

# Scientific Documentation

## FD and C Blue No. 1

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



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## Specification for FD and C Blue No. 1 (FD110)

Item Number	FD110
Item	FD and C Blue No. 1
CAS Number	3844-45-9
Molecular Formula	$C_{37}H_{34}N_2O_9S_3Na_2$
Molecular Weight	792.86
MDL Number	
Synonyms	Acid Blue 9 ; Brilliant Blue FCF ; Erioglaucine

Test	Specification	
	Min	Max
FDA LOT NUMBER		
TOTAL COLOR	85 %	
ARSENIC (As)		3 ppm
CHROMIUM (as Cr)		50 ppm
N-ETHYL,N-(M-SULFOBENZYL)SULFANILIC ACID		0.3 %
LEAD (Pb)		10 ppm
LEUCO BASE		5 %
SUM OF O-, M-, AND P-SULFOBENZALDEHYDES		1.5 %
MANGANESE (AS MN)		100 ppm
SUBSIDIARY COLORS		6 %
SUM OF VOLATILE MATTER (@ 135 C) AND CHLORIDES AND (CALCULATED AS SODIUM SALTS)		15 %
WATER INSOLUBLE MATTER		0.2 %
IDENTIFICATION	TO PASS TEST	
CERTIFIED HALAL		
APPEARANCE		
EXPIRATION DATE		
DATE OF MANUFACTURE		

*Spectrum Chemical Mfg Corp*

Corporate Headquarters: West Coast Facility:

769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

## Certificate Of Analysis

Item Number	FD110	Lot Number	1ML0070
Item	FD and C Blue No. 1	CAS Number	3844-45-9
Molecular Formula	C <sub>37</sub> H <sub>34</sub> N <sub>2</sub> O <sub>9</sub> S <sub>3</sub> Na <sub>2</sub>	Molecular Weight	792.86

TEST	SPECIFICATION		RESULT
	MIN	MAX	
FDA LOT NUMBER			BC6677
TOTAL COLOR	85 %		90.62 %
ARSENIC (As)		3 ppm	<1 ppm
CHROMIUM (as Cr)		50 ppm	<2 ppm
N-ETHYL,N-(M-SULFOBENZYL)SULFANILIC ACID		0.3 %	0.03 %
LEAD (Pb)		10 ppm	<2 ppm
LEUCO BASE		5 %	0.37 %
SUM OF O-, M-, AND P-SULFOBENZALDEHYDES		1.5 %	0.15 %
MANGANESE (AS MN)		100 ppm	<5 ppm
SUBSIDIARY COLORS		6 %	1.99 %
SUM OF VOLATILE MATTER (@ 135 C) AND CHLORIDES AND (CALCULATED AS SODIUM SALTS)		15 %	4.78 %
WATER INSOLUBLE MATTER		0.2 %	<0.2 %
IDENTIFICATION	TO PASS TEST		PASSES TEST
CERTIFIED HALAL			CERTIFIED HALAL
APPEARANCE			PURPLE POWDER
EXPIRATION DATE			01-SEP-2029
DATE OF MANUFACTURE			03-SEP-2023

Certificate of Analysis Results Entered By:

DGARCIA  
Dylan Garcia  
28-DEC-23 12:34:39

Certificate of Analysis Results Approved By:

SHANSEN  
Selin Hansen  
28-DEC-23 13:42:13

Spectrum Chemical Mfg Corp  
14422 South San Pedro Street  
Gardena 90248 CA



**All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.**

**Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.**

# SAFETY DATA SHEET

# spectrum®



Revision date 02-February-2023

Revision Number 3

## 1. Identification

### Product identifier

Product Name FDANDC BLUE NO. 1

### Other means of identification

Product Code(s) FD110

Synonyms None

### Recommended use of the chemical and restrictions on use

Recommended use Coloring agent

Restrictions on use No information available

### Details of the supplier of the safety data sheet

#### **Supplier Address**

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

### Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

## 2. Hazard(s) identification

### Classification

### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

#### **Warning**

#### **Hazard statements**

**Appearance** Powder or Crystalline powder

**Physical state** Solid

**Odor** Odorless

### Precautionary Statements - Response

Unknown acute toxicity

Other information

No information available.

### 3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%
FD&C Blue #1	3844-45-9	100

### 4. First-aid measures

Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance.
Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash skin with soap and water.
Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.

Most important symptoms and effects, both acute and delayed

Symptoms	No information available.
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Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.
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### 5. Fire-fighting measures

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
Specific hazards arising from the chemical	No information available.
Hazardous combustion products	Carbon dioxide (CO <sub>2</sub> ). Hydrocarbons. Sulfur oxides.
Explosion data	
Sensitivity to mechanical impact	none.
Sensitivity to static discharge	none.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.



## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

**Personal precautions** Ensure adequate ventilation.

### Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Pick up and transfer to properly labeled containers.

## 7. Handling and storage

### Precautions for safe handling

**Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice.

### Conditions for safe storage, including any incompatibilities

**Storage Conditions** Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Sensitive to light. Store in light-resistant containers.

