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PHENYTOIN CHEWABLE TABLETS, USP 50 MG SAFETY DATA SHEET

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

Product Identifier

Product name: Phenytoin Chewable Tablets, USP 50 mg

Intended Use of the Product

Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information.

Name, Address, and Telephone of the Responsible Party

Supplier:

Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Road
Morgantown, WV 26505 USA
+1 304-599-2595

www.mylan.com

Emergency Telephone Number

Emergency number : +1 877-446-3679

2. HAZARDS IDENTIFICATION

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions. Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and by Canada's Food and Drugs Act. It is in solid, final form for direct administration to the patient. Therefore, is it exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(5)(iii) and in Canada's Hazardous Products Act.

3. COMPOSITION/INFORMATION ON INGREDIENTS

This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and by Canada's Food and Drugs Act. It is in solid, final form for direct administration to the patient. Therefore, is it exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(5)(iii) and in Canada's Hazardous Products Act.

4. FIRST AID MEASURES

Description of First Aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice.

Inhalation: The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

Skin Contact: Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

Eye Contact: The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion: Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention (show the label where possible).

Most Important Symptoms and Effects Both Acute and Delayed

General: Please refer to the package insert for more detailed information.

Inhalation: None expected under normal conditions of use.

Skin Contact: May cause mild skin irritation.

Eye Contact: May cause minor eye irritation.

Ingestion: Pharmaceutical. Ingestion is likely to be harmful or have adverse effects.

Chronic symptoms: May cause cancer. May cause genetic defects. May damage fertility or the unborn child.

Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

5. FIREFIGHTING MEASURES

Extinguishing Media

Suitable extinguishing media: Not flammable. Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media: None known.

Special Hazards Arising From the Substance or Mixture

Fire hazard: Not flammable.

Explosion hazard: Product itself is not explosive but if dust is generated, dust clouds suspended in air can be explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

Advice for Firefighters

Precautionary measures fire: Exercise caution when fighting any chemical fire.

Firefighting instructions: Use water spray or fog for cooling exposed containers.

Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂).

Other information: Refer to Section 9 for flammability properties.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

General measures: Avoid all eye and skin contact and do not breathe dust.

For Non-Emergency Personnel

Protective equipment: Use appropriate personal protection equipment (PPE).

Emergency procedures: Evacuate unnecessary personnel.

For Emergency Personnel

Protective equipment: Use appropriate personal protection equipment (PPE).

Emergency procedures: Avoid creating or spreading dust. Evacuate unnecessary personnel. Ventilate area.

Environmental Precautions Prevent entry to sewers and public waters.

Methods and Material for Containment and Cleaning Up

Methods for cleaning up: For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, collect spillage by sweeping up or vacuuming spilled material and place in a labeled, sealed container for proper disposal. If sweeping is required and dust is present, use a dust suppressant. Vacuum must be fitted with HEPA filter to prevent release of particulates during clean-up.

Reference to Other Sections See heading 8, Exposure Controls and Personal Protection.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

Hygiene measures: This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

Conditions for Safe Storage, Including Any Incompatibilities

Storage conditions: Store in a dry, cool and well-ventilated place. Protect from heat and direct sunlight.

Specific End Use(s) Pharmaceutical. Refer to product insert for usage instructions and product information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters Not applicable

Exposure Controls

Appropriate engineering controls: Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal protective equipment: Not generally required. The use of personal protective equipment may be necessary as conditions warrant.

Hand protection: Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.

Eye protection: In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.

Skin and body protection: In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.

Respiratory protection: When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if found to be necessary.

9. PHYSICAL AND CHEMICAL PROPERTIES**Information on Basic Physical and Chemical Properties**

Physical state	: Solid
Appearance	: Pink, round tablets
Odor and Odor threshold	: Not available
pH	: Not available
Relative evaporation rate (butyl acetate=1)	: Not available
Melting/Freezing point	: Not available
Boiling point	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition Temperature	: Not available
Flammability (solid, gas)	: Not available
Upper and Lower flammable limit	: Not available
Vapor pressure	: Not available
Relative vapor density at 20 °C	: Not available
Relative density/Specific gravity	: Not available
Solubility	: Not available
Log Pow/Log Kow	: Not available
Viscosity	: Not available
Explosion data - sensitivity to mechanical impact	: Not available
Explosion data - sensitivity to static discharge	: Not available

10. STABILITY AND REACTIVITY

Reactivity Hazardous reactions will not occur under normal conditions.

Chemical Stability Stable under normal conditions.

Possibility of Hazardous Reactions Hazardous polymerization will not occur.

Conditions to Avoid Direct sunlight. Extremely high or low temperatures.

Incompatible Materials Strong oxidizers. Strong bases. strong acids.

Hazardous Decomposition Products Carbon oxides (CO, CO₂). Nitrogen oxides.

11. TOXICOLOGICAL INFORMATION**Information on Toxicological Effects - Product**

Acute toxicity: Not classified

LD50 and LC50 Data: Not available

Skin Corrosion/Irritation: Not classified

Serious Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: May cause genetic defects.

Teratogenicity: Not available

Carcinogenicity: May cause cancer.

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: May damage fertility or the unborn child.

Specific Target Organ Toxicity (Single Exposure): Not classified

Aspiration Hazard: Not classified

Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data: Not available

12. ECOLOGICAL INFORMATION

Toxicity Not available

Persistence and Degradability Not available

Bioaccumulative Potential Not available

13. DISPOSAL CONSIDERATIONS

Waste disposal recommendations: Do not dispose of waste into sewer. Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations.

14. TRANSPORT INFORMATION

In Accordance With ICAO/IATA/DOT/TDG

UN Number Not regulated for transport

UN Proper Shipping Name Not regulated for transport

15. REGULATORY INFORMATION

US Federal Regulations Not applicable

US State Regulations Not applicable

Canadian Regulations

Phenytoin Chewable Tablets, USP 50 mg

WHMIS Classification | Uncontrolled product according to WHMIS classification criteria

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all of the information required by CPR.

16. OTHER INFORMATION

Revision date : 09/11/2014

Data sources : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

Other information : This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warnings included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

Party Responsible For The Preparation Of This Document:

Mylan Global Environmental, Health, and Safety Department

Phone Number: 304-599-2595

This MSDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions.

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

North America Mylan Pharmaceuticals