

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



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

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.0	14.04.2025	10858468-00010	Date of first issue: 29.09.2022

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

1.1 Product identifier

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

Other means of identification : COOPERS NILZAN LV ORAL DRENCH (36089)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Serious eye damage, Category 1	H318: Causes serious eye damage.
Reproductive toxicity, Category 2	H361d: Suspected of damaging the unborn child.
Specific target organ toxicity - single exposure, Category 2	H371: May cause damage to organs.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
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)

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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.
H373 May cause damage to organs through prolonged or repeated exposure.
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements

:

Prevention:

P201 Obtain special instructions before use.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

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.
P391 Collect spillage.

Hazardous components which must be listed on the label:

oxyclozanide
Silicic acid, aluminum salt
levamisole hydrochloride

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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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
oxyclozanide	2277-92-1 218-904-0	Repr. 2; H361d STOT SE 2; H371 (Central nervous system) STOT RE 2; H373 (Brain, Liver) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	>= 10 - < 20
Silicic acid, aluminum salt	1335-30-4 215-628-2	Eye Dam. 1; H318	>= 3 - < 10
levamisole hydrochloride	16595-80-5 240-654-6	Acute Tox. 3; H301 Repr. 2; H361d STOT RE 2; H373 (Blood, Testis) Aquatic Chronic 3; H412	>= 3 - < 10
Citric acid	77-92-9 201-069-1 607-750-00-3	Eye Irrit. 2; H319 STOT SE 3; H335	>= 1 - < 10

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,

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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 | : | 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. |

4.2 Most important symptoms and effects, both acute and delayed

- | | | |
|-------|---|--|
| Risks | : | Causes serious eye damage.
Suspected of damaging the unborn child.
May cause damage to organs.
May cause damage to organs through prolonged or repeated exposure. |
|-------|---|--|

4.3 Indication of any immediate medical attention and special treatment needed

- | | | |
|-----------|---|---|
| Treatment | : | Treat symptomatically and supportively. |
|-----------|---|---|

SECTION 5: Firefighting measures

5.1 Extinguishing media

- | | | |
|--------------------------------|---|--|
| Suitable extinguishing media | : | Water spray
Alcohol-resistant foam
Carbon dioxide (CO ₂)
Dry chemical |
| Unsuitable extinguishing media | : | None known. |

5.2 Special hazards arising from the substance or mixture

- | | | |
|---------------------------------------|---|--|
| Specific hazards during fire-fighting | : | Exposure to combustion products may be a hazard to health. |
|---------------------------------------|---|--|

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Hazardous combustion products : Carbon oxides
Chlorine compounds
Nitrogen oxides (NOx)

5.3 Advice for firefighters

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

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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

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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.
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. |

7.2 Conditions for safe storage, including any incompatibilities

- | | | |
|---|---|---|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations. |
| Advice on common storage | : | Do not store with the following product types:
Strong oxidizing agents
Gases |

7.3 Specific end use(s)

- | | | |
|-----------------|---|-------------------|
| Specific use(s) | : | No data available |
|-----------------|---|-------------------|

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Oxyclozanide	2277-92-1	TWA	0.4 mg/m3 (OEB 2)	Internal

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Silicic acid, aluminium salt	1335-30-4	TWA	2 mg/m ³ (Aluminium)	FOR-2011-12-06-1358
levamisole hydrochloride	16595-80-5	TWA	20 µg/m ³ (OEB 3)	Internal
Further information: Skin				
		Wipe limit	200 µg/100 cm ²	Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
Silicic acid, aluminum salt	Workers	Ingestion	Long-term systemic effects	3 mg/m ³

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

Substance name	Environmental Compartment	Value
Citric acid	Fresh water	0,44 mg/l
	Marine water	0,044 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	34,6 mg/kg dry weight (d.w.)
	Marine sediment	3,46 mg/kg dry weight (d.w.)
	Soil	33,1 mg/kg dry weight (d.w.)
Silicic acid, aluminum salt	Fresh water	4,1 mg/l
	Freshwater - intermittent	25 mg/l
	Marine water	0,082 mg/l

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/face 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

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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 NS EN 143
Filter type	:	Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	suspension
Colour	:	yellow
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Viscosity	:	
Viscosity, kinematic	:	No data available

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Solubility(ies)
Water solubility : No data available

Partition coefficient: n-
octanol/water : Not applicable

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics
Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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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

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

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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

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
Method : OECD Test Guideline 405

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||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.

