

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

Version 3.1 Revision Date: 30.09.2023 SDS Number: 10857713-00005 Date of last issue: 04.04.2023
Date of first issue: 29.09.2022

Section 1: Identification

Product name : Levamisole (6.5%) / Oxyclozanide (13%) Formulation

Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800 CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

Section 2: Hazard identification

GHS Classification

Serious eye damage/eye irritation : Category 1

Respiratory sensitisation : Category 1

Skin sensitisation : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - single exposure (Oral) : Category 2 (Central nervous system)

Specific target organ toxicity - repeated exposure : Category 2 (Brain, Liver)


Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Blood, Testis)

Hazardous to the aquatic environment - chronic hazard : Category 2

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GHS label elements

- Hazard pictograms : 
- Signal word : Danger
- Hazard statements : H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
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 prolonged or repeated exposure if swallowed.
H411 Toxic to aquatic life with long lasting effects.
- 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 vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P284 Wear respiratory protection.
- Response:**
P302 + P352 IF ON SKIN: Wash with plenty of water.
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
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/ doctor.
P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.
P391 Collect spillage.

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Storage:

P405 Store locked up.

Disposal:

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

Other hazards which do not result in classification

None known.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
oxyclozanide	2277-92-1	>= 10 -< 20
Silicic acid, aluminum salt	1335-30-4	>= 3 -< 10
levamisole hydrochloride	16595-80-5	>= 2.5 -< 10
Citric acid	77-92-9	>= 1 -< 10
Sodium metabisulphite	7681-57-4	>= 0.1 -< 1

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.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
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.
If easy to do, remove contact lens, if worn.
Get medical attention immediately.
- If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.
- Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.
Causes serious eye damage.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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Suspected of damaging the unborn child.
 May cause damage to organs if swallowed.
 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
 Alcohol-resistant foam
 Carbon dioxide (CO₂)
 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
 Chlorine compounds
 Nitrogen oxides (NO_x)

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
 Use water spray to cool unopened containers.
 Remove undamaged containers from fire area if it is safe to do so.
 Evacuate area.

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
 Use personal protective equipment.

Hazchem Code : 3Z

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
 Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.
 Prevent further leakage or spillage if safe to do so.
 Prevent spreading over a wide area (e.g. by containment or oil barriers).
 Retain and dispose of contaminated wash water.
 Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Soak up with inert absorbent material.
 For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.

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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 vapours.
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.
- 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.
- Conditions for safe storage : Keep in properly labelled 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

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of)	Control parameters / Permissible	Basis
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SAFETY DATA SHEET



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		exposure)	concentration	
oxyclozanide	2277-92-1	TWA	0.4 mg/m ³ (OEB 2)	Internal
Silicic acid, aluminum salt	1335-30-4	WES-TWA	5 mg/m ³ (Aluminium)	NZ OEL
levamisole hydrochloride	16595-80-5	TWA	20 µg/m ³ (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	200 µg/100 cm ²	Internal
Sodium metabisulphite	7681-57-4	WES-TWA	5 mg/m ³	NZ OEL
	Further information: Skin sensitiser, Respiratory sensitiser			
		TWA	5 mg/m ³	ACGIH

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type
Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.
Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

Section 9: Physical and chemical properties

Appearance : suspension

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

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Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

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

Exposure routes : 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

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

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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

Sodium metabisulphite:

Acute oral toxicity : LD50 (Rat): 1,540 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): > 5.5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on data from similar materials

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

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levamisole hydrochloride:

Remarks : No data available

Citric acid:

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

Sodium metabisulphite:

Result : Skin irritation
Remarks : Based on national or regional regulation.

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

Sodium metabisulphite:

Species : Rabbit
Result : Irreversible effects on the eye
Method : OECD Test Guideline 405

Respiratory or skin sensitisation**Skin sensitisation**

May cause an allergic skin reaction.