## 8. Exposure controls/personal protection

### Control parameters

**Exposure Limits** The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

### Appropriate engineering controls

**Engineering controls** Showers  
Eyewash stations  
Ventilation systems.

### Individual protection measures, such as personal protective equipment

**Eye/face protection** No special protective equipment required.

**Skin and body protection** No special protective equipment required.

**Respiratory protection** No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

<b>Physical state</b>	Solid
<b>Appearance</b>	Powder or Crystalline powder
<b>Color</b>	purple Violet
<b>Odor</b>	Odorless
<b>Odor threshold</b>	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>pH</b>	no data available	None known
<b>Melting point / freezing point</b>	no data available	None known
<b>Boiling point / boiling range</b>	no data available	None known
<b>Flash point</b>	no data available	None known
<b>Evaporation rate</b>	no data available	None known
<b>Flammability (solid, gas)</b>	no data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Vapor pressure</b>	No data available	None known
<b>Vapor density</b>	no data available	None known
<b>Relative density</b>	no data available	None known
<b>Water solubility</b>	Soluble in water	None known
<b>Solubility(ies)</b>	Soluble in Glycerol	None known
	Soluble in Propylene glycol	
	Very slightly soluble in Ethanol	
<b>Partition coefficient</b>	No data available	None known
<b>Autoignition temperature</b>	no data available	None known
<b>Decomposition temperature</b>	283 - °C 541.4 °F	None known
<b>Kinematic viscosity</b>	no data available	None known
<b>Dynamic viscosity</b>	No data available	None known
<b><u>Other information</u></b>		
<b>Explosive properties</b>	No information available	
<b>Oxidizing properties</b>	No information available	
<b>Softening point</b>	No information available	
<b>Molecular weight</b>	792.86	
<b>VOC Content (%)</b>	No information available	
<b>Liquid Density</b>	No information available	
<b>Bulk density</b>	No information available	

## 10. Stability and reactivity

<b>Reactivity</b>	No information available.
<b>Chemical stability</b>	Stable under normal conditions.
<b>Possibility of hazardous reactions</b>	None under normal processing.
<b>Conditions to avoid</b>	None known based on information supplied.
<b>Incompatible materials</b>	None known based on information supplied.
<b>Hazardous decomposition products</b>	None known based on information supplied.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Product Information</b>	.
<b>Inhalation</b>	Specific test data for the substance or mixture is not available.
<b>Eye contact</b>	Specific test data for the substance or mixture is not available.

**Skin contact**

Specific test data for the substance or mixture is not available.

**Ingestion**

Specific test data for the substance or mixture is not available. Harmful if swallowed. (based on components).

**Symptoms related to the physical, chemical and toxicological characteristics****Symptoms**

No information available.

**Acute toxicity****Numerical measures of toxicity****Unknown acute toxicity****Component Information**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
FD&C Blue #1 3844-45-9	> 2 g/kg ( Rat )	-	-

**Delayed and immediate effects as well as chronic effects from short and long-term exposure****Skin corrosion/irritation**

No information available.

**Serious eye damage/eye irritation**

No information available.

**Respiratory or skin sensitization**

No information available.

**Germ cell mutagenicity**

No information available.

**Carcinogenicity**

No information available.

The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical name	ACGIH	IARC	NTP	OSHA
FD&C Blue #1 3844-45-9	-	Supplement 7 [1987] Monograph 16 [1978]	-	-

**Legend****Reproductive toxicity**

No information available.

**STOT - single exposure**

No information available.

**STOT - repeated exposure**

No information available.

**Aspiration hazard**

No information available.

**Other adverse effects**

No information available.

**Interactive effects**

No information available.

**12. Ecological information****Ecotoxicity**

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
FD&C Blue #1 3844-45-9	-	LC50 - Oncorhynchus mykiss (rainbow trout) - 412/mg/l - 96 h	-	EC50 - Daphnia magna (water flea) - >97 mg/l - 48 h

**Persistence and degradability**

No information available.

**Bioaccumulation**

Inherently biodegradable.

**Other adverse effects**

No information available.

**13. Disposal considerations**

#### Waste treatment methods

<b>Waste from residues/unused products</b>	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
<b>Contaminated packaging</b>	Do not reuse empty containers.

### 14. Transport information

<b>DOT</b>	not regulated
<b>TDG</b>	not regulated
<b>MEX</b>	not regulated
<b>ICAO (air)</b>	not regulated
<b>IATA</b>	not regulated
<b>IMDG</b>	not regulated
<b>RID</b>	not regulated
<b>ADR</b>	not regulated
<b>ADN</b>	not regulated

### 15. Regulatory information

#### International Inventories

<b>TSCA</b>	Complies
<b>DSL/NDSL</b>	Complies
<b>EINECS/ELINCS</b>	Complies
<b>ENCS</b>	This product complies with ENCS:
<b>IECSC</b>	This product complies with China:
<b>KECL</b>	Complies
<b>PICCS</b>	Complies
<b>AICS</b>	All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS).

