

# SAFETY DATA SHEET



## Cyclosporine Formulation

Version  
4.1

Revision Date:  
28.09.2024

SDS Number:  
608873-00022

Date of last issue: 06.07.2024  
Date of first issue: 08.04.2016

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### SECTION 1. IDENTIFICATION

Product identifier : Cyclosporine Formulation  
Other means of identification : Optimimmune (A007869)  
OPTIMMUNE OPHTHALMIC OINTMENT (51551)

#### Manufacturer or supplier's details

Company : MSD  
Address : Rua Coronel Bento Soares, 530  
Cruzeiro - Sao Paulo - Brazil CEP 12730-340  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product  
Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification in accordance with ABNT NBR 14725 Standard

Carcinogenicity : Category 1B

#### GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H350 May cause cancer.

Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.  
**Response:**  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
**Storage:**

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P405 Store locked up.

### Other hazards which do not result in classification

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Petrolatum	8009-03-8		>= 50 -< 70
Cyclosporine	59865-13-3	Acute Tox. (Oral), 4 Carc., 1B Repr., 1B STOT RE, (Kidney, Liver, Immune system), 1	>= 0,1 -< 0,3

## SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : 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.

## SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

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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 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. 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 diking or other appropriate containment to keep material from spreading. If diked 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.

## SECTION 7. HANDLING AND STORAGE

Technical measures	: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	: If sufficient ventilation is unavailable, use with local exhaust

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Advice on safe handling	<p>ventilation.</p> <ul style="list-style-type: none"> <li>: Do not get on skin or clothing.</li> <li>Do not breathe vapors or spray mist.</li> <li>Do not swallow.</li> <li>Avoid contact with eyes.</li> <li>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment</li> <li>Keep container tightly closed.</li> <li>Take care to prevent spills, waste and minimize release to the environment.</li> </ul>
Hygiene measures	<ul style="list-style-type: none"> <li>: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.</li> <li>When using do not eat, drink or smoke.</li> <li>Wash contaminated clothing before re-use.</li> <li>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.</li> </ul>
Conditions for safe storage	<ul style="list-style-type: none"> <li>: Keep in properly labeled containers.</li> <li>Store locked up.</li> <li>Keep tightly closed.</li> <li>Store in accordance with the particular national regulations.</li> </ul>
Materials to avoid	<ul style="list-style-type: none"> <li>: Do not store with the following product types:</li> <li>Strong oxidizing agents</li> <li>Self-reactive substances and mixtures</li> <li>Organic peroxides</li> <li>Explosives</li> <li>Gases</li> </ul>

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Petrolatum	8009-03-8	TWA (Inhalable particulate matter)	5 mg/m <sup>3</sup>	ACGIH
Cyclosporine	59865-13-3	TWA	10 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal

Engineering measures	<ul style="list-style-type: none"> <li>: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).</li> <li>All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.</li> <li>Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of</li> </ul>
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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 Hand protection	: Combined particulates and organic vapor type
Material	: Chemical-resistant gloves
Remarks Eye protection	: Consider double gloving. : 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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Physical state	: ointment
Color	: colorless, to, light yellow
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	: 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

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Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor 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

Autoignition 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

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## SECTION 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.

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## SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

### Acute toxicity

Not classified based on available information.

### Components:

#### **Petrolatum:**

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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.

### **Components:**

#### **Petrolatum:**

Species	:	Rabbit
Result	:	No eye irritation
Method	:	OECD Test Guideline 405
Remarks	:	Based on data from similar materials

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### **Cyclosporine:**

Remarks : No data available  
May irritate eyes.

### **Respiratory or skin sensitization**

#### **Skin sensitization**

Not classified based on available information.

#### **Respiratory sensitization**

Not classified based on available information.

### **Components:**

#### **Petrolatum:**

Test Type : Buehler Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative  
Remarks : Based on data from similar materials

### **Cyclosporine:**

Remarks : May cause sensitization 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

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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
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.

**Reproductive toxicity**

Not classified based on available information.

**Components:****Petrolatum:**

Effects on fertility	: Test Type: Reproduction/Developmental toxicity screening
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test  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal 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 fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 30 mg/kg body weight  
Result: Embryotoxic effects and adverse effects on the off-spring were detected only at high maternally toxic doses, Reduced fetal weight., Fetal mortality., Retardations., Teratogenic effects.

Test Type: Embryo-fetal development  
Species: Rabbit  
Developmental Toxicity: LOAEL: 100 mg/kg body weight  
Result: Embryotoxic effects and adverse effects on the off-spring were detected only at high maternally toxic doses, Reduced fetal weight., Fetal 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

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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 y

**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	:	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.

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Date of first issue: 08.04.2016**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

**SECTION 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 (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

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### **Mobility in soil**

No data available

### **Other adverse effects**

No data available

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## 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.

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## SECTION 14. TRANSPORT INFORMATION

### **International Regulations**

#### **UNRTDG**

Not regulated as a dangerous good

#### **IATA-DGR**

Not regulated as a dangerous good

#### **IMDG-Code**

Not regulated as a dangerous good

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

Not applicable for product as supplied.

### **Domestic regulation**

#### **ANTT**

Not regulated as a dangerous good

#### **Special precautions for user**

Not applicable

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## SECTION 15. REGULATORY INFORMATION

### **Safety, health and environmental regulations/legislation specific for the substance or mixture**

National List of Carcinogenic Agents for Humans - (LINACH)

Group 1: Carcinogenic to humans

Cyclosporine

59865-13-3

Brazil. List of chemicals controlled by the Federal Police : Not applicable

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

AICS : not determined

DSL : not determined

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IECSC : not determined

**SECTION 16. OTHER INFORMATION**

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**Further information**

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/>

**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 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

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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.

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