

Product Name: Cyclosporine Toluene Distillate
Issued: Dec-17-2004



MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name and Address: Abbott Laboratories
North Chicago, IL 60064

Customer Service Telephone: Global Environmental Materials Management Operations: 1 - 847 - 938 - 3810

Emergency Telephone: 1 - 800 - 424 - 9300 CHEMTREC (USA)
1 - 703 - 527 - 3887 CHEMTREC (INTERNATIONAL)

Product Name: Cyclosporine Toluene Distillate

Synonyms: Cyclosporine Toluene Distillate; Cyclosporine Toluene Stream; Toluene - Low-Grade; Low-Grade Toluene

Product Use: Spent solvent for sale / recycling

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Percent	OSHA PEL	ACGIH TLV	AIHA WEEL	Abbott EEL	Skin Notation
Toluene 108-88-3	75 - 95	200 ppm TWA 300 ppm Ceiling	50 ppm TWA	Not Applicable	Not Applicable	Skin (ACGIH)
Ethyl Alcohol 64-17-5	4 - 15	1000 ppm TWA 1900 mg/m ³ TWA	1000 ppm TWA	Not Applicable	Not Applicable	None
Methyl Alcohol 67-56-1	0.1 - 1	200 ppm TWA 260 mg/m ³ TWA	250 ppm STEL 200 ppm TWA	Not Applicable	Not Applicable	Skin (ACGIH)
Acetone 67-64-1	1 - 10	1000 ppm TWA 2400 mg/m ³ TWA	750 ppm STEL 500 ppm TWA	Not Applicable	Not Applicable	None
Water 7732-18-5	0 - 2	Not Listed	Not Listed	Not Applicable	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.

3. HAZARDS IDENTIFICATION

Emergency Overview:

Clear, water-white liquid to cloudy, faintly yellow liquid.
Odor: Aromatic solvent odor.
Flammable liquid.

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No data are available for evaluation of this material.

Components may cause skin, eye and/or respiratory tract irritation. May cause fatigue, headache and dizziness.
Potential for absorption through the skin.

Routes of Exposure:

Oral: Yes (one or more components)
Dermal: Yes (one or more components)
Inhalation: Yes

Hazard Information:

Ingestion Rating: Not determined.
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: Possible target organs include: , pancreas , Kidney , Liver , Respiratory System , Nervous System , Hematopoietic System , Cardiovascular System , Female Reproductive System , Eyes .

Carcinogenicity Rating:

Ingredients	Percent	OSHA:	NTP:	IARC:	ACGIH:
Toluene	75 - 95	Not Listed	Not Listed	Not Listed	Not Listed
Ethyl Alcohol	4 - 15	Not Listed	Not Listed	Not Listed	Not Listed
Methyl Alcohol	0.1 - 1	Not Listed	Not Listed	Not Listed	Not Listed
Acetone	1 - 10	Not Listed	Not Listed	Not Listed	Not Listed
Water	0 - 2	Not Listed	Not Listed	Not Listed	Not Listed

NFPA Rating:

Health: Not determined.
Fire: Not determined.
Reactivity: 0

Signs and Symptoms:

Major ingredient - eye irritation, corneal injury, defatting of skin, headaches, respiratory irritation, hilarity, lassitude, tearing, visual impairment, nasal discharge, drowsiness, ataxia, dizziness, metallic taste, cognitive dysfunction. Chronic exposure may result in the following: loss of appetite, altered reaction time, memory lapse, palpitation, abnormal liver function, abnormal kidney function, muscle weakness, altered hematology profile, cardiac changes.

**Medical Conditions
Aggravated by Exposure:**

Data suggest any preexisting ailments in the following organs: skin, eyes, nervous system, female reproductive system, cardiovascular system, respiratory system, hematopoietic system, liver, kidneys. Concurrent intake of depressants like alcohol. Concurrent use of stimulants.

