



SAFETY DATA SHEET

**URSODEOXYCHOLIC ACID**

Sheet no. 03

Edition: 04

Date: 01/03/2020

Page 1 of 12

**Safety Data Sheet**

In accordance with Regulation (EC) N. 1907/2006, modified by Regulation (EC) N. 2015/830

**SECTION 1  
IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY/UNDERTAKING****1.1. Product identifier**

Substance name:	<b>Ursodeoxycholic acid</b>
CAS number:	128-13-2
IUPAC name:	(4R)-4-[(3R,5S,7S,8R,9S,10S,13R,14S,17R)-3,7-dihydroxy-10,13-dimethyl-2,3,4,5,6,7,8,9,11,12,14,15,16,17-tetradecahydro-1H-cyclopenta[a]phenanthren-17-yl]pentanoic acid
CAS name:	Cholan-24-oic acid, 3,7-dihydroxy-, (3 $\alpha$ ,5 $\beta$ ,7 $\beta$ )-
REACH registration number:	01-2119969941-23-0000

**1.2. Relevant identified uses of the substance and uses advised against**

Relevant identified uses:	Intermediate of synthesis; active pharmaceutical ingredient (API)
---------------------------	---

**1.3. Details of the supplier of the Safety Data Sheet**

Manufacturer:	ICE S. p. A.
Address:	Basaluzzo Site Via Novi 78 - Basaluzzo (AI) - Italia
Phone number:	0143.48831

E-mail address of the competent person responsible for the safety data sheet: [rspp@iceitaly.com](mailto:rspp@iceitaly.com)**1.4. Emergency telephone number**

Emergency telephone number:	++39 0143 48831 (from monday to friday h 8.30 – 12.30, 14.30 – 18.30) Poison centers with access to the information stored at the Institute of Health (24 hours 24) - see section. 16
-----------------------------	--

**ICE S.p.A. a socio unico**

Cod. Fisc./Part. IVA IT 01227810353 - R.E.A. RE 169836 - Posiz. Comm. Estero RE 003868 - Capitale Sociale €120.000,00 i.v.

**Stabilimento di Reggio Emilia**  
(e Sede Legale ed Amministrativa)  
Via Sicilia 8/10 - 42122 REGGIO EMILIA - ITALIA  
Tel. 0522 551250 - Fax: 0522 558963  
[www.iceitaly.com](http://www.iceitaly.com)  
E-mail: [info@iceitaly.com](mailto:info@iceitaly.com)

**Stabilimento di Basaluzzo**  
Via Novi 78 - 15060 BASALUZZO (AI) - ITALIA  
Tel. 0143 48831 - Fax 0143 489719  
[www.iceitaly.com](http://www.iceitaly.com)  
E-mail: [info@iceitaly.com](mailto:info@iceitaly.com)



SAFETY DATA SHEET

# URSODEOXYCHOLIC ACID

Sheet no. 03

Edition: 04

Date: 01/03/2020

Page 2 of 12

## SECTION 2 HAZARDS IDENTIFICATION

### 2.1 Classification of the substance

- Classification of the substance in accordance with Regulation (EC) n. 1272/2008:

**Skin Irrit. 2, H315** - Causes skin irritation.

**Eye Irrit. 2, H319** - Causes serious eye irritation.

### 2.2 Label elements

- Labelling in accordance with regulation n. 1272/2008/EC

- Hazard pictogram	
- Signal word:	<b>Warning</b>
- Hazard statements	H315: Causes skin irritation. H319: Causes serious eye irritation
- Precautionary statements	P264: Wash hands. thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection/face protection. P302+P352: IF ON SKIN: Wash with plenty of soap and water. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P332+P313: If skin irritation occurs: Get medical advice/attention. P337+P313: If eye irritation persists: Get medical advice/attention.

### 2.3 Other hazards

The components of the mixture do not satisfy the PBT or vPvB criteria, according to Annex XIII of REACH Regulation.

- Physic-chemical hazards      The substance is an organic powder, explosive mixtures with air may be formed under certain conditions (e.g. temperature, pressure, particle size, moisture, concentration comburent).

#### ICE S.p.A. a socio unico

Cod. Fisc./Part. IVA IT 01227810353 - R.E.A. RE 169836 - Posiz. Comm. Estero RE 003868 - Capitale Sociale €120.000,00 i.v.

