

# Albendazole Sulfoxide (1.9%) Formulation

Version Revision Date: SDS Number: Date of last issue: 23.04.2024 3.0 06.07.2024 3903423-00019 Date of first issue: 10.12.2018

#### **SECTION 1. IDENTIFICATION**

Product name : Albendazole Sulfoxide (1.9%) 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

#### **SECTION 2. HAZARDS IDENTIFICATION**

**GHS Classification** 

Skin sensitization : Category 1

Short-term (acute) aquatic

hazard

Category 2

Long-term (chronic) aquatic

hazard

Category 2

**GHS** label elements

Hazard pictograms





Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.

H411 Toxic to aquatic life with long lasting effects.

Precautionary Statements : Prevention:

P261 Avoid breathing mist or vapors.

P272 Contaminated work clothing should not be allowed out of

the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves.



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## Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.

P333 + P313 If skin irritation or rash occurs: Get medical ad-

vice/ attention.

P362 + P364 Take off contaminated clothing and wash it before

reuse

P391 Collect spillage.

#### 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)
Glycerine	56-81-5	>= 5 -< 10
Albendazole Sulfoxide	54029-12-8	>= 1 -< 2,5

#### **SECTION 4. FIRST AID MEASURES**

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

advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse. Flush eyes with water as a precaution.

In case of eye contact

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting. If swallowed

Get medical attention.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and

May cause an allergic skin reaction.

delayed 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).

Treat symptomatically and supportively. Notes to physician

## **SECTION 5. FIRE-FIGHTING MEASURES**



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Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical None known.

Unsuitable extinguishing

media

Specific hazards during fire

fighting

Hazardous combustion prod-

ucts

Carbon oxides

Nitrogen oxides (NOx) Sulfur oxides

Specific extinguishing meth-

Use extinguishing measures that are appropriate to local cir-

Exposure to combustion products may be a hazard to health.

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 fire-fighters

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 protective equipment recommendations (see section 8).

Avoid release to the environment. Environmental precautions

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 diking or other appropriate

containment to keep material from spreading. If diked material

can be pumped, store recovered material in appropriate

container.

Clean up remaining materials from spill with suitable

absorbent.

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 See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.



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Local/Total ventilation Use only with adequate ventilation. Do not get on skin or clothing. Advice on safe handling

Do not breathe mist or vapors.

Do not swallow.

Avoid contact with eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure

assessment

Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

Conditions for safe storage Keep in properly labeled containers.

Store in accordance with the particular national regulations.

Materials to avoid Do not store with the following product types:

Strong oxidizing agents

Gases

#### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis		
Glycerine	56-81-5	CMP (Mist)	10 mg/m <sup>3</sup>	AR OEL		
Albendazole Sulfoxide	54029-12-8	TWA	45 μg/m3 (OEB 3)	Internal		
	Further inform	Further information: DSEN				
		Wipe limit	100 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

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 Hand protection Combined particulates and organic vapor type

Material Chemical-resistant gloves

Remarks Consider double gloving.

Eye protection Wear safety glasses with side shields or goggles.



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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.

Contaminated work clothing should not be allowed out of the

workplace.

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 : suspension

Color : white

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling :

range

No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available



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Vapor pressure No data available

Relative vapor density No data available

Relative density No data available

Density No data available

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

Autoignition temperature No data available

No data available Decomposition temperature

Viscosity

No data available Viscosity, kinematic

Explosive properties Not explosive

Oxidizing properties The substance or mixture is not classified as oxidizing.

Not applicable

Molecular weight No data available

Particle characteristics

Particle size Not applicable

#### **SECTION 10. STABILITY AND REACTIVITY**

Not classified as a reactivity hazard. Reactivity Chemical stability Stable under normal conditions. Possibility of hazardous reac-Can react with strong oxidizing agents.

