1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Diclazuril 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

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
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards which do not result in classification
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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Diclazuril</td>
<td>101831-37-2</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical ad-
vice 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

: 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.

Most important symptoms and effects, both acute and delayed

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

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
  Metal oxides
  Sulphur 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. 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:
- 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.

7. HANDLING AND STORAGE

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.

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 (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>TWA (Mist)</td>
<td>5 mg/m3</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Mist)</td>
<td>10 mg/m3</td>
<td>IN OEL</td>
</tr>
</tbody>
</table>
Diclazuril Formulation

<table>
<thead>
<tr>
<th>Engineering measures</th>
<th>TWA (Inhalable particulate matter)</th>
<th>5 mg/m³</th>
<th>ACGIH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diclazuril</td>
<td>101831-37-2</td>
<td>TWA</td>
<td>30 µg/m³ (OEB 3)</td>
</tr>
<tr>
<td></td>
<td>Wipe limit</td>
<td>300 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

**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**

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

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., 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: pellets

Colour: green-brown
SAFETY DATA SHEET

Diclazuril Formulation

Version 1.4
Revision Date: 07.11.2020
SDS Number: 6490734-00004
Date of last issue: 23.10.2020
Date of first issue: 01.10.2020

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>No data available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

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

White mineral oil (petroleum):
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

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:**

White mineral oil (petroleum):
Species: Rabbit
Result: No skin irritation

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

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

**Components:**

White mineral oil (petroleum):
Species: Rabbit
Result: No eye irritation

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:**

White mineral oil (petroleum):
Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

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

Germ cell mutagenicity
Not classified based on available information.

**Components:**

White mineral oil (petroleum):
Genotoxicity in vitro: 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: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

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:
White mineral oil (petroleum):
Species: Rat
Application Route: Ingestion
Exposure time: 24 Months
Result: negative

Diclazuril:
Species: Mouse
Application Route: Oral
Exposure time: 25 Months
NOAEL: 3 mg/kg body weight
**Diclazuril Formulation**

**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**:

**White mineral oil (petroleum):**

- **Effects on fertility**
  - Test Type: One-generation reproduction toxicity study  
  - Species: Rat  
  - Application Route: Skin contact  
  - Result: negative

- **Effects on foetal development**
  - Test Type: Embryo-foetal 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:

White mineral oil (petroleum):
Species : Rat
LOAEL : 160 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Species : Rat
LOAEL : >= 1 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 4 Weeks
Method : OECD Test Guideline 412

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:

White mineral oil (petroleum):
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity): NOEC: 1,000 mg/l
Exposure time: 28 d
Species: Oncorhynchus mykiss (rainbow trout)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: 1,000 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)

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

Persistence and degradability

Components:

White mineral oil (petroleum):
- Biodegradability: Result: Not readily biodegradable.
- Biodegradation: 31 %
- Exposure time: 28 d

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
- 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 IMO instruments
- Not applicable for product as supplied.
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:

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

16. OTHER INFORMATION

Further information

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

Date format:
- dd.mm.yyyy

Full text of other abbreviations

ACGIH / TWA: USA. ACGIH Threshold Limit Values (TLV)
IN OEL / TWA: India. Permissible levels of certain chemical substances in work environment.
IN OEL / STEL: Time-Weighted Average Concentration (TWA) (8 hrs.)
IN OEL / STEL: Short-term exposure limit STEL (15 min)

ACGIH - 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;
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