



# SAFETY DATA SHEET

Issue Date 19-Jul-2006

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Version 1

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION

**Product Name** Colace® (docusate sodium) Capsules

**Synonyms** Docusate sodium (active ingredient)

**Recommended Use** Stool softener

**Uses advised against** No information available.

**Distributor Address** Purdue Products L.P.  
One Stamford Forum  
201 Tresser Boulevard  
Stamford, Connecticut 06901-3431  
(888) 726-7535

**24 Hour Emergency Phone Number** Chemtrec (800) 424-9300  
For all international transportation emergencies, call Chemtrec collect at (703) 527-3887.

## 2. HAZARDS IDENTIFICATION

Drugs when in solid final form (e.g. capsules, tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard, 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous.

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

### Emergency Overview

The product contains no substances which at their given concentration are considered to be hazardous to health.

**Appearance** Gelatin Capsule

**Physical state** Solid

**Odor** No characteristic odor

### Hazards Not Otherwise Classified (HNOC)

Not Applicable.

### Other Information

No information available.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No	Weight %
Docusate Sodium	577-11-7	20-30
Polyethylene glycol	25322-68-3	30-40
Propylene glycol	57-55-6	1-5

### 4. FIRST AID MEASURES

#### First aid measures

<b>Eye contact</b>	In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
<b>Skin contact</b>	In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.
<b>Inhalation</b>	In case of inhalation, remove to fresh air. If not breathing, provide artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.
<b>Ingestion</b>	In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
<b>Self-protection of the first aider</b>	Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

#### **Most important symptoms and effects, both acute and delayed**

<b>Symptoms</b>	The therapeutic use (oral administration) of this product has been associated with abdominal cramping, nausea, diarrhea, throat irritation, bitter taste, and rash.
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#### **Indication of any immediate medical attention and special treatment needed**

<b>Note to physicians</b>	Treat symptomatically.
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### 5. FIRE-FIGHTING MEASURES

#### **Suitable Extinguishing Media**

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Unsuitable Extinguishing Media** No information available.

#### **Specific hazards arising from the chemical**

No information available.

#### **Explosion Data**

**Sensitivity to Mechanical Impact** None.

**Sensitivity to Static Discharge** None.

#### **Protective equipment and precautions for firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear.

## 6. ACCIDENTAL RELEASE MEASURES

### Personal precautions, protective equipment and emergency procedures

**Personal precautions** Evacuate personnel to safe areas. Use personal protection recommended in Section 8.

**Other Information** Not Applicable.

### Environmental precautions

**Environmental precautions** See section 12 for additional Ecological Information.

### Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Pick up and transfer to properly labeled containers.

## 7. HANDLING AND STORAGE

### Precautions for safe handling

**Advice on safe handling** Avoid contact with skin, eyes or clothing. Wash thoroughly after handling. Wash contaminated clothing before reuse. Use only with adequate ventilation.

### Conditions for safe storage, including any incompatibilities

**Storage conditions** Store in a closed, airtight container. Store at room temperature.

**Incompatible materials** None known based on available information.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Exposure Guidelines** This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by specific regulatory bodies.

**Engineering Controls** Handle material under adequate ventilation (e.g., chemical fume hood, vented balance enclosure [VBE]). Keep container tightly closed. Minimize the amount of material handled at any one time.

### **Individual Protection Measures (Personal Protective Equipment)**

**Eye/face protection** None required for consumer use. In laboratory or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting or possibility of splashing. Contact a health and safety professional for specific information.

**Skin and body protection** None required for consumer use. In laboratory or industrial settings, gloves and lab coats are recommended. Contact a health and safety professional for specific information.

**Respiratory protection**

Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. In the United States of America, if respirators are used, they are to be NIOSH-approved and part of a respiratory protection program instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Contact a health and safety professional or manufacturer for specific information.

**General Hygiene Considerations**

Handle in accordance with good industrial hygiene and safety practice.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical and Chemical Properties**

<b>Physical state</b>	Solid
<b>Appearance</b>	Gelatin Capsule
<b>Odor</b>	No characteristic odor
<b>Color</b>	Clear pinkish
<b>Odor threshold</b>	No information available.

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	No information available.	
Melting point / melting range	No information available.	
Boiling point / boiling range	No information available.	
Flash point	No information available.	
Evaporation rate	No information available.	
Flammability (solid, gas)	No information available.	
Flammability limits in air		
Upper flammability limits		
Lower flammability limits		
Vapor pressure	No information available.	
Vapor density	No information available.	
Specific gravity	No information available.	
Water solubility	Miscible in water	
Solubility in other solvents	No information available.	
Partition coefficient (n-octanol/water)	No information available.	
Autoignition temperature	No information available.	
Decomposition temperature	No information available.	
Kinematic viscosity	No information available.	
Dynamic viscosity	No information available.	
Explosive properties	No information available.	
Oxidizing properties	No information available.	

**Other Information**

<b>Softening point</b>	No information available.
<b>Molecular weight</b>	No information available.
<b>VOC content; (%)</b>	No information available.
<b>Density</b>	No information available.
<b>Bulk density</b>	No information available.

## 10. STABILITY AND REACTIVITY

<b>Chemical stability</b>	Stable under recommended storage conditions.
<b>Possibility of hazardous reactions</b>	No information available.
<b>Hazardous polymerization</b>	Hazardous polymerization does not occur.
<b>Conditions to avoid</b>	None known based on available information.
<b>Incompatible materials</b>	None known based on available information.
<b>Hazardous decomposition products</b>	None known based on available information.

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

<b>Product Information</b>	No data available.
<b>Inhalation</b>	No data available.
<b>Eye contact</b>	No data available.
<b>Skin contact</b>	No data available.
<b>Ingestion</b>	No data available.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Docusate Sodium	>1900 mg/kg ( Rat ) 2643 mg/kg ( Mouse )	10000 mg/kg ( Rabbit )	-
Sorbitol	15900 mg/kg ( Rat )	-	-
Methylparaben	2100 mg/kg ( Rat )	-	-
Polyethylene glycol	28000 mg/kg ( Rat )	20 mL/kg ( Rabbit ) 20000 mg/kg ( Rabbit )	-
Propylene glycol	20000 mg/kg ( Rat )	20800 mg/kg ( Rabbit )	-

### Information on toxicological effects

<b>Symptoms</b>	The therapeutic use (oral administration) of this product has been associated with abdominal cramping, nausea, diarrhea, throat irritation, bitter taste, and rash.
<b>Skin corrosion/irritation</b>	Docusate sodium has been reported to be a moderate to severe skin irritant in animals. Propylene glycol may be a mild irritant to the skin.
<b>Serious eye damage/eye irritation</b>	Docusate sodium has been reported to be a moderate to severe eye irritant in animals. Propylene glycol may be a mild irritant to the eyes.
<b>Sensitization</b>	Docusate sodium was negative in a skin sensitizing study. Propylene glycol is a weak skin sensitizer.

### Delayed and immediate effects as well as chronic effects from short and long-term exposure

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<b>Germ cell mutagenicity</b>	<p>No evidence of mutagenicity in Ames bacterial tests for docusate sodium. However with S9 activation, results were observed for docusate sodium at treatment doses close to threshold toxicity.</p> <p>Propylene glycol was not found to be mutagenic in vivo in mice or bacterial assays with or without an exogenous metabolism system.</p>
<b>Carcinogenicity</b>	<p>Docusate sodium was not carcinogenic in rats at 1% of diet (about 200 mg/kg/day) during a 2-year study.</p> <p>Propylene glycol was tested in animals and found not to cause cancer.</p>
<b>Reproductive toxicity</b>	<p>No adverse effects on reproductive function or fetal development were observed in rats treated with docusate sodium at 0.5 and 1.0% dose, which were not maternally toxic [equivalent to 250 and 500 mg/kg bw]. A three-generation study in rats found oral administration of up to 1.0% docusate sodium did not affect the reproductive function nor produce treatment-related abnormalities in progeny. Docusate sodium is excreted in breast milk and may cause increased bowel activity in nursing infants. Altered levels of magnesium in maternal and fetal blood have been noted following chronic maternal ingestion of docusate sodium during pregnancy.</p> <p>In a study using very high oral doses, propylene glycol was found to affect breeding capacity and the ability to nurse offspring in rats. A continuous breeding reproduction study in mice failed to show reproductive toxicity following oral administration.</p>
<b>STOT-single exposure</b>	No information available.
<b>STOT-repeated exposure</b>	No information available.
<b>Chronic Toxicity</b>	<p>Docusate sodium showed no significant adverse effects at the doses administered in rat 2-year and dog 1-year studies. In dogs receiving an oral dose of 100 mg/kg of a surfactant containing an unspecified amount of docusate sodium for 24 weeks, no test article related toxic effects were seen. Three monkeys received an oral dose of 125 mg/kg/day of a surfactant containing an unspecified amount of docusate sodium for 24 weeks. All animals survived and there were no lesions seen at necropsy in any of the animals. Mice receiving docusate sodium orally for 2 years had reduced body weight gain as compared to controls.</p> <p>Minor chronic organ damage (liver, kidneys) had been noted in animal studies involving propylene glycol. Effects to blood were noted in a study where repeated IV injections of propylene glycol were given in a 2-year study with dogs. These results would not be expected to be observed with use of this product as recommended on the label.</p>
<b>Subchronic toxicity</b>	<p>Docusate sodium is typically given orally as a laxative for adults and children. Treatment, which may continue for one week or a period of time as perscribed by a healthcare professional, has not normally resulted in any overt adverse effects or clinical changes.</p> <p>Only minor toxic effects have been reported after repeated exposure to propylene glycol. Other effects were noted after higher, repeated exposures well above clinical doses (i.e. CNS depression).</p>
<b>Aspiration hazard</b>	No information available.

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**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Docusate Sodium		LC50 96 h = 37 mg/L (Lepomis macrochirus - static) LC50 96 h < 24 mg/L (Oncorhynchus mykiss - static) LC50 96 h 20 - 40 mg/L (Oncorhynchus mykiss - semi-static)		EC50 48 h = 36 mg/L (Daphnia magna - static)
Polyethylene glycol		LC50 24 h > 5000 mg/L (Carassius auratus)		
Propylene glycol	EC50 96 h = 19000 mg/L (Pseudokirchneriella subcapitata - )	LC50 96 h = 710 mg/L (Pimephales promelas) LC50 96 h = 51600 mg/L (Oncorhynchus mykiss - static) LC50 96 h 41 - 47 mL/L (Oncorhynchus mykiss - static) LC50 96 h = 51400 mg/L (Pimephales promelas - static)		EC50 24 h > 10000 mg/L (Daphnia magna - static) EC50 48 h > 1000 mg/L (Daphnia magna - static)

Persistence and degradability      No information available.

Bioaccumulation      No information available.

**Other adverse effects**      No information available.

**13. DISPOSAL CONSIDERATIONS**

**Waste treatment methods**

**Disposal of wastes**      Disposal should be in accordance with applicable regional, national, and local laws, and regulations.

**Contaminated Packaging**      Do not reuse container.

**14. TRANSPORT INFORMATION**

**DOT**      Not regulated.

**IATA**      Not regulated.

## 15. REGULATORY INFORMATION

### International Inventories

TSCA Not determined.  
DSL Not determined.

### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8 (b) Inventory  
**DSL/NDL** - Canadian Domestic Substances List/Non-Domestic Substances List

### US Federal Regulations

#### SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

#### SARA 311/312 Hazard Categories

<b>Acute Health Hazard</b>	No
<b>Chronic Health Hazard</b>	No
<b>Fire Hazard</b>	No
<b>Sudden Release of Pressure Hazard</b>	No
<b>Reactive Hazard</b>	No

#### CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

#### CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

### US State Regulations

#### California Proposition 65

This product does not contain any Proposition 65 chemicals.

#### US State Right-to-Know Regulations

This product does not contain any substances regulated by state right-to-know regulations.

#### US EPA Label Information

**EPA Pesticide Registration Number** Not Applicable.

## 16. OTHER INFORMATION

<b>NFPA</b>	<b>Health Hazards</b> 0	<b>Flammability</b> 0	<b>Instability</b> 0	<b>Physical and Chemical Properties</b> -
<b>HMIS</b>	<b>Health Hazards</b> 0	<b>Flammability</b> 0	<b>Physical Hazards</b> 0	<b>Personal protection</b> X

#### General Information

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.

#### Prepared By

This SDS was prepared by the Occupational and Environmental Assessment Section of Purdue Pharma L.P.

#### Issue Date

19-Jul-2006

#### Revision Date

23-Apr-2015



**Revision Note**

SDS reformated for OSHA (GHS) 2012.

**Disclaimer**

The information contained in this Safety Data Sheet is believed to be accurate and represents the best information available at the time of preparation. However, no warranty, express or implied, with respect to such information, is made. The data in this Safety Data Sheet relate only to the specific material designated herein and do not relate to use in combination with any other material. The data in this Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

**End of Safety Data Sheet**