

## SAFETY DATA SHEET

Preparation Date: 03/29/2016

Revision Date: 03/29/2016

Revision Number: G1

### 1. IDENTIFICATION

#### Product identifier

**Product code:** U1304  
**Product Name:** URSODIOL, USP

#### Other means of identification

**Synonyms:** Acido ursodeossicolico (Italian)  
 Cholan-24-oic acid, 3,7-dihydroxy-, (3-alpha,5-beta,7-beta)- (9CI)  
 7-beta-Hydroxylithocholic acid  
 Litursol  
 17-beta-(1-Methyl-3-carboxypropyl)etiocholane-3-alpha,7-beta-diol  
 3-alpha,7-beta-Dihydroxycholanic acid  
 3-alpha,7-beta-Dihydroxy-5-beta-cholanoic acid  
 3,7-Dihydroxycholan-24-oic acid  
 3-alpha,7-beta-Dioxycholanic acid  
 Ursacol  
 Ursobilin  
 Ursochol  
 Ursodeoxycholic acid  
 Ursodesoxycholic acid

**CAS #:** 128-13-2  
**RTECS #** Not available  
**CI#:** Not available

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

**Recommended use:** No information available.  
**Uses advised against** 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 number** Chemtrec 1-800-424-9300  
**Contact 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)

## Label elements

Not classified

## Hazards not otherwise classified (HNOC)

Not Applicable

## Other hazards

Not available

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

| Components           | CAS-No.  | Weight % |
|----------------------|----------|----------|
| Ursodiol<br>128-13-2 | 128-13-2 | 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 clothes 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/respiratory tract irritation. May cause hypermotility, diarrhea. May affect the liver. Central nervous system effects. May cause central nervous system effects. Somnolence. Convulsions.

#### 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:

Carbon dioxide (CO<sub>2</sub>). Dry chemical. Water spray mist or foam.

|   |   |
|---|---|
| <b>Unsuitable Extinguishing Media:</b>                    | No information available.   |
| <b><u>Specific hazards arising from the chemical</u></b>  |   |
| <b>Hazardous Combustion Products:</b>                     | Carbon monoxide, Carbon dioxide   |
| <b>Specific hazards:</b>                                  | May be combustible at high temperatures   |
| <b><u>Special Protective Actions for Firefighters</u></b> |   |
| <b>Specific Methods:</b>                                  | No information available.   |
| <b>Special Protective Equipment for Firefighters:</b>     | As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear |

## 6. ACCIDENTAL RELEASE MEASURES

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

|   |   |
|---|---|
| <b>Personal Precautions:</b>            | Ensure adequate ventilation. Use personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid contact with skin, eyes and clothing. Avoid dust formation. Remove all sources of ignition. |
| <b><u>Environmental precautions</u></b> | Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.   |

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

|                                |   |
|--------------------------------|---|
| <b>Methods for containment</b> | Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.           |
| <b>Methods for cleaning up</b> | 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. Avoid dust formation. 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. Avoid dust formation. Do not ingest. Do not breathe vapors/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**

U.S Occupational Exposure Limits: Not determined

### United States

| Components           | OSHA | NIOSH | ACGIH | AIHA WHEEL |
|----------------------|------|-------|-------|------------|
| Ursodiol<br>128-13-2 | None | None  | None  | None       |

### Canada

Canada Occupational Exposure Limits: Not determined

| Components           | Alberta | British Columbia | Ontario | Quebec |
|----------------------|---------|------------------|---------|--------|
| Ursodiol<br>128-13-2 | None    | None             | None    | None   |

### Australia and Mexico

Occupational Exposure Limits for Australia and Mexico: Not determined

| Components           | Australia | Mexico |
|----------------------|-----------|--------|
| Ursodiol<br>128-13-2 | None      | None   |

### Appropriate engineering controls

#### Engineering measures to reduce exposure:

Ensure adequate ventilation. 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

