





Specification

Concerning Product:	
Article number	67970NEUL1
Trade name / designation / denomination	Vitamin D3 100TIU/g
CAS number	67-97-0
Other names / synonyms	•Cholecalciferol; •Vitamin D3; •colecalfiferol;
EC number	200-673-2
EC index number	603-180-00-4
Customs tariff number / CN code / TARIC	29362900
Molecular weight [g / mol]	384,65
Formula	C ₂₇ H ₄₄ O
Danger   2811, 6.1 (Giftige Stoffe), II	
Toxic if swallowed. Toxic in contact with skin. Fatal if inhaled. Causes damage to organs through prolonged or repeated exposure . Wear protective gloves/protective clothing/eye protection/face protection. IF INHALED: IF exposed or if you feel unwell: Immediately call a POISON CENTER or doctor/physician. Wash with plenty of soap and water.	

Parameter	Test Method	Specification	Unit
Organoleptic test			
Appearance		Cholecalciferol 100 000 IU/g (EP) in a matrix of sucrose, gum arabic (E 414), corn starch, medium-chain triglycerides (vegetable oil), tricalcium phosphate (E 341) and DL-alpha tocopherol (E 307).	
Colour		white to off-white	
Physical parameter			
Form	visual	free-flowing powder consisting of spherical particles	
Loss on drying	PE / USP	≤ 5	%
Identity			
Assay	HPLC	(incl.pre D) ≥ 100000	IU/g
Impurities			
Heavy Metals (as Pb)		≤ 10	mg/kg
Elemental Impurities			

Arsenic (As)		≤ 1	mg/kg
Cadmium (Cd)		≤ 0,5	mg/kg
Mercury (Hg)		≤ 0,1	mg/kg
Microbiological data			
Aerobic microorganisms	PE / USP	≤ 1000	1/g
Escherichia Coli.	PE / USP	neg.	/1 g
Salmonella	PE / USP	neg.	/25 g
Yeast and Mould	PE / USP	≤ 200	CFU/g
Particle size distribution			
Particles	sieving (USP)	< 100 mesh: ≤ 15	%
Particles	sieving (USP)	< 20 mesh: ≥ 100	%
Particles	sieving (USP)	< 40 mesh: ≥ 90	%

Annotation:

1 international Unit (IU) = 0.025 µg Vitamin D3

Regulatory information:

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

Supplemental information:

Shelf life: 2 years

Derivation: active substance: synthetic, animal
 formulation: synthetic, vegetable, mineral

Storage conditions: Protect from light and store cool and dry in well-closed original packaging. The temperature should not exceed 15 °C.

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 05. Aug. 2019

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