

## Albendazole Sulfoxide (10%) Formulation

Version **Revision Date:** SDS Number: Date of last issue: 04.04.2023 30.09.2023 3884314-00017 Date of first issue: 30.11.2018 2.10

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

Product name Albendazole Sulfoxide (10%) Formulation

Manufacturer or supplier's details

Company MSD

Address Talcahuano 750, 6th floor, Ciudad Autonoma

Buenos Aires, Argentina C1013AAP

Telephone 908-740-4000

1-908-423-6000 Emergency telephone

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

Reproductive toxicity Category 2

single exposure (Oral)

Specific target organ toxicity - : Category 2 (Gastrointestinal tract, Central nervous system)

Specific target organ toxicity - :

repeated exposure (Oral)

Category 2 (Gastrointestinal tract, Central nervous system,

Immune system, Liver)

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 1

**GHS** label elements

Hazard pictograms







Signal Word Warning

**Hazard Statements** H317 May cause an allergic skin reaction.



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H361d Suspected of damaging the unborn child.

H371 May cause damage to organs (Gastrointestinal tract,

Central nervous system) if swallowed.

H373 May cause damage to organs (Gastrointestinal tract, Central nervous system, Immune system, Liver) through pro-

longed or repeated exposure if swallowed.

H410 Very toxic to aquatic life with long lasting effects.

#### **Precautionary Statements**

#### Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P260 Do not breathe mist or vapors.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product. P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

#### Response:

P302 + P352 IF ON SKIN: Wash with plenty of water. P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

P362 + P364 Take off contaminated clothing and wash it before

P391 Collect spillage.

## Storage:

P405 Store locked up.

#### Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

### Other hazards which do not result in classification

None known.

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

Substance / Mixture : Mixture

## Components

Chemical name	CAS-No.	Concentration (% w/w)
Albendazole Sulfoxide	54029-12-8	>= 10 -< 20
Glycerine	56-81-5	>= 5 -< 10

#### **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. Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and

In case of eye contact

delayed

If swallowed

May cause an allergic skin reaction.

Suspected of damaging the unborn child. May cause damage to organs if swallowed.

May cause damage to organs through prolonged or repeated

exposure if swallowed.

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**

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fighting

Hazardous combustion prod-

ucts

Exposure to combustion products may be a hazard to health.

Carbon oxides

Nitrogen oxides (NOx)

Sulfur 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 fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec- :

Use personal protective equipment.

tive equipment and emer-Follow safe handling advice (see section 7) and personal



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gency procedures protective 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 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.

Local/Total ventilation Advice on safe handling Use only with adequate ventilation.

Do not get on skin or clothing. 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 locked up.

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	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	



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Albendazole Sulfoxide	54029-12-8	TWA	40 μg/m3 (OEB 3)	Internal	
	Further information: DSEN				
		Wipe limit	100 μg/100 cm2	Internal	
Glycerine	56-81-5	CMP (Mist)	10 mg/m <sup>3</sup>	AR OEL	

**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.

Laboratory operations do not require special containment.

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. Combined particulates and organic vapor type

Filter type
Hand protection

Material

: Chemical-resistant gloves

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.

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



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Initial boiling point and boiling

range

No data available

Flash point Not applicable

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

No data available Vapor pressure

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

Not applicable

No data available Autoignition temperature

Decomposition temperature No data available

Viscosity

No data available Viscosity, kinematic

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

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

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

tions

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



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

Hazardous decomposition : No hazardous decomposition products are known.

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

Method: Calculation method

**Components:** 

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

Glycerine:

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

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

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

Albendazole Sulfoxide:

Species : Rabbit

Result : No skin irritation

Glycerine:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.



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#### **Components:**

Albendazole Sulfoxide:

Species : Rabbit

Result : No eye irritation

Glycerine:

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.

**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:** 

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

Glycerine:

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

Result: negative



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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

#### Carcinogenicity

Not classified based on available information.

#### Components:

#### 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.

Glycerine:

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

## Reproductive toxicity

Suspected of damaging the unborn child.

#### **Components:**

#### 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.



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Test Type: Development

Species: Rabbit

Application Route: Oral

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

Maternal toxicity observed.

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

offspring were detected.

Reproductive toxicity - As-

sessment

Suspected of damaging the unborn child.

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

### STOT-single exposure

May cause damage to organs (Gastrointestinal tract, Central nervous system) if swallowed.

### **Components:**

## Albendazole Sulfoxide:

Routes of exposure : Oral

Target Organs : Gastrointestinal tract, Central nervous system

Assessment : May cause damage to organs.

#### STOT-repeated exposure

May cause damage to organs (Gastrointestinal tract, Central nervous system, Immune system, Liver) through prolonged or repeated exposure if swallowed.

#### 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



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exposure.

## Repeated dose toxicity

### **Components:**

#### 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

**Glycerine:** 

 Species
 : Rat

 NOAEL
 : 0,167 mg/l

 LOAEL
 : 0,622 mg/l

Application Route : inhalation (dust/mist/fume)



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Exposure time : 13 Weeks

Species : Rat

NOAEL : 8.000 - 10.000 mg/kg

Application Route : Ingestion Exposure time : 2 y

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

**Aspiration toxicity** 

Not classified based on available information.

**Experience with human exposure** 

**Components:** 

Albendazole Sulfoxide:

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

turbance, Headache, Dizziness

Skin contact : Target Organs: Skin

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:** 

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



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icity)

M-Factor (Chronic aquatic

toxicity)

10

Glycerine:

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

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

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

Persistence and degradability

**Components:** 

Glycerine:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 92 % Exposure time: 30 d

Method: OECD Test Guideline 301D

Bioaccumulative potential

**Components:** 

Albendazole Sulfoxide:

Partition coefficient: n-

octanol/water

log Pow: 1,27

pH: 7

Glycerine:

Partition coefficient: n-

octanol/water

log Pow: -1,75

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.



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#### **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

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.

964

(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



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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 : 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 Agen-

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

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 Svstem; 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 Sub-



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stances 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