

Cyclosporine Capsules Finished Product
Material Safety Data Sheet



1090 Horsham Road
North Wales, PA 19454

Telephone Calls: (201) 930-3413
Emergency Contact: Chemtrec
1-800-424-9300 24 hours

SECTION 1 - IDENTIFICATION

PRODUCT NAME	Cyclosporine Capsules Finished Product	SYNONYMS	Sandimmune, Neoral
CHEMICAL FAMILY	Cyclic polypeptide produced as a metabolite by the fungus species <i>Beauveria nivea</i> .	THERAPEUTIC CATEGORY	Immunosuppressant

SECTION 2 – HEALTH HAZARD INFORMATION

EMERGENCY OVERVIEW

CAUTION – The information in this MSDS is based on the hazards of the active ingredient. While diluted, this material may present the following hazards – IMMUNOSUPPRESSANT, CARCINOGEN.

EYE

May cause irritation or permanent tissue damage.

SKIN

May cause irritation and contact dermatitis.

INGESTION

Ingestion may cause irritation.

INHALATION

Material may be irritating to mucous membranes and upper respiratory tract.

ADVERSE SYSTEMIC EFFECTS

Serious: Allergic reaction; blood in urine; chest pain; loss of appetite, nausea; fever, chills, new or worsening numbness; seizures, confusion, changes in mood or behavior; yellowing of skin or eyes.
Less Serious: Acne, excess hair growth, headache, joint pain, muscle ache, runny or stuffy nose; stomach upset, diarrhea, constipation; swelling or bleeding gums; tremors.

CHRONIC (CANCER) INFORMATION

NTP – Yes
IARC – YES
OSHA – NO
An increased incidence of malignancy is shown with patients receiving cyclosporine therapy. (Non Hodgkin's Lymphoma and skin cancers are the most common types).

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REPRODUCTION INFO FDA Pregnancy Category C. No adequate and well-controlled studies in pregnant women have been conducted.

MEDICAL CONDITIONS/MEDS AGGRAVATED BY EXPOSURE Hypersensitivity to material, current malignancy or premalignant skin lesions, chickenpox (including recent exposure), herpes zoster, impaired liver or kidney function, and infection.

TARGET ORGANS Immune System, blood.

APPEARANCE Capsules. **ODOR** No information found.

SECTION 3 – INGREDIENT INFORMATION

COMPONENT	CAS NUMBER	% BY WEIGHT
Cyclosporine	59865-13-3	NA
Corn Oil Mono-di-Tri-Glycerides	68308-54-3	NA
Gelatin	9000-70-8	NA
Glycerol	56-81-5	NA
Propylene Glycol	57-55-6	NA

SECTION 4 – FIRST AID MEASURES

EYES Flush with large quantities of water for 15 minutes.

SKIN Brush off material; remove contaminated clothing, flush with large quantities of water for 15 minutes.

INGESTION Flush mouth with water – obtain medical attention.

INHALATION Remove to fresh air.

NOTE TO PHYSICIANS NA

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SECTION 5 – FIRE FIGHTING MEASURES

***FLAMMABLE
PROPERTIES***

Material is assumed to be combustible.

***HAZARDOUS
COMBUSTION
PRODUCTS***

CO_x & NO_x.

***EXTINGUISHING
MEDIA***

Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

***FIRE FIGHTING
INSTRUCTION***

As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

SPILL

Wear appropriate PPE. Scoop up slowly without breaking capsules and generating dust. (NO DRY SWEEPING). Wet wipe surfaces.

SECTION 7 – HANDLING AND STORAGE

HANDLING

Keep container closed, minimize dust generation during transfer.

STORAGE

Store in tight container.

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SECTION 8 – EXPOSURE CONTROL AND PPE

**ENGINEERING
CONTROLS**

Operations involving handling/transferring of dry power should be performed using containment measures (i.e. enclosures, etc.) and local exhaust ventilation.

**RESPIRATORY
PROTECTION**

Wear appropriate PPE according to dust level.

SKIN PROTECTION

Wear appropriate PPE according to dust level.

EYE PROTECTION

Wear appropriate PPE according to dust level.

COMPONENT

Cyclosporine
Corn Oil Mono-di-Tri-Glycerides
Gelatin
Glycerol
Propylene Glycol

EXPOSURE LIMIT

PIEL 30 µg/m³
No information found.
No information found.
No information found.
AIHA WEEL 10 mg/m³

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

BOILING POINT

No information found.

**MELTING
POINT**

No information found.

pH

No information found.

VAPOR PRESSURE

No information found.

**VAPOR
DENSITY**

No information found.

**SOLUBILITY IN
WATER**

No information found.

ODOR

No information found.

APPEARANCE

Capsules.

**SPECIFIC
GRAVITY**

No information found.

**AUTOIGNITION
TEMPERATURE**

No information found.

**FLAMMABLE
LIMITS**

NA

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MOLECULAR WEIGHT	1202.61 (API)	FLASHPOINT	NA
OCTANOL/WATER COEFFICIENT	No information found.	EVAPORATION RATE	NA

SECTION 10 – STABILITY AND REACTIVITY

**CHEMICAL STABILITY
(CONDITIONS TO
AVOID)** Stable at ambient temperature (15-30 degrees C).

INCOMPATIBILITY Strong oxidizers.

**HAZARDOUS
DECOMPOSITION
PRODUCTS** Carbon oxides and nitrogen oxides.

**HAZARDOUS
POLYMERIZATION** Will not occur.

SECTION 11 – TOXICOLOGICAL INFORMATION

EYE No information found.

SKIN No information found.

INGESTION No information found.

INHALATION No information found.

ACUTE/SUBCHRONIC API Oral LD50 (rat) = 1480 mg/kg
API Oral LD50 (mouse) = 2329 mg/kg

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**MUTAGENICITY/
CARCINOGENICITY**

No evidence of mutagenicity was observed in appropriate test systems. Some cancers are associated with cyclosporine. It is considered that this effect is due to the pharmacological action of cyclosporine and that cyclosporine has no direct effect on the genetic material and is not a tumor initiator.

REPRODUCTION

No impairment of fertility was observed in male and female rats. Cyclosporine was not teratogenic in appropriate test systems. Cyclosporine has been shown to be embryo and feto toxic at maternally toxic doses.

SECTION 12 – ECOLOGICAL INFORMATION

**ECOTOXICOLOGICAL
INFORMATION**

API
Biological elimination: 84% (aerobic, 20-24 C, CO₂). Initial concentration: approx. 11mg/L, 28d. rapid and complete biodegradation.
LC50 (Rainbow trout, 96h):> 100mg/L
EC50 (Daphnia magna, 48h): 20.2 mg/L
IC50 (Green algae, 72h):>100mg/L
IC50 (Activated sludge, 3h):>100mg/L

**CHEMICAL FATE
INFORMATION**

No information found.

SECTION 13 – DISPOSAL CONSIDERATIONS

Dispose of in accordance with all applicable federal, state, and local regulations.

SECTION 14 – TRANSPORTATION INFORMATION

Finished products in final packaging ready for consumer use are NOT regulated by DOT.

SECTION 15 – REGULATORY INFORMATION

OSHA

NA

CERCLA

NA

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**SECTION 313 (SARA
TITLE III)** NA

OTHER REGULATIONS NA

SECTION 16 – OTHER INFORMATION

PREPARED BY Rob McCafferty

REVISIONS New MSDS.

DISCLAIMER:

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