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mulation**

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Respiratory sensitisation

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components:**oxyclozanide:**

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

Silicic acid, aluminum salt:

Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Method : OECD Test Guideline 429
Result : negative

levamisole hydrochloride:

Remarks : No data available

Sodium metabisulphite:

Assessment : Probability or evidence of skin sensitisation in humans
Remarks : Based on national or regional regulation.

Assessment : May cause sensitisation by inhalation.
Remarks : Based on national or regional regulation.

Chronic toxicity**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

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mulation**

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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.

Silicic acid, aluminum salt:

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

Test Type: Chromosome aberration test in vitro
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

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

Sodium metabisulphite:

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- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
- Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
- Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo
cytogenetic assay)
Species: Mouse
Application Route: Subcutaneous
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

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

Sodium metabisulphite:

Species : Mouse
Application Route : Ingestion
Exposure time : 24 Months
Result : negative

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Remarks : Based on data from similar materials

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

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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 foetal development : Test Type: Embryo-foetal 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 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

Sodium metabisulphite:

Effects on fertility : Test Type: Three-generation study
 Species: Rat
 Application Route: Ingestion
 Result: negative

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Effects on foetal development : Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Ingestion
Result: negative

STOT - single exposure

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

Components:

oxyclozanide:

Exposure routes : 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:

oxyclozanide:

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:

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

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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

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

Sodium metabisulphite:

Species : Rat
NOAEL : 110 mg/kg
LOAEL : 220 mg/kg
Application Route : Ingestion
Exposure time : 104 Weeks

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Aspiration toxicity

Not classified based on available information.

Components:**oxyclozanide:**

Not applicable

Experience with human exposure**Components:****oxyclozanide:**

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

levamisole hydrochloride:

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

Section 12: Ecological information**Ecotoxicity****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

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

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Citric acid:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 1,535 mg/l
aquatic invertebrates Exposure time: 24 h

Sodium metabisulphite:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 178 mg/l
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 89 mg/l
aquatic invertebrates Exposure time: 48 h

Toxicity to algae/aquatic : ErC50 (Desmodesmus subspicatus (green algae)): 43.8 mg/l
plants Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): 33.3 mg/l
Exposure time: 72 h

Toxicity to fish (Chronic tox- : NOEC (Danio rerio (zebra fish)): >= 316 mg/l
icity) Exposure time: 34 d
Method: OECD Test Guideline 210
Remarks: Based on data from similar materials

Toxicity to daphnia and other : NOEC (Daphnia magna (Water flea)): >= 10 mg/l
aquatic invertebrates (Chron- Exposure time: 21 d
ic toxicity)

Toxicity to microorganisms : EC10 (Pseudomonas putida): 30.8 mg/l
Exposure time: 17 h

Persistence and degradability**Components:****oxyclozanide:**

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

Citric acid:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 97 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

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

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.1	30.09.2023	10857713-00005	Date of first issue: 29.09.2022

Bioaccumulative potential

Components:

oxyclozanide:

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

Citric acid:

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

Mobility in soil

Components:

oxyclozanide:

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

Other adverse effects

No data available

Section 13: Disposal considerations

Disposal methods

Waste from residues : Do not dispose of waste into sewer.
 Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
 If not otherwise specified: Dispose of as unused product.

Section 14: Transport information

International Regulations

UNRTDG

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

IATA-DGR

UN/ID No. : UN 3082
 Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.

**Levamisole (6.5%) / Oxyclozanide (13%) For-
mulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.1	30.09.2023	10857713-00005	Date of first issue: 29.09.2022

(oxyclozanide)

Class : 9
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.

National Regulations**NZS 5433**

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

Class : 9
Packing group : III
Labels : 9
Hazchem Code : 3Z
Marine pollutant : no

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**Safety, health and environmental regulations/legislation specific for the substance or mixture****HSNO Approval Number**

HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard

**Levamisole (6.5%) / Oxyclozanide (13%) For-
mulation**

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HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

Section 16: Other information

Revision Date : 30.09.2023

Further information

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

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect

**Levamisole (6.5%) / Oxyclozanide (13%) For-
mulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
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Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

NZ / EN