

SAFETY DATA SHEET**Section 1: Identification**

Material	Deferasirox Oral Granules 90 mg, 180 mg and 360 mg
Recommended use	Used to treat ongoing high levels of iron in the body caused by multiple blood transfusions.
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
Distributor	Camber Pharmaceuticals, Inc. , Piscatway, NJ 08854

Section 2: Hazard(s) Identification**Classification of the Substance or Mixture:**

- Skin Corrosion/Irritation, Category 2
- Serious Eye Damage/Eye Irritation, Category 2
- Specific Target Organ Toxicity (single exposure), Category 3
- Aquatic Toxicity (Chronic), Category 1

Adverse Human Health Effects and symptoms:

- Causes serious eye irritation.
- Causes skin irritation.
- Material may be irritating to the mucous membranes and upper respiratory tract.
- May be harmful by inhalation, ingestion, or skin absorption.
- May cause respiratory system irritation.

Section 3: Composition/Information on Ingredients

Ingredients	CAS No
Deferasirox	201530-41-8
Crospovidone	9003-39-8
Colloidal Silicon Dioxide	7631-86-9
Microcrystalline Cellulose	9004-34-6
Poloxamer	9003-11-6
Povidone	25655-41-8
Sodium Stearyl Fumarate	4070-80-8

Section 4: First-Aid Measures

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

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.
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.
Section 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 available
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.
Section 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.
Section 7: Handling and storage	
Handling	Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid prolonged or repeated exposure.
Storage	Store deferasirox oral granules at 20°C to 25°C (68°F to 77°F); excursions are permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Protect from moisture.
Section 8: Exposure Controls/Personal Protection	

Exposure Parameters	
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.
Work/Hygienic/Maintenance Practices	Do not take internally. Facilities storing or utilizing this material should be equipped with an eyewash and a safety shower. Wash thoroughly after handling. No data available

Section 9: Physical and Chemical Properties

Description	<p>Deferasirox Oral Granules 90 mg are supplied as white to off white granular powder in sachet. They are available in Carton of 30 child-resistant sachets NDC 31722-029-32</p> <p>Deferasirox Oral Granules 180 mg are supplied as white to off white granular powder in sachet. They are available in Carton of 30 child-resistant sachets NDC 31722-030-32</p> <p>Deferasirox Oral Granules 360 mg are supplied as white to off white granular powder in sachet. They are available in Carton of 30 child-resistant sachets NDC 31722-031-32</p>
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Section 10: Stability and Reactivity

Reactivity:	No data available
Stability	Unstable [] Stable [x]
Stability Note(s)	Stable if stored in accordance with information

Section 11: Toxicological Information	
Information on Toxicological Effects	The toxicological effects of this product have not been thoroughly studied. Deferasirox - Toxicity Data: Intraperitoneal TDLO (rat): 525 mg/kg/7D (intermittent);
Chronic Toxicological Effects	Deferasirox - Investigated as a drug. Only select Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See actual entry in RTECS for complete information. Deferasirox RTECS Number: DG443840
Section 12: Ecological Information	
Toxicity: Persistence and Degradability: Bioaccumulative Potential: Mobility in Soil: Results of PBT and vPvB assessment: Other adverse effect	Avoid release into the environment. Runoff from fire control or dilution water may cause pollution. No data available. No data available. No data available. No data available. No data available.
Section 13: Disposal Considerations	
Waste Disposal Method:	Dispose in accordance with local, state, and federal regulations.
Section 14: Transport Information	
LAND TRANSPORT (US DOT):	
DOT Proper Shipping Name:	Not dangerous goods.
DOT Hazard Class:	
UN/NA Number:	
LAND TRANSPORT (European ADR/RID):	
ADR/RID Shipping Name:	Not dangerous goods.
UN Number:	
Hazard Class:	
AIR TRANSPORT (ICAO/IATA):	
ICAO/IATA Shipping Name:	Not dangerous goods.
Additional Transport	Transport in accordance with local, state, and federal regulations
Section 15: Regulatory Information	
This SDS was prepared in accordance with 29 CFR 1910.1200 and Regulation (EC)	

Section 16: Other Information

Issue Date : 17-06-2023

Version : 01

Further Information

Revision Date: 17-06-2023

Revision note: New Strength added in product name

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Annora Pharma Private Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero Labs Limited reserves the right to revise this SDS.