

## **Caspofungin Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 7.0 06.07.2024 24293-00026 Date of first issue: 21.10.2014

#### **SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Caspofungin Formulation

Manufacturer or supplier's details

Company name of supplier : MSD

Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

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** 

Serious eye damage/eye

irritation

Category 1

Effects on or via lactation

**GHS** label elements

Hazard pictograms

Signal Word : Danger

Hazard Statements : H318 Causes serious eye damage.

H362 May cause harm to breast-fed children.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P260 Do not breathe dust.

P263 Avoid contact during pregnancy and while nursing.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P280 Wear eye protection/ face protection.

Response:

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON

CENTER or doctor/ physician.

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

attention.



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#### Other hazards

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)
Caspofungin	179463-17-3	>= 30 -< 50
Sucrose	57-50-1	>= 30 -< 50
Acetic acid	64-19-7	>= 1 -< 3

#### **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 : Get medical attention.
In case of skin contact : Wash with water and soap.

Get medical attention.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water

for at least 15 minutes.

If easy to do, remove contact lens, if worn.

Get medical attention immediately.

If swallowed : Get medical attention.

Most important symptoms : Causes serious eye damage.

and effects, both acute and May cause harm to breast-fed children.

delayed Contact with dust can cause mechanical irritation or drying of

the skin.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

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

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

nedia

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- :

icts

Carbon 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

Use only with adequate ventilation.

Advice on safe handling : Avoid contact during pregnancy and while nursing.

Do not breathe dust. Do not swallow. Do not get in eyes.

Avoid prolonged or repeated contact with skin.

Wash skin thoroughly after handling.

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.



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Keep away from heat and sources of ignition.

Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product.

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

environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working

place.

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

Conditions for safe storage : Keep in properly labeled containers.

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

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

### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Caspofungin	179463-17-3	TWA	140 μg/m3 (OEB 2)	Internal
Sucrose	57-50-1	VLE-PPT	10 mg/m <sup>3</sup>	NOM-010- STPS-2014
		TWA	10 mg/m <sup>3</sup>	ACGIH
Acetic acid	64-19-7	VLE-PPT	10 ppm	NOM-010- STPS-2014
		VLE-CT	15 ppm	NOM-010- STPS-2014
		TWA	10 ppm	ACGIH
		STEL	15 ppm	ACGIH

**Engineering measures** : Ensure adequate ventilation, especially in confined areas.

Minimize workplace exposure concentrations. Apply measures to prevent dust explosions.

Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection.

Filter type

Combined particulates and organic vapor type

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending



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on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before

breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment:

Chemical resistant goggles must be worn.

If splashes are likely to occur, wear:

Face-shield

Skin and body protection : Select appropriate protective clothing based on chemical

resistance data and an assessment of the local exposure

potential.

Skin contact must be avoided by using impervious protective

clothing (gloves, aprons, boots, etc).

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : powder

Color : off-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 : Not applicable

Evaporation rate : Not applicable

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



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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

Viscosity, kinematic Not applicable

Explosive properties Not explosive

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

Molecular weight No data available

100 - 300 mJ Minimum ignition energy

30 - 100 mJ

Particle characteristics

Particle size No data available

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

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

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing,

handling or other means.

Can react with strong oxidizing agents.

Conditions to avoid Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Oxidizing agents Hazardous decomposition

products

No hazardous decomposition products are known.

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

### Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

#### **Acute toxicity**

Not classified based on available information.

#### **Product:**



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Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg

Method: Calculation method

**Components:** 

Caspofungin:

Acute oral toxicity : LD50 (Mouse): > 2,000 mg/kg

Acute toxicity (other routes of:

administration)

LD50 (Mouse): 19 mg/kg

Application Route: Intravenous

LD50 (Rat): 38 mg/kg

Application Route: Intravenous

Sucrose:

Acute oral toxicity : LD50 (Rat): 29,700 mg/kg

Acetic acid:

Acute oral toxicity : LD50 (Rat): > 2,000 - 5,000 mg/kg

Remarks: Based on data from similar materials

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

Caspofungin:

Species : Rabbit

Result : Mild skin irritation

Acetic acid:

Species : Rabbit

Result : Corrosive after 3 minutes or less of exposure

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

Caspofungin:

Species : Rabbit

Result : Irreversible effects on the eye Method : Bovine cornea (BCOP)

Acetic acid:

Species : Rabbit



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Result : Irreversible effects on the eye

#### Respiratory or skin sensitization

### Skin sensitization

Not classified based on available information.

## Respiratory sensitization

Not classified based on available information.

## Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

#### Caspofungin:

Genotoxicity in vitro : Test Type: Chromosomal aberration

Test system: Chinese hamster ovary cells

Result: negative

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Alkaline elution assay Test system: rat hepatocytes

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Test system: Chinese hamster fibroblasts

Result: negative

Genotoxicity in vivo : Test Type: Chromosomal aberration

Species: Mouse

Cell type: Bone marrow

Result: negative

Sucrose:

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

Result: negative

Acetic acid:

Genotoxicity in vitro : 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

Test Type: In vitro mammalian cell gene mutation test

Result: equivocal

Remarks: Based on data from similar materials



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

cytogenetic assay) Species: Rat

Application Route: inhalation (vapor)

Result: negative

Remarks: Based on data from similar materials

### Carcinogenicity

Not classified based on available information.

