

**Diclazuril Formulation**

Version 1.9      Revision Date: 30.09.2023      SDS Number: 6490716-00010      Date of last issue: 04.04.2023  
Date of first issue: 01.10.2020

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**SECTION 1. IDENTIFICATION**

Product name : Diclazuril Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma  
Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Veterinary product

Restrictions on use : Not applicable

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**SECTION 2. HAZARDS IDENTIFICATION****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

**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.

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**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
White mineral oil (petroleum)	8042-47-5	>= 1 -< 5
Diclazuril	101831-37-2	>= 1 -< 3

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**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.

## Diclazuril Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.9	30.09.2023	6490716-00010	Date of first issue: 01.10.2020

---

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.

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**SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Metal oxides Sulfur 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 fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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**SECTION 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

## Diclazuril Formulation

Version 1.9      Revision Date: 30.09.2023      SDS Number: 6490716-00010      Date of last issue: 04.04.2023  
 Date of first issue: 01.10.2020

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.

## SECTION 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, vapors 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 labeled 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

## Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
White mineral oil (petroleum)	8042-47-5	CMP (Mist)	5 mg/m <sup>3</sup>	AR OEL
		CMP - CPT (Mist)	10 mg/m <sup>3</sup>	AR OEL
		TWA (Inhalable)	5 mg/m <sup>3</sup>	ACGIH

# SAFETY DATA SHEET



## Diclazuril Formulation

Version 1.9      Revision Date: 30.09.2023      SDS Number: 6490716-00010      Date of last issue: 04.04.2023  
Date of first issue: 01.10.2020

		particulate matter)		
Diclazuril	101831-37-2	TWA	30 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	300 µg/100 cm <sup>2</sup>	Internal

**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 vapor 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. 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.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : pellets

Color : green-brown

Odor : No data available

## Diclazuril Formulation

Version 1.9      Revision Date: 30.09.2023      SDS Number: 6490716-00010      Date of last issue: 04.04.2023  
Date of first issue: 01.10.2020

---

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	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
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	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	No data available

## Diclazuril Formulation

Version 1.9      Revision Date: 30.09.2023      SDS Number: 6490716-00010      Date of last issue: 04.04.2023  
 Date of first issue: 01.10.2020

**SECTION 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.

**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:****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

**Diclazuril Formulation**

Version 1.9      Revision Date: 30.09.2023      SDS Number: 6490716-00010      Date of last issue: 04.04.2023  
Date of first issue: 01.10.2020

---

**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 sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****White mineral oil (petroleum):**

Test Type : Buehler Test  
Routes of exposure : 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

## Diclazuril Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.9	30.09.2023	6490716-00010	Date of first issue: 01.10.2020

---

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

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.9	30.09.2023	6490716-00010	Date of first issue: 01.10.2020

---

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 fetal development : Test Type: Embryo-fetal 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 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.

## Diclazuril Formulation

Version 1.9      Revision Date: 30.09.2023      SDS Number: 6490716-00010      Date of last issue: 04.04.2023  
Date of first issue: 01.10.2020

---

**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

## Diclazuril Formulation

Version 1.9      Revision Date: 30.09.2023      SDS Number: 6490716-00010      Date of last issue: 04.04.2023  
 Date of first issue: 01.10.2020

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Diclazuril:**

Ingestion : Symptoms: Diarrhea

**SECTION 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 (Oncorhynchus mykiss (rainbow trout)): 1.000 mg/l  
 Exposure time: 28 d
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 1.000 mg/l  
 Exposure time: 21 d

**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 (Daphnia magna (Water flea)): 0,16 mg/l  
 Exposure time: 21 d

## Diclazuril Formulation

Version 1.9      Revision Date: 30.09.2023      SDS Number: 6490716-00010      Date of last issue: 04.04.2023  
Date of first issue: 01.10.2020

---

ic toxicity)      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

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**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.

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**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.

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## Diclazuril Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.9	30.09.2023	6490716-00010	Date of first issue: 01.10.2020

---

**Special precautions for user**

Not applicable

**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

**SECTION 16. OTHER INFORMATION**Revision Date : 30.09.2023  
Date format : dd.mm.yyyy**Further information**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/>**Full text of other abbreviations**ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
AR OEL : Argentina. Occupational Exposure LimitsACGIH / TWA : 8-hour, time-weighted average  
AR OEL / CMP : TLV (Threshold Limit Value)  
AR OEL / CMP - CPT : STEL (Short Term Limit Value)

All abbreviations used in this document are defined in the following table:

AllC - 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

**Diclazuril Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.9	30.09.2023	6490716-00010	Date of first issue: 01.10.2020

---

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; TECl - 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.

AR / Z8