

SAFETY DATA SHEET



Levamisole Formulation

Version 4.0 Revision Date: 14.04.2025 SDS Number: 9081925-00009 Date of last issue: 06.04.2024
Date of first issue: 21.07.2021

Section 1: Identification

Product identifier : Levamisole Formulation

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

Manufacturer or supplier's details

Company : MSD
Address : 50 Tuas West Drive
Singapore - Singapore 638408
Telephone : +1-908-740-4000
Emergency telephone number : 65 6697 2111 (24/7/365)
E-mail address : EHSDATASTEWARD@msd.com

Section 2: Hazard identification

Classification of the substance or mixture

Acute toxicity (Oral) : Category 4
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Blood, Testis)

GHS Label elements, including precautionary statements

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

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and understood.

P260 Do not breathe dust.

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/ hearing 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

Description of necessary 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.

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Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed

- | | |
|----------------------------|--|
| Risks | : Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.
Harmful if swallowed.
Suspected of damaging the unborn child.
May cause damage to organs through prolonged or repeated exposure if swallowed. |
| Protection of first-aiders | : 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). |

Indication of any immediate medical attention and special treatment needed

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| Treatment | : Treat symptomatically and supportively. |
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Section 5: Fire-fighting measures**Extinguishing media**

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| Suitable extinguishing media | : Water spray
Alcohol-resistant foam
Carbon dioxide (CO ₂)
Dry chemical |
|------------------------------|--|

- | | |
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| Unsuitable extinguishing media | : None known. |
|--------------------------------|---------------|

Special hazards arising from the substance or mixture

- | | |
|---------------------------------------|---|
| 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. |
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- | | |
|-------------------------------|-----------------|
| Hazardous combustion products | : Carbon oxides |
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Special protective actions for fire-fighters

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|---|--|
| Special protective equipment for firefighters | : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment. |
|---|--|

- | | |
|--------------------------------|---|
| Specific extinguishing methods | : 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. |
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Personal precautions

- : Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions

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.

Methods and materials for containment and cleaning up

Methods for cleaning up

- : Sweep up or vacuum up spillage and collect in suitable container for disposal.
- 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**Precautions for safe handling**

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.

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Hygiene measures	<p>Take care to prevent spills, waste and minimize release to the environment.</p> <p>If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.</p> <p>When using do not eat, drink or smoke.</p> <p>Wash contaminated clothing before re-use.</p> <p>The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.</p>
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Conditions for safe storage, including any incompatibilities

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**Control parameters****Occupational Exposure Limits**

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

Appropriate engineering control 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 containment devices).
	Minimize open handling.

Individual protection measures, such as personal protective equipment (PPE)

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 aerosols.
Skin protection	: Work uniform or laboratory coat. Additional body garments should be used based upon the

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	task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
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	: Consider double gloving.

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
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)	

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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 characteristics	
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. 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

Information on likely routes of exposure	: Inhalation Skin contact Ingestion Eye contact
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Acute toxicity

Harmful if swallowed.

Product:

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

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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
: TestisSpecies
LOAEL
Application Route
Exposure time
Target Organs: Dog
: 20 mg/kg
: Oral
: 18 Months
: BloodSpecies
LOAEL
Application Route
Exposure time: Dog
: 40 mg/kg
: Oral
: 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**Toxicity****Components:****levamisole hydrochloride:**

Toxicity to fish

: LC50 (Oryzias latipes (Japanese medaka)): 37.3 mg/l

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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.

Section 14: Transport information

International Regulations

UNRTDG

UN number : Not applicable
UN proper shipping name : Not applicable
Transport hazard class(es) : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable
UN proper shipping name : Not applicable
Transport hazard class(es) : 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

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IMDG-Code

UN number	:	Not applicable
UN proper shipping name	:	Not applicable
Transport hazard class(es)	:	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 IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

Section 15: Regulatory information

Safety, health and environmental regulations specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subject to the requirements in the Act/Regulations.

Environmental Protection and Management Act and	:	Not applicable
Environmental Protection and Management (Hazardous Substances) Regulations	:	
Fire Safety (Petroleum and Flammable Materials)	:	Not applicable
Regulations	:	

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/>

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

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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; KECL - 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

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.

SG / EN