#### **Legend:**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**KECL** - Korean Existing and Evaluated Chemical Substances  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

#### US Federal Regulations

##### **SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

##### **SARA 311/312 Hazard Categories**

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

#### **CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

#### **CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

#### **US State Regulations**

##### **California Proposition 65**

This product does not contain any Proposition 65 chemicals.

#### **U.S. State Right-to-Know Regulations**

Chemical name	New Jersey	Massachusetts	Pennsylvania
FD&C Blue #1 3844-45-9	-	Present	-

#### **U.S. EPA Label Information**

**EPA Pesticide Registration Number** Not applicable

### **16. Other information**

#### **NFPA**

**Health hazards** 1

**Flammability** 0

**Instability** 0

**Physical and chemical properties** -

#### **HMIS**

**Health hazards** 1

**Flammability** 0

**Physical hazards** 0

**Personal protection** X

#### **Key or legend to abbreviations and acronyms used in the safety data sheet**

##### **Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA TWA (time-weighted average)

STEL

STEL (Short Term Exposure Limit)

Ceiling Maximum limit value

#### **Key literature references and sources for data used to compile the SDS**

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)  
NIOSH (National Institute for Occupational Safety and Health)  
National Library of Medicine's ChemID Plus (NLM CIP)  
National Library of Medicine's PubMed database (NLM PUBMED)  
National Toxicology Program (NTP)  
New Zealand's Chemical Classification and Information Database (CCID)  
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications  
Organization for Economic Co-operation and Development High Production Volume Chemicals Program  
Organization for Economic Co-operation and Development Screening Information Data Set  
World Health Organization

**Revision date** 02-February-2023  
**Revision Note** No information available.

**Disclaimer**

**The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.**

**End of Safety Data Sheet**



**Certification of Compliance with current Good Manufacturing Practices**

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies 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
FD110	FD and C Blue No. 1

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

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com)

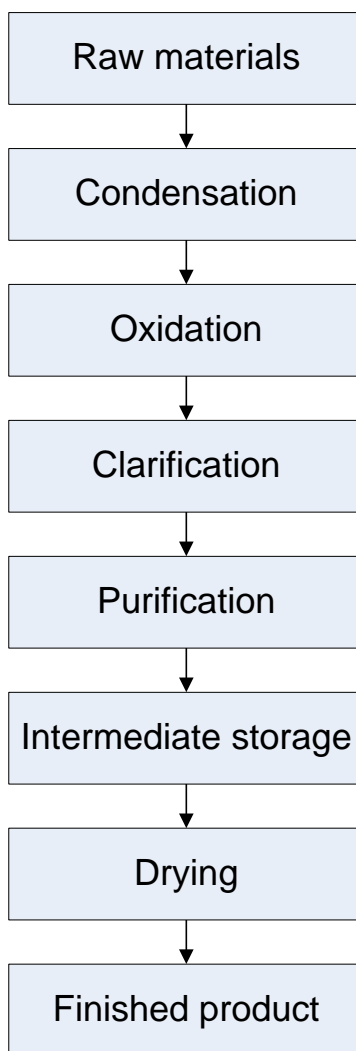
Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez  
Quality Assurance Specialist

## Manufacturing Process Flowchart

### FD and C Blue No. 1 - FD110



#### ***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



## FD110, FD and C Blue No. 1

### Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

### BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

### Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Soy
- Latex
- Sulfites > 10 ppm

### EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

### GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

### Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

## **Nitrosamine Statement**

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

## **Animal Testing Statement**

The above mentioned catalog item has not been tested on animals.

## **Organic Compliance Statement**

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

## **Shelf Life Statement**

The above mentioned catalog item is typically assigned a shelf life of 72 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

## **Other Chemicals Statement**

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- |                     |                 |
|---------------------|-----------------|
| • Aflatoxins        | • Parabens      |
| • Antibiotics       | • Pesticides    |
| • Bisphenol A (BPA) | • Phthalates    |
| • CMR Substances    | • Preservatives |

## 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. Below you will find a typical label example for this catalog item.

FD110/11-01-2016/RC GHS



**USE CARE:** This material has been evaluated per GHS/OSHA criteria and is not classified as hazardous. All chemicals may pose unknown hazards and must be used with caution. Use personal protection and safe handling methods consistent with proper workplace safety practices. Consult SDS for additional properties and precautions. If adverse reaction occurs seek medical attention.

**KEEP FROM CHILDREN**

### FD110      SIZ SY FD&C Blue #1

C.I. 42090  
CAS 3844-45-9



**CAUTION:** For manufacturing and laboratory use, and for coloring foods, drugs and cosmetics including products used in the area of the eye. Must be used in amounts consistent with good manufacturing practice and in conformity with section 401 of the Federal Food, Drug and Cosmetic Act. Not for use in coloring drugs for injection or surgical sutures. **Read and understand the label and Safety Data Sheet (SDS) prior to use.**

FDA Lot Number .....

**LIGHT SENSITIVE:** Keep tightly closed in light-resistant containers.

**Chemical Emergency: (800)424-9300**

[www.SpectrumChemical.com](http://www.SpectrumChemical.com)

G 7/F10GHS

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Lot No. XQ####

### 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