

92783-UREA**1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION****1.1 Identification of the substance or preparation**

Name: Urea

Bulk code: 92783

Internal code: 405159

1.2 Synonyms

Carbamide

2. DESCRIPTION

Appearance: Crystalline powder.

Colour: White.

Odour: Odourless.

Origin: Chemical synthesis.

Geographical origin: Germany.

3. COMPOSITION/INFORMATION ON COMPONENTSFormula: $\text{NH}_2\text{-CO-NH}_2$

CAS: 57-13-6

EINECS: 200-315-5

INCI: Urea.

Molecular weight: 60.06 g/mol

INCI: Urea

Method of production: The product is obtained by condensing carbamate, pressing and reaction of the urea, until crystals are obtained. These are then dried, filtered and analysed before being packaged.

4. PHYSICO-CHEMICAL DATA

For more information, see the analysis report.

Solubility: The product is soluble in water and ethanol and practically insoluble in methylene chloride.

5. PROPERTIES/USES

Excipient for pharmaceutical use.

Cosmetic use.

Oral use.

Not suitable for the manufacture of food supplements or foods.

92783-UREA**6. DOSAGE**

No information available.

7. REMARKS

The product has been handled in a NON-sterile room; for batches suitable for sterile use, check availability.

STORAGE:

Store at room temperature in a cool, dry place in a tightly closed container, away from sunlight and moisture.

The documentation available related to the product's regulatory compliance is included below.

BSE/TSE:

The product is produced through chemical synthesis without using substances of animal or plant origin. As such, the product does not contain BSE/TSE pathogens due to the production technology and raw and auxiliary materials used.

GMOs:

The product is produced through chemical synthesis without using substances of animal or plant origin. As such, the product does not contain GMOs/GVOs due to the production technology and raw and auxiliary materials used.

CMR substances:

The product is not a CMR substance nor does it have any of its properties.

SVHC:

The product is not listed by the ECHA as an SVHC substance according to Regulation (EU) No 1907/2006 (REACH Regulation), Article 59.

NANOPARTICLES:

The product does not fall within the definition of microplastics and does not contain nanoparticles or microplastics as additives.

IONISING RADIATION:

The product has not been treated with ionising radiation anywhere throughout the production process.

PESTICIDES:

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The product does not contain pesticides.

RESIDUAL SOLVENTS:

No residual solvents are used during the manufacture of urea, and therefore these substances are not expected to be present in the final product.

IMPURITIES:

The product does not contain the following substances:

- Aflatoxins
- Hormones
- Nitrosamines
- N-(hydroxymethyl) acrylamide

ELEMENTAL IMPURITIES:

In the following table, an excerpt from the manufacturer's PQR 2020 on the active substance for the risk assessment according to ICH Q3D.

Parámetro	unit	n	MW	Min.	Max.	s	CV
As	mg/kg	154	< 0,05	-	-	-	-
Pb	mg/kg	154	< 0,05	-	-	-	-
Cu	mg/kg	154	0,05	0,05	0,07	0,00	3,28
Zn	mg/kg	152	< 0,05	-	-	-	-
Cd	mg/kg	154	< 0,05	-	-	-	-
Ca	mg/kg	154	< 0,05	-	-	-	-
Cr	mg/kg	154	0,06	0,05	0,36	0,03	46,94
Fe	mg/kg	154	0,07	0,05	0,43	0,04	56,74
Co	mg/kg	154	< 0,05	-	-	-	-
Mn	mg/kg	154	< 0,05	-	-	-	-
Ni	mg/kg	154	0,05	0,05	0,15	0,01	16,27
Hg	mg/kg	154	< 0,01	-	-	-	-
V	mg/kg	154	< 0,05	-	-	-	-
Se	mg/kg	154	< 0,01	-	-	-	-
Li	mg/kg	154	< 0,05	-	-	-	-
Sb	mg/kg	154	< 0,01	-	-	-	-

Table 1: the analysed levels of elemental impurities for 154 samples of active substance in 2020

HEAVY METALS:

The product is produced by chemical synthesis, whereby no catalysts are used in the urea production technology. Thus, the product does not contain residual metal catalysts.

CALIFORNIA PROPOSITION 65:

The product is not subject to the Proposition 65 List.



GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.

Type of document:

TECHNICAL DATA SHEET

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ALLERGENS:

- **Food allergens:** The product does not contain any of the products listed in Annex II to Regulation (EU) 1169/2011 that may cause allergies or intolerances.
- **Cosmetic allergens:** The product does not contain any substance and/or product that causes allergies and/or intolerances listed in Annex III to Regulation (EC) 1223/2009.

HALAL:

The starting material is of inorganic origin, so it meets Halal requirements.

KOSHER:

The starting material is of inorganic origin, so it meets Kosher requirements.

VEGAN/VEGETARIAN:

The product is produced through chemical synthesis without using substances of animal origin.

TESTED ON ANIMALS:

The product has not been tested on animals.

REACH:

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