

## SPECIFICATION

### Acetic Acid, Glacial Ph. Eur.\* / USP\* / JP\*

product code: 223

Testing specifications: Ph. Eur.\* / USP\* / JP\* / LSM 223\*  
**The material meets all requirements of Ph. Eur.\*, USP\* and JP\***

Parameter	Ph. Eur.*		USP*		JP*	
	Specification	Method	Specification	Method	Specification	Method
Characters Ph. Eur.* / Description JP*	conforms	Ph. Eur.*	-	-	conforms	JP*
Assay	99.0 – 100.5 %	Ph. Eur.*	99.5 –100.5%	USP*	≥ 99.0 %	JP*
Identification	A / B	Ph. Eur.*	conforms Acetate test	USP*	Acidity and Acetate	JP*
Appearance	clear / colourless	Ph. Eur.*	-	-	-	-
Freezing point Ph. Eur.* / Congealing point JP* / Congealing temperature USP*	≥ 14.8 °C	Ph. Eur.*	≥ 15.6 °C	USP*	≥ 14.5 °C	JP*
Reducing substances Ph. Eur.* / Potassium permanganate reducing substances JP*	conforms	Ph. Eur.*	-	-	conforms	JP*
Readily oxidizable substances	-	-	conforms	USP*	-	-
Chloride(s)	≤ 25 mg/l	Ph. Eur.*	conforms	USP*	conforms	JP*
Sulfate(s)	≤ 50 mg/l	Ph. Eur.*	conforms	USP*	conforms	JP*
Iron	≤ 5 ppm	Ph. Eur.*	-	-	-	-
Heavy metals	-	-	≤ 5 ppm	USP*	≤ 10 ppm	JP*
Residue on evaporation Ph. Eur.* / Limit of non-volatile residue USP* / Non-volatile residue JP*	≤ 0.01 %	Ph. Eur.*	≤ 0.005 % (m/V)	USP*	≤ 0.01 % (m/V)	JP*
Specific Gravity	-	-	-	-	$d_{20}^{20} \approx 1.049$	JP*

\*current version

\*\*typical value, should not be interpreted as specification

Compiled by: 06.12.2016	Approved by: 09.12.2016	Released by: 23.12.2016	Effective:	Supersedes:
Dr. Katja Dahms QC-Manager	Elisabeth Bartel Qualified Person (GMP)	Dr. Frank Milek Qualified Person (GMP)	01.01.2017	22.04.2014

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Parameter	Additional Parameters (by Hedinger)	
	Specification	Method
Assay (Freezing point / Congealing temperature)	≥ 99.9 %	Freezing point/Congealing temperature
Aluminium	≤ 0.5 ppm	AAS LSM 223*

Property	Typical Properties** (by Wacker)	
	Typical Value	Method
Color Hazen (APHA)	≤ 5	ISO 6271

**Shelf life:** 36 months  
**Manufacturer:** Wacker Chemie AG  
**Manufacturing site:** Burghausen (Germany)  
**Storage:** Store in air tight containers

No plant or animal derived raw materials are used for the manufacture (no BSE risk); the material is not derived from GMO. Aflatoxin content exceeding the limits of the German Aflatoxin Directive is not expected because of the manufacturing process.

#### **Residual solvents (ICH Q3C\*):**

The product complies with the requirements of the ICH Q3C\* Residual Solvents Guideline: The class 2 solvent methanol as starting material for the synthesis can occur in trace amounts, but far from the stipulated limit. The class 3 solvents (except from acetic acid) that can occur in trace amounts are below 0.02%.

Every batch is analysed according to all Ph. Eur.\*, USP\*, JP\* and Additional Parameters (except Characters / Description) of this specification. The Certificate of analysis (COA) provides all results like above including batch release date 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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