

**Diclazuril Formulation**

Version 2.1      Revision Date: 09.05.2025      SDS Number: 6490718-00012      Date of last issue: 14.04.2025  
Date of first issue: 01.10.2020

**SECTION 1. IDENTIFICATION**

Product identifier : Diclazuril Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : Rua Coronel Bento Soares, 530  
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

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

**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification in accordance with ABNT NBR 14725 Standard**

Not classified as hazardous in accordance with ABNT NBR 14725

**GHS label elements in accordance with ABNT NBR 14725 Standard**

Not classified as hazardous in accordance with ABNT NBR 14725

**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.

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

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Classification	Concentration (% w/w)
White mineral oil (petroleum)	8042-47-5		>= 1 -< 5
Diclazuril	101831-37-2	Repr., 2 STOT RE, (Lungs, Lymph nodes, Liver) , 2	>= 1 -< 3

**SECTION 4. FIRST AID MEASURES**

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

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		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	:	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, protec-	:	Use personal protective equipment.
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|---|---|--|
| tive equipment and emergency procedures               | : | 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>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 | : | Sweep up or vacuum up spillage and collect in suitable container for disposal.<br>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).<br>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.<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      | : | Static electricity may accumulate and ignite suspended dust causing an explosion.<br>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.<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<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>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.<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.                                   |

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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	TWA (Inhalable particulate matter)	5 mg/m <sup>3</sup>	ACGIH
Diclazuril	101831-37-2	TWA	70 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	700 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.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : pellets

# SAFETY DATA SHEET



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Color	:	green-brown
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	:	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

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Particle characteristics  
Particle size : No data available

**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

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Acute toxicity (other routes of administration) : LD50 (Mouse): > 5.000 mg/kg  
Application Route: Subcutaneous  
Target Organs: Central nervous system

**Skin corrosion/irritation**

Not classified based on available information.

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

Species	:	Rabbit
Result	:	No skin irritation

**Diclazuril:**

Remarks : Not classified due to lack of data.

**Serious eye damage/eye irritation**

Not classified based on available information.

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

Species	:	Rabbit
Result	:	No eye irritation

**Diclazuril:**

Remarks : Not classified due to lack of data.

**Respiratory or skin 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.

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

Genotoxicity in vitro	:	Test Type: In vitro mammalian cell gene mutation test Result: negative
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Method: OECD Test Guideline 474 Result: negative Remarks: Based on data from similar materials

**Diclazuril:**

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative  Test Type: In vitro mammalian cell gene mutation test Test system: mouse lymphoma cells Result: negative  Test Type: unscheduled DNA synthesis assay Test system: rat hepatocytes Result: negative  Test Type: Chromosomal aberration Test system: Human lymphocytes Result: negative
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Result: negative  Test Type: Sex-linked recessive lethal test in Drosophila melanogaster (in vivo) Result: negative  Test Type: dominant lethal test Species: Mouse Result: negative

**Carcinogenicity**

Not classified based on available information.

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

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	24 Months
Result	:	negative

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

Effects on fertility	: Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Skin contact Result: negative
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Effects on fetal development	: Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Result: negative
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**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.
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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.
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	: 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
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Reproductive toxicity - As-	: Suspected of damaging the unborn child.
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essment

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

Not classified based on available information.

**Components:****Diclazuril:**

Target Organs	:	Liver, Lungs, Lymph nodes
Assessment	:	May cause damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****White mineral oil (petroleum):**

Species	:	Rat
LOAEL	:	160 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days
Species	:	Rat
LOAEL	:	>= 1 mg/l
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	4 Weeks
Method	:	OECD Test Guideline 412

**Diclazuril:**

Species	:	Rat
NOAEL	:	6 mg/kg
LOAEL	:	74 mg/kg
Application Route	:	Oral
Exposure time	:	12 Months
Target Organs	:	Liver, Lungs, Lymph nodes

Species	:	Rat
NOAEL	:	4 mg/kg
LOAEL	:	69 mg/kg
Application Route	:	Oral
Exposure time	:	3 Months
Target Organs	:	Liver

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

Species	:	Dog
NOAEL	:	20 mg/kg

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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:****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

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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:****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

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

Not applicable for product as supplied.

**Domestic regulation****ANTT**

Not regulated as a dangerous good

**Special precautions for user**

Not applicable

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Calcium carbonate

**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	: 09.05.2025
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)

ACGIH / TWA : 8-hour, 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

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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; 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.

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