SAFETY DATA SHEET

Diclazuril Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Diclazuril Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
   Company : MSD
              20 Spartan Road
              1619 Spartan, South Africa
   Telephone : +27119239300
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

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

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Not a hazardous substance or mixture.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Not a hazardous substance or mixture.

   Additional Labelling
   EUH210 Safety data sheet available on request.

2.3 Other hazards
   This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
   Dust contact with the eyes can lead to mechanical irritation.
   Contact with dust can cause mechanical irritation or drying of the skin.
   May form explosive dust-air mixture during processing, handling or other means.
SAFETY DATA SHEET  
Diclazuril Formulation

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diclazuril</td>
<td>101831-37-2</td>
<td>Repr. 2; H361d STOT RE 2; H373 (Lungs, Lymph nodes, Liver)</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

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 : If in eyes, rinse well with water. Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.
SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

Unsuitable extinguishing media:
- None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting:
- Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Carbon oxides
- Metal oxides
- Sulphur oxides

5.3 Advice for firefighters

Special protective equipment for firefighters:
- In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:
- Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions:
- Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spills cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up:
- Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling: Do not breathe dust, fume, gas, mist, vapours or spray. 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. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. 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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types: Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s): No data available
SECTION 8: Exposure controls/personal protection

8.1 Control parameters

**Occupational Exposure Limits**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<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>

**Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>6,36 mg/m³</td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Acute systemic effects</td>
<td>6,1 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>1,06 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>6,1 mg/kg bw/day</td>
<td></td>
</tr>
</tbody>
</table>

**Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>Sewage treatment plant</td>
<td>100 mg/l</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

**Engineering measures**

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**

**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.

**Hand protection**

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

Skin and body protection

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.

**Respiratory protection**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

**Filter type**: Combined particulates and organic vapour type (A-P)

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

- **Appearance**: pellets
- **Colour**: green-brown
- **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**: Not applicable
- **Flammability (solid, gas)**: May form explosive dust-air mixture during processing, handling or other means.
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapour pressure**: Not applicable
- **Relative vapour density**: Not applicable
- **Relative density**: No data available
- **Density**: No data available
- **Solubility(ies)**
  - **Water solubility**: No data available
- **Partition coefficient: n-octanol/water**: Not applicable
- **Auto-ignition temperature**: No data available
- **Decomposition temperature**: No data available
- **Viscosity**
  - **Viscosity, kinematic**: Not applicable
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information
Flammability (liquids) : No data available
Molecular weight : No data available
Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

10.5 Incompatible materials
Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

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

Acute toxicity
Not classified based on available information.

Components:

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:
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
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:

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:

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:

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
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Diclazuril Formulation

Version: 1.4  Revision Date: 09.04.2021  SDS Number: 6490717-00005  Date of last issue: 07.11.2020
Date of first issue: 01.10.2020

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

SECTION 12: Ecological information

12.1 Toxicity

Components:

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: 0,16 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Remarks: No toxicity at the limit of solubility

12.2 Persistence and degradability
No data available

12.3 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
12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment

**Product:**
Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

**Product:**
Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

**Product**
Waste treatment methods : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

**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

14.1 UN number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.
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Diclazuril Formulation

SECTION 15: Regulatory information

15.1 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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H361d : Suspected of damaging the unborn child.

H373 : May cause damage to organs through prolonged or repeated exposure.

Full text of other abbreviations

Repr. : Reproductive toxicity

STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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 sub-
 Further information

Sources of key data used to compile the Safety Data Sheet:

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.

ZA / EN