



SAFETY DATA SHEET

Page No. 1 of 4

Product Name Fingolimod Capsules 0.25 mg and 0.5mg

1. Product Information

Product Name: Fingolimod Capsules 0.25 mg and 0.5mg

Intended use: Treatment of Patient with relapsing forms of multiple sclerosis.

Details of the manufacturer:

MSN Laboratories Private Limited., Formulation Division-II,
Survey Nos.1277 & 1319 to 1324, Nandigama (Village & Mandal),
Rangareddy (District)- 509228, Telangana, India.

2. Composition/Information on Ingredients

C.A.S. No: : 162356-0
Molecular Formula : $C_{19}H_{33}NO_2.HCL$
Molecular Weight : 343.93g/mol
Chemical Name : 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol hydrochloride

3. Hazards Identification

Potential Health effects

The toxicological properties of this study have not been investigated. Use appropriate procedure to prevent the opportunities for the direct contact with skin or eyes and to prevent inhalation. Compound is Non-hazardous, Non-Toxic /Non-Flammable

4. First Aid Measures

Eyes:

Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids.

Skin:

Flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.

Ingestion:

Do NOT induce vomiting. If conscious and alert, rinse mouth and drink 2-4 cup of milk or water.

Inhalation:

Remove from exposure and move to fresh air immediately.

5. Emergency Overview

Harmful if swallowed.

6. Fire Fighting Measures

SAFETY DATA SHEET		Page No. 2 of 4
Product Name	Fingolimod Capsules 0.25 mg and 0.5mg	

General Information: As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear. During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion.

Extinguishing Media:

In case of fire, use water, dry chemical, chemical foam, or alcohol-resistant foam.

7. Accidental Release Measures

General Information: Use proper personal protective equipment as indicated in Section 9.

Spills/Leaks:

Clean up spills immediately, observing precautions in the Protective Equipment section. Sweep up, then place into a suitable container for disposal.

8. Handling and Storage

Handling:

Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Avoid contact with eyes, skin, and clothing. Avoid ingestion and inhalation.

Storage Conditions: Do not store above 25°C. Store in the original package in order to protect from moisture.

9. Exposure Controls/Personal Protection

Engineering controls:

Use adequate general or local exhaust ventilation to keep airborne concentration below the permissible exposure limits. Use process enclosure and local exhaust ventilation other engineering controls to control airborne levels.

Personal Protective Equipments

EYES: Wear safety glasses and chemical goggles if splashing is possible.

SKIN: Wear appropriate protective gloves and clothing to prevent skin exposure.

CLOTHING: Wear appropriate protective clothing to minimize contact with skin.

RESPIRATORS: Wear to NIOSH/MSHA or European standard EN 149 approved full-face piece airline respirator in positive pressure mode with emergency escape provisions.

10. Physical and Chemical Properties

Appearance:

FDQA CONTROLLED COPY

SAFETY DATA SHEET

Page No. 3 of 4

Product Name Fingolimod Capsules 0.25 mg and 0.5mg

0.25mg: Size "4" hard gelatin capsules having White opaque cap imprinted "0.25 mg" and White opaque body imprinted "MF" with black ink, filled with white to off white colored fine powder.

0.5 mg: Size "3" hard gelatin capsules having White opaque cap imprinted "0.5 mg" and White opaque body imprinted "MF" with black ink, filled with white to off white colored fine powder.

11. Stability and Reactivity

Chemical Stability:

Stable under normal temperatures and pressures.

Conditions to Avoid:

Incompatible materials, strong oxidants.

Incompatibilities with Other Materials:

Strong oxidizing agents, strong bases.

Hazardous Decomposition Products:

Nitrogen oxides, carbon monoxide, irritating and toxic fumes and gases, carbon dioxide, nitrogen.

Hazardous Polymerization: Has not been reported.

12. Toxicological Information

RTECS#:

CAS#: LD50/LC50:

CAS#: Draize test, rabbit, eye: 100 mg/24H Moderate; Oral,

mouse: LD50 = 300 mg/kg; Oral, rabbit: LD50 = 3200 mg/kg; Oral,

rat: LD50 = 980 mg/kg.

Carcinogenicity:

Salicylamide -

Not listed by ACGIH, IARC, NIOSH, NTP, or OSHA.

See actual entry in RTECS for complete information.

13. Disposal Considerations

Dispose of in a manner consistent with federal, state and local regulations.

14. Transport Information

International Regulations

UNRTDG

Not Regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMBG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and IBC code

FDQA CONTROLLED COPY

SAFETY DATA SHEET		Page No. 4 of 4
Product Name	Fingolimod Capsules 0.25 mg and 0.5mg	

Not Applicable for product as supplied

National Regulations

49 CFR

Not regulated as a dangerous good

15. Regulatory Information

- European/International Regulations
- European Labeling in Accordance with EC Directives
- Hazard Symbols: XN
- Risk Phrases:
- R 22 Harmful if swallowed.
- Safety Phrases:
- WGK (Water Danger/Protection)
- CAS# United Kingdom Occupational Exposure Limits
- United Kingdom Maximum Exposure Limits
- Canada
- CAS# is listed on Canada's DSL List.
- CAS#is not listed on Canada's Ingredient Disclosure List.
- Exposure Limits
- US FEDERAL
- TSCA
- CAS# is listed on the TSCA inventory

16. Additional Information

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty to merchantability and any other warranty express or implied, with respect such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no way shall the company be liable for any claims, losses or damages of any third party or for lost profits or any special, direct, incidental consequential or exemplary damages, howsoever arising, even if the company has been advised of the possibility of such damages.

FDQA CONTROLLED COPY