

# Diclazuril (0.25%) Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 3.2 22.02.2024 6193396-00010 Date of first issue: 14.08.2020

**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 : MSD

Address : 33 Whakatiki Street - Private Bag 908

Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800

CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

**Section 2: Hazard identification** 

**GHS Classification** 

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 protec-

tion/ face protection.



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Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Other hazards which do not result in classification

None known.

## Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	
Cellulose	9004-34-6	>= 1 -< 10	
Diclazuril	101831-37-2	>= 0.1 -< 1	

#### Section 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 : Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

delaved

: Suspected of damaging the unborn child.

Protection of first-aiders

-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.



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#### 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

Hazardous combustion prod-

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

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, protec- : tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 dyking or other appropriate containment 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 absor-

bent.

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

### Section 7: Handling and storage



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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 as-

sessment

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

Components	CAS-No.	Value type (Form of	Control parameters / Permissible	Basis
		exposure)	concentration	
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



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technologies to control airborne concentrations (e.g., drip-

less 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-

tainment devices).
Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type Hand protection

Particulates type

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, dis-

posable 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

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available



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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

Vapour pressure : No data available

Relative vapour 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

Auto-ignition 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 reac-

tions

Can react with strong oxidizing agents.

Conditions to avoid : None known.
Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.



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products

## **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.



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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



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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 mel-

anogaster (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

Species: Rat

Application Route: Ingestion

Result: negative



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Effects on foetal develop-

ment

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 develop-

ment

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 Resorp-

tions / 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 - As-

sessment

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



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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

## **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:



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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 (Chron-

ic 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.

Empty containers should be taken to an approved waste han-Contaminated packaging

dling site for recycling or disposal.



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If not otherwise specified: Dispose of as unused product.

## **Section 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
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo : Not applicable

aircraft)

Packing instruction (passen- : Not applicable

ger aircraft)

**IMDG-Code** 

**UN** number Not applicable Proper shipping name Not applicable Not applicable Class : Not applicable Subsidiary risk Not applicable Packing group Not applicable Labels Not applicable EmS Code Marine pollutant Not applicable

### 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

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Hazchem Code : Not applicable

### Special precautions for user

Not applicable



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#### **Section 15: Regulatory information**

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

#### **HSNO Approval Number**

HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard

#### **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

Revision Date : 22.02.2024

**Further information** 

Sources of key data used to

compile the Safety Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

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 Atmospher-

ic 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 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 Chemi-



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cal 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

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.

NZ / EN