Conditions to avoid None known. Incompatible materials Oxidizing agents

No hazardous decomposition products are known. Hazardous decomposition

products

### **SECTION 11. TOXICOLOGICAL INFORMATION**

Information on likely routes of: Inhalation exposure Skin contact

Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

**Product:** 

Acute toxicity estimate: > 5.000 mg/kg Acute oral toxicity

Method: Calculation method



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## **Components:**

Glycerine:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute dermal toxicity : LD50 (Guinea pig): > 5.000 mg/kg

Albendazole Sulfoxide:

Acute oral toxicity : LD50 (Mouse): 1.500 mg/kg

LD50 (Rat): 2.400 mg/kg

Acute toxicity (other routes of:

administration)

LD50 (Rat): 265 mg/kg

Application Route: Intravenous

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

Glycerine:

Species : Rabbit

Result : No skin irritation

Albendazole Sulfoxide:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

**Components:** 

**Glycerine:** 

Species : Rabbit

Result : No eye irritation

Albendazole Sulfoxide:

Species : Rabbit

Result : No eye irritation

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.



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#### **Components:**

#### Albendazole Sulfoxide:

Test Type : Maximization Test

Routes of exposure : Dermal

Assessment : Probability or evidence of low to moderate skin sensitization

rate in humans

Result : positive

Test Type : Maximization Test

Routes of exposure : Dermal Result : Sensitizer

## Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

## Glycerine:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro)

Result: negative

#### Albendazole Sulfoxide:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse

Cell type: Bone marrow

Result: negative

#### Carcinogenicity

Not classified based on available information.

#### **Components:**

#### Glycerine:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years



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Result : negative

Albendazole Sulfoxide:

Species : Mouse
Application Route : Oral
Exposure time : 2 Years

NOAEL : 400 mg/kg body weight

Result : negative

Species : Rat
Application Route : Oral
Exposure time : 2 Years

NOAEL : 20 mg/kg body weight

Result : negative

Carcinogenicity - Assess-

ment

: No evidence of carcinogenicity in animal studies.

## Reproductive toxicity

Not classified based on available information.

#### **Components:**

Glycerine:

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

Species: Rat

**Application Route: Ingestion** 

Result: negative

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

**Application Route: Ingestion** 

Result: negative

Albendazole Sulfoxide:

Effects on fertility : Test Type: Fertility

Species: Rat

Application Route: Oral

Fertility: NOAEL: 30 mg/kg body weight

Result: No effects on fertility.

Effects on fetal development : Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 10 mg/kg body weight Result: Embryotoxic effects., Skeletal malformations.

Test Type: Development

Species: Rabbit Application Route: Oral

Developmental Toxicity: LOAEL: 30 mg/kg body weight Result: Embryotoxic effects., Skeletal malformations., Mater-

nal toxicity observed.



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Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: NOAEL: 5,8 mg/kg body weight

Result: Effects on postnatal development.

Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 7 mg/kg body weight Result: Embryotoxic effects and adverse effects on the off-

spring were detected.

Reproductive toxicity - As-

sessment

Suspected of damaging the unborn child.

## STOT-single exposure

Not classified based on available information.

#### **Components:**

#### Albendazole Sulfoxide:

Routes of exposure : Oral

Target Organs : Gastrointestinal tract, Central nervous system

Assessment : May cause damage to organs.

#### STOT-repeated exposure

Not classified based on available information.

#### **Components:**

### Albendazole Sulfoxide:

Routes of exposure : Oral

Target Organs : Gastrointestinal tract, Central nervous system, Immune sys-

tem, Liver

Assessment : May cause damage to organs through prolonged or repeated

exposure.

## Repeated dose toxicity

#### **Components:**

#### Glycerine:

 Species
 : Rat

 NOAEL
 : 0,167 mg/l

 LOAEL
 : 0,622 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 13 Weeks

Species : Rat

NOAEL : 8.000 - 10.000 mg/kg

Application Route : Ingestion Exposure time : 2 y

Species : Rabbit



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NOAEL : 5.040 mg/kg Application Route : Skin contact Exposure time : 45 Weeks

