

Product: 7.FD.002000          D &amp; C VIOLET 2

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**
**Product identifiers:**

 Product Form: Substance  
 Product Name: **D & C VIOLET 2**  
 Product Number: **7.FD.002000**  
 Color Index Name: SOLVENT VIOLET 013  
 C.I. No: 60725  
 CAS number: 81-48-1  
 Formula: ANTHRAQUINONE DYE  
 Synonyms:

**Intended Use of the Product**

## USE STATEMENT;

Not to exceed by weight of suture: 0.2% in glycolic-lactic acid polyester synthetic absorbable sutures of 0.3% in polydioxanone synthetic absorbable sutures for use in general and ophthalmic surgery, and 0.1% in poly(epsilon-caprolactone) absorbable sutures for use in general surgery. Externally applied Drugs and Cosmetics -- consistent with Good Manufacturing Practice.

**Name, Address, and Telephone of the Responsible Party**

Spectra Colors Corporation	Telephone	800-527-8588 (USA), 201-997-0606 (Int'l)
25 Rizzolo Road	Fax number	201-997-0504
Kearny, NJ 07032 USA	Email	dyes@spectracolors.com

**EMERGENCY TELEPHONE NUMBER**

 Emergency phone number: **Chemtrec 800-424-9300 (USA)**  
**+1 703-527-3887 (Outside USA)**
**SECTION 2: Hazards Identification**
**Classification of the substance or mixture**
**GHS-US Classification**

 Acute tox. – inhalation 5    H333  
 Eye dam./irritation 2B    H320  
 Acute tox – oral 5          H303

**Label Elements**
**GHS Labelling:**

Hazard Pictograms (GHS-US):          No Symbol

Signal Word (GHS-US):                  Warning

## Hazard Statements (GHS-US)

 H333 - May be harmful if inhaled  
 H320 - Causes eye irritation  
 H303 – May be harmful if swallowed

## Precautionary Statements (GHS-US)

# SAFETY DATA SHEET (SDS)

According to OSHA HazCom Standard 29 CFR 1910.1200 (g), Rev 2012 and GHS Rev 03  
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P305 + 351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.  
P337 + P313 - If eye irritation persists: Get medical advice attention  
P261 - Avoid breathing dust/fumes/gas/mist/vapors/spray  
P264 – Wash face thoroughly after handling  
P312 – Call a POISON CENTER / doctor/physician if you feel unwell

**Other Hazards:** No data available

**Unknown acute toxicity (GHS US):** No data available

## SECTION 3: Composition/Information on Ingredients

### Substances

Name	Product Identifier CAS No.	Weight%	GHS-US Classification
SOLVENT VIOLET 013	81-48-1	100	Acute tox. – inhalation 5 H333 Eye dam./irritation 2B H320 Acute tox – oral 5 H303

## SECTION 4: First Aid Measures

### Description of first aid measures

First Aid Measures General: Remove contaminated clothing

**First-aid measures after inhalation:** Remove to fresh air. If breathing is difficult, give oxygen and get immediate medical attention.

**First-aid measures after skin contact:** Wash affected area thoroughly with soap and water. If any irritation develops, consult a Physician.

**First-aid measures after eye contact:** Flush with plenty of cool water for at least 15 minutes, holding eyelids apart for thorough irrigation. Get immediate medical attention.

**First-aid measures after ingestion:** Induce vomiting – seek immediate medical attention.

### Most important symptoms and effects, both acute and delayed:

THIS PRODUCT IS NOT HAZARDOUS AS DEFINED BY HAZARDOUS COMMUNICATION STANDARD. HOWEVER, AS WITH ALL CHEMICAL; HANDLE WITH CARE AVOID EYE & SKIN CONTACT, AVOID INHALATION OF DUSTS OR VAPORS. WASH THOROUGHLY AFTER HANDLING. KEEP CONTAINERS CLOSED.

### Indication of any immediate medical attention and special treatment needed:

No additional information

## SECTION 5: Firefighting Measures

### Extinguishing media

**Suitable Extinguishing Media:** WATER, DRY CHEMICAL, CARBON DIOXIDE, FOAM

Unsuitable Extinguishing Media:

**Special hazards arising from the substance or mixture:** NONE EXPECTED. FIREFIGHTERS SHOULD BE EQUIPPED WITH SELF-CONTAINED BREATHING APPARATUS TO GUARD AGAINST POTENTIALLY TOXIC AND IRRITATING FUMES. AVOID DUSTING. DUST CAN FORM EXPLOSIVE MIXTURES WITH AIR.

**Fire Hazard:** N/A

**Explosion Hazard:** N/A

**Reactivity:** N/A

### Advice for firefighters

**Firefighting Instructions:** WEAR SELF-CONTAINED BREATHING APPARATUS.

**Protection during firefighting:** Wear fully protective suit.

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## SECTION 6: Accidental release measures

### Personal precautions, protective equipment and emergency procedures

**General Measures:** Remove persons from danger area.

#### For non-emergency personnel

**Protective equipment:**

**Emergency procedures:** No additional information

#### For emergency responders

**Protective equipment:** See Section 8 for information on personal protection equipment.

**Emergency procedures:** No additional information

**Environmental precautions:** Avoid any uncontrolled release of material. Do not empty into drains or the aquatic environment.

### Methods and materials for containment and cleaning up

**For containment:** Where spills are possible, a comprehensive spill response plan should be developed and implemented. Steps to be taken if material is released or spilled are as follows: Utilize recommended protective clothing and equipment. Spills should be swept by using an absorbent dust control product and placed in containers.

**For cleaning up:** Spill area can be washed with water. Collect water for approved disposal. In the event of an uncontrolled release of this material, the user should determine if the release is reportable under applicable laws and regulations.

#### Reference to other sections

No additional information available.

## SECTION 7: Handling and storage

### Precautions for safe handling

**Additional hazards when processed:** N/A

**Precautions for safe handling:** USE STATEMENT;

Not to exceed by weight of suture: 0.2% in glycolic-lactic acid polyester synthetic absorbable sutures of 0.3% in polydioxanone synthetic absorbable sutures for use in general and ophthalmic surgery, and 0.1% in poly(epsilon-caprolactone) absorbable sutures for use in general surgery. Externally applied Drugs and Cosmetics -- consistent with Good Manufacturing Practice.

**Hygiene measures:** N/A

### Conditions for safe storage, including any incompatibilities

**Technical measures:** Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits.

**Storage conditions:** Above is offered as a guide. Consult title 21, Code of Federal Regulations (CFR) as the authoritative source should questions arise. (parts 1-99) Color additive Regulations are updated each year as of April 1.

**Incompatible products:** Keep away from heat. Keep away from sources of ignition.

**Incompatible materials:**

**Storage area:** Keep away from strong oxidizing and reducing agents

**Special rules on packaging:** None

**Specific end use(s):** USE STATEMENT;

Not to exceed by weight of suture: 0.2% in glycolic-lactic acid polyester synthetic absorbable sutures of 0.3% in polydioxanone synthetic absorbable sutures for use in general and ophthalmic surgery, and 0.1% in poly(epsilon-caprolactone) absorbable sutures for use in general surgery. Externally applied Drugs and Cosmetics -- consistent with Good Manufacturing Practice.

## SECTION 8: Exposure controls / personal protection

### Control parameters

Ingredients with limit values that require monitoring at the workplace: Not required.

### Exposure controls

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Appropriate engineering controls:  
The usual precautionary measures are to be adhered to when handling chemicals.

## Personal protective equipment:



Hand protection: Wear protective gloves  
Eye protection: Tightly sealed safety goggles or full face shield  
Skin and body protection: Wear suitable protective clothing  
Respiratory protection: Dust Mask  
Thermal hazard protection:  
Other information: No additional information

## SECTION 9: Physical and chemical properties

### Information on basic physical and chemical properties

Appearance	
Physical state, appearance, color, odor	DARK PURPLE POWDER, ODORLESS
Odor Threshold:	No data
pH:	N/A
Melting Point/Freezing Point:	ND
Initial boiling point/boiling range:	0.00
Flashpoint:	NORMALLY STABLE, NOT COMBUSTIBLE NOR FLAMMABLE.
Evaporation rate:	No data
Flammability (solid, gas):	NORMALLY STABLE, NOT COMBUSTIBLE NOR FLAMMABLE.
Upper explosive limits:	N/A
Lower explosive limits:	N/A
Vapor pressure:	N/A
Vapor density:	N/A
Relative density:	n/a
Solubility in water:	Insoluble
Partition coefficient n-octanol/water	No data
Auto-ignition temperature	No data
Decomposition temperature	No data
Viscosity, dynamic	No data
Viscosity, cinematic	No data
Explosive properties	N/A
Oxidizing properties	N/A

