

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078948682

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078948674 078948675 078948677 078948678 078948679 078948681 078948683 078948684

**Phenobarbital Tablets, USP, 16.2 mg, 32.4 mg, 64.8 mg, 97.2 mg**  
**e5 Pharma, LLC**  
**Safety Data Sheet**



Revision date: 07 November 2022  
Revision Number: 01

## 1. Product and Company Identification

### 1.1 Product identifiers

Product Name	Phenobarbital Tablets, USP, 16.2 mg, 32.4 mg, 64.8 mg, 97.2 mg
Producer	e5 Pharma, LLC
NDC Number	13517-625-** 13517-626-** 13517-627-** 13517-628-**

### 1.2 Identified uses of the product and uses advised against

Identified Uses	Sedative, Anticonvulsant, for the treatment of generalized and partial seizures.
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### 1.3 Manufacturer Information

Company	e5 Pharma, LLC
Address	225 NE Mizner Blvd., Suite 770, Boca Raton, FL 33432 USA

### 1.4 Emergency phone number


Emergency phone number	(561) 288-4885
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## 2. Hazards Identification

### 2.1 Classification of the substance or mixture

OSHA/HCS status	This material is considered hazardous by the OSHA Hazard Communication Standard (29CFR 110.1200)
GHS Class	Acute Toxicity (oral) - Category 4 Skin Sensitization - Category 1 Carcinogenicity - Category 2 Toxic to Reproduction (Fertility) - Category 1B Toxic to Reproduction (Unborn child) - Category 1B

### 2.2 GHS Label elements, including precautionary statements

Label elements	The substance is classified and labelled according to the Global Harmonized System (GHS)
GHS Pictograms	

Signal word	Danger
Hazard statements	Harmful if swallowed May cause an allergic skin reaction May damage fertility or unborn child Suspected of causing cancer
Precautionary statements	Read label before use. Keep out of reach of children. If medical advice is needed, have product container or label at hand.

### 2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - None

## 3. Composition / Information on Ingredients

Ingredient	CAS Number	GHS Classification	%
Phenobarbital, USP	50-06-6	Not Listed	*
Microcrystalline Cellulose	9004-34-6	Not Listed	*
Colloidal Silicon Dioxide	7631-86-9	Not Listed	*
Lactose Monohydrate	64044-51-5	Not Listed	*
Sodium starch Glycolate	9063-38-1	Not Listed	*
Magnesium Stearate	577-04-0	Not Listed	*

## Remarks

\* Proprietary

There are no hazardous ingredients greater than or equal to 1.0 %wt concentration or carcinogenic ingredients greater than or equal to 0.1 %wt concentration.

## 4. First Aid Measures

### 4.1 Description of first aid measures

## General advice

Immediately remove any clothing soiled with this product. Remove breathing apparatus only after contaminated clothing have been completely removed. In case of irregular breathing or respiratory arrest provide artificial respiration.

## Skin contact

If causes irritation, wash contact area with soap water.

## Eye contact

Flush eyes with water for at least 15 minutes, remove contact lenses. If eye irritation persists, seek medical attention.

## Inhalation

If causes irritation, remove victim to fresh air, Seek medical attention.

## Ingestion

Do not induce vomiting. Seek medical assistance.

### 4.2 Most important symptoms and effects, both acute and delayed

## Symptoms and effects

No data available

### 4.3 Indication of any immediate medical attention and special treatment needed

## Other first aid

No data available

## 5. Fire Fighting Measures

### 5.1 Suitable (and unsuitable) extinguishing media

## Suitable extinguishing media

Use an extinguishing agent suitable for the surrounding fire.

### 5.2 Special hazards arising from the substance or mixture

## Special hazards

No specific fire or explosion hazard.

### 5.3 Advice for firefighters

## Protective equipment

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

## 6. Accidental Release Measures

### 6.1 Personal precautions, protective equipment, and emergency procedures

## Personal precautions

No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

### 6.2 Environmental precautions

## Environmental precautions

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil, or air).

