

Levamisole Formulation

Version 3.1 Revision Date: 30.09.2023 SDS Number: 9081926-00007 Date of last issue: 04.04.2023
Date of first issue: 21.07.2021

Section 1: Identification

Product name : Levamisole Formulation

Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800 CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

Section 2: Hazard identification

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.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.

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P202 Do not handle until all safety precautions have been read and understood.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

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.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

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

Section 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.

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Most important symptoms and effects, both acute and delayed	:	<p>Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. Harmful if swallowed. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure if swallowed. Contact with dust can cause mechanical irritation or drying of the skin.</p>
Protection of first-aiders	:	<p>Dust contact with the eyes can lead to mechanical irritation. First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).</p>
Notes to physician	:	Treat symptomatically and supportively.

Section 5: Fire-fighting measures

Suitable extinguishing media	:	<p>Water spray Alcohol-resistant foam Carbon dioxide (CO₂) Dry chemical</p>
Unsuitable extinguishing media	:	None known.
Specific hazards during fire-fighting	:	<p>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.</p>
Hazardous combustion products	:	Carbon oxides
Specific extinguishing methods	:	<p>Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.</p>
Special protective equipment for firefighters	:	<p>In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.</p>

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures	:	<p>Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).</p>
Environmental precautions	:	<p>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.</p>
Methods and materials for containment and cleaning up	:	Sweep up or vacuum up spillage and collect in suitable container for disposal.

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Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
 Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
 Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
 Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

Section 7: Handling and storage

- | | | |
|-----------------------------|---|---|
| Technical measures | : | Static electricity may accumulate and ignite suspended dust 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 assessment
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. |
| Hygiene measures | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use. |
| 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 |

Section 8: Exposure controls/personal protection**Components with workplace control parameters**

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

Engineering measures : Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment: Safety goggles

Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

Section 9: Physical and chemical properties

Appearance : powder

Colour : white

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

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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 processing, handling or other means.
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
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.
Molecular weight	:	No data available
Particle size	:	No data available

Section 10: Stability and reactivity

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

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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.

Section 11: Toxicological information

Exposure routes : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 1,200 mg/kg
Method: Calculation method

Components:**levamisole hydrochloride:**

Acute oral toxicity : LD50 (Rat): 180 mg/kg
LD50 (Mouse): 223 mg/kg
LD50 (Rabbit): 458 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation

Not classified based on available information.

Components:**levamisole hydrochloride:**

Remarks : No data available

Serious eye damage/eye irritation

Not classified based on available information.

Components:**levamisole hydrochloride:**

Remarks : No data available

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Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**levamisole hydrochloride:**

Remarks : No data available

Chronic toxicity**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 : Mouse
Application Route : Oral
Exposure time : 2 Years
NOAEL : 80 mg/kg body weight
Remarks : No significant adverse effects were reported

Species : Rat
Application Route : Oral
Exposure time : 2 Years
NOAEL : 40 mg/kg body weight
Remarks : No significant adverse effects were reported

Reproductive toxicity

Suspected of damaging the unborn child.

Components:**levamisole hydrochloride:**

Effects on fertility : Test Type: Three-generation reproduction toxicity study

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	Species: Rat
	Application Route: Oral
	Result: No significant adverse effects were reported
Effects on foetal development	: 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
	Result: Fetotoxicity
Reproductive toxicity - Assessment	: Some evidence of adverse effects on development, based on animal experiments.

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

Repeated dose toxicity**Components:****levamisole hydrochloride:**

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

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

Species	: Dog
LOAEL	: 40 mg/kg

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Application Route : Oral
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

Section 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

Section 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 handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

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Section 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

IATA-DGR

UN/ID No.	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Packing instruction (cargo aircraft)	:	Not applicable
Packing instruction (passenger aircraft)	:	Not applicable

IMDG-Code

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
EmS Code	:	Not applicable
Marine pollutant	:	Not applicable

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

Not applicable for product as supplied.

National Regulations**NZS 5433**

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Hazchem Code	:	Not applicable

Special precautions for user

Not applicable

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Section 15: Regulatory information

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

HSNO Approval Number

HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard

HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

Section 16: Other information

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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/>

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 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

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es; (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.

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