Stabilimento di Reggio Emilia  
(e Sede Legale ed Amministrativa)  
Via Sicilia 8/10 - 42122 REGGIO EMILIA - ITALIA  
Tel. 0522 551250 - Fax: 0522 558963  
[www.iceitaly.com](http://www.iceitaly.com)  
E-mail: [info@iceitaly.com](mailto:info@iceitaly.com)

Stabilimento di Basaluzzo  
Via Novi 78 - 15060 BASALUZZO (AI) - ITALIA  
Tel. 0143 48831 - Fax 0143 489719  
[www.iceitaly.com](http://www.iceitaly.com)  
E-mail: [info@iceitaly.com](mailto:info@iceitaly.com)

# URSODEOXYCHOLIC ACID

Sheet no. 03

Edition: 04

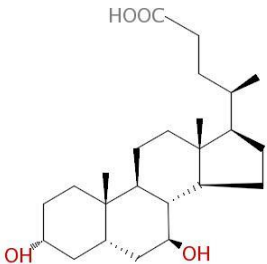
Date: 01/03/2020

Page 3 of 12

## SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substance

Description:

<i>Name of the component:</i>	Ursodeoxycholic acid
<i>Concentration</i>	> 98.5%
<i>Structural formula</i>	
<i>Chemical formula</i>	C <sub>24</sub> H <sub>40</sub> O <sub>4</sub>
<i>Molecular weight</i>	392.572
<i>CAS name</i>	Cholan-24-oic acid, 3,7-dihydroxy-, (3 $\alpha$ ,5 $\beta$ ,7 $\beta$ )-
<i>CAS number</i>	128-13-2
<i>IUPAC name</i>	(4R)-4-[(3R,5S,7S,8R,9S,10S,13R,14S,17R)-3,7-dihydroxy-10,13-dimethyl-2,3,4,5,6,7,8,9,11,12,14,15,16,17-tetradecahydro-1H-cyclopenta[a]phenanthren-17-yl]pentanoic acid
<i>EC number</i>	204-879-3

## SECTION 4 FIRST AID MEASURES

### 4.1 Description of the first aid measures

- *Eye contact:* Flush eyes with water for at least 15 minutes, lifting eyelids. If eye irritation persists, consult a physician immediately.
- *Skin contact:* Wash the affected area with water.
- *Ingestion:* If swallowed rinse mouth with plenty of water provided person is conscious. Get medical advice if adverse symptoms appear.
- *Inhalation:* If inhaled, move person to fresh air. Get medical advice if adverse symptoms appear.

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

- *Acute effects:* In case of contact with eyes, severe irritation and/or burns with lesions of the cornea and a possible worsening of eyesight might occur.  
Skin contact may cause irritation; a prolonged exposure may cause dermatitis.

#### ICE S.p.A. a socio unico

Cod. Fisc./Part. IVA IT 01227810353 - R.E.A. RE 169836 - Posiz. Comm. Estero RE 003868 - Capitale Sociale €120.000,00 i.v.

Stabilimento di Reggio Emilia  
(e Sede Legale ed Amministrativa)  
Via Sicilia 8/10 - 42122 REGGIO EMILIA - ITALIA  
Tel. 0522 551250 - Fax: 0522 558963  
[www.iceitaly.com](http://www.iceitaly.com)  
E-mail: [info@iceitaly.com](mailto:info@iceitaly.com)

Stabilimento di Basaluzzo  
Via Novi 78 - 15060 BASALUZZO (AI) - ITALIA  
Tel. 0143 48831 - Fax 0143 489719  
[www.iceitaly.com](http://www.iceitaly.com)  
E-mail: [info@iceitaly.com](mailto:info@iceitaly.com)



## SAFETY DATA SHEET

## URSODEOXYCHOLIC ACID

Sheet no. 03

Edition: 04

Date: 01/03/2020

Page 4 of 12

- *Delayed effects:* Delayed symptoms and effects are not known.

**4.3 Indication of any immediate medical attention and special treatment needed**

- *Medical monitoring:* Health surveillance of workers is foreseen in accordance with Article 10 of Directive 98/24/EC, if it is appropriate to the nature of the risk.

