

# Scientific Documentation

## FD and C Red No. 40

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 Red No. 40 (FD140)

Item Number	FD140
Item	FD and C Red No. 40
CAS Number	25956-17-6
Molecular Formula	$C_{18}H_{14}N_2O_8S_2Na_2$
Molecular Weight	496.43
MDL Number	
Synonyms	Allura Red AC ; Red 40

Test	Specification	
	Min	Max
FDA LOT NUMBER		
TOTAL COLOR	85.0 %	
ARSENIC (As)		3 ppm
LEAD (Pb)		10 ppm
DISODIUM SALT 6,6'-OXYBIS(2-NAPHTHALENE-SULFONIC ACID)		1.0 %
SUM OF VOLATILE MATTER (CHLORIDES AND SULFATES)		14.0 %
WATER-INSOLUBLE MATTER		0.2 %
HIGHER SULFONATED SUBSIDIARY COLORS		1.0 %
LOWER SULFONATED SUBSIDIARY COLORS		1.0 %
DISODIUM SALT OF 6-HYDROXY-5(2-METHOXY-5-METHYL-4-SULFOPHENYL)AZO		
-8-(2-METHOXY-5-METHYL-4-SULFOPHENOXY)-2-NAPHTHALENESULFONIC ACID		1.0 %
SODIUM SALT OF 6-HYDROXY-2-NAPHTHALENESULFONIC ACID		0.3 %
4-AMINO-5-METHOXY-O-TOLUENESULFONIC ACID		0.2 %
IDENTIFICATION		TO PASS TEST
CERTIFIED KOSHER		
APPEARANCE		
EXPIRATION DATE		

Test	Specification	
	Min	Max
DATE OF MANUFACTURE		

***Spectrum Chemical Mfg Corp***

<i><b>Corporate Headquarters:</b></i>	<i><b>West Coast Facility:</b></i>
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	FD140	Lot Number	2LI0291
Item	FD and C Red No. 40	CAS Number	25956-17-6
Molecular Formula	C <sub>18</sub> H <sub>14</sub> N <sub>2</sub> O <sub>8</sub> S <sub>2</sub> Na <sub>2</sub>	Molecular Weight	496.43

TEST	SPECIFICATION		RESULT
	MIN	MAX	
FDA LOT NUMBER			BB6234
TOTAL COLOR	85.0 %		90.23 %
ARSENIC (As)		3 ppm	<1 ppm
LEAD (Pb)		10 ppm	<2 ppm
DISODIUM SALT 6,6'-OXYBIS(2-NAPHTHALENE-SULFONIC ACID)		1.0 %	<1.0 %
SUM OF VOLATILE MATTER (CHLORIDES AND SULFATES)		14.0 %	4.54 %
WATER-INSOLUBLE MATTER		0.2 %	0.03 %
HIGHER SULFONATED SUBSIDIARY COLORS		1.0 %	<0.2 %
LOWER SULFONATED SUBSIDIARY COLORS		1.0 %	<0.2 %
DISODIUM SALT OF 6-HYDROXY-5(2-METHOXY-5-METHYL-4-SULFOPHENYL)AZO			.
-8-(2-METHOXY-5-METHYL-4-SULFOPHENOXY)-2-NAPHTHALENESULFONIC ACID		1.0 %	<1.0 %
SODIUM SALT OF 6-HYDROXY-2-NAPHTHALENESULFONIC ACID		0.3 %	<0.3 %
4-AMINO-5-METHOXY-O-TOLUENESULFONIC ACID		0.2 %	<0.2 %
IDENTIFICATION		TO PASS TEST	PASSES TEST
APPEARANCE			DARK RED POWDER
EXPIRATION DATE			25-APR-2028
DATE OF MANUFACTURE			27-APR-2022

Certificate of Analysis Results Entered By:

SVANGOOR  
Swetha Vangoor  
04-OCT-22 08:06:36

Certificate of Analysis Results Approved By:

BPATEL  
Bhargavi Patel  
04-OCT-22 12:15:12

Spectrum Chemical Mfg Corp  
755 Jersey Avenue  
New Brunswick 08901 NJ



**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-September-2022

Revision Number 2

## 1. Identification

### Product identifier

Product Name FDANDC RED NO. 40

### Other means of identification

Product Code(s) FD140

Synonyms None

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

Recommended use No information available

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

Combustible dust	Yes
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### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

#### Warning

#### Hazard statements

May form combustible dust concentrations in air

**Appearance** Powder

**Physical state** Solid

**Odor** No information available

### Precautionary Statements - Prevention

Keep away from all ignition sources including heat, sparks, and flame  
Keep container closed and grounded  
Prevent dust accumulations to minimize explosion hazard

**Other information**

No information available.

