SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Levamisole Formulation

Version 1.1  Revision Date: 27.08.2021  SDS Number: 9097899-00002  Date of last issue: 21.07.2021
Date of first issue: 21.07.2021

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name : Levamisole Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
Company : MSD
Kilsheean
Clonmel Tipperary, IE
Telephone : 353-51-601000
E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Acute toxicity, Category 4 H302: Harmful if swallowed.
Reproductive toxicity, Category 2 H361d: Suspected of damaging the unborn child.
Specific target organ toxicity - repeated exposure, Category 2 H373: May cause damage to organs through prolonged or repeated exposure.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms :
Signal word : Warning
Hazard statements : H302 Harmful if swallowed.
H361d Suspected of damaging the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure.
Precautionary statements : Prevention:
P201 Obtain special instructions before use.
Levamisole Formulation

P260  Do not breathe dust.
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.

Hazardous components which must be listed on the label:
levamisole hydrochloride

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

3.2 Mixtures
Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>levamisole hydrochloride</td>
<td>16595-80-5</td>
<td>240-654-6</td>
<td></td>
<td></td>
<td>Acute Tox. 3; H301 Repr. 2; H361d STOT RE 2; H373 (Blood, Testis) Aquatic Chronic 3; H412</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures
General advice: In the case of accident or if you feel unwell, seek medical ad-
vice immediately.  
When symptoms persist or in all cases of doubt seek medical 
advice.

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).

If inhaled  
If inhaled, remove to fresh air.  
Get medical attention.

In case of skin contact  
In case of contact, immediately flush skin with soap and plenty 
of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.

In case of eye contact  
If in eyes, rinse well with water.  
Get medical attention if irritation develops and persists.

If swallowed  
If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.  
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

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

4.3 Indication of any immediate medical attention and special treatment needed

Treatment  
Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media  
Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO2)  
Dry chemical

Unsuitable extinguishing media  
None known.
5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: 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

5.3 Advice for firefighters

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 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.

6.3 Methods and material 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

7.1 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.
- 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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types: Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>levamisole hydrochloride</td>
<td>16595-80-5</td>
<td>TWA</td>
<td>20 µg/m³ (OEB 3)</td>
<td>Internal</td>
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</table>

Further information: Skin
## 8.2 Exposure controls

**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**

### Eye protection

Wear the following personal protective equipment:
- Safety goggles
- Equipment should conform to I.S. EN 166

### 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.

### 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).

### Respiratory protection

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

- **Equipment should conform to I.S. EN 143**
- **Filter type**: Particulates type (P)

## 9.1 Information on basic physical and chemical properties

### Physical state
- Powder

### Colour
- White

### Odour
- No data available

### Odour Threshold
- No data available

### Melting point/freezing point
- No data available

### Initial boiling point and boiling range
- No data available

### Flammability (solid, gas)
- May form combustible dust concentrations in air during processing, handling or other means.
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- **Upper explosion limit** / **Upper flammability limit**: No data available
- **Lower explosion limit** / **Lower flammability limit**: No data available
- **Flash point**: Not applicable
- **Auto-ignition temperature**: No data available
- **Decomposition temperature**: No data available
- **pH**: No data available
- **Viscosity**: Not applicable
- **Solubility(ies)**
  - **Water solubility**: No data available
- **Partition coefficient: n-octanol/water**: Not applicable
- **Vapour pressure**: Not applicable
- **Relative density**: No data available
- **Density**: No data available
- **Relative vapour density**: Not applicable
- **Particle characteristics**
  - **Particle size**: No data available

#### 9.2 Other information

- **Explosives**: Not explosive
- **Oxidizing properties**: The substance or mixture is not classified as oxidizing.
- **Evaporation rate**: Not applicable
- **Molecular weight**: No data available

### SECTION 10: Stability and reactivity

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions
Hazardous reactions: May form combustible dust concentrations in air during processing, handling or other means. Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: Heat, flames and sparks. Avoid dust formation.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
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
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

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 through prolonged or repeated exposure.

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
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- **LOAEL**: 40 mg/kg
- **Application Route**: Oral
- **Exposure time**: 3 Months

**Aspiration toxicity**
Not classified based on available information.

#### 11.2 Information on other hazards

**Endocrine disrupting properties**

**Product:**

- **Assessment**: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

**Experience with human exposure**

**Components:**

- **levamisole hydrochloride**:
  - Ingestion: Symptoms: Nausea, Vomiting, Headache, Dizziness, Hypotension

### SECTION 12: Ecological information

#### 12.1 Toxicity

**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

#### 12.2 Persistence and degradability

No data available

#### 12.3 Bioaccumulative potential

No data available

#### 12.4 Mobility in soil

No data available

#### 12.5 Results of PBT and vPvB assessment

**Product:**
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Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product: Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number or ID number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Maritime transport in bulk according to IMO instruments
Remarks : Not applicable for product as supplied.
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SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

REACH - List of substances subject to authorisation (Annex XIV): Not applicable


Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements
H301 : Toxic if swallowed.
H361d : Suspected of damaging the unborn child.
H373 : May cause damage to organs through prolonged or repeated exposure if swallowed.
H412 : Harmful to aquatic life with long lasting effects.

Full text of other abbreviations
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ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information


Classification of the mixture:

| Acute Tox. 4 | H302 | Calculation method |
| Repr. 2 | H361d | Calculation method |
| STOT RE 2 | H373 | Calculation method |

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
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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.

IE / EN