

# MATERIAL SAFETY DATA SHEET

Boehringer Ingelheim Pharmaceuticals, Inc.

**Dulcolax<sup>®</sup> Suppositories**

900 Ridgebury Road  
P.O. Box 368  
Ridgefield, CT 06877  
(203) 798-5521 9AM - 4PM EST

DATE ISSUED 9/4/01

**EMERGENCY TELEPHONE NUMBER**  
**CHEMTREC - 24 hours**  
**1-800-424-9300**

## 1. SUBSTANCE IDENTIFICATION

CHEMICAL NAME: Bis(p-acetoxyphenyl)-2-pyridylmethane

CAS TYPE: 1

GENERIC NAME: Bisacodyl

MOLECULAR FORMULA: C<sub>22</sub>H<sub>19</sub>NO<sub>4</sub>

TRADEMARK: DULCOLAX<sup>®</sup> Tablets

MOLECULAR WEIGHT: 361.42

CHEMICAL FAMILY: Laxative

CAS NUMBER: 603-50-9

SYNONYMS: Laxans, Theralax, Dulcolan, Durolox, LA 96a, Pylilax

## 2. COMPONENTS PER UNIT DOSE

MATERIAL

EXPOSURE LIMITS

**Active Ingredient:**

Bisacodyl

No TLV established\*

**Excipients:**

Hydrogenated vegetable oil

10mg/m<sup>3</sup> (as a mist) 2000 ACGIH TLV<sup>®</sup>  
Booklet

## 3. HAZARD IDENTIFICATION

## EMERGENCY OVERVIEW

**For Product:**

Warning! Exposing product to high heat or flames may cause harmful fumes.

**ROUTES OF ENTRY:** Ingestion, Skin and Eye contact.

**ACUTE EXPOSURE:** Eye, skin (especially moist skin).

**SIGNS AND SYMPTOMS OF EXPOSURE:** Mucous membrane irritation; abdominal cramps; diarrhea.

**CHRONIC EXPOSURE:** Possible hypersensitization (development of abnormal sensitivity).

**CARCINOGENICITY:** Not listed as carcinogen/potential carcinogen by NTP, IARC Monographs or OSHA.

**CONTRAINDICATIONS:** This product should not be used by patients with acute surgical abdomen, appendicitis, rectal bleeding, gastroenteritis, or intestinal obstruction. **Dulcolax**<sup>®</sup> is not recommended when abdominal pain, nausea, or vomiting are present.

**ADVERSE REACTIONS TO PRODUCT:** Abdominal discomfort.

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## 4. EMERGENCY FIRST AID PROCEDURES

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**INGESTION:** Rinse out mouth then give 3-4 glasses of water, but **DO NOT** induce vomiting. If vomiting occurs, give fluids again. Get medical attention to determine whether vomiting or evacuation of stomach is necessary. Do not give anything by mouth to an unconscious or convulsing person.

**SKIN CONTACT:** Remove contaminated clothing. Wash affected areas with plenty of water, and soap if available, for several minutes. Seek medical attention if irritation or rash develops and persists.

**INJECTION:** In case of accidental injection, wash and thoroughly disinfect, get medical attention.

**EYE CONTACT:** Flush eyes with large amounts of running water for 15 minutes. Get immediate medical attention.

**INHALATION:** Remove from area to fresh air. Seek medical attention if respiratory irritation develops or if breathing becomes difficult.

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## 5. FIRE AND EXPLOSION HAZARD DATA

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**Flash Point**  
N/A

**Flammable Limits**  
**Upper**  
N/A

**Lower**  
N/A

**FIRE EXTINGUISHING MEDIA:** Water spray, dry chemicals, carbon dioxide or foam as appropriate for surrounding fire and materials.

**SPECIAL FIRE FIGHTING PROCEDURES:** As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use water spray to keep fire-exposed containers cool and protect against all exposures.

**UNUSUAL FIRE AND EXPLOSION HAZARDS:** It can burn in a fire, producing acrid fumes including acid gases, and oxides of carbon and nitrogen.

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## **6. SPILL AND ACCIDENTAL RELEASE MEASURES**

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**STEPS TO BE TAKEN IN THE EVENT OF A SPILL:** STEPS TO BE TAKEN IN THE EVENT OF A SPILL: Wear chemically compatible gloves if containers have been compromised. Vacuum or sweep up spillage. Avoid creating dust. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before reuse. Ventilate area, wash down spill site and control wash water. Do not allow product to reach sewage system or waterway.

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## **7. PRECAUTIONS FOR SAFE HANDLING AND USE**

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**HANDLING AND STORAGE PRECAUTIONS:** Avoid contact with eyes, skin or clothing. Avoid breathing dust. Avoid generating dust. Store in tight, light-resistant containers away from foodstuffs.

**OTHER PRECAUTIONS:** Wash thoroughly after handling material. Wear fresh clothing daily. Wash contaminated clothing before reuse.

Store at temperatures below 77°C (25°C). Avoid excessive humidity.

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## **8. CONTROL MEASURES**

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**ENGINEERING CONTROLS: VENTILATION:** General ventilation should be adequate to maintain exposure levels below recommended established exposure limits. If general ventilation is not sufficient, local exhaust is recommended.

**RESPIRATORY PROTECTION:** A qualified person should determine the need for respiratory protection. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

### **PERSONAL PROTECTIVE EQUIPMENT**

**Eye Protection:** Safety glasses with side shields or goggles

**Hand Protection:** Disposable gloves

**Protective Clothing:** Laboratory coats or protective work clothing

**Other:** Eye wash & safety shower

**WORK/HYGIENIC PRACTICES:** Do not permit eating, drinking or smoking near this material. Wash thoroughly after handling material, before eating and at the end of work.

## 9. PHYSICAL/CHEMICAL CHARACTERISTICS

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### For Product:

APPEARANCE AND ODOR: Waxy bullet shaped suppositories

### For Active Ingredient:

APPEARANCE AND ODOR: Colorless, odorless suppositories.

Boiling Point: N/A

Vapor Pressure (mmHg): N/A

Vapor Density: N/A

Water Solubility: Practically Insoluble

Specific Gravity: N/A

Melting Point: N/E

Evaporation Rate: N/A

pH: N/A

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## 10. REACTIVITY DATA

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STABILITY: Stable

CONDITIONS TO AVOID: Do not expose to open fire.

INCOMPATIBLE MATERIALS: N/D

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: Oxides of carbon and nitrogen.

HAZARDOUS POLYMERIZATION: Will not occur.

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## 11. TOXICOLOGICAL INFORMATION

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### ACUTE TOXICITY:

4,320 mg/kg oral – rat

17,500 mg/kg oral – mouse

> 15gm/kg oral - dog

TERATOGENICITY: No epidemiological studies of congenital abnormalities in infants whose mothers were treated with Bisacodyl during pregnancy have been reported. No animal teratology studies of Bisacodyl have been reported.

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## 12. ECOLOGICAL INFORMATION

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None known.

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## 13. DISPOSAL CONSIDERATIONS

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**WASTE DISPOSAL CONSIDERATIONS:** Dispose of in accordance with local, state and federal regulations. Recommended method is by incineration.

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## 14. TRANSPORT INFORMATION

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This product is not subject to the regulations for the safe transport of hazardous materials

DOT Hazard Class: Not regulated.

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## 15. REGULATORY INFORMATION

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This 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.

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## 16. OTHER INFORMATION

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### ABBREVIATIONS:

BIPI - Boehringer Ingelheim Pharmaceuticals, Inc.

N/A - Not applicable

### PREPARATION INFORMATION

Prepared by: Environmental Affairs & Safety

### REVISION INFORMATION:

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