# SAFETY DATA SHEET

# Levamisole Hydrochloride (8%) Liquid Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 2024/02/20 |
|---|---|---|---|
| 5.0 | 2024/09/28 | 10848173-00005 | Date of first issue: 2022/09/09 |

## 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Levamisole Hydrochloride (8%) Liquid Formulation

Other means of identification : COOPERS NILVERM LV ORAL WORMER (36152)

**Supplier's company name, address and phone number**

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

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

Recommended use : Veterinary product

Restrictions on use : Not applicable

## 2. HAZARDS IDENTIFICATION

**GHS classification of chemical product**

Reproductive toxicity : Category 2

**GHS label elements**

Hazard pictograms :

Signal word : Warning

Hazard statements : H361d Suspected of damaging the unborn child.

Precautionary statements :

**Prevention:**

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

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**

None known.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name | CAS-No. | Concentration (% w/w) | ENCS No. |
|---|---|---|---|
| levamisole hydrochloride | 16595-80-5 | 7.77 | - |
| Citric acid | 77-92-9 | >= 1 - < 10 | 2-1318 |
| Tetrasodium ethylenediaminetetraacetate | 64-02-8 | >= 0.1 - < 1 | 2-1265 |

## 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.
Get medical attention.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : 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. |

## 5. FIREFIGHTING MEASURES

| | | |
|---|---|---|
| Suitable extinguishing media | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO2)<br>Dry chemical |
| Unsuitable extinguishing media | : | None known. |
| Specific hazards during firefighting | : | 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.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment. |

## 6. ACCIDENTAL RELEASE MEASURES

| | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g. by containment or oil barriers).<br>Retain and dispose of contaminated wash water.<br>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.<br>For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked 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 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

**Handling**

| | | |
|---|---|---|
| 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 vapours.<br>Do not swallow.<br>Avoid contact with eyes.<br>Avoid prolonged or repeated contact with skin.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Take care to prevent spills, waste and minimize release to the environment. |
| Avoidance of contact | : | Oxidizing agents |
| Hygiene measures | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>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. |

**Storage**

| | | |
|---|---|---|
| Conditions for safe storage | : | Keep in properly labelled containers.<br>Store locked up.<br>Store in accordance with the particular national regulations. |
| Materials to avoid | : | Do not store with the following product types:<br>Strong oxidizing agents |
| Packaging material | : | Unsuitable material: None known. |

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Threshold limit value and permissible exposure limits for each component in the work environment**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Concentration standard / Permissible concentration | Basis |
|---|---|---|---|---|
| levamisole hydrochloride | 16595-80-5 | TWA | 20 µg/m3 (OEB 3) | Internal |
| | Further information: Skin | | | |
| | | Wipe limit | 200 µg/100 cm² | Internal |

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

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : liquid

Colour : clear

yellow

| | | |
|---|---|---|
| Odour | : | No data available |
| Odour Threshold | : | No data available |
| Melting point/freezing point | : | No data available |
| Boiling point, initial boiling point and boiling range | : | No data available |
| Flammability (solid, gas) | : | Not applicable |
| Flammability (liquids) | : | No data available |
| Lower explosion limit and upper explosion limit / flammability limit | | |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Flash point | : | No data available |
| Decomposition temperature | : | No data available |
| pH | : | No data available |
| Evaporation rate | : | No data available |
| Auto-ignition temperature | : | No data available |
| Viscosity | | |
| Viscosity, kinematic | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Vapour pressure | : | No data available |
| Density and / or relative density | | |
| Relative density | : | No data available |
| Density | : | No data available |
| Relative vapour density | : | No data available |
| Explosive properties | : | Not explosive |

| | | |
|---|---|---|
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight | : | No data available |
| Particle characteristics | | |
| Particle size | : | Not applicable |

## 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. |

## 11. TOXICOLOGICAL INFORMATION

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

**Acute toxicity**

Not classified based on available information.