- *Immediate treatment at workplace:* Provide emergency showers and eyewash stations.

**SECTION 5  
FIREFIGHTING MEASURES****5.1 Extinguishing media**

- *Suitable extinguishing media:* Dry powder, foam, water mist and CO<sub>2</sub>

- *Unsuitable extinguishing media:* Not known

**Special hazards arising from the substance or mixture**

- *Hazardous combustion products:* Combustion may produce toxic fumes containing CO<sub>x</sub>.

**5.3 Advice for firefighters**

*Special protective equipment for fire-fighters and protection measures* Cool containers with water jets. Wear self-contained breathing apparatus (SCBA), protective equipments for eyes and face, boots, gloves, complying with the relevant EN standards. Use the devices in maximum precautionary conditions based on information reported in previous subsections.

**SECTION 6  
ACCIDENTAL RELEASE MEASURES****6.1 Personal precautions, protective equipment and emergency procedures**

The substance is an organic powder, explosive mixtures with air may be formed under certain conditions (e.g. temperature, pressure, particle size, moisture, concentration comburent). In case of accidental spillage remove sources of ignition and ventilate the area.

**- Personal protective equipment**

- *Eye:* Wear eye protection.

- *Skin:* Wear suitable protective clothing.

- *Inhalation:* Wearing masks with filters.

**6.2 Environmental precautions**

## ICE S.p.A. a socio unico

Cod. Fisc./Part. IVA IT 01227810353 - R.E.A. RE 169836 - Posiz. Comm. Estero RE 003868 - Capitale Sociale €120.000,00 i.v.

**Stabilimento di Reggio Emilia**

(e Sede Legale ed Amministrativa)

Via Sicilia 8/10 - 42122 REGGIO EMILIA - ITALIA

Tel. 0522 551250 - Fax: 0522 558963

[www.iceitaly.com](http://www.iceitaly.com)E-mail: [info@iceitaly.com](mailto:info@iceitaly.com)**Stabilimento di Basaluzzo**

Via Novi 78 - 15060 BASALUZZO (AI) - ITALIA

Tel. 0143 48831 - Fax 0143 489719

[www.iceitaly.com](http://www.iceitaly.com)E-mail: [info@iceitaly.com](mailto:info@iceitaly.com)



SAFETY DATA SHEET

# URSODEOXYCHOLIC ACID

Sheet no. 03

Edition: 04

Date: 01/03/2020

Page 5 of 12

In case of accidental release or spills, prevent contamination of surface and ground waters, sewers, soil.

## 6.3 Methods and material for containment and cleaning up

- *Containment procedures and cleaning up* Stop the spill if it can be done safely. Collect the material with mechanic means, wearing appropriate protective equipment, and store in a clean and appropriate waste disposal container. Wash the area with water.

## 6.4 Reference to other sections

See Sections 8 and 13.

## SECTION 7 HANDLING AND STORAGE

### 7.1. Precautions for safe handling

- *Recommendations for handling:* Handle away from sparkles and flames - sources of ignition.  
Avoid dispersal of dust.  
Avoid contact with incompatible materials.  
Wear suitable Personal Protection Equipment (see section 8).  
Keep the substance away from drains, surface or ground waters.
- *Recommendation for personal hygiene:* Do not eat, drink and smoke in the working areas.  
Wash hands after handling the substance.  
Remove contaminated clothing and protective equipment before entering eating areas.

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

- *Recommendations for storage* Avoid direct exposure to sunlight. Store in a cool, well ventilated, dry place. Store at room temperature.  
Keep containers tightly closed. Store in containers correctly labeled.

### 7.3. Specific end use

- Recommendation for the end-use:  
See exposure scenario attached.

## SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

- National/ European Occupational Exposure Limits Not established.

#### ICE S.p.A. a socio unico

Cod. Fisc./Part. IVA IT 01227810353 - R.E.A. RE 169836 - Posiz. Comm. Estero RE 003868 - Capitale Sociale €120.000,00 i.v.

