



MATERIAL SAFETY DATA SHEET

Page 1 of 5

1. PRODUCT IDENTIFICATION

Product Name Extended Phenytoin Sodium Capsules, USP, 100 mg

Company Name Sun Pharmaceutical Industries Ltd.

Acme Plaza, Andheri-Kurla Road, Andheri (E)

Mumbai – 400 059, INDIA

Product Use Medical Treatment; Antiepileptic

Chemical Name Phenytoin sodium

Chemical Formula C₁₅H₁₁N₂NaO₂

Chemical Family Antiepileptic

2. COMPOSITION AND INGREDIENTS

For 100 mg/Capsule product

Chemical Name	CAS No.	Concentration (%)
Phenytoin Sodium	630-93-3	40
Lactose Monohydrate NF	5989-81-1	53.34
Magnesium Stearate	557-04-0	4
Talc	14807-96-6	2.4
Sodium Lauryl sulfate	151-21-3	0.26

3. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW:

Toxicological Data on Ingredients: Phenytoin sodium: ORAL (LD50): Acute: 1530 mg/kg [Rat]. 165 mg/kg [Mouse].

Potential Acute Health Effects:

Hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation. Severe over-exposure can result in death.

Potential Chronic Health Effects:

CARCINOGENIC EFFECTS: Not available.

MUTAGENIC EFFECTS: Not available.

TERATOGENIC EFFECTS: Not available.

DEVELOPMENTAL TOXICITY: Not available.

Repeated exposure to an highly toxic material may produce general deterioration of health by an accumulation in one or many human organs.



MATERIAL SAFETY DATA SHEET

Page 2 of 5

Section 4: First Aid Measures

Eye Contact: Check for and remove any contact lenses. Do not use an eye ointment. Seek medical attention.

Skin Contact: After contact with skin, wash immediately with plenty of water. Gently and thoroughly wash the contaminated skin with running water and non-abrasive soap. Be particularly careful to clean folds, crevices, creases and groin. Cover the irritated skin with an emollient. If irritation persists, seek medical attention. Wash contaminated clothing before reusing.

Serious Skin Contact: Wash with a disinfectant soap and cover the contaminated skin with an anti-bacterial cream. Seek immediate medical attention.

Inhalation: Allow the victim to rest in a well ventilated area. Seek immediate medical attention.

Serious Inhalation: 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.

Ingestion: Do not induce vomiting. Examine the lips and mouth to ascertain whether the tissues are damaged, a possible indication that the toxic material was ingested; the absence of such signs, however, is not conclusive. Loosen tight clothing such as a collar, tie, belt or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention.

Serious Ingestion: Not available.

Section 5: Fire and Explosion Data

Flammability of the Product: May be combustible at high temperature. Auto-Ignition

Temperature: Not available. Flash Points: Not available.

Flammable Limits: Not available. Products of Combustion: These products are carbon oxides (CO, CO₂), nitrogen oxides (NO, NO₂...). Some metallic oxides.

Fire Hazards in Presence of Various Substances: Not available. Explosion Hazards in

Presence of Various Substances: Risks of explosion of the product in

presence of mechanical impact: Not available. Risks of explosion of the product in

presence of static discharge: Not available.

Fire Fighting Media and Instructions:

SMALL FIRE: Use DRY chemical powder.

LARGE FIRE: Use water spray, fog or foam. Do not use water jet.



MATERIAL SAFETY DATA SHEET

Page 3 of 5

Special Remarks on Fire Hazards: Not available.

Special Remarks on Explosion Hazards: Not available.

Section 6: Accidental Release Measures

Small Spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container.

Large Spill: Use a shovel to put the material into a convenient waste disposal container.

Section 7: Handling and Storage

Precautions: Keep locked up Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe dust. Wear suitable protective clothing In case of insufficient ventilation, wear suitable respiratory equipment If ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes

Storage: Store at 25°C (77°F); excursions permitted to 15-30°C(59-86°F).

Section 8: Exposure Controls/Personal Protection

Engineering Controls: Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection: Splash goggles. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

Personal Protection in Case of a Large Spill: Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits: Not available.

Section 9: Physical and Chemical Properties

Physical state and appearance: Hard gelatin capsules.

Odor: Not available.

Taste: Not available.

Molecular Weight: 274.25 g/mole

Color: Orange/White.

pH (1% soln/water): Not available.

Boiling Point: Not available.

Melting Point: Decomposes.



MATERIAL SAFETY DATA SHEET

Page 4 of 5

Critical Temperature: Not available.
Vapor Pressure: Not applicable.
Volatility: Not available.
Water/Oil Dist. Coeff.: Not available.
Dispersion Properties: Not available.

Specific Gravity: Not available.
Vapor Density: Not available.
Odor Threshold: Not available.
Ionicity (in Water): Not available.
Solubility: Not available.

Section 10: Stability and Reactivity Data

Stability: The product is stable.
Conditions of Instability: Not available.
Corrosivity: Non-corrosive in presence of glass.
Special Remarks on Corrosivity: Not available.

Instability Temperature: Not available.
Incompatibility with various substances: Not available.
Special Remarks on Reactivity: Not available.
Polymerization: No.

Section 11: Toxicological Information

Routes of Entry: Absorbed through skin. Eye contact. Inhalation. Ingestion.
Toxicity to Animals: Acute oral toxicity (LD50): 165 mg/kg [Mouse].
Chronic Effects on Humans: Not available.
Other Toxic Effects on Humans: Hazardous in case of skin contact (irritant), of ingestion, of inhalation.
Special Remarks on Toxicity to Animals: Not available.
Special Remarks on Chronic Effects on Humans: Not available.
Special Remarks on other Toxic Effects on Humans: Not available.

Section 12: Ecological Information

Mobility: Slightly soluble in water: <20 g/l.
BOD5 and COD: Not available.
Products of Biodegradation: Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.
Toxicity of the Products of Biodegradation: The products of degradation are more toxic.
Special Remarks on the Products of Biodegradation: Not available.

Ecotoxicity: Not available.

Section 13: Disposal Considerations

Spilled materials: Sweep up spilled material being careful not to create dust. Place sweepings in a chemical waste container. Flush contaminated area with water and alkaline detergent. Dispose of waste in accordance with federal state and local laws.

Packing materials: Dispose contaminated packing material in accordance with federal state and local laws.



MATERIAL SAFETY DATA SHEET

Page 5 of 5

Section 14: Transport Information

<u>ADR/RID/GGVS/GGVE:</u>	free.
<u>IMGD/GGVSea:</u>	free.
<u>ICAO/IATA:</u>	free.
<u>ADN/ADNR:</u>	free.