4. FIRST AID MEASURES

Product Name:	Cyclosporine Toluene Distillate
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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.
Notes To Physician:	Aspiration may cause severe lung damage. Evacuate stomach in a way which avoids aspiration.

5. FIRE FIGHTING MEASURES

FLAMMABILITY:

Autoignition Temp. (°C): Not determined.

FIRE-FIGHTING INFORMATION:

Suitable Extinguishing Media: Foam. Carbon dioxide Dry chemical Water fog

Special Protective Equipment: Fire fighters should wear full protective clothing, including self-contained breathing equipment.

Special Exposure Hazards: Avoid inhalation of combustion products.

U.S. Emergency Response Guidebook No.: 128

6. ACCIDENTAL RELEASE MEASURES

Methods of Cleaning and Collecting: Restrict spill area to those equipped with personal protection specified in Section 8. Absorb with suitable material. Place into an appropriate container for disposal.

Personal Precautions: Restrict spill area to those equipped with personal protection specified in Section 8.

Environmental Precautions: Keep away from drains and surface waters.

Incompatibilities: Oxidizing materials.

7. HANDLING AND STORAGE

Handling: Bond and ground containers during transfer operations.

Storage: Keep away from heat and open flame.

Special Precautions: Not applicable.

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: Local exhaust ventilation as necessary to maintain exposures to within applicable limits.

Respiratory Protection: Use approved NIOSH respiratory protection if TLV exceeded or overexposure is likely.

Eyes: Wear eye protection appropriate to handling activities.

Gloves: Impervious gloves.

Other PPE Data: Not determined.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear, water-white liquid to cloudy, faintly yellow liquid.

Odor: Odor: Aromatic solvent odor.

Boiling Pt. @ 760 mm Hg (°C): Not determined.

Melting/Freezing Point: Not determined.

Vapor Pressure (mm Hg) Not determined.

Bulk Density at 20°C: Not determined.

Solubility: Not determined.

Specific Gravity: Not determined.

Density, g / mL: 0.83 - 0.86

pH: 6 - 7

Viscosity (centipoise): Not determined.

10. STABILITY AND REACTIVITY

Chemical Stability: Stable at normal temperature and pressures.

Self-Heating Tendency: Not determined.

Materials to Avoid: Oxidizers.

Hazardous Decomposition Products: May emit under fire conditions: CO, CO₂.

Hazardous Polymerization: Not known to occur.

Conditions to Avoid: Avoid contact with heat, sparks, open flame, and static discharge.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Oral: LD50 not determined for product. Data for component (s) given below.

Ingredients	Percent	Acute Test	Value	Units	Species
Toluene	75 - 95	LD50 =	636-7400	mg/kg	Rats
Ethyl Alcohol	4 - 15	LD50 =	5560-13,700	mg/kg	Guinea Pigs Rats Mice Rabbits
Methyl Alcohol	0.1 - 1	LD50 =	5000-7300	mg/kg	Rats Mice
Acetone	1 - 10	LD50 =	1738-10,700	mg/kg	Mice Rats Rabbits

Acute Toxicity - Dermal: LD50 not determined for product. Data for component (s) given below.

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Ingredients	Percent	Acute Test	Value	Units	Species
Toluene	75 - 95	LD50 >	12,000 - 14,000	mg/kg	Rats Rabbits
Ethyl Alcohol	4 - 15	LD50 =	20000	mg/kg	Rabbits
Methyl Alcohol	0.1 - 1	LD50 =	15,800	mg/kg	Rabbits
Acetone	1 - 10	LD50 =	20,000	mg/kg	Rabbits

Acute Toxicity - Inhalation: LC50 not determined for product. Data for component (s) given below.

Ingredients	Percent	Test	Value	Units	Species
Toluene	75 - 95	LC 50 =	5300-26,700	ppm (variable exposure times)	Rats Mice Rabbits
Ethyl Alcohol	4 - 15	LC 50 =	20000	ppm	Rats
Methyl Alcohol	0.1 - 1	LC 50 =	64,000	ppm	Rats
Acetone	1 - 10	LC 50 <	16,000	ppm , 4 hour	Rats

Corrosivity: Not determined.

