



# Scientific Documentation

DO105, Docusate Sodium, USP

Not appropriate for regulatory submission.  
Please visit [www.spectrumchemical.com](http://www.spectrumchemical.com) or  
contact Tech Services for the most up-to-date  
information contained in this information  
package.

**Spectrum Chemical Mfg Corp**

769 Jersey Avenue  
New Brunswick, NJ 08901  
Phone 732.214.1300



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,

A handwritten signature in black ink, appearing to read "Alan Wang", with a large, sweeping flourish at the end.

Alan Wang, MSQA, ASQ CQA  
Senior Manager of Technical Services  
[techservices@spectrumchemical.com](mailto:techservices@spectrumchemical.com)

**DO105**, Docusate Sodium, USP

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**spectrum**<sup>®</sup>  
CHEMICAL MFG CORP

Item Number	DO105
Item	Docusate Sodium, USP
CAS Number	577-11-7
Molecular Formula	C <sub>20</sub> H <sub>37</sub> NaO <sub>7</sub> S
Molecular Weight	444.56
MDL Number	
Synonyms	Diocetyl Sodium Sulfosuccinate ; DSS ; Sodium 1,4-Bis(2-ethylhexyl) Sulphosuccinate

Test	Specification	
	Min	Max
ASSAY (ANHYDROUS)	99.0 - 100.5 %	
CLARITY OF SOLUTION		TO PASS TEST
RESIDUE ON IGNITION	15.5 - 16.5 %	
WATER		2.0 %
HEAVY METALS		0.001 %
BIS(2-ETHYLHEXYL) MALEATE		0.4 %
IDENTIFICATION		TO PASS TEST
EXPIRATION DATE		
RESIDUAL SOLVENTS		TO PASS TEST

**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

Preparation Date: 5/18/2016

Revision Date: 5/18/2016

Revision Number: G1

### 1. IDENTIFICATION

**Product identifier**

**Product code:** DO105  
**Product Name:** DOCUSATE SODIUM, USP

**Other means of identification**

**Synonyms:** Di-(2-ethylhexyl) sodium sulfosuccinate  
 Dioctlyn  
 Dioctylal  
 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 sulfojantarunu 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** Chemtrec 1-800-424-9300

**Product code:** DO105

**Product name:** DOCUSATE SODIUM,  
 USP

**Contact Person:** Martin LaBenz (West Coast)  
**Contact Person:** Ibad Tirmiz (East Coast)

## 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)

Acute toxicity - Oral	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A

### 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

Components	CAS-No.	Weight %
Docusate Sodium 577-11-7	577-11-7	100

## 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

#### **Symptoms**

Causes eye irritation. Causes skin irritation. May cause anorexia. May cause gastritis. May cause hypermotility, diarrhea. Vomiting. Somnolence.

### 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**

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
Docosate Sodium 577-11-7	None	None	None	None

##### **Canada**

Components	Alberta	British Columbia	Ontario	Quebec
Docosate Sodium 577-11-7	None	None	None	None

