MSDS: Nembutal® Sodium Solution
(Pentobarbital Sodium Injection, USP) CII

Manufacturer: Oak Pharmaceuticals
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Section 1 - IDENTIFICATION

Trade/Material Name: Nembutal® Sodium Solution
Description: Nembutal® is a sterile solution for intravenous or intramuscular injection. It is a short-acting barbiturate indicated as a sedative, hypnotic, preanesthetic, or anticonvulsant.
Chemical Name: Pentobarbital Sodium;
Chemical Family: Barbiturate
Formula: C11H18N2O3Na / C3H8O2 / C2H6O / H2O

Section 2 – HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>% W/V</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentobarbital Sodium</td>
<td>57-33-0</td>
<td>5%</td>
</tr>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>10%</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>57-55-6</td>
<td>40%</td>
</tr>
<tr>
<td>Water For Injection</td>
<td>7732-18-5</td>
<td>45%</td>
</tr>
</tbody>
</table>

Section 3 – HEALTH HAZARD DATA

Emergency Overview:

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Health Hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>This product is supplied as a clear, colorless solution.</td>
<td>This product is a Controlled Substance. The chief health hazard associated with overexposures during normal occupational use and handling is irritation of contaminated tissues. Contains material that may cause birth defects based on animal data.</td>
</tr>
<tr>
<td>Flammability Hazards</td>
<td>Reactivity Hazards: This product is not flammable. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including e.g., carbon oxides, nitrogen oxides, and sodium oxides).</td>
</tr>
<tr>
<td>Environmental Hazards</td>
<td>This product is not reactive.</td>
</tr>
</tbody>
</table>

Large quantities released to the aquatic and terrestrial environment may have an adverse effect.
Symptoms of overexposure: The health hazard information provided below is pertinent to medical employees using this product in an occupational setting.

- **Acute Toxicity - Dermal:** Not determined
- **Acute Toxicity - Inhalation:** Inhalation of mists or sprays may temporarily irritate the respiratory system.
- **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:** Not determined
- **Skin Absorption:** Not determined
- **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 "Other Potential Health Effects".
- **Injection:** If accidentally injected, effects may occur that could occur as described under "Other Potential Health Effects".

### Other Potential Health Effects –

**Therapeutic Doses:** 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, hyperventilation, 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.

### Health effects or risks from exposure:

**Acute:** 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 "Other Potential Health Effects" may result.

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

**Target Organs:** Central nervous system, respiratory system, gastrointestinal system, blood system.
Section 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 MSDS to physician or health professional with the affected individual.

Skin Exposure: Basic hygiene should prevent any problems. If contact with the skin causes irritation, rinse with soap and running water. Remove contaminated clothing, taking care not to contaminate eyes. If an adverse reaction occurs, seek medical attention.

Eye Exposure: If product contacts the eyes rinse eyes thoroughly. Minimum flushing is for 15 minutes. If the exposure has resulted in an adverse effect, seek medical attention.

Inhalation: In unlikely event that inhalation occurs and adverse effect occurs, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention.

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.

Medical Conditions Aggravated by Exposure: There is no information on pre-existing 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.

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.
**Section 5 – FIRE FIGHTING MEASURES**

- **Flash Point:** Not applicable  
- **Autoignition Temperature:** Not applicable  
- **Flammable Limits (in air by volume, %):**  
  - Lower (LEL): Not applicable  
  - Upper (UEL): Not applicable  
- **NFPA Rating**  
  - Flammability: 0  
  - Instability: 0  
  - Health: 1  
  - Hazard Scale: 0 = Minimal, 1 = Slight, 2 = Moderate, 3 = Serious, 4 = Severe

**Fire Extinguishing Materials:** Use extinguishing media appropriate for surrounding fire.  
- Water Spray: OK  
- Carbon Dioxide: OK  
- Dry Chemical: OK  
- Halon: OK  
- Foam: OK  
- Other: Any "ABC" Class

**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.  
- **Explosion Sensitivity to Mechanical Impact:** Not sensitive  
- **Explosion Sensitivity to Static Discharge:** Not sensitive

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

**Section 6 – ACCIDENTAL RELEASE MEASURES**

**Spill Response:** 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 a 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.

**Section 7 – HANDLING AND STORAGE**

**Work Practices and Hygiene Practices:** As with all chemicals, avoid getting this material ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics while handling this product. Wash hands thoroughly after handling. Follow SPECIFIC USE INSTRUCTIONS supplied with this product. Use of this product should meet the following provisions:  
- Work should be performed in a designated area for working with hazardous drugs or Controlled Substances;  
- Containment devices, such as a Biological Safety Cabinet, Ventilated Enclosures should be used;  
- Contaminated waste must be properly handled;  
- Work areas must be regularly decontaminated.
Storage and Handling Practices: 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. 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.

Section 8 – EXPOSURE CONTROLS / PERSONAL PROTECTIVE EQUIPMENT


<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>EXPOSURE LIMITS/GUIDELINES:</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>EXPOSURE LIMITS IN AIR</td>
<td>ACGIH-TLVs TWA</td>
<td>OSHA-PELs STEL</td>
<td>NIOSH-RELs TWA</td>
<td>NIOSH IDLH TWA</td>
<td>AIHA WEELS TWA</td>
<td>OTHER TWA</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>mg/m³</td>
<td>mg/m³</td>
<td>mg/m³</td>
<td>mg/m³</td>
<td>mg/m³</td>
<td>mg/m³</td>
</tr>
<tr>
<td>Pentobarbital Sodium (active</td>
<td>57-33-0</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>ingredient)</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>1880</td>
<td>NE</td>
<td>1900</td>
<td>NE</td>
<td>1900</td>
<td>NE</td>
<td>8237 (based on</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>LEL)</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>57-55-6</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>11</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
</tbody>
</table>

NE = Not Established

Respiratory Protection: A respirator is not required for routine use of this product.

