3-DIOXALANE	Solvent Component	~45%	5464-28-8		

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

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 are known to induce gastrointestinal disturbances as well as irritate eye and respiratory tract

SECTION 4.3 **: Indication of Any Immediate Medical Attention & Special Treatment Needed**
: Notes to Physician: Treat Symptomatically. Consider use of activated charcoal slurry or laxative/ gastric lavage/ emetic therapy.

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 Carbon Oxides (COx) & Toxic Fumes. Can react with strong oxidisers.

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:
For Non-Emergency Personnel:

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. 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 or Sodium Hypochlorite Solution after pick-up

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. Cats and certain breeds of Dogs can be overly susceptible to IVERMECTIN Toxicity therefore access & exposure to this product should be restricted. 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 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 Powder	Clear, Colourless to Pale Yellow Liquid
Odour	Mild Odour	Characteristic Scent
Odour Threshold	Not Available	Not Available
.pH	Not Available	Not Available
Melting/Freezing Point	Melting : 155-157°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 (not considered flammable)
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	Soluble: Methanol/ DCM/Acetonitrile/Acetone Insoluble: Water/Hexane	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**	: Strong Oxidising Agents/Strong Acids/Strong Bases, Ammonia, Peroxides
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
IVERMECTIN	Oral	Rat	2.0 to 50.0 mg/kg
		Mouse	25.00 mg/kg
		Dog	80.00 mg/kg
		Monkey	>24.00 mg/kg
	Dermal	Rabbit	406.00 mg/kg
GLYCERIN FORMAL	Oral	Rat	8.0 ml / kg
	I.P.		9500.00 mg/kg
	Oral	Mouse	8000.00 mg/kg
	I.P.		~4.0 ml / 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**. The European Medicines Agency (EMEA) has stated that IVERMECTIN has displayed interspecies differences in toxicity. This is clearly evident in the LD50 Result values provided as information (above). The EMEA has also stated that the DOG species data is considered to be the most conservative animal data with regard to IVERMECTIN.
As presented in the above table, Glycerin Formal is considered to be of **LOW ACUTE TOXICITY** based on the information available at time of compilation.
For the purposes of this SDS, the Acute Toxicity Estimate (ATE) for the Finished Product is estimated using the Rat LD50 data (as worst case) and is estimated at >2,000.00mg/kg by calculation and accordingly, classification of the Finished Product within **Section 2** is based on the GHS-CLP guidance based on this calculated figure. 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.

Section 11 continues overleaf:

11.1.2	: Skin Irritation/Corrosion Data	: No Available Data for Finished Product: **Specific Ingredients May Cause Skin Irritation.**
11.1.3	: Eye Irritation/Damage Data	: No Available Data for Finished Product: **Specific Ingredients May Cause Eye Irritation.**
11.1.4	: Respiratory &/or Skin Sensitisation Data	: No Available Data for Finished Product:
11.1.5	: Germ Cell Mutagenicity	: Finished Product Not Classified. Contains no ingredient classified as Mutagenic
11.1.6	: Carcinogenicity	: Finished Product Not Classified. Contains no ingredient classified as Carcinogenic
11.1.7	: Reproductive Toxicity	*: Note: IVERMECTIN & GLYCERIN FORMAL are both classified as Repr Cat2* *Finished Product is classified in Section 2 based on this data and classification.*

Ivermectin was teratogenic at 8.1 times Maximum Recommended Human Dose in Rat
Ivermectin was teratogenic at 4.5 times Maximum Recommended Human Dose in Mice
These events occurred at Maternotoxic Doses. No effects on Fertility Noted for Ivermectin

Glycerol Formal showed evidence of Teratogenicity in Rats at high doses (300-600mg/kg BW)
Doses in a Rat Study of 75mg/kg BW indicated no teratogenicity, but had fetotoxic effects.

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:

Ingredient	LC50	Species	Result
IVERMECTIN	Fish	Trout	3.0 µg/L
		Bluegill Sun Fish	4.8 µg/L
	Crustacean	Water Flea	0.025 µg/L
Glycerin Formal	n/a	n/a	No Available Data

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: **Active Ingredient considered acutely environmentally toxic**

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	: UN3082
SECTION 14.2	: UN PROPER SHIPPING NAME	: Environmentally Hazardous Substance, Liquid, n.o.s. (Ivermectin)
SECTION 14.3	: TRANSPORT HAZARD CLASS (ES)	: 9
SECTION 14.4	: PACKING GROUP	: III
SECTION 14.5	: ENVIRONMENTAL HAZARDS	: No (Refer to Section 12)
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 18-July-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

PRECAUTIONARY STATEMENTS

Prevention	Response	Storage	Disposal
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 to details listed in Section 13.1**
P202- Do Not Handle until all Safety Precautions have been Read and Understood			
P273-Avoid Release to the Environment			
P280- Wear Protective Gloves/Protective Clothing/Eye Protection/Face Protection			

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Prepared by: _____ **Date of Approval:** 18-07-2016

Material Safety Data Officer

END OF SDS