

# Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 SDS Reference Number: 04096

Issue date: 4/9/2014 Revision date: 5/5/2025 Supersedes version of: 12/1/2017 Version: 1.1

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

#### 1.1. Product identifier

Product form : Substance

Trade name : HYDROCORTISONE ACETATE EXTRA PURE

EC-No. : 200-004-4 CAS-No. : 50-03-3 Product code : 04096

Type of product : Organic compound

Formula : C23H32O6

Chemical structure

HO H<sub>3</sub>C H H H H H

Synonyms : Cortisol 21-acetate

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

#### Relevant identified uses

Use of the substance/mixture : Industrial;For professional use only

Use of the substance/mixture : Laboratory chemicals

Manufacture of substances

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

LOBA CHEMIE PVT.LTD.

107 Wode House Road, Jehangir Villa, Colaba

400005 Mumbai

INDIA

T +91 22 6663 6663, F +91 22 6663 6699

info@lobachemie.com, www.lobachemie.com

## 1.4. Emergency telephone number

Emergency number : + 91 22 6663 6663 (9:00am - 6:00 pm)

#### **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 H361

Full text of H- and EUH-statements: see section 16

### Adverse physicochemical, human health and environmental effects

Suspected of damaging fertility or the unborn child.

# 2.2. Label elements

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

Hazard pictograms (CLP)



Signal word (CLP) : Warning

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Hazard statements (CLP) : H361 - Suspected of damaging fertility or the unborn child.

Precautionary statements (CLP) : P201 - Obtain special instructions before use.

P202 - Do not handle until all safety precautions have been read and understood. P280 - Wear protective gloves, protective clothing, eye protection, face protection.

P308+P313 - IF exposed or concerned: Get medical advice/attention.

P405 - Store locked up.

P501 - Dispose of contents/container to hazardous or special waste collection point, in

accordance with local, regional, national and/or international regulation.

#### 2.3. Other hazards

Contains no PBT and/or vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

# **SECTION 3: Composition/information on ingredients**

#### 3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%
HYDROCORTISONE ACETATE	CAS-No.: 50-03-3 EC-No.: 200-004-4	100

## **SECTION 4: First aid measures**

#### 4.1. Description of first aid measures

First-aid measures general : IF exposed or concerned: Get medical advice/attention.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Remove person to fresh air

and keep comfortable for breathing. If you feel unwell, seek medical advice.

First-aid measures after skin contact : Gently wash with plenty of soap and water. Take off contaminated clothing. If skin irritation

occurs: Get medical advice/attention. Wash skin with plenty of water.

First-aid measures after eye contact : Remove contact lenses, if present and easy to do. Continue rinsing. Rinse cautiously with

water for several minutes. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

First-aid measures for first aider : First aid workers will be equipped with suitable personal protective equipment.

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

Symptoms/effects : May cause damage to organs.

Symptoms/effects after inhalation : None under normal conditions. Dust of the product, if present, may cause respiratory

irritation after excessive inhalation exposure.

Symptoms/effects after skin contact : None under normal conditions. Dust may cause irritation in skin folds or by contact in

combination with tight clothing.

Symptoms/effects after eye contact : None under normal conditions. Dust from this product may cause eye irritation.

Symptoms/effects after ingestion : None under normal conditions.

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

Treat symptomatically.

## **SECTION 5: Firefighting measures**

# 5.1. Extinguishing media

Suitable extinguishing media : Dry chemical, CO2, or water spray or regular foam. Water spray. Dry powder. Foam.

Unsuitable extinguishing media : Carbon dioxide (CO2).

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

Fire hazard : No fire hazard.

No direct explosion hazard. **Explosion hazard** Hazardous decomposition products in case of fire Toxic fumes may be released.

### 5.3. Advice for firefighters

Firefighting instructions : Fight fire from safe distance and protected location. Do not enter fire area without proper

protective equipment, including respiratory protection.

Protection during firefighting Do not attempt to take action without suitable protective equipment. Self-contained

breathing apparatus. Complete protective clothing.

# **SECTION 6: Accidental release measures**

### 6.1. Personal precautions, protective equipment and emergency procedures

General measures : Notify authorities if product enters sewers or public waters. Absorb spillage to prevent

material damage.

For non-emergency personnel

: Wear recommended personal protective equipment. Protective equipment

**Emergency procedures** Ventilate spillage area. Evacuate unnecessary personnel.

For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. Avoid breathing

dust/fume/gas/mist/vapours/spray. For further information refer to section 8: "Exposure

controls/personal protection".

**Emergency procedures** : Ventilate area. Evacuate unnecessary personnel.

### 6.2. Environmental precautions

Avoid release to the environment.

Methods for cleaning up

# 6.3. Methods and material for containment and cleaning up

For containment Using a clean shovel, put the material in a dry container and cover without compressing it.

Mechanically recover the product. Clear up rapidly by scoop or vacuum. Notify authorities if

product enters sewers or public waters.