##### **Australia and Mexico**

Components	Australia	Mexico
Docosate Sodium 577-11-7	None	None



## 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

<b>Physical state:</b> Solid	<b>Appearance:</b> Flakes. Waxy.	<b>Color:</b> White.
<b>Odor:</b> odor suggestive of octyl alcohol. Soapy.	<b>Taste</b> No information available	<b>Formula:</b> C20-H37-Na-O7-S
<b>Molecular/Formula weight:</b> 444.56	<b>Flammability:</b> No information available	<b>Flashpoint (°C/°F):</b> No information available.
<b>Flash Point Tested according to:</b> Not available	<b>Autoignition Temperature (°C/°F):</b> No information available	<b>Lower Explosion Limit (%):</b> No information available
<b>Upper Explosion Limit (%):</b> No information available	<b>pH:</b> No information available	<b>Melting point/range(°C/°F):</b> 153-157 °C/307.4-314.6 °F
<b>Decomposition temperature(°C/°F):</b> No information available	<b>Boiling point/range(°C/°F):</b> >180 °C/356 °F	<b>Bulk density:</b> No information available
<b>Density (g/cm3):</b> 1.1	<b>Specific gravity:</b> No information available	<b>Vapor pressure @ 20°C (kPa):</b> No information available
<b>Evaporation rate:</b> No information available	<b>Vapor density:</b> No information available	<b>VOC content (g/L):</b> No information available
<b>Odor threshold (ppm):</b> No information available	<b>Partition coefficient (n-octanol/water):</b> No information available	<b>Viscosity:</b> No information available
<b>Miscibility:</b> No information available	<b>Solubility:</b> Soluble in Acetone Soluble in Carbon tetrachloride Soluble in Dibutyl phthalate Soluble in hot water Soluble in Petroleum Ether Soluble in organic solvents Soluble in Xylene Partially soluble in cold water Freely soluble in Glycerin Solubility in Water: 15 g/L @ 25°C; 23 g/L @ 40°C; 30 g/L @ 50°C; 55 g/L @ 70°C	

## 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:**

Heat. Ignition sources. Incompatible materials. Exposure to moisture.

#### **Incompatible Materials:**

Oxidizing agents.

#### **Hazardous decomposition products:**

Carbon oxides. Sulfur oxides. Sodium oxides.

### Other Information

**Product code:** DO105

**Product name:** DOCUSATE SODIUM,  
USP

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**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*

**LD50/oral/rat** = 1900 mg/kg Oral LD50 Rat  
**LD50/oral/mouse** = 2643 mg/kg oral LD50 mouse  
**LD50/dermal/rabbit** = 10000 mg/kg Dermal LD50Rabbit  
**LD50/dermal/rat** = No information available  
**LC50/inhalation/rat** = No information available  
**LC50/inhalation/mouse** = No information available  
**Other LD50 or LC50information** = 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.

**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

Components	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Docusate Sodium	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

**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)

**Developmental Effects:** No information on reproductive toxicity effects on humans was found  
Evidence of developmental effects in animals is limited and is only reported in the Registry of Toxic Effects of Chemical Substances (RTECS)

**Teratogenic Effects:** No information on developmental toxicity effects on humans was found  
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

Docusate Sodium - 577-11-7

**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

Components	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Docusate Sodium	None	None	None	None

### 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

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## 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

Components	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
<i>Docosate Sodium</i>	Present	Present KE-32402	Present	Present (2)-1623	Present	Present	Present 209-406-4

### U.S. Regulations

*Docosate 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

### California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

#### 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)

Components	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
<i>Docosate Sodium</i>	Not Listed	Not Listed	Not Listed	Not Listed

**CERCLA/SARA**

Components	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
<i>Docusate Sodium</i>	None	None	None	None	None

**U.S. TSCA**

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

**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.

Components	WHMIS Ingredient Disclosure List -
<i>Docusate Sodium</i>	1 %

**Inventory**

Components	Canada (DSL)	Canada (NDSL)
<i>Docusate Sodium</i>	Present	Not Listed

Components	CEPA Schedule I - Toxic Substances
<i>Docusate Sodium</i>	Not listed

Components	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
<i>Docusate Sodium</i>	Not listed

**EU Classification****R-phrases)**

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.

Components	Classification	Concentration Limits:	Safety Phrases
<i>Docusate Sodium</i>		No information	

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,

A handwritten signature in black ink, appearing to read "Alan Wang", is written over a light gray rectangular background.

Alan Wang, MSQA, ASQ CQA  
Senior Manager of Technical Services  
[techservices@spectrumchemical.com](mailto:techservices@spectrumchemical.com)

07.June.2016

# 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

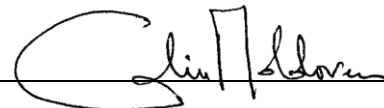
## ISO 9001:2008

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 facilities 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](mailto: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

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



014

A handwritten signature in black ink, appearing to read 'Calin Moldovean'.