Eye Protection: Not needed during normal use. For situations in which excessive splashes or sprays may be generated, wear splash goggles.

Hand Protection: For situations, in which prolonged skin contact is anticipated, double glove, using natural rubber, neoprene, or nitrite gloves.

Body Protection: During patient administration, use of lightweight cotton gown or other medical attire is recommended.
Section 9 – PHYSICAL/CHEMICAL CHARACTERISTICS

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling Point</td>
<td>Not Established</td>
</tr>
<tr>
<td>Evaporation Rate (nBuAc = 1)</td>
<td>Not Established</td>
</tr>
<tr>
<td>Specific Gravity (water= 1)</td>
<td>Not Established</td>
</tr>
<tr>
<td>Coefficient Water/Oil Distribution</td>
<td>Not Established</td>
</tr>
<tr>
<td>pH</td>
<td>Approximately 9.5</td>
</tr>
<tr>
<td>Vapor Pressure (air = 1)</td>
<td>Not applicable for product</td>
</tr>
<tr>
<td>Appearance and Color</td>
<td>Clear, colorless solution</td>
</tr>
<tr>
<td>Freezing/Melting Point</td>
<td>Not Established</td>
</tr>
<tr>
<td>Solubility in Water</td>
<td>Soluble</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Latex Free</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Section 10 – STABILITY AND REACTIVITY

Stability: This product is stable when properly stored per label instructions.
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).

Materials with which Substance is Incompatible: 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 Polymerization: Will not occur
Conditions to Avoid: Avoid heat, light, and contact with incompatible chemicals

Section 11 – TOXICOLOGICAL INFORMATION

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 secobarbital or pentobarbital.

Irritancy of Product: This product may irritate contaminated tissue.
Sensitization Potential of Product: No information is available.
Toxicity Data: Pentobarbital Sodium:
- TDL0 (Oral-Woman) 60 mg/kg: Behavioral: wakefulness
- TDL0 (Oral-Man) 6430 lag/kg: Behavioral: changes in motor activity ataxia, antipsychotic
- LD50 (Oral-Rat) 118 mg/kg
- LD50 (Oral-Mouse) 239 mg/kg

Carcinogen Information: 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.

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:

**Pentobarbital Sodium**
- Micronucleus Test (Intraperitoneal-Mouse) 64,800 μg/kg
- DNA Inhibition (Mouse Cells-Not Otherwise Specified) 500 μmol/L
- DNA Inhibition (unreported-Mouse) 60μg/kg
- Mutation Test Systems-Not Otherwise Specified (Unreported-Mouse) 60 mg/kg
- Mutation Test Systems-Not Otherwise Specified (Mouse Cells-Not Otherwise Specified) 500 μmol/L
- Mutation Test Systems-Not Otherwise Specified (Mouse-Lymphocyte) 1500 μmol/L

**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.

**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.

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

**ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs):** ACGIH Biological Exposure Indices have not been determined for the components of this product.

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**Section 12 – ECOLOGICAL INFORMATION**

All work practices must be aimed at eliminating environmental contamination.

**Environmental Stability:** The chemical (medicinal) components of this product will slowly degrade in the environment and form a variety of organic materials.

**Effect on Plants or Animals:** 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.

**Effect on Aquatic Life:** 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.

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**Section 13 – DISPOSAL INFORMATION**

**Preparing Wastes for Disposal:** Waste disposal must be in accordance with appropriate U.S.Federal, State, and local regulations. Incineration is recommended. Reusable equipment should be cleaned with soap and water.

**U.S. EPA Waste Number:** Not applicable to wastes consisting only of this product.
Section 14 – TRANSPORTATION INFORMATION

This product is not hazardous (as defined by 49 CFR 172.101) by the U.S. Department of Transportation.

Proper Shipping Name: Not Regulated
Hazard Class Number and Description: Not Applicable
UN Identification Number: Not Applicable
Packing Group: Not Applicable
DOT Label(s) Required: Not Applicable
Emergency Response Guidebook Number (2004): Not Applicable

Marine Pollutant: No component of this product is classified by the U.S. DOT as a Marine Pollutant (as defined by 49 CFR 172.101, Appendix B).

Section 15 – REGULATORY INFORMATION

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U. S. SARA Threshold Planning Quantity: There are no specific Threshold Planning Quantities for any component of this product. The default Federal MSDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

U.S. CERCLA Reportable Quantities (RQ): Not applicable.

U.S. TSCA Inventory Status: This product is regulated under Food and Drug Administration standards; it is not subject to requirements under TSCA.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): The Pentobarbital Sodium component of this product is on the California 65 Proposition List. Contains a chemical known to the State to cause reproductive toxicity.

OTHER U.S. Federal Regulations: This product is regulated under the DEA and FDA per Schedules of Controlled Substances, by section 202 of the Controlled Substances Act (21 U.S.C. 812).

Pentobarbital Sodium is a Schedule II material; DEA Code #2270. Drug Class: Depressants

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