SAFETY DATA SHEET

Diclazuril (0.25%) Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Diclazuril (0.25%) Formulation

Manufacturer or supplier's details
Company: MSD
Address: 50 Tuas West Drive
Singapore - Singapore 638408
Telephone: +1-908-740-4000
Emergency telephone number: 65 6697 2111 (24/7/365)
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

GHS Classification
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Diclazuril</td>
<td>101831-37-2</td>
<td>&gt;= 0.1 - &lt; 1</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.

In case of skin contact: Wash with soap and water. Get medical attention if irritation persists.

If swallowed: Do not induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: None known.

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: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon 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 spills 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 contain-
ment 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 : Avoid inhalation of vapour or mist. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Take care to prevent spills, waste and minimize release to the environment.
Conditions for safe storage : Keep in properly labelled containers. 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</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>PEL (long term)</td>
<td>10 mg/m3</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Diclazuril</td>
<td>101831-37-2</td>
<td>TWA</td>
<td>30 µg/m3 (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>300 µg/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. 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 con-
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.
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.
  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 : suspension
Colour : No data available
Odour : No data available
Odour Threshold : No data available
10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
SAFETY DATA SHEET

Diclazuril (0.25%) Formulation

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:

Cellulose:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 5.8 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

Diclazuril:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
LD50 (Mouse): > 5,000 mg/kg
LD50 (Dog): > 5,000 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 2.24 mg/l
Acute dermal toxicity: LD50 (Rabbit): > 4,000 mg/kg
Acute toxicity (other routes of administration): LD50 (Mouse): > 5,000 mg/kg
  Application Route: Subcutaneous
  Target Organs: Central nervous system

Skin corrosion/irritation:
Not classified based on available information.

Components:

Diclazuril:
Remarks: Not classified due to lack of data.

Serious eye damage/eye irritation:
Not classified based on available information.
Components:

Diclazuril:
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:

Diclazuril:
Remarks : Not classified due to lack of data.

Germ cell mutagenicity
Not classified based on available information.

Components:

Cellulose:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

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

Diclazuril:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Result: negative

Test Type: unscheduled DNA synthesis assay
Test system: rat hepatocytes
Result: negative

Test Type: Chromosomal aberration
Test system: Human lymphocytes
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow  
Result: negative  

Test Type: Sex-linked recessive lethal test in Drosophila melanogaster (in vivo)  
Result: negative  

Test Type: dominant lethal test  
Species: Mouse  
Result: negative  

Carcinogenicity  
Not classified based on available information.

Components:

Cellulose:  
Species: Rat  
Application Route: Ingestion  
Exposure time: 72 weeks  
Result: negative

Diclazuril:  
Species: Mouse  
Application Route: Oral  
Exposure time: 25 Months  
NOAEL: 3 mg/kg body weight  
LOAEL: 11 mg/kg body weight  
Result: negative

Species: Rat  
Application Route: Oral  
Exposure time: 28 Months  
NOAEL: 4 mg/kg body weight  
LOAEL: 15 mg/kg body weight  
Result: negative

Reproductive toxicity  
Not classified based on available information.

Components:

Cellulose:  
Effects on fertility: Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

Effects on foetal development: Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative
Diclazuril (0.25%) Formulation

Effects on fertility:
- Test Type: Two-generation study
- Species: Rat
- General Toxicity - Parent: NOAEL: 5 mg/kg body weight
- Early Embryonic Development: LOAEL: 20 mg/kg body weight
- Symptoms: Reduced offspring weight gain
- Remarks: Maternal toxicity observed.

Effects on foetal development:
- Test Type: Development
- Species: Rabbit
- Application Route: Oral
- Developmental Toxicity: NOAEL: 80 mg/kg body weight
- Embryo-foetal toxicity: LOAEL: 320 mg/kg body weight
- Symptoms: Early Resorptions / resorption rate, Late Resorptions / resorption rate
- Test Type: Development
- Species: Rat
- Application Route: Oral
- General Toxicity Maternal: LOAEL: 20 mg/kg body weight
- Developmental Toxicity: NOAEL: 5 mg/kg body weight

Reproductive toxicity - Assessment:
- Suspected of damaging the unborn child.

STOT - single exposure
- Not classified based on available information.

STOT - repeated exposure
- Not classified based on available information.

