



MSN Laboratories Private Limited
R&D Center, Formulation Division.

SAFETY DATA SHEET

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| Product Name | Deferasirox Tablets for Oral Suspension 125 mg, 250 mg and 500 mg | Page No: Page 1 of 5 |
|---------------------|--|-----------------------------|

1. Identification

Product Name: Deferasirox Tablets for Oral Suspension 125 mg, 250 mg and 500 mg

Chemical Family: Mixture

Intended use: Treatment of chronic iron overload due to frequent blood transfusions

Details of the manufacturer:

MSN Laboratories Private Limited.

Formulation Division, Unit - II,

Sy No 1277 & 1319 to 1324

Nandigama Village & Mandal

Ranga Reddy Dist

Telangana State, India.

PIN 509228

Phone: +918548699000

2. Hazard (s) Identification

Potential Health Effects

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

3. Composition/Information on Ingredients

C.A.S. No : 201530-41-8

Molecular Formula : $C_{21}H_{15}N_3O_4$

Molecular Weight : 373.4 g/mol

Chemical Name : 4-[3,5-bis(2-hydroxyphenyl)-1,2,4-triazol-1-yl]benzoic acid

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 cupfuls of milk or water.

Inhalation: Remove from exposure and move to fresh air immediately.

SAFETY DATA SHEET

| | | |
|---------------------|--|-----------------------------|
| Product Name | Deferasirox Tablets for Oral Suspension 125 mg, 250 mg and 500 mg | Page No: Page 2 of 5 |
|---------------------|--|-----------------------------|

5. Fire Fighting Measures**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.

6. Accidental Release Measures

General Information: Use proper personal protective equipment as indicated in Section 8.

Spills/Leaks:

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

7. 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: Store as directed by product packaging.

8. Exposure Controls/Personal Protection

Personal protective equipment as follows:

- **Breathing equipment:** NIOSH/MSHA-approved respirator.
- **Protection of hands:** chemical-resistant rubber gloves.
- **Eye protection:** chemical safety goggles.

9. Physical and Chemical Properties**Appearance:**

125 mg: White to off white, round, flat, uncoated tablets, with debossing 'D' on one side and '125' on other side.

250 mg: White to off white, round, flat, uncoated tablets, with debossing 'D' on one side and '250' on other side.

SAFETY DATA SHEET

| | | |
|---------------------|--|-----------------------------|
| Product Name | Deferasirox Tablets for Oral Suspension 125 mg, 250 mg and 500 mg | Page No: Page 3 of 5 |
|---------------------|--|-----------------------------|

500 mg : White to off white, round, flat, uncoated tablets, with debossing 'D' on one side and '500' on other side.

10. 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.

11. 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.

12. Ecological Information

Persistence and degradability: no data available

Toxicity: no data available

Bio accumulative potential: no data available

Mobility in soil: no data available

PBT and vPvB assessment: no data available

Other adverse effects: no data available

SAFETY DATA SHEET

| | | |
|---------------------|--|-----------------------------|
| Product Name | Deferasirox Tablets for Oral Suspension 125 mg, 250 mg and 500 mg | Page No: Page 4 of 5 |
|---------------------|--|-----------------------------|

13. Disposal Considerations

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 waste water.

14. Transport Information

U.S. DEPARTMENT OF TRANSPORTATION REGULATIONS: This product is not classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

TRANSPORT CANADA, TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product is not classified as Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product is not classified as Dangerous Goods, by rules of IATA.

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is not classified as Dangerous Goods by the International Maritime Organization.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF

DANGEROUS GOODS BYROAD (ADR): This product is not classified by the United Nations Economic Commission for Europe to be dangerous goods.

TRANSPORT IN BULK ACCORDING TO THE IBC CODE: Not applicable.

ENVIRONMENTAL HAZARDS: This product does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) and not component is specifically listed in Annex III under MARPOL 73/78.

Environmental hazard: None.

Transport in bulk: Not available.

Special precautions needed with transport: Always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

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

SAFETY DATA SHEET

| | | |
|---------------------|--|-----------------------------|
| Product Name | Deferasirox Tablets for Oral Suspension 125 mg, 250 mg and 500 mg | Page No: Page 5 of 5 |
|---------------------|--|-----------------------------|

- 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. Other Information

While the information herein is believed to be reliable, it is furnished without warranty of any kind. It shall be used only as a guide. We assume no liabilities from the use of this product or information contained herein.