SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Cerebyx® (Fosphenytoin Sodium) Injection

Trade Name: Cerebyx®, PRO-EPANUTIN; PRODILANTIN; CERENEU

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as anticonvulsant

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 2
Carcinogenicity: Category 2

EU Classification:

EU Indication of danger: Carcinogenic: Category 3
Toxic to Reproduction: Category 3

EU Risk Phrases:

R40 - Limited evidence of a carcinogenic effect.
R63 - Possible risk of harm to the unborn child.

Label Elements

Signal Word: Warning

Hazard Statements:

H361d - Suspected of damaging the unborn child
H351 - Suspected of causing cancer

Precautionary Statements:

P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations
3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fosphenytoin sodium</td>
<td>92134-98-0</td>
<td>Not Listed</td>
<td>Repr.Cat.3;R63</td>
<td>Repr.2 (H361d)</td>
<td>5</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Carc.Cat.3;R40</td>
<td>Carc.2 (H351)</td>
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<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Tromethamine</td>
<td>77-86-1</td>
<td>201-064-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Water for injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed
Symptoms and Effects of Exposure:
For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure:
None known

Indication of the Immediate Medical Attention and Special Treatment Needed
Notes to Physician:
None

5. FIRE FIGHTING MEASURES

Extinguishing Media:
Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture
Hazardous Combustion Products:
None known or expected.

Fire / Explosion Hazards:
Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up
Measures for Cleaning / Collecting:
Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills:
Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions:
Store as directed by product packaging.

Specific end use(s):
Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
Fosphenytoin sodium
Pfizer OEL TWA-8 Hr:
600µg/m³

Analytical Method:
Analytical method available for fosphenytoin sodium. Contact Pfizer Inc for further information.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:
Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Solution</td>
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<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
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<tr>
<td>Color</td>
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<tr>
<td>Odor Threshold</td>
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</tr>
<tr>
<td>Molecular Weight</td>
<td>Mixture</td>
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<tr>
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<tr>
<td>Boiling Point (°C)</td>
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<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td>Tromethamine, Predicted 7.4 Log D 2.47</td>
</tr>
<tr>
<td>Flammability</td>
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<tr>
<td>Autoignition Temperature (Solid) (°C):</td>
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<tr>
<td>Flammability (Solids):</td>
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<tr>
<td>Flash Point (Liquid) (°C):</td>
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<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
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</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
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</tr>
<tr>
<td>Polymerization</td>
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</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
  Oxidizing Properties: No data available
  Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
  Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
  Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: Fosphenytoin sodium is a prodrug of phenytoin and is converted to phenytoin inside the body. The effects seen with fosphenytoin are similar to those of phenytoin.
Short Term: Antiepileptic drug: may cause nervous system effects. Accidental ingestion may cause effects similar to those seen in clinical use.
Long Term: Increased frequencies of major malformations, minor anomalies, growth abnormalities, mental deficiency, and malignancies have been reported among children born to women who took phenytoin during pregnancy.
Known Clinical Effects: The most common adverse effects observed with the clinical use of this drug were rapid eye twitching, dizziness, pruritus, numbness and tingling of the skin, headache, somnolence, and ataxia. Sensory disturbances (severe burning, itching, and/or numbness and tingling of the skin) have been reported following IV administration of fosphenytoin. Other, more serious effects seen with IV use of this drug, particularly when it is administered rapidly, are cardiovascular collapse, central nervous system depression, and/or hypotension.

Acute Toxicity: (Species, Route, End Point, Dose)
Tromethamine
Rat Oral LD50 5900 mg/kg

Fosphenytoin sodium
Mouse IV LD50 234 mg/kg
Rat IV LD50 363mg/kg
Rat IV (bolus) LD50 319.2mg/kg

Phenytoin
Mouse Oral LD50 150 mg/kg
Rat Oral LD50 1635mg/kg
Rat Intravenous LD 50 96mg/kg
Rat IM LD 50 >337mg/kg
Rabbit Oral LD 50 >3000mg/kg

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)
Fosphenytoin sodium
4 Week(s) Rat Intravenous <30 mg/kg/day NOAEL Central nervous system
13 Week(s) Rat Intramuscular 30 mg/kg/day NOAEL Liver
4 Week(s) Dog Intravenous < 15 mg/kg/day NOAEL Central Nervous System
13 Week(s) Dog Intramuscular 15 mg/kg/day NOAEL Central Nervous System, Liver
11. TOXICOLOGICAL INFORMATION

Phenytoin
2 Week(s)  Rat  Oral  <3125 ppm/day  NOEL  Bone marrow
2 Week(s)  Mouse  Oral  <125 ppm/day  NOEL  Central Nervous System
13 Week(s)  Rat  Oral  300 ppm/day  NOEL  None identified
13 Week(s)  Mouse  Oral  150 ppm/day  NOEL  Blood forming organs, Gastrointestinal system, Liver

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Phenytoin
Embryo / Fetal Development  Rat  Intramuscular  25 mg/kg/day  NOEL  Maternal toxicity, Developmental toxicity, Teratogenic

Embryo / Fetal Development  Rat  Intravenous  50 mg/kg/day  NOEL  Maternal Toxicity

Embryo / Fetal Development  Rabbit  Intravenous  50 mg/kg/day  NOEL  Maternal Toxicity

Embryo / Fetal Development  Mouse  Oral  75 mg/kg/day  NOEL  Maternal toxicity, Fetotoxicity, Teratogenic

Embryo / Fetal Development  Mouse  Oral  45 mg/kg/day  NOEL  Teratogenic

Embryo / Fetal Development  Rabbit  Oral  50 mg/kg/day  NOEL  Fetotoxicity, Teratogenic

Embryo / Fetal Development  Monkey  Oral  10 mg/kg/day  NOEL  Fetotoxicity, Teratogenic

Embryo / Fetal Development  Mouse  Subcutaneous  <12.5 mg/kg/day  NOEL  Maternal Toxicity, Fetotoxicity, Teratogenic

Phenytoin
Embryo / Fetal Development  Rat  Intramuscular  25 mg/kg/day  NOEL  Maternal toxicity, Developmental toxicity, Teratogenic

Embryo / Fetal Development  Rat  Intravenous  50 mg/kg/day  NOEL  Maternal Toxicity

Embryo / Fetal Development  Rabbit  Intravenous  50 mg/kg/day  NOEL  Maternal Toxicity

Embryo / Fetal Development  Mouse  Oral  75 mg/kg/day  NOEL  Maternal toxicity, Fetotoxicity, Teratogenic

Embryo / Fetal Development  Mouse  Oral  45 mg/kg/day  NOEL  Teratogenic

Embryo / Fetal Development  Rabbit  Oral  50 mg/kg/day  NOEL  Fetotoxicity, Teratogenic

Embryo / Fetal Development  Monkey  Oral  10 mg/kg/day  NOEL  Fetotoxicity, Teratogenic

Embryo / Fetal Development  Mouse  Subcutaneous  <12.5 mg/kg/day  NOEL  Maternal Toxicity, Fetotoxicity, Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Fosphenytoin sodium
Bacterial Mutagenicity (Ames)  Salmonella  Negative

In Vitro Mammalian Cell Mutagenicity  Hamster Lung Cells  Negative

In Vitro Chromosome Aberration  Hamster Lung Cells  Negative

In Vivo Micronucleus Chromosome Aberration  Mouse Bone Marrow  Negative

Phenytoin
Bacterial Mutagenicity (Ames)  Salmonella  Negative

In Vitro Chromosome Aberration  Chinese Hamster Ovary (CHO) cells  Negative

In Vitro Chromosome Aberration  Human Lymphocytes  Negative

In Vivo Sister Chromatid Exchange  Human Lymphocytes  Positive

In Vivo Mitotic Spindle Exchange  Human Lymphocytes  Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Phenytoin
2 Year(s)  Male Rat  Oral, in feed  50 mg/kg/day  NOEL  Benign neoplasms, Skin
2 Year(s)  Mouse  Oral, in feed  25 mg/kg/day  NOEL  Benign tumors, Liver
2 Year(s)  Female Mouse  Oral, in feed  60 ppm  LOAEL  Liver, neoplasms
2 Year(s)  Female Rat  Oral, in feed  240 ppm  NOAEL  Not carcinogenic

Carcinogen Status:  See below

Phenytoin
IARC:  Group 2B (Possibly Carcinogenic to Humans)
NTP:  Reasonably Anticipated To Be A Human Carcinogen
12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided. The information in this section includes the potential hazards of a chemically related material.

Toxicity:
Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Phenytoin
Hyallela azteca (Freshwater Amphipod)  OPPTS  LC50  96 Hours  18 mg/L
Daphnia magna (Water Flea)  TAD  EC50  48 Hours  >39 mg/L
Pimephales promelas (Fathead Minnow)  OPPTS  LC50  96 Hours  >23 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential:
Partition Coefficient: (Method, pH, Endpoint, Value)
Phenytoin
Predicted  7.4  Log D  2.47

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications
15. REGULATORY INFORMATION

WHMIS hazard class:
Class D, Division 2, Subdivision A

Fosphenytoin sodium
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
EU EINECS/ELINCS List Not Listed

Tromethamine
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
EU EINECS/ELINCS List 201-064-4

Water for injection
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
REACH - Annex IV - Exemptions from the obligations of Register: Present
EU EINECS/ELINCS List 231-791-2

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3
Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child
Carcinogenicity-Cat.2; H351 - Suspected of causing cancer

Carcinogenic: Category 3
Toxic to Reproduction: Category 3

R40 - Limited evidence of a carcinogenic effect
R63 - Possible risk of harm to the unborn child.

Data Sources: Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 16 - Other Information. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage.

Revision date: 10-Mar-2015
Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet