







Specification

Concerning Product:	
Article number	6004246SPE
Trade name / designation / denomination	Cetylpyridiniumchlorid monohyd, Ph. EUR.
CAS number	6004-24-6
Other names / synonyms	•1-hexadecylpyridin-1-ium chloride hydrate;
EC number	204-593-9
Customs tariff number / CN code / TARIC	29333999
Molecular weight [g / mol]	358.0014
Formula	C ₂₁ H ₄₀ ClNO
Danger     2811, 6.1, II	
Toxic if swallowed. Causes skin irritation. Causes serious eye damage. Causes serious eye irritation. Fatal if inhaled. May cause respiratory irritation. Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects. Do not breathe dust/fume/gas/mist/vapours/spray. Avoid release to the environment. Wear respiratory protection. Dispose of contents/container in accordance with local/regional/(inter)national regulations.	

Parameter	Test Method	Specification	Unit
Organoleptic test			
Appearance of solution	Ph.Eur.	Solution S should not be more opalescent than reference Suspension II and is colourless.	
Appearance	Ph. Eur.	A white powder, slightly soapy to the touch.	
Physical parameter			
Acidity/Alkalinity	Ph. Eur.	The quantity of 0.02 M sodium hydroxide that is required to change the colour of the indicator should be ≤ 2,5	ml
Loss on drying	Ph.Eur. (2.5.12)	4,5 – 5,5	% w/w
Solubility	Ph. Eur.	Soluble in water and in alcohol. An aqueous solution froths copiously when shaken.	
Identity			
Assay	Ph. Eur.	96,0 – 101,0	% w/w
Identification	Ph.Eur. (2.2.25)	Test A. Ultraviolet absorbtion spectrometry: Examine between 240 nm and 300 nm, the solution shows an absorbtion maximum at	

		259 nm and 2 shoulders at about 254 nm and at about 265 nm. The specific absorbance at the maximum is 126 to 134, calculated with reference to the anhydrous substance.	
Identification	Ph.Eur. (2.2.24)	Test B. Infrared absorption spectrometry: IR absorption spectrum should be concordant with Ph.Eur. Reference spectrum.	
Identification	Ph.Eur.	Test C. Colour development: The Chloroform layer becomes blue.	
Identification	Ph.Eur. (2.3.1)	Test D. Chlorides: Solution S should give test for chlorides.	
Impurities			
Residual solvents	GC-HS	(1.) Pyridine: ≤ 200	ppm
Residual solvents	GC-HS	(2.) Ethyl acetate: ≤ 5000	ppm
Residual solvents	GC-HS	(3.) Methyl ethyl ketone: ≤ 5000	ppm
Sulphated ash	Ph.Eur. (2.4.14)	$\leq 0,2$	% w/w
Impurity	Ph. Eur. (potentiometric titration)	Amines and amine salts: $\leq 5,0$	ml
Microbiological data			
Aerobic microorganisms		≤ 1000	CFU/g
Yeast and Mould		≤ 100	CFU/g

Supplemental information:

Shelf life: ≥ 58 Mon.

Storage conditions: under warehouse conditions in closed original packaging

Packing: HDPE drums, inner double lined with LLDPE bags, 250 gauge.

Regional origin: IND

Conclusion: The product complies as per EP 8.3 specification.

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 05. Aug. 2019

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