

**Product Name:** Cyclosporine Oral Solution, USP, 100 MG/ML  
**Issued:** 30-Dec-2002



**MATERIAL SAFETY DATA SHEET**

**1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION**

**Manufacturer Name and Address:** Abbott Laboratories,  
 Pharmaceutical Products Division,  
 200 Abbott Park Road,  
 Abbott Park, Illinois 60064-3537

**Customer Service Telephone:** 1- 800 - 441 - 4987

**Emergency Telephone:** CHEMTREC: 1-800-424-9300

**Product Name:** Cyclosporine Oral Solution, USP, 100 MG/ML

**Synonyms:** Gengraf Oral Solution 100mg/ml

**List Number:** 7269

**National Drug Code Number:** 0074-7269-50

**2. COMPOSITION/INFORMATION ON INGREDIENTS**

| Ingredients                          | Percent     | OSHA PEL   | ACGIH TLV  | AIHA WEEL  | Abbott EEL                   | Skin Notation |
|--------------------------------------|-------------|------------|------------|--|------------------------------|---------------|
| Cyclosporine<br>59865-13-3           | proprietary | Not Listed | Not Listed | Not Applicable   | 0.2 mg/m <sup>3</sup><br>TWA | None          |
| Sorbitan Monooleate<br>1338-43-8     | proprietary | Not Listed | Not Listed | Not Applicable   | Not Applicable               | None          |
| Polyoxyl 35 Castor Oil<br>61791-12-6 | proprietary | Not Listed | Not Listed | Not Applicable   | Not Applicable               | None          |
| Propylene Glycol<br>57-55-6          | proprietary | Not Listed | Not Listed | 50 ppm TWA<br>(total); 10<br>mg/m <sup>3</sup> TWA<br>(aerosol only) | Not Applicable               | None          |

**Notes:**

OSHA PEL: US Occupational Safety and Health Administration- Permissible Exposure Limit.  
 ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value.  
 AIHA WEEL: American Industrial Hygiene Association - Workplace Environmental Exposure Level.  
 Abbott EEL: Abbott Laboratories Employee Exposure Limit.  
 TWA: 8-hour Time Weighted Average.  
 STEL: 15-minute Short Term Exposure Limit.  
 C: Ceiling Limit.  
 Abbott : Hazardous per OSHA criteria

**3. HAZARDS IDENTIFICATION**

**Emergency Overview:**  
 Liquid.  
 Not determined.  
 Listed carcinogen. Reproductive hazard. By analogy, this material may be a skin and eye irritant.

**Routes of Exposure:**

**Oral:** No

**Dermal:** Not determined.

**Inhalation:** Yes

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**Hazard Information:**

**Ingestion Rating:** None.  
**Skin Absorption Rating:** Not determined.  
**Inhalation Rating:** Not determined.  
**Corrosiveness Rating:** Not determined.  
**Skin Contact Rating:** Not determined.  
**Skin Sensitization Rating:** Not determined.  
**Eye Contact Rating:** Not determined.  
**Target Organs:** Nervous System , Cardiovascular System , Kidney , Immune System , Liver , Digestive System , Male Reproductive System , Fetus .

**Carcinogenicity Rating:**

| Ingredients            | Percent     | OSHA:      | NTP:       | IARC:      | ACGIH:     |
|------------------------|-------------|------------|------------|------------|------------|
| Cyclosporine           | proprietary | Listed     | Listed     | Listed     | Not Listed |
| Sorbitan Monooleate    | proprietary | Not Listed | Not Listed | Not Listed | Not Listed |
| Polyoxyl 35 Castor Oil | proprietary | Not Listed | Not Listed | Not Listed | Not Listed |
| Propylene Glycol       | proprietary | Not Listed | Not Listed | Not Listed | Not Listed |

**Carcinogenicity Comment:** NTP 1 : Known Human Carcinogen. IARC Group 1 : Carcinogenic Humans.

**NFPA Rating:** Not determined.

**Signs and Symptoms:** Clinical data suggests the following: abnormal kidney function, tremor, hirsutism (abnormal hairiness), gastrointestinal upset, rash, increased blood pressure, abnormal liver function, excessive urination. convulsion, alterations in blood chemistry.

