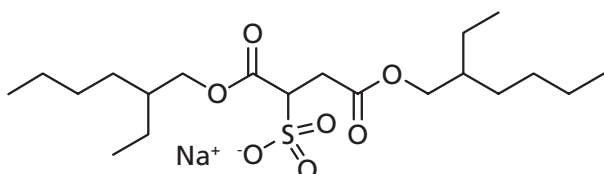


# SPECIALTY ADDITIVES

## Docusate Sodium USP (DSS)

### 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

Our pharmaceutical-grade DSS products are manufactured to the highest quality standards under cGMP and are EP and USP compliant. DSS can be used as an excipient to aid in the formulation of poorly soluble APIs using three different manufacturing techniques:

- Granulation Processes
- Nanoparticulate Systems
- Hot Melt Extrusion (HME)

Some of the other known uses for Docusate as an excipient include:

#### 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.

### TYPICAL PROPERTIES

Products	100% DSS	85% DSS granular with sodium benzoate
Appearance	Rolls of waxlike plastic sheets	White crystalline powder
Assay (DSS)	99.0%-100.5% on anhydrous basis	83.0%-87.0%
Moisture (KF titration; maximum)	2.0%	2.0%
Heavy metals (as Pb; maximum)	10 ppm	10 ppm

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## TYPICAL PROPERTIES

Applications	Typical Use Levels:
Wetting agent	0.025%-0.25%
Tablet formulations	0.1%-1.0% by weight
Tablet coating formulations	20% typical
Solubilizing agent for dyes, chlorophyll, bile acids	0.1%-1.0% on weight of material
Emulsifying agent for oil and water mixtures.	Amount of DSS required must be determined for each application
Dispersing agent for hard-to-wet materials.	Amount of DSS required must be determined for each application

## PACKAGING

Docusate sodium is available in tamper proof, sealed containers.

## STORAGE AND HANDLING

Docusate sodium should be stored at temperatures around 24°C with a relative humidity of about 60%. Detailed handling and storage information on this product can be found in the corresponding Material Safety Data Sheet.

## HEALTH AND SAFETY INFORMATION

Before handling this material, read the corresponding Material Safety Data Sheet for safety, health and environmental data.

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