Dermal Irritation: Not determined for product. Major ingredient: Produced mild to moderate skin irritation in animals. Minor ingredients are skin irritants.

Eye Irritation: Not determined for product. Major ingredient: Produced mild to severe eye irritation in animal testing. Minor ingredients are eye irritants.

Sensitization: Not determined.

Target Organ Effects: Not determined for this mixture. Volatile organic solvents typically target the central nervous system and skin.
Major Ingredient : In animal testing, target organs include: skin, eyes, respiratory system, cardiovascular system, nervous system, female reproductive system, hematopoietic system, liver, kidneys. Minor Ingredient : gastrointestinal tract, pancreas, eyes.

Ingredients	Percent	Target Organs:	Species	Dosage	Units	Route	Duration
Acetone	1 - 10	Kidney.	Rats	500	mg/kg	Oral	90 days

Reproductive Effects: Not determined.

Ethyl Alcohol : Use of alcohol during pregnancy can lead to retarded growth, development delays and abnormalities (fetal alcohol syndrome).

Carcinogenicity: Not determined.

Mutagenicity: Data for component (s) given below.

Ingredients	Percent	Ames Test:	Mouse Lymphoma Assay	Micronucleus Assay	Chromosomal Abbr. Assay
Toluene	75 - 95	Negative	No Data.	Negative	Negative
Acetone	1 - 10	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: Data for component (s) given below.

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Ingredients	Percent	LC 50 (mg/l)	Species	Duration
Acetone	1 - 10	5540	Rainbow Trout	96 Hours

Biodegradation: Not determined.

General Notes: Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

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: This material is regulated in the U.S. as a hazardous waste under 40 CFR, part 261 due to its ignitability characteristic. All waste must be packaged, labeled, transported and disposed of in conformance with applicable local, state, and federal laws and regulations and in accordance with good engineering practices.

14. TRANSPORT INFORMATION

DOT:

Status: Regulated.
DOT Basic Shipping Description: Flammable Liquid, N.O.S. (Toluene, Ethanol), 3, UN1993, PGII

ICAO/IATA:

Status: Regulated.
Hazard Class: 3
UN ID: UN1993
Packing Group: II

IMDG:

Status: Regulated.
Dangerous Goods Description: Flammable Liquid, N.O.S. (Toluene, Ethanol)
Hazard Class: 3
UN ID: UN1993
Packing Group: II

TDG (Canada):

Status: Not determined.

15. REGULATORY INFORMATION

SARA 313 Information

Product Name: Cyclosporine Toluene Distillate
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Ingredients	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Toluene	75 - 95	1.0 % de minimis concentration	1000 lb 454 kg	Not applicable
Ethyl Alcohol	4 - 15	No	Not Applicable	Not applicable
Methyl Alcohol	0.1 - 1	1.0 % de minimis concentration	2270 kg 5000 lb	Not applicable
Acetone	1 - 10	No	2270 kg 5000 lb	Not applicable
Water	0 - 2	No	Not Applicable	Not applicable

SARA 311/312 Hazard Catagories:

Immediate Health: Yes
Delayed Health: Not determined.
Fire: Yes
Sudden Pressure: No
Reactivity: No

TSCA Inventory Status: Not determined.

CERCLA Status: Not determined.

RCRA Status: Not determined.

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

Ingredients	Percent	Proposition 65 Listed Materials
Ethyl Alcohol	4 - 15	Developmental toxicity (when in alcoholic beverages); initial date 10/1/87.

EC HAZARD CLASSIFICATION:

Category of Danger: Not determined.
Indication of danger: Not Determined
Risk Phrases: Not determined
ICH Classification: Not determined.

CANADIAN REGULATIONS:

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

Notes:

1. SARA = Superfund Ammendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insectacide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

16. OTHER INFORMATION

Document Authored By: Julie Nowak

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Disclaimer:

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