# SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

## Cyclosporine Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 07/06/2024 |
|---|---|---|---|
| 5.1 | 09/28/2024 | 608889-00022 | Date of first issue: 04/08/2016 |

### SECTION 1. IDENTIFICATION

Product name : Cyclosporine Formulation
Other means of identification : Optimmune (A007869)
OPTIMMUNE OPHTHALMIC 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

**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.

**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards**

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name | CAS-No. | Concentration (% w/w) |
|---|---|---|
| Petrolatum | 8009-03-8 | >= 50 - < 70 |
| Corn oil | 8001-30-7 | >= 30 - < 50 |
| Cyclosporine | 59865-13-3 | >= 0.1 - < 1 |

Actual concentration 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

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.<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. |

### 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.<br>Do not breathe vapors or spray mist.<br>Do not swallow.<br>Avoid contact with eyes.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Conditions for safe storage | : | Keep in properly labeled containers.<br>Store locked up.<br>Keep tightly closed.<br>Store in accordance with the particular national regulations. |
| Materials to avoid | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Explosives<br>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/m³ | OSHA Z-1 |
| | | TWA (Inhalable particulate matter) | 5 mg/m³ | ACGIH |
| | | TWA (Mist) | 5 mg/m³ | NIOSH REL |
| | | ST (Mist) | 10 mg/m³ | NIOSH REL |
| Corn oil | 8001-30-7 | TWA (mist - total) | 10 mg/m³ | NIOSH REL |
| | | TWA (mist - respirable) | 5 mg/m³ | NIOSH REL |
| Cyclosporine | 59865-13-3 | TWA | 10 µg/m3 (OEB 3) | Internal |
| | | Wipe limit | 100 µg/100 cm² | Internal |

| | | |
|---|---|---|
| **Engineering measures** | : | Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections).<br>All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.<br>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.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>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.<br>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.<br>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.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>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 |
| 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 |

### 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<br>Method: OECD Test Guideline 401<br>Remarks: Based on data from similar materials |
| Acute dermal toxicity | : | LD50 (Rat): > 2,000 mg/kg<br>Method: OECD Test Guideline 402<br>Assessment: The substance or mixture has no acute dermal toxicity<br>Remarks: Based on data from similar materials |

**Corn oil:**

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

**Cyclosporine:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): 1,480 mg/kg<br><br>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<br>Application Route: Intravenous<br><br>LD50 (Rat): 25.8 mg/kg<br>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<br>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 |

**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<br>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 |

**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. |

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**Petrolatum:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Chromosome aberration test in vitro<br>Result: negative<br>Remarks: Based on data from similar materials |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Intraperitoneal injection<br>Method: OECD Test Guideline 474<br>Result: negative<br>Remarks: Based on data from similar materials |

**Corn oil:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative |

**Cyclosporine:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Test system: Chinese hamster cells<br>Result: negative<br><br>Test Type: sister chromatid exchange assay<br>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.

**IARC** Group 1: Carcinogenic to humans
Cyclosporine 59865-13-3

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

| | | |
|---|---|---|
| **NTP** | Known to be human carcinogen<br>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.

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 |
| 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<br>Exposure time: 96 h<br>Test substance: Water Accommodated Fraction<br>Method: OECD Test Guideline 203<br>Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 10,000 mg/l<br>Exposure time: 48 h<br>Test substance: Water Accommodated Fraction<br>Remarks: Based on data from similar materials |
| Toxicity to algae/aquatic plants | : | NOEL (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l<br>Exposure time: 72 h<br>Test substance: Water Accommodated Fraction<br>Method: OECD Test Guideline 201<br>Remarks: Based on data from similar materials |

| | | |
|---|---|---|
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 10 mg/l<br>Exposure time: 21 d<br>Test substance: Water Accommodated Fraction<br>Remarks: Based on data from similar materials |

**Corn oil:**

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

**Persistence and degradability**

**Components:**

**Petrolatum:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 31 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301F<br>Remarks: Based on data from similar materials |

**Corn oil:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Readily biodegradable.<br>Remarks: Based on data from similar materials |

**Bioaccumulative potential**

**Components:**

**Corn oil:**

| | | |
|---|---|---|
| Partition coefficient: n-octanol/water | : | log Pow: > 4<br>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.<br>Do not dispose of waste into sewer. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>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 Annex II of MARPOL 73/78 and the IBC Code**
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<br>Reproductive toxicity |

**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.

**California List of Hazardous Substances**

| | |
|---|---|
| Petrolatum | 8009-03-8 |

**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

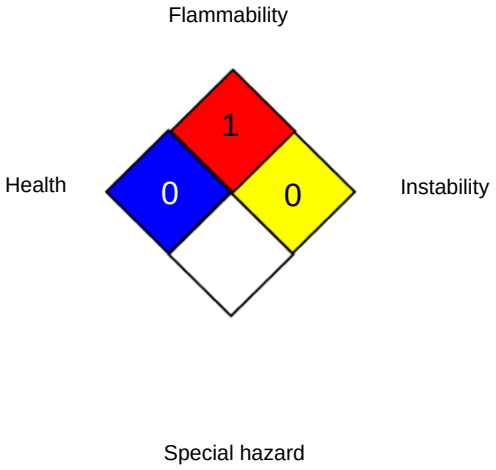
## SECTION 16. OTHER INFORMATION

**Further information**

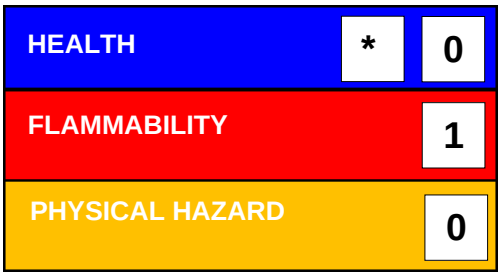
# Cyclosporine Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 07/06/2024 |
|---|---|---|---|
| 5.1 | 09/28/2024 | 608889-00022 | Date of first issue: 04/08/2016 |

**NFPA 704:**




**HMIS® IV:**




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

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; 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

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| 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/ |
| Revision Date | : | 09/28/2024 |

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.

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