

**SCL Italia**

Larderello Group

lot. 0280920

CERTIFICATE OF ANALYSIS

Certificate of Analysis n° : 728/20

Issue Date: **September 10, 2020**Lot. n°: **C010520005**Manufacturing date: **September 08, 2020**Expiry date: **September 08, 2025**Print date: **September 10, 2020****BORIC ACID EP POWDER**

The product is in accordance with the European Pharmacopoeia 10.0 for Boric Acid

Analysis:

<u>Characteristics</u>		Units	Test	Specific		<u>Analytical chemistry procedure employed</u>
			Results	Min.	Max.	
Description			: Powder, white granules			
Identification			: Positive			European Pharmacopoeia
Appearance of the solution			: According to Ph. Eur.			European Pharmacopoeia
Solubility in alcohol			: According to Ph. Eur.			European Pharmacopoeia
Organic volatile impurities			: According to Ph. Eur.			European Pharmacopoeia
pH of 3,3 % solution			: 4,0	3,8	4,8	pH-Meter
Chloride	Cl	ppm	< 2	-	-	Ion Chromatography
Sulphate	SO ₄	ppm	< 5	-	450	Ion Chromatography
Heavy metals	as Pb	ppm	< 1	-	15	Colorimetry after concentration
Iron	Fe	ppm	< 1	-	-	Colorimetry (Tripyridil Triazine)
Boric Acid	H ₃ BO ₃	%	: 100,0	99,0	100,5	Potentiometric Titration

Particle Size Distribution (% Progressive Residue)

<u>Characteristics</u>		Units	Test Results	Specific		<u>Analytical chemistry procedure employed</u>
				Min.	Max.	
<u>ISO 3310</u>						
> 300 µm		%	1,0	-	5,0	Laser diffraction

► Shelf life statement/Date Limite d'Utilisation Optimale

- The product stored in its original and properly sealed containers is chemically stable for at least 5 years from the manufacturing date indicated in the documents.
- Store cool, dry and well-ventilated place, away from strong reducing agents; keep preferably at a temperature between 20°C and 35°C; To avoid:
 - high air humidity
 - sunlight exposure
 - temperatures under -5°C and over 40°C

Laboratory / Quality Control

Michele Ciampoli

SCL Italia SpA

Via Fabio Filzi 25/A - 20124 Milano, Italy - Tel +39 02 6771681 - Fax +39 02 67716820 - info@scl.it - www.scl.it

Socio unico, soggetta a direzione e coordinamento di IPI srl - CCIAA MI 1504336 - C.F. / P.IVA 01231260504 - Cap. Soc. € 520.000 i.v.

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