

### SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

**1.1 Product identifier**

**Product Name:** Phenytoin Oral Suspension, USP (125 mg/5 ml)  
**Product Codes(s):** Phenytoin Oral Suspension, USP (125 mg/5 ml)  
**Synonym(s):** Active ingredient - Phenytoin

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

**Recommended use:** Phenytoin Oral Suspension, USP is indicated for the control of tonic-clonic (grand mal) and psychomotor (temporal lobe) seizures.

**Restrictions on use:** Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

**1.3 Details of the supplier and of the safety data sheet**

**Manufactured by**  
 VistaPharm, Inc.  
 7265 Ulmerton Road  
 Largo FL 33771 USA  
 +1-727-530-1633

**1.4 Emergency telephone number**

In the continental USA: +1-727-530-1633

### SECTION 2 - HAZARDS IDENTIFICATION

**2.1 Classification of substance or mixture**

**Product definition:** Mixture

**Classification in accordance with 29 CFR 1910 (OSHA HCS) and Regulation (EC) No 1272/2008**

Acute toxicity, oral - Category 4 [H302]

Carcinogenicity - Category 2 [351]

Reproductive toxicity - Category 2 [H361d]

Specific target organ toxicity, repeated exposure - Category 2 ( STOT RE 2) [H372]

**2.2 Label Elements**

**Hazard Symbol(s):**



GHS07    GHS08

**Signal Word:**

Warning

**Hazard Statement(s):**

H302 - Harmful if swallowed  
 H351 - Suspected of causing cancer  
 H361d - Suspected of damaging fertility or the unborn child  
 H372 - May cause damage to the central nervous system and liver through prolonged or repeated exposure.

**Precautionary Statements:**

**[Prevention]**

P201 - Obtain special instructions before use.  
 P202 - Do not handle until all safety precautions have been read and understood.  
 P260 - Do not breathe vapor or mist.  
 P264 - Wash hands and exposed skin areas thoroughly after handling.  
 P270 - Do not eat, drink or smoke when using this product.  
 P281 - Use personal protective equipment as required.

**[Response]**

P301 + P330 + P313 - IF SWALLOWED: Rinse mouth. Call a POISON CENTER or doctor if you feel unwell.  
 P309 + P313 - IF exposed or concerned or if you feel unwell: Call a POISON CENTER or doctor.

**[Storage]**

P405 - Store locked up.

**[Disposal]**

P501 - Dispose of contents and containers in accordance with national and local regulations.

### SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

**3.1 Substances**

Not applicable

**3.2 Mixtures**

% by Weight	Ingredient	CAS Number	EC Number	Index Number	GHS Classification
<18.0	Glycerin	56-81-5	200-289-5	-----	-----
<12.0	Sucrose	57-50-1	200-334-9	-----	-----
<3.0	Phenytoin	57-41-0	200-328-6	-----	-----

Inactive ingredients: Water; Magnesium Aluminum Silicate; Carboxymethylcellulose Sodium; Sodium Benzoate; Orange Vanilla Flavoring; Polysorbate 80; FD&C Yellow #6; Citric Acid

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

## SECTION 4 - FIRST AID MEASURES

### 4.1 Description of first aid measures

**Inhalation:** If product vapor causes respiratory irritation or distress, move the exposed person to fresh air immediately. If breathing is difficult or irregular, administer oxygen; if respiratory arrest occurs, start artificial respiration by trained personnel. Get immediate medical attention. If unconscious place in the recovery position and get immediate medical attention. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. Symptoms may be delayed. Ensure that medical personnel are aware of the material involved. In the event of any complaints or symptoms, avoid further exposure and seek medical attention.

**Eyes:** Immediately flush eyes with large amounts of water for 15 minutes, occasionally lifting the upper and lower eyelids. Remove contact lenses after the first 2 minutes and continue rinsing. If irritation persists seek medical attention, preferably from an ophthalmologist.

**Skin:** Rinse skin with water while removing contaminated clothing. Wash affected area with soap and water. Wash contaminated clothing and shoes thoroughly before reuse. In the event of any complaints or symptoms, avoid further exposure and seek medical attention.

**Ingestion:** Rinse mouth with water if the victim is conscious. Remove dentures, if present. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept lower than the waist so that vomit does not enter into the lungs. Never give anything by mouth to an unconscious or convulsing person. Do not leave the victim unattended. If the victim is unconscious, place in the recovery position and get immediate medical attention. Immediately contact a poison center or doctor if a large quantity of material has been ingested. Seek medical attention if adverse health effects persist or are severe.

