

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

1.1 Product identifier

Trade name: Levamisole / Oxytocanide 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
Kilsheelan
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)

Reproductive toxicity, Category 2: H361d: Suspected of damaging the unborn child.
Long-term (chronic) aquatic hazard, Category 2: H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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:

P201 Obtain special instructions before use.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
Response:
P308 + P313  IF exposed or concerned: Get medical advice/attention.
P391  Collect spillage.

Storage:
P405  Store locked up.

Hazardous components which must be listed on the label:
oxyclozanide

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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<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>
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<tbody>
<tr>
<td>oxyclozanide</td>
<td>2277-92-1</td>
<td>218-904-0</td>
<td></td>
<td></td>
<td>Repr. 2; H361d STOT SE 2; H371 (Central nervous system) STOT RE 2; H373 (Brain, Liver) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1</td>
<td>&gt;= 3 - &lt; 10</td>
</tr>
<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</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Levamisole / Oxyclozanide Formulation

Version: 1.6
Revision Date: 27.08.2021
SDS Number: 5360528-00007
Date of last issue: 09.04.2021
Date of first issue: 19.12.2019

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC Number</th>
<th>UN/CoP number</th>
<th>Aquatic Chronic</th>
<th>H (Eye Irritation)</th>
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<tbody>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>201-069-1</td>
<td>(Blood, Testis)</td>
<td>H412</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic Chronic 3; H412</td>
<td>Eye Irr. 2; H319</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>&gt;= 1 - &lt; 10</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 advice 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:
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.

4.2 Most important symptoms and effects, both acute and delayed

Risks:
Suspected of damaging the unborn child.

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 : Exposure to combustion products may be a hazard to health.
Hazardous combustion products : Carbon oxides
Silicon oxides
Metal oxides
Chlorine compounds
Nitrogen oxides (NOx)

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.
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.

6.3 Methods and material for containment and cleaning up
Methods for cleaning up : Soak up with inert absorbent material.
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.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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.

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.

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.

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

<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>Kaolin</td>
<td>1332-58-7</td>
<td>OELV - 8 hrs (TWA)</td>
<td>2 mg/m³</td>
<td>IE OEL</td>
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<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>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>200 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information: Skin</td>
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<td></td>
<td></td>
<td></td>
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</table>

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

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<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
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<tbody>
<tr>
<td>Citric acid</td>
<td>Fresh water</td>
<td>0.44 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.044 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>34.6 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>3.46 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>33.1 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

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

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.

Hand protection
Material: Chemical-resistant gloves
Remarks:
Consider double gloving.

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.

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)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state:
liquid

Colour:
No data available

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):
Not applicable

Flammability (liquids):
No data available

Upper explosion limit / Upper flammability limit:
No data available

Lower explosion limit / Lower flammability limit:
No data available

Flash point:
No data available

Auto-ignition temperature:
No data available

Decomposition temperature:
No data available

pH:
No data available

Viscosity:
Viscosity, kinematic:
No data available

Partition coefficient: n-octanol/water:
Not applicable

Vapour pressure:
No data available
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Relative density: No data available
Density: No data available
Relative vapour density: No data available
Particle characteristics
  Particle size: Not applicable

9.2 Other information
Explosives: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Evaporation rate: No data available
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: Can react with strong oxidizing agents.

10.4 Conditions to avoid
  Conditions to avoid: None known.

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
  Not classified based on available information.

Product:
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**Acute oral toxicity**:
- Acute toxicity estimate: > 2,000 mg/kg
  - Method: Calculation method

**Components:**

- **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:**

- **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:

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
### Germ cell mutagenicity assessment

- **Species**: Rat  
- **Cell type**: Liver cells  
- **Application Route**: Oral  
- **Result**: negative

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
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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<td>1.6</td>
<td>27.08.2021</td>
<td>5360528-00007</td>
<td>09.04.2021</td>
<td>19.12.2019</td>
</tr>
</tbody>
</table>

**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**:

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

**STOT - repeated exposure**

Not classified based on available information.

