

SOLARA ACTIVE PHARMA SCIENCES LIMITED	SAFETY DATA SHEET	FORMAT NO.:EHS/F/008/R1
Material Name: Rifaximin	DOC NO: SDS/040/R2	Effective Date : 26/04/2018

1. **Identification of the substance / preparation and of the company / undertaking**
 Identification of the product
 Product Name : RIFAXIMIN
 Manufacturer / supplier identification
 Company: M/s. Solara Active Pharma Sciences Ltd.,
 120 A&B, 36, 120P & 121,
 Industrial Area, Baikampady, New Mangalore
 New Mangalore, Tel : 0091-824-2402100, Fax : 0091-824-2402256

2. **Classification of the Substance or Mixture:**
Classification according to Regulation (EC) No 1272/2008 (CLP):
Labelling according to Regulation (EC) No 1272/2008 (CLP):



Signal Word: Warning
 H332: Harmful if inhaled.
 H312: Harmful in contact with skin.
 H335: May cause respiratory irritation

Precaution
 P261: Avoid breathing (dust/fume/gas/mist/vapour/spray).
 P280: Wear (protective gloves/protective clothing/eye protection/face protection). P362+364:
 Take off contaminated clothing and wash it before reuse.

Response
 P304+340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
 P312: Call a (POISON CENTER/doctor/...) if you feel unwell.
 P302+352: IF ON SKIN: Wash with plenty of soap and water. P321: Specific treatment (see ... on this label).

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3. **Composition / Information on Ingredients**

Synonyms : (2S,16Z,18E,20S,21S,22R,23R,24R,25S,26S,27S,28E)-5,6,21,23,25-pentahydroxy-27-methoxy-2,4,11,16,20,22,24,26-octamethyl-2,7-(epoxypentadeca-[1,11,13]trienimino)benzofuro [4,5-c]pyrido[1,2-a]-benzimidazole-1,15(2H)-dione,2S-acetate
 CAS-No. : 80621-81-4
 Molecular Weight : 785.88
 Molecular formula : C₂₈H₃₁N₃O₁₁

4. **First Aid Measures**

Description of First Aid Measures : No data available

In Case of Inhalation :
 Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention

In Case of Eye Contact :
 Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.

In Case of Skin Contact :
 Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

In Case of Ingestion :
 Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

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5.

Fire-Fighting Measures Suitable**Extinguishing**

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

Use water spray to cool fire-exposed containers.

Unsuitable Extinguishing Media: A solid water stream may be inefficient.

Flammable Properties and Hazards : No data available **Flash Pt:** No data.

Fire Fighting Instructions : As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

Autoignition Pt : No data.

Explosive Limits : LEL: No data. UEL: No data.

6.

Accidental Release Measures**Protective Precautions, Protective Equipment and Emergency Procedures**

Avoid raising and breathing dust, and provide adequate ventilation. As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

Environmental Precautions: Take steps to avoid release into the environment, if safe to do so.

Methods and Material For Containment and Cleaning Up : Contain spill and collect, as appropriate. Transfer to a chemical waste container for disposal in accordance with local regulations

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7.

Handling and Storage

Handling: Do not ingest. Avoid contact with skin and eyes. Wash thoroughly after Handling.

Storage : Preserve in well closed, light resistant container. Store at 25°C (excursion Permitted between 15 to 30°C)

8.

Exposure Controls**Engineering Controls**

(Ventilation etc.): Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

Personal protection equipment:

Eye Protection: Safety glasses

Protective Gloves: Compatible chemical-resistant gloves **Other Protective Clothing:**

Lab coat,

Respiratory Equipment NIOSH approved respirator, as conditions warrant. (Specify Type):

Work/Hygiene/Maintenance Practices: Do not take internally.

Facilities storing or utilizing this material should be equipped with eyewash and a safety shower. Wash thoroughly after handling

9. **Physical and Chemical Properties**

Form :	Crystalline, hygroscopic powder
Color :	Red orange
Odor :	Odorless
pH value	Not available
Melting temperature:	200-205°C (dec)
Boiling temperature:	Not available
Ignition temperature:	Not available
Flash point:	Not available

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Explosion limits lower Not available
 Upper Not available
Relative vapor density : Not available
Density: Not available
Solubility in water: Practically insoluble in water.
 Soluble in acetone and methanol.

10. Stability and Reactivity

Reactivity: No data available.

Stability: Stable

Conditions To Avoid: No data available

Incompatibility – Materials To Avoid: strong oxidizing agents

Hazardous Decomposition Or By products: carbon dioxide, carbon monoxide, nitrogen oxides

Polymerization: Will not occur

Stability Note(s): Stable if stored in accordance with information listed on the product insert

11. Toxicological Information**Information on Toxicological Effects:**

The toxicological effects of this product have not been thoroughly studied. Rifaximin -
Toxicity Data: Oral LD50 (rat): >2 g/kg.

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12. Ecological Information Toxicity:

Avoid release into the environment. Runoff from fire control or dilution water may cause pollution

Persistence and Degradability: No data available.

Bio accumulative Potential: No data available.

Mobility in Soil: No data available.

Results of PBT and vPvB assessment: No data available.

Waste Disposal Method: Dispose in accordance with local, state, and federal regulations.

13. Disposal Considerations

Dissolve or mix material with a suitable combustible solvent and incinerate in a chemical incinerator equipped with an afterburner and scrubber. Haulie contaminated containers as product.

Dispose in accordance with local, state, and federal regulations.

Packaging: Disposal in compliance with official regulations. Handle contaminated packaging in the same way as the substance itself. If not officially specified differently, non-contaminated packaging may be treated like household waste or recycled.

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14. Transport information**LAND TRANSPORT (US DOT):**

DOT Proper Shipping Name: Not dangerous goods.

LAND TRANSPORT (European ADR/RID):

ADR/RID Shipping Name: Not dangerous goods.

AIR TRANSPORT (ICAO/IATA):

ICAO/IATA Shipping Name: Not dangerous goods

Additional Transport Information:

Transport in accordance with local, state, and federal regulations.

15. Regulatory Information

This SDS was prepared in accordance with 29 CFR 1910.1200 and Regulation (EC)

16. Other information

No data available

THE ABOVE INFORMATION IS BELIEVED TO BE CORRECT BUT DOES NOT PURPORT TO BE ALL INCLUSIVE AND SHALL BE USED ONLY AS A GUIDE

DISCLAIMER OF LIABILITY

The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable.

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Signature Page

Rifaximin

Approver

Meaning

Date (UTC)

Effective date:: 15-OCT-2020

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