**Product:**

Acute oral toxicity : Acute toxicity estimate: > 2,000 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<br>Method: OECD Test Guideline 402<br>Assessment: The substance or mixture has no acute dermal toxicity |

**Tetrasodium ethylenediaminetetraacetate:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): 1,780 mg/kg<br>Method: OECD Test Guideline 401 |
| Acute inhalation toxicity | : | LC50 (Rat): > 1 mg/l<br>Exposure time: 6 h<br>Test atmosphere: dust/mist<br>Remarks: Based on data from similar materials |

**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 |

**Tetrasodium ethylenediaminetetraacetate:**

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

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**levamisole hydrochloride:**

| | | |
|---|---|---|
| Remarks | : | No data available |

**Citric acid:**

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

**Tetrasodium ethylenediaminetetraacetate:**

| | | |
|---|---|---|
| Result | : | Irreversible effects on the eye |
| Remarks | : | Based on national or regional regulation. |

**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 |

**Tetrasodium ethylenediaminetetraacetate:**

| | | |
|---|---|---|
| Test Type | : | Maximisation Test |
| Exposure routes | : | Skin contact |
| Species | : | Guinea pig |
| Method | : | OECD Test Guideline 406 |
| Result | : | negative |
| Remarks | : | Based on data from similar materials |

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**levamisole hydrochloride:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: Chromosome aberration test in vitro<br>Result: negative |

**Citric acid:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: in vitro micronucleus test<br>Result: positive<br><br>Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) |

Species: Rat
Application Route: Ingestion
Result: negative

**Tetrasodium ethylenediaminetetraacetate:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Chromosome aberration test in vitro<br>Result: negative<br>Remarks: Based on data from similar materials |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Ingestion<br>Method: OECD Test Guideline 474<br>Result: negative<br>Remarks: Based on data from similar materials |

**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 |

**Tetrasodium ethylenediaminetetraacetate:**

| | | |
|---|---|---|
| Species | : | Rat |
| Application Route | : | Ingestion |
| Exposure time | : | 103 weeks |
| Result | : | negative |
| Remarks | : | Based on data from similar materials |

| | | |
|---|---|---|
| Species | : | Mouse |
| Application Route | : | Ingestion |
| Exposure time | : | 103 weeks |
| Result | : | negative |
| Remarks | : | Based on data from similar materials |

**Reproductive toxicity**

Suspected of damaging the unborn child.

**Components:**

**levamisole hydrochloride:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Three-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Oral<br>Result: No significant adverse effects were reported |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 20 mg/kg body weight<br>Result: Fetotoxicity<br><br>Test Type: Embryo-foetal development<br>Species: Rabbit<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 40 mg/kg body weight<br>Result: Fetotoxicity |
| Reproductive toxicity - Assessment | : | Some evidence of adverse effects on development, based on animal experiments. |

**Citric acid:**

| | | |
|---|---|---|
| Effects on foetal development | : | Test Type: One-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |

**Tetrasodium ethylenediaminetetraacetate:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Four-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative<br>Remarks: Based on data from similar materials |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |

**STOT - single exposure**

Not classified based on available information.

**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. |

**Tetrasodium ethylenediaminetetraacetate:**

| | | |
|---|---|---|
| Exposure routes | : | inhalation (dust/mist/fume) |
| Target Organs | : | Respiratory Tract |
| Assessment | : | Shown to produce significant health effects in animals at concentrations of >0.02 to 0.2 mg/l/6h/d. |

**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 |

**Tetrasodium ethylenediaminetetraacetate:**

| | | |
|---|---|---|
| Species | : | Mouse |
| NOAEL | : | >= 938 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 103 Weeks |
| Remarks | : | Based on data from similar materials |

| | | |
|---|---|---|
| Species | : | Rat |
| LOAEL | : | 0.03 mg/l |
| Application Route | : | inhalation (dust/mist/fume) |
| Exposure time | : | 4 Weeks |
| Remarks | : | Based on data from similar materials |

**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<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203 |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 64 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202 |

