Section 1: Identification

Product name: Diclazuril (0.25%) Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand
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

Section 2: Hazard 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.

Section 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>&lt; 10</td>
</tr>
<tr>
<td>Diclazuril</td>
<td>101831-37-2</td>
<td>&lt; 3</td>
</tr>
</tbody>
</table>

Section 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.

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.

Section 5: Fire-fighting 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

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.

Section 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 dyeing 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.

Section 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.

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.

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.

Section 8: Exposure controls/personal protection

Components with workplace control parameters
SAFETY DATA SHEET

Diclazuril (0.25%) Formulation

Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
--- | --- | --- | --- | --- |
Cellulose | 9004-34-6 | WES-TWA | 10 mg/m³ | NZ OEL |
 |  | TWA | 10 mg/m³ | ACGIH |
Diclazuril | 101831-37-2 | TWA | 30 µg/m³ (OEB 3) | Internal |
 |  | Wipe limit | 300 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: 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., sleevelts, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

Section 9: Physical and chemical properties

Appearance: suspension
Colour: No data available
Odour: No data available
Odour Threshold: No data available
pH: No data available
Section 10: Stability and reactivity

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reac-
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes: 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.
SAFETY DATA SHEET

Diclazuril (0.25%) Formulation

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.

Chronic toxicity

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

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Cell type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micronucleus test</td>
<td>Mouse</td>
<td>Bone marrow</td>
<td>negative</td>
</tr>
<tr>
<td>Sex-linked recessive lethal test in Drosophila melanogaster (in vivo)</td>
<td></td>
<td></td>
<td>negative</td>
</tr>
<tr>
<td>Dominant lethal test</td>
<td>Mouse</td>
<td></td>
<td>negative</td>
</tr>
</tbody>
</table>

### 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:
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
- Mouse
- Dog

### NOAEL
- 4 mg/kg
- 30 mg/kg
- 20 mg/kg

### LOAEL
- 69 mg/kg
- 60 mg/kg
- 80 mg/kg

### Application Route
- Oral

### Exposure time
- 3 Months

### Target Organs
- Liver

### Aspiration toxicity
Not classified based on available information.

### Experience with human exposure

#### Components:

**Diclazuril:**

**Ingestion:** Symptoms: Diarrhoea

### Section 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 capricornutum (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

Section 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.

Section 14: Transport information

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

NZS 5433
Not regulated as a dangerous good

Section 15: Regulatory information

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

HSNO Approval Number
Not applicable

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

Section 16: Other information

Further information
Date format : dd.mm.yyyy

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
ACGIH / TWA : 8-hour, time-weighted average
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

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
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