



# SAFETY DATA SHEET

Revision date 14-Jun-2025

Version 4

Page 1 / 12

## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

**Product Name** Cerebyx® (Fosphenytoin Sodium) Injection  
**Product Code(s)** PD020  
**Trade Name:** Cerebyx® ; PRO-EPANUTIN; PRODILANTIN; CERENEU  
**Item Code** H000401231,H000401232  
**Chemical Family:** Mixture

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Recommended Use** Pharmaceutical product used as anticonvulsant

### 1.3. Details of the supplier of the safety data sheet

Pfizer Inc  
66 Hudson Boulevard East  
New York, New York 10001  
1-800-879-3477

Pfizer Ireland Pharmaceuticals  
OSG Building  
Ringaskiddy, Co. Cork.  
Ireland  
+353 21 4378701

**E-mail address** pfizer-MSDS@pfizer.com

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

**Carcinogenicity** Category 2  
**Reproductive toxicity** Category 2

#### OSHA Classification

**Hazards not otherwise classified (HNOC)**  
Not applicable

**Hazards classified under paragraph (d)(1)(ii) of 1910.1200**  
Not applicable

### 2.2. Label elements



# SAFETY DATA SHEET

Product Name Cerebyx® (Fosphenytoin Sodium) Injection  
Revision date 14-Jun-2025

Page 2 / 12  
Version 4

## Signal word

Warning

## Hazard statements

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

## Precautionary Statements - EU (§28, 1272/2008)

P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
P280 - Wear protective gloves and protective clothing  
P308 + P313 - IF exposed or concerned: Get medical advice/attention  
P405 - Store locked up  
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

## 2.3. Other hazards

### Other hazards

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

## PBT & vPvB

The product does not contain any substance(s) classified as PBT or vPvB.

## Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors.

## 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.

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

#### Substances

Not applicable

### 3.2 Mixtures

#### Hazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Fosphenytoin sodium (CAS #: 92134-98-0)	5		Not Listed	Repr.2 (H361d) Carc.2 (H351)	Not classified	No data available	No data available

#### NonHazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified	Not classified	No data available	No data available
Tromethamine (CAS #: 77-86-1)	*	-	201-064-4	Not classified	Not classified	No data available	No data available

# SAFETY DATA SHEET

Product Name Cerebyx® (Fosphenytoin Sodium) Injection  
Revision date 14-Jun-2025

Page 3 / 12  
Version 4

## **Full text of H- and EUH-phrases: see section 16**

Acute Toxicity Estimate No information available

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Tromethamine 77-86-1	5900	5000	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59).

## **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. Non-hazardous ingredients provided for completeness.

## **Section 4: FIRST AID MEASURES**

### **4.1. Description of first aid measures**

<b>Inhalation</b>	Remove to fresh air. Seek immediate medical attention/advice.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	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.

### **4.2. Most important symptoms and effects, both acute and delayed**

<b>Most important symptoms and effects</b>	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
--	--

### **4.3. Indication of any immediate medical attention and special treatment needed**

<b>Note to physicians</b>	None.
---------------------------	-------

## **Section 5: FIRE-FIGHTING MEASURES**

### **5.1. Extinguishing media**

<b>Suitable Extinguishing Media</b>	Dry chemical, CO <sub>2</sub> , alcohol-resistant foam or water spray.
-------------------------------------	--

### **5.2. Special hazards arising from the substance or mixture**

<b>Specific hazards arising from the</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
--	--

# SAFETY DATA SHEET

Product Name Cerebyx® (Fosphenytoin Sodium) Injection  
Revision date 14-Jun-2025

Page 4 / 12  
Version 4

## chemical

**Hazardous combustion products** None known or expected.

## Explosion data

**Sensitivity to mechanical impact** No information available.

**Sensitivity to static discharge** No information available.

## 5.3. Advice for firefighters

**Special protective equipment and precautions for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## Section 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

**Personal precautions** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**For emergency responders** Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

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

### 6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

### 6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## Section 7: HANDLING AND STORAGE

### 7.1. Precautions for safe handling

**Advice on safe handling** Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

### 7.2. Conditions for safe storage, including any incompatibilities

**Storage Conditions** Store as directed by product packaging.

### 7.3. Specific end use(s)

**Specific use(s)** Pharmaceutical drug product.

# SAFETY DATA SHEET

Product Name Cerebyx® (Fosphenytoin Sodium) Injection  
Revision date 14-Jun-2025

Page 5 / 12  
Version 4

## Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

#### Fosphenytoin sodium

Pfizer OEL TWA-8 Hr: 600 µg/m<sup>3</sup>

#### Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

### 8.2. 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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

#### Eye/face protection

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

#### Hand protection

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

#### Skin and body protection

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

#### Respiratory protection

Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.).