**Citric acid:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 1,535 mg/l<br>Exposure time: 24 h |

**Tetrasodium ethylenediaminetetraacetate:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Lepomis macrochirus (Bluegill sunfish)): 121 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 140 mg/l<br>Exposure time: 48 h<br>Method: DIN 38412<br>Remarks: Based on data from similar materials |
| Toxicity to algae/aquatic plants | : | NOEC (Desmodesmus subspicatus (green algae)): 100 mg/l<br>Exposure time: 72 h<br>Method: Directive 67/548/EEC, Annex V, C.3. |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Danio rerio (zebra fish)): > 25.7 mg/l<br>Exposure time: 35 d<br>Method: OECD Test Guideline 210<br>Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 25 mg/l<br>Exposure time: 21 d<br>Remarks: Based on data from similar materials |
| Toxicity to microorganisms | : | EC10: > 1,000 mg/l<br>Exposure time: 30 min<br>Method: ISO 8192 |

**Persistence and degradability**

**Components:**

**Citric acid:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Readily biodegradable.<br>Biodegradation: 97 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301B |

**Tetrasodium ethylenediaminetetraacetate:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 0 - 10 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301E<br>Remarks: Based on data from similar materials |

**Bioaccumulative potential**

**Components:**

**Citric acid:**

| | | |
|---|---|---|
| Partition coefficient: n-octanol/water | : | log Pow: -1.72 |

**Tetrasodium ethylenediaminetetraacetate:**

| | | |
|---|---|---|
| Bioaccumulation | : | Species: Lepomis macrochirus (Bluegill sunfish)<br>Bioconcentration factor (BCF): 1.8 |

**Mobility in soil**

No data available

**Hazardous to the ozone layer**

Not applicable

**Other adverse effects**

No data available

## 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

| | | |
|---|---|---|
| Waste from residues | : | Dispose of in accordance with local regulations.<br>Do not dispose of waste into sewer. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>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.

**National Regulations**

Refer to section 15 for specific national regulation.

**Special precautions for user**

Not applicable

## 15. REGULATORY INFORMATION

**Related Regulations**

**Fire Service Law**

Not applicable to dangerous materials / designated flammables.

**Chemical Substance Control Law**

Priority Assessment Chemical Substance

| Chemical name | Number |
|---|---|
| Sodium salt of 2,2',2'',2'''-(ethane-1,2-diyldinitrilo)tetraacetic acid | 268 |

**Industrial Safety and Health Law**

**Harmful Substances Prohibited from Manufacture**

Not applicable

**Harmful Substances Required Permission for Manufacture**

Not applicable

**Substances Prevented From Impairment of Health**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**

Not applicable

**Substances Subject to be Notified Names**

Article 57-2 (Enforcement Order Table 9)

| Chemical name | Concentration (%) | Remarks |
|---|---|---|
| levamisole hydrochloride | >=1 - <10 | From April 1st, 2025 |

**Substances Subject to be Indicated Names**

Article 57 (Enforcement Order Article 18)

| Chemical name | Remarks |
|---|---|
| levamisole hydrochloride | From April 1st, 2025 |

**Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2)**

Not applicable

**Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)**

Not applicable

**Ordinance on Prevention of Hazards Due to Specified Chemical Substances**

Not applicable

**Ordinance on Prevention of Lead Poisoning**

Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

**Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

**Poisonous and Deleterious Substances Control Law**

Deleterious substance

| Chemical name | Cabinet Order Number |
|---|---|
| (S)-2,3,5,6-Tetrahydro-6-phenylimidazo[2,1-b]thiazole, its salts and preparations containing some of them | 71.3 |

**Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

Not applicable

**High Pressure Gas Safety Act**

Not applicable

**Explosive Control Law**

Not applicable

**Vessel Safety Law**

Not regulated as a dangerous good

**Aviation Law**

Not regulated as a dangerous good

**Marine Pollution and Sea Disaster Prevention etc Law**

| | | |
|---|---|---|
| Bulk transportation | : | Noxious liquid substance(Category Z) |
| Pack transportation | : | Not classified as marine pollutant |

**Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

**Waste Disposal and Public Cleansing Law**

Industrial waste

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

| | | |
|---|---|---|
| AICS | : | not determined |
| DSL | : | not determined |
| IECSC | : | not determined |

## 16. OTHER INFORMATION

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

**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 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.

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