

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
6.0	04/14/2025	608889-00023	Date of first issue: 04/08/2016

### SECTION 1. IDENTIFICATION

Product name : Cyclosporine Formulation  
Other means of identification : Optimmune (A007869)  
OPTIMMUNE OPTHALMIC OINTMENT (51551)

#### 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 : Veterinary product  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION


#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Carcinogenicity : Category 1B  
Reproductive toxicity : Category 1B

#### Other hazards

None known.

#### GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H350 May cause cancer.  
H360Df May damage the unborn child. Suspected of damaging fertility.

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 and face protection.  
**Response:**  
P308 + P313 IF exposed or concerned: Get medical attention.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Cyclosporine Formulation

Version 6.0      Revision Date: 04/14/2025      SDS Number: 608889-00023      Date of last issue: 09/28/2024  
Date of first issue: 04/08/2016

### Storage:

P405 Store locked up.

### Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Petrolatum	8009-03-8*	$\geq 45 - \leq 70$	TSC
Corn oil	8001-30-7*	$\geq 30 - \leq 60$	TSC
Cyclosporine	59865-13-3*	$\geq 0.1 - \leq 1$	TSC

\* Indicates that the identifier is a CAS No.

TSC- the actual concentration or concentration range is withheld as a trade secret

## 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.  
May damage the unborn child. Suspected of damaging fertility.
- 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
6.0	04/14/2025	608889-00023	Date of first issue: 04/08/2016

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|--|---|---|
| Suitable extinguishing media                   | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>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.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |

### SECTION 6. ACCIDENTAL RELEASE MEASURES

- |   |   |   |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).  |
| Environmental precautions   | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g., by containment or oil barriers).<br>Retain and dispose of contaminated wash water.<br>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.<br>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.<br>Clean up remaining materials from spill with suitable absorbent.<br>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.<br>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Cyclosporine Formulation

Version 6.0      Revision Date: 04/14/2025      SDS Number: 608889-00023      Date of last issue: 09/28/2024  
Date of first issue: 04/08/2016

### 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 ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe vapors 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 labeled 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  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Petrolatum	8009-03-8	TWA (Mist)	5 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Inhalable particulate matter)	5 mg/m <sup>3</sup>	ACGIH
		TWA (Mist)	5 mg/m <sup>3</sup>	NIOSH REL
		ST (Mist)	10 mg/m <sup>3</sup>	NIOSH REL
Corn oil	8001-30-7	TWA (mist - total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (mist - respirable)	5 mg/m <sup>3</sup>	NIOSH REL
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 : 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
6.0	04/14/2025	608889-00023	Date of first issue: 04/08/2016

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 : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

### 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.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : ointment

Color : colorless, to, light yellow

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
6.0	04/14/2025	608889-00023	Date of first issue: 04/08/2016

---

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
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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
6.0	04/14/2025	608889-00023	Date of first issue: 04/08/2016

### 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.

### 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:**

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

##### **Corn oil:**

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 401 Remarks: Based on data from similar materials
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##### **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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
6.0	04/14/2025	608889-00023	Date of first issue: 04/08/2016

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

#### Corn oil:

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

#### Corn oil:

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 sensitization

#### Skin sensitization

Not classified based on available information.



# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
6.0	04/14/2025	608889-00023	Date of first issue: 04/08/2016

### 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

##### **Corn oil:**

Test Type	: Human repeat insult patch test (HRIPT)
Routes of exposure	: Skin contact
Result	: negative

##### **Cyclosporine:**

Remarks	: May cause sensitization 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

##### **Corn oil:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
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##### **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
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# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
6.0	04/14/2025	608889-00023	Date of first issue: 04/08/2016

	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

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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IARC	Group 1: Carcinogenic to humans Cyclosporine	59865-13-3
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OSHA	No component of this product present at levels greater than or equal to 0.1% is
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# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Cyclosporine Formulation

Version 6.0	Revision Date: 04/14/2025	SDS Number: 608889-00023	Date of last issue: 09/28/2024 Date of first issue: 04/08/2016
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on OSHA's list of regulated carcinogens.

### NTP

Known to be human carcinogen  
Cyclosporine

59865-13-3

### Reproductive toxicity

May damage the unborn child. Suspected of damaging fertility.

