Material Safety Data Sheet

MSDS Number: 1102374  
Revision date: 11/12/2003  
Print date: 11/13/2003

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MSDS Number: 1102374  
Product name: Phenobarbital Sodium Injection, USP  
Product code: NDC 0641-0476-25, NDC 0641-0477-25, NDC 0641-0476-21, NDC 0641-0477-21  
Synonyms: None  
Chemical Family: Anticonvulsant, sedative  
Product Type: Regulated Prescription Drug  
Container Information: 1 ml dosette® vials  
Product Use: Pharmaceutical

Supplier:  
BAXTER HEALTHCARE CORPORATION  
DEERFIELD, ILLINOIS 60015  
(800) 422-9837 or (847) 948-4770

Emergency telephone number:  
PROSAR: USA (888) 990-0996     OUTSIDE USA (615)917-6114  
CHEMTREC: USA (800) 424-9300     OUTSIDE USA (743)741-6089

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Component</th>
<th>Weight %</th>
<th>UN Number:</th>
<th>Classification:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenobarbital Sodium 57-30-7</td>
<td>6.5-13</td>
<td>None</td>
<td>T</td>
</tr>
<tr>
<td>Benzyl Alcohol 100-51-6</td>
<td>&lt;2</td>
<td>UN1986 (flammable, toxic); UN1987 (alcohol); UN3065 (alcoholic beverages)</td>
<td>Xn;R20/22</td>
</tr>
<tr>
<td>Ethyl Alcohol 64-17-5</td>
<td>7-9</td>
<td>UN1170</td>
<td>F;R11</td>
</tr>
<tr>
<td>Propylene Glycol 57-55-6</td>
<td>68-70</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Water 7732-18-5</td>
<td>&gt;7</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

3. HAZARDS IDENTIFICATION

Emergency overview: Warning! Harmful if swallowed. Avoid eye contact. Central Nervous System depression.

Principle routes of exposure: Absorbed through skin. Eye contact. Ingestion.

Inhalation: Inhalation not likely under normal use conditions.

Ingestion: Harmful if swallowed.

Skin contact: May cause skin irritation.
Eye contact: Irritating to eyes.

4. FIRST AID MEASURES

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

Skin contact: In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Get medical attention if irritation develops.

Ingestion: Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

Eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.

Notes to physician: See patient package insert in shipping carton for complete information.

5. FIRE FIGHTING MEASURES

Suitable extinguishing media: Use foam or all purpose dry chemicals to extinguish.

Special protective equipment for firefighters: Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

Specific methods: No information available.

Flash point: 115°F (46°C)

Autoignition temperature: Not applicable

Flammable limits in air-lower (%): Not applicable

Flammable limits in air-upper (%): Not applicable

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).

Environmental precautions: No information available.

Methods for cleaning up: If emergency personnel are unavailable, contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

7. HANDLING AND STORAGE

Handling: Technical measures/precautions: Do not ingest. Wash thoroughly after handling.

Storage: Technical measures/storage conditions: Keep containers tightly closed in a cool, well-ventilated place. Keep at temperatures between 15 and 30 °C (59 to 86°F). Follow Schedule IV controlled substance requirements.

Product id: 1102374
Product name: Phenobarbital Sodium Injection, USP
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Component</th>
<th>OSHA- Time Weighted Average</th>
<th>OSHA- Short Term Exposure Limit</th>
<th>OSHA- Ceiling Limits</th>
<th>ACGIH- Time Weighted Average</th>
<th>ACGIH- Short Term Exposure Limit</th>
<th>ACGIH- Ceiling Limit Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenobarbital Sodium 57-30-7</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Benzyl Alcohol 100-51-6</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Ethyl Alcohol 64-17-5</td>
<td>= 1000 ppm TWA</td>
<td>None</td>
<td>= 1000 ppm TWA</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Propylene Glycol 57-55-6</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Water 7732-18-5</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

Engineering measures: No special containment is required. Good general ventilation should be sufficient to control airborne levels.

Personal protective equipment:
Respiratory protection: Perform exposure monitoring for this product and its components to ensure that employees are not exposed to levels greater than applicable regulatory limits. If exposure levels exceed regulatory limits, implement a respiratory protection program including respiratory protection that is in compliance with OSHA 29 CFR1910.134 (in the US) or equivalent regulation in other regions. Fire fighting requires the use of a self-contained breathing apparatus with full face piece and positive pressure mode.

