

MATERIAL SAFETY DATA SHEET

Boehringer Ingelheim Pharmaceuticals, Inc.
Consumer Healthcare Products
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Dulcolax® Tablets

Revised: 06/07/06

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

1. SUBSTANCE IDENTIFICATION

CHEMICAL NAME: 4, 4'-(2-pyridinylmethylene) bisphenol, diacetate ester

GENERIC NAME: Bisacodyl

MOLECULAR FORMULA: C₂₂H₁₉NO₄

TRADEMARK: Dulcolax®

MOLECULAR WEIGHT: 361.42

CHEMICAL FAMILY: Diphenylmethane Derivative
Stimulant Laxative

CAS NUMBER: 603-50-9

PRODUCT USE: Relieves occasional constipation and irregularity

SYNONYMS: Laxans, Theralax, Dulcolan, Durolax, LA 96a, Pylilax, bis (p-acetoxyphenyl)-2-pyridylmethane

2. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW

Physical State: 5 mg tablets – Light orange enteric coated tablets.

Low hazard if taken as directed.
Keep out of reach of children.

Potential Health Effects Product:

CONTRAINDICATIONS: Hypersensitivity to Bisacodyl® or to any other component of the therapeutic system. This product should not be used by patients with acute surgical abdomen, appendicitis, rectal bleeding, gastroenteritis, colostomy or intestinal obstruction. Dulcolax® is not recommended when abdominal pain, nausea or vomiting are present. Do not take if unable to swallow without chewing.

ADVERSE REACTIONS TO PRODUCT: Abdominal discomfort, nausea, diarrhea, in rare circumstances, skin rash.

Dulcolax® Tablet

WARNING

Do not chew or crush tablet.
Do not use if unable to swallow without chewing.
Do not use within 1 hour after taking an antacid or milk.
Do not use if rectal bleeding occurs or if there has not been a bowel movement in 12 hours.
Do not use a laxative for more than a week.
If pregnant or breast-feeding, ask a doctor before use.
May interact with other drugs.

Overdosage: Symptoms of overexposure are watery stools (diarrhea), abdominal pain, hypokalemia, secondary hyperaldosteronism and renal calculi. Renal tubular damage, metabolic alkalosis and muscle weakness secondary to hypokalemia has been associated with laxative abuse. In case of overdose, get medical attention or contact a Poison Control Center immediately.

ROUTES OF ENTRY: Ingestion

ACUTE EXPOSURE:

INHALATION: Not expected to be an inhalation hazard.

EYE CONTACT: Not expected to be a hazard to the eye.

SKIN CONTACT: Can cause hypersensitive reactions. Exposure may cause severe rash, redness, itching and inflammation, which in some cases have been life-threatening.

INGESTION: Low hazard if taken as directed. May cause stomach discomfort, faintness or abdominal cramps.

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

TARGET ORGANS: Gastrointestinal tract, skin

MEDICAL CONDITIONS POTENTIALLY AGGRAVATED BY EXPOSURE: Gastrointestinal disorders.

OSHA REGULATORY STATUS: OSHA Exempt for Product, FDA Regulated.

CARCINOGENICITY: Not listed as a carcinogen or potential carcinogen by NTP, IARC Monographs or OSHA. Titanium Dioxide: IARC 2B (possibly carcinogenic to humans).

3. COMPONENTS PER UNIT DOSE

MATERIAL	WT	EXPOSURE LIMITS
Active Ingredient: Bisacodyl	5 mg	25 ug/m ³ BIEL (Category 3A)
Excipients:		
FD & C Red No. 30 aluminum lake		No TLV established
FD & C Yellow No. 10 aluminum lake		No TLV established
Dibutyl phthalate		No TLV established
Docusate sodium		No TLV established
Gelatin		No TLV established
Glycerin		ACGIH 8-hr TLV-TWA 10mg/m ³ (Glycerin, mist: irritation)

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Iron oxides	OSHA Z-1 PEL 5 mg/m ³ (Glycerin mist, respirable fraction)
Kaolin	OSHA Z-1 PEL 15 mg/m ³ (Glycerin mist, total dust) No TLV established
Lactose	ACGIH 8-hr TLV-TWA 2 mg/m ³ (Kaolin, respirable fraction: Pneumoconiosis)
Magnesium Stearate	OSHA Z-1 PEL 5 mg/m ³ (Kaolin, respirable fraction) OSHA Z-1 PEL 15 mg/m ³ (Kaolin, total dust) No TLV established
Methylparaben	ACGIH 8-hr TLV-TWA 10mg/m ³ (Generic group name: Stearates; except stearates of toxic metals :Irritation)
Polyethylene Glycol	No TLV established
Povidone	No TLV established
Propylparaben	No TLV established
Sodium benzoate	No TLV established
Sorbitan monooleate	No TLV established
Sucrose	No TLV established ACGIH 8-hr TLV-TWA 10mg/m ³ (Lung) OSHA Z-1 PEL 5 mg/m ³ (Sucrose, respirable fraction) OSHA Z-1 PEL 15 mg/m ³ (Sucrose, total dust)
Talc	ACGIH 8-hr TLV-TWA 2 mg/m ³ (Talc, containing no asbestos fibers, respirable fraction: lung) OSHA Z-3 8-hr TWA 20 mppcf (Silicates, less than 1% crystalline silica: Talc : not containing asbestos) OSHA Z-3 8-hr TWA 2.4 mppcf ; .1 mg/m ³ (Talc not containing asbestos; 1% or more crystalline silica : respirable OSHA Z-3 8-hr TWA .3 mg/m ³
Titanium Dioxide	ACGIH 8-hr TLV-TWA 10mg/m ³ (Lung) OSHA Z-1 PEL 15 mg/m ³ (Titanium dioxide: total dust)

*BIEL is the BI Exposure Control Level. Where lower governmentally imposed occupational exposure limits exist, such limits should take precedence.

4. EMERGENCY FIRST AID PROCEDURES

Persons developing anaphylactic (life-threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.

Product:

INHALATION: Should not pose a hazard in final form. Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.

EYE CONTACT: Should not pose a hazard in final form. Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses if worn. Get medical attention if irritation persists.

SKIN CONTACT: Should not pose a hazard in final form. Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention.

INGESTION: Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: There are no specific antidotes that are required to be administered in the event of overdose; however, supportive care may be required to prevent dehydration and/or electrolyte imbalance.

5. FIRE AND EXPLOSION HAZARD DATA

Flash Point	Flammable Limits	
	Upper	Lower
N/A	N/A	N/A

FIRE EXTINGUISHING MEDIA: Water spray, dry chemical, carbon dioxide or material appropriate for surrounding fire.

SPECIAL FIRE FIGHTING PROCEDURES: Wear self-contained breathing apparatus and protective clothing. Cool fire exposed containers with water.

UNUSUAL FIRE AND EXPLOSION HAZARDS: None

HAZARDOUS COMBUSTION PRODUCTS: Carbon dioxide, carbon monoxide, oxides of nitrogen

6. SPILL AND ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF TABLETS ARE BROKEN: Wear an approved respirator, eye protection, personal protective coverings and gloves. Use HEPA filtered vacuum or wet sweeping to clean up spillage. Avoid dust. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before use.

7. PRECAUTIONS FOR SAFE HANDLING AND USE

HANDLING AND STORAGE PRECAUTIONS: Store in a tight container. Store below 25°C (77°F). Keep in a dry place. Avoid excessive humidity. Store away from foodstuffs.

HANDLING SIGNIFICANT QUANTITIES OF BROKEN TABLETS: Avoid contact with eyes, skin and clothing. Avoid generating dust. Wash hands thoroughly after handling.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls: Not generally required when handling containers or tablets. (See Section 3 for exposure limits). Good ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If operations involve crushing or other processes that may release powder, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Respiratory Protection: Not generally required when handling containers or tablets. The need for respiratory protection should be determined by an industrial hygiene survey. (See Section 3 for exposure limits). NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

PERSONAL PROTECTIVE EQUIPMENT: Not generally required when handling containers. If containers are compromised or exposure to the active ingredient or mixture is likely wear:

Eye Protection: Safety goggles w/side shields (or goggles)	Hand Protection: Neoprene or nitrile gloves
Protective Clothing: Laboratory coats	Other: Eye wash

WORK/HYGIENIC PRACTICES: Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work.

