SDS: Nembutal® Sodium Solution CII (pentobarbital sodium injection, USP)

SAFETY DATA SHEET

1. Identification

Product Identifier: Nembutal® Sodium Solution CII
(pentobarbital sodium injection, USP)

Synonyms: Pentobarbitone

National Drug Code (NDC): 76478-501-20
76478-501-50

Recommended Use: Pharmaceutical.

Company: Oak Pharmaceuticals, Inc. (Subsidiary of Akorn, Inc.)
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards: Not classifiable.

Health Hazards: Harmful if swallowed — Category 4

Symbol(s):

Signal Word: Warning.

Hazard Statement(s):

H302	Harmful if swallowed.

Precautionary Statement(s):

P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P301 + P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P330	Rinse mouth.

Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: None.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Pentobarbital Sodium	57-33-0	Pentobarbitone	$C_{11}H_{18}N_2O_3Na$	226.27	5%

*The formula also contains Propylene Glycol, 40%; Alcohol, 10% and Water for Injection. The pH is adjusted to approximately 9.5 with Sodium Hydroxide and/or Hydrochloric Acid.

4. First Aid Measures

Persons developing hypersensitivity reactions to preparations containing Pentobarbital Sodium should receive medical attention. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Take a copy of container label, Product Insert and SDS to physician or health professional with the affected individual

Ingestion: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Maintain an open airway and obtain immediate medical attention.

Eye Contact: Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact: Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Inhalation: Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Protection of First-Aiders: Use personal protective equipment (see section 8).

Signs and Symptoms: Employees administering the product should not experience adverse effects if handled properly. Adverse effects from therapeutic doses have included the following: sleepiness, agitation, confusion, an abnormal increase in muscular activity, loss of the ability to

coordinate muscular movement, CNS depression, nightmares, nervousness, psychiatric disturbance, hallucinations, insomnia, anxiety, dizziness, thinking abnormality, hypoventilation, difficulty breathing, slow heart rate, low blood pressure, a brief loss of consciousness, nausea, vomiting, constipation, headache, angioedema, skin rashes, exfoliative dermatitis, fever, and liver damage. Chronic exposure to this product may be habit forming. Tolerance, psychological dependence, and physical dependence may occur especially following prolonged use of high doses of barbiturates.

Medical Conditions Aggravated by Exposure:

There is no information on preexisting medical conditions that may be aggravated by occupational exposure to this product. With therapeutic use, pre-existing physical and psychological dependency, porphyria and neurological conditions may be aggravated by exposure to this product.

Notes to Physician:

Treatment of over dosage is mainly supportive and consists of the following:

1. Maintenance of an adequate airway, with assisted respiration and oxygen administration.
2. Monitoring of vital signs and fluid balance.
3. Fluid therapy and other standard treatment for shock, if needed.
4. If renal function is normal, forced diuresis may aid in the elimination of the barbiturate.
5. Hemodialysis may be used in severe barbiturate intoxications or if the patient is anuric or in shock.
6. Patient should be rolled from side to side every 30 minutes.
7. Antibiotics should be given if pneumonia is suspected.
8. Appropriate nursing care to prevent hypostatic pneumonia, decubiti, aspiration and other complications in patients with altered states of consciousness.

5. Firefighting Measures

Flammability:

This product is not flammable.

Suitable Extinguishing Media:

Use water, carbon dioxide, dry chemical or foam as necessary.

Unusual Fire and Explosion Hazards:

When involved in a fire, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon oxides, nitrogen oxides, and sodium oxides). If involved in a fire, evaporation of the water in this solution may make this product become combustible.

Unsuitable Extinguishing Media:

Not determined.

Special Fire Fighting Procedures: No special procedures are necessary. Fire fighters should follow normal fire response procedures consistent with surrounding materials.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: Not determined.

Other Specific Hazards: Not determined.

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

6. Accidental Release Measures

Personal Precautions: Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: For small releases of this compound; wear double latex or butyl rubber gloves and safety glasses. Clean up solution with a damp sponge, polypad, or other appropriate material for small spills then place in a bag and hold for waste disposal. Avoid producing sprays or mists of this product during cleanup. In case of large spill, clear the affected area and protect people. Trained personnel using pre-planned procedures should respond to large or uncontrolled releases. Proper protective equipment should be used, including double natural rubber, neoprene or nitrile gloves, full body gown, and full-face respirator equipped with a High Efficiency Particulate (HEPA) filter. Self-Contained Breathing Apparatus (SCBA) can be used instead of an air-purifying respirator in the event of a large spill. Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Dispose of as a Controlled Substance in accordance with appropriate U.S. Federal, State, and local regulations.

