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: 06.07.2024 28.09.2024 10858484-00009 Date of first issue: 29.09.2022 5.1

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 Sub-: Veterinary product

stance/Mixture

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 eve damage.

Reproductive toxicity, Category 2 H361d: Suspected of damaging the unborn child.

Specific target organ toxicity - single ex-H371: May cause damage to organs.

posure, Category 2

Specific target organ toxicity - repeated

exposure, Category 2

egory 2

longed or repeated exposure.

H373: May cause damage to organs through pro-

Long-term (chronic) aquatic hazard, Cat-H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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: 06.07.2024 5.1 28.09.2024 10858484-00009 Date of first issue: 29.09.2022

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.

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: 06.07.2024

 5.1
 28.09.2024
 10858484-00009
 Date of first issue: 29.09.2022

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 ad-

vice 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,

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: 06.07.2024 28.09.2024 10858484-00009 Date of first issue: 29.09.2022 5.1

> 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 (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

5.2 Special hazards arising from the substance or mixture

fighting

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

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: 06.07.2024 5.1 28.09.2024 10858484-00009 Date of first issue: 29.09.2022

Hazardous combustion prod: :

ucts

: 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 meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 pro-

tective 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 absor-

bent.

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 deter-

mine 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.

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: 06.07.2024 5.1 28.09.2024 10858484-00009 Date of first issue: 29.09.2022

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 as-

sessment

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 contami-

nated 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	Control parameters	Basis
		of exposure)		
oxyclozanide	2277-92-1	TWA	0.4 mg/m3 (OEB 2)	Internal

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: 06.07.2024

 5.1
 28.09.2024
 10858484-00009
 Date of first issue: 29.09.2022

Silicic acid, alumi- num salt	1335-30-4	OELV - 8 hrs (TWA)	2 mg/m3 (Aluminium)	IE OEL
levamisole hydro- chloride	16595-80-5	TWA	20 μg/m3 (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/m3

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

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: 06.07.2024 5.1 28.09.2024 10858484-00009 Date of first issue: 29.09.2022

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, dis-

posable 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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143

Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : 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

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: 06.07.2024 5.1 28.09.2024 10858484-00009 Date of first issue: 29.09.2022

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.

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: 06.07.2024 5.1 28.09.2024 10858484-00009 Date of first issue: 29.09.2022

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 tox-

icity

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

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: 06.07.2024 5.1 28.09.2024 10858484-00009 Date of first issue: 29.09.2022

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

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: 06.07.2024 5.1 28.09.2024 10858484-00009 Date of first issue: 29.09.2022

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

Test Type: Mouse Lymphoma

Result: positive

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse Application Route: Oral Result: negative

Test Type: unscheduled DNA synthesis assay

Species: Rat Cell type: Liver cells

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: 06.07.2024 5.1 28.09.2024 10858484-00009 Date of first issue: 29.09.2022

Application Route: Oral Result: negative

Germ cell mutagenicity- As-

sessment

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

Carcinogenicity

Not classified based on available information.

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: 06.07.2024 5.1 28.09.2024 10858484-00009 Date of first issue: 29.09.2022

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

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: 06.07.2024 5.1 28.09.2024 10858484-00009 Date of first issue: 29.09.2022

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 develop-

ment

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 - As-

sessment

Suspected of damaging the unborn child.

Silicic acid, aluminum salt:

Effects on foetal develop-

ment

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 develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral

Developmental Toxicity: NOAEL: 20 mg/kg body weight

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: 06.07.2024 5.1 28.09.2024 10858484-00009 Date of first issue: 29.09.2022

Result: Fetotoxicity

Test Type: Embryo-foetal development

Species: Rabbit Application Route: Oral

Developmental Toxicity: LOAEL: 40 mg/kg body weight

Result: Fetotoxicity

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

Citric acid:

Effects on foetal develop-

ment

Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

STOT - single exposure

May cause damage to organs.

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 through prolonged or repeated exposure.

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.

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: 06.07.2024 5.1 28.09.2024 10858484-00009 Date of first issue: 29.09.2022

Repeated dose toxicity

Components:

oxyclozanide:

Species : Rat
NOAEL : 9 mg/kg
LOAEL : 44.5 mg/kg
Application Route : Oral
Exposure time : 3 Months

Target Organs : Brain, Liver, spleen, Adrenal gland

Symptoms : Liver effects

Species : Dog
NOAEL : 5 mg/kg
LOAEL : 25 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Brain, Liver

Symptoms : blood effects, alteration in liver enzymes

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

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: 06.07.2024 28.09.2024 10858484-00009 Date of first issue: 29.09.2022 5.1

Application Route Ingestion Exposure time 10 Days

Aspiration toxicity

Not classified based on available information.

Components:

oxyclozanide: Not applicable

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment The substance/mixture does not contain components consid-

> ered 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:

Symptoms: Nausea, Vomiting, Headache, Dizziness, hypo-Ingestion

tension

SECTION 12: Ecological information

12.1 Toxicity

Components:

oxyclozanide:

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 0.69 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

M-Factor (Acute aquatic tox- : 1

icity)

M-Factor (Chronic aquatic

toxicity)

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: 06.07.2024 5.1 28.09.2024 10858484-00009 Date of first issue: 29.09.2022

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

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-

octanol/water

log Pow: -1.72

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: 06.07.2024 5.1 28.09.2024 10858484-00009 Date of first issue: 29.09.2022

12.4 Mobility in soil

Components:

oxyclozanide:

Distribution among environ:

mental compartments

log Koc: 4.83

Method: OECD Test Guideline 106

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

ADN : UN 3082 ADR : UN 3082 RID : UN 3082

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: 06.07.2024 5.1 28.09.2024 10858484-00009 Date of first issue: 29.09.2022

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
Labels : 9

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: 06.07.2024 5.1 28.09.2024 10858484-00009 Date of first issue: 29.09.2022

IMDG

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

IATA (Cargo)

Packing instruction (cargo : 964

aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen: 964

ger aircraft)

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:

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: 06.07.2024 5.1 28.09.2024 10858484-00009 Date of first issue: 29.09.2022

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.

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 conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or

not. Not applicable

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

Regulation (EC) on substances that deplete the ozone

layer

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

tants (recast)

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import

of dangerous chemicals

REACH - List of substances subject to authorisation : Not applicable

(Annex XIV)

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

Not applicable

Not applicable

Not applicable

Quantity 2

200 t 500 t

Other regulations:

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

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

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: 06.07.2024 5.1 28.09.2024 10858484-00009 Date of first issue: 29.09.2022

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
H319
Causes serious eye damage.
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

IE OEL : Ireland. List of Chemical Agents and Carcinogens with Occu-

pational Exposure Limit Values - Code of Practice, Schedule 1

and 2

IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL

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: 06.07.2024 5.1 28.09.2024 10858484-00009 Date of first issue: 29.09.2022

- 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; 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:

Classification procedure:

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

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

IE / EN