#### Components:

#### Acetic acid:

Species: MouseApplication Route: Skin contactExposure time: 32 weeksResult: negative

#### Reproductive toxicity

May cause harm to breast-fed children.

#### **Components:**

#### Caspofungin:

Effects on fertility : Test Type: Fertility

Species: Rat, male and female

Application Route: Intravenous injection Fertility: NOAEL Parent: 5 mg/kg body weight Result: No effects on fertility and early embryonic

development were detected.

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

Species: Rat

Application Route: Intravenous injection

General Toxicity Maternal: LOAEL: 5 mg/kg body weight Embryo-fetal toxicity.: NOAEL F1: 2 mg/kg body weight Symptoms: Abnormalities of the musculosketal system. Result: Embryotoxic effects and adverse effects on the

offspring were detected.

Test Type: Development

Species: Rabbit

Application Route: Intravenous injection

General Toxicity Maternal: NOAEL: 3 mg/kg body weight Developmental Toxicity: NOAEL F1: >= 6 mg/kg body weight Result: Embryotoxic effects and adverse effects on the

offspring were detected.

Reproductive toxicity - As-

sessment

Studies indicating a hazard to babies during the lactation

period

### Acetic acid:

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



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Species: Rat

Application Route: Ingestion

Result: negative

#### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

Not classified based on available information.

### Repeated dose toxicity

## **Components:**

### Caspofungin:

Species Monkey NOAEL 2 mg/kg LOAEL 5 mg/kg Application Route Intravenous Exposure time 27 Weeks Number of exposures daily Target Organs Liver

: Rat Species LOAEL 1.8 mg/kg Application Route : Intravenous Exposure time : 27 Weeks Symptoms : Swelling of tissue

Species : Rat NOAEL 2 mg/kg LOAEL : 5 mg/kg LOAEL : Unity
Application Route : Intrav
Exposure time : 14 W
Number of exposures : daily
Swell : Intravenous 14 Weeks

Symptoms Swelling of tissue

#### Acetic acid:

Species Rat NOAEL 290 mg/kg Application Route Ingestion Exposure time 8 Weeks

## **Aspiration toxicity**

Not classified based on available information.

## **Components:**

### Caspofungin:

No aspiration toxicity classification



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

### **Ecotoxicity**

#### Components:

Caspofungin:

Toxicity to fish LC50 (Pimephales promelas (fathead minnow)): 2.4 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 22.6 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 0.1

Exposure time: 72 h

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.05

Exposure time: 72 h

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 0.084 mg/l

Exposure time: 32 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other:

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0.67 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Toxicity to microorganisms EC50: > 127 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

NOEC: 38 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Acetic acid:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

Exposure time: 96 h

Remarks: Based on data from similar materials

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

ErC50 (Skeletonema costatum (marine diatom)): > 100 mg/l

Exposure time: 72 h

Remarks: Based on data from similar materials

NOEC (Skeletonema costatum (marine diatom)): > 1 mg/l



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Exposure time: 72 h

Remarks: Based on data from similar materials

Toxicity to daphnia and other: aquatic invertebrates (ChronNOEC (Daphnia magna (Water flea)): > 1 mg/l

Exposure time: 21 d

ic toxicity) Toxicity to microorganisms

NOEC (Pseudomonas putida): 1,150 mg/l

Exposure time: 16 h

Persistence and degradability

**Components:** 

Caspofungin:

Biodegradability Result: Not readily biodegradable.

Biodegradation: 71.9 % Exposure time: 28 d

Method: OECD Test Guideline 302B

Stability in water Degradation half life (DT50): 2.8 h

Acetic acid:

Biodegradability Result: Readily biodegradable.

Biodegradation: 96 % Exposure time: 20 d

Bioaccumulative potential

**Components:** 

Caspofungin:

Partition coefficient: n-

: log Pow: -1.6

octanol/water

Sucrose:

Partition coefficient: n-

Pow: < 1

octanol/water Acetic acid:

Partition coefficient: n-

octanol/water

log Pow: -0.17

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



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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 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Caspofungin)

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.

(Caspofungin)

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

(Caspofungin)

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.

**Domestic regulation** 

NOM-002-SCT

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Caspofungin)

Class : 9
Packing group : III
Labels : 9



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#### 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

Federal Law for the control of chemical precursors, : Not applicable essential chemical products and machinery for

producing capsules, tablets and pills.

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

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting

the Work Environment - Identification, Assessment and Con-

trol - Appendix 1 Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average ACGIH / STEL : Short-term exposure limit

NOM-010-STPS-2014 / VLE- : Time weighted average limit value

PPT

NOM-010-STPS-2014 / VLE- : Short term exposure limit value

CT

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 Con-



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centration 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

Sources of key data used to compile the Material Safety Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

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

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8