

SOLVAY

SOLVAY GmbH

## SOLVAY Product Data Sheet

CoA Healthcare products

SPE – B 05.03.43 - 12/2024 - Ed. 2

**Customer**  
CG-CHEMIKALIENGESELLSCHAFT  
GMBH & CO. KG  
ULMER STR 1A  
30880 LAATZEN

**Certificate recipient**  
CG-CHEMIKALIEN GESELLSCHAFT  
GMBH & CO. KG  
Zertifikate  
ULMER STR. 1  
30880 LAATZEN  
Fax +4951187803477

<b>Transport</b>	4112398271	<b>Batch number</b>	RBA0042600
<b>Delivery note</b>	74724615 900001	<b>Order</b>	6316190 000010
<b>Shipping date</b>	15.01.2026	<b>Customer ref.</b>	EA25304514
<b>Packaging</b>	882 bag	<b>Transport ID</b>	HEICT166 HEIH396

## BICAR PHARMA EXC 0/13 SODIUM BICARBONATE

Industrial origin RHEINBERG

Batch number RBA0042600 / Quantity 22.050 kg

**Appearance** : A white or almost white, crystalline powder.**Solubility** : Soluble in water, practically insoluble in ethanol 96 per cent.

When heated in the dry state or in solution, it gradually changes into sodium carbonate.

Characteristics	Units	Value	Specification	Method	Ref
Total alkalinity (NaHCO <sub>3</sub> )	%	100,2	99,0 - 100,5	Solvay	1
Bicarbonate (NaHCO <sub>3</sub> )	%	99,6	>= 99,0	Solvay	1
PHE Identification A, B, C	-	Conform	Conform	Euro PH 2.3.1	3
Identification Bicarbonate	-	Conform	Conform	USP	3
Identification Sodium	-	Conform	Conform	USP	3
Appearance - Limpidity	-	Clear	Clear	Solvay	1
Appearance - Colouring	-	Colourless	Colourless	Solvay	1
Carbonates (pH Solution 5%)	-	8,1	<= 8,6	Solvay	1
Test normal Carbonate	-	Faint pink color	Faint pink color	USP	3
Chlorides (Cl)	ppm	11	<= 150	Solvay	1
Sulfates (SO <sub>4</sub> )	ppm	< 6	<= 150	Solvay	4
Sulfur Compounds (SO <sub>4</sub> )	ppm	< 6	<= 150	Solvay	4
Ammonium (NH <sub>4</sub> )	ppm	2	<= 20	Solvay	1
Arsenic (As)	ppm	< 1,0	<= 2,0	Solvay	4
Calcium (Ca)	ppm	75	<= 100	Solvay	1
Iron (Fe)	ppm	0,2	<= 5,0	Solvay	1
Heavy metals (Pb)	ppm	< 5	<= 5	Solvay	4
Loss on drying (H <sub>2</sub> O)	%	< 0,25	<= 0,25	Solvay	1
Test insoluble substances	-	Complete/clear	Complete/clear	Solvay	1
Free flowing density	kg/dm <sup>3</sup>	1,11	0,80 - 1,30	Solvay	1
European Pharmacopoeia	-	Conform 12th ed.	Conform 12th ed.		1
US Pharmacopoeia	-	Conform USPNF 2025	Conform USPNF 2025		1
< 0,200 mm	%	100,0	>= 80,0	Solvay	1
< 0,063 mm	%	1,4	<= 35,0	Solvay	1
Production date		04.01.2026			
Retest date		04.01.2029			



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**Container (s)**

- 1 - Analysis made on each batch
- 3 - Analysis made once per month
- 4 - Analysis made once per quarter

The Solvay methods have been validated in our laboratory. The specifications are as defined in the product data sheet.

This product is manufactured under GMP conditions (IPEC-PQG GMP for excipients)

This product is suitable to be used as pharmaceutical excipient. It is not authorized as active pharmaceutical ingredient (API)

This product is not intended to be used for parenteral applications or peritoneal dialysis.

Residual solvents: Test not applicable, no organic solvent is used in the manufacturing process.

**Your product number 110082**

This Certificate was automatically produced and is valid without signature.

This certificate is issued on the basis of analytical results recorded in the Laboratory informatic database system. Data are entered in such system after validation by managers in charge of these analytical controls.

**Manufacturer**

SOLVAY GmbH  
XANTENER STRASSE 237  
47495 RHEINBERG

**Product released**

By Sebastian LINDER HERR  
Date 05.01.2026 Time 14:35:22