

## SPECIFICATION

## D-Biotin pure Food Grade (USP/EP)

### Description

Ingredients	D-Biotin pure
Synonym	Vitamin H; Biotin; 1H-Thieno[3,4-d]imidazole-4-pentanoic acid
Formula	$C_{10}H_{16}N_2O_3S$
Product code	SPVH01
CAS No	58-85-5

### Properties

Shelf life	36 months after production date in unopened original packaging
Aspect	A white or almost white, crystalline powder or colourless crystals, clear and colourless of 10g/L in 4 g/L solution of sodiumhydroxide
Assay (Titration, 0,1 N NaOH)	98,5 % - 101 %
Assay (HPLC)	97,5 % - 102 %
Loss on drying	max. 0,2 %
Solubility	Very slightly soluble in water and in alcohol, practically insoluble in acetone. It dissolves in diluted solutions of alkali hydroxides
Identification	A Ph. Eur.: IR B Ph. Eur.: TLC C Ph. Eur.: Reaction with bromine water C USP: (HPLC) The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay
Specific optical rotation	+ 89° – + 93 ° (Ph. Eur., USP, FCC)
Melting point	229 °C – 232 °C (FCC)
Sulphated ash	max. 0,1 %

### Heavy metals

Arsenic (As)	max. 10 mg/Kg
Lead (Pb)	max. 1 mg/Kg
Mercury (Hg)	max. 2 mg/Kg
Cadmium (Cd)	max. 0,1 mg/Kg
	max. 1,0 mg/Kg

### Microbiological specs

Total plate count	≤ 1000 CFU/g
Mould and Yeast	≤ 100 CFU/g
Coliforms	≤ 0,3 MPN/g
Salmonella spp.	Negative (in 25 g)

Related substances	Ph. Eur.: TLC: Any impurity obtained in test sol. (a) shall not be more intense than that in ref (b) (0,5 %) and at most one of ref (c) (0,25 %) USP: HPLC: Individual impurity not more than 1,0 %; total impurities not more than 2,0 %
Organic volatile impurity	Meets USP requirements
<b>Handling</b>	
Stability	The product is stable to air, heat and light
Storage	Store in a tight container in a dry place
Usage	For cosmetic and food industry, product can also be used as feed additive which consists of Biotin (3a880) dosage in feed: as per latest version of European feedstuff law
Transport instructions	See our latest safety data sheet

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