




Specification

Concerning Product:	
Article number	58559P50
Trade name / designation / denomination	Theophylline anhydrous, powder 50kg Theophyllin wasserfrei, Pulver 50kg
CAS number	58-55-9
Other names / synonyms	•1,3-dimethyl-7H-purine-2,6-dione; •theophylline;
EC number	200-385-7
Customs tariff number / CN code / TARIC	29395900
Molecular weight [g / mol]	180,17
Formula	C7H8N4O2
Danger  2811, 6.1 (Giftige Stoffe), III	
Toxic if swallowed. Wash thoroughly after handling. Do no eat, drink or smoke when using this product. IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth.	

Parameter	Test Method	Specification	Unit
Organoleptic test			
Appearance of solution	Ph.Eur.	complies	
Colour	visual	white	
Physical parameter			
Acidity/Alkalinity	Ph.Eur.	complies	
Form	visual	crystalline powder	
Loss on drying	Ph.Eur.	≤ 0,5	%
Melting range	USP	271 – 274	°C
Identity			
Assay	Ph.Eur., USP	99,5 – 100,5	%
Identification	inhouse	HPLC: conforms to the chromatography of the standard preparation	
Identification	inhouse	RAMAN: conforms to reference spectrum	

Impurities			
Heavy Metals (as Pb)	Ph.Eur.	≤ 20	ppm
Sulphated ash	Ph.Eur., USP	≤ 0,1	%
Related substances	Ph.Eur., USP	each other impurity: ≤ 0,10	% [w/w]
Related substances	Ph.Eur., USP	Impurity A: ≤ 0,10	% [w/w]
Related substances	Ph.Eur., USP	Impurity B: ≤ 0,10	% [w/w]
Related substances	Ph.Eur., USP	Impurity C: ≤ 0,10	% [w/w]
Related substances	Ph.Eur., USP	Impurity D: ≤ 0,10	% [w/w]
Related substances	Ph.Eur., USP	in sum: ≤ 0,50	% [w/w]
Particle size distribution			
Particles		300 µm ≥ 97	%

Supplemental information:

Shelf life: 4 years

Note: The product is manufactured according to current GMP requirements.

Complies with monographie: Tests are based on Ph.Eur. & USP. Identification tests are inhouse.

Regional origin: D

Conclusion: The product meets the requirements of current monograph of Ph.Eur., USP and JP.

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 12. Feb. 2020

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