

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Product form	: Substance
Trade name	: CELIPROLOL HYDROCHLORIDE
Chemical name	: 3-[3-acetyl-4-[3-(tert-butylamino)-2-hydroxypropoxy]phenyl]-1,1-diethylurea hydrochloride
EC-No.	: 260-752-2
CAS-No.	: 57470-78-7
Product code	: 71480 / 71510
Type of product	: Active Ingredient for Medicinal / Pharmaceutical Use
Formula	: C20H34ClN3O4
Other means of identification	: SMILES: CCN(CC)C(=O)Nc1ccc(c(c1)C(=O)C)OCC(CNC(C)(C)C)O.Cl

**1.2. Relevant identified uses of the substance or mixture and uses advised against****1.2.1. Relevant identified uses**

Main use category	: API, Industrial use
Industrial/Professional use spec	: Industrial For professional use only
Function or use category	: Pharmaceuticals

**1.2.2. Uses advised against**

No additional information available

**1.3. Details of the supplier of the safety data sheet****Supplier**

MOEHS IBÉRICA, S.L.  
Roma, 8 - P.I. Cova Solera  
08191 Rubi  
Spain  
T +34 93 586 05 20 - F +34 93 699 8350  
[hse@moehs.es](mailto:hse@moehs.es) - [www.moehs.com](http://www.moehs.com)

**Manufacturer**

COPRIMA S.L.  
Pablo Picasso, 15  
08213 Polinya  
SPAIN  
T +34 93 713 19 56 - F +34 93 713 15 28  
[hse@moehs.es](mailto:hse@moehs.es) - [www.moehs.com](http://www.moehs.com)

**Manufacturer**

MOEHS CATALANA, S.L.  
Cesar Martinell i Brunet, 12 A P.I. Rubi Sud  
08191 Rubi  
Spain  
T +34 93 586 05 20 - F +34 93 699 8350  
[hse@moehs.es](mailto:hse@moehs.es) - [www.moehs.com](http://www.moehs.com)

**1.4. Emergency telephone number**

Emergency number	: +34 93 586 05 20 (9:00 - 17:00)
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**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Not classified

**Adverse physicochemical, human health and environmental effects**

No additional information available

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### 2.2. Label elements

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

Precautionary statements (CLP) : P233 - Keep container tightly closed.  
P271 - Use only outdoors or in a well-ventilated area.  
P262 - Do not get in eyes, on skin, or on clothing.  
P270 - Do not eat, drink or smoke when using this product.  
P280 - Wear protective gloves, eye protection, face protection.  
P314 - Get medical advice/attention if you feel unwell.  
P273 - Avoid release to the environment.

### 2.3. Other hazards

Other hazards which do not result in classification : None under normal conditions.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%
CELIPROLOL HYDROCHLORIDE	CAS-No.: 57470-78-7 EC-No.: 260-752-2	100

### 3.2. Mixtures

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).  
First-aid measures after inhalation : Allow affected person to breathe fresh air. Allow the victim to rest.  
First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.  
First-aid measures after eye contact : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.  
First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. If you feel unwell, seek medical advice.

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

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

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

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

Fire hazard : Dust may form explosive mixture in air.  
Hazardous decomposition products in case of fire : Carbon dioxide. fume. Carbon monoxide. Nitrogen oxides.

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### 5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. 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 : Evacuate unnecessary personnel.

#### 6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.
- Emergency procedures : Ventilate area.

### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

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

- Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimise generation of dust. Store away from other materials.

### 6.4. Reference to other sections

See Section 8. Exposure controls and personal protection.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

- Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.
- Hygiene measures : Do not eat, drink or smoke when using this product. Wash contaminated clothing before reuse.

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

- Storage conditions : Keep only in the original container in a cool, well ventilated place away from : Store at room temperature. Keep container closed when not in use.
- Incompatible products : Strong bases. Strong acids.
- Incompatible materials : Sources of ignition. Direct sunlight.

### 7.3. Specific end use(s)

API.

## 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

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### 8.1.4. DNEL and PNEC

No additional information available

### 8.1.5. Control banding

Control banding : MOEHS occupational exposure band: 2 (0.1 - 1 mg/m<sup>3</sup>)

## 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls

No additional information available

### 8.2.2. Personal protection equipment

#### Personal protective equipment:

Avoid all unnecessary exposure. Gloves. Safety glasses. Dust/aerosol mask with filter type P3.

#### Personal protective equipment symbol(s):



#### 8.2.2.1. Eye and face protection

##### Eye protection:

Chemical goggles or safety glasses

#### 8.2.2.2. Skin protection

##### Hand protection:

Wear protective gloves.

Hand protection		
Type	Material	Standard
Disposable gloves	Nitrile rubber (NBR), Polyvinylalcohol (PVA), Butyl rubber, Natural rubber, Polyvinylchloride (PVC), Latex	EN ISO 374

#### 8.2.2.3. Respiratory protection

Respiratory protection		
Device	Filter type	Standard
Dust mask	Type P3	EN 134

#### 8.2.2.4. Thermal hazards

No additional information available

### 8.2.3. Environmental exposure controls

#### Other information:

Do not eat, drink or smoke during use.