**Stabilimento di Reggio Emilia**  
(e Sede Legale ed Amministrativa)  
Via Sicilia 8/10 - 42122 REGGIO EMILIA - ITALIA  
Tel. 0522 551250 - Fax: 0522 558963  
[www.iceitaly.com](http://www.iceitaly.com)  
E-mail: [info@iceitaly.com](mailto:info@iceitaly.com)

**Stabilimento di Basaluzzo**  
Via Novi 78 - 15060 BASALUZZO (AI) - ITALIA  
Tel. 0143 48831 - Fax 0143 489719  
[www.iceitaly.com](http://www.iceitaly.com)  
E-mail: [info@iceitaly.com](mailto:info@iceitaly.com)



## SAFETY DATA SHEET

## URSODEOXYCHOLIC ACID

Sheet no. 03

Edition: 04

Date: 01/03/2020

Page 6 of 12

- Other Occupational Exposure Limits:	Not established.
- National/ European Biological Limits (BEI):	Not established.
- Recommended monitoring procedures:	The measurement of substances at the workplace must be carried out with standardized methods (e.g. EN 689:1997: Workplace atmospheres. Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy.; EN 482:2006: Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) or, failing that, with appropriate methods.
- DNEL values	<b>DNELs for workers</b> Long-term systemic effects - inhalation: 9.8 mg/m <sup>3</sup>
- PNEC values	<b>PNEC water</b> PNEC fresh water: 310 µg/L PNEC marine water: 31 µg/L <b>PNEC sediment</b> PNEC fresh water: 2.57 mg/kg sediment dw PNEC marine water: 0.257 mg/kg sediment dw <b>PNEC soil</b> PNEC: 0.335 mg/kg soil dw <b>PNEC for sewage treatment plant</b> PNEC - STP: 100 mg/L

**8.2. Exposure controls**

Where possible the dispersion of dust in working environment, equipping the stations of local exhaust ventilation. During special activities, such as maintenance and cleaning, where exposures are possible uncontrolled, equipping workers with appropriate personal protective equipment.

<i>Eye/ Face protection</i>	Goggles (EN166), if you can make contact with the eyes.
<i>Skin protection</i>	Wear full protective clothing.
<i>Hand protection</i>	Chemical protective gloves (EN 374). Type of material: rubber or plastic material. Breakthrough time: class to be established on the basis of duration of dermal exposure (Class 1 <10 min., Class 6 > 480 min.).
<i>Respiratory protection</i>	Filtering face dust (EN149) medium degree of protection (FFP2).

**SECTION 9  
PHYSICAL AND CHEMICAL PROPERTIES****9.1. Information on basic physical and chemical properties**

Appearance:	white or almost white crystalline powder
pH:	This information is not available.
Melting point/freezing point:	203 °C at 101.3 kPa
Initial boiling point and boiling range:	547.1 °C at 101.3 kPa (predicted)
Flash point:	298.8 °C at 1013 hPa (predicted)
Flammability (solids, gas):	non flammable
Vapor pressure:	3 x 10 <sup>-13</sup> mm Hg at 25° C (predicted)
Relative density:	1.128 g/cm <sup>3</sup> at 20°C (predicted)
Water solubility:	20 mg/L at 25 °C

## ICE S.p.A. a socio unico

Cod. Fisc./Part. IVA IT 01227810353 - R.E.A. RE 169836 - Posiz. Comm. Estero RE 003868 - Capitale Sociale €120.000,00 i.v.

**Stabilimento di Reggio Emilia**  
(e Sede Legale ed Amministrativa)  
Via Sicilia 8/10 - 42122 REGGIO EMILIA - ITALIA  
Tel. 0522 551250 - Fax: 0522 558963  
[www.iceitaly.com](http://www.iceitaly.com)  
E-mail: [info@iceitaly.com](mailto:info@iceitaly.com)

**Stabilimento di Basaluzzo**  
Via Novi 78 - 15060 BASALUZZO (AI) - ITALIA  
Tel. 0143 48831 - Fax 0143 489719  
[www.iceitaly.com](http://www.iceitaly.com)  
E-mail: [info@iceitaly.com](mailto:info@iceitaly.com)



SAFETY DATA SHEET

# URSODEOXYCHOLIC ACID

Sheet no. 03

Edition: 04

Date: 01/03/2020

Page 7 of 12

Partition coefficient Octanol/water  
(Log Kow):

Log Kow (Pow): 3.38 at 20 °C (predicted)

Ignition temperature:

> 400° C

Decomposition temperature:

This information is not available.