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

#### Potential health symptoms and effects

**Eyes:** May cause eye irritation.

**Skin:** Not expected to cause skin irritation.

**Inhalation:** Not expected to cause irritation by inhalation.

**Ingestion:** May cause gastrointestinal irritation with nausea, vomiting and constipation. May cause lack of appetite, headache, dizziness, transient nervousness, ataxia, slurred speech, incoordination, mental confusion and insomnia. Mild hypersensitivity reactions, such as skin rashes, are common. Effects on blood-forming organs and the liver may occur. May cause swollen lymph nodes, sore mouth and symptoms of dependence/withdrawal.

**Chronic:** Phenytoin is a suspected carcinogen and is suspected of damaging the unborn child. Refer to Section 11.2. Refer to product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

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

#### Advice to doctor and hospital personnel

Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved to enable them to take precautions to protect themselves.

## SECTION 5 - FIRE FIGHTING MEASURES

### 5.1 Extinguishable media

**Suitable methods of extinction:** Use extinguishing media suitable for the surrounding fire.

**Unsuitable methods of extinction:** None known

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

Non-combustible liquid. During emergency conditions overexposure to decomposition products may cause a health hazard. Symptoms may not be immediately apparent or may be delayed. Obtain medical attention.

### 5.3 Advice for firefighters

Full protective equipment including self-contained breathing apparatus should be used. If possible, firefighters should control runoff water contaminated with this material and prevent it from being discharged to any waterway, sewer or drain to prevent environmental contamination.

## SECTION 6 - ACCIDENTAL RELEASE MEASURES

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

Evacuate non-essential personnel from the area. Wear appropriate protective clothing designated in Section 8. Remove all sources of ignition. Ventilate the area. Spill creates a slip hazard.

### 6.2 Environmental precautions

Avoid dispersal of spilled material or runoff and prevent contact with soil and entry into drains, sewers and waterways.

### 6.3 Methods and materials for containment and cleaning up

Cover drains and contain spill. Small spills can be wiped up with absorbent material (e.g. cloth, fleece). Cover larger spills with inert absorbent. Do not use combustible material such as sawdust. Collect material and place into an approved, labeled container for proper disposal. Observe possible material restrictions (Sections 7.2 and 10.5). Dispose of material via a licensed pharmaceutical waste contractor and in accordance with FDA and DEA regulations. Clean contaminated area with soap and water.

### 6.4 Reference to other sections

For symptoms of over-exposure and first aid treatment, see Section 4.

## SECTION 7 - HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Observe label precautions. Wear all appropriate protective equipment specified in Section 8. Do not get in eyes or on skin or clothing. If normal use presents a respiratory hazard, use only adequate ventilation or wear an appropriate respirator.

#### Advice on protection against fire and explosion

Not expected to be a fire or explosion hazard.

## 7.2 Conditions for safe storage, including any incompatibilities

Store at 20 - 25 °C (68 - 77 °F) in a dry, well-ventilated area away from incompatible materials, food and drink. Keep from freezing. Protect from sunlight. Keep container tightly closed when not in use. Protect containers from physical damage. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Containers of this material may be hazardous when empty as they contain product residues. Use appropriate containment to avoid environmental contamination. Ventilate closed areas. Keep locked up and out of reach of children.

## 7.3 Specific end uses

Apart from the uses mentioned in Section 1.2, no other specific uses are stipulated.

# SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

## 8.1 Control parameters

### Occupational Exposure Limits

CAS Number	Ingredient	OSHA PEL	ACGIH TLV	NIOSH
56-81-5	Glycerin	5 mg/m <sup>3</sup> TWA, resp. fraction	10 mg/m <sup>3</sup> TWA	-----

## 8.2 Exposure controls

**Engineering Measures:** Use adequate ventilation. Local exhaust is preferable. Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

**Individual protection measures:** Not normally required. Wear protective clothing to prevent repeated or prolonged contact with product. Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of hazardous substances handled.

**Hygiene measures:** Facilities storing or using this material should be equipped with an eyewash station and safety shower. Change contaminated clothing. Wash hands and forearms thoroughly after use, before eating, drinking or using the lavatory.

**Eye/face protection:** None normally required. If there is a danger of splashing wear safety glasses with unperforated side shields during use.

**Hand Protection:** Not normally needed. For prolonged or repeated skin contact wear gloves recommended by supplier for protection against materials in Section 3. Breakthrough time of selected gloves must be greater than the intended use period.

**Other protective equipment:** Not normally needed. Wear protective clothing and protective boots if the situation requires.

**Respiratory Protection:** No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to vapor/fume at levels exceeding the exposure limits.

