HEDINGER 1843 A pure decision.

SPECIFICATION

Acetone Ph. Eur.* / USP (NF)*

Testing specifications: Ph. Eur.* / USP (NF)* / LSM 011 Product Code: 011

The material meets all requirements of the monographs "Acetone" in Ph. Eur.* and USP (NF)*

Parameter	Ph. Eur.*	USP* (NF*)	Additional Specification	Test method
Assay (GC)	–	≥ 99.0 %	≥ 99.7 %	LSM011
Identification	A/FT-IR	FT-IR/B**	-	Ph. Eur.*/ USP (NF)*
Appearance of solution	clear, colourless	–	–	Ph. Eur.* (2.2.1, 2.2.2)
Colour of substance	–	–	APHA ≤ 5	ASTM D1209
Acidity or alkalinity	conforms Ph. Eur.*	–	–	Ph. Eur.*
Relative density / Specific gravity	d^{20}_{20} = 0.790 – 0.793	d^{25}_{25} ≤ 0.789	-	Ph. Eur.* (2.2.5) USP (NF)*
Refractive index n^{20}_{D}	–	–	1.358 – 1.360	Ph. Eur.* (2.2.6)
Matter insoluble in water	clear solution	–	–	Ph. Eur.*
Reducing substances / Readily oxidizable substances	conforms Ph. Eur.*	conforms USP (NF)*	–	Ph. Eur.*/ USP (NF)*
Residue on evaporation / Non-volatile residue	50 ppm = 0.004% m/V	≤ 0.004% m/V	≤ 0.001% m/V	Ph. Eur.*/ USP (NF)*
Water	≤ 0.3% m/V	≤ 0.5 %***	≤ 0.20 % m/m	Ph. Eur.*/ LSM011
Related substances	each ≤ 0.05 % V/V	–	–	Ph. Eur.*/ LSM011
Benzene	≤ 2 ppm (V/V)	–	≤ 2 ppm (m/m)	Ph. Eur.*/ LSM011
Isopropyl alcohol	≤ 0.05 % V/V	–	–	Ph. Eur.*/ LSM011
Methanol	≤ 0.05 % V/V	–	–	Ph. Eur.*/ LSM011

*** The requirements of USP Water are covered by internal validated Karl-Fischer-titration method LSM 011

** The requirements of USP Identification B are covered by internal validated GC method LSM 011.

*current version

Compiled by: 17.10.2016	Approved by: 18.10.2016	Released by: 20.10.2016	Effective:	Supersedes:	Page 1 of 2
Dr. Philipp Hoch QA-Manager	Tanja Natterer Head of QC / Qualified Person (GMP)	Dr. Frank Milek Qualified Person (GMP)	31.10.2016	23.11.2015	

SPECIFICATION

Acetone Ph. Eur.* / USP (NF)*

Manufacturing process: Cumene hydroperoxide process

Shelf Life: 2 years

Manufacturer and manufacturing site: INEOS Phenol GmbH, D-Gladbeck

Residual solvents (Ph.Eur* 5.4 / CPMP/ICH/82 260/06; USP <467>):

Within the manufacturing process out of class 1 solvents only benzene can occur in a concentration not more than 2 ppm. Solvents of class 2 and 3 can occur as by-products, but only in concentrations far below the stipulated limits.

Every batch is analysed according to all parameters of this specification. The Certificate of Analysis (CoA) provides all results plus analysis date, date of manufacture and residual solvents statement. All CoAs are signed by a Qualified Person according to GMP or a responsible QA/QC-Manager.

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