Hand protection: Use chemical resistant, impervious gloves.

Skin and body protection: Work uniform or laboratory coat.

Eye protection: Safety glasses with side-shields. Goggles, face shield, or other full-face protection if potential exists for direct exposure to aerosols or splashes.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid
Appearance: Aqueous solution
Color: Colorless
Odor: Not available.
pH: 9.2 - 10.2
Molecular weight: Not available.
Boiling point/range: Not available.
Melting point/range: Not available.
Density: Not available.
Vapor pressure: Not available.
Evaporation rate: Not available.
Solubility: Soluble in water.
Partition coefficient (n-octanol/water): Not available.
Viscosity: Not available.
% Volatile by Volume: Not available.

10. STABILITY AND REACTIVITY

Stability: Stable under recommended storage conditions.
Polymerization: None under normal processing.
Hazardous decomposition products: Not available.

11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Component</th>
<th>LD50s and LC50s</th>
</tr>
</thead>
</table>
| Phenobarbital Sodium 57-30-7 | Oral LD50 Rat = 150 mg/kg  
Oral LD50 Mouse = 200 mg/kg  
Intravenous LD50 Rat = 83 mg/kg  
Intravenous LD50 Mouse = 226 mg/kg |
| Benzyl Alcohol 100-51-6 | Oral LD50 Rat = 1230 mg/kg  
Oral LD50 Mouse = 1360 mg/kg  
Dermal LD50 Rabbit = 2 gm/kg |
| Ethyl Alcohol 64-17-5 | Inhalation LC50 Rat = 20000 ppm/10H  
Inhalation LC50 Mouse = 39 gm/m³/4H  
Oral LD50 Rat = 7060 mg/kg  
Oral LD50 Mouse = 3450 mg/kg |
| Propylene Glycol 57-55-6 | Oral LD50 Rat = 20 gm/kg  
Oral LD50 Mouse = 22 gm/kg  
Dermal LD50 Rabbit = 20800 mg/kg |
| Water 7732-18-5 | Oral LD50 Rat: >50000 mg/kg |
Acute toxicity: Signs and symptoms of overexposure to barbiturates may include nausea, vomiting, dehydration, diarrhea, gastrointestinal tract pain, reduced activity, drowsiness progressing to stupor or coma, reduced or loss of reflexes, heart rate changes, low blood pressure, and possibly death.

Chronic toxicity: Contains material which may cause damage to the following organs: skin, eye, lens or cornea. Target Organs: Nervous System.

Carcinogenic effects: Potential increased incidence of neoplasm based on chronic animal administration. See patient package insert for additional information.

Mutagenic effects: No data is available on the product itself.

Reproductive toxicity: May be fetotoxic based on animal data. See patient package insert for additional information.

FDA Pregnancy Catagory D

12. ECOLOGICAL INFORMATION

Environmental properties:
<table>
<thead>
<tr>
<th>Component</th>
<th>Ecotoxicity - Water Flea Data</th>
<th>Fish Species Ecotoxicity</th>
<th>Ecotoxicity - Freshwater Algae Data</th>
<th>Microtox Eotoxicity Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenobarbital Sodium 57-30-7</td>
<td>None.</td>
<td>None.</td>
<td>None.</td>
<td>None.</td>
</tr>
<tr>
<td>Benzyl Alcohol 100-51-6</td>
<td>= 23 mg/L EC50 water flea</td>
<td>LC50 (96 hr) fathead minnow: 460 mg/L Static, 18-22 °C LC50 (96 hr) bluegill: 10 mg/L Static</td>
<td>None.</td>
<td>= 63.7 mg/L EC50 Photobacterium phosphoreum</td>
</tr>
<tr>
<td>Ethyl Alcohol 54-17-5</td>
<td>None.</td>
<td>LC50 (96 hr) rainbow trout (30 days old): 12900-15300 mg/L Flow-through, 24-24.3 °C, pH 7.56-7.60, 40.9-43.7 mg/L CaCO3 LC50 (24 hr) fingerling trout: 11200 mg/L LC50 (96 hr) fathead minnow: 14200 mg/L</td>
<td>None.</td>
<td>= 34634 mg/L EC50 Photobacterium phosphoreum</td>
</tr>
<tr>
<td>Propylene Glycol 57-55-6</td>
<td>&gt; 10000 mg/L EC50 water flea</td>
<td>LC50 (24 hr) goldfish: &gt;5000 mg/L LC50 (48 hr) guppy: &gt;10000 mg/L</td>
<td>None.</td>
<td>= 710 mg/L EC50 Photobacterium phosphoreum</td>
</tr>
<tr>
<td>Water 7732-18-5</td>
<td>None.</td>
<td>None.</td>
<td>None.</td>
<td>None.</td>
</tr>
</tbody>
</table>