Environmental Precautions: Large quantities released to the aquatic and terrestrial environment nay have an adverse effect.

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

7. Handling and Storage

Precautions for Safe Handling: Employees must be trained to properly use this product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Operations associated with the use of this product include withdrawal of needles from drug vials, drug transfers using syringes and needles, and

expulsion of air from drug-filled syringes. Ensure vials are properly labeled.

Conditions for Safe Storage, Including Any Incompatibilities: As a Controlled Substance, this product should be stored in a designated Controlled Substance area. Store this product away from incompatible materials. Store at room temperature, according to Package Labeling instructions. Protect from freezing and avoid excessive heat.

Product Preparation Instructions for Medical Personnel: Handle this material following standard medical practices and following the recommendations presented on the Package Labeling.

Protective Practices During Maintenance of Contaminated Equipment: When cleaning non disposable equipment, wear latex or butyl rubber gloves, goggles, and lab coat. Wash equipment with soap and water.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Pentobarbital Sodium	Not established.
Propylene Glycol	AIHA WEEL: 10 mg/m^3 TWA
Alcohol	ACGIH-TLV: 1,000 ppm TWA ACGIH-REL: 1,900 mg/m^3 TWA ACGIH-REL: 1,000 ppm TWA OSHA-PEL: 1,000 ppm TWA NIOSH-PEL: 1,900 mg/m^3 TWA NIOSH-IDLH: 3,300 ppm STEL: 1,000 ppm

Engineering Controls: Use with adequate ventilation. Follow standard medical product handling procedures.

Respiratory Protection: A respirator is not required for routine use of this product. Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection: Not required for the normal use of this product. Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection:	For situations, in which prolonged skin contact is anticipated, wear chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Skin Protection:	Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color:	Liquid. Clear, colorless.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	Approximately 9.5.
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 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:	This product is not reactive.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	Avoid heat, light, and contact with incompatible chemicals.
Incompatible Materials:	This product is generally compatible with common materials in a medical facility. Acids, caustics, and other chemicals that could affect its performance should be avoided.

Hazardous Decomposition Products:	If exposed to extremely high temperatures, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon oxides, nitrogen oxides, and sodium oxides).
Hazardous Polymerization:	Will not occur.

11. Toxicological Information

Information on the Likely Routes of Exposure:

General Toxicity Information:	Pentobarbital Sodium was shown to produce respiratory depression when given in low and high doses. The toxic dose of barbiturate varies considerably but, in general, a severe reaction is likely to occur when the amount ingested is more than 10 times the usual oral hypnotic dose. Potentially lethal blood concentrations are those in excess of approximately 30 mg/mL for secobarbitai or pentobarbital.
Irritancy of Product:	This product may irritate contaminated tissue.
Inhalation:	Inhalation of mists or sprays may temporary irritate to the respiratory system.
Injection:	If accidentally injected, effects may occur that could occur as described under “Signs and Symptoms”.
Ingestion:	Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product may cause nausea, vomiting, gastrointestinal upset, sleepiness, confusion convulsions central nervous system depression, respiratory system depression, and symptoms such as those described under "Signs and Symptoms".
Skin Contact:	Prolonged skin contact may be irritating.
Eye Contact:	May cause temporary redness and irritation.
Symptoms Related to the Physical, Chemical and Toxicological Characteristics:	See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.
Delayed and Immediate Effects of Exposure:	No data available.

Acute Toxicity:

Compound	Species	Route	Type	Dose	Behavioral
Pentobarbital Sodium	Rat	Oral	LD_{50}	118 mg/kg	N/A
Pentobarbital Sodium	Mouse	Oral	LD_{50}	239 mg/kg	N/A
Pentobarbital Sodium	Man	Oral	TD_{Lo}	6,430 lag/kg	Change in motor activity ataxia, antipsychotic
Pentobarbital Sodium	Woman	Oral	TD_{Lo}	60 mg/kg	Wakefulness

Acute Toxicity – Dermal: No data available.
Acute Toxicity – Inhalation: No data available.

Corrosivity: Not corrosive.

Dermal Irritation: Prolonged skin contact may be irritating. Repeated skin contact may cause dermatitis.

Eye Irritation: Eye contact may cause temporary redness and irritation.

Sensitization: No data available.
Toxicokinetics/Metabolism: No data available.

