

Product: **HYDROCORTISONE BASE (EUR. PH.)**

Product code: 1084

Page 1 of 7

Emission date: 14/10/2025

Version: 1084_MSDS_ENG_0125

**1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING****1.1. Product identifier**Product name: **HYDROCORTISONE BASE (EUR. PH.)**

Product code: 1084

Nº CAS: 50-23-7

Nº EC: 200-020-1

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

Relevant identified uses: Active Pharmaceutical Ingredient

1.3. Details of the supplier of the safety data sheetCompany: **METAPHARMACEUTICAL INDUSTRIAL SL**

JOSEP PLA 163 2º 5ª

08020 BARCELONA

SPAIN

Phone number: (0034) 933 089 976

Contact e-mail: info@metaph.esWeb page: www.metaph.com**1.4. Emergency telephone number**

National Institute of Toxicology of Madrid: (0034) 915 620 420

2. HAZARDS IDENTIFICATION**2.1. Classification of the substance or mixture**

The product is classified according to the provisions of Regulation (EU) 2015/830:

Repr. 1A, H360

STOT RE 2, H373

2.2. Label Elements

Signal word (CLP): DANGER

Hazard statements:

H360: May damage fertility or the unborn child.

H373: May cause damage to organs through prolonged or repeated exposure.

Precautionary statements:

P201: Obtain special instructions before use.

P260: Do not breathe dust/fume/gas/mist/vapors/spray.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

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

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

P405: Store locked up.

Product: **HYDROCORTISONE BASE (EUR. PH.)**

Product code: 1084

Page 2 of 7

Emission date: 14/10/2025

Version: 1084_MSDS_ENG_0125



P501: Dispose of contents/container at an approved destruction plant

2.3. Other hazards

No additional information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS**3.1. Substances**

Product name: HYDROCORTISONE BASE (EUR. PH.)
Synonyms: HIDROCORTISONA BASE, HYDROCORTISONE
IUPAC name: (11β)-11,17,21-trihydroxypregn-4-ene-3,20-dione
Nº CAS: 50-23-7
Nº EC: 200-020-1
Molecular formula: C₂₁H₃₀O₅

3.2. Mixtures

Not applicable.

4. FIRST AID MEASURES**4.1. Description of first aid measures**

General advises: Consult a doctor. Show the safety data sheet to the doctor on duty.
Inhalation: Take outdoors. If breathing is irregular, call a doctor immediately. Only apply artificial respiration if breathing stops or under medical supervision.
Skin contact: Wash immediately with plenty of soap and water for at least 15 minutes. Take off all contaminated clothing immediately. Get medical attention if irritation develops and persists.
Eye contact: Remove contact lenses and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
Ingestion: If conscious, give victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately.

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

The most important known symptoms and effects are described on the label (see section 2.2) and/or in heading 11.

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

Get medical advice/attention. If possible show this sheet, if not available show packaging or label.

5. FIREFIGHTING MEASURES**5.1. Extinguishing media**

Suitable extinguishing methods: Foam, dry powder, carbon dioxide, sand, water mist
Unsuitable extinguishing methods: Direct water jet.
Neighboring fires (containers exposed to fire): Atomized or nebulized water.

5.2. Special hazards arising from the substance or mixture

In the event of fire, fumes that are harmful to health may be produced.

Product: **HYDROCORTISONE BASE (EUR. PH.)**

Product code: 1084

Page 3 of 7

Emission date: 14/10/2025

Version: 1084_MSDS_ENG_0125

**5.3. Advice for firefighters**

General information:

Cool containers with water to prevent product decomposition and development of potential health hazards. Always use full fire protection. Collect the water that should not enter the sewer. Eliminate the contaminated water used to extinguish and the remains of the second current regulations.

Equipment:

Helmet with visor, flame retardant clothing (jacket and trousers with braces around the arms, legs and waist, EN 469), gloves (fire and dielectric proof, EN 659), a mask with a full-face mask. operator's face or car (protective car) in the case of large amounts of smoke, a self-contained breathing apparatus (EN 137).

6. ACCIDENTAL RELEASE MEASURES**6.1. Personal precautions, protective equipment and emergency procedures**

Avoid any direct contact with the product. Do not breathe dust/fume/gas/mist/vapors/spray. Wear suitable protective clothing, gloves and eye or face protection.

6.2. Environmental precautions

Avoid getting into sewers and water pipes. If the product reaches drains or public water pipes, notify the authorities.

6.3. Methods and material for containment and cleaning up

Store away from other materials. If on the floor, sweep or collect (using a shovel or similar) and place in appropriate containers. Limit dust generation.

6.4. Reference to other sections

No additional information available.

7. HANDLING AND STORAGE**7.1. Precautions for safe handling**

Request special instructions before use. Wash hands and other exposed areas with mild soap and water before eating, drinking, smoking, or leaving the workplace. Ensure good ventilation in the processing area to prevent vapor formation. Avoid breathing dust, fumes, gas, mist, vapors, or spray.

7.2. Conditions for safe storage, including any incompatibilities

Keep only in the original container, in a cool and well-ventilated place. Keep the container closed when not in use. Store away from acids and strong bases, sources of ignition, and direct sunlight.

7.3. Specific end use(s)

No additional information available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1. Exposure controls/personal protection**

No additional information available.

8.2. Exposure controls

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation in the workplace by means of effective local suction. When choosing personal protective equipment, ask your chemical suppliers if necessary. Personal protective equipment must bear the CE marking that certifies compliance with the applicable regulations. Arrange an emergency shower with a viscoelastic tray.



