SAFETY DATA SHEET

Oxyclozanide Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

   Product name : Oxyclozanide Formulation

   Manufacturer or supplier’s details
   Company : MSD
   Address : JL Raya Pandaan KM. 48
             Pandaan, Jawa Timur - Indonesia
   Telephone : 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

2. HAZARDS IDENTIFICATION

   GHS Classification
   Reproductive toxicity : 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.
   Precautionary statements : Prevention:
                            P201 Obtain special instructions before use.
                            P202 Do not handle until all safety precautions have been read
                                 and understood.
                            P273 Avoid release to the environment.
                            P280 Wear protective gloves/ protective clothing/ eye protec-
                                 tion/ face protection.
   Response:
   P308 + P313 IF exposed or concerned: Get medical advice/
                                  attention.
   P391 Collect spillage.
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Version 1.5  Revision Date: 2020/10/10  SDS Number: 2784865-00006  Date of last issue: 2020/06/17

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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>oxyclozanide</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>oxyclozanide</td>
<td>2277-92-1</td>
<td>&gt;= 3 -&lt; 10</td>
</tr>
</tbody>
</table>

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 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 firefighting
Hazardous combustion products : Exposure to combustion products may be a hazard to health.
Carbon oxides
Chlorine compounds
Nitrogen oxides (NOx)
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 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.
### 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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>oxyclozanide</td>
<td>2277-92-1</td>
<td>TWA</td>
<td>0.4 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>400 mg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

#### 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.
- 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

**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.
- 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,
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

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

appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
SAFETY DATA SHEET

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Explosive properties : Not explosive

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

Molecular weight : No data available

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.

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
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.
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 embryofetal 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 embryofetal 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.

**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:**
- **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

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

Persistence and degradability

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

Bioaccumulative potential

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

Mobility in soil

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

Other adverse effects
No data available
13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : 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

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.

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use : Not applicable
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information

Date format : yyyy/mm/dd

Full text of other abbreviations

AIC - 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
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.