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 - 61-290372994; UK - 44-870-8200418

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

Product Name
Phenytoin Sodium Injection, USP

Synonyms
Sodium 5, 5-diphenyl-2, 4-imidazolidinedione

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Phenytoin Sodium

Chemical Formula
C_{15}H_{11}N_{2}O_{2}•Na

Preparation
Non-hazardous ingredients include water (45%, w/w). Hazardous ingredients present at less than 1% include sodium hydroxide which is used to adjust the pH.

<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>Propylene Glycol</td>
<td>40</td>
<td>57-55-6</td>
<td>TY2000000</td>
</tr>
<tr>
<td>Phenytoin Sodium</td>
<td>5</td>
<td>630-93-3</td>
<td>MU1400000</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>10</td>
<td>64-17-5</td>
<td>KQ6300000</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>
</thead>
<tbody>
<tr>
<td>Ethyl Alcohol</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Phenytoin Sodium</td>
<td>2B</td>
<td>REASONABLY ANTICIPATED</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Phenytoin Sodium Injection, USP, is a solution containing phenytoin sodium, a hydantoin drug used to treat epilepsy. In the workplace, this product should be considered a combustible liquid, potentially irritating to the skin and eyes, and a potential occupational reproductive hazard. Possible target organs include the central nervous system, cardiovascular system, gastrointestinal system, hematopoietic system, skin and possibly the fetus.

Occupational Exposure Potential
Information on the absorption of this product via inhalation or skin contact is not available. It has been reported that phenytoin sodium may be absorbed through the skin. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms
In the workplace, phenytoin sodium can be irritating to the respiratory tract and solutions can
Product Name: Phenytoin Sodium Injection, USP

cause severe eye and skin irritation. In clinical use, adverse central nervous system effects may include ataxia, slurred speech, dizziness, and headaches. Severe cardiotoxic reactions have included atrial and ventricular conduction depression and ventricular fibrillation. Adverse gastrointestinal effects may include nausea, vomiting, and constipation. Allergic-type reactions include dermatological manifestations sometimes accompanied by fever have included scarlatiniform or morbilliform rashes. Hemopoietic complications have included thrombocytopenia, leukopenia, granulocytopenia, agranulocytosis, and pancytopenia with or without bone marrow suppression. Local irritation, inflammation, tenderness, necrosis, and sloughing have been reported, with or without extravasation of intravenous phenytoin.

Medical Conditions Aggravated by Exposure
Pre-existing hypersensitivity to phenytoin sodium or other ingredients in this product. Pre-existing central nervous system, cardiovascular system, gastrointestinal system, hematopoietic system, or skin ailments; or pregnancy.

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
Flash Point: 63.9°C (147°F)

Fire & Explosion Hazard
Combustible liquid. Keep away from flames, sparks, or other sources of ignition.

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. Remove potential sources of ignition. Put on suitable protective clothing and equipment as specified by site spill procedures. 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. Protect from light by retaining in carton until contents have been used.

Storage
No special storage required for hazard control. For product protection, follow
Product Name: Phenytoin Sodium Injection, USP

storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions No special precautions are required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mg/m³</td>
<td>ppm</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>ACGIH 8 Hr TLV</td>
<td>N/A</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>US OSHA 8 Hr PEL</td>
<td>N/A</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>Australia NOHSC</td>
<td>N/A</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>AIHA WEEL</td>
<td>10</td>
</tr>
<tr>
<td>Phenytoin Sodium</td>
<td>Not Applicable</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Respiratory protection
Respiratory protection is normally not needed during intended product use. However, if the generation of 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 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 the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye protection
Eye protection is normally not required during intended product 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 anticipated use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Appearance/Physical State</th>
<th>Liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>Clear, Colorless to slightly yellow</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
</tr>
<tr>
<td>pH:</td>
<td>11.9 (10.0 to 12.3)</td>
</tr>
<tr>
<td>Melting point/Freezing point:</td>
<td>Not determined</td>
</tr>
<tr>
<td>Initial Boiling Point/Boiling Point Range:</td>
<td>99°C</td>
</tr>
<tr>
<td>Evaporation Rate:</td>
<td>NA</td>
</tr>
<tr>
<td>Flammability (solid, gas):</td>
<td>Combustible liquid</td>
</tr>
<tr>
<td>Upper/Lower Flammability or Explosive Limits:</td>
<td>LEL: 3.3% based on ethanol; UEL: 19% based on ethanol</td>
</tr>
<tr>
<td>Vapor Pressure:</td>
<td>43 mm Hg at 23°C  for ethyl alcohol; 0.07 mm Hg at 20°C for propylene glycol</td>
</tr>
<tr>
<td>Vapor Density:</td>
<td>1.59 for ethyl alcohol; 2.6 for propylene glycol</td>
</tr>
<tr>
<td>Specific Gravity:</td>
<td>1.0306</td>
</tr>
<tr>
<td>Solubility:</td>
<td>Ethyl alcohol</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity
Not determined.

Chemical Stability
Stable under standard use and storage conditions.

Hazardous Reactions
Not determined.

Conditions to avoid
Not determined.

Incompatibilities
Strong oxidizers, acids.

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

Hazardous Polymerization
Not anticipated to occur with this product.

