

11038-SODIUM BORATE**1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.****1.1. Identification of the substance or preparation.**

Name: Sodium borate

Bulk code: 11038

Internal code: 401338

Valid from batch: 0119257

1.2. Synonyms.

Sodium tetraborate decahydrate, Borax, E-285, decahydrate sodium borate.

2. DESCRIPTION.

Appearance: Crystalline powder, crystals.

Colour: White or almost white, colourless.

Origin: Synthetic.

Geographical origin: Italy.

3. COMPOSITION/INFORMATION ON COMPONENTS.Formula: $\text{Na}_2\text{B}_4\text{O}_7 \cdot 10\text{H}_2\text{O}$

Molecular weight: 381.4 g/mol.

CAS: 1303-96-4

EINECS: 215-540-4

4. PHYSICO-CHEMICAL DATA.

For more information see the analysis report.

Solubility: The product is soluble in water and in glycerine, and insoluble in alcohol.**Incompatibilities:** Acids, alkaloid salts and metal salts.**5. PROPERTIES/USES.**

Excipient for pharmaceutical use.

Food use.

The product complies with Regulation EU 854/2004 and with Regulation (EC) 178/2002.

11038-SODIUM BORATE**6. DOSAGE.**

Do not give to children under 3 years of age.

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, heat sources and moisture.

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

BSE/TSE:

The product is free of BSE/TSE in accordance with EMA/410/01 and Regulation 2001/999/EC.

GMOs:

The product is free of GMOs according to Regulations 1829/2003/EC and 1830/2003/EC.

NANOMATERIALS:

Absent according to Regulation (EU) 1169/2011.

VOCs:

Compliant.

RADIATION:

The product has not undergone irradiation.

PESTICIDES:

According to Regulation 396/2005/EC.

RESIDUAL SOLVENTS:

According to ICH Q3C and the Ph. Eur.

CONTAMINANTS/IMPURITIES:

According to Regulation EC 1881/2006.

Melamine according to Regulation EC 1881/2006.

The product does not contain:

- Latex
- Gelatine

11038-SODIUM BORATE

- Foreign material/metals
- Added colourings
- Flavourings
- Sweeteners
- Added sugars
- Preservatives

ALLERGENS:

- **Food allergens:** Absent according to Regulation 1169/2011.

VEGAN/VEGETARIAN:

The product is suitable for vegan/vegetarian use.

DOPING SUBSTANCES:

Absent according to the WADA list of prohibited substances.

REACH:

01-2119490790-32-0011