Product: **HYDROCORTISONE BASE (EUR. PH.)**

Product code: 1084

Page 4 of 7

Emission date: 14/10/2025

Version: 1084_MSDS_ENG_0125



Eye and face protection:	Protection masks and safety glasses according to EN 165, EN 166, EN 167, EN 168.
Hands protection:	Handle with gloves. The selected protective gloves must comply with the specifications of the EU Directive 89/686/EEC and the standards EN 374-1, EN 374-2, EN 374-3, EN 420 derived from it.
Respiratory protection:	Where risk assessment shows that air purifying respirators are appropriate, use type N95 (USA) or type P1 (EN 149) dust mask. Use respirators and components tested and approved under the appropriate government standards such as NIOSH (USA) or CEN (EU).
Skin protection:	Choose body protection based on the amount and concentration of the dangerous substance in the workplace.
Hygiene measures:	Handle with adequate industrial hygiene precautions, and respect safety practices. Wash your hands before breaks and after finishing the workday.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Aspect:	Crystalline solid
Color:	White
Odor:	Characteristic
Molecular weight (g/mol):	362.47
Melting Point (°C):	211 – 214
Density (20°C):	0.180 g/mL

9.2. Other information

No additional information available.

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

The product does not present the possibility of dangerous polymerization.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids and bases.

10.6. Hazardous decomposition products

Hazardous decomposition under fire conditions: fumes of carbon oxides (CO and/or CO₂).

Product: **HYDROCORTISONE BASE (EUR. PH.)**

Product code: 1084

Page 5 of 7

Emission date: 14/10/2025

Version: 1084_MSDS_ENG_0125



11. TOXICOLOGICAL INFORMATION

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

Acute oral toxicity (LD50, rat):	150 mg/Kg
Skin corrosion/irritation:	No additional information available (Lack of data)
Serious eye damage/eye irritation:	No additional information available (Lack of data)
Skin or respiratory sensitization:	No additional information available (Lack of data)
Germ cell mutagenicity:	No additional information available (Lack of data)
Carcinogenicity:	No additional information available (Lack of data)
Reproductive toxicity:	Suspected of damaging the unborn child (human reproductive toxic)
STOT – single exposure:	No additional information available (Lack of data)
STOT – repeated exposure:	No additional information available (Lack of data)
Aspiration Hazard:	Not classified as hazardous by aspiration

Potential Health Effects

Inhalation:	May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion:	May be harmful if swallowed.
Skin:	May be harmful if absorbed through the skin. May cause skin irritation.
Eyes:	May cause eye irritation.
Signs and Symptoms of Exposure:	No additional information available (Lack of data)

11.2. Information on other hazards

No additional information available.

12. ECOLOGICAL INFORMATION

Use in accordance with good work practices, avoiding dispersing the product in the environment. Notify the competent authorities if the product has reached water courses or if it has contaminated the soil or vegetation.

12.1. Toxicity

No additional information available.

12.2. Persistence and degradability

No additional information available.

12.3. Bioaccumulative potential

No additional information available.

12.4. Results of PBT and mPmB assessment

No additional information available.

12.5. Endocrine disrupting properties

No additional information available.

12.6. Other adverse effects

This substance/mixture does not contain components considered to be persistent, bioaccumulative, and toxic (PBT), or very persistent and very bioaccumulative (mPmB), at levels of 0.1% or higher.

Product: **HYDROCORTISONE BASE (EUR. PH.)**

Product code: 1084

Page 6 of 7

Emission date: 14/10/2025

Version: 1084_MSDS_ENG_0125



13.DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging: Dispose of as unused product.

14.INFORMACIÓN RELATIVA AL TRANSPORTE

The product is classified by the conventions of dangerous substances.

14.1. UN Number

No additional information available.

14.2. UN proper shipping name

No additional information available.

14.3. Transport hazard class(es)

No additional information available.

14.4. Packing group

No additional information available.

14.5. Environmental hazards

No additional information available.

14.6. Special precautions for user

No additional information available.

14.7. Maritime transport in bulk according to IMO instruments

No additional information available.

15.REGULATORY INFORMATION

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

The Safety Data Sheet complies with the requirements of Regulation (EU) 2020/878 of the Commission of June 18, 2020, by which Annex II of Regulation (EC) No. 1907/2006 of the European Parliament and of the Council is modified, relating to the registration, evaluation, authorization and restriction of chemical substances and mixtures (REACH).

15.2. Chemical safety assessment

No additional information available.

Product: **HYDROCORTISONE BASE (EUR. PH.)**

Product code: 1084

Page 7 of 7

Emission date: 14/10/2025

Version: 1084_MSDS_ENG_0125

**16. OTHER INFORMATION****Abbreviations and acronyms:**

PBT:	Persistent, bioaccumulative and toxic
mPmB:	Very persistent and very bioaccumulative
REACH:	Registration, Evaluation, Authorization and Restriction of Chemicals
ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
RID:	International Transport of Dangerous Goods by Rail
IMDG:	International Maritime Dangerous Goods Code
IATA:	International Air Transport Association

Data sources used:

Regulation (CE) No. 1272/2008 of the European Parliament and of the Council, of December 16, 2008, on the classification, labeling and packaging of substances and mixtures, and by which Directives 67/548/CEE and 1999 are modified and repealed /45/CE and modifies Regulation (CE) No. 1907/2006.

Regulation (EU) 2020/878 of the Commission of June 18, 2020, by which Annex II of Regulation (EC) No. 1907/2006 of the European Parliament and of the Council, regarding registration, evaluation, authorization and the restriction of chemical substances and mixtures (REACH)

Safety Data Sheet according to Annex II of REACH Regulation (EU) 2020/878**Department issuing the Safety Data Sheet:**

Technical Department

The information in this Product Safety Data Sheet is based on current knowledge and current EC and national laws, as far as the working conditions of users are beyond our knowledge and control. The product must not be used for purposes other than those specified, without first having a written instruction on its handling. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established in the legislation.