

MATERIAL SAFETY DATA SHEET

Boehringer Ingelheim Pharmaceuticals, Inc.

Dulcolax[®] Balance

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DATE ISSUED 6/4/2009

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

1. SUBSTANCE IDENTIFICATION

CHEMICAL NAME: Polyethylene Glycol 3350

GENERIC NAME: PEG-75

MOLECULAR FORMULA: $H(OCH_2CH_2)_nOH$

TRADEMARK: DULCOLAX[®] Balance

MOLECULAR WEIGHT: 3,350

CHEMICAL FAMILY: Laxative

CAS NUMBER²: 25322-68-3

SYNONYMS: PEG-75; Carbowax [™]; Sentry [™]; Polyethylene Glycol 3350 Granular NF, FCC Grade Uninhibited; Macrogol 3350 Ph. Eur.

2. COMPONENTS PER UNIT DOSE

MATERIAL

EXPOSURE LIMITS

Active Ingredient:

Polyethylene Glycol 3350

10 mg/M3 (8 Hour TWA – AIHA in Aerosol Form)

3. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW

For Product:

White Granules with mild odor

Warning! Direct water stream, for fire fighting, may spread fire.

For Active Ingredient:

White Granules with mild odor.

Caution! Dusts may be harmful if inhaled. May cause slight eye irritation and/or prolonged contact may cause skin irritation with local redness.

Danger! Dusts may form explosive clouds. High heat or flames may cause harmful fumes.

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

ACUTE EXPOSURE: Eye, skin (especially abraded skin) irritation.

SIGNS AND SYMPTOMS OF EXPOSURE: Upset stomach; bloating; gas; abdominal cramps; diarrhea; and hives.

CHRONIC EXPOSURE: No information currently available.

MEDICAL CONDITIONS POTENTIALLY AGGRAVATED BY EXPOSURE: Repeated or prolonged exposure is not known to aggravate medical conditions.

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

For Product:

CONTRAINDICATIONS: This product should not be used by patients with bowel obstruction or intestinal obstruction. Do not use this medication if you are allergic to polyethylene glycol, or if you have a bowel obstruction or intestinal blockage. If you have any these conditions, you could have dangerous or life-threatening side effects from Dulcolax® Balance. People with eating disorders (such as anorexia or bulimia) should not use this medication without the advice of a doctor. Before taking Dulcolax® Balance, tell your doctor if you are allergic to any drugs, or if you have: nausea, vomiting, or severe stomach pain; ulcerative colitis; irritable bowel syndrome; kidney disease; or a sudden change in bowel habits that has lasted 2 weeks or longer.

ADVERSE REACTIONS TO PRODUCT: Upset stomach; bloating; gas; abdominal cramps; diarrhea; and hives.

4. EMERGENCY FIRST AID PROCEDURES

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

INGESTION: Rinse mouth out with large amounts of water. Do not induce vomiting or give anything by mouth to an unconscious or convulsing person. Seek medical attention.

INHALATION: Remove affected person to a well ventilated area and get immediate medical attention. If breathing is difficult, give oxygen. If breathing stops, start artificial respiration.

SKIN CONTACT: Remove contaminated clothing. Flush affected area with copious amounts of water. If irritation or a rash develops, get medical attention.

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

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 246° C (Closed Cup)	Flammable Limits	
	Upper N/A	Lower N/A

FIRE EXTINGUISHING MEDIA: Water fog or fine spray. Dry chemical fire extinguishers. Carbon dioxide fire extinguishers. Foam. Do not use direct water stream. May spread fire. Alcohol resistant foams (ATC type) are preferred. General purpose synthetic foams (including AFFF) or protein foams may function, but will be less effective

SPECIAL FIRE FIGHTING PROCEDURES: Keep people away. Isolate fire and deny unnecessary entry. Use water spray to cool fire exposed containers and fire affected zone until fire is out and danger of re-ignition has passed. Fight fire from a protected location or safe distance. Consider the use of unmanned hose holders or monitor nozzles. Immediately withdraw all personnel from the area in case of rising sound from venting safety device or discoloration of the container. Burning liquids may be extinguished by dilution with water. Do not use direct water stream. May spread fire. Hand held dry chemical or carbon dioxide extinguishers may be used for small fires. Dust explosion hazard may result from forceful application of fire extinguisher agents. Move container from fire area if this is possible without hazard. Burning liquids may be moved by flushing with water to protect personnel and minimize property damage.

SPECIAL PROTECTIVE EQUIPMENT FOR FIREFIGHTERS: Wear positive-pressure self-contained breathing apparatus (SCBA) and protective fire fighting clothing (includes fire fighting helmet, coat pants, boots, and gloves). If protective equipment is not available or not used, fight fire from a protected location or safe distance.

