Not appropriate for regulatory submission. Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.
Dear Customer,

Thank you for your interest in Spectrum’s quality products and services.

Spectrum has been proudly serving our scientific community for over 45 years. It is our mission to manufacture and distribute fine chemicals and laboratory products with Quality and delivery you can count on every time.

To accomplish our mission, Spectrum utilizes our sourcing leverage and supplier qualification expertise in offering one of the industry’s most comprehensive line of fine chemical products under one brand, in packaging configurations designed to meet your research and production requirements. Our product grades include: USP, NF, BP, EP, JP, FCC, ACS, KSA, Reagent grade, as well as DEA controlled substances. We operate facilities in the United States on the East Coast, West Coast, as well as in Shanghai, China in order to provide the best logistical support for our customers.

At Spectrum, Quality is priority number one. Suppliers with the best qualifications are preferred and we employ full-functioning in-house analytical laboratories at each of our facilities. Our facilities and systems are USFDA registered and ISO certified. We frequently host customer audits and cherish opportunities for improvements. Quality is engrained into our culture. Quality is priority number one.

In the following pages, we have designed and prepared documented scientific information to aid you in your initial qualification or your continual use of our products. Please do not hesitate to contact us if further information or the most up-to-date documentation is desired from any of the covered areas.

We appreciate your business and we look forward to hearing from you.

Sincerely,

Alan Wang, MSQA, ASQ CQA
Senior Manager of Technical Services
techservices@spectrumchemical.com

DO105, Docusate Sodium, USP

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● Product Specification

● Safety Data Sheet (SDS)

● Manufacturer

● Certification of Quality Management System (QMS)

● Certification of current Good Manufacturing Practices (cGMP)

● Product BSE/TSE Statement

● Product Allergen Statement

● Product Aflatoxin Statement

● General Label Information – Sample Label

● Product Certificate of Analysis Sample(s)

● General Lot Numbering System Guidance

● Stability – Shelf Life Guidance
## Specification for Docusate Sodium, USP (DO105)

<table>
<thead>
<tr>
<th>Item Number</th>
<th>DO105</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>Docusate Sodium, USP</td>
</tr>
<tr>
<td>CAS Number</td>
<td>577-11-7</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>C_{20}H_{37}NaO_{7}S</td>
</tr>
<tr>
<td>Molecular Weight</td>
<td>444.56</td>
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<tr>
<td>MDL Number</td>
<td></td>
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<tr>
<td>Synonyms</td>
<td>Dioctyl Sodium Sulfosuccinate ; DSS ; Sodium 1,4-Bis(2-ethylhexyl) Sulphosuccinate</td>
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</table>

<table>
<thead>
<tr>
<th>Test</th>
<th>Specification</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Min</td>
</tr>
<tr>
<td>ASSAY (ANHYDROUS)</td>
<td>99.0 - 100.5 %</td>
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<tr>
<td>CLARITY OF SOLUTION</td>
<td>TO PASS TEST</td>
</tr>
<tr>
<td>RESIDUE ON IGNITION</td>
<td>15.5 - 16.5 %</td>
</tr>
<tr>
<td>WATER</td>
<td>2.0 %</td>
</tr>
<tr>
<td>HEAVY METALS</td>
<td>0.001 %</td>
</tr>
<tr>
<td>BIS(2-ETHYLHEXYL) MALEATE</td>
<td>0.4 %</td>
</tr>
<tr>
<td>IDENTIFICATION</td>
<td>TO PASS TEST</td>
</tr>
<tr>
<td>EXPIRATION DATE</td>
<td></td>
</tr>
<tr>
<td>RESIDUAL SOLVENTS</td>
<td></td>
</tr>
</tbody>
</table>

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Spectrum Chemical Mfg Corp

**Corporate Headquarters:**
769 Jersey Ave.
New Brunswick, NJ 08901
732.214.1300

**West Coast Facility:**
14422 S. San Pedro St.
Gardena, CA 90248
310.516.8000
SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier

Product code: DO105
Product Name: DOCUSATE SODIUM, USP

Other means of identification

Synonyms:
- Di-(2-ethylhexyl) sodium sulfosuccinate
- Dioctlyl
- Dioctyl
- Dioctyl ester of sodium sulfosuccinate
- Dioctyl ester of sodium sulfosuccinic acid
- Dioctyl-medo forte
- Dioctyl sodium sulfosuccinate
- Dioctyl sulfosuccinate sodium
- Dioctyl sulfosuccinate sodium salt
- 2-Ethylhexyl sulfosuccinate sodium
- Bis(ethylhexyl) ester of sodium sulfosuccinic acid
- Bis-2-ethylhexylester sulfojantaranu sodneho (Czech)
- Bis(2-ethylhexyl)sodium sulfosuccinate
- Bis(2-ethylhexyl) S-sodium sulfosuccinate
- 1,4-Bis(2-ethylhexyl) sodium sulfosuccinate
- Butanedioic acid, sulfo-, 1,4-bis(2-ethylhexyl) ester, sodium salt
- Sodium bis(2-ethylhexyl) sulfosuccinate
- Sodium di-(2-ethylhexyl) sulfosuccinate
- Sodium dioctyl sulfosuccinate
- Sodium dioctyl sulphosuccinate
- Sodium 2-ethylhexylsulfosuccinate
- Sodium sulfodi-(2-ethylhexyl)-sulfosuccinate
- Sulfosuccinic acid, bis(2-ethylhexyl)ester sodium salt

CAS #: 577-11-7
RTECS #: WN0525000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: No information available.
Uses advised against: No information available

Supplier:
Spectrum Chemical Mfg. Corp
14422 South San Pedro St.
Gardena, CA  90248
(310) 516-8000

Order Online At: https://www.spectrumchemical.com

Emergency telephone number:
Chemetrec 1-800-424-9300

Product code: DO105  Product name: DOCUSATE SODIUM, USP
2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity - Oral</td>
<td>Category 4</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>Category 2</td>
</tr>
<tr>
<td>Serious eye damage/eye irritation</td>
<td>Category 2A</td>
</tr>
</tbody>
</table>

Label elements

Warning

Hazard statements
Harmful if swallowed
Causes skin irritation
Causes serious eye irritation

Hazards not otherwise classified (HNOC)
Not Applicable

Other hazards
Not available

Precautionary Statements - Prevention
Do not eat, drink or smoke when using this product
Wash face, hands and any exposed skin thoroughly after handling
Wear protective gloves
Wear eye/face protection

Precautionary Statements - Response
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
IF ON SKIN: Wash with plenty of water
If skin irritation occurs: Get medical advice/attention
Take off contaminated clothing and wash it before reuse
IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Weight %</th>
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</thead>
<tbody>
<tr>
<td>Docusate Sodium</td>
<td>577-11-7</td>
<td>100</td>
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</tbody>
</table>

Product code: DO105
Product name: DOCUSATE SODIUM, USP
4. FIRST AID MEASURES

First aid measures

General Advice: National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention. If skin irritation persists, call a physician.

Eye Contact: Flush eyes with water for 15 minutes. Get medical attention.

Inhalation: Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion: Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.

Most important symptoms and effects, both acute and delayed


Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically

Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste

5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Dry chemical. Water spray mist or foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products: Carbon oxides, Sulfur oxides, sodium oxides

Specific hazards: May be combustible at high temperatures

Special Protective Actions for Firefighters

Specific Methods: No information available.

Special Protective Equipment 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: Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions: Provide sufficient air exchange and/or exhaust in work rooms. Keep away from incompatible materials.

Safe Handling Advice Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Do not ingest. Do not breathe vapors/dust. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions: Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials. Hygroscopic.

Incompatible Materials: Oxidizing agents.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

<table>
<thead>
<tr>
<th>Components</th>
<th>OSHA</th>
<th>NIOSH</th>
<th>ACGIH</th>
<th>AIHA WHEEL</th>
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<td>None</td>
<td>None</td>
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<tr>
<td>577-11-7</td>
<td></td>
<td></td>
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<td></td>
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</table>

Canada

<table>
<thead>
<tr>
<th>Components</th>
<th>Alberta</th>
<th>British Columbia</th>
<th>Ontario</th>
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<tbody>
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<tr>
<td>577-11-7</td>
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Australia and Mexico

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<tbody>
<tr>
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</tr>
<tr>
<td>577-11-7</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Product code: DO105  Product name: DOCUSATE SODIUM, USP
Appropriate engineering controls

Engineering measures to reduce exposure: Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection: Safety glasses Safety glasses with side-shields

Skin and body protection: Chemical resistant apron. Long sleeved clothing. Gloves.