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

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
Genotoxicity in vivo	Test Type: Mouse Lymphoma Result: positive
	Test Type: Micronucleus test Species: Mouse Application Route: Oral Result: negative
	Test Type: unscheduled DNA synthesis assay Species: Rat Cell type: Liver cells

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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
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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.

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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

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

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		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	:	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

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	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

May cause damage to organs.

Components:

oxytoclozanide:

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

Citric acid:

Assessment	: May cause respiratory irritation.
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STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

oxytoclozanide:

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.

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Repeated dose toxicity

Components:

oxytocanide:

Species	: Rat
NOAEL	: 9 mg/kg
LOAEL	: 44,5 mg/kg
Application Route	: Oral
Exposure time	: 3 Months
Target Organs	: Brain, Liver, spleen, Adrenal gland
Symptoms	: Liver effects

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

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

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|| 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

|| Not classified based on available information.

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

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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 : EC50 (Daphnia magna (Water flea)): 64 mg/l
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 : EC50 (Daphnia magna (Water flea)): 1.535 mg/l
aquatic invertebrates
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- : log Pow: 3,99
octanol/water
pH: 7
Method: OECD Test Guideline 107

Citric acid:

Partition coefficient: n- : log Pow: -1,72
octanol/water

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12.4 Mobility in soil

Components:

oxyclozanide:

Distribution among environmental compartments	:	log Koc: 4,83 Method: OECD Test Guideline 106
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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 0.1% or higher.
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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.
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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. Do not dispose of waste into sewer.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

ADN	:	UN 3082
ADR	:	UN 3082

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RID : UN 3082

IMDG : UN 3082

IATA : UN 3082

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S.
(oxyclozanide)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S.
(oxyclozanide)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S.
(oxyclozanide)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S.
(oxyclozanide)

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

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 9	
ADR	: 9	
RID	: 9	
IMDG	: 9	
IATA	: 9	

14.4 Packing group

ADN
Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

ADR
Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID
Packing group : III
Classification Code : M6
Hazard Identification Number : 90

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Labels : 9

IMDG

Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

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, : Conditions of restriction for the following entries should be considered:

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mixtures and articles (Annex XVII)

REACH - Restrictions on the manufacture, placing on
the market and use of certain dangerous substances,
mixtures and articles (Annex XVII)

Number on list 3

Number on list 75: If you intend to
use this product as tattoo ink, please
contact your vendor.

REACH - Restrictions on the manufacture, placing on
the market and use of certain dangerous substances,
mixtures and articles (Annex XVII)

Substance(s) or mixture(s) are listed
here according to their appearance
in the regulation, irrespective of their
use/purpose or the conditions of the
restriction. Please refer to the condi-
tions in corresponding Regulation to
determine whether an entry is appli-
cable to the placing on the market or
not.

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 (EU) No 2024/590 on substances that de-
plete the ozone layer

: Not applicable

Regulation (EU) 2019/1021 on persistent organic pollu-
tants (recast)

: Not applicable

Regulation (EU) No 649/2012 of the European Parlia-
ment and the Council concerning the export and import
of dangerous chemicals

: Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of
major-accident hazards involving dangerous substances.

E2

ENVIRONMENTAL
HAZARDS

Quantity 1
200 t

Quantity 2
500 t

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect
pregnant employees against discomfort and injury as a result of the work situation and the
working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of
children and young people.

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

AICS : not determined

DSL : not determined

IECSC : not determined

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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.
H318	: Causes serious eye damage.
H319	: Causes serious eye irritation.
H335	: May cause respiratory 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 Dam.	: Serious eye damage
Eye Irrit.	: Eye irritation
Repr.	: Reproductive toxicity
STOT RE	: Specific target organ toxicity - repeated exposure
STOT SE	: Specific target organ toxicity - single exposure
FOR-2011-12-06-1358	: Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / TWA	: Long term exposure limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - 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;

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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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; 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

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/>

Classification of the mixture:

Eye Dam. 1	H318
Repr. 2	H361d
STOT SE 2	H371
STOT RE 2	H373
Aquatic Chronic 2	H411

Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

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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