UNUSUAL FIRE AND EXPLOSION HAZARDS: Container may rupture from gas generation in a fire situation. Violent steam generation or eruption may occur upon application of direct water stream to hot liquids. Do not permit dust to accumulate. When suspended in air, dust can pose an explosion hazard. Minimize ignition sources. If dust layers are exposed to elevated temperatures, spontaneous combustion may occur. Pneumatic conveying and other mechanical handling operations can generate combustible dust. To reduce the potential for dust explosions, electrically bond and ground equipment and do not permit dust to accumulate. Dust can be ignited by static discharge.

For Product:
None known.

6. SPILL AND ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN THE EVENT OF A SPILL: Wear approved respirator and chemically compatible gloves. Vacuum or sweep up spillage. Avoid creating dust. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before reuse. Ventilate area and wash spill site.⁵

7. PRECAUTIONS FOR SAFE HANDLING AND USE

HANDLING AND STORAGE PRECAUTIONS

For Product:

Store material in original product container at room temperature.

For Active Ingredient:

Keep away from heat. Keep away from sources of ignition. Empty containers may pose a fire risk. Ground all equipment containing material. Do not ingest. Do not breathe the dust. If material is ingested, seek medical advice immediately and show the container or label.

Keep container dry. Keep in a cool, well ventilated place. Ground all equipment containing material. Keep container tightly sealed. Combustible materials should be stored away from extreme heat and away from strong oxidizing agents. Use product promptly after opening. Store in following materials: stainless steel; polypropylene; polyethylene lined container; Teflon; glass-lined container; Plasite 3066 lined container; Plasite 3070 lined container; and/or 316 stainless steel.

OTHER PRECAUTIONS: Avoid breathing dust and skin contact. Wash thoroughly after handling material. Wear fresh clothing daily. Wash contaminated clothing before reuse.

8. CONTROL MEASURES

For Active Ingredient:

ENGINEERING CONTROLS: Minimize dust generation. Use closed equipment where possible. Use spot ventilation to remove dusts from the work area. If operations generate dusts, use explosion-proof ventilation equipment to control airborne levels. (See Section 2 for exposure limits.) Use appropriate respiratory protection based on an industrial hygiene survey.

RESPIRATORY PROTECTION: The need for respiratory protection should be determined by an industrial hygiene survey. NIOSH/MSHA approved dust respirators for protection against dust should be used if respirators are found to be necessary.

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.

PERSONAL PROTECTIVE EQUIPMENT

Eye Protection: Safety Goggles
Protective Clothing: Full body suit

Hand Protection: Disposable Gloves
Other: Eye wash

WORK/HYGIENIC PRACTICES: Do not permit eating, drinking or smoking near this material.⁵

For Product:

Control methods should not be required if patient follows instructions on product label and package or under guidance of their personal health care provider.

9. PHYSICAL/CHEMICAL CHARACTERISTICS

For Product:

APPEARANCE AND ODOR: White Granules with mild odor.

For Active Ingredient:

APPEARANCE AND ODOR: White Granules with mild odor.

Boiling Point: > 200 ° C - > 392° C Decomposes	Specific Gravity (H ₂ O = 1): 1.111
Vapor Pressure (mmHg): < 0.01 mmHg	Melting Point: 129-136°F (54-58°C)
Vapor Density (air = 1): > 10	Percent Volatiles: 0.15 Wt%
Water Solubility (By Weight): 67% @ 20°C	pH (1% soln/water): 6

10. REACTIVITY DATA

STABILITY: Stable

CONDITIONS TO AVOID: Product can oxidize at elevated temperatures. Generation of gas during decomposition can cause pressure in closed systems.

INCOMPATIBLE MATERIALS: Strong Acids; Bases; and Oxidizers

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: (Decomposition products depend upon temperature, air supply, and the presence of other materials) Carbon Dioxide; Alcohols; Ethers; Hydrocarbons; Ketones; Polymer fragments.

HAZARDOUS POLYMERIZATION: Will not occur.

11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY:

Peroral

Based on information for a similar material:

Rat; LD₅₀ = > 40,000 mg/kg

Percutaneous:

Rabbit; LD₅₀ = > 20,000 mg/kg

Sensitization (Animal and Human Studies)

Did not cause allergic skin reaction when tested in humans

Chronic Toxicity and Carcinogenicity

Similar materials did not cause cancer in laboratory animals

Genetic Toxicity

In Vitro

For similar materials, *In vitro* mutagenicity studies were negative

In Vivo

For similar materials, animal mutagenicity studies were negative

Significant Data with possible relevance to humans

Based on available data, repeated exposures are not anticipated to cause significant adverse effects.

TERATOGENICITY: PREGNANCY CATEGORY C: - Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

Consult physician before using if you suspect you are pregnant, pregnant or nursing.