### 3. Composition/information on ingredients

**Substance**

Chemical name	CAS No	Weight-%	Trade secret
FD&C Red #40	25956-17-6	100	*

\*The exact percentage (concentration) of composition has been withheld as a trade secret.

### 4. First-aid measures

**Description of first aid measures**

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	Clean mouth with water and drink afterwards plenty of water.

**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

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Large Fire</b>	CAUTION: Use of water spray when fighting fire may be inefficient.
<b>Unsuitable extinguishing media</b>	Do not scatter spilled material with high pressure water streams.
<b>Specific hazards arising from the chemical</b>	Avoid generation of dust. Fine dust dispersed in air may ignite.
<b>Hazardous combustion products</b>	Carbon Monoxide, Carbon Dioxide. Nitrogen oxides (NOx). Sulfur oxides. Sodium oxides.
<b>Explosion data</b>	
<b>Sensitivity to mechanical impact</b>	none.
<b>Sensitivity to static discharge</b>	yes.
<b>Special protective equipment for</b>	Firefighters should wear self-contained breathing apparatus and full firefighting turnout



fire-fighters

gear. Use personal protection equipment.

## **6. Accidental release measures**

### **Personal precautions, protective equipment and emergency procedures**

<b>Personal precautions</b>	Ensure adequate ventilation. Avoid generation of dust. Avoid contact with eyes. Use personal protective equipment as required. Do not breathe dust. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Take precautionary measures against static discharges.
<b>Other information</b>	Refer to protective measures listed in Sections 7 and 8.

### **Methods and material for containment and cleaning up**

<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so. Prevent dust cloud.
<b>Methods for cleaning up</b>	Take up with inert, damp, non-combustible material using clean non-sparking tools and place into loosely covered plastic containers for later disposal. Pick up and transfer to properly labeled containers.

## **7. Handling and storage**

### **Precautions for safe handling**

<b>Advice on safe handling</b>	Handle in accordance with good industrial hygiene and safety practice. Ensure adequate ventilation. Avoid generation of dust. Do not breathe dust. Avoid contact with eyes. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use spark-proof tools and explosion-proof equipment. Take precautionary measures against static discharges.
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### **Conditions for safe storage, including any incompatibilities**

<b>Storage Conditions</b>	Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up. Keep out of the reach of children.
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## **8. Exposure controls/personal protection**

### **Control parameters**

<b>Exposure Limits</b>	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.
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### **Appropriate engineering controls**

<b>Engineering controls</b>	Showers Eyewash stations Ventilation systems.
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### **Individual protection measures, such as personal protective equipment**

<b>Eye/face protection</b>	Wear safety glasses with side shields (or goggles).
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<b>Skin and body protection</b>	No special protective equipment required.
<b>Respiratory protection</b>	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
<b>General hygiene considerations</b>	Do not breathe dust.

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

<b>Physical state</b>	Solid
<b>Appearance</b>	Powder
<b>Color</b>	dark red
<b>Odor</b>	No information available
<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>	>300 °C / °F	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>	Very slightly soluble in acetone	None known
<b>Partition coefficient</b>	No data available	None known
<b>Autoignition temperature</b>	no data available	None known
<b>Decomposition temperature</b>		None known
<b>Kinematic viscosity</b>	no data available	None known
<b>Dynamic viscosity</b>	No data available	None known

### Other information

<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>	No information available
<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>	Excessive heat. Heating in air. dust formation.
<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

#### Product Information

Inhalation	Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.
Eye contact	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.

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

Symptoms No information available.

### Acute toxicity

#### Numerical measures of toxicity

#### Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
FD&C Red #40 25956-17-6	10 g/kg ( Rat )	10 g/kg ( Rabbit )	-

### 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.
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	The environmental impact of this product has not been fully investigated.
Persistence and degradability	No information available.
Bioaccumulation	Inherently biodegradable.
Other adverse effects	No information available.

## 13. Disposal considerations

### Waste treatment methods

**Waste from residues/unused products**

Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

**Contaminated packaging**

Do not reuse empty containers.

