

SAFETY DATA SHEETS

This SDS packet was issued with item:

078379576

N/A

NAME: Phenobarbital Elixir, USP

Vintage Pharmaceuticals, LLC

MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND NAME

Material Name: Phenobarbital Elixir, USP

Item Number: 1508

Synonyms/Trade Names: NA

**Hazard Rating when
used as directed:**

Health: 1
Flammability: 1
Reactivity: 1

4=EXTREME
3=HIGH
2=MODERATE
1=SLIGHT

Company Identification:

Vintage Pharmaceuticals, LLC
120 Vintage Drive
Huntsville, AL 35811

Rev. & Date: R0 01/08/07

Emergency Phone Number: 1-256-859-4011

2. COMPOSITION & INGREDIENTS

Components

Active Ingredients: per 5 mL

Phenobarbital (20 mg)
Ethyl Alcohol (15%)

Inactive Ingredients:

FD&C Red # 40
flavors
glycerin
sucrose
water

NAME: Phenobarbital Elixir, USP

HAZARDS IDENTIFICATION

Emergency Overview: This mixture is a drug product regulated by the FDA. Within the meaning of the OSHA Hazard Communication Standard [29 CFR 1910.1200]: this mixture is not considered a hazard when used in a manner which is consistent with the labeled directions.

Potential Health Effects: None expected with the occupational handling of this product.

4. FIRST AID MEASURES

Eye-Rinse eye thoroughly with water. If irritation occurs, seek medical attention.

Skin- Wash thoroughly with water.

Inhalation- Inhalation is not an anticipated route of occupational exposure. For the intended use, see product label.

Ingestion- Seek medical attention, or call a poison control center only if the recommended dosage is exceeded.

5. FIRE FIGHTING MEASURES

Flash Point & Method: NA

Explosive Limits: NA

Autoignition Temperature: NA

Flammability Classification: NA

Hazardous Products of Combustion: NA

Extinguishing Media: NA

Fire Fighting Instructions: NA

Other Fire Fighting Considerations: NA

6. ACCIDENTAL RELEASE MEASURES

Personal Precaution: Avoid excessive contact. Avoid contact with eyes.

Environmental Precautions: N.K.

Procedures for Spill/Leak Clean-up: Collect and place in a suitable container. Sorbents may be used. Waste disposal method: To be performed in compliance with all regulations.

NAME: Phenobarbital Elixir, USP

7. HANDLING AND STORAGE

Precautions for Safe Handling: Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature]. Other Precautions: Dispense in a tight, light resistant container as defined in the USP/NF with a child-resistant closure.

Conditions for Safe Storage: Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature]. Other Precautions: Dispense in a tight, light resistant container as defined in the USP/NF with a child-resistant closure.

Other Recommendations: None.

8. EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:

Personal Protective Equipment

- **Eye:** NIOSH/OSHA approved safety glasses.
- **Skin:** None.
- **Inhalation:** None.
- **Other Controls:** None.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: The solution is clear and dark pink in color with an odor of cherry. **pH:** 5.6-6.7

Physical State: liquid

10. STABILITY AND REACTIVITY

Possible Hazardous Reactions/Conditions: None.

Conditions to Avoid: None.

Materials to Avoid: None.

Hazardous Decomposition Products: N.K.

Other Recommendations: None.

NAME: Phenobarbital Elixir, USP

11. TOXICOLOGICAL INFORMATION

NA

12. ECOLOGICAL INFORMATION

NA

13. DISPOSAL CONSIDERATIONS

NA

14. TRANSPORT INFORMATION

NA

15. ADDITIONAL REGULATORY INFORMATION

NA

16. OTHER INFORMATION

DISCLAIMER: This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. It is not meant to be an all-inclusive document on worldwide hazard communications regulations.

This information is offered in good faith. Each user of this material needs to evaluate the conditions of use and design the appropriate mechanisms to prevent employee exposures, property damage or release to the environment.

Issue Date 08-Jan-2007

Revision Date 17-Mar-2015

Version 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING**Product identifier****Product Name** Phenobarbital Elixir, USP**Other means of identification****Product Code** 1508**Synonyms** Refer to Medical Insert Sheet**Recommended use of the chemical and restrictions on use****Recommended Use** For use as a sedative and anticonvulsant for the treatment of generalized and partial seizures.**Uses advised against** Not available.**Details of the supplier of the safety data sheet****Supplier Address**Vintage Pharmaceuticals, LLC
120 Vintage Drive
Huntsville, AL 35811**Emergency telephone number****24 Hour Emergency Phone Number** Chemtrec
1-800-424-9300**Emergency Telephone** 1-256-859-4011**2. HAZARDS IDENTIFICATION****Classification****Health Hazards**

Carcinogenicity	Category 1A
Reproductive toxicity	Category 1B

Physical hazards

Not classified.

