

Scientific Documentation

FD and C Yellow No. 6

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.

Spectrum Chemical Mfg Corp 769 Jersey Avenue New Brunswick, NJ 08901 Phone 732.214.1300





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Specification for FD and C Yellow No. 6 (FD155)

Item Number	FD155
Item	FD and C Yellow No. 6
CAS Number	2783-94-0
Molecular Formula	$C_{16}H_{10}N_2O_7S_2Na_2$
Molecular Weight	452.38
MDL Number	
Synonyms	Sunset Yellow FCF

Test	Specification	
	Min	Max
FDA LOT NUMBER		
APPEARANCE		
TOTAL COLOR	87 %	
SUM OF VOLATILE MATTER (AT 135°C) AND CHLORIDES AND SULFATES-		
(CALCULATED AS SODIUM SALTS)		13 %
WATER INSOLUBLE MATTER		0.2 %
SODIUM SALT OF 4-AMINOBENZENESULFONIC ACID		0.2 %
SODIUM SALT OF 6-HYDROXY-2- NAPHTHALENESULFONIC ACID		0.3 %
DISODIUM SALT OF 6,6?-OXYBIS[2-NAPHTHALENESULFONIC ACID]		1 %
DISODIUM SALT OF 4,4?-(1-TRIAZENE-1,3- DIYL)BIS[BENZENESULFONIC ACID]		0.1 %
SUM OF THE SODIUM SALT OF 6-HYDROXY-5- (PHENYLAZO)-2-NAPHTHALENESULFONIC ACID		
AND THE SODIUM SALT OF 4-[(2-HYDROXY-1-NAPHTHALENYL)AZO]BENZENESULFONIC ACID		1 %
SUM OF THE TRISODIUM SALT OF 3-HYDROXY-4- [(4-SULFOPHENYL)AZO]-2,7-NAPHTHALENE		
DISULFONIC ACID AND OTHER HIGHER SULFONATED SUBSIDIARIES		5 %
4-AMINOAZOBENZENE		50 ppb

Test	Specificat	tion
	Min	Max
4-AMINOBIPHENYL		15 ppb
ANILINE		250 ppb
AZOBENZENE		200 ppb
BENZIDINE		1 ppb
1,3-DIPHENYLTRIAZENE		40 ppb
1-(PHENYLAZO)-2-NAPHTHALENOL		10 ppm
LEAD (Pb)		10 ppm
ARSENIC (As)		3 ppm
MERCURY (Hg)		1 ppm
IDENTIFICATION	APPROX. 0.054 AT (484) nm	
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 08901Gardena, CA 90248

732.214.1300 310.516.8000



Certificate Of Analysis

Item Number	FD155	Lot Number	2MC0288
Item	FD and C Yellow No. 6	CAS Number	2783-94-0
Molecular Formula	$C_{16}H_{10}N_2O_7S_2Na_2$	Molecular Weight	452.38

TEST	SPECIF	ICATION	RESULT
IEST	MIN	MAX	RESULI
FDA LOT NUMBER			BB8596
APPEARANCE			DARK RED COLOR FINE POWDER
TOTAL COLOR	87 %		>87%
SUM OF VOLATILE MATTER (AT 135°C) AND CHLORIDES AND SULFATES-			
(CALCULATED AS SODIUM SALTS)		13 %	<13%
WATER INSOLUBLE MATTER		0.2 %	<0.2%
SODIUM SALT OF 4-AMINOBENZENESULFONIC ACID		0.2 %	<0.2%
SODIUM SALT OF 6-HYDROXY-2- NAPHTHALENESULFONIC ACID		0.3 %	<0.2%
DISODIUM SALT OF 6,6'-OXYBIS[2-NAPHTHALENESULFONIC ACID]		1 %	<1%
DISODIUM SALT OF 4,4'-(1-TRIAZENE-1,3- DIYL)BIS[BENZENESULFONIC ACID]		0.1 %	<0.1%
SUM OF THE SODIUM SALT OF 6-HYDROXY-5- (PHENYLAZO)-2-NAPHTHALENESULFONIC ACID			
AND THE SODIUM SALT OF 4-[(2-HYDROXY-1- NAPHTHALENYL)AZO]BENZENESULFONIC ACID		1 %	<1%
SUM OF THE TRISODIUM SALT OF 3-HYDROXY-4-[(4-SULFOPHENYL)AZO]-2,7-NAPHTHALENE			
DISULFONIC ACID AND OTHER HIGHER SULFONATED SUBSIDIARIES		5 %	<5%
4-AMINOAZOBENZENE		50 ppb	<5 ppb
4-AMINOBIPHENYL		15 ppb	<1 ppb
ANILINE		250 ppb	70 ppb
AZOBENZENE		200 ppb	<5 ppb

