

Cimetidine Formulation

Version **Revision Date:** SDS Number: Date of last issue: 04.04.2023 30.09.2023 4242350-00011 Date of first issue: 03.05.2019 2.1

SECTION 1. IDENTIFICATION

Product name Cimetidine Formulation

Manufacturer or supplier's details

MSD Company

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 Pharmaceutical Restrictions on use Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Reproductive toxicity Category 1B

repeated exposure (Oral)

Specific target organ toxicity - : Category 2 (Liver, Kidney, Testis)

GHS label elements

Hazard pictograms

Signal Word Danger

H360D May damage the unborn child. Hazard Statements

> H373 May cause damage to organs (Liver, Kidney, Testis) through prolonged or repeated exposure if swallowed.

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.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.



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Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Additional Labeling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 40 %

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)
cimetidine	51481-61-9	>= 30 -< 50
Cellulose	9004-34-6	>= 10 -< 20
Starch	9005-25-8	>= 1 -< 5
Magnesium stearate	557-04-0	>= 1 -< 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.

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.

May damage the unborn child. Most important symptoms

and effects, both acute and May cause damage to organs through prolonged or repeated



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delayed 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 None known.

Unsuitable extinguishing

Protection of first-aiders

media

.....9

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-

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, 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.



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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 : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Advice on safe handling : Do not get on skin or clothing.

Do not breathe dust. Do not swallow.

Avoid contact with eyes.

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

assessment

Keep container tightly closed.

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges.

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

environment.

Conditions for safe storage : Keep in properly labeled containers.

Store locked up. Keep tightly closed.

Store in accordance with the particular national regulations.

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

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

	•			
Components	CAS-No.	Value type (Form of	Control parameters / Permissible	Basis
		exposure)	concentration	
cimetidine	51481-61-9	TWA	1000 μg/m3 (OEB	
			1)	
Cellulose	9004-34-6	CMP	10 mg/m ³	AR OEL
		TWA	10 mg/m ³	ACGIH
Starch	9005-25-8	CMP	10 mg/m ³	AR OEL
	Further information: A4 - Not classifiable as a human carcinogen			



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		TWA	10 mg/m ³	ACGIH		
Magnesium stearate	557-04-0	CMP	10 mg/m ³	AR OEL		
	Further infor	Further information: A4 - Not classifiable as a human carcinogen				
		TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH		
		TWA (Respirable particulate matter)	3 mg/m³	ACGIH		

Engineering measures : Use feasible engineering controls to minimize exposure to

compound.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

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

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

Hygiene measures

Work uniform or laboratory coat.

If exposure to chemical is likely during typical use, provide

eye flushing systems and safety showers close to the

working place.

When using do not eat, drink or smoke.

Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : No data available



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Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : Not applicable

Evaporation rate : Not applicable

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

handling or other means.

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : Not applicable

Relative vapor density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.



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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

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

Not classified based on available information.

Components:

cimetidine:

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

LD50 (Mouse): 2.550 mg/kg

LD50 (Hamster): > 4.000 mg/kg

Acute toxicity (other routes of:

administration)

LD50 (Rat): 106 mg/kg

Application Route: Intravenous

LD50 (Rabbit): 164 mg/kg Application Route: Intravenous

LD50 (Rat): 860 mg/kg

Application Route: Subcutaneous

LD50 (Mouse): 437 mg/kg

Application Route: Subcutaneous

Symptoms: Convulsions

Cellulose:

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

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

Starch:

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



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

Magnesium stearate:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg

Method: OECD Test Guideline 423

Assessment: The substance or mixture has no acute oral tox-

icity

Remarks: Based on data from similar materials

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

Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

Components:

Magnesium stearate:

Species : Rabbit

Result : No skin irritation

Remarks : Based on data from similar materials

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Starch:

Species : Rabbit

Result : No eye irritation

Magnesium stearate:

Species : Rabbit

Result : No eye irritation

Remarks : Based on data from similar materials

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Starch:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative



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Magnesium stearate:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Remarks : Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:

cimetidine:

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

Result: negative

Test Type: Chromosomal aberration

Result: negative

Test Type: unscheduled DNA synthesis assay

Test system: rat hepatocytes

Result: negative

Test Type: unscheduled DNA synthesis assay

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

Starch:

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

Result: negative

Magnesium stearate:

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

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative



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Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

Components:

cimetidine:

Species : Rat
Application Route : Oral
Exposure time : 2 Years
Target Organs : Testis

Remarks : Benign tumor(s)

Carcinogenicity - Assess-

ment

: No evidence of carcinogenicity in animal studies.

Cellulose:

Species : Rat
Application Route : Ingestion
Exposure time : 72 weeks
Result : negative

Reproductive toxicity

May damage the unborn child.

Components:

cimetidine:

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

Species: Rat

Application Route: Oral

Fertility: NOAEL: 950 mg/kg body weight Result: No effect on reproduction capacity.

Effects on fetal development : Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 17 mg/kg body weight

Symptoms: male reproductive effects

Remarks: Adverse effects were observed in males only.

Reproductive toxicity - As-

sessment

May damage the unborn child.

Cellulose:

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

Species: Rat

Application Route: Ingestion

Result: negative



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

Species: Rat

Application Route: Ingestion

Result: negative

Magnesium stearate:

Effects on fertility Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 422

Result: negative

Remarks: Based on data from similar materials

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

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

May cause damage to organs (Liver, Kidney, Testis) through prolonged or repeated exposure if swallowed.

Components:

cimetidine:

Routes of exposure : Oral

Target Organs : Liver, Kidney, Testis

Assessment May cause damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

Components:

cimetidine:

Species Rat LOAEL 160 mg/kg Application Route Oral Exposure time 2 Months

Target Organs Gastrointestinal tract Remarks May cause damage to organs.

Species Rat

NOAEL 200 mg/kg **Application Route** Oral 12 Months Exposure time

Symptoms No adverse effects.

Species Rat



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LOAEL : 950 mg/kg Application Route : Oral Exposure time : 2 y

Target Organs : Liver, Testis, Prostate

Remarks : May cause damage to organs.

Species : Dog NOAEL : 366 mg/kg Application Route : Oral Exposure time : 12 Months

Target Organs : Liver, Kidney, Prostate

Remarks : May cause damage to organs.

Species : Dog NOAEL : 144 mg/kg Application Route : Oral Exposure time : 4 y

Symptoms : No adverse effects.

Cellulose:

Species : Rat

NOAEL : >= 9.000 mg/kg

Application Route : Ingestion Exposure time : 90 Days

Starch:

Species : Rat

NOAEL : >= 2.000 mg/kg
Application Route : Skin contact
Exposure time : 28 Days

Method : OECD Test Guideline 410

Magnesium stearate:

Species : Rat

NOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Remarks : Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

cimetidine:

Ingestion : Symptoms: The most common side effects are:, Headache,

Dizziness, Nausea, skin rash, Itching, May cause, central nervous system effects, gynecomastia, impotence, kidney

effects

Remarks: May cause harm to breast-fed children.



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SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

cimetidine:

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

Cellulose:

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

Exposure time: 48 h

Remarks: Based on data from similar materials

Magnesium stearate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l

Exposure time: 48 h Method: DIN 38412

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EL50 (Daphnia magna (Water flea)): > 1 mg/l

Exposure time: 47 h

Test substance: Water Accommodated Fraction Method: Directive 67/548/EEC, Annex V, C.2. Remarks: Based on data from similar materials

No toxicity at the limit of solubility.

Toxicity to algae/aquatic

plants

EL50 (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

No toxicity at the limit of solubility.

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (Pseudomonas putida): > 100 mg/l

Exposure time: 16 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials



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Persistence and degradability

Components:

Cellulose:

Biodegradability : Result: Readily biodegradable.

Magnesium stearate:

Biodegradability : Result: Not biodegradable

Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

cimetidine:

Partition coefficient: n-

octanol/water

log Pow: 0,40

Magnesium stearate:

Partition coefficient: n-

octanol/water

: log Pow: > 4

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

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

MSD Public

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Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents :

Registry.

: Not applicable

Control of precursors and essential chemicals for the

preparation of drugs.

Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

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Further information

Sources of key data used to

compile the Material Safety eCl Data Sheet cv.

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

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

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 Or-



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ganisation 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