



## Material Safety Data Sheet

MSDS Number: 1102375  
Revision date: 11/12/2003  
Print date: 11/13/2003

### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MSDS Number: 1102375  
Product name: Phenytoin Sodium Injection, USP  
Product code: NDC 0641-0493-25, NDC 0641-2555-45, NDC 0641-0493-21, NDC 0641-2555-21  
Synonyms: None  
Chemical Family: Anticonvulsant  
Product Type: Regulated Prescription Drug  
Container Information: 2 ml dosette® vials and 5 ml single use 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

Component	Weight %	UN Number:	Classification:
Phenytoin Sodium 630-93-3	4-6	None	None
Propylene Glycol 57-55-6	39-41	None	None
Ethyl Alcohol 64-17-5	7-9	UN1170 UN1986 (flammable, toxic); UN1987 (alcohol); UN3065 (alcoholic beverages)	F;R11
Water 7732-18-5	>45	None	None

### 3. HAZARDS IDENTIFICATION

**Emergency overview:** Caution! Harmful if swallowed. Do not ingest. May cause eye and skin irritation. Suspect Cancer hazard. Combustible liquid and vapor.

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

**Inhalation:** Inhalation not likely under normal use conditions.

**Ingestion:** Harmful if swallowed. Gastrointestinal effects (may include nausea, upset stomach, loss of appetite). Nervous system effects (may include drowsiness, confusion, hallucinations, convulsions, visual disturbances, headache, coma).

**Skin contact:** May cause skin irritation.

**Eye contact:** May cause eye irritation.

#### 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

<b>Suitable extinguishing media:</b>	Use foam or all purpose dry chemicals to extinguish.
<b>Special protective equipment for firefighters:</b>	Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.
<b>Specific methods:</b>	No information available.
<b>Flash point:</b>	113°F (45°C)
<b>Autoignition temperature:</b>	Not applicable
<b>Flammable limits in air-lower (%):</b>	Not applicable
<b>Flammable limits in air-upper (%):</b>	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. Store between 15-30°C (59 to 86°F).

**Incompatible products:** No special restrictions on storage with other products.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Occupational Exposure Limits

Component	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Phenytoin Sodium 630-93-3	None	None	None	None	None	None
Propylene Glycol 57-55-6	None	None	None	None	None	None
Ethyl Alcohol 64-17-5	= 1000 ppm TWA = 1900 mg/m <sup>3</sup> TWA	None	None	= 1000 ppm TWA	None	None
Water 7732-18-5	None	None	None	None	None	None

**Engineering measures:** Provide general or local exhaust ventilation.

### 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. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

**Eye protection:** Safety glasses. 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:** 10.0 - 12.3  
**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:** Not available.

**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:** Not applicable  
**Hazardous decomposition products:** Not available.  
**Materials to avoid:** Acids. Bases. Oxidizing agents.

## 11. TOXICOLOGICAL INFORMATION

Component	LD50s and LC50s
Phenytoin Sodium 630-93-3	Oral LD50 Rat = 1530 mg/kg Oral LD50 Mouse = 165 mg/kg Intravenous LD50 Rat = 90 mg/kg Intravenous LD50 Mouse = 98 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
Ethyl Alcohol 64-17-5	Inhalation LC50 Rat = 20000 ppm/10H Inhalation LC50 Mouse = 39 gm/m <sup>3</sup> /4H Oral LD50 Rat = 7060 mg/kg Oral LD50 Mouse = 3450 mg/kg
Water 7732-18-5	Oral LD50 Rat: >50000 mg/kg

**Acute toxicity:** Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Cardiovascular effects (may include fluctuations in heart rate, changes in blood pressure, chest pain). Nervous System effects (may include ataxia, tremor, disturbance of speech, lethargy, headache, dizziness, blurred vision). See patient package insert for additional information.

**Chronic toxicity:** Target Organs: Immune System.

**Carcinogenic effects:** May be carcinogenic. See patient package insert for additional information.

**Mutagenic effects:** May be mutagenic. See patient package insert for additional information.

**Reproductive toxicity:** Considered fetotoxic. See patient package insert for additional information.

**FDA Pregnancy Category** Not available.

## 12. ECOLOGICAL INFORMATION

**Environmental properties:**

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Microtox Eotoxicity Data
Phenytoin Sodium 630-93-3	None.	None.	None.	None.
Propylene Glycol 57-55-6	> 10000 mg/L EC50 water flea	LC50 (24 hr) goldfish:>5000 mg/L.;LC50 (48 hr) guppy:>10000 mg/L.:	None.	= 710 mg/L EC50 Photobacterium phosphoreum
Ethyl Alcohol 64-17-5	None.	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:	None.	= 34634 mg/L EC50 Photobacterium phosphoreum = 35470 mg/L EC50 Photobacterium phosphoreum
Water 7732-18-5	None.	None.	None.	None.

**Ecotoxicity effects:** No data available

**Bioaccumulation:** No data available

**13. DISPOSAL CONSIDERATIONS**

**Waste Classification:** Not regulated.

**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 - OTHER REGULATIONS:** The product is exempt from TSCA, it is FDA Regulated

**Japanese Inventory (ENCS)** This product does not comply with JPENCS

Component	Weight %	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Phenytoin Sodium	4-6	Not Listed	Not Listed	Not Listed	Not Listed
Propylene Glycol	39-41	Not Listed	Not Listed	Not Listed	Not Listed
Ethyl Alcohol	7-9	Not Listed	Not Listed	Not Listed	Not Listed
Water	>45	Not Listed	Not Listed	Not Listed	Not Listed

**STATE REGULATIONS:**

Component	California Prop 65:	Minnesota Right-To - Know:	Florida Right-to-Know Reporting List:	Rhode Island Right-to-Know List:	Massachusetts Right-to-Know List:	Pennsylvania Right-to-Know:	New Jersey Right-to-Know:
Phenytoin Sodium	carcinogen; initial date 1/1/88	Not Listed	Not Listed	Not Listed	Not Listed	special hazardous substance	Not Listed
Propylene Glycol	Not Listed	Present	Not Listed	Flammable	Not Listed	Present	Not Listed
Ethyl Alcohol	developmental toxicity (when in alcoholic beverages); initial date 10/1/87	Present	Not Listed	Toxic, Flammable	Teratogen	Present	sn 0844
Water	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

This product contains component(s) known to the State of California to cause cancer or reproductive/developmental harm.

**CANADIAN REGULATIONS:**

**Canada DSL Inventory List -** This product complies with DSL

**EU EINECS List -**

This product complies with EINECS

**Risk Phrases:**

NONE

**Safety Phrases:**

NONE

<b>16. OTHER INFORMATION</b>
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**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

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**End of safety data sheet:**