Ecotoxicity effects: No data available
Bioaccumulation: No data available

### 13. DISPOSAL CONSIDERATIONS

**Waste Classification:** Follow Schedule IV controlled substance requirements.

**Waste from residues / unused products:** Waste disposal must be in accordance with appropriate Federal, State, and local regulations.

### 14. TRANSPORT INFORMATION

**DOT:**
- DOT shipping name: None
- UN Number: None
- DOT Packing Group: None
- DOT Hazard class: None

**TDG (Canada):**
- TDG Proper shipping name: None
- TDG UN/NA Number: None
- TDG Packing Group: None
- TDG Hazard class: None
ADR/RID:
ADR Official Transport Name: None
ADR Proper shipping name: None
ADR UN/NA number: None
ADR Hazard Class: None

ICAO / IATA:
IATA Proper shipping name: None
IATA UN NUMBER None
IATA Primary Hazard None
IATA Packing group: None
ICAO ERG Code: None

IMO / IMDG:
IMDG Proper Shipping Name: None
IMDG Hazard Class and Division: None
IMDG Packing Group: None
IMDG Subsidiary Risks: None

15. REGULATORY INFORMATION

U.S. Regulations:
TSCA Inventory List - The product is exempt from TSCA, it is FDA Regulated
OTHER REGULATIONS:
Japanese Inventory (ENCS) This product does not comply with JPNENCS

<table>
<thead>
<tr>
<th>Component</th>
<th>Weight %</th>
<th>RCRA Status:</th>
<th>CERCLA Reportable Quantity:</th>
<th>CERCLA/SARA - 302 Ext. haz. substances:</th>
<th>Listed as Sara 313 title III:</th>
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</thead>
<tbody>
<tr>
<td>Phenobarbital Sodium</td>
<td>6.5-13</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>&lt;2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>7-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>68-70</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
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<td>Water</td>
<td>&gt;7</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
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</tbody>
</table>

STATE REGULATIONS:

<table>
<thead>
<tr>
<th>Component</th>
<th>California Prop 65:</th>
<th>Minnesota Right-To-Know:</th>
<th>Florida Right-to-Know Reporting List:</th>
<th>Rhode Island Right-to-Know List:</th>
<th>Massachusetts Right-to-Know List:</th>
<th>Pennsylvania Right-to-Know:</th>
<th>New Jersey Right-to-Know:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenobarbital Sodium</td>
<td>Not Listed</td>
<td>Not Listed</td>
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<td>Not Listed</td>
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</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>Not Listed</td>
<td>Present</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>[present]</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>developmenta l toxicity (when in alcoholic beverages); initial date 10/1/87</td>
<td>Present</td>
<td>Not Listed</td>
<td>Toxic, Flammable</td>
<td>Teratogen</td>
<td>Present</td>
<td>sn 0844</td>
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<td>Propylene Glycol</td>
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<td>Present</td>
<td>Not Listed</td>
<td>Flammable</td>
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<td>Not Listed</td>
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<tr>
<td>Water</td>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

CANADIAN REGULATIONS:

Canada DSL Inventory List - This product does not comply with DSL

Product id: 1102374 Product name: Phenobarbital Sodium Injection, USP
This product complies with EINECS

Risk Phrases:
NONE

Safety Phrases:
NONE

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s)?:
Additional product codes.

Additional information:
Not Available.

Prepared by: Technology Resources, Baxter Healthcare Corporation

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

End of safety data sheet: