

Certification of Substances Department

## Certificate of suitability No. CEP 2024-486 - Rev 00

1 *Name of the substance:*

2 **SODIUM HYDROGEN CARBONATE**

3 *Details of holder:*

4 **QEMETICA SODA DEUTSCHLAND GMBH & CO. KG**

5 An Der Loederburger Bahn 4a

6 Germany-39418 Stassfurt, Saxony-Anhalt

7 SPOR ORG ID: 100033772

8 SPOR LOC ID: 100053126

9 After examination of the information provided on the production method and control strategy for the  
10 substance, we certify that its quality is suitably controlled by the current version of the European  
11 Pharmacopoeia monograph for **SODIUM HYDROGEN CARBONATE** No. 195 and any  
12 supplementary tests deemed necessary. The approved site(s) of production, specification and any  
13 supplementary test procedure(s) are included on the following pages, which constitute an integral  
14 part of this certificate.

15 In the last steps of the process, purified water is used as solvent.

16 No elemental impurity classified in ICH Q3D is intentionally introduced in the production of the  
17 substance.

18 The substance is packed either in a polyethylene lined paper bag or a polyethylene lined  
19 polypropylene big bag.

20 No material of human or animal origin is used in the production of the substance.

21 The holder of the certificate should fulfil the following conditions in order to maintain the validity of  
22 this certificate.

23 The dossier submitted must be updated in accordance with EDQM guidance on the requirements  
24 for revision of certificates of suitability.

25 Production of the substance shall take place in accordance with the dossier submitted and Good  
26 Manufacturing Practice.

27 Necessary information from the submitted dossier shall be shared with authorised users in order  
28 to enable them to evaluate the suitability of this substance for its intended use. This includes  
29 informing them of any relevant change in the associated dossier.

- 30 Failure to comply with any of these provisions will render this certificate void.
- 31 This certificate is granted within the framework of Resolution AP-CSP (07) 1 adopted by the Council  
32 of Europe Public Health Committee (Partial Agreement) (CD-P-SP) in February 2007. With regard  
33 to its use in the member states of the European Union/European Economic Area, it is granted in  
34 accordance with the provisions of Directive 2001/83/EC and Regulation (EU) 2019/6 as amended,  
35 and the related guidelines.
- 36 This certificate is valid from 6 February 2026.

On behalf of the  
Director of EDQM

**Site(s) of Production**  
**CEP 2024-486 - Rev 00**

***SITE(S) OF PRODUCTION OF THE SUBSTANCE:***

QEMETICA SODA DEUTSCHLAND GMBH & CO. KG

An Der Loederburger Bahn 4a

Germany-39418 Stassfurt, Saxony-Anhalt

SPOR ORG ID: 100033772

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**Specification**  
**CEP 2024-486 - Rev 00**

## 1. Eigenschaften / Characteristics

**Aussehen:** weißes bis fast weißes, kristallines Pulver  
Appearance: white to almost white, crystalline powder

**Löslichkeit:** löslich in Wasser, praktisch unlöslich in Ethanol 96 %  
Solubility: soluble in water, practically insoluble in ethanol 96 %

Beim Erhitzen der Substanz oder der Lösung der Substanz entsteht allmählich Natriumcarbonat.  
When the substance or solution of the substance is heated, sodium carbonate is gradually formed.

## 2. Prüfungen / Tests

Nr. No.	Prüfparameter Test parameters	Prüfmethode Testing method	Spezifikation Specification
	<b>Prüfung auf Identität</b> Testing of Identity		
1	Farbreaktion Color reaction	Ph.Eur.	Rotfärbung der Lösung Red color of solution
2	Carbonat und Hydrogencarbonat Carbonate and Hydrogen carbonate	Ph.Eur. (2.3.1)	muss entsprechen must corresponds
3	Natrium Sodium	Ph.Eur. (2.3.1)	muss entsprechen must corresponds
	<b>Prüfung auf Gehalt</b> Testing of Content		
4	Natriumhydrogencarbonat (NaHCO <sub>3</sub> ) Sodium hydrogen carbonate	Ph.Eur. (2.2.20)	99,0 – 101,0 % 99.0 – 101.0 %
	<b>Prüfung auf Reinheit</b> Testing of Purity		
5	Aussehen der Lösung Appearance of solution	Ph.Eur. (2.2.1; 2.2.2, Methode II)	klar und farblos clear and colorless
6	Carbonat / pH-Wert Carbonate / pH-value	Ph.Eur. (2.2.3)	max. 8,6 max. 8.6
7	Chlorid Chloride	QSD (Photometer)	max. 150 ppm
8	Sulfat Sulfate	Ph.Eur. (2.4.13)	max. 150 ppm
9	Ammonium Ammonium	Ph.Eur. (2.4.1)	max. 20 ppm
10	Calcium Calcium	QSD (ICP)	max. 100 ppm
11	Eisen Iron	QSD (ICP)	max. 20 ppm

Prüfmethode: Ph. Eur. = European Pharmacopoeia, QSD = Qemetica Soda Deutschland GmbH & Co. KG  
Testing methods: Ph. Eur. = European Pharmacopoeia, QSD = Qemetica Soda Deutschland GmbH & Co. KG (Germany)