

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Levamisole (6.5%) / Oxyclozanide (13%) Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 05/16/2024  |
| 3.0     | 07/06/2024     | 10857501-00007 | Date of first issue: 09/29/2022 |

### SECTION 1. IDENTIFICATION

Product name : Levamisole (6.5%) / Oxyclozanide (13%) Formulation  
Other means of identification : COOPERS NILZAN LV ORAL DRENCH (36089)

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

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

Recommended use : Veterinary product  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Serious eye damage : Category 1  
Reproductive toxicity : Category 2  
Specific target organ toxicity : Category 2 (Central nervous system)  
- single exposure (Oral)  
Specific target organ toxicity : Category 2 (Brain, Liver)  
- repeated exposure  
Specific target organ toxicity : Category 2 (Blood, Testis)  
- repeated exposure (Oral)

#### GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H318 Causes serious eye damage.  
H361d Suspected of damaging the unborn child.  
H371 May cause damage to organs (Central nervous system) if swallowed.  
H373 May cause damage to organs (Brain, Liver) through prolonged or repeated exposure.  
H373 May cause damage to organs (Blood, Testis) through

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prolonged or repeated exposure if swallowed.

### Precautionary Statements

:

#### Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P260 Do not breathe mist or vapors.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves, protective clothing, eye protection and face protection.

#### Response:

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER.

P308 + P311 IF exposed or concerned: Call a doctor.

P308 + P313 IF exposed or concerned: Get medical attention.

#### Storage:

P405 Store locked up.

#### Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

### Other hazards

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture

:

Mixture

### Components

| Chemical name               | CAS-No.    | Concentration (% w/w) |
|-----------------------------|------------|-----------------------|
| Oxyclozanide                | 2277-92-1  | 13                    |
| Silicic acid, aluminum salt | 1335-30-4  | 6.51                  |
| Levamisole hydrochloride    | 16595-80-5 | 6.5                   |
| Citric acid                 | 77-92-9    | 1.77                  |

## SECTION 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.

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|                                                             |   |                                                                                                                                                                                         |
|-------------------------------------------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                             |   | Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse.                                                |
| In case of eye contact                                      | : | In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention immediately.          |
| If swallowed                                                | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.<br>Never give anything by mouth to an unconscious person.                         |
| Most important symptoms and effects, both acute and delayed | : | Causes serious eye damage.<br>Suspected of damaging the unborn child.<br>May cause damage to organs if swallowed.<br>May cause damage to organs through prolonged or repeated exposure. |
| Protection of first-aiders                                  | : | First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).             |
| Notes to physician                                          | : | Treat symptomatically and supportively.                                                                                                                                                 |

### SECTION 5. FIRE-FIGHTING MEASURES

|                                                |   |                                                                                                                                                                                                                                                 |
|------------------------------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Suitable extinguishing media                   | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO2)<br>Dry chemical                                                                                                                                                                   |
| Unsuitable extinguishing media                 | : | None known.                                                                                                                                                                                                                                     |
| Specific hazards during fire fighting          | : | Exposure to combustion products may be a hazard to health.                                                                                                                                                                                      |
| Hazardous combustion products                  | : | Carbon oxides<br>Chlorine compounds<br>Nitrogen oxides (NOx)                                                                                                                                                                                    |
| Specific extinguishing methods                 | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.                                                                                                                                            |

### SECTION 6. ACCIDENTAL RELEASE MEASURES

|                                                                     |   |                                                                                                                                                      |
|---------------------------------------------------------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions                                           | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.                                                           |

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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 diking or other appropriate containment to keep material from spreading. If diked 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.