TECT	SPECIFICATION		DECLUT
TEST	MIN	MAX	RESULT
BENZIDINE		1 ppb	<1 ppb
1,3-DIPHENYLTRIAZENE		40 ppb	<5 ppb
1-(PHENYLAZO)-2-NAPHTHALENOL		10 ppm	<0.2 ppm
LEAD (Pb)		10 ppm	<2 ppm
ARSENIC (As)		3 ppm	<1 ppm
MERCURY (Hg)		1 ppm	<1 ppm
IDENTIFICATION	APPROX. 0.054 AT (484) nm		0.05349 nm
EXPIRATION DATE			19-AUG-2028
DATE OF MANUFACTURE			19-AUG-2022

Certificate of Analysis Results Entered By:

GHERRERA Genaro Herrera 03-APR-23 09:54:34

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS Allison Williams 03-APR-23 14:24:22

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.





Revision date 18-March-2020 Revision Number 2

1. Identification

Product identifier

Product Name FDANDC YELLOW NO. 6

Other means of identification

Product Code(s) FD155

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use No information available

Restrictions on useNo 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

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Hazard statements

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

The product contains no substances which at their given concentration, are considered to be hazardous to health.

Appearance crystalline Physical state Solid Odor Odorless

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
FD&C Yellow #6	2783-94-0	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.

Indication of any immediate medical attention and special treatment needed

5. Fire-fighting measures

surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing mediaDo not scatter spilled material with high pressure water streams.

Specific hazards arising from the

chemical

No information available.

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 container tightly closed in a dry and well-ventilated place.

8. Exposure controls/personal protection

Control parameters

Exposure LimitsThe 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

Physical state Solid
Appearance crystalline

Color orange; yellow-orange; red

Odor Odorless

Odor threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

pН 7-8 (pH value (10g/l) at 20 deg. C None known > 300 °C / 572 °F Melting point / freezing point None known Boiling point / boiling range no data available None known Flash point no data available None known **Evaporation rate** no data available None known Flammability (solid, gas) no data available None known Flammability Limit in Air None known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

No data available None known Vapor pressure Vapor density no data available None known Relative density no data available None known Water solubility No data available None known Solubility(ies) Soluble in water None known -1.18None known Partition coefficient **Autoignition temperature** no data available None known 390 - °C 734 °F None known **Decomposition temperature** Kinematic viscosity no data available None known

No data available

None known

Other information

Dynamic viscosity

Explosive propertiesNo information availableOxidizing propertiesNo information availableSoftening pointNo information available

Molecular weight 452.38

VOC Content (%)

Liquid Density

No information available
No information available

Bulk density 650 kg/m³

10. Stability and reactivity

Reactivity No information available.

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions
None under normal processing.

Conditions to avoid None known based on information supplied.

Incompatible materialsNone known based on information supplied.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

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

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

10000 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
FD&C Yellow #6	10 g/kg (Rat)	-	-
2783-94-0			

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

Skin corrosion/irritation
Serious eye damage/eye irritation
Respiratory or skin sensitization
Germ cell mutagenicity
Carcinogenicity

No information available.
No information available.
No information available.
No information available.

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

	miner caen agency man	s note a any migrounom as a		
Chemical name	ACGIH	IARC	NTP	OSHA
FD&C Yellow #6	-	Group 3 - Supplement 7	-	-
2783-94-0		[1987]		
		Monograph 8 [1975]		

Legend

Reproductive toxicity No information available.

STOT - single exposure
STOT - repeated exposure
Aspiration hazard

No information available.
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

Bioaccumulation

No information available. Inherently biodegradable.

Other adverse effects No information available.

13. Disposal considerations

Waste treatment methods

products

Waste from residues/unused

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

Note *Contact supplier for details. One or more substances in this product are either not listed

on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise

exempted from inventory listing requirements

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 0 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 18-March-2020

Revision Note No information available.

<u>Disclaimer</u>
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
FD155	FD and C Yellow No. 6

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

Sincerely,

Oralia Chavez

Quality Assurance Specialist

Order Clony



FD155, FD and C Yellow No. 6

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
- Soy

- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- 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 been tested on animals before year 1985.

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
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Preservatives
- 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.



Spectrum Chemical Mfg Corp

Corporate Headquarters:West Coast Facility:769 Jersey Ave.14422 S. San Pedro St.New Brunswick, NJ 08901Gardena, CA 90248

310.516.8000