HEDINGER 1843 A pure decision.

SPECIFICATION

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

Product code: 091

Testing specifications: Ph. Eur.* / USP* / LSM 091*
The material meets all requirements of Ph. Eur.*, USP*, 21 CFR 182.1320

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

Parameter	Ph. Eur.*		USP*	
	Specification	Method	Specification	Method
Assay	98.0 – 101.0%	Ph. Eur.*	99.0 – 101.0%	USP*
Identification	A / B / C	Ph. Eur.*	A / B / C	USP*
Appearance of solution	clear, colourless	Ph. Eur.*	—	—
Color	—	—	conforms	USP*
Acidity or alkalinity	≤ 0.2 ml 0.1N NaOH	Ph. Eur.*	—	—
Esters (Ph. Eur.*) Fatty acids and esters (USP*)	conforms	Ph. Eur.*	conforms	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.*	—	—
Chloride(s)	≤ 10 ppm	Ph. Eur.*	≤ 10 ppm	USP*
Sulfate	—	—	≤ 20 ppm	USP*
Relative density (Ph. Eur.*) Specific gravity (USP*)	d_{20}^{20} 1.258 – 1.268	Ph. Eur.*	d_{25}^{25} ≥ 1.249	USP*
Refractive index n_D^{20}	1.470 – 1.475	Ph. Eur.*	—	—
Residue on ignition	—	—	≤ 0.01%	USP*
Sulfated ash	≤ 0.01% (m/m)	Ph. Eur.*	—	—
Water[1]	≤ 2.0%	Ph. Eur.*	≤ 5.0%	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.*	—	—
Limit of diethylene glycol and ethylene glycol: - DEG - EG	—	—	≤ 0.10% ≤ 0.10%	USP*
Related compounds: - total impurities - any individual impurity	—	—	≤ 1.0% ≤ 0.1% each	USP*

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

*current version

Effective date: 07.10.2026
Supersedes version from: 01.04.2021

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Quality Assurance and Quality Control	
Process/Operation	**Standard / Requirement**
Production at chemical manufacturer	IPEC PQG – GMP Guidelines for Pharmaceutical Excipients*
Final manufacturing steps and supplier	IPEC PQG – GMP Guidelines for Pharmaceutical Excipients* & IPEC GDP Guideline*
Analytical quality control at final manufacturer	Full analysis of specification for each batch in a GMP qualified laboratory (in compliance with EU-GMP Part I, Chapter 6*)
Batch release at final manufacturer	Qualified Person according to EU-GMP (2001/83/EC; Articles 48 & 49)
Packaging at final manufacturer	Grade D (100,000) clean room according to GMP [EU-GMP Part I Annex 1 (classification and operating conditions), US cGMP (as applicable)]
Primary packaging material at final manufacturer	Specified packaging materials from audited suppliers: 1 L, 2.5 L Amber glass bottles 5 L, 10 L, 20 L HDPE containers 200 L HDPE-Steel combi-drums 1000 L HDPE Intermediate bulk containers

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

Shelf-life: 36 months from date of manufacture

The specified shelf-life relates to originally closed containers.

Chemical manufacturer and manufacturing site: Blue Cube Germany Assets GmbH & Co. KG, Stade (Germany)

Manufacturing process: synthetic, key raw material: epichlorohydrin

Final manufacturing steps and supplier: Aug. Hedinger GmbH & Co. KG, 70327 Stuttgart, Germany
Aug. Hedinger GmbH & Co. KG, 06179 Teutschenthal, Germany

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Regulatory compliance

The material is stored, repacked, tested and released at Aug. Hedinger GmbH & Co. KG according to IPEC PQG – GMP Guidelines for Pharmaceutical Excipients.
Regulatory information for this product, e.g., information on Aflatoxins, Allergens, BSE/TSE, Dietary Laws, Elemental Impurities (ICH Q3D*), GMO, Nitrosamines and Residual Solvents (ICH Q3C*) is available upon request.

Application:

This product is not for use as a pharmaceutical excipient in parenteral and biopharmaceutical finished dosage forms. Hedinger accepts no liability for damages resulting from use as pharmaceutical excipient in parenteral and biopharmaceutical finished dosage forms.

Food additive application:

Olin/Blue Cube does not support food related uses for synthetic Glycerol in the US and has not registered its Stade facility under the Bioterrorism Act, as directed by FDA Food Safety Modernization Act (FSMA) under section 415 of the Federal Food, Drug and Cosmetic Act and 21 CFR part 1, subpart H (Registration of Food Facilities) as the facility is not supplying food grade product to the U. S. and synthetic Glycerol should not be used for such purpose.

Batch certification:

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

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Dr. Katja Teufel QA-Manager	Dr. Stefan Heß QA-Manager	Elisabeth Bartel Qualified Person (GMP)	07.10.2026	01.04.2021