

**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**

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

<b>COMPONENT</b>	<b>CAS NUMBER</b>	<b>% BY WEIGHT</b>
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<sub>x</sub> & NO<sub>x</sub>.

***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.

<b><u>COMPONENT</u></b>	<b><u>EXPOSURE LIMIT</u></b>
Cyclosporine	PIEL 30 µg/m <sup>3</sup>
Corn Oil Mono-di-Tri-Glycerides	No information found.
Gelatin	No information found.
Glycerol	No information found.
Propylene Glycol	AIHA WEEL 10 mg/m <sup>3</sup>

**SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES**

<b>BOILING POINT</b>	No information found.	<b>MELTING POINT</b>	No information found.	<b>pH</b>	No information found.
<b>VAPOR PRESSURE</b>	No information found.	<b>VAPOR DENSITY</b>	No information found.		
<b>SOLUBILITY IN WATER</b>	No information found.	<b>ODOR</b>	No information found.		
<b>APPEARANCE</b>	Capsules.	<b>SPECIFIC GRAVITY</b>	No information found.		
<b>AUTOIGNITION TEMPERATURE</b>	No information found.	<b>FLAMMABLE LIMITS</b>	NA		

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<b>MOLECULAR WEIGHT</b>	1202.61 (API)	<b>FLASHPOINT</b>	NA
<b>OCTANOL/WATER COEFFICIENT</b>	No information found.	<b>EVAPORATION RATE</b>	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 fetotoxic at maternally toxic doses.

**SECTION 12 – ECOLOGICAL INFORMATION**

**ECOTOXICOLOGICAL  
INFORMATION**

API  
Biological elimination: 84% (aerobic, 20-24 C, CO<sub>2</sub>). 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:**

*Teva Pharmaceuticals, Inc. provides the information contained in this MSDS sheet in good faith but makes no claim as to its accuracy or Comprehensiveness. This MSDS sheet is intended as a guide for a properly trained person to utilize appropriate precautionary methods while handling this product. Individuals must exercise their own judgment in determining the appropriateness of this information for a particular purpose. All MSDS sheets are subject to revision from time-to-time as new information becomes available. Anyone proposing to rely on information regarding the substance that is the subject of this MSDS sheet is responsible for ensuring that he or she has obtained and reviewed the most recent version of the sheet available at the time. Barr Laboratories, Inc. will not be responsible for damages resulting from the use or misuse of the information contained in this MSDS sheet.*