according to GB/T 16483 and GB/T 17519



## Levamisole Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
3.0	2024/09/28	9081930-00009	Date of first issue: 2021/07/21

### **1. PRODUCT AND COMPANY IDENTIFICATION**

Product name	:	Levamisole Formulation				
••	Manufacturer or supplier's details					
Company	:	MSD				
Address	:	No. 485 Jing Tai Road Pu Tuo District - Shanghai - China 200331				
Telephone	:	+1-908-740-4000				
Emergency telephone number	:	86-571-87268110				
E-mail address	:	EHSDATASTEWARD@msd.com				
Recommended use of the chemical and restrictions on use						
Recommended use Restrictions on use	:	Veterinary product Not applicable				

### 2. HAZARDS IDENTIFICATION

### **Emergency Overview**

Appearance Colour Odour	:	powder white No data available
Harmful if swallowed. Suspected through prolonged or repeated		of damaging the unborn child. May cause damage to organs posure.
GHS Classification		
Acute toxicity (Oral)	:	Category 4
Reproductive toxicity	:	Category 2
Specific target organ toxicity - repeated exposure	:	Category 2
GHS label elements		
Hazard pictograms	:	
Signal word	:	Warning

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Hazard	statements		d of damaging the unborn child. a damage to organs through prolonged or re-
Precau	tionary statements	P202 Do not har and understood. P260 Do not bre P264 Wash skin P270 Do not eat P280 Wear protect ion/ face protect <b>Response:</b> P301 + P312 + F CENTER/ doctor P308 + P313 IF attention.	thoroughly after handling. , drink or smoke when using this product. active gloves/ protective clothing/ eye protec-
		Storage: P405 Store locke Disposal: P501 Dispose of disposal plant.	ed up. contents/ container to an approved waste
•	<b>al and chemical haza</b> ssified based on availa	rds	
Harmfu	hazards Il if swallowed. Suspect prolonged or repeated		nborn child. May cause damage to organs
	nmental hazards ssified based on availa	ble information.	

### Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin. May form combustible dust concentrations in air during processing, handling or other means.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
levamisole hydrochloride	16595-80-5	>= 10 -< 20

4. FIRST AID MEASURES

according to GB/T 16483 and GB/T 17519



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# General advice In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice. If inhaled If inhaled, remove to fresh air. Get medical attention. In case of skin contact In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

		Thoroughly clean shoes before reuse.
In case of eye contact	:	If in eyes, rinse well with water.
		Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting.
		Get medical attention.
		Rinse mouth thoroughly with water.
		Never give anything by mouth to an unconscious person.
Most important symptoms	:	Harmful if swallowed.
and effects, both acute and		Suspected of damaging the unborn child.
delayed		May cause damage to organs through prolonged or repeated
		exposure.
		Contact with dust can cause mechanical irritation or drying of the skin.
		Dust contact with the eyes can lead to mechanical irritation.
Protection of first-aiders	:	······································
		and use the recommended personal protective equipment
		when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

### **5. FIREFIGHTING MEASURES**

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire- fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides
Specific extinguishing meth-	:	Use extinguishing measures that are appropriate to local cir-

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с	ods			Use water spray	the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to do
		l protective equipment ighters	:		e, wear self-contained breathing apparatus. tective equipment.
6. AC	CIDE	NTAL RELEASE MEAS	SUF	RES	
ti	ive eq	al precautions, protec- uipment and emer- procedures	:	Follow safe hand	tective equipment. ling advice (see section 7) and personal pro- t recommendations (see section 8).
E	Enviror	nmental precautions	:	Retain and dispos	akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages
		ds and materials for ment and cleaning up	:	tainer for disposa Avoid dispersal o with compressed Dust deposits sho es, as these may leased into the at Local or national posal of this mate employed in the o mine which regula Sections 13 and	f dust in the air (i.e., clearing dust surfaces
7. HA	NDLI	NG AND STORAGE			
F	Handli	ng			
T	Fechni <sup>,</sup> _ocal/T	cal measures Total ventilation on safe handling	:	causing an explor Provide adequate and bonding, or in	e precautions, such as electrical grounding nert atmospheres. equate ventilation. ust.