Respiratory protection: Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds), inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.

Hygiene measures: Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES
### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Solid</td>
</tr>
<tr>
<td>Appearance</td>
<td>Flakes. Waxy.</td>
</tr>
<tr>
<td>Color</td>
<td>White</td>
</tr>
<tr>
<td>Odor</td>
<td>odor suggestive of octyl alcohol. Soapy.</td>
</tr>
<tr>
<td>Taste</td>
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<tr>
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<tr>
<td>Decomposition temperature (°C/°F)</td>
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<tr>
<td>Density (g/cm³)</td>
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</tr>
<tr>
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</tr>
<tr>
<td>Evaporation rate</td>
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<tr>
<td>Vapor density</td>
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</tr>
<tr>
<td>Odor threshold (ppm)</td>
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<tr>
<td>Partition coefficient (n-octanol/water)</td>
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</tr>
<tr>
<td>Miscibility</td>
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</tr>
<tr>
<td>Solubility</td>
<td>Soluble in Acetone</td>
</tr>
<tr>
<td></td>
<td>Soluble in Carbon tetrachloride</td>
</tr>
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<td></td>
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</tr>
<tr>
<td></td>
<td>Soluble in hot water</td>
</tr>
<tr>
<td></td>
<td>Soluble in Petroleum Ether</td>
</tr>
<tr>
<td></td>
<td>Soluble in organic solvents</td>
</tr>
<tr>
<td></td>
<td>Soluble in Xylene</td>
</tr>
<tr>
<td></td>
<td>Partially soluble in cold water</td>
</tr>
<tr>
<td></td>
<td>Freely soluble in Glycerin</td>
</tr>
<tr>
<td></td>
<td>Solubility in Water: 15 g/L @ 25°C; 23 g/L @ 40°C; 30 g/L @ 50°C; 55 g/L @ 70°C</td>
</tr>
<tr>
<td>Flow rate</td>
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<tr>
<td>Vapor density</td>
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<td>VOC content (g/L)</td>
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<td>Flammability</td>
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<tr>
<td>Flashpoint (°C/°F)</td>
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<tr>
<td></td>
<td>Soluble in organic solvents</td>
</tr>
<tr>
<td></td>
<td>Soluble in Xylene</td>
</tr>
</tbody>
</table>

### 10. STABILITY AND REACTIVITY

**Reactivity**
Reactive with oxidizing agents

**Chemical stability**
Stability: Hygroscopic. Stable under recommended storage conditions.

**Possibility of Hazardous Reactions:**
Hazardous polymerization does not occur

**Conditions to avoid:**

**Incompatible Materials:**
Oxidizing agents.

**Hazardous decomposition products:**
Carbon oxides. Sulfur oxides. Sodium oxides.

**Other Information**
Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:
Eyes. Ingestion. Inhalation. Skin.

Acute Toxicity

Component Information

*Docusate Sodium - 577-11-7*

<table>
<thead>
<tr>
<th>Route</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50/oral/rat</td>
<td>1900 mg/kg Oral LD50 Rat</td>
</tr>
<tr>
<td>LD50/oral/mouse</td>
<td>2643 mg/kg oral LD50 mouse</td>
</tr>
<tr>
<td>LD50/dermal/rabbit</td>
<td>10000 mg/kg Dermal LD50 Rabbit</td>
</tr>
<tr>
<td>LD50/dermal/rat</td>
<td>No information available</td>
</tr>
<tr>
<td>LC50/inhalation/rat</td>
<td>No information available</td>
</tr>
<tr>
<td>LC50/inhalation/mouse</td>
<td>No information available</td>
</tr>
</tbody>
</table>

Other LD50 or LC50 information = No information available

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = 1900mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = 2643mg/kg

LD50/dermal/rabbit
VALUE-Acute Tox Dermal = 10000mg/kg

LD50/dermal/rat
VALUE -Acute Tox Dermal = No information available

LC50/inhalation/rat
VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse
VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: Causes skin irritation.

Eye Contact: Causes serious eye irritation.

Inhalation: It is a waxy solid in the form of flakes and it not expected to cause irritation of the respiratory tract. Not expected to be an inhalation hazard.

