



according to the Globally Harmonized System

Levamisole Formulation

Version 3.0	Revision Date: 28.09.2024		S Number: 31933-00008	Date of last issue: 24.01.2024 Date of first issue: 21.07.2021		
1. PROD	UCT AND COMPANY IDE	ENT	IFICATION			
Prod	Product name		Levamisole Formulation			
Man	ufacturer or supplier's d	leta	ils			
Com	ipany	:	MSD			
Addr	ess	:	Briahnager - Off Wagholi - Pune -	Pune Nagar Road India 412 207		
Tele	phone	:	+1-908-740-4000)		
Eme	rgency telephone number	· :	+1-908-423-6000)		
E-ma	ail address	:	EHSDATASTEW	/ARD@msd.com		
Reco	ommended use of the ch	nem	ical and restriction	ons on use		
	ommended use rictions on use	:	Veterinary produ	ct		

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification Acute toxicity (Oral)	:	Category 4
Reproductive toxicity	:	Category 2
Specific target organ toxicity - repeated exposure (Oral)	:	Category 2 (Blood, Testis)
GHS label elements Hazard pictograms	:	
Signal word	:	Warning
Hazard statements	:	H302 Harmful if swallowed. H361d Suspected of damaging the unborn child. H373 May cause damage to organs (Blood, Testis) through prolonged or repeated exposure if swallowed.

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Preca	utionary statements	P260 Do not br P264 Wash ha P270 Do not ea	nds thoroughly after handling. at, drink or smoke when using this product. tective gloves/ protective clothing/ eye protec-
		Response: P301 + P317 + Rinse mouth.	P330 IF SWALLOWED: Get medical help.
		P318 IF expose	ed or concerned, get medical advice.
		Storage:	
		P405 Store loc	ked up.
		Disposal:	
		P501 Dispose disposal plant.	of contents/ container to an approved waste
	, herende which de n		lian

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

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.
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.



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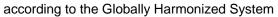
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	and effe delayed Protecti	nportant symptoms ects, both acute and d ion of first-aiders o physician	:	 Harmful if swallowed. Suspected of damaging the unborn child. May cause damage to organs through prolonged or reexposure if swallowed. Contact with dust can cause mechanical irritation or of the skin. Dust contact with the eyes can lead to mechanical irrit First Aid responders should pay attention to self-prote and use the recommended personal protective equiption when the potential for exposure exists (see section 8) Treat symptomatically and supportively. 	
5. FI	IREFIGH	ITING MEASURES			
	Suitable	e extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical	
	Unsuita media	ble extinguishing	:	None known.	
	Specific fighting	c hazards during fire-	:	concentrations, an potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. oustion products may be a hazard to health.
	Hazard ucts	ous combustion prod-	:	Carbon oxides	
	Specific ods	c extinguishing meth-	:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do
	Special for firefi	protective equipment ghters	:		e, wear self-contained breathing apparatus. ective equipment.
	for firefi			Use personal prot	

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- tive equipment and emer- gency procedures	· :	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Mathada and matarials for		Sween up or vacuum up spillage and collect in suitable con

Methods and materials for : Sweep up or vacuum up spillage and collect in suitable con-





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conta	inment and cleaning up		with compresse Dust deposits s es, as these ma leased into the Local or nationa posal of this ma employed in the mine which reg Sections 13 an	Date of first issue: 21.07.2021 al. of dust in the air (i.e., clearing dust surfaces	
7. HANDL	ING AND STORAGE				
Tech	nical measures	:	Static electricity	may accumulate and ignite suspended dust	

rechinical measures	•	causing an explosion.
		Provide adequate precautions, such as electrical grounding
		and bonding, or inert atmospheres.
Local/Total ventilation	:	Use only with adequate ventilation.
Advice on safe handling	:	Do not breathe dust.
		Do not swallow.
		Avoid contact with eyes.
		Avoid prolonged or repeated contact with skin.
		Wash skin thoroughly after handling.
		Handle in accordance with good industrial hygiene and safety
		practice, based on the results of the workplace exposure as-
		sessment
		Minimize dust generation and accumulation.
		Keep container closed when not in use.
		Keep away from heat and sources of ignition.
		Take precautionary measures against static discharges.
		Do not eat, drink or smoke when using this product.
		Take care to prevent spills, waste and minimize release to the environment.
Conditions for safe storage	:	Keep in properly labelled containers.
-		Store locked up.
		Store in accordance with the particular national regulations.
Materials to avoid	:	Do not store with the following product types:
		Strong oxidizing agents