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Avo	idance of contact	:	practice, based of sessment Minimize dust ge Keep container of Keep away from Take precautiona Do not eat, drink	ance with good industrial hygiene and safety n the results of the workplace exposure as- neration and accumulation. losed when not in use. heat and sources of ignition. ary measures against static discharges. or smoke when using this product. vent spills, waste and minimize release to the
Sto	rage			
Con	ditions for safe storage	:	Store locked up.	labelled containers.
Mat	erials to avoid	:		the following product types:
Pac	kaging material	:	Unsuitable mater	ial: None known.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
levamisole hydrochloride	16595-80-5	TWA	20 µg/m3 (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	200 µg/100 cm <sup>2</sup>	Internal

Engineering measures :	All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face con- tainment devices). Minimize open handling.
Personal protective equipment	

#### Personal protective equipment

Respiratory protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
Filter type	:	Particulates type
Eye/face protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

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Skin	and body protection	Additional b task being p	m or laboratory coat. ody garments should be used based upon the performed (e.g., sleevelets, apron, gauntlets, dis- ts) to avoid exposed skin surfaces.
Hond	protection		riate degowning techniques to remove potentially
Hano	protection		
М	aterial	: Chemical-re	esistant gloves
	emarks ene measures	: If exposure eye flushing ing place. When using Wash conta The effectiv engineering appropriate industrial hy	buble gloving. to chemical is likely during typical use, provide systems and safety showers close to the work- do not eat, drink or smoke. minated clothing before re-use. e operation of a facility should include review of controls, proper personal protective equipment, degowning and decontamination procedures, rgiene monitoring, medical surveillance and the nistrative controls.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Colour	:	white
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form combustible dust concentrations in air during pro- cessing, handling or other means.
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available

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Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n- octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties		The substance or mixture is not classified as oxidizing.
Oxidizing properties	•	The substance of mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics Particle size	:	No data available

### **10. STABILITY AND REACTIVITY**

Reactivity Chemical stability Possibility of hazardous reac- tions	: :	Not classified as a reactivity hazard. Stable under normal conditions. May form combustible dust concentrations in air during pro- cessing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

### 11. TOXICOLOGICAL INFORMATION

Exposure routes	: Inhalation Skin contact Ingestion
	Eye contact

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	e toxicity		
	nful if swallowed.		
Prod Acute	l <b>uct:</b> e oral toxicity	· Acute toxicity	v estimate: 1,200 mg/kg
Acut	oral toxicity		culation method
Com	ponents:		
levar	nisole hydrochloride:		
Acute	e oral toxicity	: LD50 (Rat): 7	180 mg/kg
		LD50 (Mouse	e): 223 mg/kg
		LD50 (Rabbi	t): 458 mg/kg
Acute	e inhalation toxicity	: Remarks: No	data available
Acute	e dermal toxicity	: Remarks: No	data available
Not c	corrosion/irritation classified based on avainated ponents:	lable information.	
	misole hydrochloride:	: No data avai	lable
Not c	ous eye damage/eye i classified based on avai ponents:		
levar Rema	nisole hydrochloride: arks	: No data avai	lable
Resp	piratory or skin sensit	isation	
	sensitisation classified based on avai	lable information.	
-	<b>biratory sensitisation</b> classified based on avai	lable information.	
<u>Com</u>	ponents:		
levar Rema	<b>nisole hydrochloride:</b> arks	: No data avai	able

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#### Germ cell mutagenicity

Not classified based on available information.

### Components:

### levamisole hydrochloride:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: Chromosome aberration test in vitro Result: negative

### Carcinogenicity

Not classified based on available information.

### **Components:**

### levamisole hydrochloride:

Species Application Route Exposure time NOAEL Remarks	<ul> <li>Mouse</li> <li>Oral</li> <li>2 Years</li> <li>80 mg/kg body weight</li> <li>No significant adverse effects were reported</li> </ul>
Species Application Route Exposure time NOAEL Remarks	<ul> <li>Rat</li> <li>Oral</li> <li>2 Years</li> <li>40 mg/kg body weight</li> <li>No significant adverse effects were reported</li> </ul>

#### Reproductive toxicity

Suspected of damaging the unborn child.

