

SAFETY DATA SHEET



Levamisole Formulation

Version
3.0

Revision Date:
2025/04/14

SDS Number:
9081932-00008

Date of last issue: 2024/01/24
Date of first issue: 2021/07/21

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Levamisole Formulation

Manufacturer or supplier's details

Company : MSD

Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065

Telephone : +1-908-740-4000

Emergency telephone number : +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

2. HAZARDS IDENTIFICATION

GHS Classification

Acute toxicity (Oral) : Category 4

Reproductive toxicity : Category 2

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

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

Levamisole FormulationVersion
3.0Revision Date:
2025/04/14SDS Number:
9081932-00008Date of last issue: 2024/01/24
Date of first issue: 2021/07/21

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.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|--------------------------|------------|-----------------------|
| levamisole hydrochloride | 16595-80-5 | >= 10 -< 25 |

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.

Levamisole Formulation

| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 3.0 | Revision Date: 2025/04/14 | SDS Number: 9081932-00008 | Date of last issue: 2024/01/24 Date of first issue: 2021/07/21 |
|----------------|------------------------------|------------------------------|---|

| | |
|---|--|
| Most important symptoms and effects, both acute and delayed | Never give anything by mouth to an unconscious person. 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). |
| Notes to physician | Treat symptomatically and supportively. |

5. FIREFIGHTING MEASURES

| | |
|---|---|
| Suitable extinguishing media | Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) 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 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 firefighters | In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. |

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. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained. |

SAFETY DATA SHEET



Levamisole Formulation

Version
3.0

Revision Date:
2025/04/14

SDS Number:
9081932-00008

Date of last issue: 2024/01/24
Date of first issue: 2021/07/21

Methods and materials for containment and 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.

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
Advice on safe handling

- : Use only with adequate ventilation.

- : 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.

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 |
|------------|---------|-------------------------------------|--|-------|
| | | | | |

SAFETY DATA SHEET



Levamisole Formulation

Version 3.0 Revision Date: 2025/04/14 SDS Number: 9081932-00008 Date of last issue: 2024/01/24
Date of first issue: 2021/07/21

| | | | | |
|--------------------------|---------------------------|------------|------------------------------|----------|
| 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 : 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

Eye protection : Consider double gloving.
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.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Colour : white

SAFETY DATA SHEET



Levamisole Formulation

Version 3.0 Revision Date: 2025/04/14 SDS Number: 9081932-00008 Date of last issue: 2024/01/24
Date of first issue: 2021/07/21

| | |
|--|---|
| 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) | |
| 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 | |

SAFETY DATA SHEET



Levamisole Formulation

Version 3.0 Revision Date: 2025/04/14 SDS Number: 9081932-00008 Date of last issue: 2024/01/24 Date of first issue: 2021/07/21

Particle size : No data available

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.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : 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 |
|---------|---------------------|

SAFETY DATA SHEET



Levamisole Formulation

Version 3.0 Revision Date: 2025/04/14 SDS Number: 9081932-00008 Date of last issue: 2024/01/24
Date of first issue: 2021/07/21

Serious eye damage/eye irritation

Not classified based on available information.

Components:

levamisole hydrochloride:

||| Remarks : No data available

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

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

Levamisole FormulationVersion
3.0Revision Date:
2025/04/14SDS Number:
9081932-00008Date of last issue: 2024/01/24
Date of first issue: 2021/07/21**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.

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

SAFETY DATA SHEET



Levamisole Formulation

Version 3.0 Revision Date: 2025/04/14 SDS Number: 9081932-00008 Date of last issue: 2024/01/24
Date of first issue: 2021/07/21

||| 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

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

levamisole hydrochloride:

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

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

Levamisole FormulationVersion
3.0Revision Date:
2025/04/14SDS Number:
9081932-00008Date of last issue: 2024/01/24
Date of first issue: 2021/07/21

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.

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

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.

Special precautions for user

Not applicable

SAFETY DATA SHEET



Levamisole Formulation

| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 3.0 | Revision Date: 2025/04/14 | SDS Number: 9081932-00008 | Date of last issue: 2024/01/24 Date of first issue: 2021/07/21 |
|----------------|------------------------------|------------------------------|---|

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

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

16. OTHER INFORMATION

Revision Date : 2025/04/14

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 : 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

SAFETY DATA SHEET



Levamisole Formulation

Version
3.0

Revision Date:
2025/04/14

SDS Number:
9081932-00008

Date of last issue: 2024/01/24
Date of first issue: 2021/07/21

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; 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.

ID / EN