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

<table>
<thead>
<tr>
<th>Pfizer Inc</th>
<th>Pfizer Ltd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer Pharmaceuticals Group</td>
<td>Ramsgate Road</td>
</tr>
<tr>
<td>235 East 42nd Street</td>
<td>Sandwich, Kent</td>
</tr>
<tr>
<td>New York, New York 10017</td>
<td>CT13 9NJ</td>
</tr>
<tr>
<td>1-212-573-2222</td>
<td>United Kingdom</td>
</tr>
<tr>
<td></td>
<td>+00 44 (0)1304 616161</td>
</tr>
</tbody>
</table>

Material Name: Cerebyx® (Fosphenytoin Sodium) Injection 75 mg/ml

<table>
<thead>
<tr>
<th>Trade Name:</th>
<th>Cerebyx®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Family:</td>
<td>Not determined</td>
</tr>
<tr>
<td>Intended Use:</td>
<td>anticonvulsant</td>
</tr>
</tbody>
</table>

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fosphenytoin sodium</td>
<td>92134-98-0</td>
<td>Not listed</td>
<td>7.0</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tromethamine</td>
<td>77-86-1</td>
<td>201-064-4</td>
<td>*</td>
</tr>
<tr>
<td>Water for injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Colorless/pale yellow, clear solution

Signal Word: CAUTION

Statement of Hazard:
Antiepileptic drug: may cause nervous system effects
Possible carcinogen
Possible risk of harm to the unborn child

Eye Contact: Not expected to cause eye irritation.

Skin Contact: Not expected to cause skin irritation.

Inhalation: An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8).

Ingestion: Accidental ingestion may cause effects similar to those seen in clinical use. See 'Statements of hazard', 'Known clinical effects', and/or 'Other potential health effects' in this section.

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.
Material Name: Cerebyx® (Fosphenytoin Sodium) Injection 75 mg/ml
Revision date: 21-Aug-2006
Version: 2.2

Potential Health Effects: 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.

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

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

Additional Information: For a more detailed discussion of potential health hazards and toxicity see Section 11.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: None known or expected.

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

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

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Use non-combustible absorbent material to wipe up spill and place in a sealed container for disposal. Clean spill area thoroughly.

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

Additional Consideration for Large Spills: Contain the source of the spill or leak if it is safe to do so. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal.
**7. HANDLING AND STORAGE**

**General Handling:** Use with adequate ventilation. Avoid breathing vapor or mist.

**Storage Conditions:** Store in a refrigerated area. Vials that develop particulate matter should not be used.

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

**Analytical Method:** Fosphenytoin sodium; SAM# 172.0 (Contact Pfizer for additional details)

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. Local exhaust ventilation is required unless used in a closed system. For laboratory use, handle in a lab fume hood.

**Personal Protective Equipment:**
- **Hands:** Rubber gloves
- **Eyes:** Safety glasses or goggles
- **Skin:** Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
- **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:**

**Physical State:** Solution

**Molecular Formula:** Mixture

**Solubility:** Soluble: Water

**pH:** 8.6-9.0

**Flash Point (°C):** >61

**Boiling Point (°C):** 100

**Color:** Colorless to pale yellow

**Molecular Weight:** Mixture

**10. STABILITY AND REACTIVITY**

**Stability:** Stable under normal conditions of use.

**Conditions to Avoid:** Avoid direct sunlight, conditions that might generate heat, and sources of ignition.

**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers.

**Hazardous Decomposition Products:** None known

**Polymerization:** No data available

**11. TOXICOLOGICAL INFORMATION**

**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.

**Carcinogenicity:** See below
NTP: Group 2: reasonably anticipated to be a human carcinogen (Phenytoin/Phenytoin sodium)
IARC: 2B: possibly carcinogenic to humans (Phenytoin/Phenytoin sodium)

Acute Toxicity: (Species, Route, End Point, Dose)

Fosphenytoin sodium

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

Inhalation Acute Toxicity  No data available
Ingestion Acute Toxicity  No data available.

Eye Irritation / Sensitization  Fosphenytoin caused negligible irritation in IM and IV studies in animals. Although skin irritation has been observed in humans it is generally not seen near injection sites and should not be considered a local effect.

Skin Irritation / Sensitization  Hypersensitivity reactions to phenytoin and other hydantoins have been reported. Fosphenytoin caused negligible irritation in IM and IV studies in animals. Although skin irritation has been observed in humans it is generally not seen near injection sites and should not be considered a local effect.

Subchronic Effects  IV and IM studies in rats and dogs ranging from 2-13 weeks in length resulted in transient CNS effects (ataxia, decreased activity, mydriasis, and tremors) in both species. Increased liver weights, glycogen deposition, and liver enzyme changes were also seen.

Chronic Effects/Carcinogenicity  Chronic toxicity studies have not been conducted with fosphenytoin. In a two-year dietary carcinogenicity study conducted with phenytoin, an increased incidence of liver tumors was seen in mice receiving 45 mg/kg/day. In the IARC monograph for phenytoin and phenytoin sodium it is also reported that oral administration of 60 mg/kg/day caused an increased incidence of thymic or generalized lymphomas in mice.

Reproductive Effects  Maternal toxicity and altered estrous cycles, delayed mating, and prolonged gestation length were observed following administration of fosphenytoin to rats during mating, gestation, and lactation at doses of 50 mg/kg or higher.

Teratogenicity  Administration of fosphenytoin sodium to pregnant rats resulted in increased frequencies of malformations (brain, cardiovascular, digit, and skeletal anomalies) death, growth retardation, and functional impairment (chromodacryorrhea, hyperactivity, circling). Doses of 75 mg/kg/day and higher resulted in increased resorption and malformation rates in rabbits. A recent epidemiological study in pregnant women found that phenytoin caused teratogenicity (hypoplasia of the fingers) when taken alone. Due to confounding factors, such as the individuals disease state, these results are difficult to interpret. Phenytoin has been shown to cause developmental toxicity in mice, rats, rabbits, and monkeys. Effects seen include cleft lip, with or without cleft palate, shortened long bones, hydronephrosis with renal hemorrhaging, delayed ossification of the axial skeleton, neural tube defects, and cardiac, digital and ocular abnormalities.

Mutagenicity  Non-mutagenic in bacterial cells or mammalian cells. This material was not clastogenic in vivo but was positive in vitro with metabolic activation only.

Carcinogen Status:  See below

12. ECOLOGICAL INFORMATION

Environmental Overview:  The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.
13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Observe all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: Xn
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.

EU Safety Phrases:
S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
CAUTION
Antiepileptic drug: may cause nervous system effects Possible carcinogen Possible risk of harm to the unborn child

Canada - WHMIS: Classifications

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

Tromethamine
EU EINECS List 201-064-4
Inventory - United States TSCA - Sect. 8(b) Listed

Water for injection
EU EINECS List 231-791-2
Inventory - United States TSCA - Sect. 8(b) Listed

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients.
End of Safety Data Sheet