



IN CASE OF EMERGENCY CALL:
National Poison Control 800-222-1222

Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Phenytoin Oral Suspension
CAS No: 57-41-0
Chemical Name: 5,5-diphenyl-2,4 imidazolidinedione
Chemical Formula: $C_{15}H_{12}N_2O_2$
Molecular Weight: 252.27
Product Use: Treatment of epilepsy.

Manufacturer's Name: VistaPharm, Inc.
Address: 7265 Ulmerton Road
Largo, FL 33771

2. COMPOSITION / INFORMATION ON INGREDIENTS

Composition: Phenytoin USP (125mg/5mL) active ingredient

Please refer to current package insert for other components.

3. HAZARDS IDENTIFICATION

Primary Route of Entry: Absorbed through skin. Eye contact. Inhalation. Ingestion.

Medical Conditions Aggravated by Exposure: Antiepileptic drugs, including Phenytoin Oral Suspension, increase the risk of suicidal thoughts or behavior. Patients should be carefully monitored.

4. FIRST AID MEASURES

Eye Exposure: Check for and remove any contact lenses. Do not use an eye ointment. Seek medical attention.

Skin Exposure: After contact with skin, wash immediately with plenty of water. Gently and thoroughly wash the contaminated skin with running water and non-abrasive soap. Be particularly careful to clean folds, crevices, creases and groin. Cover the irritated skin with an emollient. If irritation persists, seek medical attention. Wash contaminated clothing before reusing.

Inhalation: Allow the victim to rest in a well ventilated area. Seek immediate medical attention.

Ingestion: Do not induce vomiting. Examine the lips and mouth to ascertain whether the tissues are damaged, a possible indication that the toxic material was ingested; the absence of such signs, however, is not conclusive. Loosen tight clothing such as a collar, tie, belt or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention.

Special Protection Information

Ventilation: Not required under normal conditions of therapeutic use.

Respiratory Protection: Not required under normal conditions of therapeutic use.

Protective Gloves and Clothing: Not required under normal conditions of therapeutic use.

Eye Protection: Safety glasses recommended.

5. FIRE AND EXPLOSION HAZARD

May be combustible at high temperatures.

Flash Point: Not determined.

Extinguishing Media: Water spray, multipurpose dry chemical, carbon dioxide or foam as appropriate for the surrounding fire or material.

Fire Fighting Procedures: Use self contained breathing apparatus and protective clothing.

Hazardous Combustion Products: Not determined.

6. ACCIDENTAL RELEASE MEASURES

If Material is Spilled or Released: Wearing suitable protective clothing, absorb liquid on to appropriate absorbent material and place into a container for disposal. Impermeable gloves and eye protection should be worn as a minimum precaution. Additional protective clothing/equipment may be needed depending on the extent of the spill. The spill area should be ventilated and decontaminated after material has been picked up.

7. HANDLING AND STORAGE

Handling: Observe good industrial hygiene practices. Shake well before using.

Storage: Store at controlled temperature of 20° to 25°C (68° to 77°F). Keep out of reach from children.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

OSHA Exposure Limits: None

Engineering Controls: Not required when handling liquid or containers. Good ventilation should be use. Ventilation should be matched to conditions.

Respiratory Protection: Not required when handling liquid or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.

Personal Protection: Not required when handling final product. If containers are compromised or exposure is likely wear: goggles, lab coat, and gloves.

Recommended Facilities: Eye wash, washing facilities

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor: Opaque orange-colored, orange-flavored
Melting Point (deg. C): Not determined.
Boiling Point (deg. C): Not determined.
Solubility: Insoluble

10. STABILITY AND REACTIVITY

Chemical Stability: Stable
Conditions to Avoid: Protect from freezing and light.
Incompatibility: Not determined.
Hazardous Decomposition: May produce noxious or toxic products.
Hazardous Polymerization: Does not occur.

11. TOXICOLOGICAL INFORMATION

Acute Studies:

Oral LD50 (rat): 1635 mg/kg
Oral LD50 (mouse): 150 mg/kg

Other Studies:

Pregnancy: Pregnancy Category D.
To provide information regarding the effects of in utero exposure to Phenytoin Oral Suspension, physicians are advised to recommend that pregnant patients taking Phenytoin Oral Suspension enroll in the NAAED Pregnancy Registry. This can be done by calling the toll free number 1-888-233-2334, and must be done by patients themselves. Information on the registry can also be found at the website <http://www.aedpregnancyregistry.org/>.

Nursing Mothers: Infant breast feeding is not recommended for women taking this drug because phenytoin appears to be secreted in low concentrations in human milk.

Pediatrics: See dosage and administration.

12. ECOLOGICAL INFORMATION

Environmental Effects: Not determined.

13. WASTE DISPOSAL INFORMATION

Waste Disposal Considerations: Dispose of this material in accordance with applicable international, national, state and local waste disposal regulations.

At Home: Discard away from children's reach.

14. TRANSPORTATION INFORMATION

This product is authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals.

15. REGULATORY INFORMATION

FDA: Phenytoin Oral Suspension is an approved prescription medication.

Inventory Status: The material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.
This material is not listed on the DSL Inventory but is exempt.

16. DISCLAIMER

The above information has been obtained from a number of sources and its accuracy cannot be guaranteed. It is the user's responsibility to evaluate the information and use it in a prudent manner for its particular purpose. VistaPharm, Inc. assumes no responsibility for the use of this information.

Date: May 2010

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION