



Material Safety Data Sheet

May be used to comply with
OSHA's Hazard Communication Standard,
29 CFR 1910.1200. This Standard must be
consulted for specific requirements.

U.S. Department of Labor

Occupational Safety and Health Administration
(Non-Mandatory Form)
Form Approved
OMB No. 1218-0072

IDENTITY	<i>Phenobarbital USP Tablets</i> <i>16.2mg (1/4 grain), 32.4mg (1/2 grain), 64.8mg (1 grain), 97.2mg (1 1/2 grain)</i>
APPEARANCE	<i>White, round standard convex tablet embossed (625, 626, 627 or 628) under a score on one side and embossed ECI on the other side.</i>

Section 1

Manufacturer's Name	Emergency Telephone Number
<i>ECI Pharmaceuticals LLC</i>	Dial 911 or NPCC 1-800-222-1222
Address (Number, Street, City, State, and ZIP Code)	Telephone Number for Information
<i>5311 35th Terrace</i>	<i>954-486-8181</i>
<i>Ft. Lauderdale, FL 33309</i>	Date Prepared
	<i>11/24/2014</i>
	Intended Use: Sedative, Anticonvulsant, for the treatment of generalized and partial seizures.

Section 2 - Hazard Ingredients/Identity Information

Hazardous Components (Specific Chemical Identity; Common Name(s))	CAS Number	% composition
Phenobarbital, USP	50-06-6	(16.20%)
Microcrystalline cellulose	9004-34-6	*
Colloidal Silicon Dioxide, NF	7631-86-9	*
Lactose Monohydrate, NF	64044-51-5	*
Sodium Starch Glycolate, NF	9063-38-1	*
Magnesium Stearate, NF	557-04-0	*

See current package insert for further information: *= Proprietary

Section 3 - Physical/Chemical Characteristics

Boiling Point	Decomposes	Specific Gravity (H ₂ O = 1)	No data
Vapor Pressure (mm Hg.)	No data	Melting Point	176° (348.8°F)
Vapor Density (AIR = 1)	No data	Evaporation Rate (Butyl Acetate = 1)	No data
Solubility in cold water.....yes			
Appearance and Odor..... <i>White, round standard convex tablet embossed (625, 626, 627 or 628) under a score on side and embossed ECI on the other side. No Odor</i>			



Section 4 - Fire and Explosion Hazard Data

Flash Point (Method Used).... Not Available	Flammable Limits Possible at elevated temperatures	LEL ...N/A	UEL....N/A
Extinguishing Media Small fire = regular dry chemical Large fire = Use regular foam or flood with fine Water spray			
Special Fire Fighting Procedures..... Wear a NIOSH/MSHA approved self-contained breathing apparatus and full protective clothing.			
Hazardous Combustion Products: Combustion emits toxic fumes of carbon oxides (CO, CO ₂) and nitrogen oxides, (NO, NO ₂).			
Fire and Explosion Hazards: Not applicable			

Section 5 - Reactivity Data

Stability	Unstable	Incompatibility:	Conditions to Avoid:
2 years	Stable.....at normal temperatures and pressure	N/A	Avoid heat, flames, sparks. Avoid generating dust.
Hazardous Decomposition or Byproducts.....Carbon Monoxide, Nitrogen Oxides			
Hazardous Polymerization	No		

Section 6 - Health Hazard Data

Route(s) of Entry: Oral	Inhalation? dust	Skin? N/A	Ingestion? N/A
Health Hazards (<i>Acute and Chronic</i>) Acute: respiratory depression, excess ingestion may lead to skin rash Chronic: respiratory depression, drowsiness, nausea, upper respiratory tract irritation, coma. Death may occur.			
Carcinogenicity:	NTP? No Data	IARC Monographs? No Data	OSHA Regulated? N/A
Signs and Symptoms of Exposure: Respiratory tract irritation (difficulty breathing), dizziness, drowsiness, allergic reaction, rash and nausea			
Medical Conditions Generally Aggravated by Exposure			
Emergency and First Aid Proceduresfollow the National Poison Control Center, 1-800-222-1222			

Section 7 - Precautions for Safe Handling and Use

Steps to Be Taken in Case Material is Released or SpilledClean up spills
Waste Disposal Method..... Place waste in an appropriately labeled, sealed container for disposal.
Precautions to Be taken in Handling and Storing..... KEEP OUT OF REACH OF CHILDREN. See package insert for complete instructions and precautions. Avoid direct or prolonged contact with skin, can lead to habituation or addiction
Avoid breathing dust
Other Precautions.....follow additional instructions on product insert document



Section 8 - Control Measures

Respiratory Protection (<i>Specify Type</i>)..... <i>ANSI/OSHA approved mist face or half face mask protection from product dust if crushed/ spilled</i>		
Ventilation.....open	Local Exhaust.....N/A	SpecialN/A
	Mechanical (<i>General</i>).....N/A	OtherN/A
Protective Gloves.....None required		Eye ProtectionNone required
Other Protective Clothing or Equipment.....N/A		
Work/Hygienic Practices.....Do not store, use or consume food while handling this product, if it is crushed. Wash hands and face after handling this product, before eating or drinking.		

Section 9 – Physical and Chemical Properties

Physical State: Tablet	Color: White	Odor: None
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Section 10 – Stability and Reactivity

Stability: Stable under normal conditions of use. Conditions to Avoid: None known Incompatible Materials: As a precautionary measure, keep away from carbon oxides and nitrogen oxides.

Section 11 – Toxicological Information

Routes of Entry: Inhalation, Ingestion Toxicity to Animals: Acute oral toxicity (LD50): 162 mg/kg (Rat)
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Section 12 – Ecological Information

Environmental properties have not been investigated. Releases to the environment should be avoided.

Section 13 – Disposal Considerations

Notify site Drug Enforcement Agency compliance officer and local DEA office for appropriate disposal procedures. It is the user's responsibility to comply with all applicable local, state, and federal laws, rules, regulations and standards.
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Section 14 – Transport Information

DOT Classification: Class 6.1: Poisonous material
Phenobarbital is a “Hazardous Chemical” as defined by the OSHA Hazard Communication
Identification: Toxic solid, organic, n.o.s. (Phenobarbital) : UN2811 PG: 111
Special Provisions for Transport: Not available

Section 15 – Other Regulatory Information

References: DEA = Schedule IV
Other Special Considerations: Not available

Section 16 – Other Information

Disclaimer

The information provided is believed to be complete and accurate. If this product is combined with other materials, deteriorates or becomes contaminated. It may pose hazards not mentioned in this MSDS.

It is the user's responsibility to use the information according to the applications indicated by a health care professional.

Disclaimer:

Any person utilizing this document should seek competent professional advise to verify and assume responsibility for the suitability of this information to their particular situation.

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