1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Levamisole / Oxyoclozanide Formulation

Manufacturer or supplier's details
Company: MSD
Address: Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207
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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Reproductive toxicity: Category 2
Short-term (acute) aquatic hazard: Category 2
Long-term (chronic) aquatic hazard: Category 2

GHS label elements
Hazard pictograms:

Signal word: Warning
Hazard statements: H361d Suspected of damaging the unborn child.
H411 Toxic to aquatic life with long lasting effects.
Precautionary statements: Prevention:
P203 Obtain, read and follow all safety instructions before use.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protec-
SAFETY DATA SHEET

Levamisole / Oxyclozanide Formulation

Version 1.4 
Revision Date: 10.10.2020 
SDS Number: 5360098-00005 
Date of last issue: 17.06.2020 
Date of first issue: 19.12.2019

Protection/ face protection.

Response:
P318 IF exposed or concerned, get medical advice.
P391 Collect spillage.

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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kaolin</td>
<td>1332-58-7</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td>oxyclozanide</td>
<td>2277-92-1</td>
<td>&gt;= 3 - &lt; 5</td>
</tr>
<tr>
<td>levamisole hydrochloride</td>
<td>16595-80-5</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

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.
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed
Protection of first-aiders : Suspected of damaging the unborn child.

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).
5. FIREFIGHTING MEASURES

Suitable extinguishing media:
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- 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
- Silicon oxides
- Metal oxides
- Chlorine compounds
- Nitrogen oxides (NOx)

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.
- 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 dyeing or other appropriate containment to keep material from spreading. If dyed 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
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.
- 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.
- 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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kaolin</td>
<td>1332-58-7</td>
<td>TWA (Respirable particulate matter)</td>
<td>2 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>oxyclozanide</td>
<td>2277-92-1</td>
<td>TWA</td>
<td>0.4 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>400 mg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>levamisole hydrochloride</td>
<td>16595-80-5</td>
<td>TWA</td>
<td>20 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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., drip-less 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.

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 : liquid
Colour : No data available
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 : No data available
Evaporation rate : No data available
Flammability (solid, gas) : Not applicable
Flammability (liquids) : No data available
Upper explosion limit / Upper : No data available
SAFETY DATA SHEET

Levamisole / Oxytociclonide Formulation

flammarility limit
Lower explosion limit / Lower flammable limit : No data available
Vapour pressure : No data available
Relative vapour 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
Auto-ignition 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

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reac-
tions : 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.
**SAFETY DATA SHEET**

**Levamisole / Oxyclozanide Formulation**

<table>
<thead>
<tr>
<th>Version</th>
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</tr>
</tbody>
</table>

**Product:**

Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

**Components:**

**Kaolin:**

Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Remarks: Based on data from similar materials

Acute inhalation toxicity: LC50 (Rat): > 2.07 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity
Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rat): > 5,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: Based on data from similar materials

**Oxyclozanide:**

Acute oral toxicity: LD50 (Rat): 3,519 mg/kg
Target Organs: Central nervous system

Acute toxicity (other routes of administration): LDLo (sheep): 10 mg/kg
Application Route: Intravenous

**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:

Kaolin:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

Oxyclozanide:
Remarks: Not classified due to lack of data.

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.

Components:

Kaolin:
Species: Rabbit
Result: No eye irritation
Remarks: Based on data from similar materials

Oxyclozanide:
Remarks: Not classified due to lack of data.

Levamisole hydrochloride:
Remarks: No data available

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

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.
Components:

oxyclozanide:
Exposure routes: Dermal
Remarks: Not classified due to lack of data.

levamisole hydrochloride:
Remarks: No data available

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Test Type: Chromosomal aberration
Test system: Human lymphocytes
Result: positive

Test Type: Mouse Lymphoma
Result: positive

Genotoxicity in vivo:
Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

Test Type: unscheduled DNA synthesis assay
Species: Rat
Cell type: Liver cells
Application Route: Oral
Result: negative

Germ cell mutagenicity - Assessment:
Weight of evidence does not support classification as a germ cell mutagen.

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  

Carcinogenicity  
Not classified based on available information.  

