

**9307-POWDERED BORIC ACID PH. EUR****1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION****1.1. Identification of the substance or preparation**

Name: Powdered boric acid Ph. Eur.

Bulk code: 9307

Internal code: 46042

**1.2. Synonyms**

Boric acid, orthoboric acid.

**2. DESCRIPTION**

Appearance: Granulated crystals.

Colour: White.

Origin: Inorganic.

Geographical origin: Italy.

**3. COMPOSITION/INFORMATION ON COMPONENTS**Formula:  $H_3BO_3$ 

CAS: 10043-35-3

EINECS: 233-139-2

Molecular weight: 61.83 g/mol.

**Method of production:** The product is manufactured from a reaction between a mother liquor and BA Tec. The product is then filtered, ion exchanged with purification resins and crystallised. It is subsequently thickened, centrifuged and dried. The process has numerous analysis points to ensure adequate control throughout the manufacturing process.

**4. PHYSICO-CHEMICAL DATA**

For more information, see the analysis report.


**Solubility:** The product is soluble in water, glycerol (85%) and alcohol. The solubility of boric acid in water is increased with hydrochloric, citric or tartaric acid.

**5. PROPERTIES/USES**

Pharmaceutical industry: excipient with mandatory reporting.

**6. DOSAGE**

No information available.

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	Type of document:	
	<b>TECHNICAL DATA SHEET</b>	
	Review date:	Version:
	<b>29.11.2022</b>	<b>9.0</b>
<b>9307-POWDERED BORIC ACID PH. EUR</b>		

## 7. REMARKS

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

### **STORAGE:**

Store in a cool, dry, well-ventilated place away from sunlight, in a tightly closed container. If stored correctly, the product is chemically and physically stable.

If heated, it loses its hydration water, changing to metaboric acid and eventually anhydrous boric acid.

Store the product in a dry, well-ventilated storehouse away from heat sources.

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

### **BSE/TSE:**

The product does not contain BSE (bovine spongiform encephalopathy) or TSE (transmissible spongiform encephalopathy). The product is of fully inorganic origin and does not contain substances of biological origin nor are biological materials used and/or authorised to be in contact with the product. Therefore, the product is not subject to BSE/TSE Regulations, as per EMEA/410/01, final Rev. 03/2011, and is compliant with applicable European regulations (EC) 1829/2003, (EC) 1830/2003 and European Directive 2011/18/EC.

### **GMOs:**

The product does not contain GMOs (genetically modified organisms). The product is of fully inorganic origin and does not contain substances of biological origin nor are biological materials used and/or authorised to be in contact with the product.

### **SVHC:**

The product has been included since 18/06/2010 in the Candidate List of Substances of Very High Concern for Authorisation (SVHC) published in accordance with Article 59 (10) of the REACH Regulation due its being considered toxic for reproduction (Article 57c). For additional information, please consult the ECHA website (<https://echa.europa.eu/candidate-list-ta>).

### **NANOMATERIALS:**

The product does not fall within the definition of nanomaterials according to 2011/696/EU of the Member States. Although the product is not intentionally manufactured in nanoscale, it cannot be ruled out that it may contain particles within the range of 1 nm-100 nm.

### **IONISING RADIATION:**

The product has not been subjected to treatment with ionising radiation.

### **RESIDUAL SOLVENTS:**

The product does not contain residual solvents listed in the ICH Q3D Guide (Pb content <0.002 ppm). It is also compliant with the requirements set forth in the CPMP/ICH/283/95-ICH Q3C (R6) Guide.

**9307-POWDERED BORIC ACID PH. EUR****CONTAMINANTS:**

The product does not contain products of animal origin, and the only raw materials used to manufacture the product are of fully inorganic origin and are not cross contaminated or contaminated with the following products, which are therefore not expected to be present:

- Aflatoxins
- Allergens
- Dioxin
- Ethylene oxide
- Formaldehyde
- Latex and melamine
- Metal catalyst
- Nanomaterials
- Preservatives, antioxidants
- Pesticides, PCBs
- Gluten
- DEHP and DINP phthalates
- Volatile organic compounds (VOCs)
- Plant hormones + growth promoters
- Bisphenol A (BPA)
- Polyvinyl chloride (PVC)
- Silicones
- Polyurethane
- Nitrosamines and salts thereof
- Ethylene oxide

Thus, any possibility of such substances being present in the final product, even in minimal quantities, is ruled out.

**ALLERGENS:**

- **Food allergens:** The product does not contain allergens as defined in EU Regulation 1169/2011/EC.

**GLUTEN:**

The product is gluten free.

**LACTOSE:**

The product does not contain lactose.

**HALAL:**

The product meets the requirements but does not have a Halal certificate.

**KOSHER:**

The product is Kosher certified.

**TESTED ON ANIMALS:**

The product has not been tested on animals.



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**RSPO:**

The product is of inorganic origin and does not contain substances or come into contact with substances of organic or biological origin.

**REACH:**

01-2119486683-25-0026

**TARIFF ITEM NUMBER:**

28100090