SAFETY DATA SHEET

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

1. IDENTIFICATION

Product Identifier:	Nembutal® Sodium Solution (pentobarbital sodium injection, USP) CII
Synonyms:	5-ethyl-5-(1-methylbutyl) barbiturate
National Drug Code (NDC):	76478-501-20 76478-501-50
Recommended Use:	Pharmaceutical. Nembutal® is used as a sedative to treat insomnia and emergency treatment for seizures.
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:

Acute Toxicity, Oral	Category 4
Serious Eye Damage/Eye Irritation	Category 2B

Symbol(s):

Signal Word: Warning.

Hazard Statement(s):

H302	Harmful if swallowed.
H320	Causes eye irritation.

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.

P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue Rinsing.
P337 + P313	If eye irritation persists: Get medical advice/attention.
P501	Dispose of contents/container in accordance with all local and national regulations.

Hazards Not Otherwise Classified: None.
Supplementary Information: None.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Synonyms	CAS Number	Chemical Formula	Molecular Weight	Percentage
Pentobarbital Sodium	5-ethyl-5-(1-methylbutyl) barbiturate	57-33-0	$C_{11}H_{18}N_2O_3Na$	226.27	5%
Alcohol	Ethyl alcohol	64-17-5	C_2H_5OH	46.07	10%

The formula also contains Propylene Glycol, 40% 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

Suitable Extinguishing Media: Use water, carbon dioxide, dry chemical or alcohol-resistant foam as necessary.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical

Hazardous Combustion Products: Not determined.

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

Special Protective Equipment and Precautions for Firefighters: Wear self-contained breathing apparatus and full and 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: 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. Large quantities released to the aquatic and terrestrial environment may 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:

In the US, Nembutal® is a Schedule CII controlled substance. Appropriate training and procedures may be required during the routine handling of this product. 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:

Avoid excessive heat. Protect from freezing. Store at 20° to 25°C (68° to 77°F), excursions permitted between 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

Specific End Use:

Pharmaceuticals drug product.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Guidelines:

Ingredient	Type	Value
Pentobarbital Sodium	Not established	Not established
Alcohol	OSHA PEL	1,000 ppm; 1,900 mg/m^3
	NIOSH IDLH	3,300 ppm
	NIOSH REL	1,900 mg/m^3
	ACGIH TWA	1,000 ppm
	ACGIH TLV STEL	1,000 ppm

OSHA: Occupational Safety and Health Administration; PEL: Permissible Exposure Limits; NIOSH: National Institute for Occupational Safety and Health; REL: Recommended Exposure Limits. ACGIH: American Conference of Governmental Industrial Hygienists; TLV: Threshold Limit Value; STEL: Short Term Exposure Limit; TWA: Time Weighted Average.

Engineering Controls:

Engineering controls should be used as the primary means to control exposures.

Respiratory Protection:

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. 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:	Not required for the normal use of this product. Chemically compatible gloves should be worn when working with large quantities. 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.
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

Physical State/Color:	Clear, colorless liquid.
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:	The product is stable and non-reactive under normal conditions of use, storage and transport.
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).

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.
Inhalation:	Inhalation of mists or sprays may temporary irritate to the respiratory system.
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:	Causes eye 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

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
Pentobarbital Sodium	Rat	Oral	LD_{50}	118 mg/kg
	Mouse	Oral	LD_{50}	170 mg/kg
Alcohol	Rat	Oral	LD_{50}	2,404 mg/kg

Irritation / Sensitization

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

Repeated Does Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Test Type	Effect(s)
No data available	No data available	No data available	No data available	No data available	No data available	No data available

Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
No data available	No data available	No data available	No data available

Aspiration Hazard: No data available.

Toxicokinetics/Metabolism: No data available.

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

Systemic Effects: No data available.

Reproductive Effects: Pregnancy Category D. 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.

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: No data available.

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.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
Alcohol	Water flea (Daphnia magna)	EC_{50}	7.7-11.2 mg/l	48 hours
	Fathead minnow (Pimephales promelas)	LC_{50}	>100 mg/l	96 hours

Terrestrial Toxicity: No data available.
Persistence and Degradability: No data available.
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

Department of Transportation (DOT): Not regulated as a hazardous material.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
No applicable	No applicable	No applicable	No applicable

International Air Transport Association (IATA): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
No applicable	No applicable	No applicable	No applicable

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
No applicable	No applicable	No applicable	No applicable

15. REGULATORY INFORMATION

US FEDERAL REGULATIONS

Toxic Substance Control Act (TSCA):

Ingredient	Inventory
Pentobarbital Sodium	Yes
Alcohol	Yes

CERCLA Hazardous Substance:

Ingredient	Reportable Quantity
Not applicable	Not applicable

EPCRA Extremely Hazardous Substances and Toxic Chemicals:

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable

U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Pentobarbital Sodium	Listed	Listed	Not listed
Alcohol	Listed	Listed	Listed

California Proposition 65:

Pentobarbital Sodium is listed to cause birth defects, or other reproductive harm.

Alcohol is listed to cause cancer and birth defects or other reproductive harm.

16. OTHER INFORMATION

The vial stopper is not made with natural rubber latex.

See footer of this document for Revision Date and Revision Number.

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