### SECTION 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 vapors.  
Do not swallow.  
Do not get in 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  
Keep container tightly closed.  
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 labeled containers.  
Store locked up.  
Keep tightly closed.  
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

| Components | CAS-No. | Value type | Control parame- | Basis |
|------------|---------|------------|-----------------|-------|
|------------|---------|------------|-----------------|-------|

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|                             |            | (Form of exposure) | ters / Permissible concentration |           |
|-----------------------------|------------|--------------------|----------------------------------|-----------|
| Oxyclozanide                | 2277-92-1  | TWA                | 0.4 mg/m <sup>3</sup> (OEB 2)    | Internal  |
| Silicic acid, aluminum salt | 1335-30-4  | TWA                | 2 mg/m <sup>3</sup> (Aluminum)   | NIOSH REL |
| Levamisole hydrochloride    | 16595-80-5 | TWA                | 20 µg/m <sup>3</sup> (OEB 3)     | Internal  |
| Further information: Skin   |            |                    |                                  |           |
|                             |            | Wipe limit         | 200 µg/100 cm <sup>2</sup>       | 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** : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

### 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.

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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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

|                                                  |                     |
|--------------------------------------------------|---------------------|
| Appearance                                       | : suspension        |
| Color                                            | : yellow            |
| Odor                                             | : No data available |
| Odor 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 flammability limit | : No data available |
| Lower explosion limit / Lower flammability limit | : No data available |
| Vapor pressure                                   | : No data available |
| Relative vapor density                           | : No data available |
| Relative density                                 | : No data available |
| Density                                          | : No data available |
| Solubility(ies)                                  |                     |
| Water solubility                                 | : No data available |

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|                                        |   |                                                          |
|----------------------------------------|---|----------------------------------------------------------|
| Partition coefficient: n-octanol/water | : | Not applicable                                           |
| Autoignition 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 characteristics               | : |                                                          |
| Particle size                          | : | Not applicable                                           |

### SECTION 10. STABILITY AND REACTIVITY

|                                    |   |                                                |
|------------------------------------|---|------------------------------------------------|
| Reactivity                         | : | Not classified as a reactivity hazard.         |
| Chemical stability                 | : | Stable under normal conditions.                |
| Possibility of hazardous reactions | : | Can react with strong oxidizing agents.        |
| Conditions to avoid                | : | None known.                                    |
| Incompatible materials             | : | Oxidizing agents                               |
| Hazardous decomposition products   | : | No hazardous decomposition products are known. |

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Product:

|                     |   |                                                                    |
|---------------------|---|--------------------------------------------------------------------|
| Acute oral toxicity | : | Acute toxicity estimate: 2,512 mg/kg<br>Method: Calculation method |
|---------------------|---|--------------------------------------------------------------------|

#### Components:

##### **Oxyclozanide:**

|                     |   |                                                                  |
|---------------------|---|------------------------------------------------------------------|
| Acute oral toxicity | : | LD50 (Rat): 3,519 mg/kg<br>Target Organs: Central nervous system |
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Acute toxicity (other routes of administration) : LDLo (sheep): 10 mg/kg  
Application Route: Intravenous

### Silicic acid, aluminum salt:

Acute oral toxicity : LD50 (Rat, female): > 2,000 mg/kg  
Method: OECD Test Guideline 423  
Assessment: The substance or mixture has no acute oral toxicity

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

### 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.

#### Silicic acid, aluminum salt:

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

#### Levamisole hydrochloride:

Remarks : No data available

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### Citric acid:

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

### Serious eye damage/eye irritation

Causes serious eye damage.

### Components:

#### Oxyclozanide:

|         |                                       |
|---------|---------------------------------------|
| Remarks | : Not classified due to lack of data. |
|---------|---------------------------------------|

#### Silicic acid, aluminum salt:

|         |                                                  |
|---------|--------------------------------------------------|
| Species | : Chicken eye                                    |
| Method  | : Chorioallantoic membrane vascularization assay |
| Result  | : Irreversible effects on the eye                |

#### Levamisole hydrochloride:

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

### Citric acid:

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

### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

### Components:

#### Oxyclozanide:

|                    |                                       |
|--------------------|---------------------------------------|
| Routes of exposure | : Dermal                              |
| Remarks            | : Not classified due to lack of data. |

#### Silicic acid, aluminum salt:

|                    |                                 |
|--------------------|---------------------------------|
| Test Type          | : Local lymph node assay (LLNA) |
| Routes of exposure | : Skin contact                  |
| Species            | : Mouse                         |
| Method             | : OECD Test Guideline 429       |
| Result             | : negative                      |

