MATERIAL SAFETY DATA SHEET

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

Pfizer Inc
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Phenytoin Oral Suspension (30 mg/5mL; 37.5 mg/5mL)

Trade Name: Dilantin®; Epanutin®; Epamin®
Chemical Family: Mixture
Intended Use: Pharmaceutical product used for seizures and epilepsy.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Ethyl alcohol (ethanol)	64-17-5	200-578-6	< 1
Phenytoin	57-41-0	200-328-6	0.6-0.75
Glycerol	56-81-5	200-289-5	*
Sucrose	57-50-1	200-334-9	*

Ingredient	CAS Number	EU EINECS List	%
Bananna Flavor	Not Assigned	Not listed	*
Carboxymethylcellulose sodium	9004-32-4	Not listed	*
Carmoisine red E122	3567-69-9	222-657-4	*
Citric Acid Monohydrate	5949-29-1	Not listed	*
FD&C Yellow No. 6; (Sunset yellow)	2783-94-0	220-491-7	*
Magnesium aluminum silicate	1327-43-1	215-478-8	*
Orange Oil	Not Assigned	Not listed	*
Polysorbate 40	9005-66-7	Not listed	*
Purified water	7732-18-5	231-791-2	*
Sodium benzoate	532-32-1	208-534-8	*
Vanillin	121-33-5	204-465-2	*

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

3. HAZARDS IDENTIFICATION

Appearance: Orange suspension
Signal Word: WARNING

Statement of Hazard: Suspected of causing cancer.

Additional Hazard Information:

Short Term:	May cause eye irritation (based on components) .
Long Term:	Repeat-dose studies in animals have shown a potential to cause adverse effects on blood and blood forming organs, gastrointestinal system and liver.
Known Clinical Effects:	The most common adverse effects observed with clinical use of phenytoin are lack of appetite, headache, dizziness, transient nervousness, ataxia, slurred speech, decreased coordination, mental confusion, insomnia, and GI disturbances (nausea, vomiting, and constipation). IV administration has been associated with hypotension and CNS depression. Mild hypersensitivity reactions (skin rashes) are common. Effects on blood- forming organs and the liver have occurred rarely. Other less common effects include swollen lymph nodes, sore mouth and symptoms of dependence/withdrawal. There is an unconfirmed association between the use of anticonvulsants during pregnancy and an increased risk of birth defects. This material has been shown to be secreted in low concentrations in human breast milk.
EU Indication of danger:	Not classified

Australian Hazard Classification (NOHSC):	Non-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 active substance or its intermediates 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. 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:	No data available
Fire Fighting Procedures:	Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.
Fire / Explosion Hazards:	No data available

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 to avoid 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:	Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist.
Storage Conditions:	Protect from freezing. Protect from light.
Storage Temperature:	Store at controlled room temperature 20-25°C (68-77°F)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Ethyl alcohol (ethanol)

OSHA - Final PELS - TWAs:	= 1000 ppm TWA = 1900 mg/m^3 TWA
ACGIH Threshold Limit Value (TWA)	= 1000 ppm TWA
Australia TWA	= 1000 ppm TWA = 1880 mg/m^3 TWA

Phenytoin

Pfizer OEL TWA-8 Hr:	0.4 mg/m^3

Glycerol

OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA total = 5 mg/m^3 TWA
ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA
Australia TWA	= 10 mg/m^3 TWA

Sucrose

OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA total = 5 mg/m^3 TWA
ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA
Australia TWA	= 10 mg/m^3 TWA

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

Analytical Method:	Analytical method available for Phenytoin. Contact Pfizer Inc for further information.
Engineering Controls:	Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands:	Wear impervious gloves if skin contact is possible.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Wear protective clothing when working with large quantities.
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:	Suspension	**Color:**	Orange
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Exposure to light and freezing .
Incompatible Materials: None identified

Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

Sodium benzoate
Rat Oral LD50 4,070 mg/kg
Mouse Oral LD50 1600 mg/kg

Carboxymethylcellulose sodium
Mouse Oral LD50 > 27,000 mg/kg
Rat Oral LD50 27,000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Sucrose
Rat Oral LD50 29.7 g/kg

Ethyl alcohol (ethanol)
Mouse Oral LD50 3450 mg/kg
Rat Oral LD50 7060 mg/kg
Rat Inhalation LC50 10h 20,000 ppm

Vanillin
Rat Oral LD 50 1580 mg/kg

FD&C Yellow No. 6; (Sunset yellow)
Rat Oral LD50 > 10,000 mg/kg
Mouse Oral LD50 > 6,000 mg/kg

Glycerol
Rat Oral LD 50 12600 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

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)

Ethyl alcohol (ethanol)
Eye Irritation Rabbit Severe

Glycerol
Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

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

Sodium benzoate
10 Day(s) Rat Oral 27370 mg/kg LOAEL Liver, Blood
10 Day(s) Mouse Oral 45 g/kg LOAEL Liver, Kidney, Blood, Ureter, Bladder

Carboxymethylcellulose sodium
13 Week(s) Rat Oral 227 g/kg LOAEL Liver, Kidney, Ureter, Bladder

Glycerol
28 Day(s) Rat Oral 16800 mg/kg LOAEL Endocrine system

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))

Sodium benzoate
Embryo / Fetal Development Rat Oral 44 g/kg LOEL Developmental toxicity

Glycerol
Reproductive & Fertility-Males Rat Oral 100 mg/kg LOEL Fertility

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)

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, 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

FD&C Yellow No. 6; (Sunset yellow)
IARC: Group 3

Carmoisine red E122
IARC: Group 3

Phenytoin
IARC: Group 2B
NTP: Reasonably Anticipated To Be A Carcinogen
OSHA: Present

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided. See aquatic toxicity data, below:

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

Ethyl alcohol (ethanol)
Rainbow Trout LC50/96h 12,900-15,300 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

Aquatic Toxicity Comments: A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:
WARNING
Suspected of causing cancer.

Canada - WHMIS: Classifications

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

Ethyl alcohol (ethanol)

California Proposition 65	developmental toxicity, initial date 10/1/87 (when in alcoholic beverages)
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-578-6

Phenytoin

CERCLA/SARA 313 Emission reporting	= 0.1 % de minimis concentration
California Proposition 65	carcinogen, initial date 1/1/88 developmental toxicity, initial date 7/1/87
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS List	200-328-6

Glycerol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-289-5

Sucrose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-334-9

Carboxymethylcellulose sodium

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Carmoisine red E122

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	222-657-4

Citric Acid Monohydrate

Australia (AICS):	Present

FD&C Yellow No. 6; (Sunset yellow)

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	220-491-7

Magnesium aluminum silicate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	215-478-8

Polysorbate 40

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Purified water

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

Sodium benzoate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	208-534-8

Vanillin

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	204-465-2

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 12 - Ecological Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet