

Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/05/16
4.0	2024/07/06	608880-00021	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 : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

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

GHS Classification

Carcinogenicity : Category 1B

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H350 May cause cancer.

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 protection/ face protection.

Response:

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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.

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	≥ 30 -< 60
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 advice immediately.
When symptoms persist or in all cases of doubt seek medical advice. |
| If inhaled | : If inhaled, remove to fresh air.
Get medical attention. |
| In case of skin contact | : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse. |
| In case of eye contact | : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists. |
| If swallowed | : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water. |
| Most important symptoms and effects, both acute and delayed | : May cause cancer. |
| 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. |

5. FIREFIGHTING MEASURES

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- 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 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 firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.
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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.
Prevent spreading over a wide area (e.g. by containment or oil 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 absorbent.
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.
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7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
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- 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 assessment
Keep container tightly closed.
Take care to prevent spills, waste and minimize release to the environment.
- 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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Petrolatum	8009-03-8	NAB (Mist)	5 mg/m ³	ID OEL
		PSD (Mist)	10 mg/m ³	ID OEL
		TWA (Inhalable particulate matter)	5 mg/m ³	ACGIH
Cyclosporine	59865-13-3	TWA	10 µg/m ³ (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 containment devices).
Minimize open handling.

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 vapour type

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Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.
Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

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.
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

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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
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 reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
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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 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.
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Serious eye damage/eye irritation

Not classified based on available information.

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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.
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Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

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.
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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

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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 Result: negative Test Type: Chromosomal aberration Species: Mouse Result: negative

Carcinogenicity

May cause cancer.

Components:**Petrolatum:**

Species	: Rat
Application Route	: Ingestion
Exposure time	: 2 Years
Result	: 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

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Species	: Humans
Result	: May cause cancer.
Target Organs	: Immune system, Skin
Remarks	: Information taken from reference works and the literature.

Carcinogenicity - Assessment	: May cause cancer.
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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 Remarks: Based on data from similar materials
Effects on foetal development	: 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 development	: 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, Teratogenic effects Test Type: Embryo-foetal development Species: Rabbit Developmental Toxicity: LOAEL: 100 mg/kg body weight

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Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, Reduced foetal weight, foetal mortality, Retardations, Teratogenic 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

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

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Species	: Monkey
NOAEL	: 20 mg/kg
LOAEL	: 60 mg/kg
Application Route	: Oral
Exposure 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

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

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	Method: OECD Test Guideline 201
	Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic 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:**

Biodegradability	: Result: Not readily biodegradable.
	Biodegradation: 31 %
	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 handling 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

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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 aircraft) : Not applicable
Packing instruction (passenger aircraft) : Not applicable

IMDG-Code

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

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

Not applicable for product as supplied.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

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Type of hazardous materials subject to distribution and control, Annex II : Not applicable

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 : 2024/07/06

Further information

Sources of key data used to compile the 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.

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
ID OEL	: Indonesia. Occupational Exposure Limits

ACGIH / TWA	: 8-hour, time-weighted average
ID OEL / NAB	: Long term exposure limit
ID OEL / PSD	: Short term exposure limit

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

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Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

ID / EN