

## Docusate Sodium USP

### Active Ingredient for Laxatives & Stool Softeners

Docusate sodium USP (DSS) is used extensively in stool softener formulations to provide consistent, predictable, and gentle relief. This highly effective and versatile anionic surfactant (surface active agent) is used as an active ingredient in a variety of combination laxative/stool softener formulations. Cytec's pharmaceutical-grade DSS products are manufactured to the highest quality standards under cGMP, and offer exceptional quality and performance as both active ingredients and as excipients.

#### Applications

In addition to being used as a formulating aid (excipient) in oral dosage forms, DSS is particularly effective as an active ingredient in:

- Laxatives & stool softeners – for prevention and treatment of various types of constipation
- Prenatal & geriatric vitamin preparations – to overcome constipation induced by iron salts
- Colon cleansing aids – in preparation of a patient for X-ray examination or surgery

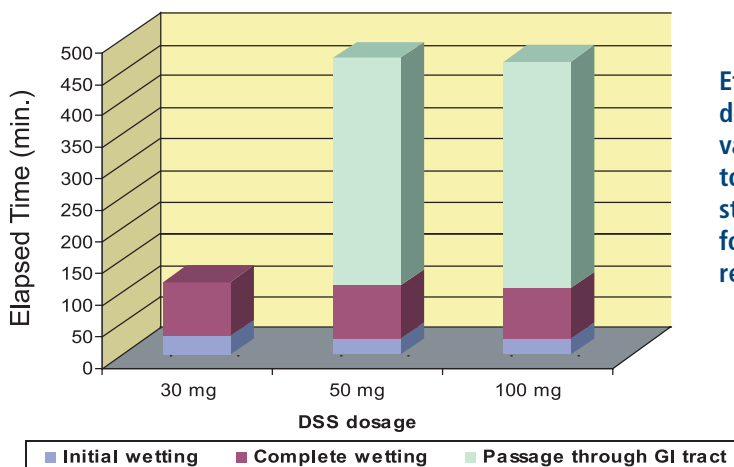
#### Features

- Pharmaceutical grade, manufactured under cGMP; EP and USP compliant
- Virtually free from adverse reactions when used in recommended doses
- Effective alone or in combination with peristaltic stimulants and bulking agents
- 3 product forms: 100%, 85% granular, 50% in PEG

#### Benefits

- Meets standards of quality, strength, purity, and potency recognized worldwide
- Causes the least possible disturbance of normal body physiology; non habit-forming
- Allows ability to optimize formulations and enhance performance results
- Multiple product types provide flexibility in handling and ease of use

#### Timing index of stool softening with DSS

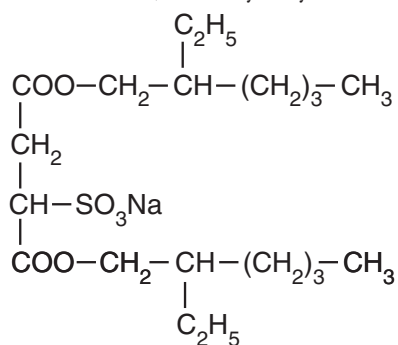


Effective dosages will vary according to laxative or stool softener formulation requirements

## Product Information

### Composition

DSS is the dioctyl ester of sodium sulfosuccinate (bis-2-ethylhexyl sodium sulfosuccinate).



Molecular formula  $\text{C}_{20}\text{H}_{37}\text{NaO}_7\text{S}$

Molecular weight 444.57

### Typical Properties

Products	100% DSS	85% DSS granular with sodium benzoate	50% DSS in polyethylene glycol
Appearance	Rolls of waxlike plastic sheets	White crystalline powder	White to yellow, clear, viscous liquid
Assay (DSS)	99.0%-100.5% on anhydrous basis	83.0%-87.0%	48.5%-51.5%
Moisture (KF titration; maximum)	2.0%	2.0%	1.0%
Heavy metals (as Pb; maximum)	10 ppm	10 ppm	10 ppm

### Storage

DSS should be stored in tightly closed containers at temperatures below 75°F (24°C) with relative humidity of less than 60%. Higher temperatures may cause the 100% material to fuse and discolor.

### Health and Safety Information

Direct contact may cause eye or skin irritation. Sodium dioctyl sulfosuccinate has acute oral LD50 values for the rat and mouse of 1,900-4,000 mg/kg and 2,640 mg/kg, respectively. Acute dermal (rabbit) LD50 value is greater than 10,000 mg/kg. Read the Cytec Industries Inc. Material Safety Data Sheet on this product, before using, for detailed safety and handling information. The Material Safety Data Sheet is available and is routinely provided at the time of first shipment of this product.

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