Explosive properties:

The substance is an organic powder, explosive mixtures with air may be formed under certain conditions (e.g. temperature, pressure, particle size, moisture, concentration comburent).

Oxidizing properties:

no oxidizing

## SECTION 10 STABILITY AND REACTIVITY

### 10.1. Reactivity

The substance reacts with strong oxidizing, strong acid and bases.

### 10.2. Chemical stability

The mixture is stable under recommended conditions of storage and use.

### 10.3. Possibility of hazardous reactions

The substance is an organic powder, explosive mixtures with air may be formed under certain conditions (e.g. temperature, pressure, particle size, moisture, concentration comburent).

### 10.4. Condition to avoid

Do not expose containers to heat sources.

### 10.5. Incompatible materials

Avoid contact with strong oxidizing, strong acid and base.

### 10.6. Hazardous decomposition product

Combustion may produce toxic and hazardous fumes (COx).

## SECTION 11 TOXICOLOGICAL INFORMATION

### 11.1. Information on toxicological effects

- Acute toxicity:

#### ICE S.p.A. a socio unico

Cod. Fisc./Part. IVA IT 01227810353 - R.E.A. RE 169836 - Posiz. Comm. Estero RE 003868 - Capitale Sociale €120.000,00 i.v.

Stabilimento di Reggio Emilia  
(e Sede Legale ed Amministrativa)  
Via Sicilia 8/10 - 42122 REGGIO EMILIA - ITALIA  
Tel. 0522 551250 - Fax: 0522 558963  
[www.iceitaly.com](http://www.iceitaly.com)  
E-mail: [info@iceitaly.com](mailto:info@iceitaly.com)

Stabilimento di Basaluzzo  
Via Novi 78 - 15060 BASALUZZO (AI) - ITALIA  
Tel. 0143 48831 - Fax 0143 489719  
[www.iceitaly.com](http://www.iceitaly.com)  
E-mail: [info@iceitaly.com](mailto:info@iceitaly.com)



## SAFETY DATA SHEET

## URSODEOXYCHOLIC ACID

Sheet no. 03

Edition: 04

Date: 01/03/2020

Page 8 of 12

- *Oral:* LD<sub>50</sub> (rat): 4600 mg/kg bw <sup>[1]</sup>
- *Dermal:* This information is not available.
- *Inhalation:* This information is not available.
- *Other information:*  
subcutaneous LD<sub>50</sub> (rabbit): > 2000 mg/kg bw <sup>[2]</sup>
- **Corrosivity/Irritation:** Ursodeoxycholic acid resulted potentially irritating to the skin and the eyes.<sup>[3]</sup>
- **Sensitization:**
- *Dermal:* Ursodeoxycholic acid is not sensitizing.<sup>[3]</sup>
- *Respiratory:* This information is not available.
- **Repeated dose toxicity (experimental.):** The lowest toxic dose identified was 91 g/kg bw. The numerical dose data is a cumulative amount over the duration of the study. Observed effects were: gastrointestinal hypermotility, diarrhea, hepatitis and diffuse hepatocellular necrosis, and changes in serum composition. <sup>[9]</sup>
- **CMR effects:**
- *Germinal cell mutagenicity* Ursodeoxycholic acid is not mutagenic. <sup>[3]</sup>
- *Carcinogenicity:* This information is not available.
- *Reproductive toxicity:* No effects on fertility have been reported by repeated dose toxicity (oral) studies and the lack of toxicity on fertility is confirmed by the developmental studies and by the high doses at which negative effects have been generally observed. The LOAEL for mouse was estimated at 1500 mg/kg bw/day. <sup>[8]</sup>
- *Developmental toxicity:* The developmental effects of the substance have been observed only at high doses, with the exception of the effects on the offspring of rabbits, but considering that this is the only species in which negative effects have been observed at 65 mg/kg bw/day and that the extent of the effects has not been reported, the TDLo value can be considered not relevant for the overall assessment. NOAEL: 1000 mg/kg bw/day (rat) <sup>[8]</sup>
- **Specific Target Organ Toxicity (STOT)-single exposure:**  
This information is not available.
- **Specific Target Organ Toxicity (STOT)- repeated exposure :**  
The observed effects of studies on repeated dose toxicity after oral administration were: gastrointestinal hypermotility, diarrhea, hepatitis and diffuse hepatocellular necrosis, and changes in serum composition. <sup>[9]</sup>
- **Aspiration hazards:**  
Not applicable.

