

## URSODEOXYCHOLIC ACID UNLABELED

### Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 and according to

Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Date of issue: 23/07/2014 Revision date: 07/07/2020 Supersedes: 18/03/2016 Version: 2.1

ULM-9573

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Substance

Substance name : URSODEOXYCHOLIC ACID UNLABELED

 EC-No.
 : 204-879-3

 CAS-No.
 : 128-13-2

 Product code
 : ULM-9573

 Formula
 : C24H40O4

Synonyms : 3alpha,7Beta-dihydroxy-5Beta-cholan-24-oic acid / 7(beta)-Hydroxylithocholic acid / UDCS /

5Beta-Cholan-24-oic acid-3alpha,7Beta-diol

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

#### 1.2.1. Relevant identified uses

Main use category : Professional use

Industrial/Professional use spec : For professional use only

### 1.2.2. Uses advised against

No additional information available

### 1.3. Details of the supplier of the safety data sheet

Cambridge Isotope Laboratories, Inc.

50 Frontage Road Andover, MA 01810

USA

USA: 1-800-322-1174 Int: 1-978-749-8000 <u>cilsales@isotope.com</u> www.isotope.com

#### **Emergency telephone number**

Emergency numbers:

Chemtrec: 1-800-424-9300 (24 hours) International: 1-703-741-5970 (24 hours)

### **SECTION 2: Hazards identification**

### 2.1. Classification of the substance or mixture

### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

### Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Not classified

### **GHS-US** classification

Not classified

### Adverse physicochemical, human health and environmental effects

No additional information available

### 2.2. Label elements

### Labeling according to Regulation (EC) No. 1272/2008 [CLP]

No labeling applicable

#### **GHS-US** labeling

No labeling applicable

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#### 2.3. Other hazards

No additional information available

### **SECTION 3: Composition/Information on ingredients**

#### 3.1. Substances

Name	Product identifier	%	Classification according to Directive 67/548/EEC
URSODEOXYCHOLIC ACID UNLABELED	(CAS-No.) 128-13-2 (EC-No.) 204-879-3	100	Not classified
Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
URSODEOXYCHOLIC ACID UNLABELED	(CAS-No.) 128-13-2 (EC-No.) 204-879-3	100	Not classified

Full text of R- and H- phrases: see section 16

Name	Product identifier	%	GHS-US classification
URSODEOXYCHOLIC ACID UNLABELED (Main constituent)	(CAS-No.) 128-13-2	100	Not classified

Full text of H-phrases: see section 16

#### 3.2. Mixtures

Not applicable

#### **SECTION 4: First aid measures**

#### 4.1. Description of first aid measures

First-aid measures general : If you feel unwell, seek medical advice (show the label where possible). Evacuate danger area.

First-aid measures after inhalation : When symptoms occur: go into open air and ventilate suspected area. If not breathing give

artificial respiration. Get medical advice/attention.

First-aid measures after skin contact : Wash with plenty of soap and water. Get immediate medical advice/attention.

First-aid measures after eye contact : Rinse cautiously with water for several minutes.

First-aid measures after ingestion : Never give anything by mouth to an unconscious person. Rinse mouth out with water. Get

medical advice/attention.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation : May be harmful if inhaled. May cause respiratory tract irritation.

Symptoms/effects after skin contact : May be harmful if absorbed through skin. May cause skin irritation.

Symptoms/effects after eye contact : May cause eye irritation.

Symptoms/effects after ingestion : May be harmful if swallowed.

#### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

### **SECTION 5: Firefighting measures**

#### 5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry chemical powder, alcohol-resistant foam, carbon dioxide (CO2).

### 5.2. Special hazards arising from the substance or mixture

No additional information available

#### 5.3. Advice for firefighters

Firefighting instructions : Fight fire with normal precautions from a reasonable distance. Wear a self contained breathing apparatus. Do not enter fire area without proper protective equipment, including respiratory

protection.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

Wear recommended personal protective equipment.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

### 6.1.1. For non-emergency personnel

Emergency procedures : Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Avoid breathing dust.

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#### 6.1.2. For emergency responders

: Do not attempt to take action without suitable protective equipment. For further information Protective equipment

refer to section 8: "Exposure controls/personal protection".

#### **Environmental precautions**

Prevent entry to sewers and public waters. Do not allow to enter drains or water courses. Avoid release to the environment.

#### Methods and material for containment and cleaning up 6.3.

For containment : Take up mechanically (sweeping, shoveling) and collect in suitable container for disposal. : This material and its container must be disposed of in a safe way, and as per local legislation. Methods for cleaning up

#### Reference to other sections

For further information refer to section 13.

### **SECTION 7: Handling and storage**

#### Precautions for safe handling

Additional hazards when processed : Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where

dust is formed. Normal measures for preventive fire protection.

Wash hands and other exposed areas with mild soap and water before eating, drinking or Hygiene measures

smoking and when leaving work. Handle in accordance with good industrial hygiene and safety practice.

#### Conditions for safe storage, including any incompatibilities

Technical measures : Store in a well-ventilated place. Keep container tightly closed.

Storage conditions : Store in freezer (-20°C). Protect from light.

#### Specific end use(s)

No additional information available

### **SECTION 8: Exposure controls/personal protection**

#### Control parameters

URSODEOXYCHOLIC ACID UNLABELED (128-13-2)	
DNEL/DMEL (Workers)	
Acute - systemic effects, dermal	>= mg/kg bodyweight/day

### **Exposure controls**

Appropriate engineering controls : Handle in accordance with good industrial hygiene and safety practice. Wash hands before

breaks and at the end of workday.