#### Thermal hazards

No information available.

#### Environmental exposure controls

No information available.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

# SAFETY DATA SHEET

Product Name Cerebyx® (Fosphenytoin Sodium) Injection  
Revision date 14-Jun-2025

Page 6 / 12  
Version 4

## 9.1. Information on basic physical and chemical properties

Appearance	Solution
Physical state	Liquid
Color	Colorless to pale yellow
Odor	No information available.
Odor threshold	No information available

Property	Values
Melting point / freezing point	No data available
Boiling point or initial boiling point and boiling range	100
Flammability (solid, gas)	No data available
Lower and upper explosion limit/flammability limit	
Lower explosion limit	No data available
Upper explosion limit	No data available
Flash point	No data available
Autoignition temperature	No data available
Decomposition temperature	
SADT (°C)	No data available
pH	8.6-9.0
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	Soluble Water
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

### Partition Coefficient: (Method, pH, Endpoint, Value)

#### Tromethamine

Predicted 7.4 Log D -4.668

#### Phenytoin

Predicted 7.4 Log D 2.47

## 9.2. Other information

Molecular formula	Mixture
Molecular weight	Mixture

### 9.2.1. Information with regard to physical hazard classes

No information available

### 9.2.2. Other safety characteristics

No information available

## Section 10: STABILITY AND REACTIVITY

### 10.1. Reactivity

Reactivity No information available.

### 10.2. Chemical stability

Stability Stable up to .?°C.

#### Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

# SAFETY DATA SHEET

Product Name Cerebyx® (Fosphenytoin Sodium) Injection  
Revision date 14-Jun-2025

Page 7 / 12  
Version 4

## 10.3. Possibility of hazardous reactions

**Possibility of hazardous reactions** No information available.

**Hazardous polymerization** No data available.

## 10.4. Conditions to avoid

**Conditions to avoid** Fine particles (such as dust and mists) may fuel fires/explosions.

## 10.5. Incompatible materials

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

## 10.6. Hazardous decomposition products

**Hazardous decomposition products** No data available.

## Section 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

<b>General Information:</b>	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.
<b>Short term</b>	Antiepileptic drug: may cause nervous system effects Accidental ingestion may cause effects similar to those seen in clinical use.
<b>Long Term:</b>	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.
<b>Known Clinical Effects:</b>	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.
<b>Acute toxicity</b>	Based on available data, the classification criteria are not met.
<b>Serious eye damage/eye irritation</b>	Based on available data, the classification criteria are not met.
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.
<b>Respiratory or skin sensitization</b>	Based on available data, the classification criteria are not met.
<b>STOT - single exposure</b>	Based on available data, the classification criteria are not met.
<b>STOT - repeated exposure</b>	Based on available data, the classification criteria are not met.
<b>Reproductive toxicity</b>	Based on available data, the classification criteria are not met.
<b>Germ cell mutagenicity</b>	Based on available data, the classification criteria are not met.
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met.
<b>Aspiration hazard</b>	Based on available data, the classification criteria are not met.

### 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

#### Tromethamine

Rat Oral LD50 5900 mg/kg  
Rat Dermal LD 50 > 5000 mg/kg

#### Phenytoin

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

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
---------------	-----------	-------------	-----------------

# SAFETY DATA SHEET

Product Name Cerebyx® (Fosphenytoin Sodium) Injection  
Revision date 14-Jun-2025

Page 8 / 12  
Version 4

Water	> 90 mL/kg ( Rat )	-	-
Tromethamine	= 5900 mg/kg ( Rat )	> 5000 mg/kg ( Rat )	-

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

## **Irritation / Sensitization: (Study Type, Species, Severity)**

### **Tromethamine**

Eye Irritation Rabbit Slight  
Skin Irritation Rabbit Slight

## **Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**

### **Fosphenytoin sodium**

4 Week(s) Rat Intravenous < 30 mg/kg/day NOEL Central nervous system  
13 Week(s) Rat Intramuscular 30 mg/kg/day NOEL Liver  
4 Week(s) Dog Intravenous < 15 mg/kg/day NOEL Central Nervous System  
13 Week(s) Dog Intramuscular 15 mg/kg/day NOEL Central Nervous System, Liver

### **Phenytoin**

2 Week(s) Rat Oral 3125 ppm NOEL Bone marrow  
2 Week(s) Mouse Oral 500 ppm NOEL Central Nervous System, Gastrointestinal system  
13 Week(s) Rat Oral 4800 ppm NOEL None identified  
13 Week(s) Mouse Oral 600 ppm NOEL Blood forming organs, Gastrointestinal system, Central Nervous System  
2 Year(s) Rat Oral 25 mg/kg/day NOEL None identified  
2 Year(s) Mouse Oral 45 mg/kg/day NOEL Liver, Blood