Other information Dispose of materials or solid residues at an authorized site.

#### 6.4. Reference to other sections

For further information refer to section 13.

# **SECTION 7: Handling and storage**

# 7.1. Precautions for safe handling

Additional hazards when processed : Not expected to present a significant hazard under anticipated conditions of normal use.

Precautions for safe handling Ensure good ventilation of the work station. Avoid contact with skin and eyes. Obtain special

instructions before use. Do not handle until all safety precautions have been read and

understood. Wear personal protective equipment.

Hygiene measures : Wash hands and other exposed areas with mild soap and water before eating, drinking or

smoking and when leaving work. Do not eat, drink or smoke when using this product.

Always wash hands after handling the product.

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

Technical measures : Keep in a cool, well-ventilated place away from heat.

Storage conditions : Keep container tightly closed. Store in a well-ventilated place. Keep cool. Store locked up.

Packaging materials : Store always product in container of same material as original container.

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# 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

#### Appropriate engineering controls:

Ensure good ventilation of the work station.

#### Personal protection equipment

#### Personal protective equipment:

Wash hands, forearms and face thoroughly after handling.

### Personal protective equipment symbol(s):







#### Eye and face protection

#### Eye protection:

Chemical goggles or safety glasses

#### Skin protection

# Skin and body protection:

Wear a mask

# Hand protection:

Protective gloves

#### **Respiratory protection**

## Respiratory protection:

Wear appropriate mask

#### **Environmental exposure controls**

# Environmental exposure controls:

Avoid release to the environment.

#### Other information:

Do not breathe dust/fume/gas/mist/vapours/spray. Do not eat, drink or smoke when using this product.

# **SECTION 9: Physical and chemical properties**

# 9.1. Information on basic physical and chemical properties

Physical state : Solid

Colour White to almost white. Appearance Crystalline powder. Molecular mass 404.51 g/mol Odour Odourless. Odour threshold : Not available Melting point 222 - 225 °C Freezing point : Not applicable Boiling point : Not available Flammability : Non flammable. Lower explosion limit : Not applicable Upper explosion limit : Not applicable

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Flash point : Not applicable
Auto-ignition temperature : Not applicable
Decomposition temperature : Not available
pH : Not available
pH solution : Not available
Viscosity, kinematic : Not applicable

Solubility : Water: Insoluble in water

Ether: Partially soluble in Diethyl ether Acetone: Partially soluble in Acetone

Partition coefficient n-octanol/water (Log Kow) : Not available Vapour pressure : Not available Vapour pressure at 50°C : Not available Density : 1.289 g/cm³ Relative density : Not available Relative vapour density at 20°C : Not applicable Particle size : Not available

#### 9.2. Other information

No additional information available

# **SECTION 10: Stability and reactivity**

## 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

#### 10.2. Chemical stability

Stable under normal conditions.

# 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

# 10.4. Conditions to avoid

Direct sunlight. Moisture.

#### 10.5. Incompatible materials

No additional information available

## 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

# **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 Skin corrosion/irritation : Not classified Serious eye damage/irritation : Not classified Respiratory or skin sensitisation : Not classified Germ cell mutagenicity : Not classified : Not classified Carcinogenicity

Reproductive toxicity : Suspected of damaging fertility or the unborn child.

STOT-single exposure : Not classified STOT-repeated exposure : Not classified Aspiration hazard : Not classified

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Viscosity, kinematic	Not applicable
HYDROCORTISONE ACETATE (50-03-3)	
Viscosity, kinematic	Not applicable

#### 11.2. Information on other hazards

No additional information available

## **SECTION 12: Ecological information**

## 12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse

effects in the environment.

Hazardous to the aquatic environment, short–term

(acute)

: Not classified

Hazardous to the aquatic environment, long-term

(chronic)

: Not classified

# 12.2. Persistence and degradability

HYDROCORTISONE ACETATE EXTRA PURE (50-03-3)	
Persistence and degradability	Rapidly degradable
HYDROCORTISONE ACETATE (50-03-3)	
Persistence and degradability Rapidly degradable	

# 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

# **SECTION 13: Disposal considerations**

# 13.1. Waste treatment methods

Regional waste regulation : Disposal must be done according to official regulations.

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

Sewage disposal recommendations : Disposal must be done according to official regulations.

Product/Packaging disposal recommendations : Dispose of contents/container to hazardous or special waste collection point, in accordance

with local, regional, national and/or international regulation. Disposal must be done

according to official regulations.

Additional information : Do not re-use empty containers.

