



**Ciech**  
Soda Deutschland

CIECH Soda Deutschland GmbH & Co. KG \* An der Löderburger Bahn 4a \* 39418 Staßfurt

Azelis Italia S.r.l.

Via Leonardo da Vinci, 43  
I 20090 Trezzano sul Naviglio (MI)

## Certificate of Analysis

**Contract** 2020018 Order-No.: PO201023904  
**Delivery order** 474618  
**Date** 14.12.2020

**Product:** Sodium Bicarbonate, pharmaceutical grade  
Standard granulation (NK)

Batch-No.: 030117111122020  
Production Date: 11.12.2020  
Retest/Expiry Date: 11.12.2022

| <u>Chemical Analysis:</u>           | limit value               | current value       |
|-------------------------------------|---------------------------|---------------------|
| NaHCO <sub>3</sub> content          | %, 99,0 - 101,0           | 100,03              |
| Normal Carbonate                    | %, meets USP requirements |                     |
| loss on drying%                     | < 0,25 <0,25              |                     |
| Aspect of solution                  | : clear and colorless     | clear and colorless |
| water-insoluble substances          | %, meets USP requirements |                     |
| Carbonate pH                        |                           | 8,3                 |
| (5 % solution in water)             | : ≤ 8,6                   |                     |
| Ammonium (NH <sub>4</sub> )         | %, < 0,0020               | < 0,0020            |
| Aluminium (Al)                      | %, < 0,0002               | < 0,0002            |
| Arsenic (As)                        | %, < 0,0002               | < 0,0002            |
| Calcium (Ca)                        | %, < 0,0100               | < 0,0100            |
| Magnesium (Mg)                      | %, < 0,0040               | < 0,0040            |
| Copper (Cu)                         | %, < 0,0001               | < 0,0001            |
| Iron (Fe)                           | %, < 0,0005               | <0,0005             |
| Heavy metals (Pb)                   | %, < 0,0010               | < 0,0005            |
| Chloride (Cl)                       | %, < 0,0150               | <0,0150             |
| Sulfur Compounds (SO <sub>4</sub> ) | %, < 0,0150               | < 0,0150            |
| Bulk density (g/ml)                 | : 0,950 - 1,200           | 1,174               |

### Grain Size Distribution:

|              |        |      |
|--------------|--------|------|
| < 0,500 mm/% | : ≥ 95 | 99,9 |
| < 0,315 mm/% | :      | 96,8 |
| < 0,200 mm/% | :      | 81,6 |
| < 0,100 mm/% | :      | 46,4 |

We hereby confirm that the above product complies with the requirements (limits) of the current PH. EUR/ USP/ BP Pharmacopoeia.

# Certificate of Analysis

Page 2  
Delivery order 474618

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7/52

7/52

7/52

Schug  
Head of Quality Control

*This document was created using computer system.*

FB-PQ-078/00

7/52

## BULLETIN ANALYTIQUE / CERTIFICATE OF ANALYSIS

**REFERENCE PRODUIT** : Actilight 950P " Fructo-Oligosaccharides"  
**PRODUCT**

**FICHE TECHNIQUE** : S-STR-050 / Version 15  
**TECHNICAL SPECIFICATION**

**DATE DE FABRICATION** : 16/11/20  
**MANUFACTURING DATE**

**DLUO / USE BEFORE** : 16/11/22

**LOT N° / BATCH N°** : 0175003210

### COMPOSITION GLUCIDIQUE : *SUGAR CONTENT :*

|  |                   |
|--|-------------------|
| <b>Glucose + Fructose + Saccharose % MS</b>    | <b>5,0 %</b>      |
| <b><i>Glucose + Fructose + Sucrose %DM</i></b> |                   |
| <b>GF2%FOS</b>                                 | <b>36,5 % FOS</b> |
| <b>GF3%FOS</b>                                 | <b>48,9 % FOS</b> |
| <b>GF4%FOS</b>                                 | <b>14,6 % FOS</b> |
| <b>Total FOS % MS</b>                          | <b>95,0 %</b>     |
| <b><i>Total FOS % DM</i></b>                   |                   |

**BULLETIN ANALYTIQUE / CERTIFICATE OF ANALYSIS**

Actilight 950P " Fructo-Oligosaccharides" -  
0175003210

**MICROBIOLOGIE :**  
**MICROBIOLOGY :**

|  |                             |
|--|-----------------------------|
| <b>Mésophiles totaux</b><br><i>Total plate count</i> | <b>2 UFC / 10g MS</b>       |
| <b>Levures</b><br><i>Yeasts</i>                      | <b>Moins de 1 /10 g MS</b>  |
| <b>Moisissures</b><br><i>Moulds</i>                  | <b>Moins de 1 / 10 g MS</b> |
| <b>Entérobactéries</b><br><i>Enterobacteria</i>      | <b>Moins de 1 /10g MS</b>   |
| <b>Coliformes totaux</b><br><i>Entero coliformes</i> | <b>Moins de 1 /10g MS</b>   |

**PHYSICO-CHIMIE :**  
**PHYSICO-CHEMICAL DATA :**

|   |                         |
|---|-------------------------|
| <b>Humidite</b><br><i>Moisture</i>                              | <b>2,50 %</b>           |
| <b>pH</b><br><i>pH</i>  | <b>6,25</b>             |
| <b>Couleur ICUMSA</b><br><i>Colouration</i>                     | <b>16,6 Icumsa</b>      |
| <b>Cendres conductimétriques</b><br><i>Conductimetric ashes</i> | <b>0,0118 g%g de MS</b> |

Chevrières, le 31/12/2020

Laboratoire FOS / SLI