MATERIAL SAFETY DATA SHEET

Product Name: Pentothal (Thiopental Sodium for Injection, USP)

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name and Address
Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA
60045

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia (02) 8014 4880

Hospira, Inc., Non-Emergency
224-212-2000

Product Name
Pentothal (Thiopental Sodium for Injection, USP)

Synonyms
Sodium 5-ethyl-5-(1-methylbutyl)-2-thiobarbiturate; Pentothal Sodium; Sodium thiopentobarbital

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Thiopental Sodium

Chemical Formula
C_{11}H_{17}N_{2}O_{2}S \cdot Na

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Carbonate</td>
<td>4</td>
<td>497-19-8</td>
<td>VZ4050000</td>
</tr>
<tr>
<td>Thiopental Sodium</td>
<td>94</td>
<td>71-73-8</td>
<td>CQ6475000</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
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<tbody>
<tr>
<td>Sodium Carbonate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
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<td>Thiopental Sodium</td>
<td>Not Listed</td>
<td>Not Listed</td>
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</tbody>
</table>

Emergency Overview
Pentothal (Thiopental Sodium for Injection, USP) is a powder containing thiopental sodium, a short-acting thiobarbiturate that produces depression of the central nervous system, inducing hypnosis and anesthesia, but not analgesia. It produces hypnosis within 30 to 40 seconds of intravenous injection. In the workplace, this material should be considered potentially irritating to the skin, eyes, and respiratory tract. Based on clinical use, possible target organs include the central nervous system, respiratory system, and cardiovascular system.

Occupational Exposure Potential
Information on the absorption of this material via inhalation or skin contact is not available. Avoid dust or aerosol generation and skin contact.

Signs and Symptoms
None known from workplace exposures. In clinical use, adverse reactions may include respiratory depression, myocardial depression, cardiac arrhythmias, prolonged somnolence and recovery, sneezing, coughing, bronchospasm, laryngospasm and shivering. Anaphylactic and anaphylactoid reactions with symptoms including urticaria, bronchospasm, vasodilation and edema have been reported. Rarely, immune hemolytic anemia with renal failure and radial
nerve palsy has been reported. Overdosage, or too rapid administration, may produce a dramatic fall in blood pressure, apnea, occasional laryngospasm, coughing and other respiratory difficulties.

Medical Conditions Aggravated by Exposure
Pre-existing sensitivity to thiopental sodium or other barbiturates; pre-existing central nervous system, respiratory system, or cardiovascular system disorders.

4. FIRST AID MEASURES

Eye contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability
None anticipated from this product.

Fire & Explosion Hazard
None anticipated from this product. However, generation of airborne dusts should be minimized.

Extinguishing media
As with any fire, use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting Procedures
No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal
Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Collect powder using procedures that minimize the generation of airborne dust. If a spill occurs after reconstitution, absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling
No special handling required under conditions of normal product use.

Storage
No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions
Protect from freezing, light, oxidizing materials, and extreme heat.
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>mg/m³</th>
<th>ppm</th>
<th>µg/m³</th>
<th>Note</th>
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</thead>
<tbody>
<tr>
<td>Thiopental Sodium</td>
<td>Hospira EEL</td>
<td>N/A</td>
<td>N/A</td>
<td>1000</td>
<td>8hr TWA</td>
</tr>
<tr>
<td>Thiopental Sodium</td>
<td>Hospira STEL</td>
<td>N/A</td>
<td>N/A</td>
<td>6000</td>
<td>STEL</td>
</tr>
<tr>
<td>Sodium Carbonate</td>
<td>Not Applicable</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>None Established</td>
</tr>
</tbody>
</table>

**Respiratory protection**
Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne dust or aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA’s 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

**Skin protection**
If skin contact with this material is likely, the use of latex or nitrile gloves is recommended.

**Eye protection**
Eye protection is normally not required during intended use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

**Engineering Controls**
Engineering controls are normally not needed during the normal use of this material.

9. PHYSICAL/CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Appearance/Physical State</td>
<td>Solid</td>
</tr>
<tr>
<td>Color</td>
<td>Yellowish-white</td>
</tr>
<tr>
<td>Odor</td>
<td>Garlic like</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
</tr>
<tr>
<td>pH:</td>
<td>Reconstituted 4.5 to 7.0 depending on diluent and product</td>
</tr>
<tr>
<td>Melting point/Freezing point:</td>
<td>NA</td>
</tr>
<tr>
<td>Initial Boiling Point/Boiling Point</td>
<td>NA</td>
</tr>
<tr>
<td>Range:</td>
<td>NA</td>
</tr>
<tr>
<td>Evaporation Rate:</td>
<td>NA</td>
</tr>
<tr>
<td>Flammability (solid, gas):</td>
<td>NA</td>
</tr>
<tr>
<td>Upper/Lower Flammability or Explosive Limits:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Pressure:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Density:</td>
<td>NA</td>
</tr>
<tr>
<td>Specific Gravity:</td>
<td>NA</td>
</tr>
<tr>
<td>Solubility:</td>
<td>Soluble in water and alcohol. Insoluble in ether, benzene, or petroleum ether</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water:</td>
<td>NA</td>
</tr>
<tr>
<td>Auto-ignition temperature:</td>
<td>NA</td>
</tr>
<tr>
<td>Decomposition temperature:</td>
<td>NA</td>
</tr>
</tbody>
</table>
Product Name: Pentothal (Thiopental Sodium for Injection, USP)

10. STABILITY AND REACTIVITY

Reactivity
Not determined.

Chemical Stability
Stable under standard use and storage conditions.

Hazardous Reactions
Not determined

Conditions to avoid
Acidic diluents or an acid environment may cause a visible precipitate.

Incompatibilities
Not determined

Hazardous decomposition products
Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and sulfur oxides (SOx).

Hazardous Polymerization
Not anticipated to occur with this material.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity
Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
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<tbody>
<tr>
<td>Thiopental Sodium</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>117</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>208</td>
<td>mg/kg</td>
<td>Mouse</td>
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<tr>
<td>Thiopental Sodium</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>43.6</td>
<td>mg/kg</td>
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<td></td>
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<td>mg/kg</td>
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<td></td>
<td></td>
<td>36</td>
<td>mg/kg</td>
<td>Dog</td>
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<tr>
<td>Thiopental Sodium</td>
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<td>LD50</td>
<td>Oral</td>
<td>600</td>
<td>mg/kg</td>
<td>Mouse</td>
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<tr>
<td>Thiopental</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>70</td>
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<td>Mouse</td>
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<td>Sodium Carbonate</td>
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<td>Oral</td>
<td>4090</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6600</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
</tbody>
</table>

Aspiration Hazard
None anticipated from normal handling of this material.

Dermal Irritation/Corrosion
Not anticipated from normal use of this product. However, inadvertent contact may produce slight irritation to the skin.

Ocular Irritation/Corrosion
Not anticipated from normal use of this product. However, inadvertent contact of this product with the eyes may produce irritation with redness and pain.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this material. In clinical use, anaphylactic and anaphylactoid reactions with symptoms including urticaria, bronchospasm, vasodilation and edema have been occasionally reported.

Reproductive Effects
No developmental defects were reported in the offspring of female mice receiving dosages up to 100 mg/kg by injection on day 11 of pregnancy. Some reduction in fetal weight was found at dosages ≥ 50 mg/kg. In another study, thiopental was injected at doses of 50 and 100 mg into pregnant rats on the 4th day of gestation and no defective offspring were found.
Product Name: Pentothal (Thiopental Sodium for Injection, USP)

Mutagenicity
Studies to assess the genotoxic potential of thiopental sodium have not been conducted.

Carcinogenicity
Studies to assess the carcinogenic potential of thiopental sodium have not been conducted.

Target Organ Effects
Based on clinical use, possible target organs include the central nervous system, respiratory system, and cardiovascular system.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity
Not available for product. Information for sodium carbonate is listed below:
LC50 = 320 mg/L; 96 Hr.; static Conditions, for Bluegill/Sunfish.

