



SAFETY DATA SHEET

Version 1.0

Revision Date 05/08/2019

1. PRODUCT AND COMPANY IDENTIFICATION

1.0 Product identifiers

Product name : Sirolimus Oral Solution, 1 mg/ml

Product codes :

1.1 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Pharmaceutical preparation

Uses advised against : All other uses

1.2 Details of the supplier of the safety data sheet

Company : Amneal Pharmaceuticals
1 New England Avenue
Piscataway, NJ 08854
USA

Telephone : +1 732-645-3030

1.3 Emergency telephone number

Emergency Phone # (24hrs) : CHEMTREC 1-800-424-9300 CCN796801 [US and Canada]
+1 703-527-3887 (collect calls accepted)

2. HAZARDS IDENTIFICATION

2.0 Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Reproductive toxicity Category 2

STOT-SE Category 3 (immune system)

2.1 GHS Label elements, including precautionary statements



H361 Suspected of damaging fertility or the unborn child

H371 May cause immune system effects

Signal Word: **Warning**

P202 Do not handle until all safety precautions are read and understood.

P264 Wash hands thoroughly after handling product.

- P302+P352 If ON SKIN: wash with plenty of soap and water.
- P332+P313 If skin irritation or rash occurs: Get medical attention or advice.
- P305+P351+P338 If IN EYES: Rinse continuously with water for several minutes. Remove contacts if present and easy to do. Get medical attention or advice.
- P304+P341 If INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a comfortable position for breathing.
- P273 Avoid release to the environment.

2.2 Hazards not otherwise classified (HNOC) or not covered by GHS – none

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.0 Substances

Active Ingredient	CAS Number	GHS* Classification Active Ingredient	%
Sirolimus	53123-88-9	Reproductive toxicity Category 1B	0.1
Excipients/Additives	CAS Number	GHS Classification	%
Polysorbate 80, NF	9005-65-6	Not classified GHS	1-1.2
Phosal 50 PG	8030-76-0 64-17-5	Not classified GHS	>98
Nitrogen NF	7727-37-9	Not classified GHS	QS

* based on active ingredient

4. FIRST AID MEASURES

4.0 Description of first aid

INHALATION: Move individual to fresh air. Seek medical advice.

SKIN: In the event of occupational skin contact, remove contaminated clothing and rinse off exposed area with water.

EYES: In case of eye contact, rinse immediately with water for 15 minutes and seek medical advice.

INGESTION: In the event of accidental ingestion, seek medical advice. Do Not Induce Vomiting.

4.1 Measures-General Advice

Consult a physician or poison control center. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

Evidence of accidental or purposeful ingestion overdose requires immediate medical attention.

5. FIREFIGHTING MEASURES

5.0 Extinguishing media

5.1 Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Carbon oxides

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

No data available

6. ACCIDENTAL RELEASE MEASURES**6.0 Personal precautions, protective equipment and emergency procedures**

Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. For personal protection see section 8.

6.1 Environmental precautions

Do not let product enter drains.

6.2 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Mop up. Keep in suitable, closed containers for disposal.

6.3 Reference to other sections

For disposal see section 13.

7. HANDLING AND STORAGE**7.0 Precautions for safe handling**

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.

7.1 Conditions for safe storage, including any incompatibilities

Store locked up.

Keep container tightly closed in a dry and well-ventilated place.

Recommended storage temperature: room temperature or refrigerated

7.2 Specific end use(s)

Sirolimus Oral Solution, 1 mg/ml is a pharmaceutical preparation used as an immunosuppressive agent for renal transplants. This product may be used in conjunction with other immunosuppressive agents.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**8.0 Control parameters****Components with workplace control parameters**

Component	CAS Number	OSHA
Ethanol	64-17-5	500 ppm

8.1 Exposure controls**Appropriate engineering controls**

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday. Follow approved Good Manufacturing Practices. Local exhaust ventilation normally not required.

Personal protective equipment**Eyeface protection**

Safety glasses with side-shields.

Skin protection

Handle with gloves to prevent skin contact and product contamination. Product components may be absorbed through the skin.

Body Protection

Wear appropriate covering to prevent dusting and contamination of work clothing.

Respiratory protection

Use approved respirators and components when mixing, formulating or packaging product.

This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use. This SDS 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. 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.

Control of environmental exposure
Do not let product enter drains.

9. PHYSICAL AND CHEMICAL PROPERTIES**9.0 Information on basic physical and chemical properties**

a)	Appearance	Clear to cloudy solution
b)	Odor	No data available
c)	Odor Threshold	No data available
d)	pH	No data available
e)	Melting point/freezing point	No data available
f)	Initial boiling point and boiling range	No data available
g)	Flash point	No data available
h)	Evaporation rate	No data available
i)	Flammability (solid, gas)	No data available
j)	Upper/lower flammability or explosive limits	No data available
k)	Vapor pressure	No data available
l)	Vapor density	No data available
m)	Relative density	No data available
n)	Water solubility	No data available
o)	Partition coefficient: n- octanol/water	No data available
p)	Auto-ignition temperature	No data available
q)	Decomposition temperature	No data available
r)	Viscosity	No data available
s)	Explosive properties	No data available
t)	Oxidizing properties	No data available

9.1 Other safety information

No data available

10. STABILITY AND REACTIVITY**10.0 Reactivity**

No data available

10.1 Chemical stability

Stable under normal use and storage conditions.

10.2 Possibility of hazardous reactions

No data available

10.3 Conditions to avoid

No data available

10.4 Incompatible materials

Strong oxidizing agents

10.5 Hazardous decomposition products

No data available

11. TOXICOLOGICAL INFORMATION**11.0 Information on toxicological effects****Acute toxicity**

No data available for the formulated product.

Skin corrosion/irritation

No data available for the formulated product.

Serious eye damage/eye irritation

May be Irritating to eyes

Respiratory or skin sensitization

May cause skin or respiratory irritation

Germ cell mutagenicity

Product not classified

Carcinogenicity

No data available for the formulated product.

Reproductive toxicity

No data available for formulated product. Sirolimus is classified as Reprotox Cat 1B.

Specific target organ toxicity - single exposure

No data available for formulated product. Based on Sirolimus, immune system effects are possible.

Specific target organ toxicity - repeated exposure

No data available for formulated product.

Aspiration hazard

No data available for the formulated product.

Additional Information

No data available.

12. ECOLOGICAL INFORMATION**12.0 Toxicity**

No data available on formulated product

12.1 Persistence and degradability

No data available

12.2 Bioaccumulative potential

No data available

12.3 Mobility in soil

No data available

12.4 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.5 Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS**13.0 Waste treatment methods**

Dispose in accordance with local, state and federal regulations. Do not dispose in sanitary waste sewer. Ensure product waste disposal follows FDA guidelines.

Contaminated packaging

Dispose of as unused product.

14. TRANSPORT INFORMATION**DOT (US)**

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

Product is a FDA regulated product: follow proper FDA regulations for packaging and transport of product.

15. REGULATORY INFORMATION

This product is an FDA regulated pharmaceutical product that may not be classified, regulated and/or is exempt from certain requirements contained in 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200). Consult product packaging insert for additional health and safety information on dosage and potential side effects from use of this product.

16. OTHER INFORMATION

The above information is presented in good faith and believed to be accurate as of the date indicated. No warranty, expressed or implied is granted by Amneal Pharmaceuticals in regard to this information. Amneal Pharmaceuticals shall not be held liable for any damage resulting from improper handling or misuse of the above product.

Preparation Information

Amneal Pharmaceuticals

Regulatory Affairs

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