**Components**:

- **oxyclozanide**:
  - **Target Organs**: Brain, Liver
  - **Assessment**: May cause damage to organs through prolonged or repeated exposure.
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### Components:

#### Oxyclozanide:

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>9 mg/kg</td>
<td>44.5 mg/kg</td>
<td>Oral</td>
<td>3 Months</td>
<td>Brain, Liver, spleen, Adrenal gland</td>
<td>Liver effects</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>5 mg/kg</td>
<td>25 mg/kg</td>
<td>Oral</td>
<td>3 Months</td>
<td>Brain, Liver</td>
<td>blood effects, alteration in liver enzymes</td>
</tr>
</tbody>
</table>

#### Levamisole hydrochloride:

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>2.5 mg/kg</td>
<td>Oral</td>
<td>18 Months</td>
<td>Testis</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
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<tr>
<td>Dog</td>
<td>20 mg/kg</td>
<td>Oral</td>
<td>18 Months</td>
<td>Blood</td>
<td></td>
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#### Citric acid:

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>4,000 mg/kg</td>
<td>8,000 mg/kg</td>
<td>Ingestion</td>
<td>10 Days</td>
</tr>
</tbody>
</table>

**Repeated dose toxicity**

**Target Organs:** Blood, Testis

**Assessment:** May cause damage to organs through prolonged or repeated exposure.
Aspiration toxicity
Not classified based on available information.

Components:
oxyclozanide:
Not applicable

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

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

SECTION 12: Ecological information

12.1 Toxicity

Components:
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
12.2 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

12.3 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

12.4 Mobility in soil

Components:

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

12.5 Results of PBT and vPvB assessment

Product:
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
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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

ADN: UN 3082
ADR: UN 3082
RID: UN 3082
IMDG: UN 3082
IATA: UN 3082

14.2 UN proper shipping name

ADN: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxyclozanide)
ADR: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxyclozanide)
RID: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxyclozanide)
IMDG: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
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IATA

Environmentally hazardous substance, liquid, n.o.s.
(oxyclozanide)

14.3 Transport hazard class(es)

| ADN   | 9 |
| ADR   | 9 |
| RID   | 9 |
| IMDG  | 9 |
| IATA  | 9 |

14.4 Packing group

| ADN   | Packing group: III  |
|       | Classification Code: M6  |
|       | Hazard Identification Number: 90  |
|       | Labels: 9  |
| ADR   | Packing group: III  |
|       | Classification Code: M6  |
|       | Hazard Identification Number: 90  |
|       | Labels: 9  |
|       | Tunnel restriction code: (-) |
| RID   | Packing group: III  |
|       | Classification Code: M6  |
|       | Hazard Identification Number: 90  |
|       | Labels: 9  |
| IMDG  | Packing group: III  |
|       | Labels: 9  |
|       | EmS Code: F-A, S-F |
| IATA (Cargo) | Packing instruction (cargo aircraft): 964 |
|               | Packing instruction (LQ): Y964 |
|               | Packing group: III |
|               | Labels: Miscellaneous |
| IATA (Passenger) | Packing instruction (passenger aircraft): 964 |
|                  | Packing instruction (LQ): Y964 |
|                  | Packing group: III |
|                  | Labels: Miscellaneous |

14.5 Environmental hazards

ADN
Environmentally hazardous: yes
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14.6 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.

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

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): Conditions of restriction for the following entries should be considered: Number on list 3
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
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

<table>
<thead>
<tr>
<th>Quantity</th>
<th>E2</th>
<th>ENVIROMENTAL HAZARDS</th>
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</thead>
<tbody>
<tr>
<td>200 t</td>
<td></td>
<td></td>
</tr>
<tr>
<td>500 t</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

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

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.
H319 : Causes serious eye irritation.
H361d : Suspected of damaging the unborn child.
H371 : May cause damage to organs if swallowed.
H373 : May cause damage to organs through prolonged or repeated exposure.
H373 : May cause damage to organs through prolonged or repeated exposure if swallowed.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.
H412 : Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Repr. : Reproductive toxicity
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

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 Organiza-
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Further information

Classification of the mixture:
Repr. 2 H361d Calculation method
Aquatic Chronic 2 H411 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 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