Components:  

**oxyclozanide:**  
Remarks: Not classified due to lack of data.  

**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:  

**oxyclozanide:**  
Effects on fertility: Test Type: Two-generation reproduction toxicity study  
Species: Rat, male and female  
Application Route: Oral  
General Toxicity - Parent: NOAEL: 25 - 35 mg/kg body weight  
Symptoms: Reduced body weight, No effects on embryofoetal and postnatal development  
Result: No effects on fertility  

Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Oral  
General Toxicity - Parent: LOAEL: 75 - 100 mg/kg body weight  
Symptoms: Reduced body weight, No effects on embryofoetal
and postnatal development
Result: No effects on fertility

Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Oral
Early Embryonic Development: LOAEL: 75 - 100 mg/kg body weight
Result: No fetotoxicity, No teratogenic effects

Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Oral
General Toxicity - Parent: LOAEL: 80 - 160 mg/kg body weight
Result: No fetotoxicity, No teratogenic effects, No effects on fertility

Effects on foetal development:

Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 200 mg/kg body weight
Result: No fetotoxicity, No teratogenic effects

Test Type: Development
Species: Rat
Application Route: Oral
General Toxicity Maternal: LOAEL: 100 mg/kg body weight
Result: No fetotoxicity, No teratogenic effects

Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 32 mg/kg body weight
Result: Fetotoxicity, Skeletal malformations

Reproductive toxicity - Assessment:
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.

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

STOT - single exposure
Not classified based on available information.

Components:

oxytocanide:
Exposure routes: Oral
Target Organs: Central nervous system
Assessment: May cause damage to organs.

STOT - repeated exposure
Not classified based on available information.

Components:

oxytocanide:
Target Organs: Brain, Liver
Assessment: May cause damage to organs through prolonged or repeated exposure.

levamisole hydrochloride:
Target Organs: Blood, Testis
Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

oxytocanide:
Species: Rat
NOAEL: 9 mg/kg
LOAEL: 44.5 mg/kg
Application Route: Oral
Exposure time: 3 Months
Target Organs: Brain, Liver, spleen, Adrenal gland
Symptoms: Liver effects

Species: Dog
NOAEL: 5 mg/kg
LOAEL: 25 mg/kg
Application Route: Oral
Exposure time: 3 Months
Target Organs: Brain, Liver
Symptoms: blood effects, alteration in liver enzymes

**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.

**Components:**

**oxyclozanide:**
Not applicable

**Experience with human exposure**

**Components:**

**oxyclozanide:**
Ingestion: Symptoms: May cause, Gastrointestinal disturbance, Central nervous system depression

**levamisole hydrochloride:**
Ingestion: Symptoms: Nausea, Vomiting, Headache, Dizziness, hypotension
12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Kaolin:
Toxicity to fish (Chronic toxicity):
- NOELR: > 100 mg/l
- Exposure time: 30 d
- Species: Oncorhynchus mykiss (rainbow trout)

oxyclozanide:
Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): 0.69 mg/l
- Exposure time: 48 h
- Method: OECD Test Guideline 202

M-Factor (Acute aquatic toxicity):
- 1

M-Factor (Chronic aquatic toxicity):
- 1

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:

oxyclozanide:
Stability in water:
- Hydrolysis: 50 % (156 d)
- Method: OECD Test Guideline 111

Citric acid:
Biodegradability:
- Result: Readily biodegradable.
- Biodegradation: 97 %
- Exposure time: 28 d
- Method: OECD Test Guideline 301B
Bioaccumulative potential

**Components:**

**oxyclozanide:**
- Partition coefficient: n-octanol/water: log Pow: 3.99
- pH: 7
- Method: OECD Test Guideline 107

**Citric acid:**
- Partition coefficient: n-octanol/water: log Pow: -1.72

Mobility in soil

**Components:**

**oxyclozanide:**
- Distribution among environmental compartments: log Koc: 4.83
- Method: OECD Test Guideline 106

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

- Waste from residues: 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: UN 3082
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxyclozanide)
- Class: 9
- Packing group: III
- Labels: 9

**IATA-DGR**
- UN/ID No.: UN 3082
- Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (oxyclozanide)
- Class: 9
- Packing group: III
- Labels: Miscellaneous
SAFETY DATA SHEET

Levamisole / Oxyclozanide Formulation

Version: 1.4
Revision Date: 10.10.2020
SDS Number: 5360098-00005
Date of last issue: 17.06.2020
Date of first issue: 19.12.2019

Packing instruction (cargo aircraft): 964
Packing instruction (passenger aircraft): 964
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxyclozanide)

Class: 9
Packing group: III
Labels: 9
EmS Code: F-A, S-F
Marine pollutant: yes

Transport in bulk according to IMO instruments
Not applicable for product as supplied.

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

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

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

16. OTHER INFORMATION

Further information
Date format: dd.mm-yyyy

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA: 8-hour, time-weighted average
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.

IN / EN