according to GB/T 16483 and GB/T 17519



Cyclosporine Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/07/06 3.0 2024/09/28 608877-00023 Date of first issue: 2016/04/08

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Cyclosporine Formulation

Other means of identification : Optimmune (A007869)

OPTIMMUNE OPHTHALMIC OINTMENT (51551)

Manufacturer or supplier's details

Company : MSD

Address : No. 485 Jing Tai Road

Pu Tuo District - Shanghai - China 200331

Telephone : +1-908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance : ointment

Colour : colourless, to, light yellow

Odour : No data available

May cause cancer.

GHS Classification

Carcinogenicity : Category 1B

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements : H350 May cause cancer.

according to GB/T 16483 and GB/T 17519



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Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

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.

Physical and chemical hazards

Not classified based on available information.

Health hazards

May cause cancer.

Environmental hazards

Not classified based on available information.

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Petrolatum	8009-03-8	>= 50 -< 70
Cyclosporine	59865-13-3	>= 0.1 -< 0.3

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice 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.

according to GB/T 16483 and GB/T 17519



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Get medical attention.

Wash clothing before reuse.

Thoroughly clean shoes before reuse. Flush eyes with water as a precaution.

In case of eye contact Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

If swallowed

Get medical attention.

Rinse mouth thoroughly with water. May cause cancer.

Most important symptoms and effects, both acute and

delayed

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

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

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

SO.

Evacuate area.

Special protective equipment:

for firefighters

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

Use personal protective equipment.

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 pro-

tective equipment recommendations (see section 8).

Environmental precautions Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g. by containment or oil

according to GB/T 16483 and GB/T 17519



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barriers).

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

Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

7. HANDLING AND STORAGE

Handling

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

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 vapours or spray mist.

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 as-

sessment

Keep container tightly closed.

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

environment.

Avoidance of contact : Oxidizing agents

Storage

Conditions for safe storage : Keep in properly labelled 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

Packaging material : Unsuitable material: None known.

according to GB/T 16483 and GB/T 17519



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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	
Petrolatum	8009-03-8	TWA (Inhal-	5 mg/m3	ACGIH
		able particu-		
		late matter)		
Cyclosporine	59865-13-3	TWA	10 μg/m3 (OEB 3)	Internal
		Wipe limit	100 μg/100 cm ²	Internal

Engineering measures : Use appropriate engineering controls and manufacturing

technologies to control airborne concentrations (e.g., drip-

less quick connections).

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

protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face con-

tainment devices).

Minimize open handling.

Personal protective equipment

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

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type : Combined particulates and organic vapour type Eye/face protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a

potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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

eye flushing systems and safety showers close to the work-

ing place.

When using do not eat, drink or smoke.

according to GB/T 16483 and GB/T 17519



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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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : ointment

Colour : colourless, to, light yellow

Odour : No data available

Odour 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 : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: Not applicable

Auto-ignition temperature : No data available

according to GB/T 16483 and GB/T 17519



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Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Particle characteristics

Particle size : Not applicable

10. STABILITY AND REACTIVITY

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

Possibility of hazardous reac- : Can react with strong oxidizing agents.

tions

Conditions to avoid : None known.
Incompatible materials : Oxidizing agents

Hazardous decomposition :

products

: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation

Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Components:

Petrolatum:

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

Method: OECD Test Guideline 401

Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Remarks: Based on data from similar materials

Cyclosporine:

Acute oral toxicity : LD50 (Rat): 1,480 mg/kg

according to GB/T 16483 and GB/T 17519



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LD50 (Mouse): 2,329 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of :

administration)

LD50 (Mouse): 107 mg/kg Application Route: Intravenous

, | |

LD50 (Rat): 25.8 mg/kg Application Route: Intravenous

Skin corrosion/irritation

Not classified based on available information.

Components:

Petrolatum:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : Based on data from similar materials

Cyclosporine:

Remarks : No data available

May irritate skin.

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Petrolatum:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Remarks : Based on data from similar materials

Cyclosporine:

Remarks : No data available

May irritate eyes.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

according to GB/T 16483 and GB/T 17519



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Components:

Petrolatum:

Test Type : Buehler Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative

Remarks : Based on data from similar materials

Cyclosporine:

Remarks : May cause sensitisation of susceptible persons.

Germ cell mutagenicity

Not classified based on available information.

Components:

Petrolatum:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro

Result: negative

Remarks: Based on data from similar materials

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

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection Method: OECD Test Guideline 474

Result: negative

Remarks: Based on data from similar materials

Cyclosporine:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Test system: Chinese hamster cells

Result: negative

Test Type: sister chromatid exchange assay

Result: positive

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse Application Route: Oral Result: negative

Test Type: Chromosomal aberration

Species: Chinese hamster Cell type: Bone marrow

according to GB/T 16483 and GB/T 17519



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Result: negative

Test Type: Chromosomal aberration

Species: Mouse Result: negative

Carcinogenicity

May cause cancer.

