according to the Hazardous Products Regulations



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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

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 availa- ble	179463-17-3	47.1
Sucrose	.alphaD- Glucopyra- noside, .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.

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

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

Treat symptomatically and supportively. Notes to physician

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

None known.

media

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.

according to the Hazardous Products Regulations



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Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- :

Carbon 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

Evacuate area.

Special protective equipment:

for fire-fighters

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

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Avoid release to the environment. Environmental precautions

> 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

Static electricity may accumulate and ignite suspended dust Technical measures

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.

according to the Hazardous Products Regulations



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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/m3 (OEB 2)	Internal
Sucrose	57-50-1	TWA	10 mg/m ³	CA AB OEL
		TWA (Total dust)	10 mg/m³	CA BC OEL
		TWA (respirable dust fraction)	3 mg/m³	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/m³	CA AB OEL
		TWA	10 ppm	CA BC OEL
		STEL	15 ppm	CA BC OEL
		TWAEV	10 ppm 25 mg/m³	CA QC OEL
		STEV	15 ppm 37 mg/m³	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.

Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are

according to the Hazardous Products Regulations



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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
Hand protection

Combined particulates and organic vapor type

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

Evaporation rate : Not applicable

according to the Hazardous Products Regulations



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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 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.

according to the Hazardous Products Regulations



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: Heat, flames and sparks. Conditions to avoid

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

Components:

Caspofungin:

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

administration)

Acute toxicity (other routes of : 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:

according to the Hazardous Products Regulations



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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

Genotoxicity in vivo : Test Type: Chromosomal aberration

Species: Mouse

according to the Hazardous Products Regulations



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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

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.

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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

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

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

Species : Rat

according to the Hazardous Products Regulations



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

Swelling of tissue **Symptoms**

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 :

aquatic invertebrates

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

according to the Hazardous Products Regulations



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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 (Chron-

ic 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)

956

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo

aircraft)

Packing instruction (passen- : 956

according to the Hazardous Products Regulations



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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 safe-

ty, 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 Agen-

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

Revision Date : 09/26/2023 Date format : mm/dd/yyyy

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

according to the Hazardous Products Regulations



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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.

CA / Z8