Authorised Signature: Calin Moldovean – President, Business Assurance  
Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom  
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](mailto: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:	<u>2020632</u>
Spectrum-New Brunswick, NJ:	<u>2246824</u>
Spectrum -Shanghai, China:	<u>3006174778</u>

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](mailto:qualityassurance@spectrumchemical.com) if we may be of further assistance.

Sincerely,

A handwritten signature in cursive script that reads "Michelle Weston".

Michelle Weston  
Quality Assurance Specialist



June 1, 2016

**Certificate of cGMP**

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.

Catalog Number	Product Name
DO105	Docusate Sodium, USP

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](mailto: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](mailto: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 SO<sub>2</sub>; 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](mailto: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](mailto: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



## 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.

**A** **WARNING**  
 • Harmful if swallowed • Causes serious eye irritation • Causes skin irritation.  
 • Do not eat, drink or smoke when using this product • Wear protective gloves, eye protection, face protection • Wash face, hands and any exposed skin thoroughly after handling.  
**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.

**C** **Exp. Date: 03-31-2025**

**B**

**L** **KEEP FROM CHILDREN**

**SPECTRUM**<sup>®</sup>

**DO105** **D** **F** **2.5 KG**

**Docusate Sodium**  
(Diocetyl Sodium Sulfosuccinate)

**E** **U.S.P.**

**G** **CAS 577-11-7**

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

**J** **Chemical Emergency: (800)424-9300**  
www.SpectrumChemical.com

**K** **C<sub>20</sub>H<sub>37</sub>NaO<sub>7</sub>S** **F.W. 444.56**

Wax-like.

Assay (Anhydrous) .....	99.0-100.5%
Clarity of Solution .....	To pass test
Residue on Ignition .....	15.5-16.5%

MAXIMUM LIMITS

Water .....	2.0%
Heavy Metals .....	0.001%
Bis(2-ethylhexyl) Maleate .....	0.4%
Residual Solvents .....	To pass test

**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.

**M** **HYGROSCOPIC:** Keep tightly closed.

**O** **G 14/E2GHS** **A** **Lot No. 062233**

**SPECTRUM CHEMICAL MFG. CORP.**
**Gardena, CA 90248 • New Brunswick, NJ 08901**

- |  |   |   |
|--|---|---|
| <p><b>A</b> Bar Code</p> <p><b>B</b> GHS Hazard Pictograms</p> <p><b>C</b> Warning, Safety Data and Precautionary Information</p> <p><b>D</b> Product Catalog Number</p> <p><b>E</b> Item Name, Form, Grade</p> <p><b>O</b> Storage Color Band</p> | <p><b>F</b> Size/Quantity</p> <p><b>G</b> Chemical Abstracts Service (CAS) Registry Number</p> <p><b>H</b> Caution Information</p> <p><b>I</b> DOT Shipping Information</p> <p><b>J</b> Toll-Free 24-Hour Chemical Emergency Telephone Number</p> | <p><b>K</b> Empirical Formula, Formula Weight and Technical Specifications Panel</p> <p><b>L</b> Expiration Information</p> <p><b>M</b> Lot Number</p> <p><b>N</b> Kosher Certified by Kosher Supervision of America (KSA).</p> |
|--|---|---|

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.

- YELLOW:** Oxidizer
- RED:** Flammable
- GREEN:** General Storage
- BLUE:** Health Hazard
- WHITE:** Corrosive

### 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

Item Number	DO105	Lot Number	2EK0262
Item	Docusate Sodium, USP		
CAS Number	577-11-7		
Molecular Formula	$C_{20}H_{37}NaO_7S$	Molecular Weight	444.56

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

Spectrum Chemical Mfg Corp  
755 Jersey Avenue  
New Brunswick 08901 NJ

Certificate of Analysis Results Certified By:



Mulbah F. Dwanah  
Laboratory Supervisor  
Spectrum Chemicals & Laboratory Products

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 928<sup>th</sup> 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 706<sup>th</sup> 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](mailto: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

A handwritten signature in black ink that reads "Adan R. Hernandez".

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