# SECTION 1 CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

## SECTION 1.1 Product Identifier

| | |
|---|---|
| **Product Name** | IVERMECTIN 18.7mg/g – PASTE (All Presentations & Volumes) |
| **Product Type** | MIXTURE |
| **Reach Registration** | Not Available |

## SECTION 1.2 Relevant Identified Uses, & Uses Advised Against

| | |
|---|---|
| **Identified Uses** | **VETERINARY USE;** Anti-parasitic & Anthelmintic Agent (Equine Use) |

## 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

(ACCORDING TO REGULATION 1272/2008/EC)

| Hazard Type | Category | H-Statement | Signal |
|---|---|---|---|
| **Physical** | **Not Classified** | **NONE** | **NONE** |
| **Health** | **Acute Tox. Cat.5 (oral)** | **H303** | **WARNING** |

## SECTION 2.2 Label Elements

**Labelling According To Regulation 1272/2008/EC [CLP]**

| LABEL | Hazard Statements | Precautionary Statements | | | |
|---|---|---|---|---|---|
| | | Prevention | Response | Storage | Disposal |
| ***None*** | | | | | |
| **SIGNAL** | **H303**<br>**May be harmful if swallowed.** | | **P312**<br>**Call a POISON CENTER/ doctor/ [emergency service] if you feel unwell.** | | |
| **Warning** | | | | | |

## 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 | Label |
|---|---|---|---|---|---|
| IVERMECTIN | API | <2% | 70288-86-7 | Acute Tox Cat 1 (ORAL)<br>Acute Tox Cat 3 (DERMAL)<br>Repr Tox Cat 2<br>Aquatic Acute Cat 1 |  <br>H300: Fatal If Swallowed<br>H311: Toxic in contact with skin<br>H361: Suspected of damaging fertility or the unborn child<br>H400: Very Toxic to Aquatic Life |

**All other ingredients, either are below reportable levels for their hazard category, or, not classed as hazardous according to GHS-CLP.**

## SECTION 4 FIRST AID MEASURES.

### SECTION 4.1 Description of First Aid Measures (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; contact physician if irritation develops.
**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.

### SECTION 4.2 Most Important Symptoms and Effects (Acute & Delayed)

Signs of Toxicity: Nausea, Vomiting, Diarrhoea &/or Allergic Reaction.

### SECTION 4.3: Indication of Any Immediate Medical Attention & Special Treatment Needed

**Notes to Medical Physician Only.** Accidental Exposure/Overdose; Treat Symptomatically. No Specific Antidote.

## 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: Carbon Oxides (COx), or other toxic 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.
Cool containers exposed to flame with water.

## 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. 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 Dilute Caustic (<2%).

### 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. DO NOT eat, drink or smoke during use of product.
Wash Hands after use. Keep container safely secured 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 overly susceptible to Toxicity therefore access & exposure to this product should be restricted. In all cases of accidental exposure through ingestion, contact medical physician immediately.

**SECTION 7.2** **Conditions For Safe Storage (including incompatibilities);** Finished Product does not require any special storage conditions but 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 administering product. Wash hands thoroughly after handling product. Eye protection normally required when handling the finished product, protective eyewear **(EN 166)** is recommended when working with, or administering this product.

## 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 | Yellowish Semi-Solid "Paste" |
| Odour | Mild Odour | Apple Slight Sweet Odour |
| 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 |
| 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 in Methanol/ DCM: Insoluble: 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**
Strong Acids; Strong Base; Strong Oxidisers

