



CONSEIL DE L'EUROPE

# Lithium clavulanate

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 03/04/2023 Version: 1.0

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

#### **1.1. Product identifier** Product form : Substance Substance name : Lithium clavulanate Product code

201700107 ÷

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

1.2.1. Relevant identified uses	
Main use category	: The product is intended for research, analysis and scientific education.
Use of the substance/mixture	: For professional use only
Function or use category	: Laboratory chemicals
1.2.2. Uses advised against	
Restrictions on use	: Do not use : Ingestion, Inhalation, Dermal
1.3. Details of the supplier of the sa	fety data sheet
European Directorate for the Quality of Med	dicines & Healthcare

EDQM, Council of Europe 7, Allée Kastner, CS30026 F-67081 Strasbourg France T +33(0)388412035 - F +33(0)388412771 sds@edqm.eu - www.edqm.eu

### 1.4. Emergency telephone number

Emergency number

: +33(0)390215608

# **SECTION 2: Hazards identification**

### 2.1. Classification of the substance or mixture

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

Reproductive toxicity, Category 2 Full text of H- and EUH-statements: see section 16 H361d

## Adverse physicochemical, human health and environmental effects

Expert judgement and weight of evidence determination.

## 2.2. Label elements

Hazard pictograms (CLP)	
	GHS08
Signal word (CLP)	: Warning
Hazard statements (CLP)	: H361d - Suspected of damaging the unborn child.
Precautionary statements (CLP)	: P202 - Do not handle until all safety precautions have been read and understood.
	P308+P313 - IF exposed or concerned: Get medical advice/attention.
Labelling according to: exemption for inner	packaging where the contents do not exceed 10ml
Hazard pictograms (CLP)	

GHS08

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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 Regulation (EC) No. 1272/2008 [CLP]
Lithium clavulanate	-	≤ 100	Repr. 2, H361d

Full text of H- and EUH-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 skin contact First-aid measures after eye contact	<ul><li>Wipe off as much as possible (using a clean, soft, absorbent material).</li><li>Rinse eyes with water as a precaution.</li></ul>			
4.2. Most important symptoms and effects, both acute and delayed				
No additional information available				
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	: Extinguishing blanket.	
5.2. Special hazards arising from the substance or mixture		
Fire hazard	: See Heading 2.2.	
5.3. Advice for firefighters		
Firefighting instructions	: Use extinguishing media appropriate for surrounding fire.	

SECTION 6: Accidental release measures		
6.1. Personal precautions, protective equipment and emergency procedures		
6.1.1. For non-emergency personnel         Emergency procedures       : Avoid all unnecessary exposure.		
6.1.2. For emergency responders No additional information available		
6.2. Environmental precautions		

No additional information available

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6.3. Methods and material for containment and cleaning up

No additional information available

6.4. Reference to other sections

No additional information available

## SECTION 7: Handling and storage

7.1. Precautions for safe handling

No additional information available

7.2. Conditions for safe storage, including any incompatibilities

No additional information available

7.3. Specific end use(s)

See Heading 1.

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

## 8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

### 8.1.3. Air contaminants formed

No additional information available

### 8.1.4. DNEL and PNEC

No additional information available

### 8.1.5. Control banding

No additional information available

8.2. Exposure controls

### 8.2.1. Appropriate engineering controls

#### Appropriate engineering controls:

Keep in a well-ventilated room. Both local exhaust and general room ventilation are usually required.

