

Product: **MINOXIDIL BASE (EUR. PH. – EUR. GMP)**

Product code: 1301

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Emission date: 25/07/2024

Version: 1301\_MSDS\_ENG\_0124



## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

Product name: **MINOXIDIL BASE (EUR. PH. – EUR. GMP)**  
Product code: 1301  
Nº CAS: 38304-91-5  
Nº EC: 253-874-2

### 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 sheet

Company: **METAPHARMACEUTICAL INDUSTRIAL SL**  
JOSEP PLA 163 2º 5ª  
08020 BARCELONA  
SPAIN  
Phone number: (0034) 933 089 976  
Contact e-mail: [info@metaph.es](mailto:info@metaph.es)  
Web page: [www.metaph.com](http://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 as dangerous according to the provisions of Regulation (EC) 1272/2008 (CLP):  
Acute Tox. 4, H302  
Skin Irrit.2, H315  
Eye Irrit. 2, H319  
STOT SE 3, H335

### 2.2. Label Elements



Signal word (CLP): WARNING

Hazard statements (CLP)

H302: Harmful if swallowed.  
H315: Causes skin irritation.  
H319: Causes serious eye damage.  
H335: May cause respiratory irritation.

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## Precautionary statements (CLP)

- P261: Avoid breathing dust/fume/gas/mist/vapors/spray.
- P264: Wash... thoroughly after handling.
- P301 + P312: IF SWALLOWED: Call a POISON CENTER/doctor/... if you feel unwell.
- P501: Dispose contents/container to...

**2.3. Other hazards**

No additional information available.

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

- Product name: MINOXIDIL BASE (EUR. PH. – ERU. GMP)
- Synonyms: MINOXIDIL
- IUPAC name: (2S,4R)-N-[(1S,2S)-2-chloro-1-[(2R,3R,4S,5R,6R)-3,4,5-trihydroxy-6-(methylsulfonyl)oxan-2-yl]propyl]-1-methyl-4-propylpyrrolidine-2-carboxamide hydrochloride
- Nº CAS: 38304-91-5
- Nº EC: 253-874-2
- Molecular formula: C<sub>23</sub>H<sub>36</sub>N<sub>2</sub>O<sub>3</sub>

**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**

Carbon oxides and nitrogen oxides (NOx).

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### 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

Equip cleaning staff with proper protective equipment. Avoid both dust formation and suction. Avoid breathing in fumes, gases, or air condensation. Ventilate the area and evacuate non-essential personnel.

For more information on exposure control and personal protective measures, see section 8.

### 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

Ensure waste is collected and contained. Clean thoroughly. Wash the non-recoverable remainder with: Sodium hypochlorite solution.

### 6.4. Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations of section 13.

## 7. HANDLING AND STORAGE

### 7.1. Precautions for safe handling

Avoid contact with skin and eyes. Avoid the powder formation and aerosols.

Wash hands and other exposed areas with mild soap and water before eating, drinking, smoking, and leaving work. Provide good ventilation of the processing area to prevent vapor formation.

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

Store in a cool place. Keep the container tightly closed in a dry and well-ventilated place.

Storage class (TRGS 510): 11 (Combustible solids)

### 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 visco-elastic tray.



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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

Physical state:	Crystalline powder
Color:	White
Molecular weight (g·mol <sup>-1</sup> ):	209.25
Density (25 °C):	0.611 g/mL
Melting Point (°C):	248
Solubility in water (20 °C):	≥ 1 mg/L
Solubility in chloroform (20 °C):	Soluble
Solubility in ethanol (20 °C):	Soluble
n-octanol/water partition coefficient (20 °C):	LogPow 1.24

### 9.2. Other information

No additional information available.

## 10. STABILITY AND REACTIVITY

### 10.1. Reactivity

No additional information available.

### 10.2. Chemical stability

Stable under the recommended handling and storage conditions (see section 7).

### 10.3. Possibility of hazardous reactions

No additional information available.

### 10.4. Conditions to avoid

No additional information available.

### 10.5. Incompatible materials

Strong oxidizing agents.

### 10.6. Hazardous decomposition products

See section 5.

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## 11. TOXICOLOGICAL INFORMATION

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

Acute oral toxicity (LD50, rat):	1321 mg/Kg
Acute intraperitoneal toxicity (LD50, rat):	No additional information available (Lack of data)
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 component of this product is identified at levels greater than or equal to 0.1% as a probable, possible, or confirmed human carcinogen by the International Agency for Research on Cancer (IARC).
Reproductive toxicity:	Based on animal tests, overexposure can lead to reproductive disorders.
STOT – single exposure:	No additional information available (Lack of data)
STOT – repeated exposure:	No additional information available (Lack of data)
Aspiration Hazard:	No additional information available (Lack of data)

#### Potential Health Effects

Inhalation:	No additional information available (Lack of data)
Ingestion:	No additional information available (Lack of data)
Skin:	No additional information available (Lack of data)
Eyes:	No additional information available (Lack of data)
Signs and Symptoms of Exposure:	No additional information available (Lack of data)

### 11.2. Information on other hazards

Nº RTECS: UV8200000

## 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 vPvB assessment

No additional information available.

### 12.5. Endocrine disrupting properties

No additional information available.

### 12.6. Other adverse effects

No additional information available.

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## 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 should not be considered dangerous according to the applicable regulations on the carriage of dangerous goods by road (ADR), by rail (RID), by sea (IMDG Code) and by air (IATA).

### 14.1. UN Number

It is not dangerous to transport.

### 14.2. UN proper shipping name

It is not dangerous to transport.

### 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.

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**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

**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.