MATERIAL SAFETY DATA SHEET

Product Name: Fosphenytoin Sodium Injection, USP

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045
Emergency Telephone Hospira, Inc.	CHEMTREC: 800 424-9300 224 212-2055
Product Name	**Fosphenytoin Sodium Injection, USP**
Synonyms	5,5-diphenyl-3-[(phosphonooxy)methyl]-2,4-imidazolidinedione disodium salt; Cerebyx®

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name	Fosphenytoin Sodium
Chemical Formula	$C_{16}H_{13}N_2Na_2O_6P$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Fosphenytoin Sodium	7.5	92134-98-0	NA
Tris (hydroxymethyl)aminomethane	1.2	77-86-1	TY2900000

Non-hazardous ingredients include: water
Hazardous ingredients present at less than 1% are sodium hydroxide and/or hydrochloric acid which are added to adjust the pH.

3. HAZARD INFORMATION

Emergency Overview	In clinical use, this material is used to treat epilepsy. Fosphenytoin is the prodrug of phenytoin, and following parenteral administration, it is rapidly converted to phenytoin, a possible human carcinogen and reproductive hazard. Possible target organs include the central nervous system, cardiovascular system, hematopoietic system, liver, peripheral nervous system, fetus, and possibly the eyes and skin.
Occupational Exposure Potential	Information on the absorption of this compound via ingestion, inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.
Signs and Symptoms	No signs or symptoms from occupational exposure are known. Clinical data suggest the following: nystagmus, ataxia, speech impairment, vomiting, nausea, rash, fever, altered white blood cells and thrombocytes, gum hyperplasia.
Medical Conditions Aggravated by Exposure	Pre-existing hypersensitivity to fosphenytoin or other ingredients. Pre-existing skin, eyes, central nervous system, cardiovascular system, liver, hematopoietic system, or peripheral nervous system 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:	None
Fire & Explosion Hazard:	None
Extinguishing Media:	Use extinguishing media appropriate for primary cause of fire.
Special Fire Fighting Procedures	No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal	Absorb with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling	No special handling required.
Storage	No special storage required for hazard control. For product protection, store at temperatures of 2-8°C (36-46°F).
Special Precautions	Protect from freezing and extreme heat.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure limits		
Component	**OSHA-PEL**	**ACGIH-TLV**	**Hospira EEL**
Fosphenytoin Sodium	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: Not Established
Tris (hydroxymethyl)aminomethane	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
EEL: Employee Exposure Limit.
TWA: 8 hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.

Respiratory Protection Respiratory protection is not needed during the normal handling of the intact product.

Skin Protection If solution contact with unprotected skin is likely, the use of impervious gloves is recommended.

Eye Protection Eye protection is not required for the normal handling of the intact product. However, the use of eye protection is strongly recommended should a splash potential exist.

Engineering Controls Engineering controls are not required for the normal handling of the intact product.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State Clear to pale yellow solution
Odor None
Boiling Point Not Determined
Freezing Point Not Determined
Vapor Pressure Not Determined
Vapor Density (Air=1) Not Determined
Evaporation Rate Not Applicable
Density 1.036 g/mL at 25^{o} C
Specific Gravity Not Determined
pH 8.6 – 9.0

10. STABILITY AND REACTIVITY

Chemical Stability Stable under standard use and storage conditions.

Incompatibilities Not Determined

Hazardous Decomposition Products Nitrogen and carbon oxides

Hazardous Polymerization Not Expected

11. TOXICOLOGICAL INFORMATION:

Acute Toxicity – Oral:

Ingredient(s)	Percent	Test Type	Value	Units	Species
Phenytoin Sodium*	100	LD50	155-490 1530	mg/kg mg/kg	Mouse Rat
Tris (hydroxymethyl) aminomethane	100	LD50	5900	mg/kg	Rat

LD50 is the dosage needed to produce 50% mortality.
*Fosphenytoin is a prodrug of phenytoin, and following parenteral administration it is rapidly converted to phenytoin. Product contains approximately 7.5% Fosphenytoin.

Aspiration Hazard
None anticipated from normal handling of this product.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product. If splashed on the skin, this material may produce irritation.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. If splashed into eyes, this material may produce severe eye irritation.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product. In clinical use, this material has produced allergic reactions in some patients.