## ICE S.p.A. a socio unico

Cod. Fisc./Part. IVA IT 01227810353 - R.E.A. RE 169836 - Posiz. Comm. Estero RE 003868 - Capitale Sociale €120.000,00 i.v.

Stabilimento di Reggio Emilia  
(e Sede Legale ed Amministrativa)  
Via Sicilia 8/10 - 42122 REGGIO EMILIA - ITALIA  
Tel. 0522 551250 - Fax: 0522 558963  
[www.iceitaly.com](http://www.iceitaly.com)  
E-mail: [info@iceitaly.com](mailto:info@iceitaly.com)

Stabilimento di Basaluzzo  
Via Novi 78 - 15060 BASALUZZO (AI) - ITALIA  
Tel. 0143 48831 - Fax 0143 489719  
[www.iceitaly.com](http://www.iceitaly.com)  
E-mail: [info@iceitaly.com](mailto:info@iceitaly.com)





## SAFETY DATA SHEET

**URSODEOXYCHOLIC ACID**

Sheet no. 03

Edition: 04

Date: 01/03/2020

Page 9 of 12

**SECTION 12  
ECOLOGICAL INFORMATION****12.1. Toxicity****Aquatic toxicity:**

<i>Toxicity to fish:</i>	LC <sub>50</sub> for freshwater fish: 70.29 mg/L <sup>[4]</sup>
<i>Toxicity to Daphnia Magna:</i>	IC <sub>50</sub> for freshwater invertebrates: 75.52 mg/L <sup>[5]</sup>
<i>Toxicity to aquatic algae:</i>	EC <sub>50</sub> for freshwater algae: 97.9 mg/L <sup>[6]</sup>
<i>Toxicity to microorganisms:</i>	EC <sub>50</sub> for aquatic micro-organisms: 1000 mg/L <sup>[7]</sup>

**12.2. Persistence and degradability**

Ursodeoxycholic acid is not expected to hydrolyze, the substance does not satisfy the REACH Regulation criteria for Persistence, because of the readily biodegradability.<sup>[8]</sup>

**12.3. Bioaccumulative potential**

According to estimated logPow values (logPow = 3.38 at 20°C) and BCFs (=313.51) and available toxicokinetic information, the substance is not expected to bioaccumulate in aquatic organisms.<sup>[8]</sup>

**12.4. Mobility in soil**

Ursodeoxycholic acid is expected to have a high mobility, according to its Koc value of 48 (logKoc: 1.69) obtained on the basis of a test performed according to OECD TG 121 (Estimation of the Adsorption/ Desorption Coefficient Koc).<sup>[8]</sup>

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

The substance does not fulfil the PBT and vPvB criteria

**12.6. Other adverse effects**

No other adverse effects are expected.

**SECTION 13  
DISPOSAL CONSIDERATIONS****13.1. Waste treatment methods**

Any disposal practice must be in compliance with all local and national laws and regulations. Send to controlled landfills or authorized incinerators. Empty contaminated containers can be reused, after a proper washing.

## ICE S.p.A. a socio unico

Cod. Fisc./Part. IVA IT 01227810353 - R.E.A. RE 169836 - Posiz. Comm. Estero RE 003868 - Capitale Sociale €120.000,00 i.v.

Stabilimento di Reggio Emilia  
(e Sede Legale ed Amministrativa)  
Via Sicilia 8/10 - 42122 REGGIO EMILIA - ITALIA  
Tel. 0522 551250 - Fax: 0522 558963  
[www.iceitaly.com](http://www.iceitaly.com)  
E-mail: [info@iceitaly.com](mailto:info@iceitaly.com)

Stabilimento di Basaluzzo  
Via Novi 78 - 15060 BASALUZZO (AI) - ITALIA  
Tel. 0143 48831 - Fax 0143 489719  
[www.iceitaly.com](http://www.iceitaly.com)  
E-mail: [info@iceitaly.com](mailto:info@iceitaly.com)



## SAFETY DATA SHEET

**URSODEOXYCHOLIC ACID**

Sheet no. 03

Edition: 04

Date: 01/03/2020

Page 10 of 12

**SECTION 14  
TRANSPORT INFORMATION**

The product is not classified for the transport.

