

SECTION 1 : CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

SECTION 1.1 : PRODUCT IDENTIFIER

PRODUCT NAME : Levamisole 7.5% ("Chanaverm") Oral Solution
 PRODUCT TYPE : MIXTURE
 REACH REGISTRATION : Not Available

SECTION 1.2 : RELEVANT IDENTIFIED USES, & USES ADVISED AGAINST

IDENTIFIED USES : VETERINARY ONLY; Anthelmintic Agent for Cattle & 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 Toxicity	Cat. 2	H361d	WARNING
Acute Toxicity	Cat. 5	H302	WARNING

SECTION 2.2 LABEL ELEMENTS

LABELLING ACCORDING TO REGULATION 1272/2008/EC [CLP]					
LABEL	Hazard Statements	Precautionary Statements			
 SIGNAL WARNING	H361d: Suspected of Damaging the Unborn Child H302: May be Harmful If Swallowed	Prevention	Response	Storage	Disposal
		P201 P202 P280	P312 P308+P313	P405	P501
Please Refer to Section 16 for a Full Explanation of P-Statements					

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

Please Note: Product has been classified in Section 2 based on information on ingredients as a MIXTURE. It is not expected that the FINISHED PRODUCT along with the H-Statements and associated P-Statements be applicable in every case, but are listed based on the Guidance Literature, and the Regulations listed.

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
Levamisole HCl	API	7.5%	16595-80-5	Acute Tox. Cat. 3 Oral H301: Toxic If Swallowed 	DANGER
				Repr. Tox. Cat. 2 H361d: Suspected of Damaging Unborn 	
Citric Acid	Excipient	< 1.8%	77-92-9	Eye Damage/ Irrit Cat.2 H319: Causes Serious Eye Damage 	WARNING
				Acute Tox. Cat. 4 Oral H302: Harmful if Swallowed 	
Na. Metabisulphite	Excipient	≤ 0.1%	7681-57-4	Eye Damage/ Irrit Cat.1 H318: Causes Serious Eye Damage 	DANGER
				Eye Damage/ Irrit Cat.1 H318: Causes Serious Eye Damage 	

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 if irritation becomes painful or persists.

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; 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): Overdose by Ingestion may include, and are not limited to: nausea, vomiting, diarrhoea, headache, dizziness, abdominal pain, and fever like symptoms, gastro-intestinal disturbances including bleeding. Agranulocytosis/neutropenia (low white blood cell count) are the most important symptoms of note.

SECTION 4.3

Indication of Any Immediate Medical Attention & Special Treatment Needed

Notes to Physician: In cases of overdose: Treat Symptomatically. Activated Charcoal for Levamisole overdose are suggested- severe neutropenia should consider administration of a colony stimulating factor (filgrastim/sargramostim); Transfusion in the case of severe bleeding Source: USP-SDS

SECTION 5 : FIREFIGHTING MEASURES.

SECTION 5.1

EXTINGUISHING MEDIA

Suitable Extinguishing Media

Dry Chemical Powder; Carbon Dioxide; Foam; Water Spray; (Water Jet may be unsuitable)

SECTION 5.2

SPECIAL HAZARDS (arising from substance/mixture)

Hazardous Thermal Decomposition Products

Possibility of: Carbon Oxides (COx); Nitrogen Oxides (NOx); Sulphur Oxides (SOx); HCl gas; Iodine

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 Run-Off from entering drains.

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. 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; Children are particularly at risk from product and may prove harmful. In all cases of accidental exposure through ingestion, contact medical physician immediately. Avoid prolonged contact with Skin/ Eyes. Emesis may be observed in cases of accidental oral exposure.

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.

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

	API-Levamisole HCl	FINISHED PRODUCT
APPEARANCE: Form/Colour	White/Off White Solid	Yellow (to Orange) Coloured Clear Solution
Odour	Not Available	Slight Odour (Sulphurous)
Odour Threshold	Not Available	Not Available
pH	3 (in 5% Aqueous Solution)	3.4-3.8
Melting/Freezing Point	Melting : 226-233°C	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	0.00001kPa @25°C	Not Available
Vapour Density	Not Available	Not Available
Relative Density	Not Available	Not Available
Solubility	Freely soluble in Water	Not Available
Partition Coefficient n-octanol/water	Log P 1.84 (source HSDB)	Not Available
Auto-Ignition Temperature	570 °C	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
Levamisole HCl	ORAL	RAT	180 mg/kg (200-500mg/kg source EMA)
Na. Metabisulphite			1,131 mg/kg
Citric Acid			11,700 mg/kg

The Information provided in this Table is for individual components for which Acute Toxicity Data is available at 100% concentration of that specific ingredient. Components listed are 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 between 2000-5000 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.

