

Product: **CRYSTALLINE UREA (EUR. PH.)**

Product code: 1861

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Emission date: 03/08/2026

Version: 1861_MSDS_ENG_0126



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

1.1. Product identifier

Product name: **CRYSTALLINE UREA (EUR. PH.)**

Product code: 1629

Nº CAS: 57-13-6

Nº EC: 200-315-5

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

Relevant identified uses: Pharmaceutical excipient

1.3. Details of the supplier of the safety data sheet

Company: **METAPHARMACEUTICAL INDUSTRIAL SLU**

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 not classified as dangerous according to the provisions of Regulation (EC) 1272/2008 (CLP).

2.2. Label Elements

The product is not classified as dangerous according to the provisions of Regulation (EC) 1272/2008 (CLP).

2.3. Other hazards

No additional information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Product name: CRYSTALLINE UREA

Synonyms: UREA

IUPAC name: Carbonyl Diamide

Nº CAS: 57-13-6

Nº EC: 200-315-5

Molecular formula: CH₄N₂O

3.2. Mixtures

Not applicable.

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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

No acute or delayed effects resulting from exposure to the product are known.

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

No data available.

5. FIREFIGHTING MEASURES

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

Non-combustible. Hazardous vapors may be generated in the event of a fire in the surrounding area. Nitrogen oxides may be produced in the event of a fire.

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

For exposure controls and personal protection measures, see Section 8.

Provide cleanup personnel with appropriate protective equipment. Ventilate the area. Evacuate unnecessary personnel.

6.2. Environmental precautions

Prevent release into the environment. Avoid entry into sewers and waterways. If the product reaches drains or public watercourses, notify the relevant authorities.

6.3. Methods and material for containment and cleaning up

Store away from other materials. If spilled on the ground, sweep up or collect using a shovel or similar tool and place in suitable containers. Minimize dust generation.

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**6.4. Reference to other sections**

For exposure controls and personal protective measures, see Section 8.
For disposal recommendations, see Section 13.

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

Avoid release of the product into the environment. Smoking, eating and drinking should be prohibited in areas where the product is handled. Comply with applicable occupational health and safety regulations. Keep the product only in containers made of the same material as the original container.

7.2. Conditions for safe storage, including any incompatibilities

The product does not require any special storage conditions. Store containers in a cool, dry place.

7.3. Specific end use(s)

No additional information available beyond that provided in Section 1.

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.



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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Aspect:	Solid
Color:	White
Odor:	Slightly ammoniacal
pH (100 g/L):	9
Molecular weight:	60.06 g/mol
Melting Point (°C):	134
Density (20°C):	0.615 g/mL
Vapor pressure (20 °C):	< 0.1 hPa
Water solubility (20 °C):	< 1000 g/L
n-Octanol/water partition coefficient (20 °C):	LogPow -1.59

9.2. Other information

No additional information available.

10. STABILITY AND REACTIVITY

10.1. Reactivity

No special conditions.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

The product does not present any risk of hazardous reactions.

10.4. Conditions to avoid

None in particular.

10.5. Incompatible materials

Perchlorates. Halogens. Bases. Chromyl chloride. Oxidizing agents. Nitrites. Phosphorus. Nitrosyl compounds. Chlorine.

10.6. Hazardous decomposition products

Hydrogen cyanide. Ammonia.

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11. TOXICOLOGICAL INFORMATION

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

Acute oral toxicity (LD ₅₀ , rat):	8471 mg/Kg
Acute dermal toxicity (LD ₅₀ , rat):	8200 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:	The IARC Working Group evaluated the biological effects of talc and concluded, based on in vivo and in vitro studies, that there is insufficient evidence of carcinogenicity or genotoxicity in either experimental animals or humans.
Reproductive toxicity:	No additional information available (Lack of data)
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 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 vPvB assessment

According to available data, the product does not contain any PBT or vPvB substances in concentrations above 0.10%.

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 hazardous according to the applicable regulations for the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code), and air (IATA).

14.1. UN Number

Not classified as dangerous for transport.

14.2. UN proper shipping name

Not classified as dangerous for transport.

14.3. Transport hazard class(es)

Not classified as dangerous for transport.

14.4. Packing group

Not classified as dangerous for transport.

14.5. Environmental hazards

Not classified as dangerous for transport.

14.6. Special precautions for user

Not classified as dangerous for transport.

14.7. Maritime transport in bulk according to IMO instruments

Not classified as dangerous for transport.

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.