OSHA Regulatory Status

This product is safe for consumers when used according to the label directions. Potential hazards that may occur if product is not used according to the consumer label are as follows in this Safety Data Sheet (SDS).

Label elements**Emergency Overview****Danger****Hazard statements**

May cause cancer

May damage fertility or the unborn child



This mixture is a drug product regulated by the FDA. Within the meaning of the OSHA Hazard Communication Standard [29 CFR 1910.1200]: this mixture is not considered a hazard when used in a manner which is consistent with the labeled directions.

Appearance Clear dark pink solution
with an odor of cherry

Physical state Liquid

Odor Cherry

Precautionary Statements - Prevention

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

Use personal protective equipment as required.

Precautionary Statements - Response

If exposed or concerned: Get medical advice/attention.

Call a POISON CENTER or doctor/physician.

Precautionary Statements - Storage

Store locked up.

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Hazards not otherwise classified (HNOC)

Not available.

Other Information

Unknown Acute Toxicity

0.24% of the mixture consists of ingredient(s) of unknown toxicity

3. COMPOSITION/INFORMATION ON INGREDIENTS**Synonyms**

Refer to Medical Insert Sheet

Chemical Name	CAS No.	Weight-%
Ethyl alcohol	64-17-5	Proprietary
Glycerin	56-81-5	Proprietary
Phenobarbital	50-06-6	0.1-1
Sucrose NF	57-50-1	Proprietary

4. FIRST AID MEASURES

First aid measures

General advice	Consult a physician. Show this safety data sheet to the doctor in attendance.
Eye contact	In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
Skin Contact	In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.
Inhalation	Inhalation is not an anticipated route for liquid handling. For the intended use, see product label.
Ingestion	In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
Self-protection of the first aider	Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Most important symptoms and effects, both acute and delayed

Symptoms	Common side effects with the use of this product include the following: residual sedation; drowsiness; lethargy; vertigo; nausea; vomiting; headache.
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Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.
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5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical

Not available.

Hazardous combustion products Not available.

Explosion data

Sensitivity to Mechanical Impact None known.

Sensitivity to Static Discharge None known.

Protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions	Avoid excessive contact. Avoid contact with eyes.
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Environmental precautions

Environmental precautions	See Section 12 for additional ecological information.
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Methods and material for containment and cleaning up

Methods for containment Collect and place in a suitable container. Sorbents may be used.

Methods for cleaning up Dispose of in accordance with local, state, and national regulations.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Store at 20°-25°C (68°-77°F). [see USP Controlled Temperature]. Other Precautions: Dispense in a tight, light-resistant container as defined in the USP/NF with a child-resistant closure.

Incompatible materials None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product, as supplied, does not contain any other hazardous materials with Occupational Exposure Limits (OEL) established by the region specific regulatory bodies.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH
Ethyl alcohol 64-17-5	STEL: 1000 ppm	TWA: 1000 ppm TWA: 1900 mg/m ³	IDLH: 3300 ppm TWA: 1000 ppm TWA: 1900 mg/m ³
Glycerin 56-81-5	-	TWA: 15 mg/m ³ mist, total particulate TWA: 5 mg/m ³ mist, respirable fraction	-
Sucrose NF 57-50-1	TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust TWA: 5 mg/m ³ respirable fraction	TWA: 10 mg/m ³ total dust TWA: 5 mg/m ³ respirable dust

Appropriate engineering controls

Engineering Controls

The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

Eye/face protection

None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

Skin and body protection

None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, and hood or head coverings may be necessary. Contact a health and safety professional for specific information.

Respiratory protection

None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA

Standard 29 CFR 1910.134. Contact a health and safety professional or manufacturer for specific information.

General Hygiene Considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Liquid		
Appearance	Clear dark pink solution with an odor of cherry	Odor	Cherry
Color	Dark pink	Odor threshold	Not available.
Property	Values	Remarks • Not applicable	
pH	5.6-6.7		
Melting point/freezing point	Not available.		
Boiling point / boiling range	Not available.		
Flash point	Not available.		
Evaporation rate	Not available.		
Flammability (solid, gas)	Not available.		
Flammability Limit in Air			
Upper flammability limit:	Not available.		
Lower flammability limit:	Not available.		
Vapor pressure	Not available.		
Vapor density	Not available.		
Specific Gravity	Not available.		
Water solubility	Not available.		
Solubility in other solvents	Not available.		
Partition coefficient	Not available.		
Autoignition temperature	Not available.		
Decomposition temperature	Not available.		
Kinematic viscosity	Not available.		
Dynamic viscosity	Not available.		
Explosive properties	Not available.		
Oxidizing properties	Not available.		