11.1.2	: Skin Irritation/Corrosion Data	No Available Data for Finished Product: Finished Product not considered to be a Skin irritant based on concentration of ingredients however specific ingredients may cause Irritation to some. In General, PPE is advised: Refer to Sections 4 & 8.
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Section 11 Continues Overleaf →

Section 11 Continued from Previous Page

11.1.3 : Eye Irritation/Damage Data No Available Data for Finished Product: Finished Product not considered to be an Eye irritant based on concentration of ingredients however specific ingredients may cause Irritation to some. In General, PPE is advised: 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.

11.1.5 : Germ Cell Mutagenicity **Finished Product Not Classified:** Levamisole was determined to induce Chromosomal Gaps & Breaks in human lymphocytes both *in-vitro* & *in-vivo*. No chromosomal damage occurred in mice at 2.5mg/kg-Levamisole by subcutaneous route. Source EMA (Data Incomplete for classification-Possibility of Hazard).

11.1.6 : Carcinogenicity **Finished Product Not Classified:** Chronic Administration (Time frame not stated) of Levamisole at 25mg/kg increased incidence of spontaneous lymphomas (Mouse).

11.1.7 : Reproductive Toxicity **Finished Product Classified in Section 2 as defined by GHS-CLP guidance.**

Ingredient	Dose Regimen	Species	Result
Levamisole HCl	As Listed	RAT	<ul style="list-style-type: none"> 60mg/kg BW No developmental Toxicity 120-240mg/kg BW No Developmental Defects; Decreased implantation rates; slight growth retardation was found at 120mg/kg BW
	Up to 90mg/kg BW	RABBIT	<ul style="list-style-type: none"> No congenital Malformations; slight increase in foetal mortality

11.1.8 : STOT- Single Exposure **No Available Data for Finished Product:**

11.1.9 : STOT- Repeated Exposure **No Available Data for Finished Product:** With Regard to STOT, certain databases Suggest specific organs affected include: Blood & Immune System, as well as CNS & Lungs. As such care is advised to limit exposure and to adhere to safety recommendations listed within this Safety Data Sheet.

11.1.10 : Aspiration Hazard No Available Data for Finished Product.

SECTION 12 : ECOLOGICAL INFORMATION.

SECTION 12.1 : TOXICITY

Ingredient	LC50/EC50/IC50	Species	Result
Levamisole HCl	Aquatic Toxicity 48hr	<i>Daphnia magna</i>	300.0 mg/L
	Aquatic Toxicity 96hr	Fish -N.S.	32.0-56.0 mg/L

SECTION 12.2 : PERSISTENCE AND DEGRADABILITY : No Available Data

SECTION 12.3 : BIOACCUMULATIVE POTENTIAL : Levamisole: Log Pow; 1.84 @20°C (source HSDB)

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

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

SECTION 15 : OTHER REGULATORY INFORMATION.

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

SECTION 16 : OTHER INFORMATION.

<u>Document History</u>	: Version 1 (Created 11 th -October-2017)
<u>Revised Sections</u>	: N/A
<u>Sourced Information</u>	: Supplier SDS, Sourced SDS (USP, EDQM), other databases including EMA Summary Reports & the HSDB.
<u>Prepared by</u>	: Materials Safety Data Officer, Chanelle Pharmaceuticals Ltd.
<u>Abbreviations Legend</u>	: 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	P312 Call a POISON CENTER/ doctor/physician if you feel unwell	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	P308 + P313 – IF exposed or concerned: Get medical advice/attention.		
P280-Wear protective gloves/protective clothing/eye protection/ face protection			

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Prepared by:  Date of Approval: 11/10/2017
Material Safety Data Officer

END OF SDS