

Safety Data Sheet

Issuing date: 23AUG2021

Revision date: 18NOV2021

Revision number: 01

1. Identification of the substance/preparation and the company/undertaking

GHS product identifier

Product name: Phenobarbital Oral Solution USP

Other means of identification

Product code(s): 0121-0942-05; 0121-1884-07; 0121-2826-15; 0121-0942-16; 0121-0942-50; 0121-1884-50; 0121-2826-50; 0121-0942-16

UN-Number: NA

Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical product used as a Sedative and Anticonvulsant.

Uses advised against: Do not use except as prescribed.

Supplier address/information

Pharmaceutical Associates, Inc.
1700 Perimeter Road
Greenville, SC 29605
(864) 277 -7282

Emergency telephone number: CHEMTREC 800.424.9300

2. Hazards Identification

Classification

This product is a mixture and is a pharmaceutical product. It is considered non-Hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

Chemical family:

Mixture

Statement of Hazard:

May cause drowsiness or dizziness. Suspected of causing cancer. Suspected of damaging fertility or the unborn child.

Additional Hazard Information:

Known Clinical Effects:

Barbiturates depress the sensory cortex, decrease motor activity, alter cerebellar function, and produce drowsiness, sedation, and hypnosis. Barbiturates are capable of producing all levels of CNS mood alteration, from excitation to mild sedation, hypnosis, and deep coma. Overdosage can produce death. In high enough therapeutic doses, barbiturates induce anesthesia.

EU Indication of danger:

Not classified.

Health Hazard:

Type	Category
Acute Toxicity	3
Carcinogenicity	2
Reproductive Toxicity	2
Specific Target Organ Toxicity	Single Exposure, Category 3 narcotic effects

Label elements

Emergency Overview

Danger

Hazard statements

Acute Toxicity
Health Hazard
-Carcinogen
-Reproductive Toxicity



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, pink to red liquid

Physical state: Liquid

Odor: Citrus

Emergency overview

Seek medical attention in case of accidental exposure or overdose. The product is generally safe when used as prescribed.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential of exposure in your workplace.

Eyes: Avoid contact with eyes.

Skin Contact: Avoid skin contact.

Inhalation: Not intended for inhalation.

Ingestion: Generally safe at recommended doses. In case of overdose, seek medical attention immediately.

Storage: There are no special storage conditions for safety. For product integrity, store under conditions specified on the label.

Disposal: Dispose of in accordance with applicable laws and regulations.

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3. Composition/Information on ingredients

Chemical name	CAS-No	Weight mg	Trade Secret
Phenobarbital	50-06-6	20 mg/5 mL	
Alcohol	64-17-5		X
Glycerin	56-81-5		X
Sucrose	57-50-1		X
Orange Flavor	Mixture		X
FD&C Red 40	25956-17-6		X
Purified water	7732-18-5		X

4. First aid measures

Description of necessary first-aid measures

Eye contact:

Flush with running water for 15 minutes holding eyelids open. Contact medical personnel if irritation persists.

Skin contact:

Wash contaminated area thoroughly. If irritation persists, contact medical personnel.

Inhalation:

Remove to fresh air and contact medical personnel.

Ingestion:

The product is intended for ingestion. In the case of accidental ingestion or overdose, contact medical personnel.

Most important symptoms/effects, acute and delayed

Phenobarbital can cause fetal harm when administered to a pregnant woman. Barbiturates readily cross the placental barrier and are distributed throughout fetal tissues; the highest concentrations are found in the placenta, fetal liver, and brain.

Indication of immediate medical attention and special treatment needed, if necessary

Immediate medical attention is required if overdose is suspected.

Notes to Physician: NA

5. Fire-fighting measures

Suitable extinguishing media:

Use carbon dioxide, dry chemical or water spray.

Specific hazards arising from the chemical

Not applicable.

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Explosion data:

Not applicable

Protective equipment and precautions for firefighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (See Section 8). Minimize exposure.

Environmental precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and materials for containment and cleaning up

- Methods for containment:
- Methods for cleaning up:

Isolate area around spill as specified by site procedures. Absorb the liquid with suitable material. Dispose of spill material in accordance with applicable federal, state or local regulations.

7. Handling and storage

Precautions for safe handling

Handling:

No special handling required for hazard control under conditions of normal product use.

Conditions for safe storage, including any incompatibilities

Storage:

No special storage required for hazard control. For product protection, follow storage recommendations on the case label, primary product label and insert.

Incompatible products:

As a precautionary measure, keep away from strong oxidizers.

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8. Exposure controls/personal protection

Control parameters

Exposure guidelines: The exposure guidelines listed below are for the individual components and not the product itself.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Phenobarbital	Not Available	Not Available	Not Available
Alcohol	Not Available	1900 mg/m ³ TWA (200 Proof)	1000 ppm TWA
Glycerin	10 mg/m ³ TWA	10 mg/m ³ TWA	Not Available
Sucrose	10 mg/m ³	15 mg/m ³	10 mg/m ³ TWA
Orange Flavor	Not Available	Not Available	Not Available
FD&C Red 40	Not Available	Not Available	Not Available
Purified water	Not Available	Not Available	Not Available

Appropriate engineering controls

Engineering measures: Engineering controls should be used to limit exposure.

Individual protection measures, such as personal protective equipment

Eye/face protection: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin and body protection: Not required under normal conditions of use. Wear protective clothing when working with large quantities.

Respiratory protection: Not required under normal use of the product.

Hygiene measures: Wash hands thoroughly after use.

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9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state: Solution
Odor: Citrus
Appearance: Clear, pink to red liquid
Odor threshold: Not available

Property	Values	Remarks/Method
pH	Natural (below 6)	cUSP Method
Melting point/range	Not applicable	
Boiling point/boiling range	Not available	
Flash point	Not applicable	
Evaporation rate	Not applicable	
Flammability (solid, gas)	Not applicable	
Flammability limits in air	Not applicable	
-upper flammability limit	Not applicable	
-lower flammability limit	Not applicable	
Vapor pressure	Not applicable	
Vapor density	Not applicable	
Specific gravity	1.438-1.1596	cUSP Method
Water solubility	Not applicable	
Solubility in other solvents	Not applicable	
Partition coefficient: n-octanol/water	Not applicable	
Autoignition temperature	Not applicable	
Decomposition temperature	Not applicable	
Viscosity	Not available	
Flammable properties	Not applicable	
Explosive properties	Not applicable	
Oxidizing properties	Not applicable	

Other information NA

VOC – 14.25% v/v Alcohol

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10. Stability and reactivity

Reactivity	Stable at normal conditions
Chemical stability	Stable at normal conditions
Possibility of hazardous reactions	Stable at normal conditions
Conditions to avoid	None known
Incompatible materials	As a precautionary measure, keep away from strong oxidizers.
Hazardous decomposition products	None known

11. Toxicological information

Information on likely routes of exposure

Product information:

- Inhalation: Not Available
- Eye contact: Not Available
- Skin contact: Not Available
- Ingestion: Not Available

The information in the table below is for the individual components and not the product.

Chemical name	LD50 oral	LD50 dermal	LC50 inhalation
Phenobarbital	162 mg/kg Rat	Not Available	Not Available
Alcohol	3632 mg/kg Mouse	Not Available	20000 ppm 10hr. Rat
Glycerin	12600 mg/kg Rat	10000 mg/kg Rabbit	Not Available
Sucrose	29700 mg/kg Rat	Not Available	Not Available
Orange Flavor	Not Available	Not Available	Not Available
FD&C Red 40	>10000mg/kg Rat	>10000 mg/kg Rabbit	Not Available
Purified water	Not Available	Not Available	Not Available

Symptoms related to the physical, chemical and toxicological characteristics

None

Delayed and immediate effects and also chronic effects from short and long term exposure

- Sensitization: No data available
- Mutagenic effects: No data available
- Carcinogenicity: Suspected of causing cancer
- Reproductive toxicity: Suspected of damaging fertility or the unborn child. Some barbiturates have been shown to cause an increased incidence of fetal abnormalities. Therapeutic use during the last

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trimester of pregnancy may cause physical dependence and withdrawal in the newborn.

- STOT – single exposure: Narcotic effects
- STOT – repeated exposure: No data available
- Aspiration hazard: Based on available data, the classification criteria are not met

Numerical measures of toxicity – product

- No data available

12. Ecological information

Ecotoxicity:

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

Persistence and Degradability

No data available

Bioaccumulation

No data available

Other adverse effects:

No data available.

The following table lists the data for the individual components, if available.

Chemical name	Toxicity to algae	Toxicity to fish	Toxicity to micro-organisms	Daphnia Magna (water flea)
Phenobarbital	Not Available	446 - 526 mg/l, 96 hours Pimephales Promelas	Not Available	Not Available
Alcohol	Not Available	Not Available	Not Available	Not Available
Glycerin	Not Available	58.5 ppm 96 hr	Not Available	Not Available
Sucrose	Not Available	Not Available	Not Available	Not Available
Orange Flavor	Not Available	Not Available	Not Available	Not Available
FD&C Red 40	Not Available	Not Available	Not Available	Not Available
Purified water	Not Available	Not Available	Not Available	Not Available

13. Disposal considerations

Waste disposal methods

Dispose of waste in accordance with all federal, state and local regulations.

Contaminated packaging

Dispose of waste in accordance with all federal, state and local regulations.

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14. Transport information

Notes:

Not regulated for transport under USDOT, IATA, TDG, IMDG or other regulations.

15. Regulatory information

International inventories

Legend

U.S. Federal regulations;

Not applicable

Chemical name	California Listed	TSCA Listed (8b)	EINECS	Sara 311/312
Phenobarbital	Carcinogenic substance – Listed January 1, 1990 Developmental toxin – Listed October 1, 1992	No	Yes	Yes
Alcohol	No	Listed	Listed	Not Applicable
Glycerin	No	Listed	Listed	Not Applicable
Sucrose	No	Listed	Listed	Not Applicable
Orange Flavor	No	No	No	Not Applicable
FD&C Red 40	No	Listed	Listed	Not Applicable
Purified water	No	No	No	Not Applicable

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 No components are listed under CERCLA.

U.S. state Right-to-Know regulations

“X” designates that the ingredients are listed on the state Right-to-Know list

Chemical name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
Phenobarbital		X			
Alcohol	X	X	X	X	X
Glycerin	X	X	X	X	X
Sucrose	X	X	X		

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Chemical name

New Jersey

Massachusetts

Pennsylvania

Illinois

Rhode Island

Orange Flavor

FD&C Red 40

Purified water

U.S. EPA label information:

Not applicable

16. Other information

Prepared by:

Pharmaceutical Associates Inc.

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Revision note:

New SDS

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Revision note:

Updated Appearance from "Clear, red liquid" to "Clear, pink to red liquid" based on updated quality specification for FN0942, Rev 02.

General Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of Safety Data Sheet