

CERTIFICATE OF ANALYSIS

Certificate of Analysis nº: 967/22

Issue Date: August 04, 2022

Lot. n°: C020222012

Manufacturing date: July 28, 2022 Expiry date: July 28, 2025

SODIUM TETRABORATE DECAHYDRATE EP

The product is an accordance with the European Pharmacopeia 10.0 for sodium tetraborate decahydrate

Analysis: Characteristics Units Test Specific Analytical chemistry procedure employed Results Min. Max. Powder, white granules Description Identification **Positive** European Pharmacopoeià Appearance of the solution According to Ph. Eur. European Pharmacopoeià Carbonate and bicarbonate According to Ph. Eur. European Pharmacopoeià Organic volatile impurities According to Ph. Eur. European Pharmacopoeià pH of 4 % solution 9,3 9.0 9,6 pH-Meter 10 Ammonium NH₄ ppm < 10 European Pharmacopoeià Ion Chromatography Sulphate SO₄ ppm < 10 50 Heavy metals as Pb ppm 5 20 Colorimetry after concentration Arsenic As < 1 5 ppm Atomic Absorption - FIAS 100 Calcium Atomic Absorption Ca ppm 100 Na₂B₄O₇ · 10H₂O 103,0 Potentiometric Titration Assay 101,6 99,0

▶ Shelf life statement/Date Limite d'Utilisation Optimale

- The product stored in its original and properly sealed containers is chemically stable for at least 3 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

SCL shall not be held responsible for any and all issues arising from incorrect storage and/or handling of the product.

Laboratory / Quality Control
Mighele Ciampol



SCL Italia SpA