

Docusate Sodium USP: A Pharmaceutical Grade Excipient

Docusate Sodium USP (DSS) is a pharmaceutical grade of the anionic surfactant, sodium dioctyl sulphosuccinate.

This powerful and versatile product has:

- Excellent solubilizing, wetting, dispersing and emulsifying properties.
- Low order of toxicity.
- Stability and compatibility with a wide range of pharmacologically active drugs.
- Proven results in many different pharmaceutical products.

Cytec's pharmaceutical-grade DSS products are manufactured to the highest quality standards under cGMP and are EP and USP compliant. Listed below are some of the known and potential uses for Docusate as an excipient.

Tableting Aid

- Helps in tablet formation giving denser, smoother, more compact tablets, which are physically stable and better accepted by patients.
- Aids in the granulation of hydrophobic powders through its wetting properties to ensure a uniform homogeneous water/oil based liquids/active ingredients blend.
- Ensures uniform diffusibility and rapid absorption eliminating the need for a separate disintegration agent.
- Facilitates tablet coating, by helping the coating "wet out on the tablet surface."

Liquid or Gel Suspensions

- Ensures homogeneous solutions of water/oil phase liquids or gel suspensions through its emulsification properties to ensuring a uniform distribution of ingredients in gelcaps, creams and gels.

Effervescing Tablets

- Aids in dispersion of ingredients in effervescing tablets.

Creams and Gels

- Acts as an emulsifier to aid in the formulation of creams or gels for topical applications.

Enema/Pre-Operative Colon Cleaners

- Use in cleaning preparations for the colon because of Docusate's stool softening and surfactant properties.

Iron Preparations

- Disperse the iron salts effectively
- Offers stool softening properties necessary with long-term use of iron preparations.

Ear Wax Removal

- Acts as a wetting agent to soften compacted wax.
- Acts as a dispersant and emulsifier to ensure that the wax is kept suspended in the solution for easier removal.

Sustained Release Dosage Forms

- At its critical micelle concentration (CMC) it rapidly traps active ingredients within micelles which could be of use in micro-encapsulation drug delivery systems.

Transdermal Patches

- Due to its wetting properties, Docusate would assist active ingredients to come into close contact with the skin and aid rapid absorption.
- Docusate could also be used in the adhesive formulation for transdermal patches, replacing industrial grade wetting agents.

Transmucosal Systems

- Docusate could be used to solubilize the active ingredients and help them spread on the nasal tissue in nasal sprays.

Biomedical Devices

- Could aid in the wetting out of blood onto the surface of biopolymers implants used for reconstructive or cosmetic surgery, to aid in the healing process.

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.

Storage and Handling

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.

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