

# Levamisole Hydrochloride (8%) Liquid Formulation

Version 1.2      Revision Date: 30.09.2023      SDS Number: 10848177-00003      Date of last issue: 04.04.2023  
Date of first issue: 09.09.2022

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## SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Levamisole Hydrochloride (8%) Liquid Formulation

### Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530  
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

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## SECTION 2. HAZARDS IDENTIFICATION

### GHS Classification in accordance with ABNT NBR 14725 Standard

Acute toxicity (Oral) : Category 5

Reproductive toxicity : Category 2

### GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H303 May be harmful if swallowed.  
H361d Suspected of damaging the unborn child.

Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**  
P312 Call a POISON CENTER/ doctor if you feel unwell.

**Storage:**

# Levamisole Hydrochloride (8%) Liquid Formulation

Version 1.2      Revision Date: 30.09.2023      SDS Number: 10848177-00003      Date of last issue: 04.04.2023  
Date of first issue: 09.09.2022

P405 Store locked up.

## Other hazards which do not result in classification

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Levamisole hydrochloride	16595-80-5	Acute toxicity (Oral), Category 3 Reproductive toxicity, Category 2 Specific target organ toxicity - repeated exposure (Oral) (Blood, Testis), Category 2 Short-term (acute) aquatic hazard, Category 3 Long-term (chronic) aquatic hazard, Category 3	$\geq 5$ - $< 10$
Citric acid	77-92-9	Eye irritation, Category 2A Specific target organ toxicity - single exposure, Category 3	$\geq 1$ - $< 5$

## 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 : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.

## Levamisole Hydrochloride (8%) Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.2	30.09.2023	10848177-00003	Date of first issue: 09.09.2022

Get medical attention.  
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : May be harmful if swallowed.  
Suspected of damaging the unborn child.

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).

Notes to physician : Treat symptomatically and supportively.

### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

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.

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

### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g., by containment or oil barriers).  
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 : Soak up with inert absorbent material.  
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and

## Levamisole Hydrochloride (8%) Liquid Formulation

Version 1.2      Revision Date: 30.09.2023      SDS Number: 10848177-00003      Date of last issue: 04.04.2023  
Date of first issue: 09.09.2022

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 : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not breathe mist or vapors.  
Do not swallow.  
Avoid contact with eyes.  
Avoid prolonged or repeated contact with skin.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
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.  
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.
- Conditions for safe storage : Keep in properly labeled 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  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

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

- Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

## Levamisole Hydrochloride (8%) Liquid Formulation

Version 1.2      Revision Date: 30.09.2023      SDS Number: 10848177-00003      Date of last issue: 04.04.2023  
Date of first issue: 09.09.2022

---

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.

### 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 : Consider double gloving.

Eye 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 and body protection : Work uniform or laboratory coat.  
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : clear  
yellow

Odor : No data available

Odor 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 : No data available

Evaporation rate : No data available

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## Levamisole Hydrochloride (8%) Liquid Formulation

Version 1.2	Revision Date: 30.09.2023	SDS Number: 10848177-00003	Date of last issue: 04.04.2023 Date of first issue: 09.09.2022
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Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	Not applicable

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### SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

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### SECTION 11. TOXICOLOGICAL INFORMATION

## Levamisole Hydrochloride (8%) Liquid Formulation

Version 1.2      Revision Date: 30.09.2023      SDS Number: 10848177-00003      Date of last issue: 04.04.2023  
Date of first issue: 09.09.2022

---

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

### Acute toxicity

May be harmful if swallowed.

### Product:

Acute oral toxicity : Acute toxicity estimate: 2.317 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

#### Citric acid:

Acute oral toxicity : LD50 (Mouse): 5.400 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg  
Method: OECD Test Guideline 402  
Assessment: The substance or mixture has no acute dermal toxicity

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Levamisole hydrochloride:

Remarks : No data available

#### Citric acid:

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

## Levamisole Hydrochloride (8%) Liquid Formulation

Version 1.2      Revision Date: 30.09.2023      SDS Number: 10848177-00003      Date of last issue: 04.04.2023  
Date of first issue: 09.09.2022

---

### Components:

#### **Levamisole hydrochloride:**

Remarks : No data available

#### **Citric acid:**

Species : Rabbit  
Result : Irritation to eyes, reversing within 21 days  
Method : OECD Test Guideline 405

### **Respiratory or skin sensitization**

#### **Skin sensitization**

Not classified based on available information.

#### **Respiratory sensitization**

Not classified based on available information.

### Components:

#### **Levamisole hydrochloride:**

Remarks : No data available

### **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

#### **Citric acid:**

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

Test Type: in vitro micronucleus test  
Result: positive

Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
Species: Rat  
Application Route: Ingestion  
Result: negative



## Levamisole Hydrochloride (8%) Liquid Formulation

Version 1.2      Revision Date: 30.09.2023      SDS Number: 10848177-00003      Date of last issue: 04.04.2023  
Date of first issue: 09.09.2022

---

### 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 fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 20 mg/kg body weight  
Result: Fetotoxicity.

Test Type: Embryo-fetal 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.

#### Citric acid:

Effects on fetal development : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

### STOT-single exposure

Not classified based on available information.

## Levamisole Hydrochloride (8%) Liquid Formulation

Version 1.2      Revision Date: 30.09.2023      SDS Number: 10848177-00003      Date of last issue: 04.04.2023  
Date of first issue: 09.09.2022

---

### Components:

#### **Citric acid:**

Assessment : May cause respiratory irritation.

#### **STOT-repeated exposure**

Not classified based on available information.

### 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  
Application Route : Oral  
Exposure time : 3 Months

#### **Citric acid:**

Species : Rat  
NOAEL : 4.000 mg/kg  
LOAEL : 8.000 mg/kg  
Application Route : Ingestion  
Exposure time : 10 Days

#### **Aspiration toxicity**

Not classified based on available information.

#### **Experience with human exposure**

### Components:

#### **Levamisole hydrochloride:**

## Levamisole Hydrochloride (8%) Liquid Formulation

Version 1.2      Revision Date: 30.09.2023      SDS Number: 10848177-00003      Date of last issue: 04.04.2023  
Date of first issue: 09.09.2022

---

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

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### 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

##### **Citric acid:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1.535 mg/l  
Exposure time: 24 h

#### Persistence and degradability

##### Components:

##### **Citric acid:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 97 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

#### Bioaccumulative potential

##### Components:

##### **Citric acid:**

Partition coefficient: n-octanol/water : log Pow: -1,72

##### **Mobility in soil**

No data available

##### **Other adverse effects**

No data available

## Levamisole Hydrochloride (8%) Liquid Formulation

Version 1.2      Revision Date: 30.09.2023      SDS Number: 10848177-00003      Date of last issue: 04.04.2023  
Date of first issue: 09.09.2022

---

### 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

Not regulated as a dangerous good

##### IATA-DGR

Not regulated as a dangerous good

##### IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

#### Domestic regulation

##### ANTT

Not regulated as a dangerous good

#### 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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

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### SECTION 16. OTHER INFORMATION

## Levamisole Hydrochloride (8%) Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.2	30.09.2023	10848177-00003	Date of first issue: 09.09.2022

---

Revision Date : 30.09.2023  
Date format : dd.mm.yyyy

### Further information

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

### 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; (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; TECl - 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.

# SAFETY DATA SHEET



## Levamisole Hydrochloride (8%) Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.2	30.09.2023	10848177-00003	Date of first issue: 09.09.2022

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