

## SAFETY DATA SHEET

Section 1: Identification	
<b>Material</b>	<b>Deferasirox Tablets.</b>
<b>Recommended use</b>	Used to treat ongoing high levels of iron in the body caused by multiple blood transfusions.
<b>Manufacturer</b>	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
<b>Distributor</b>	<b>Camber Pharmaceuticals, Inc.,</b> Piscatway, NJ 08854
Section 2: Hazard(s) Identification	
<b>Classification of the Substance or Mixture:</b>	
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	
<b>Adverse Human Health Effects and symptoms:</b>	
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	
<b>Ingredients</b>	Deferasirox
<b>CAS No</b>	201530-41-8
Section 4: First-Aid Measures	
<b>Inhalation</b>	Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.
<b>Skin Contact</b>	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.
<b>Eye Contact</b>	Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined And tested by medical personnel.
<b>Ingestion</b>	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	
<b>Suitable Extinguishing Media</b>	Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray.
<b>Unsuitable Extinguishing Media</b>	Use water spray to cool fire-exposed containers. A solid water stream may be inefficient.

<b>Flammable Properties and Hazards</b>	No data available
<b>Flash Pt:</b>	No data available
<b>Fire Fighting Instructions</b>	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.
<b>Section 6: Accidental Release Measures</b>	
<b>Protective Precautions, Protective Equipment and Emergency Procedures</b>	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).
<b>Environmental Precautions</b>	Take steps to avoid release into the environment, if safe to do so.
<b>Methods and Material For Containment and Cleaning Up</b>	Contain spill and collect, as appropriate. Transfer to a chemical waste container for disposal in accordance with local regulations.
<b>Section 7: Handling and storage</b>	
<b>HANDLING</b>	Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid prolonged or repeated exposure.
<b>STORAGE</b>	Store 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.
<b>Section 8: Exposure Controls/Personal Protection</b>	
<b>Exposure Parameters</b>	
<b>Exposure Controls</b>	
<b>Engineering Controls (Ventilation etc.)</b>	Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.
<b>Personal protection equipment:</b>	
<b>Eye Protection</b>	Safety glasses
<b>Protective Gloves</b>	Compatible chemical-resistant gloves
<b>Other Protective Clothing</b>	Lab coat
<b>Respiratory Equipment</b>	NIOSH approved respirator, as conditions warrant.
<b>Work/Hygienic/Maintenance Practices</b>	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

<b>Description</b>	<p>Deferasirox tablets 90 mg are white to off white, film coated, oval biconvex tablets, debossed with '56' on one side and 'V' on the other side. They are available in</p> <p>Bottle of 30 tablets <span style="float: right;">NDC 31722-011-30</span></p> <p>Deferasirox tablets 180 mg are white to off white, film coated, oval biconvex tablets, debossed with '57' on one side and 'V' on the other side. They are available in</p> <p>Bottle of 30 tablets <span style="float: right;">NDC 31722-012-30</span></p> <p>Deferasirox tablets 360 mg are white to off white, film coated, oval biconvex tablets, debossed with '58' on one side and 'V' on the other side. They are available in</p> <p>Bottle of 30 tablets <span style="float: right;">NDC 31722-013-30</span></p>
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## Section 10: Stability and Reactivity

<b>Reactivity:</b>	No data available.
<b>Stability:</b>	Unstable [ ] Stable [ X ]
<b>Stability Note(s)</b>	Stable if stored in accordance with information listed on the Product insert

## Section 11: Toxicological Information

<b>Information on Toxicological Effects</b>	<p>The toxicological effects of this product have not been thoroughly studied.</p> <p>Deferasirox - Toxicity Data: Intraperitoneal TDLO (rat): 525 mg/kg/7D (intermittent);</p>
<b>Chronic Toxicological Effects</b>	<p>Deferasirox - Investigated as a drug.</p> <p>Only select Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here.</p> <p>See actual entry in RTECS for complete information.</p> <p>Deferasirox RTECS Number: DG443840</p>

## Section 12: Ecological Information

<b>Toxicity:</b>	Avoid release into the environment.
<b>Persistence and Degradability:</b>	Runoff from fire control or dilution water may cause pollution.
<b>Bioaccumulative Potential:</b>	No data available.
<b>Mobility in Soil:</b>	No data available.
<b>Results of PBT and vPvB assessment:</b>	No data available.
<b>Other adverse effect</b>	No data available.

## Section 13: Disposal Considerations

<b>Waste Disposal Method:</b>	Dispose in accordance with local, state, and federal regulations.
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## 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:** 22-07-2021

**Version : 00**

### FURTHER INFORMATION

**Revision Date:** Nil

**Revision note:** New issue

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.