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### **SECTION 14: Transport information**

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

#### 14.1. UN number or ID number

Not regulated for transport

## 14.2. UN proper shipping name

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

## 14.3. Transport hazard class(es)

**ADR** 

Transport hazard class(es) (ADR) : Not regulated

**IMDG** 

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

**IATA** 

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

**ADN** 

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

**RID** 

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

## 14.4. Packing group

Packing group (ADR) : Not regulated Packing group (IMDG) : Not regulated Packing group (IATA) : Not regulated Packing group (ADN) : Not regulated Packing group (RID) : Not regulated

## 14.5. Environmental hazards

Other information : No supplementary information available

## 14.6. Special precautions for user

#### **Overland transport**

Not regulated

## Transport by sea

Not regulated

#### Air transport

Not regulated

### **Inland waterway transport**

Not regulated

# Rail transport

Not regulated

# 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

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### **SECTION 15: Regulatory information**

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

#### **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)**

Contains no substance(s) listed on the REACH Candidate List

#### **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 (2024/590)

Not listed on the Ozone Depletion list (Regulation EU 2024/590)

#### Council Regulation (EC) for the control of dual-use items

Contains no substance subject to the COUNCIL REGULATION (EC) for the control of dual-use items

#### **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)

### **National regulations**

# Germany

Water hazard class (WGK) : WGK 3, Highly hazardous to water (Classification according to AwSV).

Major Accidents Ordinance (12. BImSchV) : Is not subject to the Major Accidents 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 – : The substance is not listed

Vruchtbaarheid

SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

## Denmark

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product

Pregnant/breastfeeding women working with the product must not be in direct contact with

the product

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#### **Poland**

Polish National Regulations

: Act of 25 February 2011 on chemical substances and their mixtures (J. o L. No. 63, item 322 as amended; consolidated text J. o L. 2019, item 1225).

Act of 14 December 2012 on waste (J. o L. 2013, item 322 as amended; consolidated text J. o L. 2020, item 797).

The announcement of Marshal of the Sejm of the Republic of Poland dated 19 October 2016 concerning the consolidated text announcement of the decree on the management of packaging and packaging waste (J. o L. 2016, item 1863 as amended).

Decree of the Minister of Environment of 14 December 2014 on the catalogue of waste (J. o L. 2014, item 1923).

Act of 19 August 2011 on the Carriage of Dangerous Goods (J. o L. 2011 No. 227, item 1367 as amended; consolidated text J. o L. 2020, item 154).

Regulation of the Minister of Family, Labour and Social Policy of 12 June 2018 on the highest permissible concentration and intensity of noxious agents for health at work environment (J. o L. item 1286 as amended).

The announcement of Minister of Health dated 9 September 2016 concerning the consolidated text announcement of the decree of the Minister of Health of 30 December 2004 on health and safety at work related to exposure to chemical agents at work (J. o L. of 16 September 2016, item 1488)

Regulation of the Minister of Health of 2 February 2011 on tests and measurements of the noxious agents for health at work environment (J. o L. No. 33, item 166 as amended). Regulation of the Minister of Environment of 9 December 2003 on particularly hazardous substances to the environment (J. o L. No. 217, item 2141).

ADR Agreement: Government Statement of 13 March 2023 on the entry into force of amendments to Annexes A and B to the Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), signed in Geneva on 30 September 1957 (J. o. L. 2023, item 891)

## 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

### **SECTION 16: Other information**

Abbreviations and acronyms:		
ACGIH	American Conference of Government Industrial Hygienists	
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	
BLV	Biological limit value	
BOD	Biochemical oxygen demand (BOD)	
CAS-No.	Chemical Abstract Service number	
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008	
COD	Chemical oxygen demand (COD)	
CSA	Chemical safety assessment	
DMEL	Derived Minimal Effect level	
DNEL	Derived-No Effect Level	
EC-No.	European Community number	
EC50	Median effective concentration	
ED	Endocrine disruptor	

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Abbreviations and acronyms:		
EN	European Standard	
EWC	European waste catalogue	
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	
Log Kow	Partition coefficient n-octanol/water (Log Kow)	
Log Pow	Partition coefficient n-octanol/water (Log Pow)	
MAK	maximum workplace concentration	
NOAEC	No-Observed Adverse Effect Concentration	
NOAEL	No-Observed Adverse Effect Level	
NOEC	No-Observed Effect Concentration	
N.O.S.	Not Otherwise Specified	
OECD	Organisation for Economic Co-operation and Development	
OEL	Occupational Exposure Limit	
OSHA	Occupational Safety & Health Administration	
PBT	Persistent Bioaccumulative Toxic	
PNEC	Predicted No-Effect Concentration	
PPE	Personal protection equipment	
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail	
SDS	Safety Data Sheet	
STP	Sewage treatment plant	
TF	Technical function	
ThOD	Theoretical oxygen demand (ThOD)	
TLM	Median Tolerance Limit	
TWA	Time Weighted Average	
VOC	Volatile Organic Compounds	
vPvB	Very Persistent and Very Bioaccumulative	
UFI	Unique Formula Identifier	

Full text of H- and EUH-statements:	
Repr. 2	Reproductive toxicity, Category 2
H361	Suspected of damaging fertility or the unborn child.

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.