SAFETY DATA SHEET

1. Identification

Product Identifier: **Phenobarbital Sodium Injection, USP**

Synonyms: Phenobal sodium, Sodium luminal

National Drug Code (NDC):

65 mg/ml	NDC14789-127-05
130 mg/mL	NDC14789-128-05

Recommended Use: Pharmaceutical

Company: Nexus Pharmaceuticals, LLC.
400 Knightsbridge Pkwy
Lincolnshire IL, 60069
USA

Contact Phone: (847) 996-3790

Website: www.nexuspharma.net

Emergency Contact: Chemtrec (24 hours): 1-800-424-9300
Email: CHEMTREC@chemtrec.com

2. Hazard(s) Identification

Physical Hazards: Not classifiable.

Health Hazards:

Acute toxicity (oral)	Category 4
Skin sensitization	Category 1
Carcinogenicity	Category 2

Classification of the Substance or Mixture: This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Symbol(s):

Signal Word: Warning

Hazard Statement(s):

H301 Toxic if swallowed.

H317 May cause an allergic skin reaction.

H351 Suspected of causing cancer.

Precautionary Statement(s):

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P261 Avoid breathing dust/mist/vapor.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P363 Wash contaminated clothing before reuse.
P405 Store locked up.

Hazards Not Otherwise Classified: None.

Supplementary Information: None.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Phenobarbital Sodium, USP	50-06-6	Phenobal sodium, Sodium luminal	C12H11N2NaO3	254.22 g/mol	6.5% - 13%
Alcohol, USP	64-17-5	Ethanol	CH3CH2OH	46.068 g/mol	5% - 10%
Propylene Glycol, USP	57-55-6	1,2-propanediol, methyl glycol	C3H8O2	76.09 g/mol	60% - 100%
Benzyl Alcohol, NF	100-51-6	Hydroxytoluol, Phenylcarbinol	C6H5CH2OH	108.14 g/mol	1% - 5%
Hydrochloric Acid, NF	7647-01-0	Muriatic acid, Hydrogen chloride	HCl	36.46 g/mol	5% - 10%

Inactive Ingredients: Water for Injection.

4. First Aid Measures

Ingestion: Wash out mouth with water. Remove dentures if any. Remove person exposed to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. If necessary, call a poison center or physician. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Eye Contact:	Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention.
Skin Contact:	Wash with plenty of soap and water. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 20 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.
Inhalation:	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
Protection of First-Aiders:	Use personal protective equipment (see section 8).
Signs and Symptoms:	Symptoms of acute intoxication with phenobarbital include unsteady gait, slurred speech, and sustained nystagmus. Common exposure symptoms include lethargy, slurred speech, ataxia, hypotension and arrhythmias. Onset of symptoms is usually within an hour of ingestion and symptoms may be profound and prolonged. Serum phenobarbitone concentrations can be useful for confirming the ingestion but are not a reliable predictor of clinical course.

Medical Conditions Aggravated by Exposure: This product may cause an allergic skin reaction.

Notes to Physician: Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media: Use extinguishing media (water spray (fog), foam, dry powder, or carbon dioxide as appropriate) for type of surrounding fire.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: These products include carbon oxides, nitrogen oxides, sulfur oxides, and other hazardous products of combustion.

Other Specific Hazards: Closed containers may explode from the heat of fire.

Special Protective Equipment Precautions for FireFighters Wear self-contained breathing apparatus and full protective gear.

6. Accidental Release Measures

Personal Precautions: Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Do not touch or walk through spilled material. Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

Environmental Precautions: Contain material and prevent release to basements, confined spaces, waterways or soil.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any incompatibilities Store according to label and/or product insert information. Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Specific End Use: Pharmaceuticals

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Ethyl alcohol	ACGIH TLV STEL: 1000 ppm NIOSH REL TWA: 1000 ppm 10 hours. OSHA PEL TWA: 1000 ppm 8 hours.
Benzyl alcohol	ACGIH WEEL (8Hrs) = 10 ppm ACGIH WEEL (8Hrs) = 44 mg/m3

* Occupational Exposure Levels (OELs) have been established by private industry.

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.

Respiratory Protection: Use a powered air purifying respirator, or properly fitted air-purifying or supplied air 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.

Eyes: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mist, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Hand: 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 is difficult to be accurately estimated.

Skin: Personal protective equipment for the skin/body should be selected based on the task being performed and the risks involved before handling this product.

9. Physical and Chemical Properties

Physical State/Color: Clear, colorless liquid.

Odor: No data available.

Odor Threshold: No data available.

pH: 9.2 to 10.2

Melting Point: No data available.

Freezing Point: No data available.

Boiling Point: No data available.

Flash Point: No data available.

Evaporation Rate: No data available.

Flammability (solid, gas): No data available.

Flammability Limit - Lower: No data available.

Flammability Limit - Upper: No data available.

Vapor Pressure: No data available.

Vapor Density: No data available.

Relative Density: No data available.

Solubility(ies): Soluble in hot and cold water.

Partition Coefficient (n-octanol/water): No data available.

Auto-Ignition Temperature: No data available.

Decomposition Temperature: No data available.

Viscosity: No data available.

10. Stability and Reactivity

Reactivity: No specific test data related to reactivity available for this product or its ingredients.

Chemical Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to Avoid (e.g., static discharge, shock, or vibration): No data available.

Incompatible Materials: Oxidizing materials, acids and alkalis.

Hazardous Decomposition Products: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation: Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.

Ingestion: May be harmful if swallowed.

Skin Contact: May cause an allergic skin reaction.

Eye Contact:	No known significant effects or critical hazards.
Symptoms Related to the Physical, Chemical and Toxicological Characteristics:	See Section 4. To the best of our knowledge, the, physical and toxicological properties have not been thoroughly investigated
Delayed and Immediate Effects of Exposure:	Skin irritation and redness for skin contact; Symptoms of acute intoxication with phenobarbital include unsteady gait, slurred speech, and sustained nystagmus. Common exposure symptoms include lethargy, slurred speech, ataxia, hypotension and arrhythmias. Onset of symptoms is usually within an hour of ingestion and symptoms may be profound and prolonged.
Acute Toxicity – Oral:	ATE value: 1501.3 mg/kg
Acute Toxicity – Dermal:	No information available.
Acute Toxicity – Inhalation:	ATE value: 555.6 mg/L
Corrosivity:	No data available.
Dermal Irritation:	May cause an allergic skin reaction.
Eye Irritation:	No data available.
Sensitization:	May cause an allergic skin reaction.
Toxicokinetics/Metabolism:	Potent cytochrome P450 enzyme inducer, sedation. Overexposure can lead to prolonged coma, cardiovascular depression with hypotension and shock leading to renal failure.
Target Organ Effects:	Possible target organs include the cardiovascular system and central nervous system.
Reproductive Effects:	No data available.
Carcinogenicity:	Suspected of causing cancer.
Mutagenicity:	No data available.

Aspiration Hazard: Do not induce vomiting unless directed by a physician.

12. Ecological Information

Ecotoxicity

Product/ingredient name	Result	Species	Exposure
Ethyl Alcohol	Acute EC50 17.921 mg/L Marine water	Algae - Ulva pertusa	96 hours
	Acute EC50 2000 µg/l Fresh water	Daphnia - Daphnia magna	48 hours
	Acute LC50 25500 µg/l Marine water	Crustaceans - Artemia franchiscana - Larvae	48 hours
	Acute LC50 42000 µg/l Fresh water	Fish - Oncorhynchus mykiss	4 days
	Chronic NOEC 4.995 mg/L Marine water	Algae - Ulva pertusa	96 hours
	Chronic NOEC 0.375 ul/L Fresh water	Fish - Gambusia holbrooki - Larvae	12 weeks
Benzyl Alcohol	Acute EC50 640 mg/L	Algae - Scenedesmus subspicatus	96 hours
	Acute IC50 700 mg/L	Algae	72 hours
	Acute LC50 10000 µg/l Fresh water	Fish - Lepomis macrochirus	96 hours

Persistence and Degradability:

Product/ingredient name	Test	Result	Dose	Inoculum
Benzyl Alcohol	OECD 301C 301C Ready Biodegradability - Modified MITI Test (I)	92 to 96 % - 28 days	-	-

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
Benzyl Alcohol	-	-	Readily

Bioaccumulative Potential:

Product/ingredient name	$LogP_{ow}$	BCF	Potential
Ethyl Alcohol	-0.32	-	low
Benzyl Alcohol	0.87	-	low

Mobility in Soil: No data available.

Other Adverse Effects: No data available.

13. Disposal Considerations

The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of

environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe
way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

14. Transport Information

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.
DOT:	Not regulated as a hazardous material.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.

15. Regulatory Information

International Regulations:

Ozone depleting substance: Not applicable

Persistent Organic Pollutant: Not applicable

The Rotterdam Convention Not applicable

US Federal Regulations:

TSCA Inventory This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.

CERCLA Hazardous Substance and Reportable Quantity:	Not listed.
SARA 313:	Not listed.
SARA 302:	Not listed.
DEA:	List I Chemical.

State Regulations

Massachusetts:	The following components are listed: Ethyl Alcohol; Benzyl Alcohol.
New Jersey:	The following components are listed: Propane-1,2-diol; Ethyl Alcohol.
Pennsylvania:	The following components are listed: Propane-1,2-diol; Ethyl Alcohol; Benzyl Alcohol.
California Proposition 65:	Not listed.

16. Other Information

NFPA Rating: (Phenobarbital)	**HMIS Classification: (Phenobarbital)**
Health: 4	Health: *3
Flammability: 0	Flammability: 0
Reactivity: 0	Physical Hazard: 0

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