**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**

**SECTION 11.1.1** **Acute Toxicity** Acute Toxicity Estimate (ATE) for Product ~4,000mg/kg: **Not Considered Acutely Toxic**

| Ingredient | LD50 | Species | Result |
|---|---|---|---|
| IVERMECTIN | Oral | Rat | 2.0 to 50.0 mg/kg |
| | | Mouse | 25.0 mg/kg |
| | | Dog | 80.0 mg/kg |
| | | Monkey | >24.0 mg/kg |
| | Dermal | Rabbit | 406.0mg/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**. 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. For the purposes of this SDS, the **Acute Toxicity Estimate (ATE)** for the Finished Product is estimated using the Dog LD50 data and is estimated at **>4,000 mg/kg** by calculation and accordingly, classification of the Finished Product within **Section 2** is based on the GHS-CLP guidance on this calculated figure. 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 11.1.2** **Skin Irritation/Corrosion Data**
No Available Data for Finished Product: **Ingredients may result in Skin Irritation by contact.**

**SECTION 11.1.3** **Eye Irritation/Damage Data**
No Available Data for Finished Product: **Ingredients may result in Eye Irritation by contact.**

**SECTION 11.1.4** **Respiratory &/or Skin Sensitisation Data**
No Available Data for Finished Product: **No Specific Data for Ingredients.**

**SECTION 11.1.5** **Germ Cell Mutagenicity**
Finished Product Not Classified. **Contains no ingredient classified as Mutagenic.**
API was NEGATIVE in the Ames Assay, The Mouse Lymphoma Assay, & Unscheduled DNA synthesis.

**SECTION 11.1.6** **Carcinogenicity**
Finished Product Not Classified. **Contains no ingredient classified as Carcinogenic.**

**SECTION 11.1.7** **Reproductive Toxicity**
Finished Product Not Classified. **Information on API at 100% is as follows:**
No reproductive impairment or foetal defects noted in Rats given 1.6 mg/kg/day of API (Male and Female)
Maternal Toxicity and increase in cleft palate was noted in Rats @ 10.0mg/kg/day
Maternal Toxicity and increase in cleft palate/clubbed paw was noted in Rabbits @ 6.0mg/kg/day

**SECTION 11.1.8** **STOT- Single Exposure**
No Available Data for Finished Product. **NOT CLASSIFIED.**

**SECTION 11.1.9** **STOT- Repeated Exposure**
No Available Data for Finished Product. **NOT CLASSIFIED.**

**SECTION 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 | LD50/LC50/EC50 | Species | | Result |
|---|---|---|---|---|
| IVERMECTIN | Fish | Trout | *Oncorhyncus mykiss* | 3.0 µg/L |
| | | Bluegill Sun Fish | *Lepomis macrochirus* | 4.8 µg/L |
| | Crustacean | Water Flea | *Daphnia magna* | 0.025 µg/L |

| | | |
|---|---|---|
| **SECTION 12.2** | **Persistence And Biodegradability** | No Data Available |
| **SECTION 12.3** | **Bioaccumulative Potential** | No Data Available |
| **SECTION 12.4** | **Mobility in Soil** | No Data Available |
| **SECTION 12.5** | **Results of PBT & vPvB Assessment** | No Data Available |
| **SECTION 12.6** | **Other Adverse Effects** | No Data Available |

## 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** | Not Applicable |
| **SECTION 14.2** | **UN Proper Shipping Name** | Not Regulated as Dangerous Goods |
| **SECTION 14.3** | **Transport Hazard Class (es)** | N/A |
| **SECTION 14.4** | **Packing Group** | N/A |
| **SECTION 14.5** | **Environmental Hazards** | N/A (Refer to Section 12) |
| **SECTION 14.6** | **Special Precautions for User** | No Data |
| **SECTION 14.7** | **Transport in Bulk** | N/A |

## 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 15th-October-2019) |
| **Revised Sections** | N/A |
| **References** | Data is sourced from applicable ingredient SDS, equivalent product SDS, & recognised databases. |
| **Prepared by** | Materials Safety Data Officer, Chanelle Pharmaceuticals Ltd. |
| **Abbreviations Legend** | Listed in alphabetical order (where applicable). |

| | | | |
|---|---|---|---|
| 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** 16-10-2019

**Material Safety Data Officer**

**END OF SDS**