**SECTION 15  
REGULATORY INFORMATION**

All other information on regulation are reported if not provided in other sections/subsection of the Safety Data Sheet.

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

None

**15.2. Chemical Safety Assessment**

The chemical safety assessment has been carried out.

**SECTION 16  
OTHER INFORMATION****Revisions:**

- **Edition n. 01 dated 06/06/2013 (First edition according with Regulation 453/2010/UE, Annex I)**
- **Edition n. 02 dated 08/06/2015 (In accordance with Regulation (UE) n. 2015/830)**
- **Edition n. 03 dated 23/02/2017 (In accordance with Regulation (UE) n. 2015/830)**
- **Edition n. 04 dated 01/03/2020 (Merged by incorporation of Prodotti Chimici e Alimentari S.p.A. in ICE S.p.A)**

**Bibliographic sources:**

- [1] Bollettino Chimico Farmaceutico, 1987
- [2] BCFAAI Bollettino Chimico Farmaceutico. (Societa Editoriale Farmaceutica, Milan, Italy). 126,282
- [3] S-IN, 2011. In silico predictions by read-across and QSAR models of five biliary acids.
- [4] Noè F and Garagna D, 2012. Ursodeoxycholic acid\_ Acute toxicity to Zebra Fish (Danio rerio) in a 96-hour study under semi-static exposure. Report n. CH-469/2012
- [5] Noè F and Garagna D, 2012. Ursodeoxycholic acid: Acute toxicity to Daphnia magna in a 48-hour immobilization test under semi-static exposure. Report n. CH-470/2012
- [6] Noè F and Garagna D, 2012. Ursodeoxycholic acid: Toxicity to green algae Pseudokirchneriella subcapitata determined in a growth inhibition study. Report n. CH-471/2012
- [7] Noè F, 2012. Ursodeoxycholic acid: Toxicity to activated sludge in a respiration inhibition study. Report n. CH-473/2012
- [8] Chemical Safety Report, 2013. Ursodeoxycholic acid
- [9] Yakuri to Chiryō. Pharmacology and Therapeutics. (Raifu Saiensu Shuppan K.K., 2-5-13, Yaesu, Chuo-ku, Tokyo 104, Japan), 10,4529

**Information related to the Regulation EC/1272/2008:****List of Hazards statements****ICE S.p.A. a socio unico**

Cod. Fisc./Part. IVA IT 01227810353 - R.E.A. RE 169836 - Posiz. Comm. Estero RE 003868 - Capitale Sociale €120.000,00 i.v.

**Stabilimento di Reggio Emilia**

(e Sede Legale ed Amministrativa)

Via Sicilia 8/10 - 42122 REGGIO EMILIA - ITALIA

Tel. 0522 551250 - Fax: 0522 558963

[www.iceitaly.com](http://www.iceitaly.com)E-mail: [info@iceitaly.com](mailto:info@iceitaly.com)**Stabilimento di Basaluzzo**

Via Novi 78 - 15060 BASALUZZO (AI) - ITALIA

Tel. 0143 48831 - Fax 0143 489719

[www.iceitaly.com](http://www.iceitaly.com)E-mail: [info@iceitaly.com](mailto:info@iceitaly.com)



## SAFETY DATA SHEET

## URSODEOXYCHOLIC ACID

Sheet no. 03

Edition: 04

Date: 01/03/2020

Page 11 of 12

H315: Causes skin irritation.  
H319: Causes serious eye irritation.

**List of P statements**

P264: Wash hands thoroughly after handling.  
P280: Wear protective gloves/protective clothing/eye protection/face protection.  
P302+P352: IF ON SKIN: Wash with plenty of soap and water.  
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P332+P313: If skin irritation occurs: Get medical advice/attention.  
P337+P313: If eye irritation persists: Get medical advice/attention.

