

## **Certificate of Analysis**

Product name:

Batch number / Weight:

Analysed according to:

## Natrii hydrogenocarbonas 21I24-B10-217518 / 150 G Ph. Eur.01/2021:0195

| Tests                     | Requirement                                  | Result  | Unit | Standard remark |
|---------------------------|--|---------|------|-----------------|
| Appearance                | (Almost) White, crystalline powder           | Conform |      |                 |
| Identification A          | Pink / red                                   | Conform |      |                 |
| Identification B          | Conform                                      | Conform |      |                 |
| Identification C          | Conform                                      | Conform |      |                 |
| Solubility                | acc. to Ph. Eur.                             | Conform |      |                 |
| Appearance of solution    | Clear / colourless                           | Conform |      |                 |
| Carbonates                | <=8,6  | 8,16    |      |                 |
| Chlorides                 | <= 150                                       | <150    | ppm  |                 |
| Sulphates                 | <= 150                                       | <150    | ppm  |                 |
| Ammonium                  | <= 20  | Conform | ppm  |                 |
| Calcium                   | <= 100                                       | Conform | ppm  |                 |
| Iron                      | <= 20  | Conform | ppm  |                 |
| Metallic residues         | CHMP/ICH/353369/2013                         | Conform |      | Data producer   |
| Residual solvents         | CPMP/ICH/82 260/06                           | Conform |      | Data producer   |
| Sodium hydrogen carbonate | 99,0 - 101,0                                 | 99,77   | %m/m |                 |
| TSE/BSE-statement:        | No contamination with TSE/BSE-risk materials | Conform |      | Data producer   |

Analysis performed by the authorized lab.

Release: Dominika Sołtysik Qualified Person

11-03-2022

Expiration: 14-09-2023

Conclusion: APPROVED

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