Product code: DO105  Product name: DOCUSATE SODIUM, USP
Ingestion

Harmful if swallowed. May cause gastritis. May cause hypermotility, diarrhea. May affect behavior/central nervous system (somnolence). May cause decreased appetite or anorexia. May cause vomiting. May cause bloating.

Aspiration hazard

No information available

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

Chronic Toxicity

Prolonged and repeated ingestion may cause weight loss or anorexia. Prolonged or repeated ingestion may cause gastritis. Prolonged or repeated ingestion may cause hypermotility and diarrhea. Prolonged or repeated ingestion may affect the blood (changes in serum composition).

Sensitization:

No information available

Mutagenic Effects:

No information available

Carcinogenic effects:

Not considered carcinogenic

<table>
<thead>
<tr>
<th>Components</th>
<th>IARC</th>
<th>ACGIH - Carcinogens</th>
<th>NTP</th>
<th>OSHA HCS - Carcinogens</th>
<th>Australia - Notifiable Carcinogenic Substances</th>
<th>Australia - Prohibited Carcinogenic Substances</th>
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<tbody>
<tr>
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<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
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</tbody>
</table>

Reproductive toxicity

No data is available

Reproductive Effects:

May cause adverse reproductive effects based on animal data

Evidence of reproductive in animals is limited and is only reported in the Registry of Toxic Effects of Chemical Substances (RTECS)

No information on reproductive toxicity effects on humans was found

Developmental Effects:

Evidence of developmental effects in animals is limited and is only reported in the Registry of Toxic Effects of Chemical Substances (RTECS)

No information on developmental toxicity effects on humans was found

Teratogenic Effects:

No information available

Specific Target Organ Toxicity

STOT - single exposure: No information available

STOT - repeated exposure: No information available

Target Organs: No information available

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: Aquatic environment.

**Docusate Sodium - 577-11-7**

**Freshwater Fish Species Data:**

- 20 - 40 mg/L LC50 Oncorhynchus mykiss 96 h semi-static 1
- 24 mg/L LC50 Oncorhynchus mykiss 96 h static 1
- 37 mg/L LC50 Lepomis macrochirus 96 h static 1

**Water Flea Data:**

- 36 mg/L EC50 Daphnia magna 48 h

**Product code:** DO105 **Product name:** DOCUSATE SODIUM, USP
Persistence and degradability: No information available
Bioaccumulative potential: No information available
Mobility: No information available

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:
Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:
Empty containers should be taken for local recycling, recovery or waste disposal

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Docusate Sodium</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

14. TRANSPORT INFORMATION

DOT
UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: None
ERG No: No information available
Marine Pollutant: No data available
DOT RQ (lbs): No information available
Special Provisions: No Information available
Symbol(s): No information available

TDG (Canada)
UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant: No Information available

ADR
UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Packing Group: No information available
Subsidiary Risk: No information available

IMO / IMDG
UN-No: Not Regulated

Product code: DO105  Product name: DOCUSATE SODIUM, USP
**14. TRANSPORT INFORMATION**

- **Proper Shipping Name:** No information available
- **Hazard Class:** No information available
- **Subsidiary Risk:** No information available
- **Packing Group:** No information available
- **Marine Pollutant:** No information available

**RID**
- **UN-No:** Not Regulated
- **Proper Shipping Name:** No information available
- **Hazard Class:** No information available
- **Subsidiary Risk:** No information available
- **Packing Group:** No information available

**ICAO**
- **UN-No:** Not Regulated
- **Proper Shipping Name:** No information available
- **Hazard Class:** No information available
- **Subsidiary Risk:** No information available
- **Packing Group:** No information available

**IATA**
- **UN-No:** Not Regulated
- **Proper Shipping Name:** No information available
- **Hazard Class:** No information available
- **Subsidiary Risk:** No information available
- **Packing Group:** No information available
- **ERG Code:** No information available
- **Special Provisions:** No information available

**15. REGULATORY INFORMATION**

### International Inventories

<table>
<thead>
<tr>
<th>Components</th>
<th>U.S. TSCA</th>
<th>KOREA KECL</th>
<th>Philippines (PICCS)</th>
<th>Japan ENCS</th>
<th>CHINA</th>
<th>Australia (AICS)</th>
<th>EINECS-No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Docusate Sodium</td>
<td>Present</td>
<td>Present KE-32402</td>
<td>Present</td>
<td>Present (2)-1623</td>
<td>Present</td>
<td>Present</td>
<td>Present 209-406-4</td>
</tr>
</tbody>
</table>

### U.S. Regulations

- **Docusate Sodium**
  - **FDA - Direct Food Additives:** 21 CFR 172.810
  - **FDA - 21 CFR - Total Food Additives:**
    - 131.130 131.132 133.124 133.133 133.134 133.162 133.178 133.179 163.117 169.115
    - 169.150 172.520 172.808 172.810 175.105 175.300 175.320 176.170 176.180 176.210
    - 177.1200 177.2800 178.1010 178.3400 73.1


- **Chemicals Known to the State of California to Cause Cancer:**
  This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

- **Chemicals Known to the State of California to Cause Reproductive Toxicity:**
  This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

<table>
<thead>
<tr>
<th>Components</th>
<th>Carcinogen</th>
<th>Developmental Toxicity</th>
<th>Male Reproductive Toxicity</th>
<th>Female Reproductive Toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Docusate Sodium</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
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</table>

**Product code:** DO105  
**Product name:** DOCUSATE SODIUM, USP
### CERCLA/SARA

<table>
<thead>
<tr>
<th>Components</th>
<th>CERCLA - Hazardous Substances and their Reportable Quantities</th>
<th>Section 302 Extremely Hazardous Substances and TPQs</th>
<th>Section 302 Extremely Hazardous Substances and RQs</th>
<th>Section 313 - Chemical Category</th>
<th>Section 313 - Reporting de minimis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Docusate Sodium</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

### U.S. TSCA

<table>
<thead>
<tr>
<th>Components</th>
<th>TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)</th>
<th>TSCA 8(d) - Health and Safety Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Docusate Sodium</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

### Canada

**WHMIS hazard class:**
- D2B  Toxic materials

**Canada Controlled Products Regulation:**
This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

<table>
<thead>
<tr>
<th>Components</th>
<th>WHMIS Ingredient Disclosure List -</th>
</tr>
</thead>
<tbody>
<tr>
<td>Docusate Sodium</td>
<td>1 %</td>
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</tbody>
</table>

### Inventory

<table>
<thead>
<tr>
<th>Components</th>
<th>Canada (DSL)</th>
<th>Canada (NDSL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Docusate Sodium</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>CEPA Schedule I - Toxic Substances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Docusate Sodium</td>
<td>Not listed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Docusate Sodium</td>
<td>Not listed</td>
</tr>
</tbody>
</table>

### EU Classification

**R-phrase(s)**
- R22 - Harmful if swallowed.
- R36 - Irritating to eyes.
- R38 - Irritating to skin.

**S-phrase(s)**
- S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- S37 - Wear suitable gloves.
- S39 - Wear eye/face protection.
- S46 - If swallowed, seek medical advice immediately and show this container or label.

<table>
<thead>
<tr>
<th>Components</th>
<th>Classification</th>
<th>Concentration Limits:</th>
<th>Safety Phrases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Docusate Sodium</td>
<td></td>
<td>No information</td>
<td></td>
</tr>
</tbody>
</table>
The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:
Xn - Harmful.
Xi - Irritant.

16. OTHER INFORMATION

Preparation Date: 5/18/2016
Revision Date: 5/18/2016
Prepared by: Sonia Owen

Disclaimer: All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet
Manufacturer

Product Covered: DO105, Docusate Sodium, USP

Spectrum takes ownership as the manufacturer for the Spectrum product listed above and provides full quality assurance, customer service, and technical product support.

While information concerning the raw material manufacturer of our starting materials is considered proprietary, such information can be made available upon request contingent on demonstration of business volume justification and successful execution of confidential disclosure agreement (CDA).

Requests for disclosure of proprietary raw material manufacturer information may be submitted to the assigned account representative for consideration.

Sincerely,

Alan Wang, MSQA, ASQ CQA
Senior Manager of Technical Services
techservices@spectrumchemical.com

Certificate of Registration

Intertek

This is to certify that the quality management system of

Spectrum Chemicals and Laboratory Products, Inc

Main Site: 14422 South San Pedro Street, Gardena, California, 90248, USA
Additional Sites: 13915 South Main Street, Los Angeles, California, 90061, USA
755 Jersey Avenue, New Brunswick, New Jersey, 08901, USA
769 Jersey Avenue, New Brunswick, New Jersey, 08901, USA
7400 North Oracle Road, Suite 221, Tucson, Arizona, 85704, USA

has been assessed and registered by Intertek as conforming to the requirements of

ISO 9001:2008

The quality management system is applicable to

California and New Jersey sites: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.

Arizona site: Supporting Spectrum’s two manufacturing facilitates by: selecting and qualifying distributors of Laboratory and Safety Equipment; processing bids and quotes to generate new sales opportunities; sourcing bulk chemicals in support of bulk bids and quotes; assisting production operations through order expediting and IT infrastructure support.

Certificate Number: 94-316m-01
Initial Certification Date: 27 December 1994
Certificate Issue Date: 29 January 2016
Certificate Expiry Date: 14 September 2018

Calin Moldovean, President
Intertek Testing Services NA, Inc.
900 Chelmsford Street, Suite 301-3, Lowell, MA, USA

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate’s validity is subject to the organization maintaining their system in accordance with Intertek’s requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

The certificate remains the property of Intertek, to whom it must be returned upon request.

CT-ISO 9001-2008-ANAB-EN-LT-L-26 jun.15
Certificate of Registration

Intertek Certification Limited is a UKAS accredited body under schedule of accreditation no. 014.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the client, and then only in accordance with the agreed upon Certification Agreement. This certificate’s validity is subject to the organization maintaining their system in accordance with Intertek’s requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

The annual validity of the certificate can also be checked through the website http://www.cnca.gov.cn of CNCA in China.

The certificate remains the property of Intertek, to whom it must be returned upon request.

This is to certify that the quality management system of

Spectrum China Ltd.

Building A20, No. 3802, Shengang Road, Songjiang District, Shanghai, China

has been assessed and registered by Intertek as conforming to the requirements of

ISO 9001: 2008

The quality management system is applicable to:

Provision of service of purchase, testing and sales for chemical products, repacking of non-hazardous chemical products.

Organization Code: 77762704-8
Certificate Number: 111310001-01
Certificate Issue Date: 17 November 2015
Certificate Expiry Date: 14 September 2018

Authorised Signature: Calin Moldovean – President, Business Assurance
Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom

In the issuance of this certificate, Intertek assumes no liability to any party other than to the client, and then only in accordance with the agreed upon Certification Agreement. This certificate’s validity is subject to the organization maintaining their system in accordance with Intertek’s requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

The annual validity of the certificate can also be checked through the website http://www.cnca.gov.cn of CNCA in China.

The certificate remains the property of Intertek, to whom it must be returned upon request.
March 28, 2016

Certificate of cGMP

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify that our USP, NF, FCC, EP, BP, JP, and food grade products are produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Spectrum is an FDA registered and inspected drug establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824
Spectrum -Shanghai, China: 3006174778

Thank you for your interest with Spectrum products. Please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Michelle Weston
Quality Assurance Specialist
Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Product Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>DO105</td>
<td>Docusate Sodium, USP</td>
</tr>
</tbody>
</table>

Spectrum is an FDA registered and inspected drug establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

- Spectrum-Gardena, CA: 2020632
- Spectrum-New Brunswick, NJ: 2246824
- Spectrum-Shanghai, China: 3006174778

Thank you for your interest with Spectrum products. Please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Michelle Weston
Quality Assurance Specialist
May 27, 2016

Re: Docusate Sodium, USP- DO105

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding Bovine Spongiform Encephalopathy (BSE). Please be assured that the chemical Docusate Sodium, USP- DO105 is BSE/TSE free.

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at techservices@spectrumchemical.com.

Sincerely,

Darlene Dagdag-Lyudmirskiy
Technical Services
Spectrum Chemical Mfr. Corp.

This document has been produced electronically and is valid without a signature
May 27, 2016

Re: Docusate Sodium, USP- DO105

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding the presence of allergens in raw materials. Please be assured that the following chemical does not contain (Milk; Egg; Fish; Shellfish; Sulfur dioxide and sulfites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO₂; Lupin; Tree nuts; Mollusks; Wheat; Peanuts; Soy; Cereals containing Gluten; Celery; Mustard; Sesame Seed).

Docusate Sodium, USP- DO105

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at techservices@spectrumchemical.com.

Sincerely,

Darlene Dagdag-Lyudmirskiy
Technical Services
Spectrum Chemical Mfr. Corp.

