

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Caspofungin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
7.0	07/06/2024	24274-00028	Date of first issue: 10/21/2014

SECTION 1. IDENTIFICATION

Product name : Caspofungin Formulation
Other means of identification : No data available

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
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@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

Serious eye damage : 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 and 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.
P308 + P313 IF exposed or concerned: Get medical 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	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Caspofungin	No data available	179463-17-3	47.1
Sucrose	.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1	30.3
Acetic acid	Ethanoic acid	64-19-7	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 : 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 and effects, both acute and delayed : Causes serious eye damage.
May cause harm to breast-fed children.
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 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

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potential dust explosion hazard.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances 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 emergency 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.

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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.
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.

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/m ³ (OEB 2)	Internal
Sucrose	57-50-1	TWA	10 mg/m ³	CA AB OEL
		TWA (Total dust)	10 mg/m ³	CA BC OEL
		TWA (respirable dust fraction)	3 mg/m ³	CA BC OEL
		TWAEV	10 mg/m ³	CA QC OEL
		TWA	10 mg/m ³	ACGIH
Acetic acid	64-19-7	TWA	10 ppm 25 mg/m ³	CA AB OEL
		STEL	15 ppm 37 mg/m ³	CA AB OEL
		TWA	10 ppm	CA BC OEL
		STEL	15 ppm	CA BC OEL
		TWAEV	10 ppm 25 mg/m ³	CA QC OEL
		STEV	15 ppm 37 mg/m ³	CA QC OEL
		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.

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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 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). |
| 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. |

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 |

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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
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
Minimum ignition energy	:	100 - 300 mJ 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.

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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 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:

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
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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
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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.

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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
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

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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 synthesis 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

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 : Mouse
Application Route : Skin contact
Exposure time : 32 weeks
Result : 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

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	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 musculoskeletal 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 - Assessment	: Studies indicating a hazard to babies during the lactation period

Acetic acid:

Effects on fetal development	: Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Result: negative
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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

Species	: Rat
LOAEL	: 1.8 mg/kg
Application Route	: Intravenous
Exposure time	: 27 Weeks

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|| Symptoms : Swelling of tissue

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Caspofungin:

|| Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 2.4 mg/l
Exposure time: 96 h

|| Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 22.6 mg/l
aquatic invertebrates Exposure time: 48 h

|| Toxicity to algae/aquatic : EC50 (Pseudokirchneriella subcapitata (green algae)): 0.1
plants mg/l
Exposure time: 72 h

|| NOEC (Pseudokirchneriella subcapitata (green algae)): 0.05
mg/l
Exposure time: 72 h

|| Toxicity to fish (Chronic tox- : NOEC (Pimephales promelas (fathead minnow)): 0.084 mg/l
icity) Exposure time: 32 d
Method: OECD Test Guideline 210

|| Toxicity to daphnia and other : NOEC (Daphnia magna (Water flea)): 0.67 mg/l
aquatic invertebrates (Chron- Exposure time: 21 d
ic toxicity) Method: OECD Test Guideline 211

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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
Exposure time: 72 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): > 1 mg/l
Exposure time: 21 d

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

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Bioaccumulative potential

Components:

Caspofungin:

Partition coefficient: n-octanol/water : log Pow: -1.6

Sucrose:

Partition coefficient: n-octanol/water : Pow: < 1

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 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) : 956

Packing instruction (passen-

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ger aircraft)

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (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

TDG

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Caspofungin)

Class : 9

Packing group : III

Labels : 9

ERG Code : 171

Marine pollutant : yes(Caspofungin)

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)

CA BC OEL : Canada. British Columbia OEL

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CA QC OEL	:	Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for air-borne contaminants
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
CA AB OEL / TWA	:	8-hour Occupational exposure limit
CA AB OEL / STEL	:	15-minute occupational exposure limit
CA BC OEL / TWA	:	8-hour time weighted average
CA BC OEL / STEL	:	short-term exposure limit
CA QC OEL / TWAEV	:	Time-weighted average exposure value
CA QC OEL / STEV	:	Short-term exposure value

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

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/
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Date format	:	mm/dd/yyyy

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

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