### Other information

No additional information available

## SECTION 10: Stability and reactivity

**Reactivity:** No data

**Chemical stability:** Stable

### Possibility of hazardous reactions

No additional information available

**Conditions to avoid:** OXIDIZING & REDUCING AGENTS MAY DESTROY COLOR.

**Incompatible materials:** OXIDIZING & REDUCING AGENTS MAY DESTROY COLOR.

**Hazardous decomposition products:** CO, CO<sub>2</sub>, OXIDES OF NITROGEN AND OTHER POTENTIALLY TOXIC FUMES.

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## SECTION 11: Toxicological information

### Information on toxicological effects

Oral (Animal): NO DATA AVAILABLE.

Dermal (animal): NO DATA AVAILABLE.

Effects to eyes (Animal): NO DATA AVAILABLE.

Skin irritation (Animal): NO DATA AVAILABLE.

**Skin corrosion/irritation:** Not classified

**Serious eye damage/irritation:** Causes serious eye irritation.

**Respiratory or skin sensitization:** Not classified

**Germ cell mutagenicity:** Not classified

**Carcinogenicity:** Not classified

**Reproductive toxicity:** Not classified

**Specific target organ toxicity (single exposure):** May cause drowsiness or dizziness.

**Aspiration hazard:** Not classified

**Symptoms/injuries after inhalation:** May cause drowsiness or dizziness.

**Symptoms/injuries after eye contact:** Causes serious eye irritation.

**Symptoms/injuries after ingestion:** Ingestion may cause nausea, vomiting and diarrhea.

## SECTION 12: Ecological information

### Toxicity:

NO DATA AVAILABLE.

**Persistence and degradability:** No Data Available

**Bioaccumulative potential:** No Data Available

**Mobility in soil:** No Data Available

**Other adverse effects:** No additional information available

## SECTION 13: Disposal considerations

### Waste treatment methods

**Regional legislation (waste):** Dispose of only in an approved land-fill area or by controlled incineration in accordance with local and State regulations.

**Waste disposal recommendations:** Empty bags thoroughly. Carry out the proper recycling, re-usage or disposal. Please refer to the relevant EU regulations, in particular the guidelines/ decisions of the council regarding handling of wastes (e.g. 75/442/EEC, 91/689/EEC, 94/67/EC, 94/904/EC) as implemented in national regulations.

## SECTION 14: Transport information

**UN number:** None

**UN proper shipping name:** None

**Department of Transportation (DOT)**

**Transport hazard class(es):** N/A

**Hazard labels (DOT)**

**Packing group (DOT):** N/A

**DOT Special provisions:** N/A

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## Additional information

Overland transport: NONE

Transport by sea: NONE

Air transport: NONE

DOT Quantity Limitations Passenger Aircraft: No additional information

DOT Quantity Limitations Cargo Aircraft: No additional information

## SECTION 15: Regulatory information

### US Federal regulations

This substance is listed on United States TSCA (Toxic Substance Control Act) inventory.

### US State regulations

None

### Other regulations

Chemical Identity	TSCA	DSL	NDSL	EINECS	ELINCS	ENCS	CHINA	KECL	PICCS	AICS
81-48-1	X	-	-	X	-	-	-	-	-	-

TSCA Status: IN COMPLIANCE

E C Classification: (67/548/EEC – 88/379/EEC) n/a

EINECS Number: 201-353-5

REACH Classification: 05-2117992958-13-0000

R-phrases:

Additional Regulatory Information: 21 CFR 74.1602 The color additive D&C Violet No. 2 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.  
21 CFR 74.2602 The color additive Ext. D&C Violet No. 2 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.  
Field of Application Definition, as per EC directive 76/768/EEC for use of colors in cosmetics: 1- Coloring agents allowed in all cosmetic products.

Permitted for Cosmetic and Toiletry applications in China and Korea

CAS 81-48-1 = EINECS 201-353-5

1-hydroxy-4-(p-toluidino)anthraquinone

aka CAS# 4430-18-6 = EINECS 224-618-7

Sodium 4-[(9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthryl)amino]toluene-3-sulphonate

## SECTION 16: Other information

Indication of changes: N/A

Other information: N/A

### GHS Full Text Phrases:

H333	May be harmful if inhaled
H320	Causes eye irritation
H303	May be harmful if swallowed

NFPA Rating: N/A

HMIS Rating: Health: 0 Flammability: 0 Reactivity: 1 Personal Protection: D

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