



azienda chimica e farmaceutica

## SPECIFICA TECNICA

### TECHNICAL SPECIFICATION

Prodotto: **UREA USP**  
Product **UREA USP**

NOME INCI <i>INCI NAME</i>	Urea
NOME INCI USA <i>INCI NAME USA</i>	Urea
CAS <i>CAS NUMBER</i>	57-13-6
EINECS / ELINCS <i>EINECS / ELINCS</i>	200-315-5
FORMULA <i>FORMULA</i>	CH <sub>4</sub> N <sub>2</sub> O
PESO MOLECOLARE <i>MOLECULAR WEIGHT</i>	60,06

SPECIFICA <i>SPECIFICATION</i>	METODO <i>METHOD</i>	Lim. Inf. - Lim. Sup. <i>Lower Lim. - Upper Lim.</i>	u.m.
Identificazione IR <i>IR identification</i>		Conforme <i>Conform</i>	
Identificazione A e B <i>Identification A and B</i>		Conforme <i>Conform</i>	
Solfati <i>Sulphates</i>		<=100	mg/Kg
Metalli pesanti <i>Heavy metals</i>		<=20	mg/Kg
Titolo <i>Assay</i>		99,0 - 100,5	%
Cloruri <i>Chloride</i>		<=70	mg/Kg
Ceneri solforiche <i>Sulphated ash</i>		<=0,100	%
Punto di fusione <i>Melting point</i>		132,00 - 135,00	° C
Insolubile in alcool <i>Alcohol-insoluble matter</i>		<=0,04	%

I metodi di analisi non indicati sono metodi interni del produttore ottenibili su specifica richiesta

Le informazioni sopra riportate non Vi sollevano dall'obbligo di identificare il prodotto prima dell'impiego. La nostra società non si assume alcuna responsabilità per danni a persone o cose derivanti dall'impiego dei prodotti da noi commercializzati

The analytical methods not listed are internal methods of the manufacturer obtainable upon specific request

The above information will not relieve you to identify the product before use. Our company does not assume any responsibility for damage to persons or property arising by the use of the products we sell



azienda chimica e farmaceutica

## SPECIFICA TECNICA

TECHNICAL SPECIFICATION

Prodotto: **UREA USP**  
Product **UREA USP**

Solventi Residui <i>Residual Solvents</i>		Conformi alla USP <i>Complies with USP</i>	
Revisione Capitolato <i>Specification Revision</i>		1	
Data Approvazione <i>Approval Date</i>		09/09/2016	

I metodi di analisi non indicati sono metodi interni del produttore ottenibili su specifica richiesta

Le informazioni sopra riportate non Vi sollevano dall'obbligo di identificare il prodotto prima dell'impiego. La nostra società non si assume alcuna responsabilità per danni a persone o cose derivanti dall'impiego dei prodotti da noi commercializzati

The analytical methods not listed are internal methods of the manufacturer obtainable upon specific request

The above information will not relieve you to identify the product before use. Our company does not assume any responsibility for damage to persons or property arising by the use of the products we sell



azienda chimica e farmaceutica

## SPECIFICA TECNICA

### TECHNICAL SPECIFICATION

Prodotto: **UREA USP**  
Product *UREA USP*

#### STORAGE:

Well closed in a dry and cool place

#### SHELF LIFE:

Can be kept for 10 years, if stored in a dry and cool place (< 25 °C / < 65% air humidity) in original packaging.

#### BSE/TSE DECLARATION

The product is not of animal origin and no products of animal origin are used in its production. Urea is of synthetic origin.

#### APPLICATION:

- Used as nitrogen fertilizer, for production of other compounds (e.g. amides, hydrazine, melamine) and plastics
- A 10% aqueous solution is bactericidal and is used in wound ointments
- Used for production of cosmetic preparation, as keratolytic.

The product is not being tested on animals.

We confirm that, to the best of our knowledge, in the product UREA USP free formaldehyde is not detectable (detection limit of the standard method is 1 ppm).

The surface of Urea USP is treated with methylene diurea to improve storage properties. Therefore formaldehyde chemically bonded as methylene diurea is present in concentrations of approximately 100 to 150 ppm.

The product comes from Europe

#### ORIGIN:

The product is of synthetic origin

#### CMR

We herewith confirm that the raw material Urea (Product group 10139) is not listed as CMR (carcinogenic, mutagenic, toxic for reproduction) according to Commission Regulation Commission Regulation (EC) No 790/2009 of 10 August 2009 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. To the best of our knowledge Urea does not contain any of the substances mentioned therein.

#### MANUFACTURING PROCESS:

Ammonia and carbondioxid react at high temperature and high pressure to Urea and water. The water is separated in several steps.

