








Material Safety Data Sheet

NFPA	HMIS	Personal Protective Equipment						
	<table><tr><td>Health Hazard</td><td>1</td></tr><tr><td>Fire Hazard</td><td>1</td></tr><tr><td>Reactivity</td><td>0</td></tr></table>	Health Hazard	1	Fire Hazard	1	Reactivity	0	<div></div> <div>See Section 15.</div>
Health Hazard	1							
Fire Hazard	1							
Reactivity	0							

Section 1. Chemical Product and Company Identification		Page Number: 1
Common Name/ Trade Name	Cyclosporine	Catalog Number(s). C1698, C2659
Manufacturer	SPECTRUM LABORATORY PRODUCTS INC. 14422 S. SAN PEDRO STREET GARDENA, CA 90248	CAS# 59865-13-3
Commercial Name(s)	Not available.	RTECS GZ4120000
Synonym	Cyclosporin A; Cyclosporine A; Neoral; Ramihyphin; Sandimmune; Sandimmune; Ciclosporin	TSCA TSCA 8(b) inventory: No products were found.
Chemical Name	Cyclosporine	CI# Not available.
Chemical Family	Not available.	IN CASE OF EMERGENCY CHEMTREC (24hr) 800-424-9300 CALL (310) 516-8000
Chemical Formula	C62-H111-N11-O12	
Supplier	SPECTRUM LABORATORY PRODUCTS INC. 14422 S. SAN PEDRO STREET GARDENA, CA 90248	

Section 2. Composition and Information on Ingredients					
		Exposure Limits			
Name	CAS #	TWA (mg/m ³)	STEL (mg/m ³)	CEIL (mg/m ³)	% by Weight
1) Cyclosporine	59865-13-3				100
Toxicological Data on Ingredients	Cyclosporine: ORAL (LD50): Acute: 1480 mg/kg [Rat]. 2329 mg/kg [Mouse]. 10000 mg/kg [Rabbit].				

Section 3. Hazards Identification	
Potential Acute Health Effects	Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.
Potential Chronic Health Effects	CARCINOGENIC EFFECTS: Classified 1 (Proven for human.) by IARC, 1 (Clear evidence, known carcinogen.) by NTP. MUTAGENIC EFFECTS: Classified POSSIBLE for human. TERATOGENIC EFFECTS: Not available. DEVELOPMENTAL TOXICITY: Classified Reproductive system/toxin/female, Reproductive system/toxin/male, Developmental toxin [POSSIBLE]. The substance may be toxic to blood, kidneys, the reproductive system, liver, central nervous system (CNS). Repeated or prolonged exposure to the substance can produce target organs damage.

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Section 4. First Aid Measures

Eye Contact	Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. WARM water MUST be used. Get medical attention if irritation occurs.
Skin Contact	Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops.
Serious Skin Contact	Not available.
Inhalation	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
Serious Inhalation	Not available.
Ingestion	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.
Serious Ingestion	Not available.

Section 5. Fire and Explosion Data

Flammability of the Product	May be combustible at high temperature.
Auto-Ignition Temperature	Not available.
Flash Points	Not available.
Flammable Limits	Not available.
Products of Combustion	These products are carbon oxides (CO, CO ₂), nitrogen oxides (NO, NO ₂ ...).
Fire Hazards in Presence of Various Substances	Slightly flammable to flammable in presence of heat.
Explosion Hazards in Presence of Various Substances	Risks of explosion of the product in presence of mechanical impact: Not available. Risks of explosion of the product in presence of static discharge: Not available.
Fire Fighting Media and Instructions	SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet.
Special Remarks on Fire Hazards	When heated to decomposition it emits toxic fumes of nitrogen oxides.
Special Remarks on Explosion Hazards	Not available.

Section 6. Accidental Release Measures

Small Spill	Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.
Large Spill	Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Section 7. Handling and Storage

Precautions	Keep away from heat. Keep away from sources of ignition. Ground all equipment containing material. Do not ingest. Do not breathe dust. Wear suitable protective clothing. If ingested, seek medical advice immediately and show the container or the label.
Storage	Keep container tightly closed. Keep container in a cool, well-ventilated area. Sensitive to light. Store in light-resistant containers.

Section 8. Exposure Controls/Personal Protection

Engineering Controls	Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.
Personal Protection	Safety glasses. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.
Personal Protection in Case of a Large Spill	Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.
Exposure Limits	Not available.

Section 9. Physical and Chemical Properties

Physical state and appearance	Solid.	Odor	Not available.
Molecular Weight	1202.61 g/mole	Taste	Not available.
pH (1% soln/water)	Not available.	Color	White.
Boiling Point	Not available.		
Melting Point	148°C (298.4°F) - 151 C.		
Critical Temperature	Not available.		
Specific Gravity	Not available.		
Vapor Pressure	Not applicable.		
Vapor Density	Not available.		
Volatility	Not available.		
Odor Threshold	Not available.		
Water/Oil Dist. Coeff.	Not available.		
Ionicity (in Water)	Not available.		
Dispersion Properties	See solubility in water, methanol, diethyl ether, acetone.		
Solubility	Easily soluble in methanol, diethyl ether, acetone. Slightly soluble in cold water.		

Section 10. Stability and Reactivity Data

Stability	The product is stable.
Instability Temperature	Not available.
Conditions of Instability	Excess heat
Incompatibility with various substances	Not available.
Corrosivity	Not available.

