



Specification

Concerning Product:	
Article number	58855APER
Trade name / designation / denomination	D-Biotin
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 ₁₀ H ₁₆ N ₂ O ₃ S

Parameter	Test Method	Specification	Unit
Organoleptic test			
Appearance of solution		clear and colourless	
Appearance		Crystalline Powder	
Colour		white to off-white	
Physical parameter			
Loss on drying		≤ 1,0	%
Specific Optical Rotation		89 – 93	°
Identity			
Assay		97,5 – 102,0	%
Identification	Color reaction	Meet the requirements EP/BP	
Identification	TLC	Meet the requirements EP/BP	
Identification	IR	Meet the requirements EP/BP/USP	
Impurities			
Heavy Metals (as Pb)		≤ 10	ppm
Sulphated ash		≤ 0,1	%
Related substances		Meet the requirements	
Related substances		single impurity ≤ 1,0	% [w/w]
Related substances		Total impurities ≤ 2,0	% [w/w]
Elemental Impurities			
Arsenic (As)		≤ 1	ppm
Lead (Pb)		≤ 2	ppm
Organic volatile impurities			
Org. volat. Imp. Total		Meet the requirements	
Microbiological data			
Escherichia Coli.		Negative/25g	CFU/g
Salmonella		Negative/25g	
Total Plate Count		≤ 1000	CFU/g
Yeast and Mould		≤ 100	CFU/g

Annotation:

FOOD GRADE STATUS: Suitable for human consumption.

Suitable for vegan diet

Regulatory information:

Allergens statement: Allergen-free according to Reg. EC No. 1169/2011 Annex II

BSE/TSE statement: BSE/TSE-free

GMO statement: Non-GMO

Supplemental information:

Shelf life: 36 month

Storage conditions: In tight containers, keep in cool

Complies with monographie: EP/BP/USP

Packing: 25 kg drum

Regional origin: CN

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 12. May. 2020

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