Persistence/Biodegradability
Not determined

Bioaccumulation
Not determined

Mobility in Soil
Not determined

13. DISPOSAL CONSIDERATIONS

Waste Disposal
All waste materials must be properly characterized by the waste generator. Disposal of all pharmaceuticals should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal
Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/DOT STATUS: Regulated
Proper Shipping Name: Toxic Solids, Organic, N.O.S. (Substituted Dione)
Hazard Class: 6.1
UN number: UN2811
Packing group: III
Reportable Quantity: N/A

IMDG STATUS: Regulated
Proper Shipping Name: Toxic Solids, Organic, N.O.S. (Substituted Dione)
Hazard Class: 6.1
UN number: UN2811
Packing group: III
Reportable Quantity: N/A

ICAO/IATA STATUS: Regulated
Proper Shipping Name: Toxic Solids, Organic, N.O.S. (Substituted Dione)
Hazard Class: 6.1
UN number: UN2811
Packing group: III
Reportable Quantity: N/A

Transport Comments: None
Product Name: Pentothal (Thiopental Sodium for Injection, USP)

15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
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<tbody>
<tr>
<td>Sodium Carbonate</td>
<td>Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
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<tr>
<td>Thiopental Sodium</td>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

RCRA Status Not Listed

U.S. OSHA Classification
- Toxic by Ingestion
- Target Organ Toxin
- Irritant

GHS Classification
*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.*

Hazard Class Not Applicable

Hazard Category Not Applicable

Signal Word Not Applicable

Symbol Not Applicable

Prevention P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

Hazard Statement Not Applicable

Response:
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.
- Get medical attention if you feel unwell.

EU Classification*
*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Sodium Carbonate Thiopental Sodium.

Classification(s): Not Applicable

Symbol: Not Applicable

Indication of Danger: Not Applicable

Risk Phrases: Not Applicable

Safety Phrases:
- S23 - Do not breathe vapor.
- S24 - Avoid contact with skin.
- S25 - Avoid contact with eyes.
- S37/39 - Wear suitable gloves and eye/face protection.
## 16. OTHER INFORMATION:

Notes:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH TLV</td>
<td>American Conference of Governmental Industrial Hygienists – Threshold Limit Value</td>
</tr>
<tr>
<td>CAS</td>
<td>Chemical Abstracts Service Number</td>
</tr>
<tr>
<td>CERCLA</td>
<td>US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act</td>
</tr>
<tr>
<td>DOT</td>
<td>US Department of Transportation Regulations</td>
</tr>
<tr>
<td>EEL</td>
<td>Employee Exposure Limit</td>
</tr>
<tr>
<td>IATA</td>
<td>International Air Transport Association</td>
</tr>
<tr>
<td>LD₅₀</td>
<td>Dosage producing 50% mortality</td>
</tr>
<tr>
<td>NA</td>
<td>Not applicable/Not available</td>
</tr>
<tr>
<td>NE</td>
<td>Not established</td>
</tr>
<tr>
<td>NIOSH</td>
<td>National Institute for Occupational Safety and Health</td>
</tr>
<tr>
<td>OSHA PEL</td>
<td>US Occupational Safety and Health Administration – Permissible Exposure Limit</td>
</tr>
<tr>
<td>Prop 65</td>
<td>California Proposition 65</td>
</tr>
<tr>
<td>RCRA</td>
<td>US EPA, Resource Conservation and Recovery Act</td>
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<tr>
<td>RTECS</td>
<td>Registry of Toxic Effects of Chemical Substances</td>
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<tr>
<td>SARA</td>
<td>Superfund Amendments and Reauthorization Act</td>
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<tr>
<td>STEL</td>
<td>15-minute Short Term Exposure Limit</td>
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<tr>
<td>TSCA</td>
<td>Toxic Substance Control Act</td>
</tr>
<tr>
<td>TWA</td>
<td>8-hour Time Weighted Average</td>
</tr>
</tbody>
</table>

MSDS Coordinator: Hospira GEHS  
Date Prepared: 11/01/2011  
Obsolete Date: 08/15/2008

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