## **Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))**

### **Fosphenytoin sodium**

Reproductive & Fertility 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

### **Phenytoin**

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  
Reproductive & Fertility Rat Subcutaneous 40 mg/kg/day NOEL Fertility  
Embryo / Fetal Development Mouse Intraperitoneal 50 mg/kg/day NOEL Fetotoxicity, Teratogenic  
Embryo / Fetal Development Mouse Subcutaneous 50 mg/kg/day LOEL Fetotoxicity

## **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

### **Tromethamine**

Bacterial Mutagenicity (Ames) *E. coli* 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 Assay Human Lymphocytes Negative

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



# SAFETY DATA SHEET

Product Name Cerebyx® (Fosphenytoin Sodium) Injection  
Revision date 14-Jun-2025

Page 9 / 12  
Version 4

## 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

**Carcinogenicity** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

## 11.2. Information on other hazards

### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

### 11.2.2. Other information

**Other adverse effects** No information available.

## Section 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.

### 12.1. Toxicity

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

##### Tromethamine

*Daphnia magna* (Water Flea) OECD EC50 48 hours > 980 mg/L

*Pseudokirchneriella subcapitata* (Green Alga) OECD EC50 48 Hours 473 mg/L

##### 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

#### Bacterial Inhibition: (Inoculum, Method, End Point, Result)

##### Tromethamine

Activated sludge OECD EC50 > 1000 mg/L

### 12.2. Persistence and degradability

**Persistence and degradability** No information available.

### 12.3. Bioaccumulative potential

#### Bioaccumulation

#### Partition Coefficient: (Method, pH, Endpoint, Value)

##### Tromethamine

Predicted 7.4 Log D -4.668

##### Phenytoin

Predicted 7.4 Log D 2.47

### 12.4. Mobility in soil

**Mobility in soil** No information available.

# SAFETY DATA SHEET

Product Name Cerebyx® (Fosphenytoin Sodium) Injection  
Revision date 14-Jun-2025

Page 10 / 12  
Version 4

## 12.5. Results of PBT and vPvB assessment

**PBT and vPvB assessment** Based on available data, the classification criteria are not met.

Chemical name	PBT and vPvB assessment
Tromethamine	Not PBT/vPvB PBT assessment does not apply

## 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

## 12.7. Other adverse effects

**Other adverse effects** No information available.

**PMT or vPvM properties** Based on available data, the classification criteria are not met.

Chemical name	PMT and vPvM assessment
Phenytoin	PMT & vPvM

## Section 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

#### Waste from residues/unused products

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 wastewater 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.

## Section 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.

UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental Hazard(s):	Not applicable

## Section 15: REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

# SAFETY DATA SHEET

Product Name Cerebyx® (Fosphenytoin Sodium) Injection  
Revision date 14-Jun-2025

Page 11 / 12  
Version 4

## Water

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-791-2
<b>AICS</b>	Present

## Fosphenytoin sodium

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed

## Tromethamine

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	201-064-4
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 4

## National regulations

### Germany

#### **Chemical Prohibition Ordinance (ChemVerbotsV)**

Not applicable

### **TRGS 905**

Not applicable

### Switzerland

**Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018** Not applicable

**Storage of Hazardous Material** Not applicable

**WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20** Not applicable

**Major Accidents Ordinance SR 814.012** Not applicable

### **European Union**

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

#### **Authorizations and/or restrictions on use:**

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

#### **Persistent Organic Pollutants**

Not applicable

#### **Ozone-depleting substances (ODS) Regulation (EU) 2024/590**

Not applicable.

#### **Explosives Precursors Marketing and Use (2019/1148)**

Not applicable

# SAFETY DATA SHEET

Product Name Cerebyx® (Fosphenytoin Sodium) Injection  
Revision date 14-Jun-2025

Page 12 / 12  
Version 4

## Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**KECL** - Korean Existing Chemicals Inventory  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances  
**AICS** - Australian Inventory of Chemical Substances  
**NZIoC** - New Zealand Inventory of Chemicals  
**TCSI** - Taiwan Chemical Substance Inventory

## 15.2. Chemical safety assessment

**Chemical Safety Report** No information available

## **Section 16: OTHER INFORMATION**

### Key or legend to abbreviations and acronyms used in the safety data sheet

#### **Full text of any hazard and/or precautionary statements referred to under Sections 2-15**

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

**Data Sources:** Pfizer proprietary drug development information.

**Reason for revision** Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

**Revision date** 14-Jun-2025

**Prepared By** Pfizer Global Environment, Health, and Safety

**Pfizer Inc believes that the information contained in this 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.**