12. ECOLOGICAL INFORMATION

Material is readily biodegradable. Passes OECD Tests for ready biodegradability.

BOD (% Oxygen Consumption)

	Day 5	Day 10	Day 15	Day 20	Day 28/30
	5%	5%		11-23%	

Modified Sturm Test (OECD 301B) (% CO2 evolved)

	Day 5	Day 10	Day 15	Day 28
				90%

Material is practically non-toxic to aquatic organisms on an acute basis (LC₅₀/EC₅₀ > 100 mg/L in most species tested).

Toxicity to Aquatic Invertebrates

water flea *Daphnia magna*; Immobilization; EC₅₀

Result value: 22,100 mg/L

Toxicity to Fish

Fathead minnow (*Pimephales promelas*); LC₅₀

Result value: 58,900 mg/L

No bioaccumulation is expected because of the relatively high molecular weight (MW > 1,000). No bio-concentration is expected because of the relatively high water solubility. Chemical Oxygen Demand (COD) – measured 1.81 mg/mg

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL CONSIDERATIONS: Dispose of in accordance with local, state and federal regulations. Recommended method is by incineration. Do not dump into any sewers, on the ground, or into any body of water.

14. TRANSPORT INFORMATION

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

Non-Bulk

Proper Shipping Name: Not Regulated

Bulk

Proper Shipping Name: Not Regulated

15. REGULATORY INFORMATION

OSHA Hazard Communication Standard – This product is not a “Hazardous Chemical” as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Superfund Amendments and Reauthorization Act of 1986 Title III (Emergency Planning and Community Right to Know Act) Section 313 – To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.

Superfund Amendments and Reauthorization Act of 1986 Title III (Emergency Planning and Community Right to Know Act) Sections 311 and 312 –

Delayed (Chronic) Health Hazard:	No
Fire Hazard:	No
Immediate (Acute) Health Hazard:	No
Reactive Hazard:	No
Sudden Release of Pressure Hazard:	No

Toxic Substances Control Act (TSCA) – All components of this product are on the TSCA Inventory or are exempt from TSCA Inventory requirements

CEPA – Domestic Substance List (DSL) – All substances contained in this product are listed on the Canadian Domestic Substances List (DSL) or are not required to be listed.

European Inventory of Existing Commercial Chemical Substances (EINECS) – The components of this product are on the EINECS inventory or are exempt from the EINECS inventory requirements.

Pennsylvania (Worker and Community Right to Know Act): Pennsylvania Hazardous Substances List and/or Pennsylvania Environmental Hazardous Substance List: To the best of our knowledge this product does not contain chemicals at levels which require reporting under this statute.

Pennsylvania (Worker and Community Right to Know Act): Pennsylvania Special Hazardous Substances List: To the best of our knowledge this product does not contain chemicals at levels which require reporting under this statute.

California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986)

Warning: This product contains chemicals known to the State of California to cause cancer.

Component	CAS Number	Amount
Acetaldehyde	75-07-0	<= 0.0060%
1,4 Dioxane	123-91-1	<= 0.0001%
Ethylene oxide	75-21-8	<= 0.0001%
Formaldehyde	50-00-0	<= 0.0001%

California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986)

Warning: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

Component	CAS Number	Amount
Ethylene oxide	75-21-8	<= 0.0001%

California SCAQMD Rule 443.1 (South Coast Air Quality Management District Rule 443.1, Labeling of Materials Containing Organic Solvents)

VOC: Vapor pressure <0.01 mmHg at 20°C
1 g/l VOC
1 g/l less water and less exempted solvents

This section provides selected regulatory information on this product including its' components. This is not intended to include all regulations. It is the responsibility of the user to know and comply with all applicable rules, regulations, and laws related to the product being used.

16. OTHER INFORMATION

NFPA ratings for this product:

H – 0
F – 1
R – 0

ABBREVIATIONS:

BIPI - Boehringer Ingelheim Pharmaceuticals, Inc.
N/A - Not applicable
N/D – Not determined

PREPARATION INFORMATION

Prepared by: Environmental Affairs & Safety

Date Prepared: June 4, 2009

REVISION INFORMATION:

The opinions expressed herein are those of qualified experts within Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI). We believe that the information contained within this MSDS is current as of the date issued. Since the use of this information and these opinions and the conditions of use of this material are not within the control of BIPI, it is the user's obligation to determine the conditions of safe use of this material. BIPI urges the users of this product to study this MSDS and become aware of any hazards associated with this material. In the interests of safety, the information contained in this MSDS should be made available to your employees, agents and contractors who handle this material.

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION

REFERENCES

1. DOW MSDS #2771 dated 05/02/2002
2. Science Lab MSDS dated 11/06/2008.
3. Drugs.Com Polyethylene Glycol 3350.