# SAFETY DATA SHEET
according to the Hazardous Products Regulations

# Diclazuril (0.25%) Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 09/30/2023 |
|---|---|---|---|
| 1.10 | 02/22/2024 | 6193387-00011 | Date of first issue: 08/14/2020 |

## SECTION 1. IDENTIFICATION

Product name : Diclazuril (0.25%) Formulation
Other means of identification : Vecoxan 2.5 mg/mL Oral Suspension for Lambs and Calves (A011172)

**Manufacturer or supplier's details**

Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Veterinary product
Restrictions on use : Not applicable

## SECTION 2. HAZARDS IDENTIFICATION

**GHS classification in accordance with the Hazardous Products Regulations**

Reproductive toxicity : Category 2

**GHS label elements**

Hazard pictograms :

Signal Word : Warning

Hazard Statements : H361d Suspected of damaging the unborn child.

Precautionary Statements :

**Prevention:**

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

**Response:**

P308 + P313 IF exposed or concerned: Get medical attention.

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents and container to an approved waste disposal plant.

**Other hazards**

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name | Common Name/Synonym | CAS-No. | Concentration (% w/w) |
|---|---|---|---|
| Cellulose | No data available | 9004-34-6 | >= 1 - < 5 * |
| Diclazuril | No data available | 101831-37-2 | >= 0.1 - < 1 * |

* Actual concentration or concentration range is withheld as a trade secret

## 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 : 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.

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

| | | |
|---|---|---|
| fighting<br>Hazardous combustion products | : | Carbon oxides |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment. |

### SECTION 6. ACCIDENTAL RELEASE MEASURES

| | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g., by containment or oil barriers).<br>Retain and dispose of contaminated wash water.<br>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.<br>For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.<br>Clean up remaining materials from spill with suitable absorbent.<br>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.<br>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 vapor or mist.<br>Do not swallow.<br>Avoid contact with eyes.<br>Avoid prolonged or repeated contact with skin.<br>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 labeled containers.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Ingredients with workplace control parameters**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---|---|---|---|---|
| Cellulose | 9004-34-6 | TWA | 10 mg/m³ | CA AB OEL |
| | | TWA (Total dust) | 10 mg/m³ | CA BC OEL |
| | | TWA (respirable dust fraction) | 3 mg/m³ | CA BC OEL |
| | | TWAEV (total dust) | 10 mg/m³ | CA QC 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

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.<br>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.<br>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.<br>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.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>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.<br>If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>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. |

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|---|---|---|
| Appearance | : | suspension |
| Color | : | No data available |
| Odor | : | No data available |
| Odor 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 |
| Vapor pressure | : | No data available |
| Relative vapor density | : | No data available |
| Relative density | : | No data available |
| Density | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Autoignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity | | |
| Viscosity, kinematic | : | No data available |
| Explosive properties | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight | : | No data available |
| Particle size | : | Not applicable |

### SECTION 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. |

### SECTION 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<br>Exposure time: 4 h<br>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<br>Application Route: Subcutaneous<br>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 sensitization**

**Skin sensitization**
Not classified based on available information.

**Respiratory sensitization**
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)<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |

**Diclazuril:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Test system: mouse lymphoma cells<br>Result: negative<br><br>Test Type: unscheduled DNA synthesis assay<br>Test system: rat hepatocytes<br>Result: negative<br><br>Test Type: Chromosomal aberration<br>Test system: Human lymphocytes<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Micronucleus test<br>Species: Mouse<br>Cell type: Bone marrow<br>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**

Suspected of damaging the unborn child.

**Components:**

**Cellulose:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: One-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |
| Effects on fetal development | : | Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Ingestion<br>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 fetal development : Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 80 mg/kg body weight
Embryo-fetal 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: Diarrhea |

## SECTION 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Cellulose:**

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

**Diclazuril:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.58 mg/l<br>Exposure time: 96 h<br>Remarks: No toxicity at the limit of solubility. |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 0.63 mg/l<br>Exposure time: 48 h<br>Remarks: No toxicity at the limit of solubility. |
| Toxicity to algae/aquatic plants | : | EC50 (Selenastrum capricornutum (green algae)): > 1.1 mg/l<br>Exposure time: 72 h<br>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 : Do not dispose of waste into sewer.
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.

**Domestic regulation**

**TDG**
Not regulated as a dangerous good

**Special precautions for user**
Not applicable

## SECTION 15. REGULATORY INFORMATION

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

| | | |
|---|---|---|
| AICS | : | not determined |
| DSL | : | not determined |
| IECSC | : | not determined |

## SECTION 16. OTHER INFORMATION

**Full text of other abbreviations**

| | | |
|---|---|---|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| CA AB OEL | : | Canada. Alberta, Occupational Health and Safety Code (table 2: OEL) |
| CA BC OEL | : | Canada. British Columbia OEL |
| CA QC OEL | : | Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants |
| ACGIH / TWA | : | 8-hour, time-weighted average |
| CA AB OEL / TWA | : | 8-hour Occupational exposure limit |
| CA BC OEL / TWA | : | 8-hour time weighted average |
| CA QC OEL / TWAEV | : | Time-weighted average exposure value |

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 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; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

| | | |
|---|---|---|
| Sources of key data used to compile the Material Safety Data Sheet | : | Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/ |
| Revision Date | : | 02/22/2024 |
| Date format | : | mm/dd/yyyy |

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.

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