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

1.1 Product identifier
   Trade name: Levamisole / Oxyclozanide 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)
   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.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Levamisole / Oxyclozanide Formulation

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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>Components</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>oxyclozanide</td>
<td>2277-92-1</td>
<td>218-904-0</td>
<td></td>
<td></td>
<td></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></td>
<td>&gt;= 1 - &lt; 2,5</td>
</tr>
</tbody>
</table>

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.
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Levamisole / Oxyclozanide Formulation

<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>
</tr>
</thead>
<tbody>
<tr>
<td>1.6</td>
<td>27.08.2021</td>
<td>5360533-00007</td>
<td>09.04.2021</td>
<td>19.12.2019</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>Classification</th>
<th>Hazard Statement</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Citric acid</td>
<td>(Blood, Testis) Aquatic Chronic 3; H412</td>
<td>Eye Irrit. 2; H319</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
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 absorb-
SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006  

**Levamisole / Oxytocanide Formulation**  

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Date of first issue: 19.12.2019  

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
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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>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

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<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 EN 143

Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td></td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>No data available</td>
</tr>
<tr>
<td>Water solubility</td>
<td></td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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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:
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
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:
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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**levamisole hydrochloride:**
- **Target Organs:** Blood, Testis
- **Assessment:** May cause damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

**oxyclozanide:**
- **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

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 : EC50 (Daphnia magna (Water flea)): 64 mg/l
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aquatic invertebrates 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

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

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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

<table>
<thead>
<tr>
<th>Code</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>UN 3082</td>
</tr>
<tr>
<td>ADR</td>
<td>UN 3082</td>
</tr>
<tr>
<td>RID</td>
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</tr>
<tr>
<td>IMDG</td>
<td>UN 3082</td>
</tr>
<tr>
<td>IATA</td>
<td>UN 3082</td>
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</table>

14.2 UN proper shipping name

<table>
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<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>ADN</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxyclozanide)</td>
</tr>
<tr>
<td>ADR</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxyclozanide)</td>
</tr>
<tr>
<td>RID</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxyclozanide)</td>
</tr>
<tr>
<td>IMDG</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,</td>
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Levamisole / Oxyclozanide Formulation

14.3 Transport hazard class(es)

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<tr>
<th>Hazard</th>
<th>Class</th>
<th>Code</th>
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</thead>
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<tr>
<td>ADR</td>
<td>9</td>
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<tr>
<td>RID</td>
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<td>IMDG</td>
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<tr>
<td>IATA</td>
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</table>

14.4 Packing group

<table>
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</thead>
<tbody>
<tr>
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<td>M6</td>
</tr>
<tr>
<td>ADR</td>
<td>III</td>
<td>M6</td>
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<td>RID</td>
<td>III</td>
<td>M6</td>
</tr>
<tr>
<td>IMDG</td>
<td>III</td>
<td></td>
</tr>
<tr>
<td>IATA (Cargo)</td>
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</tr>
<tr>
<td>IATA (Passenger)</td>
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</table>

14.5 Environmental hazards

<table>
<thead>
<tr>
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<th>Code</th>
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</thead>
<tbody>
<tr>
<td>ADN</td>
<td></td>
<td></td>
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</table>
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Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes

IATA (Passenger)
Environmentally hazardous : yes

IATA (Cargo)
Environmentally hazardous : yes

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
REACH - List of substances subject to authorisation (Annex XIV) : 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

<table>
<thead>
<tr>
<th>E2</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>200 t</td>
<td>500 t</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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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Revision Date: 27.08.2021
SDS Number: 5360533-00007
Date of last issue: 09.04.2021
Date of first issue: 19.12.2019

DSL : not determined
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

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; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL -
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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; NZInC - 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 - 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

Further information

Classification of the mixture:

Classification procedure:
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.

NO / EN