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	SAFETY DATA SHEET (SDS)	
Product Name	Sirolimus Oral Solution, 1 mg/mL	

1. Product Information

Product Name: **Sirolimus Oral Solution, 1 mg/mL**

2. Composition

Sirolimus: 1%

Ethanol Content: 1.5-2.5%

3. Hazards Identification

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1B

Acute aquatic toxicity: Category 1

Chronic aquatic toxicity: Category 1

Label Elements

Signal Word: Danger

Hazard Statements:

H360FD - May damage fertility. May damage the unborn child.

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

Precautionary Statements:

P201 - Obtain special instructions before use

P281 - Use personal protective equipment as required

P308 + P313 - IF exposed or concerned: Get medical attention/advice P405 - Store locked up

P273 - Avoid release to the environment P391 - Collect spillage

P501 - Dispose of contents/container in accordance with all local and national regulations



Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

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4. First Aid Measures

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. Fire Fighting Measures

Extinguishing Media:

Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus

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6. Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

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

Methods and Material 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.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated 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 (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. 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

Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

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8. Exposure Controls/Personal Protection

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Ethanol	OSHA - Final PELS - TWAs:	1000 ppm
Sirolimus	Pfizer OEL TWA-8 Hr:	0.2µg/m ³

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal protective Equipment Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. Physical and Chemical Properties

Physical State:	Liquid
Odor:	No data available

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10. Stability and Reactivity

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	None known
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	No data available

11. Toxicological Information

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual Ingredients

Acute Toxicity: (Species, Route, End Point, Dose)

Sirolimus

Mouse Oral LD50 > 2500 mg/kg
Rat Oral LD50 > 800mg/kg

Ethanol

Mouse Oral LD50 3,450 g/m3
Rat Oral LD50 7,060mg/kg
Mouse Inhalation LC50 4h 39g/m3
Rat Inhalation LC50 10h 20,000ppm

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Mutagenicity: Not Mutagenic

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12. Ecological Information

Environmental Overview: In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater. Harmful effects to aquatic organisms could occur.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Sirolimus

Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 Hours 0.063 mg/L

Ethanol

Fingerling Trout NPDES LC50 24 Hours 11,200 mg/L

Oncorhynchus mykiss (Rainbow Trout) NPDES LC50 96 Hours 12,900 mg/L

Pimephales promelas (Fathead Minnow) NPDES LC50 96 Hours 14,200 mg/L

Mobility in Soil: No data available

13. Disposal Considerations

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws 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 water 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 releases. This may include destructive techniques for waste and wastewater.

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14. Transport Information

International Regulations: Not Classified by transport regulations, non-regulated

IATA / ICAO – Non-Hazardous - Not Regulated

IATA Proper shipping name: N/A

IATA UN / ID No: N/A

IATA Hazard Class: N/A

IATA Packing Group: N/A

IATA Label: N/A

IMDG – Non-Hazardous - Not Regulated

IMDG Proper shipping name: N/A

IMDG UN / ID No: N/A

IMDG Hazard Class: N/A

IMDG Flash Point N/A

IMDG Label: N/A

DOT – Non-Hazardous - Not Regulated

DOT Proper shipping name: N/A

DOT UN / ID No: N/A

DOT Hazard Class: N/A

DOT Flash Point N/A

DOT Packing Group: N/A

DOT Label: N/A

15. Regulatory Information

- Reporting Requirements**
- The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.
 - In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.
 - State and local regulations vary and may impose additional reporting requirements

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16. Other Information

Prepared by: MSN Pharmaceutical Inc, Piscataway, New Jersey – 08554

MSN Pharmaceutical Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

Disclaimer: This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. It is not meant to be an all-inclusive document on worldwide hazard communications regulations. This information is offered in good faith. Each user of this material needs to evaluate the conditions of use and design the appropriate mechanisms to prevent employee exposures, property damage or release to the environment.

End Of Safety Data Sheet