**Environmental exposure controls:** Do not empty into drains.

# SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

## 9.1 Information on basic physical and chemical properties

<b>Appearance</b>	Opaque, orange liquid
<b>Odor</b>	Characteristic
<b>Odor Threshold</b>	No data available
<b>Molecular Weight</b>	576.7 g/mol (Phenytoin)
<b>Chemical Formula</b>	C <sub>15</sub> H <sub>12</sub> N <sub>2</sub> O <sub>2</sub> (Phenytoin)
<b>pH</b>	No data available
<b>Freezing/Melting Point, Range</b>	No data available
<b>Initial Boiling Point</b>	No data available
<b>Evaporation Rate</b>	No data available
<b>Flammability (solid, gas)</b>	Not applicable
<b>Flash Point</b>	No data available
<b>Autoignition Temperature</b>	No data available
<b>Decomposition Temperature</b>	No data available
<b>Lower Explosive Limit (LEL)</b>	No data available
<b>Upper Explosive Limit (UEL)</b>	No data available
<b>Vapor Pressure</b>	No data available
<b>Vapor Density</b>	No data available
<b>Specific Gravity</b>	1.115
<b>Viscosity</b>	No data available
<b>Solubility in Water</b>	Dispersible
<b>Partition Coefficient: n-octanol/water</b>	No data available
<b>Volatiles by Weight @ 21° C</b>	No data available

## 9.2 Other data

No relevant additional information available

# SECTION 10 - STABILITY AND REACTIVITY

## 10.1 Reactivity

No special reactivity has been reported.

## 10.2 Chemical stability

Product is stable under recommended storage conditions.

## 10.3 Possibility of hazardous reactions

Hazardous polymerization does not occur.

#### 10.4 Conditions to avoid

Avoid temperature extremes. Avoid exposure to sunlight.

#### 10.5 Incompatible materials

None known

#### 10.6 Hazardous decomposition products

Thermal decomposition products include oxides of carbon, nitrogen oxides.

## SECTION 11 - TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

#### Acute Oral Toxicity

Expected to have low acute oral toxicity

Phenytoin - LD<sub>50</sub>, Rat: >1,635 mg/kg

Citric Acid - LD<sub>50</sub>, Rat: >3,000 mg/kg

#### Acute inhalation toxicity

Expected to have low acute inhalation toxicity

#### Acute dermal toxicity

Expected to have low acute dermal toxicity

#### Skin irritation

Not expected under normal use

#### Eye irritation

Not expected under normal use

#### Sensitization

No data available

#### Genotoxicity

No data available

#### Mutagenicity

No data available

#### Specific organ toxicity - single exposure

No data available

#### Specific organ toxicity - repeated exposure

May cause damage to the central nervous system and liver through prolonged or repeated exposure.

#### Aspiration hazard

No data available

### 11.2 Further information

Phenytoin (CAS #57-41-0): IARC Group 2B Carcinogen - *Possibly carcinogenic to humans*; NTP Group 2 Carcinogen - *Reasonably anticipated to be a carcinogen*. Not listed as a carcinogen by ACGIH or OSHA.

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.

Repeat-dose studies in animals have shown a potential to cause adverse effects on blood and blood forming organs and the liver.

Refer to product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Handle in accordance with good industrial hygiene and safety practice.

## SECTION 12 - ECOLOGICAL INFORMATION

### 12.1 Toxicity

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

### 12.2 Persistence and degradability

Material is expected to be readily biodegradable.

### 12.3 Bioaccumulation potential

This product is not expected to bioaccumulate.

### 12.4 Mobility in soil

No data available.

### 12.5 Results of PBT and vPvB assessment

No data available

### 12.6 Other adverse effects

#### Additional ecological information

Do not allow material to enter into surface waters, wastewater or soil.

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

## SECTION 13 - DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

**Methods of disposal:** The generation of waste should be avoided or minimized whenever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe way via a licensed pharmaceutical waste contractor and in accordance with FDA and DEA regulations. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

**Hazardous waste:** The classification of this product may meet the criteria for a hazardous waste.

## SECTION 14 - TRANSPORT INFORMATION

**Note:** Transportation information provided is for reference only. Customer is urged to consult 49 CFR 100 - 177, IMDG, IATA, EC, United Nations TDG and WHMIS (Canada) TDG information manuals for detailed regulations and exceptions covering specific container sizes, packaging materials and methods of shipping.

**NOT REGULATED FOR TRANSPORT**

## SECTION 15 - REGULATORY INFORMATION

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

#### U. S. Federal Regulations

**OSHA Hazard Communication Standard:** This material is classified as hazardous in accordance with OSHA 29 CFR 1910.1200.

**TSCA Status:** Phenytoin (CAS #57-41-0) is not on the Toxic Substance Control Act (TSCA) Inventory as it is intended for use in applications regulated by the Food and Drug Administration in the United States. It is not subject to TSCA 12(b) Export Notification.