## SECTION 9: Physical and chemical properties

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

Physical state	: Solid
Colour	: white to slightly yellow.
Molecular mass	: 416 g/mol
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: 197 – 200 °C [Scifinder]
Freezing point	: Not available
Boiling point	: 586.5 °C (at 760mmHg)

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Flammability	: May form combustible dust concentrations in air
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: 308.5 °C
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: 6 – 8 (15% in water)
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: 15.1 g/100ml (at 25°C)
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: 0.8 [37°C; Mazzo, D.J. et al., 1991]
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: 1.114 g/cm <sup>3</sup>
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available
Particle size distribution	: Not available
Particle shape	: Not available
Particle aspect ratio	: Not available
Particle aggregation state	: Not available
Particle agglomeration state	: Not available
Particle specific surface area	: Not available
Particle dustiness	: 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

Minimum ignition energy	: 26 mJ
Additional information	: Layer Minimum flammability Temperature : Melt. Dust Cloud minimum Flammability Temperature : 460°C. Minimum Explosive Concentration : 30 g/m <sup>3</sup> . Explosivity Pmax : 8.3 bar.g. Explosion Severity Factor Kmax (bar.m/s) : 254. Explosion Class : St2

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Stable under use and storage conditions as recommended in section 7.

### 10.2. Chemical stability

Not established.

### 10.3. Possibility of hazardous reactions

Not established.

### 10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

### 10.5. Incompatible materials

Strong acids. Strong bases.

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### 10.6. Hazardous decomposition products

fume. Carbon monoxide. Carbon dioxide.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified  
Acute toxicity (dermal) : Not classified  
Acute toxicity (inhalation) : Not classified

#### CELIPROLOL HYDROCHLORIDE (57470-78-7)

LD50 oral rat	3826 mg/kg [Scifinder]
LD50 oral	1834 mg/kg [Mouse; Scifinder]
LD50, intravenous, rat	68.3 mg/kg [Scifinder]
LD50, intravenous, mouse	56.2 mg/kg [Scifinder]
LD50, subcutaneous, rat	754 mg/kg [ChemIDplus]

Skin corrosion/irritation : Not classified  
pH: 6 – 8 (15% in water)

Additional information : Based on available data, the classification criteria are not met

Serious eye damage/irritation : Not classified  
pH: 6 – 8 (15% in water)

Additional information : Based on available data, the classification criteria are not met

Respiratory or skin sensitisation : Not classified

Additional information : Based on available data, the classification criteria are not met

Germ cell mutagenicity : Not classified

Additional information : Based on available data, the classification criteria are not met

Carcinogenicity : Not classified

Additional information : Based on available data, the classification criteria are not met

Reproductive toxicity : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-single exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-repeated exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

Aspiration hazard : Not classified

Additional information : Based on available data, the classification criteria are not met

### 11.2. Information on other hazards

#### 11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

#### 11.2.2. Other information

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met

## SECTION 12: Ecological information

### 12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified

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Hazardous to the aquatic environment, long-term (chronic) : Not classified

### 12.2. Persistence and degradability

#### CELIPROLOL HYDROCHLORIDE (57470-78-7)

Persistence and degradability	Not established.
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### 12.3. Bioaccumulative potential

#### CELIPROLOL HYDROCHLORIDE (57470-78-7)

Partition coefficient n-octanol/water (Log Pow)	0.8 [37°C; Mazzo, D.J. et al., 1991]
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Bioaccumulative potential	weak.
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### 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

Adverse effects on the environment caused by endocrine disrupting properties : The substance/mixture has no endocrine disrupting properties.

### 12.7. Other adverse effects

Other adverse effects : WGK Germany: 1 - Low hazard to waters.  
Additional information : Avoid release to the environment.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.  
Ecology - waste materials : Avoid release to the environment.

## SECTION 14: Transport information

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

### 14.1. UN number or ID number

UN-No. (ADR) : Not applicable  
UN-No. (IMDG) : Not applicable  
UN-No. (IATA) : Not applicable  
UN-No. (ADN) : Not applicable  
UN-No. (RID) : Not applicable

### 14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable  
Proper Shipping Name (IMDG) : Not applicable  
Proper Shipping Name (IATA) : Not applicable  
Proper Shipping Name (ADN) : Not applicable  
Proper Shipping Name (RID) : Not applicable

### 14.3. Transport hazard class(es)

**ADR**  
Transport hazard class(es) (ADR) : Not applicable

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### IMDG

Transport hazard class(es) (IMDG) : Not applicable

### IATA

Transport hazard class(es) (IATA) : Not applicable

### ADN

Transport hazard class(es) (ADN) : Not applicable

### RID

Transport hazard class(es) (RID) : Not applicable

## 14.4. Packing group

Packing group (ADR) : Not applicable

Packing group (IMDG) : Not applicable

Packing group (IATA) : Not applicable

Packing group (ADN) : Not applicable

Packing group (RID) : Not applicable

## 14.5. Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

## 14.6. Special precautions for user

### Overland transport

Not applicable

### Transport by sea

Not applicable

### Air transport

Not applicable

### Inland waterway transport

Not applicable

### Rail 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



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### PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

### POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

### 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

### Germany

Water hazard class (WGK) : Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV).  
Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

### Netherlands

SZW-lijst van kankerverwekkende stoffen : The substance is not listed  
SZW-lijst van mutagene stoffen : The substance is not listed  
SZW-lijst van reprotoxische stoffen – Borstvoeding : The substance is not listed  
SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : The substance is not listed  
SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

### Switzerland

Storage class (LK) : NG - Non-hazardous

## 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

### 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
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DNEL	Derived-No Effect Level
LC50	Median lethal concentration
LD50	Median lethal dose
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail

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.

Other information : None.

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Safety Data Sheet (SDS), EU

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.