### 6.3 Methods and materials for containment and cleaning up

## Methods for cleanup

Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements, or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

### 6.4 References to other sections

## Other references

For safe handling see section 7.

For information on personal protection equipment see section 8.

## 7. Handling and Storage

### 7.1 General hygiene considerations

**General hygiene** Eating, drinking, and smoking should be prohibited in areas where this material is handled, stored, and processed. Workers should wash hands and face before eating, drinking, and smoking. See also Section 8 for additional information on hygiene measures. Remove contaminated clothing and protective equipment before entering eating areas.

### 7.2 Precautions for safe handling

**Safe handling precautions** Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Avoid exposure - obtain special instructions before use. Avoid exposure during pregnancy. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not ingest. If during normal use the material presents a respiratory hazard, use only with adequate ventilation or wear appropriate respirator. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

### 7.3 Conditions for safe storage, including any incompatibilities

**Storage conditions** Store at controlled room temperature 20°C-25°C (68°F-77°F); excursion permitted to 15°C-30°C (59°F-86°F) see USP controlled room temperature.  
Dispense in tight, light-resistant containers as defined in USP/NF with a child-resistant closure.

**Incompatible Materials** None

**Specific end use(s)** Pharmaceutical drug product.

## 8. Exposure Controls/Personal Protection

### 8.1 Control and exposure limits recommended by the chemical manufacturer

**OSHA Standards** During manufacturing: Follow the OSHA (US) respirator regulations found in 29 CFR 1910.134

**Threshold Limit Values** No data available

**NIOSH Recommendations** During manufacturing: Use a NIOSH (US) approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

### 8.2 Appropriate engineering controls

**Engineering controls** If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

### 8.3 Individual protection measures, such as personal protective equipment

**Respiratory protection** Use a properly fitted, particulate filter respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

**Eye/face protection** Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

**Hand protection** Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

**Body protection** Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

## 9. Physical and Chemical Properties

### 9.1 Information on basic physical and chemical properties

- |                           |  |
|---------------------------|--|
| a) Physical State         | Solid                                  |
| b) Appearance             | White, round, biconvex, scored tablets |
| c) Odor                   | No data available                      |
| d) Odor threshold         | No data available                      |
| e) pH                     | No data available                      |
| f) Melting/Freezing point | No data available                      |
| g) Boiling point          | No data available                      |

h) Flash point	No data available
i) Evaporation rate	No data available
j) Flammability (solid, gas)	No data available
k) Upper/lower flammability or explosive limits	Upper (UEL): No data available Lower (LEL): No data available
l) Vapor pressure	No data available
m) Vapor density	No data available
n) Relative density	No data available
o) Water solubility	No data available
p) Partition coefficient octanol/water	No data available
q) Auto-ignition temp	No data available
r) Decomposition temp	No data available
s) Viscosity	No data available

## 10. Stability and Reactivity

<b>10.1 Reactivity</b>	
Reactivity	No data available
<b>10.2 Chemical stability</b>	
Chemical stability	Stable under normal conditions of use and storage.
<b>10.3 Possibility of hazardous reactions</b>	
Hazardous reactions	No data available
<b>10.4 Conditions to avoid</b>	
Conditions to avoid	No data available
<b>10.5 Incompatible materials</b>	
Incompatible materials	Keep away from carbon oxides and nitrogen oxides.
<b>10.6 Hazardous decomposition products</b>	
Hazardous products	No data available

## 11. Toxicological Information

### 11.1 Information on toxicological effects

#### Acute toxicity

Acute administration toxicity	<b>Phenobarbital</b> LD50 Rat Oral - 162 mg/kg LD50 Mouse Oral - No data available LD50 Rabbit Intravenous - No data available LD50 Mouse Intravenous - No data available
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#### Microcrystalline Cellulose

LD50 Rat Oral - > 3160mg/kg
LD50 Rabbit Dermal - > 2000 mg/kg

#### Colloidal Silicon Dioxide

LD50 Rat Oral - 3160 mg/kg
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#### Lactose Monohydrate

