

Scientific Documentation

D1139, D and C Red 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



Dear Customer,

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

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

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

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

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

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

Sincerely,

Alan Wang, MSQA, ASQ CQA
Director of Technical Services

techservices@spectrumchemical.com

Table of Contents

- Product Specification
- Safety Data Sheet (SDS)
- Manufacturer
- Certification of Quality Management System (QMS)
- Certification of current Good Manufacturing Practices (cGMP)
- Product BSE/TSE Statement
- Product Allergen Statement
- Aflatoxin Statement
- Product Certificate of Analysis Sample(s)
- General Label Information Sample Label
- General Lot Numbering System Guidance
- Stability Shelf Life Guidance



Specification for D and C Red No. 6 (D1139)

Item Number	D1139
Item	D and C Red No. 6
CAS Number	5858-81-1
Molecular Formula	$C_{I8}H_{I4}N_2O_6S.2Na$
Molecular Weight	432.38
MDL Number	
Synonyms	Lithol Rubine Na; Pigment Red 57

Test	Specification			
	Min	Max		
ASSAY	90%			
FDA LOT NUMBER				
IDENTIFICATION		TO PASS TEST		
APPEARANCE				

Spectrum Chemical Mfg Corp

Corporate Headquarters:West Coast Facility:769 Jersey Ave.14422 S. San Pedro St.New Brunswick, NJ 08901Gardena, CA 90248732.214.1300310.516.8000





SAFETY DATA SHEET

Preparation Date: 7/10/2017 Revision Date: 7/10/2017 Revision Number: G1

1. IDENTIFICATION

Product identifier

Product code: D1139

Product Name: DANDC RED NO. 6

Other means of identification

Synonyms: C.I. 15850

C.I. Pigment Red 57 (7CI)

C.I. Pigment Red 57, disodium salt (8CI)

Pigment Red 57

Red 102

CAS #: 5858-81-1 RTECS # QJ1975000 CI#: 15850

Recommended use of the chemical and restrictions on use

Recommended use:
Uses advised against
No information available.
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 numberChemtrec 1-800-424-9300Contact Person:Martin LaBenz (West Coast)Contact Person:Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

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

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

<u>Label elements</u>

Not classified			

Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

Product code: D1139 Product name: DANDC RED NO. 6 1 / 10

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
D&C Red #6	5858-81-1	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 irritation develops. Consult a physician if necessary.

Eye Contact: Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms

persist, call a physician.

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 May cause eye/skin irritation. Health injuries are not known or expected under normal use.

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 powder. Carbon dioxide (CO2). Water spray mist or

foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products: Carbon Monoxide, Carbon Dioxide. Nitrogen 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

Product code: D1139 Product name: DANDC RED NO. 6 2 / 10

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin,

eyes and clothing. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent product from entering

drains.

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. All equipment used when handling the product must be grounded. 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 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.

Incompatible Materials:

Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WHEEL
D&C Red #6	5858-81-1	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
D&C Red #6	5858-81-1	None	None	None	None

Australia and Mexico

Product code: D1139 Product name: DANDC RED NO. 6 3 / 10

Components	CAS-No.	Australia	Mexico
D&C Red #6	5858-81-1	None	None

Appropriate engineering controls

Engineering measures to reduce exposure: Ensure adequate ventilation, especially in confined areas.

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: Goggles or Safety glasses with side-shields

Skin and body protection: Long sleeved clothing

Chemical resistant apron

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

Physical state:Appearance:Color:SolidPowder.Red.

Odor: Taste Formula:

Odorless. No information available. C18H14N2O6S.2Na

Molecular/Formula weight:Flammability:Flashpoint (°C/°F):432.38 g/moleNo information availableNo information available.

Flash Point Tested according to: Autoignition

Not available No information available

Autoignition Temperature (°C/°F): Lower Explosion Limit (%): No information available

No information available

Upper Explosion Limit (%): Melting point/range(°C/°F): Decomposition temperature(°C/°F):

No information available
No information available
No information available

Boiling point/range(°C/°F): Bulk density: Density (g/cm3):

No information available No information available No information available

Specific gravity: pH: Vapor pressure @ 20°C (kPa):

Evaporation rate: Vapor density: VOC content (g/L):

Product code: D1139 Product name: DANDC RED NO. 6 4/10

Odor threshold (ppm): **Partition coefficient** No information available (n-octanol/water):

No information available

Viscosity: No information available

Miscibility: Solubility: No information available Soluble in Water

10. STABILITY AND REACTIVITY

Reactivity

May react with strong oxidizers

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Incompatible materials.

Strong oxidizing agents **Incompatible Materials:**

Hazardous decomposition Carbon monoxide. Carbon dioxide. Nitrogen oxides (NOx). Sulfur oxides. Sodium

products: oxides.