## 9. PHYSICAL AND CHEMICAL PROPERTIES

|  |   |   |
|--|---|---|
| <b>Physical state:</b><br>Solid                                      | <b>Appearance:</b><br>Powder.   | <b>Color:</b><br>White.   |
| <b>Odor:</b><br>No information available                             | <b>Taste</b><br>No information available                                    | <b>Formula:</b><br>C24-H40-O4                                   |
| <b>Molecular/Formula weight:</b><br>392.57                           | <b>Flammability:</b><br>No information available                            | <b>Flashpoint (°C/°F):</b><br>No information available.         |
| <b>Flash Point Tested according to:</b><br>Not available             | <b>Autoignition Temperature (°C/°F):</b><br>No information available        | <b>Lower Explosion Limit (%):</b><br>No information available   |
| <b>Upper Explosion Limit (%):</b><br>No information available        | <b>pH:</b><br>No information available                                      | <b>Melting point/range(°C/°F):</b><br>200-205 °C/392-401 °F     |
| <b>Decomposition temperature(°C/°F):</b><br>No information available | <b>Boiling point/range(°C/°F):</b><br>No information available              | <b>Bulk density:</b><br>No information available                |
| <b>Density (g/cm3):</b><br>No information available                  | <b>Specific gravity:</b><br>No information available                        | <b>Vapor pressure @ 20°C (kPa):</b><br>No information available |
| <b>Evaporation rate:</b><br>No information available                 | <b>Vapor density:</b><br>No information available                           | <b>VOC content (g/L):</b><br>No information available           |
| <b>Odor threshold (ppm):</b><br>No information available             | <b>Partition coefficient (n-octanol/water):</b><br>No information available | <b>Viscosity:</b><br>No information available                   |
| <b>Miscibility:</b><br>No information available                      | <b>Solubility:</b><br>Insoluble in water                                    |   |

## 10. STABILITY AND REACTIVITY

### Reactivity

No information available

### Chemical stability

**Stability:** Stable under recommended storage conditions

**Possibility of Hazardous Reactions:** Hazardous polymerization does not occur

**Conditions to avoid:** Heat. Avoid dust formation. Incompatible materials.

**Incompatible Materials:** Strong oxidizing agents.

**Hazardous decomposition products:** No information available

### Other Information

**Corrosivity:** No information available

**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

*Ursodiol - 128-13-2*

**LD50/oral/rat** = = 4600 mg/kg Oral LD50 Rat  
**LD50/oral/mouse** = >10000 mg/kg  
**LD50/dermal/rabbit** = No information available  
**LD50/dermal/rat** = No information available  
**LC50/inhalation/rat** = No information available  
**LC50/inhalation/mouse** = No information available  
**Other LD50 or LC50 information** = No information available

### Product Information

**LD50/oral/rat** =  
**VALUE- Acute Tox Oral** = 4600mg/kg

**LD50/oral/mouse** =  
**Value - Acute Tox Oral** = >10000mg/kg

**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

|                          |  |
|--------------------------|--|
| <b>Skin Contact:</b>     | May cause skin irritation.   |
| <b>Eye Contact:</b>      | May cause eye irritation.  |
| <b>Inhalation</b>        | May cause irritation of respiratory tract.   |
| <b>Ingestion</b>         | May cause hypermotility, diarrhea. May affect behavior/central nervous system (somnolence, convulsions). |
| <b>Aspiration hazard</b> | No information available   |

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

**Chronic Toxicity** Prolonged or repeated ingestion may cause hypermotility and diarrhea  
Prolonged or repeated ingestion may affect the liver

**Sensitization:** No information available

**Mutagenic Effects:** Mutations in microorganisms  
Experiments with bacteria and/or yeast have shown mutagenic effects

**Carcinogenic effects:** Not considered carcinogenic

| Components | IARC       | ACGIH - Carcinogens | NTP        | OSHA HCS - Carcinogens | Australia - Notifiable Carcinogenic Substances | Australia - Prohibited Carcinogenic Substances |
|------------|------------|---------------------|------------|------------------------|--|--|
| Ursodiol   | Not listed | Not listed          | Not listed | Not listed             | Not listed                                     | Not listed                                     |

**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**

**STOT - single exposure** No information available  
**STOT - repeated exposure** No information available  
**Target Organs:** 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 | RCRA - F Series Wastes | RCRA - K Series Wastes | RCRA - P Series Wastes | RCRA - U Series Wastes |
|------------|------------------------|------------------------|------------------------|------------------------|
| Ursodiol   | None                   | None                   | None                   | None                   |

**14. TRANSPORT INFORMATION**

**DOT**

## 14. TRANSPORT INFORMATION

|                              |                          |
|------------------------------|--------------------------|
| <b>UN-No:</b>                | Not Regulated            |
| <b>Proper Shipping Name:</b> | No information available |
| <b>Hazard Class:</b>         | No information available |
| <b>Subsidiary Risk:</b>      | No information available |
| <b>Packing Group:</b>        | None                     |
| <b>ERG No:</b>               | No information available |
| <b>Marine Pollutant</b>      | No data available        |
| <b>DOT RQ (lbs):</b>         | No information available |
| <b>Special Provisions</b>    | No Information available |
| <b>Symbol(s):</b>            | No information available |