### Albendazole Sulfoxide:

Species : Rat
LOAEL : 168 mg/kg
Application Route : Oral
Exposure time : 4 Weeks

Target Organs : Gastrointestinal tract, Testis

Symptoms : Diarrhea, Vomiting

Species : Dog
LOAEL : 48 mg/kg
Application Route : Oral
Exposure time : 4 Weeks

Target Organs : Gastrointestinal tract Symptoms : Diarrhea, Vomiting

Species : Mouse
LOAEL : 40 mg/kg
Application Route : Oral
Exposure time : 3 Months

Target Organs : Blood, Liver, Nose

Symptoms : Hematologic effects, Liver effects

Species : Rat

LOAEL : >= 30 mg/kg
Application Route : Oral
Exposure time : 6 Months
Target Organs : Blood

Symptoms : Hematologic effects

Species : Dog
LOAEL : 40 mg/kg
Application Route : Oral
Exposure time : 6 Months
Target Organs : Blood, Liver

Symptoms : Hematologic effects, Liver effects

Species : Rat

NOAEL : 7 mg/kg

Application Route : Oral

Exposure time : 60 d

Target Organs : Liver, Testis

Symptoms : Liver effects, male reproductive effects

## **Aspiration toxicity**

Not classified based on available information.

## **Experience with human exposure**

## **Components:**

#### Albendazole Sulfoxide:



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General Information Symptoms: Allergic reactions, hair loss, Gastrointestinal dis-

turbance, Headache, Dizziness

Target Organs: Skin Skin contact

Symptoms: Allergic reactions

Remarks: May cause sensitization by skin contact.

Ingestion Target Organs: Gastrointestinal tract

Symptoms: Gastrointestinal disturbance, Diarrhea, Abdominal

pain

Target Organs: Central nervous system

Symptoms: Headache, Dizziness

Target Organs: Liver

Symptoms: liver function change Target Organs: Immune system Symptoms: immune system effects

### **SECTION 12. ECOLOGICAL INFORMATION**

## **Ecotoxicity**

## **Components:**

## Glycerine:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54.000 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 1.955 mg/l

Exposure time: 48 h

Toxicity to microorganisms NOEC (Pseudomonas putida): > 10.000 mg/l

Exposure time: 16 h Method: DIN 38 412 Part 8

#### Albendazole Sulfoxide:

Toxicity to fish : EC50 (Brachydanio rerio (zebrafish)): 0,042 mg/l

Exposure time: 144 hrs

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0,068 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Raphidocelis subcapitata (freshwater green alga)):

0,024 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox- :

10

M-Factor (Chronic aquatic

10

toxicity)

## Persistence and degradability

#### **Components:**

### Glycerine:



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Biodegradability : Result: Readily biodegradable.

Biodegradation: 92 % Exposure time: 30 d

Method: OECD Test Guideline 301D

Bioaccumulative potential

**Components:** 

Glycerine:

Partition coefficient: n-

octanol/water

log Pow: -1,75

Albendazole Sulfoxide:

Partition coefficient: n-

octanol/water

log Pow: 1,27

pH: 7

Mobility in soil

No data available

Other adverse effects

No data available

**SECTION 13. DISPOSAL CONSIDERATIONS** 

**Disposal methods** 

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

**SECTION 14. TRANSPORT INFORMATION** 

**International Regulations** 

**UNRTDG** 

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Albendazole Sulfoxide)

Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3082

Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.

(Albendazole Sulfoxide)

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo : 964



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aircraft)

Packing instruction (passen: 964

ger aircraft)

Environmentally hazardous : yes

**IMDG-Code** 

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Albendazole Sulfoxide)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

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

Not applicable for product as supplied.

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

### **SECTION 15. REGULATORY INFORMATION**

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

Argentina. Carcinogenic Substances and Agents : Not applicable

Registry.

Control of precursors and essential chemicals for the : Not applicable

preparation of drugs.

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 : 06.07.2024 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 Agen-

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



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

#### Full text of other abbreviations

AR OEL : Argentina. Occupational Exposure Limits

AR OEL / CMP : TLV (Threshold Limit Value)

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China: IMDG - International Maritime Dangerous Goods: IMO - International Maritime Organization: ISHL - Industrial Safety and Health Law (Japan): ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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