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>
</tr>
</thead>
<tbody>
<tr>
<td>Phenytoin Sodium</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>1530</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>165, 490</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Phenytoin Sodium</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>90</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>98, 92</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>3450 – 11,500</td>
<td>mg/kg</td>
<td>Guinea Pig, Rat, Mouse, Dog</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>1973</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>100</td>
<td>LC50 (10h)</td>
<td>Inhalation</td>
<td>20,000</td>
<td>ppm</td>
<td>Rat</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>100</td>
<td>LD50 (4h)</td>
<td>Inhalation</td>
<td>39,000</td>
<td>mg/m3</td>
<td>Mouse</td>
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<tr>
<td>Propylene Glycol</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>10,400 - 29,536</td>
<td>mg/kg</td>
<td>Rat, Mouse, Rabbit, Dog, Guinea Pig</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>6423-6800</td>
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<td>Rat</td>
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<tr>
<td>Propylene Glycol</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>6630-8000</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>100</td>
<td>LD50</td>
<td>Dermal</td>
<td>20,800</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
</tbody>
</table>

Aspiration Hazard
None anticipated from normal handling of this product.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product. Inadvertent contact of this product with skin may produce irritation.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. Inadvertent contact of this product with eyes may produce severe irritation with redness and tearing.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product. Allergic-like reactions have been reported during the normal clinical use of this product.
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Reproductive Effects
Phenytoin is a teratogen in rats, mice, and rabbits. Days 12 and 13 are the critical period for induction of teratogenicity in CD-1 mice. Phenytoin was not teratogenic in dogs or cats. It was fetotoxic, but not teratogenic, in monkeys at dosages where maternal toxicity was seen.

Mutagenicity
It has been reported that phenytoin induced micronuclei in mice at an intravenous dose of 500 or 1000 mcg/kg. In other reports, phenytoin was not active for inducing chromosome aberrations in cultured Chinese hamster ovary cells. It was also inactive for inducing chromosome aberrations in bone marrow cells of mice injected with doses as high as 500 mg/kg. No increases in chromosome aberrations were seen in epileptic patients receiving long-term phenytoin or primidone therapy. No increases in sister chromatid exchanges were seen in lymphocytes of epileptic patients receiving phenytoin monotherapy in comparison with healthy controls.

Carcinogenicity
Elevated risks for Hodgkin’s disease, lymphosarcomas, and reticulum-cell sarcoma have been seen in patients receiving phenytoin therapy. Phenytoin sodium induced thymic lymphomas in female mice when given in the diet at a level of 60 mg/kg body weight/day for 168 days. Thymic and mesenteric lymphomas and leukemias were induced in mice with intraperitoneal doses of 0.6 mg/animal/day for 66 days. Phenytoin was not carcinogenic in rats when given in the diet at levels of 0.025 or 0.05% for 2 years. It was also not carcinogenic in mice at dietary levels of 0.006 or 0.12% for 78 weeks. Phenytoin is an IARC and NTP listed carcinogen.

Target Organ Effects
Elevated risks for Hodgkin’s disease, lymphosarcomas, and reticulum-cell sarcoma have been seen in patients receiving phenytoin therapy. Phenytoin sodium induced thymic lymphomas in female mice when given in the diet at a level of 60 mg/kg body weight/day for 168 days. Thymic and mesenteric lymphomas and leukemias were induced in mice with intraperitoneal doses of 0.6 mg/animal/day for 66 days. Phenytoin was not carcinogenic in rats when given in the diet at levels of 0.025 or 0.05% for 2 years. It was also not carcinogenic in mice at dietary levels of 0.006 or 0.12% for 78 weeks. Phenytoin is an IARC and NTP listed carcinogen.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity
Not determined for the product. Information for ingredients is provided below: LC50(24 hr) = 12,900 - 15,300 mg/L in rainbow trout for ethanol LC50 (24 hr) = 11,200 mg/L in fingerling trout for ethanol LC50(48 hr) = 9,268 - 14,221 mg/L in Daphnia magna for ethanol EC50 = 9310 mg/L in Chlorella pyrenoidosa (green algae) for ethanol LC50(96 hr) = 51,600 mg/L in rainbow trout for propylene glycol LC50(48 hr) = 34,400 - 43,500 mg/L in Daphnia magna for propylene glycol EC50(14 day) = 19,000 mg/L in algae for propylene glycol

Persistence/Biodegradability
Not determined for the product. Information for ingredients is provided below: Ethanol, an ingredient in this product, was reported to be degraded between 45% and 74% in five days in two aqueous biodegradation assays. Propylene glycol was reported to be 100% biodegradable after 24-hours in activated sludge

Bioaccumulation
Not determined for product

Mobility in Soil
Not determined.
13. DISPOSAL CONSIDERATIONS

Waste Disposal
Disposal 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

DOT STATUS: Not regulated
IMDG STATUS: Not regulated
ICAO/IATA STATUS: Not regulated

15. REGULATORY INFORMATION

USA Regulations

<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>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl Alcohol</td>
<td>Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Phenytoin Sodium</td>
<td>Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Listed</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>Listed</td>
<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
Possible Carcinogen
Target Organ Toxin
Reproductive Toxin
Possible Irritant
Combustible Liquid

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

**MSDS Coordinator:** Hospira GEHS
**Date Prepared:** 10/19/2012
**Obsolete Date:** 11/01/2011

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