Acute Effects: The primary health effects that may be experienced by medical personnel exposed to this product is irritation of contaminated tissues or gastrointestinal upset if swallowed. In the event of acute exposures to therapeutic doses of this product, effects described in "Signs and Symptoms" may result.

Chronic Effects: Repeated skin contact may cause dermatitis (dry, red skin). In the event of chronic exposures to therapeutic doses of this product, effects described in "Signs and Symptoms" may result.

Target Organ Effects: Central nervous system, respiratory system, gastrointestinal system. Blood system.

Reproductive Effects: No adequate animal studies have been conducted to determine reproductive effects. No reproductive effects have been reported in humans.

Reproductive Toxicity Information: Pentobarbital Sodium has been rated Pregnancy Category D-POSITIVE EVIDENCE OR RISK, There is a risk to fetus after drug is administered, but under certain circumstances (e.g., treatment of life-threatening illnesses) the benefits can outweigh the risk. Animal reproduction studies have not been conducted with product.

The following reproductive data are available for the active component:

Compound	Study Type	Species	Route	Type	Dose
Pentobarbital Sodium	Reproductive Toxicity	Mouse	Intraperitoneal	Micronucleus Test	64,800 µg/kg
Pentobarbital Sodium	Reproductive Toxicity	Mouse	Cells – Not Otherwise Specified	DNA Inhibition	500 µmol/L
Pentobarbital Sodium	Reproductive Toxicity	Mouse	Unreported	DNA Inhibition	60 mg/kg
Pentobarbital Sodium	Reproductive Toxicity	Mouse	Unreported	Mutation Test Systems-Not Otherwise Specified	60 mg/kg
Pentobarbital Sodium	Reproductive Toxicity	Mouse	Cells – Not Otherwise Specified	Mutation Test Systems-Not Otherwise Specified	500 µmol/L
Pentobarbital Sodium	Reproductive Toxicity	Mouse	Lymphocyte	Mutation Test Systems-Not Otherwise Specified	1,500 µmol/L

Teratogenicity: This product contains a barbiturate. Barbiturates can cause fetal damage when administered to a pregnant woman. Retrospective, case-controlled studies have suggested a connection between the maternal consumption of barbiturates and a higher than expected incidence of fetal abnormalities. Following oral or parenteral administration, barbiturates readily cross the placental barrier and are distributed throughout fetal tissues with highest concentrations found in the placenta, fetal liver, and brain. Fetal blood levels approach maternal blood levels following parenteral administration.

Carcinogenicity: ACGIH lists Ethanol as a TLV-A4 (Not Classifiable as Human Carcinogen). The DFG lists Ethanol as a MAK-5 compound (Substances with carcinogenic and genotoxic effects). The remaining components of this product are not found on the following lists: FEDERAL OSI-IA Z LIST, NTP, IARC, and CAL/OSHA and therefore are neither considered to be nor suspected to be cancer causing agents by these agencies. Currently no published studies are available on the carcinogenic status of the active ingredient Pentobarbital Sodium.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

Mutagenicity:	No adequate animal studies have been conducted to determine mutagenic effects of the active component; Pentobarbital Sodium. No mutagenic effects have been reported in humans.
Embryotoxicity:	No adequate animal studies have been conducted to determine embryotoxic effects. No embryotoxic effects have been reported in humans.
Aspiration Hazard:	Based on available data, the classification criteria are not met.

12. Ecological Information

Ecotoxicity

Aquatic:	Release of this product to an aquatic environment may be harmful to aquatic plant and animal life in contaminated bodies of water, especially in large quantities.
Terrestrial:	No specific information is currently available on the effect of this product on plants or animals in the environment. This product may be harmful to contaminated plant and animal life, especially in large quantities.
Persistence and Degradability:	The chemical (medicinal) components of this product will slowly degrade in the environment and form a variety of organic materials.
Bioaccumulative Potential:	No data available.
Mobility in Soil:	No data available.
Mobility in Environment:	No data available.
Other Adverse Effects:	No data available.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.
Department of Transportation:	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

US Federal Regulations:

Toxic Substance Control Act (TSCA): This product is regulated under Food and Drug Administration standards; it is not subject to requirements under TSCA.

CERCLA Hazardous Substance and Reportable Quantity: Not listed.

SARA 313: Not listed.
SARA 302: Not listed.

State Regulations

California Proposition 65: Listed. Contains a chemical known to the State to cause reproductive toxicity.

16. Other Information

Not made with natural rubber latex.

NFPA Rating:

Flammability:	0
Instability:	0
Health:	1

Revision Date: 05/07/2015

Revision Number: 1