SAFETY DATA SHEET

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

Version	Revision Date:	SDS Number:	Date of last issue: 2024/07/06
7.1	2024/09/28	10857724-00010	Date of first issue: 2022/09/29

1. PRODUCT AND COMPANY IDENTIFICATION

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

Supplier's company name, address and phone number

Company name of supplier	:	MSD
Address	:	Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone	:	048-588-8411
E-mail address	:	EHSDATASTEWARD@msd.com
Emergency telephone number	:	+1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use	:	Veterinary product
Restrictions on use	:	Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Serious eye damage/eye irritation	:	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)
Short-term (acute) aquatic hazard	:	Category 2
Long-term (chronic) aquatic hazard	:	Category 2

GHS label elements

Hazard pictograms :

Signal word : Danger

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

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.

oxyclozanide	2277-92-1	>= 10 - < 20	9-1297
Silicic acid, aluminum salt	1335-30-4	>= 1 - < 10	1-26
levamisole hydrochloride	16595-80-5	>= 1 - < 10	-
Citric acid	77-92-9	>= 1 - < 10	2-1318
Tetrasodium ethylenediaminetetraacetate	64-02-8	>= 0.1 - < 1	2-1265

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	:	Causes serious eye damage. 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.

5. FIREFIGHTING 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 (NOx)
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.

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. 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.

7. HANDLING AND STORAGE

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.
Avoidance of contact	:	Oxidizing agents
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.

Storage

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
Packaging material	:	Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Concentration standard / Permissible concentration	Basis

oxyclozanide	2277-92-1	TWA	0.4 mg/m3 (OEB 2)	Internal
levamisole hydrochloride	16595-80-5	TWA	20 µg/m3 (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	200 µg/100 cm²	Internal

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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.

9. 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
Boiling point, initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Lower explosion limit and upper explosion limit / flammability limit		
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Evaporation rate	:	No data available
Auto-ignition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Vapour pressure	:	No data available
Density and / or relative density		
Relative density	:	No data available
Density	:	No data available
Relative vapour density	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available

Particle characteristics
Particle size : Not applicable

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.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 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 Method: OECD Test Guideline 402 Assessment: The substance or mixture has no acute dermal toxicity

Tetrasodium ethylenediaminetetraacetate:

Acute oral toxicity	:	LD50 (Rat): 1,780 mg/kg Method: OECD Test Guideline 401
Acute inhalation toxicity	:	LC50 (Rat): > 1 mg/l Exposure time: 6 h Test atmosphere: dust/mist 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

levamisole hydrochloride:

Remarks	:	No data available

Citric acid:

Species	:	Rabbit
Method	:	OECD Test Guideline 404

Result : No skin irritation

Tetrasodium ethylenediaminetetraacetate:

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

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

oxyclozanide:

Remarks : Not classified due to lack of data.

Silicic acid, aluminum salt:

Species : Chicken eye
Method : Chorioallantoic membrane vascularization assay

Result : Irreversible effects on the eye

levamisole hydrochloride:

Remarks : No data available

Citric acid:

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

Tetrasodium ethylenediaminetetraacetate:

Result : Irreversible effects on the eye
Remarks : Based on national or regional regulation.

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

Tetrasodium ethylenediaminetetraacetate:

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative
Remarks	:	Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:

oxyclozanide:

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

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

Tetrasodium ethylenediaminetetraacetate:

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

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
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

Tetrasodium ethylenediaminetetraacetate:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	103 weeks
Result	:	negative
Remarks	:	Based on data from similar materials

Species	:	Mouse
Application Route	:	Ingestion
Exposure time	:	103 weeks
Result	:	negative
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 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

Tetrasodium ethylenediaminetetraacetate:

Effects on fertility : Test Type: Four-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
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.

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.

Tetrasodium ethylenediaminetetraacetate:

Exposure routes	:	inhalation (dust/mist/fume)
Target Organs	:	Respiratory Tract
Assessment	:	Shown to produce significant health effects in animals at concentrations of >0.02 to 0.2 mg/l/6h/d.

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
Application Route	:	Ingestion
Exposure time	:	10 Days

Tetrasodium ethylenediaminetetraacetate:

Species	:	Mouse
NOAEL	:	>= 938 mg/kg
Application Route	:	Ingestion
Exposure time	:	103 Weeks
Remarks	:	Based on data from similar materials

Species	:	Rat
LOAEL	:	0.03 mg/l
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	4 Weeks
Remarks	:	Based on data from similar materials

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

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

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

Tetrasodium ethylenediaminetetraacetate:

Toxicity to fish	:	LC50 (Lepomis macrochirus (Bluegill sunfish)): 121 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 140 mg/l Exposure time: 48 h Method: DIN 38412 Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	:	NOEC (Desmodesmus subspicatus (green algae)): 100 mg/l Exposure time: 72 h Method: Directive 67/548/EEC, Annex V, C.3.
Toxicity to fish (Chronic toxicity)	:	NOEC (Danio rerio (zebra fish)): > 25.7 mg/l Exposure time: 35 d Method: OECD Test Guideline 210 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 25 mg/l Exposure time: 21 d Remarks: Based on data from similar materials
Toxicity to microorganisms	:	EC10: > 1,000 mg/l Exposure time: 30 min Method: ISO 8192

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

Tetrasodium ethylenediaminetetraacetate:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 0 - 10 %
Exposure time: 28 d
Method: OECD Test Guideline 301E
Remarks: Based on data from similar materials

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

Tetrasodium ethylenediaminetetraacetate:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 1.8

Mobility in soil

Components:

oxyclozanide:

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

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

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

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. (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

Refer to section 15 for specific national regulation.

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.

ERG Code : 171

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Priority Assessment Chemical Substance

Chemical name	Number
Sodium salt of 2,2',2'',2'''-(ethane-1,2-diyldinitrilo)tetraacetic acid	268

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
Water-soluble aluminum salts	>=1 - <10	-
levamisole hydrochloride	>=1 - <10	From April 1st, 2025

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
Aluminium and its water-soluble salts	-
levamisole hydrochloride	From April 1st, 2025

Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2)

Not applicable

Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)
Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law
Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation	:	Noxious liquid substance(Category Z)
Pack transportation	:	Classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

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

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

16. OTHER INFORMATION

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

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	:	yyyy/mm/dd

Full text of other abbreviations

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 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; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Sub-

stances 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.

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