# Chemische Werke Hommel GmbH & Co. KG

Im Wirrigen 25 D-45731 Waltrop Tel.: +49 2309 60699-0 Fax: +49 2309 60699-30 www.hommel-pharma.com info@hommel-pharma.com



# **Specification**

Concerning Product:		
Article number	58855NPEL	
Trade name / designation / denomination	Vitamin B7 (D-Biotin), rein, Ph.Eur.	
CAS number	58-85-5	
Other names / synonyms	•5-(2-oxo-1,3,3a,4,6,6a-hexahydrothieno[3,4-d]imidazol- 4-yl)pentanoic acid; •Biotine 2%; •Biotine pure; •biotin; •vitamin H;	
EC number	200-399-3	
Customs tariff number / CN code / TARIC	29362900	
Molecular weight [g / mol]	244.31064	
Formula	C <sub>10</sub> H <sub>16</sub> N <sub>2</sub> O <sub>3</sub> S	

Parameter	Specification	Unit	
Organoleptic test			
Appearance of solution	clear and colourless		
Appearance	white or almost white, crystalline powder or colourless crystals		
Physical parameter			
Loss on drying	≤ 1,0	%	
Specific Optical Rotation	89 - 93	0	
Solubility	very slightly soluble in water and in alcohol, practically insoluble in acetone, it dissolves in dilute solutions of alkali hydroxides		
Identity			
Assay	98,5 - 101,0	%	
Identification	complies		
Impurities			
Sulphated ash	≤ 0,1	%	
Related substances	complies	% [w/w]	
Microbiological data			
Aerobic microorganisms	≤ 1000	CFU/g	
Escherichia Coli.	not detectable in 1 g		
Salmonella	not detectable in 25 g		
Yeast and Mould	≤ 200	CFU/g	

### **Regulatory information:**

**Allergens statement:** According to Annex II of Regulation (EU) No **1169/2011** of the European Parliament and of the Council of 25th October 2011 and its amendment (EU) No **78/2014** on substances or products the above mentioned product does NOT cause allergies or intolerances and does NOT contain any allergens which have to be labelled according to these regulations.

BSE/TSE statement: Risk of BSE/TSE contamination can be excluded.

### Supplemental information:

Shelf life: 36 month

**Derivation:** synthetic

Storage conditions: Protect from light and store cool and dry in well-closed original

packaging. The temperature should not exceed 25 °C.

**Usage:** The product is suitable for a vegetarian nutrition.

The product is suitable for a vegan nutrition.

The product is suitable for lactose intolerance diet.

The product is suitable for people with coeliac disease and sprue.

The product is in compliance with Jewish dietary laws. The product is in compliance with Islamic dietary laws.

#### Chemische Werke Hommel GmbH & Co.KG

This document was generated electronically and is valid without signature.

Waltrop, 06. Dec. 2019

We only confirm that we took over the data from our supplier accordingly. Despite careful working, errors in the takeover are not totally excluded. Some or all parts off the document may be translated due to our best knowledge from the original to give a better understanding. If you have any questions about specific details, please call us directly. Unless otherwise marked, these data do not originate from us and have not been tested by us on the correctness. The above information corresponds to the present state of our knowledge and is intended as a general description of our products and their possible applications. We make no warranties, expressed or implied, as to the information's accuracy, adequacy, sufficiency or freedom from defect and assumes no liability in connection with any use of this information. Any user of this product is responsible for determining the suitability of our products for its particular application. The foregoing information does not absolve the buyer of its own tests. Observing existing laws and regulations, is the responsibility of the buyer of our product. Nothing included in this information waives any of our General Terms and Conditions of Sale, which control unless it agrees other in writing. Any existing intellectual/industrial property rights must be observed. Due to possible changes in our products and applicable national and international regulations and laws, the status of our products could change. Material Safety Data Sheets providing safety precautions, that should be observed when handling or storing our products, are available upon request and are provided in compliance with applicable law. The user should obtain and review the applicable Material Safety Data Sheet information before handling any of these products. For additional information, please contact us.

Layout-Version: V2018.11a