

Docosate Sodium U.S.P.

A Versatile Formulating Aid for Oral Dosage Forms

Docosate sodium U.S.P. (DSS) is one of the most versatile and effective anionic surfactants (surface active agents) currently available. It is an excellent solubilizing, wetting, dispersing, and emulsifying agent, beneficial for use as a formulating aid for oral dosage forms. 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 excipients.

In addition to acting as a formulating aid for oral dosage forms, DSS also has application as an active ingredient in laxative and stool softener formulations, as well as in vitamin preparations and ear wax removal compounds.

Applications

DSS is particularly suitable as an excipient in

- Aiding the granulation process – Good quality granulation may be achieved rapidly by facilitating the wetting of a relatively hydrophobic powder
- Improving tablet disintegration and dissolution – May eliminate the need to incorporate a separate disintegrating agent
- Facilitating tablet coating – Provides physical stability and enhances patient acceptance
- Emulsifying gel and liquid suspensions – Ensures homogeneity of ingredients and dosages

Features

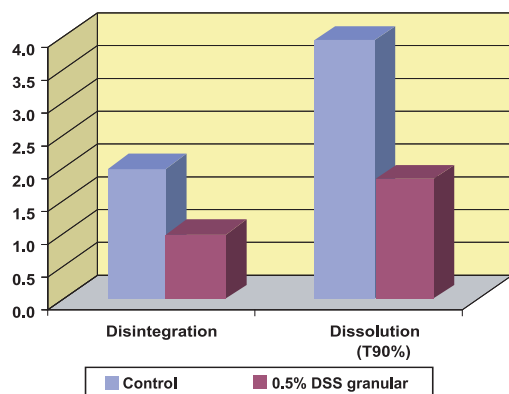
- Pharmaceutical grade, manufactured under cGMP; EP and USP compliant
- Compatible with broad range of pharmacologically active drugs
- Effective as a wetting agent at relatively low concentrations
- Promotes accelerated tablet dissolution
- Aids in uniform diffusibility of components
- Three product forms: 100%, 85% granular, 50% in PEG

Benefits

- Meets standards of quality, strength, purity, and potency recognized worldwide
- Wide range of excipient applications and pharmaceutical products
- Improves manufacturing efficiency and helps lower overall production costs
- Facilitates rapid absorption of active constituents
- Enhances efficacy of time-release formulations
- Multiple product types provide flexibility in handling and ease of use

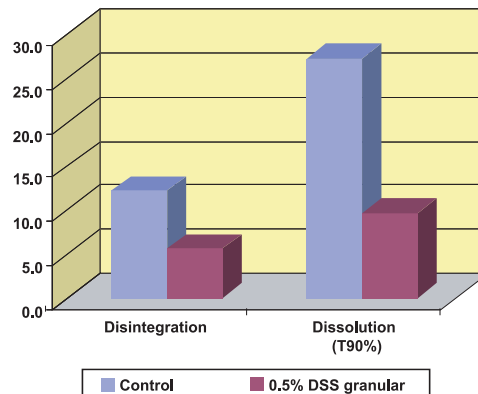
Example: Acetaminophen tablets

Granulation



DSS provided 50-65% faster disintegration and dissolution than the control tablets

Direct compression

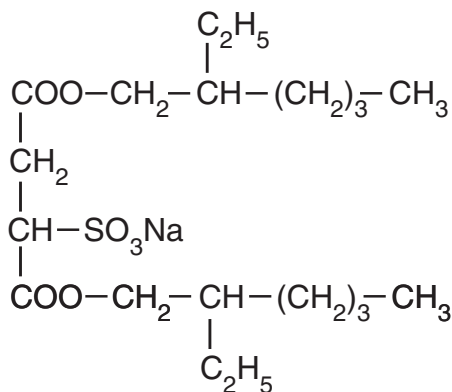


PRODUCT INFORMATION

Docosate Sodium U.S.P. (DSS)

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.

IMPORTANT NOTICE

The information and statements herein are believed to be reliable, but are not to be construed as a warranty or representation for which we assume legal responsibility or as an assumption of a duty on our part. Users should undertake sufficient verification and testing to determine the suitability for their own particular purpose of any information, products, or vendors referred to herein. NO WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE IS MADE. Nothing herein is to be taken as permission, inducement or recommendation to practice any patented invention without a license.

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10/05 FCT-225

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