9. PHYSICAL/CHEMICAL CHARACTERISTICS

For Product:

APPEARANCE AND ODOR: 5 mg tablets – Light orange enteric coated tablets

Boiling Point: N/A

Vapor Pressure (mmHg): N/A

Vapor Density: N/A

Water Solubility: Practically insoluble

Freezing Point: N/A

Flammable Limits: N/A

Flashpoint: N/A

Specific Gravity: N/A

Melting Point: 132 - 135°C (268-275°)

Evaporation Rate: N/A

Autoignition Temperature: N/A

Decomposition Temperature: N/A

Partition Coefficient (n-Octanol/water): N/A

Volatiles, %: N/A

10. REACTIVITY DATA

STABILITY: Stable

CONDITIONS TO AVOID: None known

INCOMPATIBLE MATERIALS: None known

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

HAZARDOUS POLYMERIZATION: Will not occur.

11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY:

Active Ingredient:

LD₅₀ Oral (rat) – 6, 670 mg/kg

LD₅₀ Oral (mouse) – 17, 500 mg/kg

TERATOGENICITY: - PREGNANCY CATEGORY B: **No evidence of risk in humans.** Either animal studies show risk, but human findings do not, or animal studies show no risk; however, adequate human studies have not been performed. Consult physician before using if you suspect you are pregnant, pregnant or nursing.

Studies of oral doses of **Dulcolax** have been performed in rats administered up to 70 times the human dose, and have revealed no evidence to the fetus. At the dose which equated to 70 times the human dose, there was some evidence of lower litter survival at weaning. There are, however, no adequate and well-controlled studies in pregnant women; hence **Dulcolax** should be used in pregnancy only at the discretion of the physician. Clinical experience has shown that **Dulcolax** tablets can be administered for constipation during pregnancy (Happert, 1963; Smith, 1964), and postpartum (Sichel, 1961). Due to the minimal extent of bisacodyl systemic absorption associated with **Dulcolax** usage, it is believed that the risk of harm to the fetus is very low. However, because animal reproduction studies are not always predictive of human response, **Ducolax** should be used in pregnancy only at the discretion of the physician.

IMPAIRMENT OF FERTILITY: Studies of oral doses of Ducolax have been performed in rats administered up to 70 times the human dose, and have revealed no evidence of impaired fertility.

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CARCINOGENESIS/MUTAGENESIS: Not listed as a carcinogen or potential carcinogen by NTP, IARC Monographs or OSHA.

12. ECOLOGICAL INFORMATION

No information is available.

13. DISPOSAL CONSIDERATIONS

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

For Product: (At Home):
Discard away from children's reach.

14. TRANSPORT INFORMATION

Product:

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

DOT: Not regulated

TDG: Not regulated

IATA: Not regulated

IMDG: Not regulated

15. REGULATORY INFORMATION

CANADIAN CONTROLLED PRODUCTS REGULATIONS: This product has been classified in according to the hazard criteria of the Canadian Controlled Products Regulations, Section 33, and the MSDS contains all required information.

WHMIS CLASSIFICATION FOR ACTIVE INGREDIENT: Controlled, D2B

WHMIS CLASSIFICATION FOR PRODUCT: Noncontrolled, exempt.

INVENTORY STATUS:

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.

This material is **not** listed on the DSL Inventory.

16. OTHER INFORMATION

ABBREVIATIONS:

BIPI - Boehringer Ingelheim Pharmaceuticals, Inc.
mppcf – million particles/cubic foot
N/A - Not applicable.
N/E - Not established.

PREPARATION INFORMATION

Dulcolax® Tablet

Prepared by: BIPI Environmental Affairs & Safety.

Date Revised: 06/07/06

Replaces: 05/98

REVISION INFORMATION: Section 1- Updated Product Use; Section 2 & 3- Reversed for ANSI Compliance, Section 2- All sections updated, Section 3 – Updated Exposure Limits, Section 4- Updated Emergency First Aid Procedures, Section 5 – Unusual Fire and Explosion Hazards; Section 6- Updated Spill and Accidental Release Measures, Section 7- Updated, Section 8- Updated, Section 10- Updated Conditions to Avoid, Section 13-Updated, Section 14- Added IATA, TDG, IMDG, Section 15- Added WHMIS, Canadian Inventory.

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION

REFERENCES

1. American Hospital Formulary Service, 2003
2. Ariel Research ChemExpert: Registry of Toxic Effects of Chemical Substances.
3. Ariel Research, ChemExpert Database
4. Ariel Research, Global Regulatory Database
5. Ariel Research, Hazardous Substance Bank
6. BIPI MSDS, May 1998
7. PDR for Nonprescription Drugs® and Dietary Supplements™

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