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 ²	Internal



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Engi	Engineering measures		design and ope protect product Containment te are required to	controls should be implemented by facility ated in accordance with GMP principles to , workers, and the environment. hnologies suitable for controlling compounds ontrol at source and to prevent migration of o uncontrolled areas (e.g., open-face contain- andling.		
Pers	onal protective equip	ment				
Fi	Respiratory protection Filter type Hand protection		If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Particulates type			
			<u>.</u>			
M	Material		Chemical-resis	tant gloves		
	emarks protection	:	If the work envi mists or aeroso Wear a faceshi	e gloving. asses with side shields or goggles. ronment or activity involves dusty conditions, als, wear the appropriate goggles. eld or other full face protection if there is a ect contact to the face with dusts, mists, or		
Skin	and body protection	:	Work uniform of Additional body being performe suits) to avoid e	r laboratory coat. garments should be used based upon the task d (e.g., sleevelets, apron, gauntlets, disposable exposed skin surfaces. e degowning techniques to remove potentially lothing		
Hygie	ene measures	:	If exposure to of flushing system place. When using do Wash contamin The effective of engineering co appropriate deg	chemical is likely during typical use, provide eye as and safety showers close to the working not eat, drink or smoke. hated clothing before re-use. beration of a facility should include review of ntrols, proper personal protective equipment, gowning and decontamination procedures, ne monitoring, medical surveillance and the		

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Colour	:	white
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	No data available



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ſ	Melting	point/freezing point	:	No data available)
	Initial bo range	piling point and boiling	:	No data available	
F	Flash p	oint	:	Not applicable	
E	Evapora	ation rate	:	Not applicable	
F	Flamma	ability (solid, gas)	:	May form combus cessing, handling	stible dust concentrations in air during pro- or other means.
		explosion limit / Upper bility limit	:	No data available)
		explosion limit / Lower bility limit	:	No data available)
١	Vapour	pressure	:	Not applicable	
F	Relative	e vapour density	:	Not applicable	
F	Relative	e density	:	No data available	9
Γ	Density		:	No data available)
S	Solubilit Wate	ty(ies) er solubility	:	No data available)
		n coefficient: n-	:	Not applicable	
	octanol/ Auto-igi	water nition temperature	:	No data available	9
Γ	Decom	position temperature	:	No data available)
١	Viscosit Visc	y osity, kinematic	:	Not applicable	
E	Explosi	ve properties	:	Not explosive	
(Oxidizir	ng properties	:	The substance or	r mixture is not classified as oxidizing.
Γ	Molecul	ar weight	:	No data available)
	Particle Particle	characteristics size	:	No data available	

10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac- tions	:	May form combustible dust concentrations in air during pro- cessing, handling or other means.



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			Can react with s	trong oxidizing agents.			
Cond	itions to avoid	:	Heat, flames an				
Incor	npatible materials		Avoid dust form				
	rdous decomposition	:	Oxidizing agentsNo hazardous decomposition products are known.				
1. TOXIC	OLOGICAL INFORMAT		1				
Inforn expos	nation on likely routes of sure	:	Inhalation Skin contact Ingestion Eye contact				
	e toxicity ful if swallowed.						
Prod	uct:						
Acute	oral toxicity	:	Acute toxicity est Method: Calculat	imate: 1,200 mg/kg ion method			
Com	oonents:						
	nisole hydrochloride:						
Acute	oral toxicity	•	LD50 (Rat): 180	mg/kg			
			LD50 (Mouse): 2	23 mg/kg			
			LD50 (Rabbit): 4	58 mg/kg			
Acute	inhalation toxicity	:	Remarks: No dat	a available			
Acute	e dermal toxicity	:	Remarks: No dat	a available			
Skin Not cl	corrosion/irritation lassified based on availa conents:	ble	information.				
levan	nisole hydrochloride:						
Rema	arks	:	No data available	9			
	us eye damage/eye irri lassified based on availa						
Com	oonents:						
levan Rema	nisole hydrochloride: arks		No data available	5			

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Resp	iratory or skin sensi	tisatio	on	
Skin	sensitisation			
-	lassified based on ava	ailable	information.	
Resp	iratory sensitisation			
-	lassified based on ava		information.	
Com	ponents:			
levan	nisole hydrochloride	•:		
Rema		:	No data availab	le
Germ	n cell mutagenicity			
Not c	lassified based on ava	ailable	information.	
Com	ponents:			
levan	nisole hydrochloride	:		
	otoxicity in vitro	:	Test Type: Bac	terial reverse mutation assay (AMES)
			Result: negative	e
			Test Type: Chro	omosome aberration test in vitro
			Result: negative	e e e e e e e e e e e e e e e e e e e
II Carci	inogenicity			
	lassified based on ava	ailable	information	
	ponents:			
	nisole hydrochloride):		
Speci	ies cation Route	:	Mouse Oral	
	sure time		2 Years	
NÓAI		:	80 mg/kg body	weight
Rema	arks	:	No significant a	dverse effects were reported
IIa	ies	:	Rat	
Speci		•	Oral	
Appli	cation Route		2 Voare	
Applie Expos	cation Route sure time	:	2 Years 40 mg/kg body	weight
Appli	cation Route sure time EL	:	40 mg/kg body	weight dverse effects were reported

Reproductive toxicity

Suspected of damaging the unborn child.

Components:

Effects on fertility

levamisole hydrochloride:

: Test Type: Three-generation reproduction toxicity study Species: Rat Application Route: Oral



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	s on foetal develop-	:	Test Type: Embr	cant adverse effects were reported yo-foetal development			
ment	ment		Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 20 mg/kg body weight Result: Fetotoxicity				
			Species: Rabbit Application Route	oxicity: LOAEL: 40 mg/kg body weight			
Repro sessn	oductive toxicity - As- nent	:	Some evidence o animal experime	of adverse effects on development, based on nts.			

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs (Blood, Testis) through prolonged or repeated exposure if swallowed.

Components:

levamisole hydrochloride:

Target Organs:Assessment:	Blood, Testis May cause damage to organs through prolonged or repeated exposure.
---------------------------	--

Repeated dose toxicity

Components:

levamisole hydrochloride:

Species NOAEL Application Route Exposure time Target Organs	: : : : : : : : : : : : : : : : : : : :	Rat 2.5 mg/kg Oral 18 Months Testis
Species LOAEL Application Route Exposure time Target Organs	:	Dog 20 mg/kg Oral 18 Months Blood
Species LOAEL Application Route Exposure time	:	Dog 40 mg/kg Oral 3 Months

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Aspii	ration toxicity			
Not c	lassified based on availa	able	information.	
Expe	rience with human exp	oosi	ıre	
<u>Com</u>	ponents:			
levan	nisole hydrochloride:			
Inges	tion	:	Symptoms: Nau tension	usea, Vomiting, Headache, Dizziness, hypo-
2. ECOL	OGICAL INFORMATIO	N		
Ecote	oxicity			
<u>Com</u>	ponents:			
levan	nisole hydrochloride:			
Toxic	ity to fish	:	Exposure time:	atipes (Japanese medaka)): 37.3 mg/l 96 h Test Guideline 203
	ity to daphnia and other tic invertebrates	:	Exposure time:	magna (Water flea)): 64 mg/l 48 h Test Guideline 202
	i stence and degradabi l ata available	lity		
	ccumulative potential ata available			
	lity in soil ata available			
	r adverse effects ata available			
3. DISPC	SAL CONSIDERATION	NS		
-	osal methods e from residues		Do not dispose	of waste into sewer.

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

Not regulated as a dangerous good

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IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

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

16. OTHER INFORMATION

Revision Date	:	28.09.2024
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 Agen- cy, http://echa.europa.eu/

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

Date format : dd.mm.yyyy

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 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

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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

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.

IN / EN