Personal protective equipment : Gloves. Protective clothing. Protective goggles. Self-contained breathing apparatus.



Materials for protective clothing Wear suitable protective clothing and gloves. Hand protection Wear suitable protective clothing and gloves.

Eye protection Wear safety glasses with side shields (or goggles) and a face shield.

Skin and body protection Choose body protection according to the amount and concentration of the dangerous

substance at the work place.

Respiratory protection : When appropriate, use NIOSH/CEN approved respirator.

Environmental exposure controls : Avoid release to the environment.

### **SECTION 9: Physical and chemical properties**

#### Information on basic physical and chemical properties

Physical state : Solid Appearance Powder Molecular mass 392.57 g/mol Color White

Odor : No data available : No data available Odor threshold No data available Relative evaporation rate (butyl acetate=1) : No data available

Melting point : 203 - 204 °C (397 - 399 °F)

: No data available Freezing point

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Boiling point	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Flammability (solid, gas)	:	No data available
Vapor pressure	:	No data available
Relative vapor density at 20 °C	:	No data available
Relative density	:	No data available
Solubility	:	No data available
Log Pow	:	No data available
Log Kow	:	No data available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	No data available
Explosion limits	:	No data available

### 9.2. Other information

No additional information available

### **SECTION 10: Stability and reactivity**

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

Stable if stored under recommended conditions.

### 10.3. Possibility of hazardous reactions

No additional information available

### 10.4. Conditions to avoid

No additional information available

### 10.5. Incompatible materials

Strong oxidizing agents.

### 10.6. Hazardous decomposition products

Formed under fire conditions: Carbon oxides.

### **SECTION 11: Toxicological information**

### 11.1. Information on toxicological effects

Acute toxicity : Not classified

URSODEOXYCHOLIC ACID UNLABELED (128-13-2)	
LD50 oral rat	4600 mg/kg
ATE CLP (oral)	4600.000 mg/kg body weight
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity – single exposure	: Not classified
Specific target organ toxicity – repeated exposure	: Not classified
Aspiration hazard	: Not classified
Potential Adverse human health effects and symptoms	: This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.
Symptoms/effects after inhalation	: May be harmful if inhaled. May cause respiratory tract irritation.
Symptoms/effects after skin contact	: May be harmful if absorbed through skin. May cause skin irritation.
Symptoms/effects after eye contact	: May cause eye irritation.

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Symptoms/effects after ingestion : May be harmful if swallowed.

### **SECTION 12: Ecological information**

#### 12.1. Toxicity

Ecology - general

: The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

### 12.2. Persistence and degradability

No additional information available

### 12.3. Bioaccumulative potential

No additional information available

#### 12.4. Mobility in soil

No additional information available

#### 12.5. Results of PBT and vPvB assessment

No additional information available

#### 12.6. Other adverse effects

No additional information available

#### **SECTION 13: Disposal considerations**

#### 13.1. Waste treatment methods

Regional legislation (waste)

: Waste materials should be disposed of under conditions which meet Federal, State, and local

environmental control regulations.

Product/Packaging disposal recommendations

Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed

professional waste disposal service to dispose of this material.

Ecology - waste materials : Dispose of as unused product.

### **SECTION 14: Transport information**

In accordance with ADR / RID / IMDG / IATA / ADN

### 14.1. UN number

Not applicable

#### 14.2. UN proper shipping name

Not applicable

#### 14.3. Additional information

Other information : No supplementary information available.

Special transport precautions : Not dangerous goods.

#### **Overland transport**

No additional information available

### Transport by sea

No additional information available

### Air transport

No additional information available

### 14.4. Environmental hazards

Other information : No supplementary information available.

#### 14.5. Special precautions for user

Special transport precautions : Not dangerous goods.

### 14.6. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

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SECTION 15: Regulatory information	on Carlos Ca	
15.1. US Federal regulations		
URSODEOXYCHOLIC ACID UNLABELED (128-13-2)		
SARA Section 302 Threshold Planning Quantity (TPQ)	Not subject to reporting requirements of the United States SARA Section 302	
SARA Section 313 - Emission Reporting	Not subject to reporting requirements of the United States SARA Section 313	

### 15.2. International regulations

#### **CANADA**

### **URSODEOXYCHOLIC ACID UNLABELED (128-13-2)**

Listed on the Canadian DSL (Domestic Substances List)

#### 15.2.1. National regulations

No additional information available

### 15.3. US State regulations

URSODEOXYCHOLIC ACID UNLABELED(128-13-2)		
U.S California - Proposition 65 - Carcinogens List	No	
U.S California - Proposition 65 - Developmental Toxicity	No	
U.S California - Proposition 65 - Reproductive Toxicity - Female	No	
U.S California - Proposition 65 - Reproductive Toxicity - Male	No	
State or local regulations	U.S Pennsylvania - RTK (Right to Know) List U.S New Jersey - Right to Know Hazardous Substance List	

### **SECTION 16: Other information**

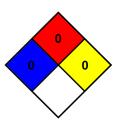
NFPA health hazard : 0 - Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials.

NFPA fire hazard : 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as

concrete, stone, and sand.

NFPA reactivity : 0 - Material that in themselves are normally stable, even

under fire conditions.



#### **Hazard Rating**

Health : 1 Slight Hazard - Irritation or minor reversible injury possible

Flammability : 0 Minimal Hazard
Physical : 0 Minimal Hazard

### CIL Substance SDS

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

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