LD50 Rat Oral - >10 g/kg
LD50 Rat Intraperitoneal - >10 g/kg
LD50 Rat Subcutaneous - >5 g/kg

#### Sodium Starch Glycolate, NF

LD50 Rat Oral – No data available
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#### Magnesium Stearate

LD50 Rat Oral - >10 g/kg
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Acute dermal toxicity	No data available
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Acute inhalation toxicity	<b>Magnesium Stearate</b> LD50 Rat Oral - >2 mg/L
<b>Skin corrosion/irritation</b>	
Skin corrosion irritation	No irritant effect
<b>Serious eye damage/eye irritation</b>	
Eye damage/eye irritation	No irritating effect
<b>Respiratory or skin sensitization</b>	
Respiratory sensitizer	No data available
Skin sensitizer	No data available
<b>Germ cell mutagenicity</b>	
Mutagenicity	No data available
<b>Suspected cancer agent</b>	
ACGIH	Substance not listed
NTP	Substance not listed
OSHA	Substance not listed
IARC	Substance not listed
<b>Reproductive toxicity</b>	
Reproductive toxicity	No data available
<b>Aspiration hazard</b>	
Aspiration hazard	No data available

## 12. Ecological Information

- 12.1 Ecotoxicity (aquatic and terrestrial)**  
Ecotoxicity Environmental properties have not been investigated. Releases to environment should be avoided.
- 12.2 Persistence and degradability**  
Degradability No data available
- 12.3 Bioaccumulation potential**  
Bioaccumulation LogP<sub>ow</sub> 1.47
- 12.4 Mobility in soil**  
Mobility in soil No data available
- 12.5 Results of PBT and vPvB assessment**  
PBT/vPvB assessment Not available as chemical safety assessment not required/not conducted.

## 13. Disposal Considerations

- 13.1 Waste treatment methods**  
Waste treatment disposal 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.

## 14. Transport Information



- 14.1 Transport Hazard Class(s)**  
UN Number Not available  
DOT Not available  
IMDG Not available  
IATA Not available
- 14.2 Packaging Group**  
DOT, ADR, IMDG, IATA Not available

## 15. Regulatory Information

### 15.1 Safety, health, and environmental regulations specific to the product or mixture

DEA Schedule	IV
Other Regulations	Not available

## 16. Other Information

HMIS Rating	Health hazard: 1 Flammability: 0 Physical Hazard: 0	
NFPA Rating	Health hazard: 1 Fire Hazard: 0 Reactivity Hazard: 0	
Revision Date	07 November 2022	

The information contained herein is based on data considered accurate. However, no warranty is expressed or implied regarding the accuracy of these data or the results to be obtained from the use thereof. e5 Pharma, LLC assumes no responsibility for injury to the vendee or third persons proximately caused by the material if reasonable safety procedures are not adhered to as stipulated in the data sheet. Additionally, e5 Pharma, LLC assumes no responsibility for injury to vendee or third persons proximately caused by use of the material even if reasonable safety procedures are followed. Furthermore, vendee assumes the risk in his use of the material.

Abbreviations and acronyms	IMDG - International Maritime Code for Dangerous Goods
	TDG - Transportation of Dangerous Goods
	IATA - International Air Transport Association
	GHS - Globally Harmonized System of Classification and Labelling of Chemicals
	PBT - Persistent, bioaccumulative and toxic assessment
	vPvB - Very persistent and very bioaccumulative assessment
	ACGIH - American Conference of Governmental Industrial Hygienists
	NIOSH - National Institute for Occupational Safety and Health
	CAS - Chemical Abstracts Service (division of the American Chemical Society)
	NFPA - National Fire Protection Association
	HMIS - Hazardous Materials Identification System
	CFR - Code of Federal Regulations
	SARA - Superfund Amendments and Reauthorization Act
	DOT - US Department of Transportation
	LD50 - Median lethal dose
	SDS - Safety Data Sheet