

**Butylhydroxytoluene Ph. Eur.\* / USP\***  
**Vulkanox® BHT GMP Grade**

**product code: 216**

Testing specifications: Ph. Eur.\* / USP\* / LSM 216  
**The material meets all requirements of Ph. Eur.\* and USP\***

Pharmacopoeia Parameters	Ph. Eur.*		USP*	
	Specification	Test method	Specification	Test method
Characters	conforms Ph. Eur.*	-	-	-
Identification	A, C	Ph. Eur.*	conforms USP*	USP*
Appearance of Solution	conforms Ph. Eur.*	Ph. Eur.*	-	-
Freezing Point (Ph. Eur.*) / Congealing temperature (USP*)	69 – 70°C	Ph. Eur.*	≥ 69.2°C	USP*
Related Substances (Ph. Eur.*) / Related Compounds (USP*)	≤ 0.5% each	Ph. Eur.*	≤ 0.5% each	USP*
Sulfated Ash (Ph. Eur.*) / Residue on Ignition (USP*)	≤ 0.1%	Ph. Eur.*	≤ 0.002%	USP*
Heavy Metals	-	-	≤ 0.001%	USP*
Additional Parameters	Specification		Test method	
Assay (GC)	≥ 99.0%		LSM 216	
2-tert.-butyl-p-cresol (GC)	≤ 0.5%		LSM 216	
p-Cresol (GC)	≤ 0.1%		LSM 216	
Any other impurity (GC)	≤ 0.5%		LSM 216	
Water (Karl Fischer)	≤ 0.2 %		LSM 216	

**Storage:** protected from light and moisture, <50°C, avoid piling of pallets

**Shelf life in originally sealed bags:** 24 months

**Manufacturer and manufacturing site:** Lanxess Deutschland GmbH, D-Leverkusen

The material also meets the requirements of current FCC\* and JPE\* but is not tested batchwise.



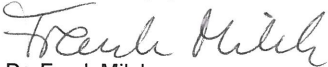
**Residual solvents (Ph. Eur.\* 5.4 / USP\* <467> / CPMP/ICH/283/95\*):**

Solvents of class 1- 3 except Methanol and Toluene are excluded by the manufacturing process. Methanol content complies with ICH limit of 3000 ppm. Toluene content complies with ICH limit of 890 ppm.

Every batch is analysed according to all parameters of this specification (except characters) listed in the table above. The Certificate of analysis (COA) provides all results like above including analysis date, manufacturing date and residual solvents statement. All COAs are signed by a Qualified Person (QP) according to GMP or a responsible QA/QC-Manager.

\*current version

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Compiled by: 04.05.2011  Florian Conzelmann Qualified Person (GMP)	Approved by: 04.05.11  Dr. Rouven Josl Head of QC	Released by: 09.05.11  Dr. Frank Milek Qualified Person (GMP)	Effective: 16.05.11	Supersedes: 30.08.2007
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