



CONSEIL DE L'EUROPI

# Cortisone acetate

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 : Cortisone acetate Product code : 201600239 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 Function or use category

# 1.2.2. Uses advised against

Restrictions on use

: Do not use : Ingestion, Inhalation, Dermal

: For professional use only

: Laboratory chemicals

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

European Directorate for the Quality of Medicines & 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] H361 Reproductive toxicity, Category 2 Specific target organ toxicity - Repeated exposure, Category 2 H373 Full text of H- and EUH-statements: see section 16 Adverse physicochemical, human health and environmental effects Expert judgement and weight of evidence determination. 2.2. Label elements Labelling according to Regulation (EC) No. 1272/2008 [CLP] Hazard pictograms (CLP) GHS08 Signal word (CLP) : Warning Hazard statements (CLP) : H361 - Suspected of damaging fertility or the unborn child. H373 - May cause damage to organs through prolonged or repeated exposure. Precautionary statements (CLP) : P201 - Obtain special instructions before use. P202 - Do not handle until all safety precautions have been read and understood.

P260 - Do not breathe dust.

P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

P314 - Get medical advice/attention if you feel unwell.

P405 - Store locked up.

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P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. Labelling according to: exemption for inner packaging where the contents do not exceed 10ml Hazard pictograms (CLP) : GHS08

### 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]
Cortisone acetate	-	≤ 100	Repr. 2, H361 STOT RE 2, H373

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	: Wipe off as much as possible (using a clean, soft, absorbent material). : Rinse eyes with water as a precaution.
4.2. Most important symptoms and effect	ts, both acute and delayed
No additional information available	
4.3. Indication of any immediate medical	I 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 sul	bstance or mixture
Fire hazard	: See Heading 2.2.
5.3. Advice for firefighters	
Firefighting instructions	: Use extinguishing media appropriate for surrounding fire.

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SECTION 6: Accidental release mea	suras
SECTION 0. Accidental release mea	bules
6.1. Personal precautions, protective eq	uipment 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	
6.3. Methods and material for containme	nt 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	ng 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

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#### 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

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
Appearance	:	Powder.
Odour	:	Not available
Odour threshold	:	Not available
Melting point	:	Not available
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	:	Not available
pH solution	:	Not available
Viscosity, kinematic	:	Not applicable
Solubility	:	Water: < 0.1 g/l
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.

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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.
10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

# SECTION 11: Toxicological information

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

Acute toxicity (oral)	: Not classified (Lack of data)
Acute toxicity (dermal)	: Not classified (Lack of data)
Acute toxicity (inhalation)	: Not classified (Lack of data)
Skin corrosion/irritation	: Not classified (Lack of data)
Serious eye damage/irritation	: Not classified (Lack of data)
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Lack of data)
Carcinogenicity	: Not classified (Lack of data)
Reproductive toxicity	: Suspected of damaging fertility or the unborn child.
STOT-single exposure	: Not classified
STOT-repeated exposure	: May cause damage to organs through prolonged or repeated exposure.
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

## 11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information	
12.1. Toxicity	
(acute)	<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	

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12.6. Endocrine disrupting properties		
No additional information available		
12.7. Other adverse effects		
No additional information available		

## **SECTION 13: Disposal considerations**

13.1. Waste treatment methods

No additional information available

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

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

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#### **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.

#### 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**

#### Indication of changes:

Identification of the substance/mixture and of the company/undertaking. Classification of the substance or mixture.

Full text of H- and EUH-statements:	
H361	Suspected of damaging fertility or the unborn child.
H373	May cause damage to organs through prolonged or repeated exposure.
Repr. 2	Reproductive toxicity, Category 2
STOT RE 2	Specific target organ toxicity – Repeated exposure, Category 2

#### Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The EDQM has created this SDS as a downstream user for regulatory compliance to rules applicable to chemicals only. This article is intended only for small-volume laboratory analysis and other routine testing prescribed in the pharmacopoeia or EDQM study protocol, under controlled conditions and by professionals only. Any other use of this article or the SDS information is the sole responsibility of the user. This substance is present in articles in quantities totalling under 10 kg per year. There is no human or environmental exposure under intended and foreseeable conditions of use. The user has the responsibility for handling, storage, use conditions and disposal of this article and for any use of the information in this SDS. The information has been obtained from suppliers and is without any warranty, express or implied, regarding its correctness. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the article.