according to GB/T 16483 and GB/T 17519



# Diclazuril (0.25%) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 2.0 2024/09/28 6193384-00012 Date of first issue: 2020/08/14

#### 1. PRODUCT AND COMPANY 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 : No. 485 Jing Tai Road

Pu Tuo District - Shanghai - China 200331

Telephone : +1-908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

### 2. HAZARDS IDENTIFICATION

## **Emergency Overview**

Appearance:suspensionColour:No data availableOdour:No data available

Not a hazardous substance or mixture.

#### **GHS Classification**

Not a hazardous substance or mixture.

### **GHS label elements**

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

## Physical and chemical hazards

Not classified based on available information.

#### **Health hazards**

Not classified based on available information.

according to GB/T 16483 and GB/T 17519



# Diclazuril (0.25%) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 6193384-00012 2.0 2024/09/28 Date of first issue: 2020/08/14

#### **Environmental hazards**

Not classified based on available information.

Other hazards which do not result in classification

None known.

#### 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

#### 4. FIRST AID MEASURES

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

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 If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

delayed Protection of first-aiders None known.

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.

according to GB/T 16483 and GB/T 17519



# Diclazuril (0.25%) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 2.0 2024/09/28 6193384-00012 Date of first issue: 2020/08/14

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

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

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, 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.

#### 7. HANDLING AND STORAGE

Handling

Technical measures : See Engineering measures under EXPOSURE

according to GB/T 16483 and GB/T 17519



# Diclazuril (0.25%) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 2.0 2024/09/28 6193384-00012 Date of first issue: 2020/08/14

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.

Avoidance of contact : Oxidizing agents

**Storage** 

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

Packaging material : Unsuitable material: None known.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	PC-TWA	10 mg/m3	CN 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., 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 : Particulates type

according to GB/T 16483 and GB/T 17519



# Diclazuril (0.25%) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 2.0 2024/09/28 6193384-00012 Date of first issue: 2020/08/14

Eye/face 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.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Hygiene measures : If exposure to chemical is likely during typical use, provide

eye flushing systems and safety showers close to the work-

ing 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 work-

ng 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 : 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

according to GB/T 16483 and GB/T 17519



# Diclazuril (0.25%) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 2.0 2024/09/28 6193384-00012 Date of first issue: 2020/08/14

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

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 characteristics

Particle size : Not applicable

#### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

according to GB/T 16483 and GB/T 17519



# Diclazuril (0.25%) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 2.0 2024/09/28 6193384-00012 Date of first issue: 2020/08/14

Possibility of hazardous reac- : Can react with strong oxidizing agents.

tions

: None known.: Oxidizing agents

Incompatible materials

Conditions to avoid

Hazardous decomposition

products

No hazardous decomposition products are known.

#### 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 : LD50 (Mouse): > 5,000 mg/kg

administration)

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.

according to GB/T 16483 and GB/T 17519



# Diclazuril (0.25%) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 2.0 2024/09/28 6193384-00012 Date of first issue: 2020/08/14

## 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:** 

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

according to GB/T 16483 and GB/T 17519



# Diclazuril (0.25%) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 2.0 2024/09/28 6193384-00012 Date of first issue: 2020/08/14

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 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

Not classified based on available information.

### **Components:**

#### Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study

according to GB/T 16483 and GB/T 17519



# Diclazuril (0.25%) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 2.0 2024/09/28 6193384-00012 Date of first issue: 2020/08/14

Species: Rat

**Application Route: Ingestion** 

Result: negative

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.

according to GB/T 16483 and GB/T 17519



# Diclazuril (0.25%) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 2.0 2024/09/28 6193384-00012 Date of first issue: 2020/08/14

### 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: RatNOAEL: 4 mg/kgLOAEL: 69 mg/kgApplication Route: OralExposure time: 3 MonthsTarget Organs: Liver

Species : Mouse
NOAEL : 30 mg/kg
LOAEL : 60 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Liver

Species: DogNOAEL: 20 mg/kgLOAEL: 80 mg/kgExposure time: 12 Months

### **Aspiration toxicity**

Not classified based on available information.

#### **Experience with human exposure**

#### Components:

### Diclazuril:

Ingestion : Symptoms: Diarrhoea

according to GB/T 16483 and GB/T 17519



# Diclazuril (0.25%) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 2.0 2024/09/28 6193384-00012 Date of first issue: 2020/08/14

#### 12. ECOLOGICAL INFORMATION

**Ecotoxicity** 

**Components:** 

Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

Diclazuril:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.58 mg/l

Exposure time: 96 h

Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 0.63 mg/l

Exposure time: 48 h

Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic

plants

EC50 (Selenastrum capricornutum (green algae)): > 1.1 mg/l

Exposure time: 72 h

Remarks: No toxicity at the limit of solubility

NOEC (Selenastrum capricornutum (green algae)): 1.1 mg/l

Exposure time: 72 h

Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other :

aquatic invertebrates (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- : log Pow: 4.5

octanol/water pH: 7

according to GB/T 16483 and GB/T 17519



# Diclazuril (0.25%) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 6193384-00012 2.0 2024/09/28 Date of first issue: 2020/08/14

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### Mobility in soil

No data available

#### Other adverse effects

No data available

### 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.

If not otherwise specified: Dispose of as unused product.

#### 14. TRANSPORT INFORMATION

### International Regulations

**UNRTDG** 

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

Environmentally hazardous no

**IATA-DGR** 

Not applicable UN/ID No. Not applicable Proper shipping name Class Not applicable Subsidiary risk Not applicable Packing group Not applicable Not applicable Labels Packing instruction (cargo Not applicable

aircraft)

Packing instruction (passen-Not applicable

ger aircraft)

**IMDG-Code** 

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

Marine pollutant no

according to GB/T 16483 and GB/T 17519



# Diclazuril (0.25%) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 2.0 2024/09/28 6193384-00012 Date of first issue: 2020/08/14

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### **National Regulations**

GB 6944/12268

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

Marine pollutant : no

Special precautions for user

Not applicable

## 15. REGULATORY INFORMATION

#### **National regulatory information**

Law on the Prevention and Control of Occupational Diseases

**Regulations on Safety Management of Hazardous Chemicals** 

Catalogue of Hazardous Chemicals : This product is not listed in the cata-

logue of hazardous chemicals and it does not meet the definition of hazardous chemicals and its principles

of determination.

Identification of Major Hazard Installations for Hazardous Chemicals (GB : Not listed

18218)

Hazardous Chemicals for Priority Management under : Not listed

SAWS

Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals : Not listed

Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import : Not listed

and Export

Regulation on the Administration of Precursor Chemicals

Catalogue and Classification of Precursor Chemicals : Not listed

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

according to GB/T 16483 and GB/T 17519



# Diclazuril (0.25%) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 2.0 2024/09/28 6193384-00012 Date of first issue: 2020/08/14

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

#### **16. OTHER INFORMATION**

Revision Date : 2024/09/28

**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/

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

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

CN OEL : Occupational exposure limits for hazardous agents in the

workplace - Chemical hazardous agents.

ACGIH / TWA : 8-hour, time-weighted average

CN OEL / PC-TWA : Permissible concentration - 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 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 Substanc-

according to GB/T 16483 and GB/T 17519



# Diclazuril (0.25%) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 2.0 2024/09/28 6193384-00012 Date of first issue: 2020/08/14

es; (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

#### **Disclaimer**

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.

CN / EN