Reproductive Effects
None anticipated from normal handling of this product. Increased frequencies of malformations (brain, cardiovascular, digit, and skeletal anomalies), death, growth retardation, and functional impairment have been reported in the offspring of rats receiving fosphenytoin during pregnancy. Most adverse effects on embryo-fetal development occurred at dosages of 33 mg phenytoin equivalents/kg or higher.

Mutagenicity
Chromosome aberrations were increased in cultured V79 Chinese hamster lung cells after exposure to fosphenytoin in the presence of metabolic activation. No evidence of mutagenicity was reported in bacteria (Ames test) or Chinese hamster lung cells in vitro, and no evidence for clastogenic activity was observed in an in vivo mouse bone marrow micronucleus test.

Carcinogenicity
The carcinogenic potential of fosphenytoin has not been fully evaluated. However, fosphenytoin is metabolized to phenytoin, which is listed by IARC as Category 2B – possibly carcinogenic to humans, and by NTP as Group 2 – anticipated to be a human carcinogen.

Target Organ Effects
None known from occupational exposure. In clinical use, possible target organs include the central nervous system, cardiovascular system, hematopoietic system, liver, peripheral nervous system, fetus, and possibly the eyes and skin.

Product Name: Fosphenytoin Sodium Injection, USP

12. ECOLOGICAL INFORMATION:

Aquatic Toxicity	Not determined.
Biodegradation	Not determined.
General Notes	None

Notes:
1. EC50: Concentration in water that produces 50% mortality in Daphnia sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

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

Proper Shipping Name:
Hazard class:
Un number:
Packing group:
Reportable quantity:

ICAO/IATA STATUS Not regulated

Proper shipping name:
Hazard class:
Un number:
Packing group:
Reportable quantity:

IMDG STATUS Not regulated

Proper shipping name:
Hazard class:
Un number:
Packing group:
Reportable quantity:
Flash point: Not regulated

Notes: DOT - US Department of Transportation Regulations

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15. REGULATORY INFORMATION

TSCA Status	Exempt
CERCLA Status	Not Listed
SARA Status	Not Listed
RCRA Status	Not Listed
PROP 65 (Calif.)	Not Listed

Notes: TSCA, Toxic Substance Control Act
CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
SARA, Superfund Amendments and Reauthorization Act
RCRA, US EPA, Resource Conservation and Recovery Act
Prop 65, California Proposition 65

U.S. OSHA Hazard Classification	Possible Skin Irritant Possible Eye Irritant Reproductive Toxin Target Organ Toxin Possible Carcinogen

GHS Classification

Hazard Class	Acute Oral Toxicity	Eye Irritation	Skin Irritation	Reproductive Toxicity	Target Organ Toxicity	Carcinogenicity
Hazard Category	Not classified	2B	3	2	2	2
Symbol						
Signal Word		Warning	Warning	Warning	Warning	Warning
Hazard Statement		Causes eye irritation	Causes mild skin irritation	Suspected of damaging the unborn child	May cause damage to the central nervous system, cardiovascular system, hematopoietic system, liver, peripheral nervous system, fetus, and possibly the eyes and skin. through prolonged or repeated exposure.	Suspected of causing cancer.

GHS Precautionary Statements:

Prevention:
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Do not eat, drink or smoke when using this product.
Do not breathe dust.
Use personal protective equipment as required.
Wash hands thoroughly after handling.
If skin irritation occurs, get medical attention.

15. REGULATORY INFORMATION: continued

Response:

IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell.

IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms call a POISON CENTER or a doctor.

IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs, seek medical attention. Take off contaminated clothing and wash before reuse.

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.

If exposed or concerned, get medical attention.

EU Classification and Labeling

Classification(s):	Reproductive Toxin Category 2	Carcinogen Category 3
Symbol:	T	Xn
Indication of Danger:	Toxic	Harmful

Risk Phrases:

R36/37/38 - Irritating to eyes, respiratory system and skin
R40 – Limited evidence of a carcinogenic effect
R61 - May cause harm to the unborn child

Safety Phrases:

S24/25 - Avoid contact with skin and eyes.
S36/37 - Wear suitable protective clothing and gloves.

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
LD_{50}	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established

16. OTHER INFORMATION: continued

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:	Global Occupational Toxicology
Date Prepared:	May 31, 2006
Revision Date:	June 21, 2007

Disclaimer:

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