# 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 COMPONENTS

Formula: $NH_2$-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.
Food use.

The main applications are:

- Cosmetic products.
- As a food additive E 927 b (Carbamide).
- Excipients in the pharmaceutical industry.
- As an ingredient for nutritive solutions in biochemistry.

## 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:

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.

## 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:

01-2119463277-33-XXXX