**Superfund Amendments and Reauthorization Act (SARA)**

**SARA Section 311/312 Hazard Categories:** None known

**SARA 313 Information:** Phenytoin (CAS #57-41-0) is subject to the threshold (de minimis) reporting levels established by Section 313 of the Emergency Planning and Community Right-to Know Act of 1986.

**SARA 302/304 Extremely Hazardous Substance:** No components of the product are subject to the reporting requirements of these sections of Title III of SARA.

**SARA 302/304 Emergency Planning & Notification:** No components of the product are subject to the reporting requirements of these sections of Title III of SARA.

**Comprehensive Response Compensation and Liability Act (CERCLA):** No components of the product exceed the threshold (de minimis) reporting levels for hazardous wastes established by CERCLA.

#### **Clean Air Act (CAA)**

This product does not contain any chemicals listed as a Hazardous Air Pollutant (HAP) designated in CAA Section 112 (b).

This product does not contain any Class 1 Ozone depleters.

This product does not contain any Class 2 Ozone depleters.

#### **Clean Water Act (CWA)**

None of the chemicals in this product are listed as Hazardous Substances under the CWA.

None of the chemicals in this product are listed as Priority Pollutants under the CWA.

None of the chemicals in this product are listed as Toxic Pollutants under the CWA.

#### U.S. State Regulations

##### **California Prop 65, Safe Drinking Water and Toxic Enforcement Act of 1986**

Phenytoin (CAS #57-41-0) is known to the State of California to cause cancer.

##### **Other U.S. State Inventories**

Phenytoin (CAS #57-41-0) is listed on the following State Hazardous Substance Inventories, Right-to-Know lists or Air Quality/Air Pollutants lists: CA, DE, MA, MN, NJ, NY, PA, RI, WI.

#### Canada

**WHMIS Hazard Symbol and Classification:** Uncontrolled product according to WHMIS classification criteria

**Canadian National Pollutant Release Inventory (NPRI):** None of the components of this product are not listed on the NPRI.

#### European Economic Community

**Labeling EC No. 1272/2008**



Xn - Harmful

**Risk Phrases:** R22 - Harmful if swallowed.  
R40 - Limited evidence of carcinogenic effect  
R63 - Possible risk of harm to the unborn child.

**Safety Phrases:** S2 - Keep out of the reach of children.  
S45 - In case of accident or if you feel unwell, seek medical advice (show the label, package or this SDS if possible).

**WGK, Germany (Water danger/protection):** No data available

## Global Chemical Inventory Lists

Country	Inventory Name	Inventory Listing*
Canada:	Domestic Substance List (DSL)	No
Canada:	Non-Domestic Substance List (NDSL)	No
Europe:	Inventory of New and Existing Chemicals (EINECS)	No
United States:	Toxic Substance Control Act (TSCA)	No
Australia:	Australian Inventory of Chemical Substances (AICS)	No
New Zealand:	New Zealand Inventory of Chemicals (NZIoC)	No
China:	Inventory of Existing Chemical Substances in China (IECSC)	No
Japan:	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea:	Existing Chemicals List (ECL)	No
Philippines:	Philippines Inventory of Chemicals and Chemical Substances (PICCS)	No

\*Yes - All components of this product are in compliance with the inventory requirements administered by the governing country.

No - One or more components of this product are not on the inventory and are not exempt from listing.

### 15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out.

## SECTION 16 - OTHER INFORMATION

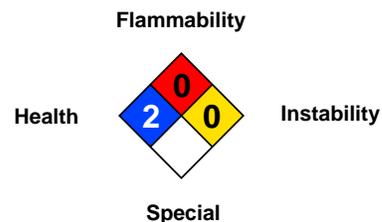
### Hazardous Material Information System (HMIS)

Health	* 2
Flammability	0
Physical Hazard	0
Personal Protection	

### HMIS & NFPA Hazard Rating Legend

\* = Chronic Health Hazard      2 = MODERATE  
 0 = INSIGNIFICANT                3 = HIGH  
 1 = SLIGHT                            4 = EXTREME

### National Fire Protection Association (NFPA)



The information herein is given in good faith and is believed to be accurate and correct; however, no warranty, expressed or implied, is made. VistaPharm, Inc assumes no responsibility for personal injury or property damage that may arise from the use of this material since the conditions of handling and use are beyond our control. It is the responsibility of the user to comply with all Federal, State and local laws and regulations regarding use of this product. Vendees or users assume all risks associated with the use of this material.

Revision date: October 2016 - Section 6.3 and Section 13

Preparation date: 16 September 2016