

Version 1.1 Revision Date: 06/03/2015 MSDS Number: 000000036973 Date of last issue: 05/28/2015
Date of first issue: 05/28/2015

SECTION 1. IDENTIFICATION

Product name : Dulcolax® Softgel

Synonyms : Active ingredient: Docusate sodium > 20%
Dulcolax® Stool Softener, 100 mg; DulcoEase®Pink(TM)
Stool Softener (Bulk)

Product code : 000000036973

Manufacturer or supplier's details

Company name of supplier : Boehringer-Ingelheim Pharmaceuticals, Incorporated

Address : 900 Ridgebury Road
Ridgefield, Connecticut
06877-0368

Emergency telephone number : +1-800-424-9300 CHEMTREC Emergency Phone Number
CHEMTREC – 24 Hours

Routine Contact Number : (203) 778-7759

Prepared by : Corp. Div. EHS & Sustainability / Global EHS Services
EHS-service@boehringer-ingelheim.com

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification (Hazard Communication Standard (HCS) 29 CFR 1910.1200)**

Skin irritation : Category 2

Serious eye damage : Category 1

GHS Label element (Hazard Communication Standard (HCS) 29 CFR 1910.1200)

Hazard pictograms :



Signal word : Danger

Hazard statements : H315 Causes skin irritation.
H318 Causes serious eye damage.

Precautionary statements : **Prevention:**
P280 Wear protective gloves/ protective clothing/ eye protection/
face protection.
P264 Wash skin thoroughly after handling.
Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

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P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Disposal:

P501 Dispose of contents/ container to an approved incineration plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

| Chemical Name | CAS-No. | Concentration (%) |
|-----------------|----------|-------------------|
| Docusate sodium | 577-11-7 | 20 |

SECTION 4. FIRST AID MEASURES

- General advice : Remove from exposure, lie down.
Take off immediately all contaminated clothing.
Victim to lie down in the recovery position, cover and keep him warm.
First Aid responders should pay attention to self-protection and use the recommended protective clothing
- If inhaled : Move to fresh air.
Call a physician immediately.
- In case of skin contact : Wash off immediately with plenty of water.
Cover wound with sterile dressing.
Call a physician immediately.
- In case of eye contact : Rinse immediately with plenty of water for at least 15 minutes.
Keep eye wide open while rinsing.
Call a physician immediately.
- If swallowed : Rinse mouth.
Drink plenty of water.
Call a physician immediately.
- Most important symptoms and effects, both acute and delayed : No information available.
Causes skin irritation.
Causes serious eye damage.
May cause damage to organs if inhaled.
- Notes to physician : Symptomatic treatment (decontamination, vital functions).
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SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Water
Foam
Dry chemical
Carbon dioxide (CO₂)
- Specific hazards during fire-fighting : In case of fire and/or explosion do not breathe fumes.
Can be released in case of fire:
Carbon oxides
Nitrogen oxides (NO_x)
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
- Special protective equipment for firefighters : Self-contained breathing apparatus (EN 133)
complete suit protecting against chemicals
-

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Wear personal protective equipment.
Ensure adequate ventilation.
Knock down dust with water spray jet.
- Environmental precautions : Do not flush into surface water or sanitary sewer system.
- Methods and materials for containment and cleaning up : Wear personal protective equipment.
Clean-up methods - large spillage
Dampen, pick up mechanically and dispose of.
Clean-up methods - small spillage
Use approved industrial vacuum cleaner for removal.
Keep in suitable, closed containers for disposal.
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SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : No special protective measures against fire required.
- Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms.
Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces.
Minimize dust generation and accumulation.
Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Breathing must be protected when large quantities are decanted without local exhaust ventilation.

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Keep container closed when not in use.

Conditions for safe storage : Store in original container.
Protect from heat and direct sunlight.
Jointless smooth floor
Keep container tightly closed.

Materials to avoid : Keep away from food, drink and animal feedingstuffs.
Advice on Segregation

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Components with workplace control parameters**

| Components | Basis | Factor | Category | Values | Remark |
|---|-------|--------|----------|-----------------------|--------|
| Sulfosuccinate acid, bis(2-ethylhexyl)ester sodium salt 577-11-7 | ECL | | 2 | 100 µg/m ³ | |
| | BIPC | | 1b | | |
| ECL (BIPI Exposure Control Limit) | | | | | |

Contains no substances with occupational exposure limit values.

Engineering measures : It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen deficient environment.
Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).
Use only appropriately classified electrical equipment and powered industrial trucks.

Personal protective equipment

Respiratory protection : Respirator with a dust filter
particle filter P3 (EN 143)

Use NIOSH approved respiratory protection.

Hand protection Material : Nitrile rubber
Break through time : 480 min
Glove thickness : 0.43 mm
Directive : Protective gloves against chemicals and micro-organisms
Protective index : Class 6

Eye protection : Safety glasses with side-shields
(Not necessary when using full face mask)

Skin and body protection : Laboratory: laboratory coat; factory: disposable Overall.