This document has been produced electronically and is valid without a signature
June 2, 2016

Re: Docusate Sodium, USP-DO105

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfg. Corp. understand the concern regarding Aflatoxins in raw materials. To the best of our knowledge, the product listed below is not contaminated with Aflatoxins. Aflatoxins are not used in production. The following product does not come in contact with Aflatoxins at any stage of production.

Docusate Sodium, USP-DO105

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at techservices@spectrumchemical.com.

Sincerely,

Darlene Dagdag-Lyudmirskiy
Technical Services
Spectrum Chemical Mfr. Corp.

This document has been produced electronically and is valid without a signature.
DO105 - 2.5 KG

Docusate Sodium (Dioctyl Sodium Sulfosuccinate) U.S.P.

CAUTION: For manufacturing or laboratory use only. Read and understand the label and Safety Data Sheet (SDS) prior to use.

FIRST AID: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention. IF ON SKIN: Wash with plenty of water. Take off contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical attention. IF SWALLOWED: Call a POISON CENTER or physician if you feel unwell. Rinse mouth.

WARNING: This product contains a chemical known to the State of California to cause cancer.

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

HYGROSCOPIC: Keep tightly closed.

This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication.
## Certificate Of Analysis

<table>
<thead>
<tr>
<th>Item Number</th>
<th>DO105</th>
<th>Lot Number</th>
<th>2EK0262</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>Docusate Sodium, USP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAS Number</td>
<td>577-11-7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>C_{20}H_{37}NaO_{7}S</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular Weight</td>
<td>444.56</td>
<td></td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test</th>
<th>Specification</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASSAY (ANHYDROUS)</strong></td>
<td>99.0 - 100.5 %</td>
<td>99.97 %</td>
</tr>
<tr>
<td><strong>CLARITY OF SOLUTION</strong></td>
<td>TO PASS TEST</td>
<td>PASSES TEST</td>
</tr>
<tr>
<td><strong>RESIDUE ON IGNITION</strong></td>
<td>15.5 - 16.5 %</td>
<td>15.95 %</td>
</tr>
<tr>
<td><strong>WATER</strong></td>
<td>2.0 %</td>
<td>1.07 %</td>
</tr>
<tr>
<td><strong>HEAVY METALS</strong></td>
<td>0.001 %</td>
<td>&lt;0.001 %</td>
</tr>
<tr>
<td><strong>BIS(2-ETHYLHEXYL) MALEATE</strong></td>
<td>0.4 %</td>
<td>&lt;0.4 %</td>
</tr>
<tr>
<td><strong>IDENTIFICATION</strong></td>
<td>TO PASS TEST</td>
<td>PASSES TEST</td>
</tr>
<tr>
<td><strong>EXPIRATION DATE</strong></td>
<td></td>
<td>30-SEP-2020</td>
</tr>
<tr>
<td><strong>RESIDUAL SOLVENTS</strong></td>
<td>TO PASS TEST</td>
<td></td>
</tr>
<tr>
<td><strong>CLASS 2 (SOLVENT) / METHANOL</strong></td>
<td></td>
<td>&lt;3000 ppm</td>
</tr>
<tr>
<td><strong>APPEARANCE</strong></td>
<td></td>
<td>WAXY SOLID</td>
</tr>
<tr>
<td><strong>DATE OF MANUFACTURE</strong></td>
<td></td>
<td>01-OCT-2015</td>
</tr>
</tbody>
</table>

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.
January 26, 2016

RE: Lot Numbering System

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products’ Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of six characters, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum’s Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

Example: ZI0928 = The 928th material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of seven characters. The first character, a number, represents the production facility:

1 = Gardena, CA Facility
2 = New Brunswick, NJ Facility
3 = China Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

Example: 2AA0706 = The 706th material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at qualityassurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Michael Dang
Manager, GMP Compliance
Stability – Shelf Life Guidance

Product Covered: DO105, Docusate Sodium, USP

Spectrum Chemical’s manufacturing partner has assigned the following shelf life guidance for the product listed above.

The product, DO105, Docusate Sodium, USP, is assigned a 60 months shelf life from date of manufacturing. The quality and integrity of the chemical depends on the handling and storage conditions. Please refer to the Safety Data Sheet for proper storage and handling procedures.

Adan R. Hernandez
Quality Control Manager

Corporate Headquarters
769 Jersey Avenue
New Brunswick, NJ 08901-3605