Components:

Petrolatum:

Species: RatApplication Route: IngestionExposure time: 2 YearsResult: negative

Cyclosporine:

Species : Mouse
Application Route : Oral
Exposure time : 78 weeks

LOAEL : 4 mg/kg body weight

Result : positive

Target Organs : Liver, lymphatic system

Species : Rat
Application Route : Oral
Exposure time : 2 Years

LOAEL : 0.5 mg/kg body weight

Result : positive Target Organs : Pancreas

Species : Humans

Result : May cause cancer. Target Organs : Immune system, Skin

Remarks : Information taken from reference works and the literature.

Carcinogenicity - Assess-

ment

: May cause cancer.

Reproductive toxicity

Not classified based on available information.

Components:

Petrolatum:

Effects on fertility : Test Type: Reproduction/Developmental toxicity screening

test

Species: Rat

Application Route: Ingestion

Result: negative

according to GB/T 16483 and GB/T 17519



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Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Skin contact

Result: negative

Remarks: Based on data from similar materials

Cyclosporine:

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

Species: Rat

Application Route: Oral

General Toxicity F1: LOAEL: 15 mg/kg body weight

Result: No effects on fertility, Effect on reproduction capacity

Test Type: Fertility Species: Rat, males

Application Route: Subcutaneous Fertility: LOAEL: 10 mg/kg body weight

Result: Reduced fertility

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 30 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, Reduced foetal weight, foetal mortality, Retardations, Teratogen-

ic effects

Test Type: Embryo-foetal development

Species: Rabbit

Developmental Toxicity: LOAEL: 100 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, Reduced foetal weight, foetal mortality, Retardations, Teratogen-

ic effects

Test Type: Development

Species: Rabbit

Application Route: Subcutaneous

Developmental Toxicity: LOAEL: 10 mg/kg body weight

Target Organs: Kidney
Result: Visceral malformations

Test Type: Development

Species: Rat

Application Route: Intravenous

Developmental Toxicity: LOAEL: 12 mg/kg body weight

Target Organs: Heart

Result: Visceral malformations

according to GB/T 16483 and GB/T 17519



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П

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

Cyclosporine:

Target Organs : Kidney, Liver, Immune system

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

Components:

Petrolatum:

Species : Rat

NOAEL : 5,000 mg/kg
Application Route : Ingestion
Exposure time : 2 yr

Cyclosporine:

Species : Rat

NOAEL : 14 mg/kg

LOAEL : 45 mg/kg

Application Route : Oral

Exposure time : 90 Days

Target Organs : Kidney, Liver, Immune system

Symptoms : hair loss

Species: MonkeyNOAEL: 20 mg/kgLOAEL: 60 mg/kgApplication Route: OralExposure time: 90 Days

Target Organs : Immune system

Symptoms : Gastrointestinal disturbance, Liver disorders, Kidney disorders

Species : Dog
LOAEL : 15 mg/kg
Application Route : Oral
Exposure time : 12 Months
Target Organs : Immune system

Symptoms : Changes in the blood count, Kidney disorders, Skin disorders,

hair loss

according to GB/T 16483 and GB/T 17519



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Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Cyclosporine:

Inhalation : Remarks: May cause irritation of respiratory tract.

Skin contact : Remarks: May irritate skin.

Eye contact : Symptoms: Eye irritation, eye pain

: Symptoms: Kidney disorders, Tremors, hypertension, blood Ingestion

effects, Gastrointestinal disturbance

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Petrolatum:

Toxicity to fish LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l

Exposure time: 96 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 10,000 mg/l

Exposure time: 48 h

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

Toxicity to algae/aquatic

plants

NOEL (Pseudokirchneriella subcapitata (green algae)): >=

100 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 daphnia and other: aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 10 mg/l

Exposure time: 21 d

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

Persistence and degradability

Components:

Petrolatum:

Result: Not readily biodegradable. Biodegradability

Biodegradation: 31 %

according to GB/T 16483 and GB/T 17519



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Exposure time: 28 d

Method: OECD Test Guideline 301F

Remarks: Based on data from similar materials

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo : Not applicable

aircraft)

Packing instruction (passen-

ger aircraft)

Not applicable

gor anoran,

IMDG-Code

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable

according to GB/T 16483 and GB/T 17519



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Subsidiary risk Not applicable Not applicable Packing group Labels Not applicable **EmS Code** Not applicable

Marine pollutant no

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

Not applicable for product as supplied.

National Regulations

GB 6944/12268

UN number Not applicable Proper shipping name Not applicable Class Not applicable Subsidiary risk Not applicable Packing group Not applicable Not applicable Labels

Marine pollutant no

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

National regulatory information

Law on the Prevention and Control of Occupational Diseases

Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals This product is not listed in the cata-

logue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of de-

termination.

Identification of Major Hazard Installations for Hazardous Chemicals (GB : Not listed

18218)

Hazardous Chemicals for Priority Management under Not listed

SAWS

Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals : Not listed

Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import : Not listed

and Export

Regulation on the Administration of Precursor Chemicals

according to GB/T 16483 and GB/T 17519



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Catalogue and Classification of Precursor Chemicals : Not listed

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

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

Internal technical data, data from raw material SDSs, OECD

eChem Portal search results and European Chemicals Agen-

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 2024/09/28

Further information

Sources of key data used to

compile the Safety Data Sheet

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

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

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

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

according to GB/T 16483 and GB/T 17519



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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

Disclaimer

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.

CN / EN