#### GENERAL PRODUCT INFORMATION:

Solubility in water:	approx. 1000 g/l (20 °C)
Molar mass:	60,06 g/mol
Melting point:	132 - 135 °C
Bulk density:	approx. 740 kg/m <sup>3</sup>

I metodi di analisi non indicati sono metodi interni del produttore ottenibili su specifica richiesta

Le informazioni sopra riportate non Vi sollevano dall'obbligo di identificare il prodotto prima dell'impiego. La nostra società non si assume alcuna responsabilità per danni a persone o cose derivanti dall'impiego dei prodotti da noi commercializzati

The analytical methods not listed are internal methods of the manufacturer obtainable upon specific request

The above information will not relieve you to identify the product before use. Our company does not assume any responsibility for damage to persons or property arising by the use of the products we sell



azienda chimica e farmaceutica

## SPECIFICA TECNICA

TECHNICAL SPECIFICATION

Prodotto: **UREA USP**  
Product *UREA USP*

To whom it may concern,  
list of Heavy Metals regarding the product Urea USP. The above mentioned parameters are not tested regularly and therefore are not part of the specification.

Lead (Pb):	max. 1 ppm
Cadmium (Cd):	max. 1 ppm
Arsenic (As):	max. 1 ppm
Nickel (Ni):	max. 1 ppm
Antimony (Sb):	max. 1 ppm
Mercury (Hg):	max. 1 ppm
Zinc (Zn):	max. 1 ppm
Chromium (Cr):	max. 1 ppm
Cobalt (Co):	max. 1 ppm

I metodi di analisi non indicati sono metodi interni del produttore ottenibili su specifica richiesta

Le informazioni sopra riportate non Vi sollevano dall'obbligo di identificare il prodotto prima dell'impiego. La nostra società non si assume alcuna responsabilità per danni a persone o cose derivanti dall'impiego dei prodotti da noi commercializzati

The analytical methods not listed are internal methods of the manufacturer obtainable upon specific request

The above information will not relieve you to identify the product before use. Our company does not assume any responsibility for damage to persons or property arising by the use of the products we sell



azienda chimica e farmaceutica

## SPECIFICA TECNICA

### TECHNICAL SPECIFICATION

Prodotto: **UREA USP**  
Product *UREA USP*

#### ALLERGEN

We would like to confirm that the product Urea USP does not contain allergens which have to be labelled as ingredients according to Annex II of Regulation (EU) No 1169/2011 of THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2011 and her amendment (EU) No 78/2014 on substances or products causing allergies or intolerances:

- Cereals containing gluten, namely: wheat (such as spelt and khorasan wheat), rye, barley, oats or their hybridised strains, and products thereof
- Crustaceans and products thereof
- Eggs and products thereof
- Fish and products thereof
- Peanuts and products thereof
- Soybeans and products thereof
- Milk and products thereof (including lactose)
- Nuts (i.e. Almond (*Amygdalus communis* L.), Hazelnut (*Corylus avellana*), Walnut (*Juglans regia*), Cashew (*Anacardium occidentale*), Pecan nut (*Carya illinoensis* (Wangenh.) K. Koch), Brazil nut (*Bertholletia excelsa*), Pistachio nut (*Pistacia vera*), Macadamia nut and Queensland nut (*Macadamia ternifolia*)) and products thereof
- Celery and products thereof
- Mustard and products thereof
- Sesame seeds and products thereof
- Sulphur dioxide and sulphites at concentrations of more than 10mg/kg or 10 mg/litre in terms of total SO<sub>2</sub>
- Lupin and products thereof
- Mollusc and products thereof

#### ABSENCE OF NANOMATERIAL DECLARATION

We hereby confirm that the product Urea USP is free from any nanomaterial. All raw and process materials used in the manufacture of Urea are not containing any nanomaterial.

#### COUNTRY OF ORIGIN

To whom it may concern, We herewith confirm that the product Urea USP originates from Germany.

#### GMO DECLARATION

We herewith confirm that the raw material Urea USP does not contain or consist of GMO's and is not produced from or does not contain ingredients produced from GMO's according to Regulation (EC) No. 1829/2003. The above product does not require GMO-labelling according to Regulations (EC) No. 1829/2003 and (EC) No. 1830/2003. Urea is of synthetic origin.

#### LIST OF INGREDIENTS

The percentage composition of the above mentioned product is stated as follows:

- Urea 99.0 % - 100.5 %
- Methylene diurea 100 to 150

I metodi di analisi non indicati sono metodi interni del produttore ottenibili su specifica richiesta

Le informazioni sopra riportate non Vi sollevano dall'obbligo di identificare il prodotto prima dell'impiego. La nostra società non si assume alcuna responsabilità per danni a persone o cose derivanti dall'impiego dei prodotti da noi commercializzati

The analytical methods not listed are internal methods of the manufacturer obtainable upon specific request

The above information will not relieve you to identify the product before use. Our company does not assume any responsibility for damage to persons or property arising by the use of the products we sell