

MATERIAL SAFETY DATA SHEET
CCI-779

Wyeth-Ayerst Laboratories
P.O. Box 8299
Philadelphia, PA 19101
(610)688-4400

SECTION I - IDENTITY

Chemical or Common Name: Rapamycin 42 - [3-hydroxy-2-(hydroxymethyl)-2-methylpropanoate]

Formula: C₅₆ H₈₇ N O₁₆

CAS No.: 162635-04-3

Chemical Family: Not Available

Synonyms: WAY -130,779

SECTION II - HAZARDOUS COMPONENTS

Component	CAS No.	Percentage	TLV
CCI-779	162635-04-3	100	Not Available

SECTION III - PHYSICAL AND CHEMICAL DATA

Boiling Point:	Not Applicable
Melting Point:	162.3 C
Specific Gravity (H ₂ O=1):	Not Available
Vapor Pressure (mm Hg):	Not Applicable
Percent Volatile by Volume:	Not Applicable
Vapor Density (Air=1):	Not Applicable
Evaporation Rate:	Not Applicable
Solubility in Water:	Less than 1.1 micrograms/ml
Appearance and Odor:	White powder, odorless
Stability:	Stable
Hazardous Polymerization:	Will not occur
Conditions to Avoid:	Stable in regard to safety concerns.
Hazardous Decomposition Products:	Not Available

SECTION IV - FIRE AND EXPLOSION DATA

Flash Point: Not Applicable
Flammable Limits: LEL - Not Applicable UEL - Not Applicable
Auto-Ignition Temperature: Not Applicable

Extinguishing Media: All media are acceptable. Choose as appropriate for surrounding fire and materials.

Special Fire Fighting Procedures: Wear protective clothing and self-contained breathing apparatus.

Unusual Fire and Explosion Hazards: Dry material is assumed to be combustible. Avoid accumulations and keep away from ignition sources.

SECTION V - TOXICOLOGY DATA

Acute Oral, Rat: > 100 mg/kg
Acute Oral, Mouse: > 100 mg/kg
Acute IV, Rat: 50 mg/kg
Acute IV, Mouse: >50 mg/kg
Acute Dermal Irritation, Rabbit: Not Applicable
Primary Eye Irritation, Rabbit: Not Applicable
Ames Test: Negative
Listed as Carcinogen: OSHA Not Available
NTP Not Available
IARC Not Available

Other Carcinogenicity/
Mutagenicity Data: Not Available

Multiple Dose Toxicity Data:
(No Toxicologic Effect Dose/
Species/Study Length): Immunesuppression, testicular atrophy. Well tolerated in rats 0.5 mg/kg IV. Well tolerated in monkeys 2.5 mg/kg IV

Other: Not Available

SECTION VI - HEALTH HAZARDS DATA

Threshold Limit Value: Not Available
Therapeutic Dose: Not Available
Routes of Absorption: Dermal (No) Inhalation (Yes) Ingestion (Yes)
Indications: - Primary: Oncology
 - Secondary: Autoimmune diseases
Effects of Overexposure: Immunosuppression, with possibility of opportunistic infections

Substance Producing
Additive Effects: Corticosteroids

Medical Conditions

Aggravated by Exposure: 130,779 is a derivative of Rapamune and its pharmacological properties are the same.

SECTION VII - EMERGENCY FIRST AID

Eye Contact: Remove contact lenses if present. Flush with copious amounts of water for fifteen minutes. Separate eyelids with fingers while flushing. Call physician for instructions.

Skin Contact: Wash with copious amounts of water. Remove contaminated clothing. See physician if redness or irritation develops.

Inhalation: Remove to fresh air. Call physician and treat symptoms.

Ingestion: Flush out mouth with water. Call physician and treat symptoms.

SECTION VIII - SPECIAL PROTECTION INFORMATION

Ventilation/

Exposure Controls: Enclose operations to prevent dust generation into the work environment. Handle material in well ventilated area. Provide local exhaust ventilation for operations with potential to generate dust until an effective enclosure is implemented. Limit access to the operations, only personnel trained on the handling of the material shall be permitted in the area.

Respiratory:

Based on limited toxicity and health hazard data available for the material, it is recommended that powered air purifying respirators with HEPA cartridges be used as the minimum respiratory protection. A lower level of respiratory protection can be considered if a hazard evaluation of the operation indicates it is appropriate.

- Eye Protection:** Safety glasses with side shields are required at a minimum.
- Protective Gloves:** Appropriate gloves are required such as latex gloves to prevent skin contact.
- Protective Clothing:** Use as required to prevent skin contact.
- Work/Hygienic Practices:** Investigational drug - handle with caution.

SECTION IX - STORAGE AND HANDLING

Storage/Handling

Precautions: No special storage precautions are required for safety. Handle and store per label and other instructions to maintain product integrity

Other Precautions: Avoid contact and inhalation. Use with adequate ventilation and avoid generating airborne particles. Wash thoroughly after handling. Do not eat, drink, or smoke near material.

SECTION X - SPILL AND LEAK PROCEDURES

Steps for Release of Spill: Clean up small spills with a damp towel. Vacuum or sweep/mop up larger spills. Avoid creating airborne material. Place in an appropriate container for waste disposal. Wash with water and ventilate area. Wear protective clothing.

Waste Disposal: Incinerate in an approved incinerator or take to an approved land disposal site. Follow all Local, State and Federal regulations.

APPROVALS

- Date Issued:** Updated (Drug Safety and Metabolism) January 31, 2001
- Chemistry:** Dr. L. Humber, Ph.D.
- Toxicity:** Dr. A. Arthur, Ph.D.
- Pharmacology:** Dr. S. Sehgal, Ph. D
- Medical:** Dr. M. Murray, D.O.
- Safety:** Mr. D. Campbell, CIH

Other Specialty: None

Retired: No



The information provided in this MSDS is based upon sources believed to be accurate. However, the Company assumes no responsibility for the accuracy, completeness or suitability of this information. The product user is responsible to determine the suitability of this information for their particular purposes.