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### 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)<br>Result: negative<br><br>Test Type: Chromosomal aberration<br>Test system: Human lymphocytes<br>Result: positive<br><br>Test Type: Mouse Lymphoma<br>Result: positive               |
| Genotoxicity in vivo                | : Test Type: Micronucleus test<br>Species: Mouse<br>Application Route: Oral<br>Result: negative<br><br>Test Type: unscheduled DNA synthesis assay<br>Species: Rat<br>Cell type: Liver cells<br>Application Route: Oral<br>Result: negative |
| Germ cell mutagenicity - Assessment | : Weight of evidence does not support classification as a germ cell mutagen.                                                                                                                                                               |

#### Silicic acid, aluminum salt:

|                       |                                                                                                                                                                                                                       |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: Chromosome aberration test in vitro<br>Result: negative<br>Remarks: Based on data from similar materials                   |
| Genotoxicity in vivo  | : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative<br>Remarks: Based on data from similar materials |

### Levamisole hydrochloride:

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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.

#### Silicic acid, aluminum salt:

Species : Rat  
Application Route : Ingestion  
Exposure time : 104 weeks  
Result : negative  
Remarks : Based on data from similar materials

#### 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

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|             |                                                                                                                                                          |
|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>IARC</b> | No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. |
| <b>OSHA</b> | No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.                                 |
| <b>NTP</b>  | No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.                 |

### Reproductive toxicity

Suspected of damaging the unborn child.

### Components:

#### **Oxyclozanide:**

|                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility         | : Test Type: Two-generation reproduction toxicity study<br>Species: Rat, male and female<br>Application Route: Oral<br>General Toxicity Parent: NOAEL: 25 - 35 mg/kg body weight<br>Symptoms: Reduced body weight, No effects on embryofetal and postnatal development.<br>Result: No effects on fertility.<br><br>Test Type: Two-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Oral<br>General Toxicity Parent: LOAEL: 75 - 100 mg/kg body weight<br>Symptoms: Reduced body weight, No effects on embryofetal and postnatal development.<br>Result: No effects on fertility.<br><br>Test Type: Two-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Oral<br>Early Embryonic Development: LOAEL: 75 - 100 mg/kg body weight<br>Result: No fetotoxicity., No teratogenic effects.<br><br>Test Type: One-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Oral<br>General Toxicity Parent: LOAEL: 80 - 160 mg/kg body weight<br>Result: No fetotoxicity., No teratogenic effects., No effects on fertility. |
| Effects on fetal development | : Test Type: Development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 200 mg/kg body weight<br>Result: No fetotoxicity., No teratogenic effects.<br><br>Test Type: Development                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

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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 : Suspected of damaging the unborn child.

### Silicic acid, aluminum salt:

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

### 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 fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 20 mg/kg body weight  
Result: Fetotoxicity.

Test Type: Embryo-fetal 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 fetal development : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

### STOT-single exposure

May cause damage to organs (Central nervous system) if swallowed.

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|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
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### Components:

#### **Oxylozanide:**

|                    |                               |
|--------------------|-------------------------------|
| Routes of exposure | : Oral                        |
| Target Organs      | : Central nervous system      |
| Assessment         | : May cause damage to organs. |

#### **Citric acid:**

|            |                                     |
|------------|-------------------------------------|
| Assessment | : May cause respiratory irritation. |
|------------|-------------------------------------|

### **STOT-repeated exposure**

May cause damage to organs (Brain, Liver) through prolonged or repeated exposure.  
May cause damage to organs (Blood, Testis) through prolonged or repeated exposure if swallowed.

### Components:

#### **Oxylozanide:**

|               |                                                                      |
|---------------|----------------------------------------------------------------------|
| 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:

#### **Oxylozanide:**

|                   |                                       |
|-------------------|---------------------------------------|
| 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 |

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### Silicic acid, aluminum salt:

Species : Rat  
NOAEL : > 100 mg/kg  
Application Route : Ingestion  
Exposure time : 104 Weeks  
Remarks : Based on data from similar materials

### 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, hypo-

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## Levamisole (6.5%) / Oxytoclozanide (13%) For- mulation

|                |                              |                               |                                                                   |
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|----------------|------------------------------|-------------------------------|-------------------------------------------------------------------|

||

tension

### SECTION 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

##### **Oxytoclozanide:**

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

##### **Silicic acid, aluminum salt:**

##### **Ecotoxicology Assessment**

Chronic aquatic toxicity : No toxicity at the limit of solubility.

