



SAFETY DATA SHEET

1. Identification:

Product Identifier: Sirolimus Oral Solution

Other means of identification Synonyms: Rapamycin (Sirolimus)

Recommended use: This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions: No other uses are advised.

Manufacturer: Novitium Pharma LLC
70 Lake Drive, East Windsor, NJ – 08520
Online Assistance: www.novitiumpharma.com

2. Hazard(s) Identification:

Potential Acute Health Effects: Hazardous in case of ingestion. Slightly hazardous in case of eye contact (irritant), of inhalation.

Potential Chronic Health Effects: The active substance is toxic to reproduction (category 2). Repeated or prolonged exposure to the substance can cause long-term adverse effects in the aquatic environment.

Carcinogenic Effects: Not available.

Mutagenic Effects: Not available.

Teratogenic Effects: Not available.

Developmental Toxicity: Not available.

Adverse Effects: Adverse effects may impair fertility, may cause harm to the inborn child, very toxic to aquatic life with long lasting effect.

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3. Composition/Information on Ingredients:

Chemical Name	CAS Number
Sirolimus (Rapamycin)	53123-88-9
Phosal 50 PG	N/A
Polysorbate 80 NF (Tween 80)	9005-65-6

4. First-aid measures:

General Information:

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention immediately.

Skin Contact: In case of skin contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

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. Get medical attention if irritation occurs.

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 swallowed, call a physician immediately. Loosen tight clothing such as collar, tie belt or waistband.

Notes to Physician:

Seek product package insert for complete information.

Overdose Treatment:

For current information about the treatment of overdose, consult a certified Regional Poison Control Center by calling the number listed in your local telephone directory.

5. Fire-Fighting Measures:

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Flammability of the product:
No Data Available

Auto- Ignition Temperature/Flash Points/Flammable Limits:
Not Available

Products of Combustion:
These products are carbon oxides (CO, CO₂), nitrogen oxides (NO, NO₂).

Fire Hazards in presence of Various Substances:
Not Available

Explosion Hazards in presence of Various Substances:
Risk 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

Extinguishing Media and Instruction:
Small fire – Use DRY chemical powder.
Large fire – Use water spray, fog, carbon dioxide or foam as appropriate for surrounding fire and materials. DO NOT use water jet.

Firefighting Equipment/Instructions:
As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific remarks:
Not available.

6. Accidental Release Measures:

Personal precautions, Protective Equipment and Emergency Procedures:
Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.

Environmental Precautions:
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Materials for Containment and Cleaning Up:
Measures for cleaning/Collecting: Contain the source of the spill or leak. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal. Clean spill area thoroughly. Prevent discharge to.
Additional Consideration for Large Spills: Non-essential Personnel should be evacuated

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Persons wearing respirators should be fit tested and approved for respirator use, under OSHA Respiratory Protection Standard 29 CFR 1910.134.

Exposure Limit:

Not available.

9. Physical and Chemical Properties:

Appearance	Yellow colored solution
Physical state	Liquid
Form	Oral Solution
Odor	Not available
Solubility	Not available

10. Stability and Reactivity:

Reactivity:	Stable under normal conditions of use
Chemical Stability:	The product is stable under normal conditions of use
Possibility of Hazardous Reaction:	Not available
Condition to Avoid:	Avoid exposure to light, heat, air and moisture
Incompatible Materials:	Not available
Corrosivity:	Not available
Polymerization:	Not available

11. Toxicological information:

Information on likely routes of exposure: Ingestion.

Toxicity to Animals: LD50: Not Available. LC50: Not Available

Chronic Effects on Humans: Cause damage to the reproductive system and Fertility

Other Toxic Effects on Humans: Hazardous in case of ingestion. Slightly hazardous in case of inhalation.

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.

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Toxicity of the products of degradation The products of degradation are more toxic.

13. Disposal considerations:

Waste Treatment Methods

Dispose of waste in accordance with all applicable law and regulations. Member state specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste ater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental release. This may include destructive techniques for waste and wastewater.

Waste from residues/unused products

Dispose of waste in accordance with all applicable federal, state and local laws

Waste disposal

Dispose of waste in accordance with all applicable federal, state and local laws

14. Transport information:

DOT	Not a DOT controlled Material (United States)
UN Number	Not applicable
UN Shipping name	Not applicable
Transport hazard class	Not applicable
Packing group	Not applicable
Environmental hazard	Not applicable
Transport in Bulk	Not applicable
Special precautions needed with transport	Not applicable

15. Regulatory information:

Federal and State Regulations: Not available

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

Other Classifications: WHMIS – Class D, Division 2, Subdivision A

DSCL (EEC): R36 – This product is not listed according to the EU regulation.

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This product does not contain any DHS chemicals.

Protective Equipment: Gloves. Lab coat. Safety glasses. Dust Respirator. Be sure to use an approved/certified respirator or equivalent.

16. Other Information:

Reference: 1. SDS of Sirolimus (Rapamycin) Oral Solution (Pfizer)

2. SDS of Rapamycin (Thermo fisher Scientific)

Other Special Considerations: Not Available

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Version # 00

Disclaimer: The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

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from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. Handling and Storage:

Precautions for Safe Handling:

Restrict access to work area. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment. Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and water disposal measures to prevent occupational exposure or environmental release. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. It is recommended that all operations be fully enclosed and no air recirculated.

Conditions for Safe Storage, Including any Incompatibilities:

Keep container tightly closed. Keep container in a cool, dry, well ventilated area (see USP CRT storage conditions). Protect from light and store at controlled room temperature 20°C to 25°C (68°F to 77°F) Refer to label instructions to ensure product integrity.

Avoid extreme heat, sparks, open flames, moisture and light.

8. Exposure Control/Personal Protection:

Biological Limit Values:

No biological exposure limits noted for the ingredients(s).

Engineering Controls:

In a manufacturing setting, local exhaust ventilation may be necessary to control air contaminants to their exposure limits. The use of local ventilation is recommended to control emissions near the source. Provide mechanical ventilation for confined spaces. If user operations generate aerosols, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual Protection Measures, such as Personal Protective Equipment:

Safety glasses. Lab coat. Gloves. Dust respirator. Be sure to use an approved/certified respirator or equivalent. In case of 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

Respiratory Protection:

Under normal use, respirators are not required. If dusts are generated, use a disposable (N95).