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Cyclosporine		Page Number: 4
Special Remarks on Reactivity	Sensitive to light.	
Special Remarks on Corrosivity	Not available.	
Polymerization	Will not occur.	

Section 11. Toxicological Information		
Routes of Entry	Inhalation. Ingestion.	
Toxicity to Animals	Acute oral toxicity (LD50): 1480 mg/kg [Rat].	
Chronic Effects on Humans	<p>CARCINOGENIC EFFECTS: Classified 1 (Proven for human.) by IARC, 1 (Clear evidence, known carcinogen.) by NTP.</p> <p>MUTAGENIC EFFECTS: Classified POSSIBLE for human.</p> <p>DEVELOPMENTAL TOXICITY: Classified Reproductive system/toxin/female, Reproductive system/toxin/male, Development toxin [POSSIBLE].</p> <p>May cause damage to the following organs: blood, kidneys, the reproductive system, liver, central nervous system (CNS).</p>	
Other Toxic Effects on Humans	Slightly hazardous in case of skin contact (irritant), of ingestion, of inhalation.	
Special Remarks on Toxicity to Animals	Not available.	
Special Remarks on Chronic Effects on Humans	<p>May cause adverse reproductive effects and birth defects (teratogenic).</p> <p>May affect genetic material (mutagenic).</p> <p>May cause cancer.</p> <p>Human: passes through the placenta, excreted in maternal milk.</p>	
Special Remarks on other Toxic Effects on Humans	<p>Acute Potential Health Effects:</p> <p>Skin: May cause skin irritation.</p> <p>Eyes: May cause eye irritation.</p> <p>Inhalation: May cause respiratory tract irritation.</p> <p>Ingestion: May be harmful if swallowed. May cause digestive tract/gastrointestinal tract irritation with altered taste, abdominal pain, nausea, vomiting, burning sensation in the mouth, hypermotility and diarrhea. May also cause sore gums, flushing of the face, sensation of increased abdominal girth, foot swelling, cyanosis, wheezing and pallor, respiratory depression. May affect behavior/central nervous system (muscle contraction or spasticity, tremor, drowsiness, headache, feeling of drunkenness).</p> <p>Chronic Potential Health Effects:</p> <p>Ingestion: Prolonged or repeated ingestion may affect the urinary system (kidneys - renal dysfunction), liver (mild hepatotoxicity), blood (changes in serum composition), - hyperlipidemia), metabolism (weight loss, metabolic acidosis), cardiovascular system (hypertension, hypotension, tachycardia), spleen, musculoskeletal system (teeth and supporting structures), behavior/central nervous system (somnolence and other symptoms similar to acute ingestion). It may also cause symptoms similar to that of acute ingestion.</p>	

Section 12. Ecological Information		
Ecotoxicity	Not available.	
BOD5 and COD	Not available.	
Products of Biodegradation	Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.	
Toxicity of the Products of Biodegradation	The products of degradation are less toxic than the product itself.	
Special Remarks on the Products of Biodegradation	Not available.	

Section 13. Disposal Considerations**Waste Disposal**

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14. Transport Information**DOT Classification**

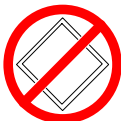
Not a DOT controlled material (United States).

Identification

Not applicable.

Special Provisions for Transport

Not applicable.

DOT (Pictograms)**Section 15. Other Regulatory Information and Pictograms****Federal and State Regulations**

California prop. 65: This product contains the following ingredients for which the State of California has found to cause cancer, birth defects or other reproductive harm, which would require a warning under the statute:

Cyclosporine

California prop. 65: This product contains the following ingredients for which the State of California has found to cause cancer which would require a warning under the statute: Ciclosporin (Cyclosporine)

California Proposition 65 Warnings

California prop. 65: This product contains the following ingredients for which the State of California has found to cause cancer which would require a warning under the statute: Ciclosporin (Cyclosporine)

Other Regulations

OSHA: Hazardous by definition of Hazard Communication Standard (29 CFR 1910.1200).

Other Classifications**WHMIS (Canada)**

Not controlled under WHMIS (Canada).

DSCL (EEC)

R22- Harmful if swallowed.

R45- May cause cancer.

R62- Possible risk of impaired fertility.

R63- Possible risk of harm to the unborn child.

S2- Keep out of the reach of children.

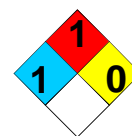
S46- If swallowed, seek medical advice immediately and show this container or label.
S53- Avoid exposure - obtain special instructions before use.

HMIS (U.S.A.)

Health Hazard	1
Fire Hazard	1
Reactivity	0
Personal Protection	E

National Fire Protection Association (U.S.A.)

Health



Flammability

Reactivity

Specific hazard

WHMIS (Canada) (Pictograms)**DSCL (Europe) (Pictograms)**

**TDG (Canada)
(Pictograms)****ADR (Europe)
(Pictograms)****Protective Equipment**

Gloves.



Lab coat.



Dust respirator. Be sure to use an approved/certified respirator or equivalent.



Safety glasses.

Section 16. Other Information**MSDS Code** C5152**References** Not available.**Other Special Considerations** Not available.

Validated by Sonia Owen on 8/11/2006.

Verified by Sonia Owen.

Printed 9/11/2006.

CALL (310) 516-8000

Notice to Reader

All chemicals may pose unknown hazards and should be used with caution. This Material Safety Data Sheet (MSDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this MSDS. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this MSDS is based on technical data judged to be reliable, Spectrum Quality Products, Inc. assumes no responsibility for the completeness or accuracy of the information contained herein.