Other Information

Softening point	Not available.
Molecular weight	Not available.
VOC Content (%)	Not available.
Density	Not available.
Bulk density	Not available.

10. STABILITY AND REACTIVITY

Reactivity

Stable at normal conditions.

Chemical stability

Stable at ambient temperatures and atmospheric pressures under recommended storage and handling conditions.

Possibility of Hazardous Reactions

None under normal processing.

Hazardous polymerization Hazardous polymerization does not occur.

Conditions to avoid

Not available.

Incompatible materials

None known based on information supplied.

Hazardous Decomposition Products

None under normal use conditions.

11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure****Product Information****Inhalation** No data available.**Eye contact** No data available.**Skin Contact** No data available.**Ingestion** No data available.

Acute effects The possible influence of the time of the year on the circadian pattern of phenobarbital acute toxicity was investigated in mice by determination of phenobarbital acute toxicity at four different months of the year (i.e., October, January, April and July). Data indicate an important variation of phenobarbital acute toxicity throughout the year, with the maximum mortality occurring in January (i.e., minimum LD50) the minimum in July (i.e., maximum LD50).

Acute Toxicity

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50	Intravenous LD50
Ethyl alcohol 64-17-5	= 7060 mg/kg (Rat)	-	= 124.7 mg/L (Rat) 4 h	-
Glycerin 56-81-5	= 12600 mg/kg (Rat)	> 10 g/kg (Rabbit)	> 570 mg/m ³ (Rat) 1 h	-
Phenobarbital 50-06-6	= 162 mg/kg (Rat)	-	> 4100 µg/m ³ (Rat) 4 h	-
Sucrose NF 57-50-1	= 29700 mg/kg (Rat)	-	-	-

Information on toxicological effects**Symptoms**

Common side effects with the use of this product include the following: residual sedation; drowsiness; lethargy; vertigo; nausea; vomiting; headache.

Delayed and immediate effects as well as chronic effects from short and long-term exposure**Skin corrosion/irritation** Not available.**Serious eye damage/eye irritation** Not available.**Irritation** Not available.**Corrosivity** Not available.**Sensitization** Not available.**Germ cell mutagenicity** Phenobarbital did not induce point mutations in Salmonella typhimurium TA100, TA1535, TA1537 or TA98.

Carcinogenicity There is inadequate evidence in humans for the carcinogenicity of phenobarbital. There is sufficient evidence in experimental animals for the carcinogenicity of phenobarbital. Overall evaluation: Phenobarbital is possibly carcinogenic to humans (Group 2B). Phenobarbital sodium is carcinogenic in mice and rats following lifetime administration; in mice, the drug produced benign and malignant liver cell tumors and, in rats, benign liver cell tumors very late in life.

Chemical Name	ACGIH	IARC	NTP	OSHA
Ethyl alcohol 64-17-5	A3	Group 1	-	X
Phenobarbital 50-06-6	-	Group 2B	-	X

Reproductive toxicity

ICI pathogen-free mice were treated with phenobarbital sodium in the diet on days 6 to 16 of pregnancy with 50 mg/kg of diet. Six percent of fetuses had cleft palates, and with 150 mg/kg, 3.9%, whereas there were very few cleft palates in untreated controls (0.3%). An increased incidence of cleft palate was also reported in mice given subcutaneous injections of 175 mg/kg body weight phenobarbital sodium between the 11th and 14th day after conception.

Phenobarbital has produced strong embryotoxic and teratogenic effects in rabbits, and daily ip dosage of 50 mg/kg to rats was associated with increased fetal death and sc ecchymosis.

Developmental Toxicity

Not available.

Teratogenicity

Not available.

STOT - single exposure

Not classified.

STOT - repeated exposure

Not classified.

Chronic toxicity

Not available.

Subchronic toxicity

Not available.

Target Organ Effects

Not available.

Neurological effects

Not available.

Aspiration hazard

Due to the physical form of the product it is not an aspiration hazard.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 0.24% of the mixture consists of ingredient(s) of unknown toxicity
The following values are calculated based on chapter 3.1 of the GHS document.