List of Poison Control Centers with access to the information stored at the Institute of Health (24 hours 24)

Name	Hospital		Telephone
Poison Center	Ospedale Pediatrico Bambino Gesù	Roma	06 68593726
Poison Center	Azienda Ospedaliera Università di Foggia	Foggia	0881 732326
Poison Center	Azienda Ospedaliera A. Cardarelli	Napoli	081 7472870
Poison Center	Policlinico Umberto I	Roma	06 49978000
Poison Center	Policlinico A. Gemelli	Roma	06 3054343
Poison Center	Azienda Ospedaliera Careggi – U.O. Tossicologia Medica	Firenze	055 7947819
Poison Center	Centro Nazionale di Informazione Tossicologica	Pavia	0382 24444
Poison Center	Ospedale Niguarda Ca' Granda	Milano	02 66101029
Poison Center	Azienda Ospedaliera Papa Giovanni XXIII	Bergamo	800883300

**\* Sections changed since the previous version of the SDS**

Section 1 – Modified subsection 1.3

Section 1 – Modified subsection 1.4

**Acronyms**

- BCF: Bio-accumulative factor
- BEI : Biological Exposure Indices
- CAS: Chemical Abstract Service (division of the American Chemical Society)
- CLP: Classification, Labelling and Packaging
- CMR: Carcinogens, Mutagens, Toxic for re production substances
- EINECS: European Inventory of existing Commercial Substances
- GHS: Globally Harmonized System
- IUPAC: International Union of Pure and Applied Chemistry
- LOEL: Lowest Observed Effect Level
- NOAEL: No Observed Adverse Effect Level
- NOEL: No Observed Effect Level
- OEL: Occupational Exposure Limit
- PPE : Personal protective Equipment
- PBT: Persistent, Bio-accumulative and Toxic substances
- vPvB: very Persistent, very Bio-accumulative

**ICE S.p.A. a socio unico**

Cod. Fisc./Part. IVA IT 01227810353 - R.E.A. RE 169836 – Posiz. Comm. Estero RE 003868 - Capitale Sociale €120.000,00 i.v.

**Stabilimento di Reggio Emilia**

(e Sede Legale ed Amministrativa)

Via Sicilia 8/10 - 42122 REGGIO EMILIA - ITALIA

Tel. 0522 551250 - Fax: 0522 558963

[www.iceitaly.com](http://www.iceitaly.com)E-mail: [info@iceitaly.com](mailto:info@iceitaly.com)**Stabilimento di Basaluzzo**

Via Novi 78 - 15060 BASALUZZO (AI) - ITALIA

Tel. 0143 48831 – Fax 0143 489719

[www.iceitaly.com](http://www.iceitaly.com)E-mail: [info@iceitaly.com](mailto:info@iceitaly.com)



SAFETY DATA SHEET

# URSODEOXYCHOLIC ACID

Sheet no. 03

Edition: 04

Date: 01/03/2020

Page 12 of 12

## Information on workers training

Follow criteria of Directive 98/24/EC, its amendments and National reinforcements

## DISCLAIMER

This document aims to provide guidance for appropriate handling and precaution of this product by qualified personnel or operating under the supervision of personnel trained in handling chemicals. The product should not be used for purposes other than those mentioned in section 1, unless they are given adequate written information received on how to handle the material. The provider of this document cannot provide any warnings about the dangers of ' use or interaction with other chemicals or materials.

And 'the user's safe use of the product, the product suitability for the purpose for which it is applied and proper disposal. The information below should not be considered a declaration or guarantee, either expressed or implied, of merchantability, fitness for a particular purpose, quality, or any other. The information contained in this SDS are in accordance with Regulation (UE) n. 2015/830.

**End of Safety Data Sheet**

ICE S.p.A. a socio unico

Cod. Fisc./Part. IVA IT 01227810353 - R.E.A. RE 169836 - Posiz. Comm. Estero RE 003868 - Capitale Sociale €120.000,00 i.v.

**Stabilimento di Reggio Emilia**

(e Sede Legale ed Amministrativa)

Via Sicilia 8/10 - 42122 REGGIO EMILIA - ITALIA

Tel. 0522 551250 - Fax: 0522 558963

[www.iceitaly.com](http://www.iceitaly.com)

E-mail: [info@iceitaly.com](mailto:info@iceitaly.com)

**Stabilimento di Basaluzzo**

Via Novi 78 - 15060 BASALUZZO (AI) - ITALIA

Tel. 0143 48831 - Fax 0143 489719

[www.iceitaly.com](http://www.iceitaly.com)

E-mail: [info@iceitaly.com](mailto:info@iceitaly.com)