SAFETY DATA SHEET

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

Manufacturer Name and Address : Acella Pharmaceuticals, LLC
1880 McFarland Pkwy, Suite 110
Alpharetta, Georgia 30005
United States
Ph: +1 (800)-541-4802

Material Name: Phenytoin Injection

Trade Name:	Not applicable
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as anticonvulsant

2. HAZARDS IDENTIFICATION

Appearance:	Colorless/pale yellow, clear solution
Signal Word:	WARNING
Statement of Hazard:	Antiepileptic drug: may cause nervous system effects Possible carcinogen Possible risk of harm to the unborn child
Additional Hazard Information:	
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.
EU Indication of danger:	Carcinogenic: Category 3 Toxic to Reproduction: Category 3

EU Hazard Symbols:



EU Risk Phrases:

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

2. HAZARDS IDENTIFICATION

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Fosphenytoin sodium	92134-98-0	Not listed	Repr.Cat.3;R63 Carc.Cat.3;R40	5

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Tromethamine	77-86-1	201-064-4	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	*

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

For the full text of the R phrases mentioned in this Section, see Section 16

4. 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 notinduce vomiting unless directed by medical personnel. Seek medical attention immediately.

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

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.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: None known or expected.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

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

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

General 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 skinafter 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 thismaterial to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Fosphenytoin sodium

Pfizer OEL TWA-8 Hr: 600µg/m^3

Analytical Method: Analytical method available for fosphenytoin sodium. Contact Pfizer Inc for further information.

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.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

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

Physical State:	Solution	**Color:**	Colorless to pale yellow
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solubility: Soluble: Water

pH: 8.6-9.0

9. PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point (°C): 100

Polymerization: No data available

10. STABILITY AND REACTIVITY

Chemical 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

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.

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 363 mg/kg
Rat IV (bolus) LD50 319.2 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

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 system13
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

Phenytoin
2 Week(s) Rat Oral <3125 ppm/day NOEL Bone marrow
2 Week(s) Mouse Oral <125 ppm/day NOEL Central Nervous System13
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))

Fosphenytoin sodium
Reproductive & Fertility Rat Intramuscular 25 mg/kg/day NOEL Maternal toxicity, Developmental toxicity, Teratogenic

11. TOXICOLOGICAL INFORMATION

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

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 Assay 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, Skin2
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, neoplasms2
Year(s) Female Rat Oral, in feed 240 ppm NOAEL Not carcinogenic

Carcinogen Status: See below

Phenytoin

IARC: Group 2B
NTP: Listed
OSHA: Present

12. ECOLOGICAL INFORMATION

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

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

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 minimizationbe practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

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:
WARNING
Antiepileptic drug: may cause nervous system effectsPossible carcinogen
Possible risk of harm to the unborn child

Canada - WHMIS: Classifications

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



Fosphenytoin sodium

Standard for the Uniform Schedulingfor Drugs and Poisons: Schedule 4

15. REGULATORY INFORMATION

Tromethamine

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Schedulingfor Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	201-064-4

Water for injection

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R40 - Limited evidence of a carcinogenic effectR63 - Possible risk of harm to the unborn child.

Acella Pharmaceuticals, LLC 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