**Medical Conditions Aggravated by Exposure:** Data suggest any preexisting ailments in the following organs: immune system, kidney, central nervous system, cardiovascular system, eyes, skin, hematopoietic system, liver. Pregnancy. Hypersensitivity to the material and/or similar materials.

**4. FIRST AID MEASURES**

**Eye Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Skin Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Inhalation:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Ingestion:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**5. FIRE FIGHTING MEASURES**

**FLAMMABILITY:**

**Autoignition Temp. (°C):** Not determined.

**FIRE-FIGHTING INFORMATION:**

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**Suitable Extinguishing Media:** Use appropriate medium for the underlying cause of the fire.

## 6. ACCIDENTAL RELEASE MEASURES

**Methods of Cleaning and Collecting:** Recover product. Place into appropriate container for disposal. Clean area with suitable cleaning materials. Dispose of as directed in Section 13.

**Personal Precautions:** Use personal protective equipment identified in Section 8.

**Environmental Precautions:** Not determined.

## 7. HANDLING AND STORAGE

**Handling:** Not determined.

**Storage :** Store according to label instructions.

**Special Precautions:** Not applicable.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Engineering Controls:** Use in a well ventilated area.

**Respiratory Protection:** An approved respirator (i.e. NIOSH, etc.) should be worn when exposures are expected to exceed the applicable limits.

**Eyes:** Safety glasses or goggles.

**Gloves:** Impervious gloves.

**Other Personal Protection Data:** Not determined.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance:** Liquid.  
**Odor:** Not determined.  
**Boiling Point @ 760 mm Hg (°C):** Not determined.  
**Melting/Freezing Point (°C):** Not determined.  
**Vapor Pressure (mm Hg)** Not determined.  
**Bulk Density at 20°C:** Not determined.  
**Solubility:** Not determined.  
**Specific Gravity:** Not determined.  
**pH:** Not determined.  
**Viscosity (centipoise):** Not determined.

## 10. STABILITY AND REACTIVITY

**Chemical Stability:** Not determined.

**Self-Heating Tendency:** Not determined.

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**Materials to Avoid:** Not determined.

**Hazardous Decomposition Products:** Not determined.

**Hazardous Polymerization:** Not determined.

**Conditions to Avoid:** Not determined.

**11. TOXICOLOGICAL INFORMATION**

**Acute Toxicity - Oral:** Non-toxic by ingestion. Data for component (s) given below.

| Ingredients            | Percent     | Acute Test | Value         | Units | Species           |
|------------------------|-------------|------------|---------------|-------|-------------------|
| Cyclosporine           | proprietary | LD50 =     | 1480          | mg/kg | Rats              |
|                        |             |            | 2329          | mg/kg | Mice              |
| Sorbitan Monooleate    | proprietary | LD50 >     | 15,000        | mg/kg | Rats              |
| Polyoxyl 35 Castor Oil | proprietary | LD50 >     | 6400          | mg/kg | Rats Cats Rabbits |
| Propylene Glycol       | proprietary | LD50 =     | 10,000-33,700 | mg/kg | Animals           |

**Acute Toxicity - Dermal:** Data for component (s) given below.

| Ingredients            | Percent     | Acute Test | Value  | Units | Species      |
|------------------------|-------------|------------|--------|-------|--------------|
| Polyoxyl 35 Castor Oil | proprietary | LD50 >     | 2500   | mg/kg | Rats Rabbits |
| Propylene Glycol       | proprietary | LD50 =     | 20,800 | mg/kg | Rabbits      |

**Acute Toxicity - Inhalation:** Not determined.

**Corrosivity:** Not determined.

**Dermal Irritation:** Not determined.

**Eye Irritation:** Not determined.

**Sensitization:** Not determined.

**Target Organ Effects:** In clinical use target organ effects include: immune system, kidney, central nervous system, cardiovascular system, liver, gastrointestinal tract.

Cyclosporine is a potent immunosuppressant agent that inhibits certain T-lymphocytes and helper cells of the immune system. In clinical use, kidney injury is a major adverse reaction along with tremor, hypertension, gum hyperplasia and hirsutism. Some liver injury is also observed.