### TDG (Canada)

|                              |                          |
|------------------------------|--------------------------|
| <b>UN-No:</b>                | Not Regulated            |
| <b>Proper Shipping Name:</b> | No information available |
| <b>Hazard Class:</b>         | No information available |
| <b>Subsidiary Risk:</b>      | No information available |
| <b>Packing Group:</b>        | No information available |
| <b>Marine Pollutant</b>      | No Information available |

### ADR

|                              |                          |
|------------------------------|--------------------------|
| <b>UN-No:</b>                | Not Regulated            |
| <b>Proper Shipping Name:</b> | No information available |
| <b>Hazard Class:</b>         | No information available |
| <b>Packing Group:</b>        | No information available |
| <b>Subsidiary Risk:</b>      | No information available |

### IMO / IMDG

|                              |                          |
|------------------------------|--------------------------|
| <b>UN-No:</b>                | Not Regulated            |
| <b>Proper Shipping Name:</b> | No information available |
| <b>Hazard Class:</b>         | No information available |
| <b>Subsidiary Risk:</b>      | No information available |
| <b>Packing Group:</b>        | No information available |
| <b>Marine Pollutant</b>      | No information available |

### RID

|                              |                          |
|------------------------------|--------------------------|
| <b>UN-No:</b>                | Not Regulated            |
| <b>Proper Shipping Name:</b> | No information available |
| <b>Hazard Class:</b>         | No information available |
| <b>Subsidiary Risk:</b>      | No information available |
| <b>Packing Group:</b>        | No information available |

### ICAO

|                              |                          |
|------------------------------|--------------------------|
| <b>UN-No:</b>                | Not Regulated            |
| <b>Proper Shipping Name:</b> | No information available |
| <b>Hazard Class:</b>         | No information available |
| <b>Subsidiary Risk:</b>      | No information available |
| <b>Packing Group:</b>        | No information available |

### IATA

|                              |                          |
|------------------------------|--------------------------|
| <b>UN-No:</b>                | Not Regulated            |
| <b>Proper Shipping Name:</b> | No information available |
| <b>Hazard Class:</b>         | No information available |
| <b>Subsidiary Risk:</b>      | No information available |
| <b>Packing Group:</b>        | No information available |
| <b>ERG Code:</b>             | No information available |
| <b>Special Provisions</b>    | No information available |

## 15. REGULATORY INFORMATION

### International Inventories

| Components | U.S. TSCA  | KOREA KECL  | Philippines (PICCS) | Japan ENCS       | CHINA       | Australia (AICS) | EINECS-No.        |
|------------|------------|-------------|---------------------|------------------|-------------|------------------|-------------------|
| Ursodiol   | Not Listed | Not present | Present             | Present (9)-2157 | Not present | Present          | Present 204-879-3 |

### 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 | Carcinogen | Developmental Toxicity | Male Reproductive Toxicity | Female Reproductive Toxicity: |
|------------|------------|------------------------|----------------------------|-------------------------------|
| Ursodiol   | Not Listed | Not Listed             | Not Listed                 | Not Listed                    |

### CERCLA/SARA

| Components | 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 <i>de minimis</i> |
|------------|---|---|--|---------------------------------|---|
| Ursodiol   | None  | None  | None   | None                            | None                                      |

### U.S. TSCA

| Components | TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS) | TSCA 8(d) -Health and Safety Reporting |
|------------|---|--|
| Ursodiol   | Not Applicable  | Not Applicable                         |

### Canada

#### WHMIS 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 | Canada (DSL) | Canada (NDSL) |
|------------|--------------|---------------|
| Ursodiol   | Not Listed   | Not Listed    |

| Components | CEPA Schedule I - Toxic Substances |
|------------|------------------------------------|
| Ursodiol   | Not listed                         |

| Components | CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting |
|------------|---|
| Ursodiol   | Not listed  |

**EU Classification**

**R-phrase(s)**  
none

**S -phrase(s)**  
none

| Components | Classification | Concentration Limits: | Safety Phrases |
|------------|----------------|-----------------------|----------------|
| Ursodiol   |                | No information        |                |

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

**Indication of danger:**  
None.

**16. OTHER INFORMATION**

## 16. OTHER INFORMATION

**Preparation Date:** 03/29/2016  
**Revision Date:** 03/29/2016  
**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**