### 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 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 offspring 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 offspring were detected only at high maternally toxic doses, Reduced fetal weight., Fetal mortality., Retardations., Teratogenic effects.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
6.0	04/14/2025	608889-00023	Date of first issue: 04/08/2016

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 y

#### Corn oil:

Species	: Rat
NOAEL	: > 300 mg/kg
Application Route	: Ingestion
Exposure time	: 28 Days
Remarks	: Based on data from similar materials

#### Cyclosporine:

Species	: Rat
NOAEL	: 14 mg/kg
LOAEL	: 45 mg/kg
Application Route	: Oral
Exposure time	: 90 Days
Target Organs	: Kidney, Liver, Immune system

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
6.0	04/14/2025	608889-00023	Date of first issue: 04/08/2016

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.

### 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
6.0	04/14/2025	608889-00023	Date of first issue: 04/08/2016

	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

### Corn oil:

Toxicity to fish	: LL50 (Danio rerio (zebra fish)): > 100 mg/l Exposure time: 96 h Method: ISO 7346/1 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	: EL50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Test substance: Water Accommodated Fraction Method: Directive 67/548/EEC, Annex V, C.2. Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	: EL50 (Desmodesmus subspicatus (green algae)): > 100 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: Directive 67/548/EEC, Annex V, C.3. Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOELR (Daphnia magna (Water flea)): > 1 mg/l Exposure time: 21 d Test substance: Water Accommodated Fraction Method: OECD Test Guideline 211 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
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##### Corn oil:

Biodegradability	: Result: Readily biodegradable. Remarks: Based on data from similar materials
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### Bioaccumulative potential

#### Components:

##### Corn oil:

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
6.0	04/14/2025	608889-00023	Date of first issue: 04/08/2016

Partition coefficient: n-octanol/water : log Pow: > 4  
Method: OECD Test Guideline 117

### Mobility in soil

No data available

### Other adverse effects

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Dispose of in accordance with local regulations.  
Do not dispose of waste into sewer.

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

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 IMO instruments

Not applicable for product as supplied.

### Domestic regulation

#### 49 CFR

Not regulated as a dangerous good

### Special precautions for user

Not applicable

## SECTION 15. REGULATORY INFORMATION

### CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Carcinogenicity  
Reproductive toxicity

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Cyclosporine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
6.0	04/14/2025	608889-00023	Date of first issue: 04/08/2016

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**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### US State Regulations

#### Pennsylvania Right To Know

Petrolatum	8009-03-8
Corn oil	8001-30-7

#### California Prop. 65

WARNING: This product can expose you to chemicals including Cyclosporine, which is/are known to the State of California to cause cancer. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

#### California List of Hazardous Substances

Petrolatum	8009-03-8
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#### California Permissible Exposure Limits for Chemical Contaminants

Petrolatum	8009-03-8
Corn oil	8001-30-7

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

AICS	: not determined
DSL	: not determined
IECSC	: not determined

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## SECTION 16. OTHER INFORMATION

### Further information



# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Cyclosporine Formulation

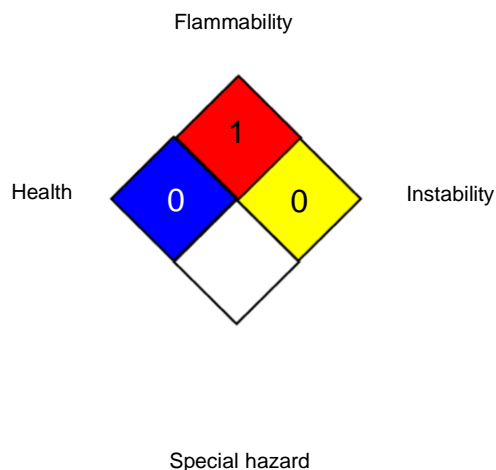
Version  
6.0

Revision Date:  
04/14/2025

SDS Number:  
608889-00023

Date of last issue: 09/28/2024  
Date of first issue: 04/08/2016

### NFPA 704:



### HMIS® IV:

HEALTH	*	0
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
NIOSH REL / ST	:	STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
OSHA Z-1 / TWA	:	8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Cyclosporine Formulation

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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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECl - 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

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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

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.

US / Z8