#### 8.2.2. Personal protection equipment

#### 8.2.2.1. Eye and face protection

No additional information available

### 8.2.2.2. Skin protection

Skin and body protection: Lab coat

Hand protection:

Protective gloves

### 8.2.2.3. Respiratory protection

No additional information available

### 8.2.2.4. Thermal hazards

No additional information available

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### 8.2.3. Environmental exposure controls

No additional information available

### 9.1. Information on basic physical and chemical properties

Physical state	:	Solid
Colour	:	Not available
Odour	:	Not available
Odour threshold	:	Not available
Melting point	:	153 – 160 °C
Freezing point	:	Not available
Boiling point	:	Not available
Flammability	:	Not available
Explosive limits	:	Not applicable
Lower explosion limit	:	Not applicable
Upper explosion limit	:	Not applicable
Flash point	:	Not applicable
Auto-ignition temperature	:	Not applicable
Decomposition temperature	:	Not available
рН	:	7,91 – 8,21 (1%)
pH solution	:	Not available
Viscosity, kinematic	:	Not applicable
Solubility	:	Not available
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Vapour pressure	:	Not available
Vapour pressure at 50°C	:	Not available
Density	:	Not available
Relative density	:	Not available
Relative vapour density at 20°C	:	Not applicable
Particle size	:	Not available

## 9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

# SECTION 10: Stability and reactivity

## 10.1. Reactivity

Stable under normal conditions.

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

No additional information available

**10.5. Incompatible materials** 

None under normal use. See Section 7.

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# **10.6. Hazardous decomposition products**

When heated to decomposition, emits dangerous fumes.

SECTION 11: Toxicological info	rmation
, , , , , , , , , , , , , , , , , , ,	as defined in Regulation (EC) No 1272/2008
Acute toxicity (oral) Acute toxicity (dermal) Acute toxicity (inhalation)	<ul> <li>Not classified</li> <li>Not classified</li> <li>Not classified</li> </ul>
Lithium clavulanate	
LD50 oral rat	> 2000 mg/kg
Skin corrosion/irritation	: Not classified (Lack of data) pH: 7,91 – 8,21 (1%)
Serious eye damage/irritation	: Not classified (Lack of data) pH: 7,91 – 8,21 (1%)
Respiratory or skin sensitisation	: Not classified (Lack of data)
Germ cell mutagenicity	: Not classified (Lack of data)
Carcinogenicity	: Not classified (Lack of data)
Reproductive toxicity	: Suspected of damaging the unborn child.

- : Suspected of damaging the unborn child.
  - : Not classified
  - : Not classified
    - : Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

No additional information available

STOT-single exposure

Aspiration hazard

STOT-repeated exposure

SECTION 12: Ecological information	
12.1. Toxicity	
Ecology - general Hazardous to the aquatic environment, short-term (acute) Hazardous to the aquatic environment, long-term (chronic)	<ul> <li>Presents no specific risk for the environment.</li> <li>Not classified</li> <li>Not classified</li> </ul>
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. Endocrine disrupting properties	
No additional information available	
12.7. Other adverse effects	
No additional information available	

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SECTION 13: Disposal considerations		
13.1. Waste treatment methods		
No additional information available		
SECTION 14: Transport information		
In accordance with ADR / IMDG / IATA		

ADR	IMDG	ΙΑΤΑ		
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable		
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable		
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable		
14.4. Packing group				
Not applicable	Not applicable	Not applicable		
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable		
No supplementary information available				

14.6. Special precautions for user

Overland transport Not applicable

Transport by sea Not applicable

Air transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

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

**REACH Annex XVII (Restriction List)** 

Not listed on REACH Annex XVII

### **REACH Annex XIV (Authorisation List)**

Not listed on REACH Annex XIV (Authorisation List)

### **REACH Candidate List (SVHC)**

Not listed on the REACH Candidate List

### PIC Regulation (Prior Informed Consent)

Not applicable.

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### POP Regulation (Persistent Organic Pollutants)

Not applicable.

### Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

### **Explosives Precursors Regulation (2019/1148)**

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

### **Drug Precursors Regulation (273/2004)**

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

### 15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

## **SECTION 16: Other information**

Full text of H- and EUH-statements:	
H361d	Suspected of damaging the unborn child.
Repr. 2	Reproductive toxicity, Category 2

Safety Data Sheet (SDS), EU

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