Components:

Diclazuril:
- Target Organs: Liver, Lungs, Lymph nodes
- Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Cellulose:
- Species: Rat
- NOAEL: >= 9,000 mg/kg
- Application Route: Ingestion
- Exposure time: 90 Days

Diclazuril:
- Species: Rat
- NOAEL: 6 mg/kg
- LOAEL: 74 mg/kg
- Application Route: Oral
- Exposure time: 12 Months
- Target Organs: Liver, Lungs, Lymph nodes
Species : Rat  
NOAEL : 4 mg/kg  
LOAEL : 69 mg/kg  
Application Route : Oral  
Exposure time : 3 Months  
Target Organs : Liver

Species : Mouse  
NOAEL : 30 mg/kg  
LOAEL : 60 mg/kg  
Application Route : Oral  
Exposure time : 3 Months  
Target Organs : Liver

Species : Dog  
NOAEL : 20 mg/kg  
LOAEL : 80 mg/kg  
Exposure time : 12 Months

Aspiration toxicity  
Not classified based on available information.

Experience with human exposure

Components:

Diclazuril:  
Ingestion : Symptoms: Diarrhoea

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cellulose:  
Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials

Diclazuril:  
Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.58 mg/l  
Exposure time: 96 h  
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 0.63 mg/l  
Exposure time: 48 h  
Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic plants : EC50 (Selenastrum capricornatum (green algae)): > 1.1 mg/l  
Exposure time: 72 h  
Remarks: No toxicity at the limit of solubility
NOEC (Selenastrum capricornutum (green algae)): 1.1 mg/l
Exposure time: 72 h
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

NOEC (Daphnia magna (Water flea)): 0.16 mg/l
Exposure time: 21 d
Remarks: No toxicity at the limit of solubility

**Persistence and degradability**

**Components:**

**Cellulose:**
Biodegradability: Result: Readily biodegradable.

**Bioaccumulative potential**

**Components:**

**Diclazuril:**
Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 160

Partition coefficient: n-octanol/water: log Pow: 4.5
pH: 7

**Mobility in soil**
No data available

**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: Not applicable
- Proper shipping name: Not applicable
- Class: Not applicable
- Subsidiary risk: Not applicable
- Packing group: Not applicable
- Labels: Not applicable

**IATA-DGR**
- UN/ID No.: Not applicable
### SAFETY DATA SHEET

**Diclazuril (0.25%) Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue: 04.11.2020</th>
<th>Date of first issue: 14.08.2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.4</td>
<td>27.08.2021</td>
<td>6193397-00005</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Proper shipping name**: Not applicable
- **Class**: Not applicable
- **Subsidiary risk**: Not applicable
- **Packing group**: Not applicable
- **Labels**: Not applicable
- **Packing instruction (cargo aircraft)**: Not applicable
- **Packing instruction (passenger aircraft)**: Not applicable

**IMDG-Code**

<table>
<thead>
<tr>
<th>UN number</th>
<th>Proper shipping name</th>
<th>Class</th>
<th>Subsidiary risk</th>
<th>Packing group</th>
<th>Labels</th>
<th>EmS Code</th>
<th>Marine pollutant</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **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**: Not applicable

### 15. REGULATORY INFORMATION

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

- **Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations**: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.
- **Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations**: Not applicable
- **Fire Safety (Petroleum and Flammable Materials) Regulations**: Not applicable

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

<table>
<thead>
<tr>
<th>AICS</th>
<th>DSL</th>
<th>IECSC</th>
</tr>
</thead>
<tbody>
<tr>
<td>not determined</td>
<td>not determined</td>
<td>not determined</td>
</tr>
</tbody>
</table>

### 16. OTHER INFORMATION

**Further information**

Sources of key data used to: Internal technical data, data from raw material SDSs, OECD
SAFETY DATA SHEET

Diclazuril (0.25%) Formulation

Version 1.4
Revision Date: 27.08.2021
SDS Number: 6193397-00005
Date of last issue: 04.11.2020
Date of first issue: 14.08.2020

compile the Safety Data Sheet
Date format: dd.mm.yyyy

Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA: 8-hour, time-weighted average
SG OEL / PEL (long term): Permissible Exposure Level (PEL) Long Term

All other abbreviations are defined in the text.

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.

http://echa.europa.eu/