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- Protective measures : Handle in accordance with good industrial hygiene and safety practice.
Do not breathe dust.
Avoid contact with skin, eyes and clothing.
Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.
- Hygiene measures : General industrial hygiene practice.
Wash hands and face before breaks and immediately after handling the product.
Keep working clothes separately.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : solid
- Colour : No data available
- Odour : No data available
- Odour Threshold : No data available
- pH : No data available
- Melting point/range : No data available
- Boiling point/boiling range : Not applicable
- Flash point : Not applicable
- Evaporation rate : Not applicable
- Flammability (solid, gas) : No data available
- Upper explosion limit : No data available
- Lower explosion limit : No data available
- Vapour pressure : Not applicable
- Relative vapour density : Not applicable
- Relative density : No data available
- Bulk density : No data available
- Solubility(ies)
Water solubility : No data available

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| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity | | |
| Viscosity, dynamic | : | Not applicable |
| Explosive properties | : | No data available |
| Oxidizing properties | : | No data available |

SECTION 10. STABILITY AND REACTIVITY

| | | |
|------------------------------------|---|---|
| Possibility of hazardous reactions | : | Dust may form explosive mixture in air. |
| Conditions to avoid | : | No data available |
| Incompatible materials | : | No data available |
| Hazardous decomposition products | : | No data available |

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified based on available information.

Product:

| | | |
|---------------------|---|--|
| Acute oral toxicity | : | Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method |
|---------------------|---|--|

Components:**Docosate sodium:**

| | | |
|---------------------|---|--|
| Acute oral toxicity | : | LD50 (Rat): = 1,900 mg/kg LD50 (Mouse): = 2,643 mg/kg |
|---------------------|---|--|

| | | |
|---------------------------|---|----------------------------|
| Acute inhalation toxicity | : | Remarks: No data available |
|---------------------------|---|----------------------------|

| | | |
|-----------------------|---|----------------------------|
| Acute dermal toxicity | : | Remarks: No data available |
|-----------------------|---|----------------------------|

Skin corrosion/irritation

Causes skin irritation.

Components:**Docosate sodium:**Species: Rabbit
Result: Skin irritation

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Serious eye damage/eye irritation

Causes serious eye damage.

Components:**Docosate sodium:**

Species: Rabbit

Result: Eye irritation

Assessment: Risk of serious damage to eyes.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Components:**Docosate sodium:**

Result: No alert for skin sensitization

Germ cell mutagenicity

Not classified based on available information.

Components:**Docosate sodium:**

Genotoxicity in vitro : Test Type: Ames-test
Species: Salmonella typhimurium
Result: negative

 : Test Type: Cytogenetic assay
Species: CHO (chinese hamster ovary)
Result: negative

 : Test Type: Cytogenetic assay
Species: CHO (chinese hamster ovary)
Result: positive

Genotoxicity in vivo : Remarks: No data available

Carcinogenicity

Not classified based on available information.

Components:**Docosate sodium:**

Remarks: No data available

IARC

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen

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by NTP.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

May cause damage to organs (Respiratory system) if inhaled.

Components:**Docusate sodium:**

Exposure routes: inhalation (dust/mist/fume)

Target Organs: Respiratory system

Assessment: The substance or mixture is classified as specific target organ toxicant, single exposure, category 2.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Docusate sodium:**

- Toxicity to fish : LC50 (Onchorhynchus mykiss): < 24 mg/l
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): = 10.3 mg/l
Exposure time: 48 h
Test Type: static test
- Toxicity to algae : EC50 (Desmodesmus subspicatus): = 39.3 mg/l
Exposure time: 72 h
Method: Directive 67/548/EEC, Annex V, C.3.
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available
- Toxicity to bacteria : Remarks: No data available

Persistence and degradability**Components:****Docusate sodium:**

- Biodegradability : Result: rapidly biodegradable
Biodegradation: 91.2 %
Exposure time: 28 d
Method: OECD Test Guideline 310

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Bioaccumulative potential**Components:****Docosate sodium:**

Bioaccumulation : Species: *Oncorhynchus mykiss* (rainbow trout)
Bioconcentration factor (BCF): 3.78
Exposure time: 72 d
Concentration: 5.5 mg/l

Partition coefficient: n-octanol/water : Remarks: No data available

Mobility in soil

No data available

Other adverse effects**Product:**

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents.
Uncontaminated packaging can be recycled.

SECTION 14. TRANSPORT INFORMATION**International Regulation****Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

National Regulations**SECTION 15. REGULATORY INFORMATION****EPCRA - Emergency Planning and Community Right-to-Know Act**

SARA 311/312 Hazards : Acute Health Hazard

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SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

| | | |
|----------------------------------|--------------|-----------|
| Non-hazardous galenic excipients | Not Assigned | 70 - 90 % |
| Docusate sodium | 577-11-7 | 20 - 30 % |

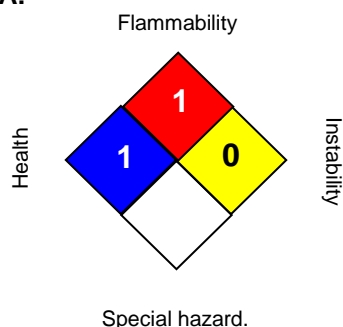
New Jersey Right To Know

| | | |
|----------------------------------|--------------|-----------|
| Non-hazardous galenic excipients | Not Assigned | 70 - 90 % |
| Docusate sodium | 577-11-7 | 20 - 30 % |

California Prop 65 : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

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SECTION 16. OTHER INFORMATION**Further information****NFPA:****HMIS III:**

| | |
|------------------------|----------|
| HEALTH | 2 |
| FLAMMABILITY | 1 |
| PHYSICAL HAZARD | 0 |

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

Vertical lines in the left hand margin indicate an amendment from the previous version. Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. Sources of key data used to compile the Safety Data Sheet : The specifications are based on own tests and/or literature data.

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.