**Reproductive Effects:** In animals adverse reproductive effects include: testicular atrophy, embryo toxicity. In clinical use adverse reproductive effects include: reduced fetal growth. Data for component (s) given below.

| Ingredients  | Percent     | Reproductive Effects                | Species      | Dosage | Units | Route | Duration                            |
|--------------|-------------|-------------------------------------|--------------|--------|-------|-------|-------------------------------------|
| Cyclosporine | proprietary | Testicular Atrophy, Embryotoxicity. | Rats Rabbits | 15     | mg/kg | Oral  | Premating in Males During Gestation |

**Carcinogenicity:** In clinical use produced tumors in the following tissue (s): lymphatic system. In animals produced tumors in the following tissue (s): lymphatic system, kidney. Data for components given below.

| Ingredients  | Percent     | Site of Tumors            | Species   | Dosage | Units | Route | Duration |
|--------------|-------------|---------------------------|-----------|--------|-------|-------|----------|
| Cyclosporine | proprietary | Lymphatic system, Kidney. | Mice Rats | 7.5    | mg/kg | Oral  | Lifetime |

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**Mutagenicity:** Negative in mutagenicity assays. Data for component (s) given below.

| Ingredients            | Percent     | Ames Test: | Mouse<br>Lymphoma Assay | Micronucleus<br>Assay | Chromosomal<br>Abbr. Assay |
|------------------------|-------------|------------|-------------------------|-----------------------|----------------------------|
| Polyoxyl 35 Castor Oil | proprietary | Negative   | No Data.                | No Data.              | No Data.                   |

**Notes:**

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

## 12. ECOLOGICAL INFORMATION

**Aquatic Toxicity:** Not determined.

**Biodegradation:** Not determined.

**General Notes:** None.

**Notes:**

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

## 13. DISPOSAL CONSIDERATIONS

**Waste Disposal Methods:** Disposal should be made in accordance with federal, state and local regulations. This material is not a RCRA hazardous waste.

## 14. TRANSPORT INFORMATION

**DOT:**  
**Status:** Not Regulated.

**ICAO/IATA:**  
**Status:** Not Regulated.

**IMDG:**  
**Status:** Not Regulated.

**TDG (Canada):**  
**Status:** Not Regulated.

## 15. REGULATORY INFORMATION

**SARA 313 Information**

**Product Name:** Cyclosporine Oral Solution, USP, 100 MG/ML  
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| Ingredients            | Percent     | SARA 313 Chemical: | CERCLA RQ/SARA EHS RQ (lbs): | SARA EHS TPQ (lbs): |
|------------------------|-------------|--------------------|------------------------------|---------------------|
| Cyclosporine           | proprietary | No                 | Not Applicable               | Not applicable      |
| Sorbitan Monooleate    | proprietary | No                 | Not Applicable               | Not applicable      |
| Polyoxyl 35 Castor Oil | proprietary | No                 | Not Applicable               | Not applicable      |
| Propylene Glycol       | proprietary | No                 | Not Applicable               | Not applicable      |

**SARA 311/312 Hazard Categories:**

**Immediate Health:** No  
**Delayed Health:** No  
**Fire:** No  
**Sudden Pressure:** No  
**Reactivity:** No

**TSCA Inventory Status:** Exempt.

**CERCLA Status:** Not regulated.

**RCRA Status:** Not a hazardous waste.

**Proposition 65 Status:** Chemicals known to the State of California to cause cancer or reproductive harm listed below.

| Ingredients  | Percent     | Proposition 65 Listed Materials |
|--------------|-------------|---------------------------------|
| Cyclosporine | proprietary | carcinogen; initial date 1/1/92 |

**EC HAZARD CLASSIFICATION:**

**Category of Danger:** Exempt.  
**Indication of danger:** Exempt.  
**ICH Classification:** Not determined.

**CANADIAN REGULATIONS:**

**Canadian Inventory:** Not determined.  
**Canadian NDSL:** Not determined.  
**WHMIS Hazard Class:** Not determined.

**Notes:**

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. ICH = International Committee for Harmonization.

**16. OTHER INFORMATION**

**Document Authored By:** Jill Sohl

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**Disclaimer:**

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