

SPECIFICATION



Glycerol Ph. Eur.* / USP* 99.7 % (synth.)

OPTIM™ Glycerine 99.7% USP/EP

Product code: 091

Testing specifications: Ph. Eur.* / USP* / LSM 091*

The material meets all requirements of Ph. Eur.*, USP*, FCC*, 21 CFR 182.1320, 2008/84/EC (E422)

Parameter	Specification	Method
Purity	≥ 99.7 % (m/m)	GC, LSM 091*

Parameter	Ph. Eur.*		USP*	
	Specification	Method	Specification	Method
Characters	viscous, colourless, clear very hygroscopic	Ph. Eur.*	—	—
Assay	98.0 – 101.0 %	Ph. Eur.*	99.0-101.0 %	USP*
Identification	A / B / C / D	Ph. Eur.*	A / B / C	USP*
Appearance of solution	clear, colourless	Ph. Eur.*	—	—
Color	—	—	conforms USP*	USP*
Acidity or alkalinity	≤ 0.2ml 0,1N NaOH	Ph. Eur.*	—	—
Esters (Ph. Eur.*) Fatty acids and esters (USP*)	conforms Ph. Eur.*	Ph. Eur.*	conforms USP*	USP*
Halogenated compounds (Ph. Eur.*) / Limit of chlorinated compounds (USP*)	≤ 35 ppm	Ph. Eur.*	≤ 30 ppm	USP*
Aldehydes	≤ 10 ppm	Ph. Eur.*	—	—
Sugars	conforms Ph. Eur.*	Ph. Eur.*	—	—
Chloride(s)	≤ 10 ppm	Ph. Eur.*	≤ 10 ppm	USP*
Sulfate	—	—	≤ 20 ppm	USP*
Heavy metals	≤ 5 ppm	Ph. Eur.*	≤ 5 ppm	USP*
Specific gravity	—	—	$d_{25}^{25} \geq 1.249$	USP*
Refractive index n_D^{20}	1.470 – 1.475	Ph. Eur.*	—	—
Residue on ignition	—	—	≤ 0.01 %	USP*
Sulphated ash	≤ 0.01 % m/m	Ph. Eur.*	—	—
Water ¹	≤ 2.0 %	Ph. Eur.*	≤ 5.0 %	USP*
Limit of diethylene glycol and ethylene glycol:				
- DEG	—	—	≤ 0.10 %	USP*
- EG	—	—	≤ 0.10 %	

¹ The limits are given in the monographs; actually the product contains not more than 0.3% water.

*current version

™Trademark of The Dow Chemical Company

Compiled by: 15.04.2011 Florian Conzelmann Qualified Person (GMP)	Approved by: 26.04.11 Dr. Rouven Josl Head of QC	Released by: 27.04.11 Dr. Frank Milek Qualified Person (GMP)	Effective: 01.05.2011	Supersedes: 15.01.2010
---	--	--	--------------------------	---------------------------

SPECIFICATION



Glycerol Ph. Eur.* / USP* 99.7 % (synth.)

OPTIM™ Glycerine 99.7% USP/EP

Product code: 091

Testing specifications: Ph. Eur.* / USP* / LSM 091*

The material meets all requirements of Ph. Eur.*, USP*, FCC*, 21 CFR 182.1320, 2008/84/EC (E422)

Parameter	Ph. Eur.*		USP*	
	Specification	Method	Specification	Method
Related compounds: - total impurities - any individual impurity	—	—	≤ 1.0 % ≤ 0.1 % each	USP*
Impurity A and related substances: - ∑ Impurities with retention time > retention time of glycerol - Each impurity with retention time < retention time of glycerol - Diethylene glycol (Impurity A)	≤ 0.5 % m/m ≤ 0.1 % m/m ≤ 0.1 % m/m	Ph. Eur.*	—	—

Storage: It is recommended to store the material in closed containers, below 30°C

Shelf life: 24 months packed in containers

Manufacturer and manufacturing site: Dow Deutschland, Stade (Germany)

Manufacturing process: synthetic, key raw material: epichlorohydrin

The material has no BSE risk, is not derived from GMO, is kosher and complies with the German Aflatoxinverbots-Verordnung.

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

Based on the process knowledge only one Class 3 solvent is likely to be present. The level of this Residual Solvent is less than 100 ppm.

Every batch is analysed according to all parameters of this specification (except Characters and Ph. Eur.* Identification C and D). The Certificate of analysis (COA) provides all results like above including analysis date, date of manufacture and residual solvents statement. All COAs are signed by a Qualified Person according to EU-GMP or a responsible QA/QC-Manager.

*current version

™Trademark of The Dow Chemical Company

Compiled by: 15.04.2011 Florian Conzelmann Qualified Person (GMP)	Approved by: 26.04.11 Dr. Rouven Josi Head of QC	Released by: 27.04.11 Dr. Frank Milek Qualified Person (GMP)	Effective: 01.05.2011	Supersedes: 15.01.2010
---	--	--	--------------------------	---------------------------