Other Information

Corrosivity: Non-corrosive in the presence of glass

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:

Ingestion. Inhalation.

Acute Toxicity

Component Information

D&C Red #6

CAS-No. 5858-81-1

LD50/oral/rat = > 10800 mg/kg Oral LD50 Rat

LD50/oral/mouse = No information available

LD50/dermal/rabbit = No information available

LD50/dermal/rat = No information available

LC50/inhalation/rat = No information available LC50/inhalation/mouse = No infomation available

Other LD50 or LC50information = No information available

Product Information

LD50/oral/rat =

VALUE- Acute Tox Oral = > 10800 mg/kg

LD50/oral/mouse =

Product code: D1139 Product name: DANDC RED NO. 6 5 / 10 Value - Acute Tox Oral = No information available

LD50/dermal/rabbit

VALUE-Acute Tox Dermal = No information available

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: May cause skin irritation.

Eye Contact: May cause eye irritation.

Inhalation May cause irritation of respiratory tract.

Ingestion Health injuries are not known or expected under normal use. No information

available.

Aspiration hazard No information available.

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

Chronic Toxicity No information available.

Sensitization: No information available.

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
D&C Red #6	5858-81-1	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

Reproductive toxicity No data is available

Reproductive Effects: No information available
Developmental Effects: No information available
Teratogenic Effects: No information available

Specific Target Organ Toxicity

Product code: D1139 Product name: DANDC RED NO. 6 6 / 10

STOT - single exposure STOT - repeated exposure Target Organs: No information available. No information available. No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

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	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
D&C Red #6	5858-81-1	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class:
Subsidiary Class
Packing group:
No information available

Number

Marine PollutantNo data availableDOT RQ (lbs):No information availableSpecial ProvisionsNo Information availableSymbol(s):No information availableDescription:No information available

TDG (Canada)

UN-No: Not Regulated

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

Product code: D1139 Product name: DANDC RED NO. 6 7 / 10

ADR

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class:
Packing Group:
Subsidiary Risk:
No information available
No information available
No information available

IMO / IMDG

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class:
Subsidiary Risk:
Packing Group:
Marine Pollutant

No information available
No information available
No information available
No information available

RID

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class:
Subsidiary Risk:
No information available
No information available
No information available
No information available

ICAO

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class:
Subsidiary Risk:
No information available
No information available
No information available
No information available

IATA

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class:
Subsidiary Risk:
Packing Group:
ERG Code:
No information available

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
D&C Red #6	5858-81-1	Present	Present KE-07936	Present	Present (9)-2396	Present	Present	Present 227-497-9

U.S. Regulations

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	CAS-No.	Carcinogen	Developmental Toxicity	Male	Female
				Reproductive	Reproductive
				Toxicity	Toxicity:

Product code: D1139 Product name: DANDC RED NO. 6 8 / 10

D&C Red #6	5858-81-1	Not Listed	Not Listed	Not Listed	Not Listed	
------------	-----------	------------	------------	------------	------------	--

CERCLA/SARA

Components	CAS-No.	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
D&C Red #6	5858-81-1	None	None	None	None	None

U.S. TSCA

Components		· · · · · · · · · · · · · · · · · · ·	TSCA 8(d) -Health and Safety Reporting
D&C Red #6	5858-81-1	Not Applicable	Not Applicable

Canada

WHIMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

Not a dangerous product according to HPR classification criteria.

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

WHMIS 1988 Hazard Class

Non-controlled

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.

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
D&C Red #6	5858-81-1	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
D&C Red #6	5858-81-1	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject
		to Mandatory Reporting
D&C Red #6	5858-81-1	Not listed

EU Classification

EU GHS - SV - CLP 172/2008

Components	CAS-No.	EU GHS - SV - CLP (172/2008)
D&C Red #6	5858-81-1	

EU - CLP (1272/2008)

R-phrase(s)

not determined (not applicable)

S -phrase(s)

none

Product code: D1139 Product name: DANDC RED NO. 6 9 / 10

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
D&C Red #6	5858-81-1		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:

None.

16. OTHER INFORMATION

Preparation Date: 7/10/2017
Revision Date: 7/10/2017
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

Product code: D1139 Product name: DANDC RED NO. 6 10 / 10



Manufacturer

Product Covered: D1139, D and C Red No. 6

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

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

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

Sincerely,

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

Certificate of Registration



This is to certify that the quality management system of

Spectrum Chemicals and Laboratory Products, Lac

Main Site: 14422 South San Pedro Street, Gardena, California, 90248, USA

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

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

ISO 9001:2008

The quality management system is applicable to

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

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

Certificate Number: 94-316m-01

Initial Certification Date: 27 December 1994 Certificate Issue Date: 29 January 2016 Certificate Expiry Date: 14 September 2018

Calin Moldovean, President Intertek Testing Services NA, Inc. 900 Chelmsford Street, Suite 301-3, Lowell, MA, USA ARAB
ACCREDITED
ISO/IEC17021
MANAGEMENT SYSTEMS
CERTIFICATION BODY



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

Certificate of Registration



This is to certify that the quality management system of

Spectrum China Ltd.