**14. Transport information**

DOT not regulated

TDG not regulated

MEX not regulated

ICAO (air) not regulated

IATA not regulated

IMDG not regulated

RID not regulated

ADR not regulated

ADN not regulated

**15. Regulatory information****International Inventories**

**TSCA** Complies

**DSL/NDSL** Complies

**EINECS/ELINCS** Complies

**ENCS** This product complies with ENCS:

**IECSC** This product complies with China:

**KECL** Complies

**PICCS** Complies

**AICS** 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**

This product does not contain any substances regulated under applicable state right-to-know regulations

**U.S. EPA Label Information**

**EPA Pesticide Registration Number** Not applicable

**16. Other information****NFPA**

**Health hazards** 0

**Flammability** 1

**Instability** 0

**Physical and chemical properties** -

**HMIS**

**Health hazards** 0

**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-September-2022  
**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
FD140	FD and C Red No. 40

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)

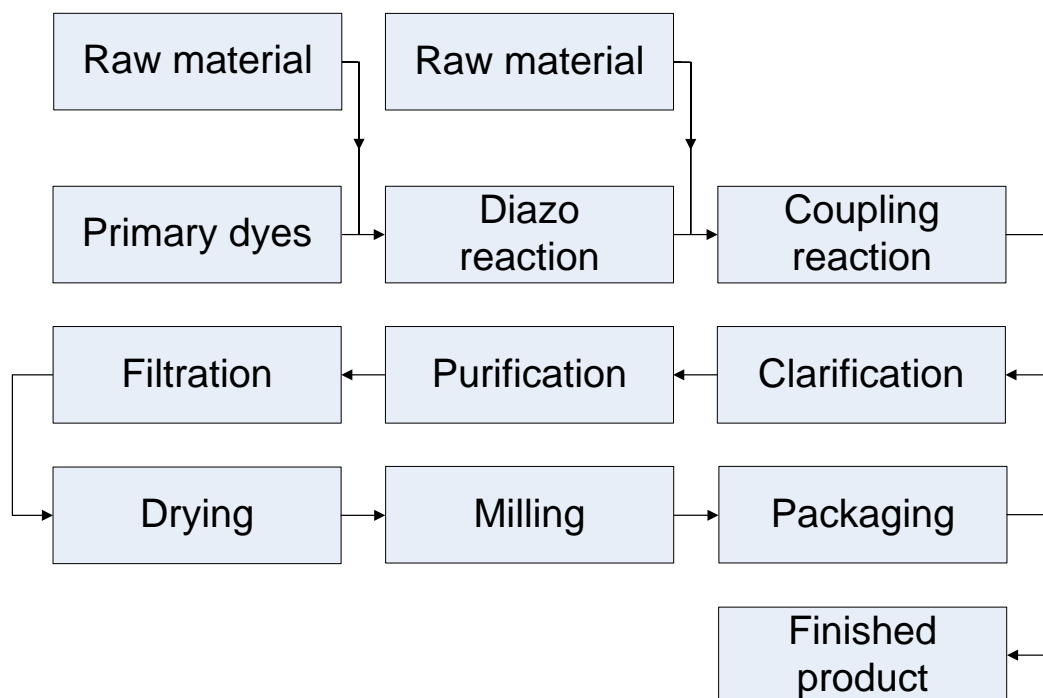
Sincerely,

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 Red No. 40 - FD140



#### ***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



## **FD140, FD and C Red No. 40**

### **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
- Corn
- Soy
- Sulfites > 10 ppm

### **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.

### **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, 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
- Bisphenol A (BPA)
- CMR Substances
- Phthalates

## 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.

**WARNING**

- May form combustible dust concentrations in air.
- Keep away from all ignition sources including heat, sparks and flame • Keep container closed and grounded • Prevent dust accumulations to minimize explosion hazard.

This material has been evaluated per GHS criteria and is not classified as hazardous under GHS. 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**

**FD140**

**SIZ SY**

**FD&C Red #40**

C.I. 16035

CAS 25956-17-6

**CAUTION:** For manufacturing and laboratory use, and for coloring foods, drugs and cosmetics. Must be used in amounts consistent with good manufacturing practice and in conformity with section 401 of the Federal Food, Drug and Cosmetic Act. Approved for use in drugs & cosmetics including those intended for use in the area of the eye. In cosmetics, the color additive shall not be exposed to oxidizing or reducing agents or any other conditions which may affect the integrity of the color.

**Read and understand the label and Safety Data Sheet (SDS) prior to use.**

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

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

$C_{18}H_{14}N_2O_8S_2Na_2$

F.W. 496.43

FDA Lot Number .....

Lot No. XQ####

Exp. Date: 00-00-0000

### Spectrum Chemical Mfg Corp

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