



# SAFETY DATA SHEET

## 1. Identification

Product identifier	Lithol Rubine BK		
Other means of identification			
Catalog number	1369055		
CAS number	5281-04-9		
Chemical name	Calcium salt of 3-hydroxy-4-[(4-methyl-2-sulfophenyl)azo]-2-naphthalenecarboxylic acid		
Recommended use	For analytical laboratory use only.		
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.		
Manufacturer/Importer/Supplier/Distributor information			
Manufacturer			
Company name	U. S. Pharmacopeia		
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States		
Telephone	Customer Service	301-881-0666	
Website	www.usp.org		
E-mail	RSTECH@usp.org		
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300	
	CHEMTREC outside US & Canada	+1 703-527-3887	

## 2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Not classified.
Environmental hazards	Not classified.
OSHA defined hazards	Not classified.

### Label elements

Hazard symbol	None.
Signal word	None.
Hazard statement	Not available.
Precautionary statement	
Prevention	Not available.
Response	Not available.
Storage	Not available.
Disposal	Not available.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	None.

## 3. Composition/information on ingredients

### Substance

Chemical name	Common name and synonyms	CAS number	%
Lithol Rubine BK		5281-04-9	100

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

## 4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Not available.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically.
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

## 5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

## 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

Precautions for safe handling	As a general rule, when handling USP materials, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.
Conditions for safe storage, including any incompatibilities	Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure controls/personal protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	For laboratory operations, use good technique and limit open handling. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

## Individual protection measures, such as personal protective equipment

<b>Eye/face protection</b>	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
<b>Skin protection</b>	
<b>Hand protection</b>	Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
<b>Other</b>	Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.
<b>Respiratory protection</b>	Respirators are generally not required for laboratory operations. Choose respiratory protection appropriate to the task and the level of existing engineering controls.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations** Handling practices in this SDS are recommendations for laboratory use of USP materials.

## 9. Physical and chemical properties

<b>Appearance</b>	Appearance descriptions are general information and not specific to any USP lot.
<b>Physical state</b>	Solid.
<b>Form</b>	Powder.
<b>Color</b>	Dark red.
<b>Odor</b>	Odorless.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	680 °F (360 °C)
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	<0.0000001 kPa (77 °F (25 °C))
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Insoluble.
<b>Partition coefficient (n-octanol/water)</b>	1.1 = log Pow (at 25 °C, pH 7)
<b>Auto-ignition temperature</b>	>842 °F (>450 °C)
<b>Decomposition temperature</b>	>473 °F (>245 °C)
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Density</b>	1.65 g/cm <sup>3</sup>
<b>Molecular formula</b>	C <sub>18</sub> H <sub>12</sub> CaN <sub>2</sub> O <sub>6</sub> S
<b>Molecular weight</b>	424.45

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.

<b>Conditions to avoid</b>	Avoid temperatures exceeding the decomposition temperature. Contact with incompatible materials.
<b>Incompatible materials</b>	None known.
<b>Hazardous decomposition products</b>	CaOx. NOx. SOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Health injuries are not known or expected under normal use.
<b>Skin contact</b>	Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Health injuries are not known or expected under normal use.
<b>Ingestion</b>	Health injuries are not known or expected under normal use.

**Symptoms related to the physical, chemical and toxicological characteristics** Not available.

### Information on toxicological effects

#### Acute toxicity

Product	Species	Test Results
Lithol Rubine BK (CAS 5281-04-9)		
<b>Acute</b>		
<b>Dermal</b>		
LD50	Rat	> 2500 mg/kg
<b>Inhalation</b>		
LC50	Rat	> 1518 mg/m3, 4 Hours
<b>Oral</b>		
LD50	Rat	≥ 5000 mg/kg

**Skin corrosion/irritation** Based on available data, the classification criteria are not met.

**Serious eye damage/eye irritation** Based on available data, the classification criteria are not met.

#### Local effects

Eye irritancy test  
Result: Non-irritating.  
Species: Rabbit  
Skin irritancy test (Draize)  
Result: Non-irritating.  
Species: Rabbit

### Respiratory or skin sensitization

<b>Respiratory sensitization</b>	Knowledge about health hazard is incomplete.
<b>Skin sensitization</b>	Based on available data, the classification criteria are not met.
Mouse local lymph node assay	
Result: Non-sensitizing.	
Patch test	
Result: Non-sensitizing.	
Species: Human	
Organ: Skin.	

**Germ cell mutagenicity** Knowledge about mutagenicity is incomplete.

#### Mutagenicity

Ames assay with S. typhimurium and E. coli  
Result: Negative (with and without activation).  
In vitro Chinese hamster lung cell chromosomal aberration assay  
Result: Negative.

**Carcinogenicity** Based on available data, the classification criteria are not met.

## Carcinogenicity

Dermal carcinogenicity study, 1 mg/0.1 mL applied to skin twice per week.

Result: Negative.

Species: Mouse

Test Duration: 18 months

## IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

## OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

## US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

## Reproductive toxicity

Based on available data, the classification criteria are not met.

### Reproductivity

0 - 1000 mg/kg/day Reproductivity and development study, administered orally.

Result: No treatment-related adverse effects observed.

Species: Rat

5 - 50 mg/kg/day Reproductivity and development study, administered via stomach tube during gestation.

Result: No fetotoxicity, teratogenicity, or maternal toxicity reported.

Species: Rabbit

## Specific target organ toxicity - single exposure

Knowledge about health hazard is incomplete.

## Specific target organ toxicity - repeated exposure

Knowledge about health hazard is incomplete.

## Aspiration hazard

Based on available data, the classification criteria are not met.

## 12. Ecological information

### Ecotoxicity

Product		Species	Test Results
Lithol Rubine BK (CAS 5281-04-9)			
<i>Acute</i>			
Other	EC50	Pseudokirchnerella subcapitata	190 mg/l, 72 hours
<i>Aquatic</i>			
<i>Acute</i>			
Crustacea	EC50	Daphnia magna	> 100 mg/l, 48 hours
Fish	LC50	Medaka, high-eyes (Oryzias latipes)	33 mg/l, 96 hours

## Persistence and degradability

Not readily biodegradable.

## Bioaccumulative potential

### Octanol/water partition coefficient log Kow

1.1, = log Pow (at 25 °C, pH 7)

## Mobility in soil

No data available.

## Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 13. Disposal considerations

### Disposal instructions

Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

### Local disposal regulations

Dispose in accordance with all applicable regulations.

### Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

### Waste from residues / unused products

Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

### Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

### DOT

Not regulated as dangerous goods.

### IATA

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

**General information** It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

## 15. Regulatory information

**US federal regulations** This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

### Toxic Substances Control Act (TSCA)

#### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

### SARA 304 Emergency release notification

Not regulated.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

#### SARA 302 Extremely hazardous substance

Not listed.

**SARA 311/312 Hazardous chemical** No

**SARA 313 (TRI reporting)**  
Not regulated.

### Other federal regulations

#### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

#### Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

### US state regulations

#### California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

### International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes

Country(s) or region	Inventory name	On inventory (yes/no)*
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

Issue date	09-16-2024
Revision date	09-16-2024
Version #	02
Disclaimer	<p>USP materials are sold for analytical laboratory use only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used for analytical laboratory use and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP materials are intended for use by persons having technical skill and at their own discretion and risk. This information has been compiled by USP staff from sources considered to be scientifically reliable but has not been independently verified by USP. USP does not guarantee the accuracy or completeness of the information from these sources included herein nor should the statements contained herein be considered an official expression by USP. USP does not independently create or develop the information included in this safety data sheet. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.</p>