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

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

ISO 9001: 2008

The quality management system is applicable to:

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

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







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





January 03, 2017

Certificate of cGMP

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certifies 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 follow:

Spectrum Gardena, California: 2020632

Spectrum New Brunswick, New Jersey: 2246824

Thank you for your interest with Spectrum products. Please feel free to contact me at 310-516-8000, extension 5610 or via email at mdang@spectrumchemical.com if I may be of further assistance.

Sincerely,

Michael Dang

Manager, GMP Compliance

CORPORATE HEADQUARTERS

769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300

FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street Gardena, California 90248 PHONE 310.516.8000 FAX 310.516.9843



July 10, 2017

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	
D1139	D and C Red 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 Spectrum-Shanghai, China: 3006174778

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

Sincerely,

Oralia Chavez

Quality Assurance Specialist

Order Clony



May 19, 2017

Re: D and C Red No. 6 -D1139

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

D and C Red No. 6 -D1139

is BSE/TSE free.

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

Sincerely,

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

This document has been produced electronically and is valid without a signature



May 19, 2017

Re: D and C Red No. 6 -D1139

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

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

D and C Red No. 6 -D1139

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

Sincerely,

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

This document has been produced electronically and is valid without a signature



May 19, 2017

Re: D and C Red No. 6 -D1139

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.

D and C Red No. 6 -D1139

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

Sincerely,

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

This document has been produced electronically and is valid without a signature



Certificate Of Analysis

Item Number	D1139	Lot Number	2FL0293
Item	D and C Red No. 6		
CAS Number	5858-81-1		
Molecular Formula	$C_{I8}H_{I4}N_2O_6S.2Na$	Molecular Weight	432.38

Test		Specification		Result
		min	max	
ASSAY	90%			90 %
FDA LOT NUMBER				AL4717
APPEARANCE				ORANGE TO RED FINE POWDER
REANALYZED ON				21-DEC-2016

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



Certificate Of Analysis Results Certified by

Ibad Tirmizi Director of Quality

Spectrum Chemical Mfg. Corp.

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

Read and understand label and MSDS/SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personal only. The customer must ensure to provide its users adequate hazardous material training and appropriate protective gears before handling our chemicals.



 $C_{18}H_{14}N_2O_6S$ •2Na F.W. 432.38

AssayMin. 90%

FDA Lot Number062233

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.

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

KEEP FROM CHILDREN

SPECTRUM CHEMICAL MFG. CORP.

D1139—0 -500 G

D&C Red No. 6

┗—C.I. 15850 -CAS 5858-81-1

CAUTION: For manufacturing, laboratory use and for coloring drugs and cosmetics only. 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, surgical sutures or products used in the area of the eye. Combined total use of D&C Red No. 6 and D&C Red No. 7 in drugs is limited to 5 mg per daily drug dose

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

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

G 3/E10GHS

Lot No. 062

Gardena, CA 90248 • New Brunswick, NJ 08901

- A Bar Code
- GHS Hazard Pictograms
- Warning, Safety Data and Precautionary Information
- Product Catalog Number
- Item Name, Form, Grade
- Storage Color Band

- Size/Quantity
- Chemical Abstracts Service (CAS) Registry Number
- Caution Information
- DOT Shipping Information
- Toll-Free 24-Hour Chemical Emergency Telephone Number
- Empirical Formula, Formula Weight and Technical Specifications Panel
- Expiration Information
- Lot Number
- Kosher Certified by Kosher Supervision of America (KSA).

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 West Coast Facility: 14422 S. San Pedro St. Gardena, CA 90248

310.516.8000

732.214.1300



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: Zl0928 = The 928th material produced in California in September 2010

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

1 = Gardena, CA Facility

2 = New Brunswick, NJ Facility

3 = China Facility

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

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

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

Sincerely,

Michael Dang

Manager, GMP Compliance



Stability – Shelf Life Guidance

Product Covered: D1139, D and C Red No. 6

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

The product, D1139, D and C Red No. 6, indefinite shelf life from date of manufacturing. The quality and integrity of the chemical depends on the handling and storage conditions. Please refer to the Safety Data Sheet for proper storage and handling procedures.

Adan R. Hernandez Quality Control Manager

Corporate Headquarters 769 Jersey Avenue

New Brunswick, NJ 08901-3605