

Albendazole Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 24.04.2024

 8.0
 06.07.2024
 10232226-00015
 Date of first issue: 16.11.2021

SECTION 1. IDENTIFICATION

Product name : Albendazole 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

Acute toxicity (Oral) : Category 5

Skin sensitization : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - :

single exposure (Oral)

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



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Hazard Statements : H303 May be harmful if swallowed.

H317 May cause an allergic skin reaction.

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 dust.

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 protective clothing/

tion/ 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 ad-

vice/ attention.

P362 + P364 Take off contaminated clothing and wash it before

reuse.

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

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.	Concentration (% w/w)
Albendazole Sulfoxide	54029-12-8	>= 50 -< 70
Cellulose	9004-34-6	>= 20 -< 30



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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.

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.

Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and

delayed

May be harmful 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.

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation. 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.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

Protection of first-aiders

media

None known.

Specific hazards during fire

fighting

Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx)

Sulfur oxides Metal oxides

Specific extinguishing meth- : Use extinguishing measures that are appropriate to local cir-



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ods 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, protective equipment and emer-

gency 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

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 : L

Advice on safe handling

Use only with adequate ventilation.

Do not get on skin or clothing.

Do not breathe dust. 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

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.



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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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
Albendazole Sulfoxide	54029-12-8	TWA	45 μg/m3 (OEB 3)	Internal	
	Further information: DSEN				
		Wipe limit	100 μg/100 cm2	Internal	
Cellulose	9004-34-6	CMP	10 mg/m ³	AR OEL	
		TWA	10 mg/m ³	ACGIH	

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

Hand protection

Particulates type

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.



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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 : powder

Color : cream

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 : Not applicable

Evaporation rate : No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing,

handling or other means.

Flammability (liquids) : Not applicable

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



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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.

No data available Molecular weight

Particle characteristics

No data available Particle size

SECTION 10. STABILITY AND REACTIVITY

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

Possibility of hazardous reac-

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

Hazardous decomposition

Oxidizing agents

No hazardous decomposition products are known.

products

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

Inhalation Skin contact

Ingestion Eye contact

Acute toxicity

May be harmful if swallowed.

Product:

Acute toxicity estimate: 3.000 mg/kg Acute oral toxicity

Method: Calculation method

Components:

Albendazole Sulfoxide:

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



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LD50 (Rat): 2.400 mg/kg

Acute toxicity (other routes of : LD50 (Rat): 265 mg/kg

administration)

Application Route: Intravenous

Cellulose:

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

Acute inhalation toxicity : LC50 (Rat): > 5,8 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Albendazole Sulfoxide:

Species : Rabbit

Result No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

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.

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



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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

Cellulose:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Ingestion

Result: negative

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.

Cellulose:

Species : Rat



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Application Route : Ingestion
Exposure time : 72 weeks
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.

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.

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.

Cellulose:

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

Species: Rat

Application Route: Ingestion

Result: negative

Effects on fetal development: Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative



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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

exposure.

Repeated dose toxicity

Components:

Albendazole Sulfoxide:

Species : Rat LOAEL : 168 mg/kg Application Route : Oral

Application Route : Oral Exposure time : 4 Weeks

Target Organs : Gastrointestinal tract, Testis

Symptoms : Diarrhea, Vomiting

Species: DogLOAEL: 48 mg/kgApplication Route: OralExposure time: 4 Weeks

Target Organs : Gastrointestinal tract Symptoms : Diarrhea, Vomiting

Species: MouseLOAEL: 40 mg/kgApplication Route: OralExposure 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



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Target Organs Blood

Symptoms Hematologic effects

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

Hematologic effects, Liver effects Symptoms

Species Rat NOAEL 7 mg/kg Application Route Oral Exposure time 60 d Target Organs Liver, Testis

Symptoms : Liver effects, male reproductive effects

Cellulose:

Species Rat

NOAEL >= 9.000 mg/kgApplication Route : Ingestion

Exposure time 90 Days

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

: Target Organs: Skin Skin contact

Symptoms: Allergic reactions

Remarks: May cause sensitization by skin contact.

Target Organs: Gastrointestinal tract Inaestion

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



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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-

ıcıty)

M-Factor (Chronic aquatic

10

10

toxicity)

Cellulose:

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

Exposure time: 48 h

Remarks: Based on data from similar materials

Persistence and degradability

Components:

Cellulose:

Biodegradability : Result: Readily biodegradable.

Bioaccumulative potential

Components:

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.



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SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Albendazole Sulfoxide)

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

IATA-DGR

UN/ID No. : UN 3077

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

(Albendazole Sulfoxide)

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo

aircraft)

Packing instruction (passen- : 956

ger aircraft)

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

956

(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

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Further information

Sources of key data used to compile the Material Safety

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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

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

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AR OEL : Argentina. Occupational Exposure Limits

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



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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