

**SAFETY DATA SHEET**

Section 1: Identification	
<b>Material</b>	Indomethacin Suppositories USP 50 mg
<b>Recommended use</b>	Pharmaceutical Product
<b>Manufacturer</b>	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India
<b>Distributor</b>	<b>Camber Pharmaceuticals, Inc.</b> , Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
<b>Potential Acute Health Effects</b>	Very hazardous in case of ingestion. Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of inhalation. Severe over-exposure can result in death.
<b>Potential Chronic Health Effects</b>	Repeated exposure to a highly toxic material may produce general deterioration of health by an accumulation in one or many human organs.
<b>CARCINOGENIC EFFECTS</b>	Not available
<b>MUTAGENIC EFFECTS</b>	Mutagenic for bacteria and/or yeast
<b>TERATOGENIC EFFECTS</b>	Not available
<b>DEVELOPMENTAL TOXICITY</b>	Not available
Section 3: Composition/Information on Ingredients	
<b>Ingredients</b>	<b>CAS</b>
Indomethacin	53-86-1
Polyethylene glycol	25322-68-3
Glycerin	56-81-5
Sodium Chloride	7647-14-5
Edetic acid	60-00-4
Butylated Hydroxy Anisole	25013-16-5
Butylated Hydroxy Toluene	128-37-0

#### Section 4: First-Aid Measures

<b>First-aid measures Ingestion</b>	If swallowed, do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention immediately.
<b>Inhalation</b>	Physical form suggests that risk of inhalation exposure is negligible.
<b>Serious Inhalation</b>	Evacuate the victim to a safe area as soon as possible. Loosen tight clothing such as a collar, tie, belt or waistband. If breathing is difficult, administer oxygen. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek medical attention.
<b>Skin Contact</b>	Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops.
<b>Eye Contact</b>	Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation occurs.

#### Section 5: Fire-Fighting Measures

<b>Fire-fighting measures</b> <b>Fire and Explosion Hazards</b>	May be combustible at high temperature
<b>Extinguishing Media</b>	SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet.
<b>Hazardous Combustion Products</b>	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

#### Section 6: Accidental Release Measures

<b>Accidental release measures</b> <b>Small Spill</b>	Use appropriate tools to put the spilled solid in a convenient waste disposal container.
<b>Large Spill</b>	Poisonous solid Stop leak if without risk. Do not get water inside container.

	Do not touch spilled material. Use water spray to reduce vapors. Prevent entry into sewers, basements or confined areas; dike if needed. Eliminate all ignition sources. Call for assistance on disposal.
<b>Section 7: Handling and Storage</b>	
<b>General Requirements</b>	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
<b>Storage</b>	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
<b>Section 8: Exposure Controls/Personal Protection</b>	
<b>Exposure controls/personal protection</b>	None required for normal handling. Wash hands and arms thoroughly after handling.
<b>Section 9: Physical and Chemical Properties</b>	
<b>Physical Form</b>	Indomethacin suppositories USP, 50 mg each, are white to off-white, bullet shaped suppository packed in Alu/PE molds.  Boxes of 30 Suppositories      NDC 31722-051-31
<b>Colour</b>	White to off white
<b>Section 10: Stability and Reactivity</b>	
<b>Stability and reactivity</b>	Stable under recommended storage conditions.
<b>Section 11: Toxicological Information</b>	
<b>Toxicological Information</b> <b>Carcinogenesis,      Mutagenesis,</b> <b>Impairment of Fertility</b>	Routes of Entry: Dermal contact. Eye contact. Inhalation. Ingestion.  Toxicity to Animals: Acute oral toxicity (LD50): 2.42 mg/kg [Rat]. Chronic Effects on Humans: Not available. Other Toxic Effects on Humans: Extremely hazardous in case of ingestion, of inhalation. Hazardous in case of skin contact (irritant, permeator).

	<p>Special Remarks on Toxicity to Animals: Not available.</p> <p>Special Remarks on Chronic Effects on Humans: Not available.</p> <p>Special Remarks on other Toxic Effects on Humans: Not available.</p>
<b>Section 12: Ecological Information</b>	
<b>Ecological Information</b>	
<b>Ecotoxicity</b>	Not available
<b>BOD5 and COD</b>	Not available
<b>Products of Biodegradation</b>	Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.
<b>Toxicity of the Products of Biodegradation</b>	The products of degradation are less toxic than the product itself.
<b>Special Remarks on the Products of Biodegradation</b>	Not available.
<b>Section 13: Disposal Considerations</b>	
<b>Disposal Considerations</b> <b>Waste Disposal</b>	Waste must be disposed of in accordance with federal, state and local environmental control regulations.
<b>Section 14: Transport Information</b>	
<b>Transport Information</b>	The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.
<b>Section 15: Regulatory Information</b>	
<b>Regulatory Information</b>	This Section Contains Information relevant to compliance with other Federal and/or state laws.

**Section 16: Other Information**

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**Version : 00**

**Further information**

**Revision date: New issue**

**Revision note: New issue**

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. 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. Annora Pharma Private Limited reserves the right to revise this SDS.