

Ursodeoxycholic acid

Safety Data Sheet

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

Date of issue: 07/02/2012 Revision date: 10/11/2017

Supersedes 20/04/2017

900158

Version: 3.0

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

1.1. Product identifier

Product form : Substance
Substance name : Ursodeoxycholic acid
IUPAC name : 3 α ,7 β -Dihydroxy-5 β -cholan-24-oic acid
EC-No. : 204-879-3
CAS-No. : 128-13-2
Product code : 900158
Formula : C₂₄H₄₀O₄
Synonyms : UDCS
Product group : Raw material

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

1.2.1. Relevant identified uses

Main use category : Pharmaceutical
Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals
Function or use category : Raw material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
A. Hofmanweg 71
2031BH Haarlem - The Netherlands
T +31(0)23-5319093
farma@duchefa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	0870 243 2241	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin corrosion/irritation, Category 2 H315
Serious eye damage/eye irritation, Category 2 H319

Full text of hazard classes and H-statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

Hazard pictograms (CLP)

:



GHS07

Signal word (CLP)

: Warning

Hazard statements (CLP)

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

Precautionary statements (CLP)

: P280 - Wear protective gloves/protective clothing/eye protection/face protection
P302+P352 - IF ON SKIN: Wash with plenty of soap and water
P305 - IF IN EYES:
P351 - Rinse cautiously with water for several minutes
P321 - Specific treatment (see supplemental first aid instruction on this label)
P337+P313 - If eye irritation persists: Get medical advice/attention

2.3. Other hazards

PBT: not relevant – no registration required

vPvB: not relevant – no registration required

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ursodeoxycholic acid	(CAS-No.) 128-13-2 (EC-No.) 204-879-3	99 - 101	Skin Irrit. 2, H315 Eye Irrit. 2, H319

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Assure fresh air breathing. Get medical advice and attention if you feel unwell.

First-aid measures after skin contact : Wash skin with mild soap and water. Seek medical attention if ill effect or irritation develops.

- First-aid measures after eye contact : Rinse immediately with plenty of water. If eye irritation persists, take medical advice.
- First-aid measures after ingestion : Rinse mouth. Seek medical advice.

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

- Symptoms/effects : Exposure may produce an allergic reaction.
- Symptoms/effects after skin contact : Skin irritation, dermatitis and sensitisation.
- Symptoms/effects after eye contact : Blurred vision.

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

No additional information available

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Carbon dioxide. Dry powder. Foam. Water spray.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : On exposure to high temperature, may decompose, releasing toxic gases. Carbon monoxide.
- Explosion hazard : Product is not explosive.
- Hazardous decomposition products in case of fire : Carbon oxides (CO, CO₂).

5.3. Advice for firefighters

- Precautionary measures fire : Exercise caution when fighting any chemical fire.
- Firefighting instructions : Prevent fire fighting water from entering the environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Emergency procedures : Avoid raising dust. Ensure adequate air ventilation.

6.1.2. For emergency responders

- Protective equipment : Wear proper protective equipment.

6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Sweep up dry powder and dispose properly. To clean the floor or objects contaminated by this product, use : Ethanol.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, well-ventilated area. Keep container tightly closed.

Incompatible materials : Direct sunlight.

Maximum storage period : 5 year

Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

No additional information available

8.2. Exposure controls**Appropriate engineering controls:**

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

Hand protection:

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Wear suitable protective clothing.

Respiratory protection:

Dustmask with filtertype P2

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 392.6 g/mol
Colour	: White.
Odour	: odourless.
Odour threshold	: No data available
pH	: No data available
pH solution	: 0 %
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 203 °C

Ursodeoxycholic acid

900158

Safety Data Sheet

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

Freezing point	: No data available
Boiling point	: 547.1 °C
Flash point	: 298.8 °C
Auto-ignition temperature	: 400 K
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 1.128 g/cm ³
Solubility	: Insoluble in water. Soluble in ethanol. Water: 20 mg/l
Log Pow	: 3.38
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

On heating/burning: release of irritant gases/vapours.

10.2. Chemical stability

Stable under normal 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 oxidizers.

10.6. Hazardous decomposition products

Carbon dioxide. Carbon monoxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Ursodeoxycholic acid (128-13-2)	
LD50 oral rat	4600 mg/kg

Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitisation	: Not classified

Ursodeoxycholic acid

900158

Safety Data Sheet

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

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ursodeoxycholic acid (128-13-2)	
LC50 fish 1	70.29 mg/l
EC50 Daphnia 1	75.72 mg/l

12.2. Persistence and degradability

Ursodeoxycholic acid (128-13-2)	
Persistence and degradability	Readily biodegradable.

12.3. Bioaccumulative potential

Ursodeoxycholic acid (128-13-2)	
Log Pow	3.38
Bioaccumulative potential	Slightly or not bioaccumulative.

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) : Dispose in a safe manner in accordance with local/national regulations.

Waste treatment methods : Avoid release to the environment.

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

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

ADR	IATA
14.1. UN number	
Not applicable	Not applicable
14.2. UN proper shipping name	
Not applicable	Not applicable
14.3. Transport hazard class(es)	
Not applicable	Not applicable
Not applicable	Not applicable
14.4. Packing group	
Not applicable	Not applicable

Ursodeoxycholic acid

900158

Safety Data Sheet

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

ADR	IATA
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

14.6. Special precautions for user

- Overland transport

No data available

- Air transport

No data available

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

No REACH Annex XVII restrictions

Ursodeoxycholic acid is not on the REACH Candidate List

Ursodeoxycholic acid is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

1.4	Emergency telephone	Modified	Added additional information
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves

Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration

Ursodeoxycholic acid

900158

Safety Data Sheet

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

NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Full text of H- and EUH-statements:

Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
H315	Causes skin irritation
H319	Causes serious eye irritation

SDS EU (REACH Annex II) Version 2017

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