##### **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:

##### **Oxytoclozanide:**

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

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### Bioaccumulative potential

#### Components:

##### **Oxyclozanide:**

|                                        |   |                                                           |
|----------------------------------------|---|-----------------------------------------------------------|
| Partition coefficient: n-octanol/water | : | log Pow: 3.99<br>pH: 7<br>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<br>Method: OECD Test Guideline 106 |
|-----------------------------------------------|---|--------------------------------------------------|

### Other adverse effects

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

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

## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### **UNRTDG**

|                           |   |                                                                       |
|---------------------------|---|-----------------------------------------------------------------------|
| UN number                 | : | UN 3082                                                               |
| Proper shipping name      | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(oxyclozanide) |
| Class                     | : | 9                                                                     |
| Packing group             | : | III                                                                   |
| Labels                    | : | 9                                                                     |
| Environmentally hazardous | : | yes                                                                   |

#### **IATA-DGR**

|                      |   |                                                                       |
|----------------------|---|-----------------------------------------------------------------------|
| UN/ID No.            | : | UN 3082                                                               |
| Proper shipping name | : | Environmentally hazardous substance, liquid, n.o.s.<br>(Oxyclozanide) |
| Class                | : | 9                                                                     |

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Packing group : III  
Labels : Miscellaneous  
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 Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Domestic regulation

#### 49 CFR

UN/ID/NA number : UN 3082  
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s. (Oxyclozanide)  
Class : 9  
Packing group : III  
Labels : CLASS 9  
ERG Code : 171  
Marine pollutant : yes(Oxyclozanide)  
Remarks : Above applies only to containers over 119 gallons or 450 liters.  
Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

### 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.

## SECTION 15. REGULATORY INFORMATION

### CERCLA Reportable Quantity

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

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### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Reproductive toxicity  
Specific target organ toxicity (single or repeated exposure)  
Serious eye damage or eye irritation

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### US State Regulations

#### Pennsylvania Right To Know

|                             |            |
|-----------------------------|------------|
| Water                       | 7732-18-5  |
| Oxyclozanide                | 2277-92-1  |
| Silicic acid, aluminum salt | 1335-30-4  |
| Levamisole hydrochloride    | 16595-80-5 |
| Sodium hydroxide            | 1310-73-2  |

#### California List of Hazardous Substances

|                             |           |
|-----------------------------|-----------|
| Silicic acid, aluminum salt | 1335-30-4 |
|-----------------------------|-----------|

#### California Permissible Exposure Limits for Chemical Contaminants

|                             |           |
|-----------------------------|-----------|
| Silicic acid, aluminum salt | 1335-30-4 |
|-----------------------------|-----------|

#### The ingredients of this product are reported in the following inventories:

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

## SECTION 16. OTHER INFORMATION

### Further information

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## Levamisole (6.5%) / Oxyclozanide (13%) Formulation

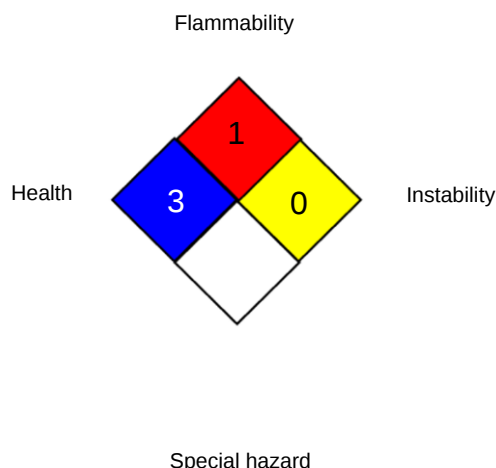
Version  
3.0

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### NFPA 704:



### HMIS® IV:

|                 |   |   |
|-----------------|---|---|
| HEALTH          | * | 3 |
| FLAMMABILITY    |   | 1 |
| PHYSICAL HAZARD |   | 0 |

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Full text of other abbreviations

NIOSH REL : USA. NIOSH Recommended Exposure Limits  
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable

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Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; 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

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 07/06/2024

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

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.

US / Z8