12. ECOLOGICAL INFORMATION**Ecotoxicity**

26.31% of the mixture consists of component(s) of unknown hazards to the aquatic environment

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Ethyl alcohol 64-17-5	–	12.0 - 16.0: 96 h Oncorhynchus mykiss mL/L LC50 static 100: 96 h Pimephales promelas mg/L LC50 static 13400 - 15100: 96 h Pimephales promelas mg/L LC50 flow-through	–	9268 - 14221: 48 h Daphnia magna mg/L LC50 2: 48 h Daphnia magna mg/L EC50 Static 10800: 24 h Daphnia magna mg/L EC50
Glycerin 56-81-5	–	51 - 57: 96 h Oncorhynchus mykiss mL/L LC50 static	–	500: 24 h Daphnia magna mg/L EC50
Phenobarbital 50-06-6	–	446 - 526: 96 h Pimephales promelas mg/L LC50 flow-through	–	

Persistence and degradability

Not available.

Bioaccumulation

Not available.

Mobility

Chemical Name	Partition coefficient
Glycerin 56-81-5	-1.76
Ethyl alcohol 64-17-5	-0.32
Phenobarbital 50-06-6	1.47

Other adverse effects Not available.

13. DISPOSAL CONSIDERATIONS

Disposal of wastes Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging Disposal should be in accordance with applicable regional, national and local laws and regulations.

US EPA Waste Number Not available.

California Hazardous Waste Codes

Chemical Name	California Hazardous Waste Status
Ethyl alcohol 64-17-5	Toxic Ignitable

14. TRANSPORT INFORMATION

DOT Not regulated.

TDG Not regulated.

MEX Not regulated.

ICAO (air) Not regulated.

IATA Not regulated.

IMDG Not regulated.

RID Not regulated.

ADR Not regulated.

ADN Not regulated.

15. REGULATORY INFORMATION

International Inventories

TSCA	Does not comply
DSL/NDL	Complies
EINECS/ELINCS	Complies
ENCS	Does not comply
IECSC	Does not comply
KECL	Complies
PICCS	Complies
AICS	Complies

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

US Federal Regulations**SARA 313**

Exempt from SARA Tier II and Section 313 of the Superfund Amendments and Reauthorization Act of 1986 reporting requirements - Any drug, cosmetic, or food regulated by the U.S. FDA or any substance used in a research laboratory, hospital or medical facility under the direct supervision of a technically qualified individual (i.e., those trained in the research or medical fields, such as doctors and nurses).

SARA 311/312 Hazard Categories

Acute health hazard	No
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations**California Proposition 65**

This product contains the following Proposition 65 chemicals

Chemical Name	California Proposition 65
Ethyl alcohol - 64-17-5	Carcinogen Developmental
Phenobarbital - 50-06-6	Carcinogen Developmental

U.S. State Right-to-Know Regulations

This product may contain substances regulated by state right-to-know regulations.

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Ethyl alcohol 64-17-5	X	X	X
Glycerin 56-81-5	X	X	X
Phenobarbital 50-06-6	-	X	-
Sucrose NF 57-50-1	-	X	X

U.S. EPA Label Information

EPA Pesticide Registration Number Not available.

16. OTHER INFORMATION

Issue Date 08-Jan-2007
Revision Date 17-Mar-2015
Revision Note
Not available.

Disclaimer

This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. It is

not meant to be an all-inclusive document on worldwide hazard communications regulations. This information is offered in good faith. Each user of this material needs to evaluate the conditions of use and design the appropriate mechanisms to prevent employee exposures, property damage or release to the environment.

End of Safety Data Sheet



One Ram Ridge Road
Chestnut Ridge, NY 10977
Tel 800-828-9393
Fax 201-829-9222
druginfo@parpharm.com

Safety Data Sheet

Dear Customer,

You have requested a Safety Data Sheet (SDS) for **Phenobarbital Elixer**, a Par Pharmaceutical product.

According to the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard, a Safety Data Sheet is not required for this product. Products such as drugs, cosmetics, food, or alcoholic beverages, wood or wood products, and tobacco or tobacco products as defined in 29 CFR Part 1910.1200(b)(6)(vii), are exempt from the entire Standard¹: “any drug... when it is in solid, final form for direct administration to the patient (e.g., tablets or capsules); drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter-drugs)...”

Items that are considered articles as defined in 29 CFR 1910.1200(c) are also exempt from this standard.

Although no Safety Data Sheet is required for this product, please refer to the prescribing information for the requested product, which may provide Safe Handling, Warnings, or Precautions to be taken when handling or taking the product.

In addition, the requested product is not regulated as hazardous material for shipping in accordance with the U.S. Department of Transportation, and has no hazardous storage limitations as defined by the National Fire Protection Association.

Sincerely,

Par Pharmaceutical

Reference

1. Occupational Safety and Health Administration. Occupational Safety and Health Standards. 29 CFR Part 1910.1200(b)(6)(vii).
https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10099. Accessed March 9, 2016.