

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

Greenstone LLC
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Material Name: Phenytoin Tablets (Greenstone LLC)

Trade Name:	Not applicable
Synonyms:	Infatabs Phenytoin Tablets USP
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used for, seizures and epilepsy

2. HAZARDS IDENTIFICATION

Appearance: Yellow chewable tablet
Signal Word: WARNING

Statement of Hazard: Suspected of causing cancer.
May cause harm to the unborn child.

Additional Hazard Information:

Short Term: Active ingredient may be harmful if swallowed.
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: Carcinogenic: Category 3
Toxic to Reproduction: Category 2

EU Hazard Symbols:**EU Risk Phrases:**

R40 - Limited evidence of a carcinogenic effect
R61 - May cause harm to the unborn child.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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2. HAZARDS IDENTIFICATION

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Phenytoin	57-41-0	200-328-6	Carc.Cat.3;R40 Repr.Cat.2;R61 Xn;R22	9
Magnesium Stearate	557-04-0	209-150-3	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Confectioner's sugar	MIXTURE	Not Listed	Not Listed	*
D&C Yellow #10, aluminum lake	Not available	Not Listed	Not Listed	*
Lactose	63-42-3	200-559-2	Not Listed	*
Purified water	7732-18-5	231-791-2	Not Listed	*
Sodium saccharin USP	128-44-9	204-886-1	Not Listed	*
Spearmint Flavor, natural	NOT ASSIGNED	Not Listed	Not Listed	*
FD&C yellow No.6 aluminum lake	15790-07-5	239-888-1	Not Listed	*

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

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 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.

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: Formation of toxic gases is possible during heating or fire.

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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 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: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and 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.

Storage Conditions: Store as directed by product packaging.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Phenytoin

Manufacturer OEL: 400ug/m³

Magnesium Stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m³

Lithuania OEL - TWA 5 mg/m³

Sweden OEL - TWAs 5 mg/m³

Talc (non-asbestiform)

ACGIH Threshold Limit Value (TWA) 2 mg/m³

Australia TWA 2.5 mg/m³

Austria OEL - MAKs 2 mg/m³

Belgium OEL - TWA 2 mg/m³

Bulgaria OEL - TWA 1.0 fiber/cm³

6.0 mg/m³

3.0 mg/m³

Czech Republic OEL - TWA 2.0 mg/m³

10 mg/m³

Denmark OEL - TWA 0.3 fiber/cm³

Finland OEL - TWA 0.5 fiber/cm³

5 mg/m³

Greece OEL - TWA 10 mg/m³

2 mg/m³

Hungary OEL - TWA 2 mg/m³

Ireland OEL - TWAs 10 mg/m³

0.8 mg/m³

Lithuania OEL - TWA 2 mg/m³

1 mg/m³

Netherlands OEL - TWA 0.25 mg/m³

OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf

Poland OEL - TWA 4.0 mg/m³

1.0 mg/m³

Portugal OEL - TWA 2 mg/m³

Romania OEL - TWA 2 mg/m³

Slovakia OEL - TWA 2 mg/m³

10 mg/m³

Slovenia OEL - TWA 2 mg/m³

Spain OEL - TWA 2 mg/m³

Sweden OEL - TWAs 2 mg/m³

1 mg/m³

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. 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.

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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: Chewable tablet
Color: Yellow
Molecular Formula: Mixture
Molecular Weight: Mixture

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
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

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)

Lactose

Rat Oral LD50 > 10 g/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

Sodium saccharin USP

Mouse Oral LD50 17.5 g/kg
Rat Oral LD50 14.2 - 17 g/kg

Talc (non-asbestiform)

Rat Oral LD50 > 1600 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.

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

Phenytoin

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

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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

Magnesium Stearate

13 Week(s)	Rat	Oral	1092 g/kg	LOAEL	Liver
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Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

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)	<i>Salmonella</i>	Negative
<i>In Vitro</i> Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Negative
<i>In Vivo</i> Sister Chromatid Exchange	Human Lymphocytes	Positive
<i>In Vivo</i> 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

Phenytoin

IARC:	Group 2B (Possibly Carcinogenic to Humans)
NTP:	Reasonably Anticipated To Be A Human Carcinogen
OSHA:	Listed

Sodium saccharin USP

IARC:	Group 3 (Not Classifiable)
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Talc (non-asbestiform)

IARC:	Group 3 (Not Classifiable)
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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)

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12. ECOLOGICAL INFORMATION

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

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

EU Symbol: T
EU Indication of danger: Carcinogenic: Category 3
Toxic to Reproduction: Category 2

EU Risk Phrases:
R40 - Limited evidence of a carcinogenic effect
R61 - May cause 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
Suspected of causing cancer.
May cause harm to the unborn child.

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15. REGULATORY INFORMATION

Canada - WHMIS: Classifications

WHMIS hazard class:
D2a very toxic materials



Phenytoin

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

Lactose

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	200-559-2

Magnesium Stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

Purified water

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

Sodium saccharin USP

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	204-886-1

Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	238-877-9

FD&C yellow No.6 aluminum lake

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	239-888-1

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16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R40 - Limited evidence of a carcinogenic effect

R61 - May cause harm to the unborn child.

R22 - Harmful if swallowed.

Data Sources:

The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Prepared by:

Product Stewardship Hazard Communication
Global Environment, Health, and Safety Operations

It is believed that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a 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