

Oxyclozanide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	14.04.2025	2784866-00013	Date of first issue: 30.05.2018

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Oxyclozanide Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.



GHS Classification

Reproductive toxicity : Category 2

Short-term (acute) aquatic hazard : Category 2

Long-term (chronic) aquatic hazard : Category 2

GHS label elements

Hazard pictograms :  

Signal word : Warning

Hazard statements : H361d Suspected of damaging the unborn child.
H411 Toxic to aquatic life with long lasting effects.

Oxyclozanide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	14.04.2025	2784866-00013	Date of first issue: 30.05.2018

Precautionary statements : **Prevention:**
P203 Obtain, read and follow all safety instructions before use.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P318 IF exposed or concerned, get medical advice.
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)
oxyclozanide	2277-92-1	$\geq 3 - < 5$

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 : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

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 : Suspected of damaging the unborn child.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment

SAFETY DATA SHEET

according to the Globally Harmonized System



Oxyclozanide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	14.04.2025	2784866-00013	Date of first issue: 30.05.2018

Notes to physician : when the potential for exposure exists (see section 8).
: 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 (NO_x)
Metal oxides

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

Oxyclozanide Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 2784866-00013 Date of last issue: 30.09.2023
Date of first issue: 30.05.2018

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

- 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.
Avoid contact with 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
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labelled containers.
Store locked up.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
oxyclozanide	2277-92-1	TWA	0.4 mg/m ³ (OEB 2)	Internal

- Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Laboratory operations do not require special containment.

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

SAFETY DATA SHEET

according to the Globally Harmonized System



Oxyclozanide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	14.04.2025	2784866-00013	Date of first issue: 30.05.2018

- 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.
- 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : liquid
- Colour : transparent, Straw-coloured
- Odour : No data available
- Odour Threshold : No data available
- pH : No data available
- Melting point/freezing point : No data available
- Initial boiling point and boiling range : No data available
- Flash point : No data available
- Evaporation rate : No data available
- Flammability (solid, gas) : Not applicable
- Flammability (liquids) : No data available
- Upper explosion limit / Upper flammability limit : No data available
- Lower explosion limit / Lower flammability limit : No data available
- Vapour pressure : No data available
- Relative vapour density : No data available

SAFETY DATA SHEET

according to the Globally Harmonized System



Oxyclozanide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	14.04.2025	2784866-00013	Date of first issue: 30.05.2018

Relative density	:	No data available
Density	:	No data available
Solubility(ies)	:	
Water solubility	:	completely miscible
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
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
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Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
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SAFETY DATA SHEET

according to the Globally Harmonized System



Oxyclozanide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	14.04.2025	2784866-00013	Date of first issue: 30.05.2018

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

Skin corrosion/irritation

Not classified based on available information.

Components:

oxyclozanide:

Remarks : Not classified due to lack of data.

Serious eye damage/eye irritation

Not classified based on available information.

Components:

oxyclozanide:

Remarks : Not classified due to lack of data.

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.

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

SAFETY DATA SHEET

according to the Globally Harmonized System



Oxyclozanide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	14.04.2025	2784866-00013	Date of first issue: 30.05.2018

	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.

Carcinogenicity

Not classified based on available information.

Components:

oxyclozanide:

Remarks	: Not classified due to lack of data.
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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
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SAFETY DATA SHEET

according to the Globally Harmonized System



Oxyclozanide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	14.04.2025	2784866-00013	Date of first issue: 30.05.2018

		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.

STOT - single exposure

Not classified based on available information.

Components:

oxyclozanide:

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

STOT - repeated exposure

Not classified based on available information.

Components:

oxyclozanide:

Target Organs	:	Brain, Liver
Assessment	:	May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

oxyclozanide:

SAFETY DATA SHEET

according to the Globally Harmonized System



Oxyclozanide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	14.04.2025	2784866-00013	Date of first issue: 30.05.2018

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

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
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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
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M-Factor (Acute aquatic toxicity)	: 1
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M-Factor (Chronic aquatic toxicity)	: 1
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SAFETY DATA SHEET

according to the Globally Harmonized System



Oxyclozanide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	14.04.2025	2784866-00013	Date of first issue: 30.05.2018

Persistence and degradability

Components:

oxyclozanide:

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

Components:

oxyclozanide:

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

Components:

oxyclozanide:

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

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

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

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
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SAFETY DATA SHEET

according to the Globally Harmonized System



Oxyclozanide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	14.04.2025	2784866-00013	Date of first issue: 30.05.2018

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 IMO instruments

Not applicable for product as supplied.

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.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 14.04.2025

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/>

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

SAFETY DATA SHEET

according to the Globally Harmonized System



Oxyclozanide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	14.04.2025	2784866-00013	Date of first issue: 30.05.2018

Date format : dd.mm.yyyy

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 Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

IN / EN