#### **Components:**

### levamisole hydrochloride:

Effects on fertility	:	Test Type: Three-generation reproduction toxicity study Species: Rat Application Route: Oral Result: No significant adverse effects were reported
Effects on foetal develop- ment	:	Test Type: Embryo-foetal development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 20 mg/kg body weight Result: Fetotoxicity
		Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral Developmental Toxicity: LOAEL: 40 mg/kg body weight



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II			Result: Fetotoxici	ty				
Reproductive toxicity - As- sessment STOT - single exposure			Some evidence of adverse effects on development, based on animal experiments.					
			animai experimer	115.				
Not classified based on available information.								
STOT - repeated exposure								
			hrough prolonged or repeated exposure.					
Components:		•	o					
	Jonents.							
levan	nisole hydrochloride:							
	et Organs	:	Blood, Testis					
Asses	ssment	:	May cause dama exposure.	ge to organs through prolonged or repeated				
			0.00000.					

### Repeated dose toxicity

### **Components:**

#### levamisole hydrochloride:

Species	:	Rat
Species NOAEL	:	2.5 mg/kg
Application Route	:	Oral
Exposure time	:	18 Months
Exposure time Target Organs	:	Testis

Species	: Dog
Species LOAEL	: 20 mg/kg
Application Route	: Oral
Exposure time	: 18 Months
Target Organs	: Blood

Species	:	Dog
LOAEL	:	40 mg/kg
Application Route	:	Oral
Species LOAEL Application Route Exposure time	:	3 Months

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

### Components:

### levamisole hydrochloride:

Ingestion

: Symptoms: Nausea, Vomiting, Headache, Dizziness, hypotension

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### **12. ECOLOGICAL INFORMATION**

### Ecotoxicity

### Components:

#### levamisole hydrochloride:

Toxicity to fish :	LC50 (Oryzias latipes (Japanese medaka)): 37.3 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other : aquatic invertebrates	EC50 (Daphnia magna (Water flea)): 64 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Persistence and degradability No data available	
Bioaccumulative potential	

No data available

## Mobility in soil

No data available

### Other adverse effects

No data available

### 13. DISPOSAL CONSIDERATIONS

Disposal methods		
Waste from residues	:	Do not dispose of waste into sewer.
		Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

### 14. TRANSPORT INFORMATION

### International Regulations

UNRTDG		
UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Environmentally hazardous	:	no
-		

### IATA-DGR

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Class Subs Packi Label Packi aircra Packi	er shipping name diary risk ng group s ng instruction (cargo		Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable	
UN n Prope Class Subsi Packi Label EmS	diary risk ng group		Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable no	

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### **National Regulations**

### GB 6944/12268

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Marine pollutant	:	no

#### Special precautions for user

Not applicable

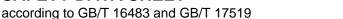
### **15. REGULATORY INFORMATION**

### National regulatory information

Law on the Prevention and Control of Occupational Diseases

#### **Regulations on Safety Management of Hazardous Chemicals**

Catalogue of Hazardous Chemicals	:	This product is not listed in the cata- logue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of de- termination.
Identification of Major Hazard Installations for Hazardo 18218)	ous C	chemicals (GB : Not listed





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	Hazardous Chemicals for Priority Management under : Not listed									
SAWS										
Regula	Regulations on Labour Protection in Workplaces where Toxic Substances are Used									
Catalogue of Highly Toxic Chemicals				Not listed						
Regulation of Environmental Management on the F and Export of Toxic Chemicals				Import of Chemicals and the Import						
China Severely Restricted Toxic Chemicals for Import : Not listed and Export										
Regula	tion on the Administ	ration of Precursor C	hemica	als						
•	gue and Classification of									
Yangtz	e River Protection La	w								

This product does not contain any dangerous chemicals prohibited for inland river transport.

### The components of this product are reported in the following inventories:

16. OTHER INFORMATION		
Revision Date	:	2024/09/28
Further information		
Sources of key data used to compile the Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/
Items where changes have be	en	made to the previous version are highlighted in the body of this

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International

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Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

### Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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