

Please note that the certificates of analysis are also conveniently available on your BASF online portal.

ELTON Corporation d.o.o.

2022-10-13

Certificate No 3840

Page 1 of 4

Sanje Zivanovica 28 D

11000 Beograd

Hr. Dr. Florian Wildschek

ENT/QA

florian.wildschek@basf.com

SRBIJA

Inspection Certificate 3.1 according to EN 10204

1,2-PROPYLENE GLYCOL USP

220KG Plastic drums

Purchase order/Customer material

306/2022

Material	52705412
Order	3018991556 000010
Delivery	3196487479 000010
Lot	97765516K0
Lot/Qty	10560.000 KG
Total	10560.000 KG
Transport	AM576NS

Test Parameter	Requirements	UoM	Results
Distilling range	must conform (99% dest.at 185-189 C)		conforms
Appearance	clear and colorless liquid		conforms
Identification A (USP-NF, IR)	must conform		conforms
Assay 1,2 Propylene glycol (GC)	Min.: 99.8	g/100g	>99.9
Relative density d(20/20)	Min.: 1.035 Max.: 1.040		1.038
Relative density d(25/25)	Min.: 1.035 Max.: 1.037		1.036
Refractive Index n(20/D)	Min.: 1.431 Max.: 1.433		1.433
Acidity	must conform (max. 0.019 mg KOH/ml)		conforms
Water (Karl Fischer-Titration)	Max.: 0.2	g/100g	<0.1
Sulfated Ash / Residue on ignition	Max.: 70	mg/kg	<10

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Test Parameter	Requirements	UoM	Results
Chloride	Max.: 70	mg/kg	<1
Sulfate	Max.: 60	mg/kg	<1
Lead *	must conform (max.1mg/kg)		conforms
Oxidizing substances	must conform		conforms
Reducing substances	must conform		conforms
Sum of unspecified impurities	Max.: 0.1	g/100g	<0.1
1,3-Propanediol (CGC)	Max.: 100	mg/kg	<50
Organic chlorine compounds as Cl	Max.: 1	mg/kg	<1
Colour (Hazen)	Max.: 10		<5
Arsenic *	must conform (max.2mg/kg)		conforms
Heavy metals *	must conform (max.5mg/kg)		conforms
Residual solvents **	must comply with the requirements of PhEur 5.4, USP <467> and ICH Q3C		conforms

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Test Parameter	Requirements	UoM	Results
Identification: Ethylene glycol *	must conform		conforms
Identification: Diethylene glycol *	must conform		conforms

* Test is verified on random samples only.

**Not tested, since no organic solvents are likely to be present.

The product meets the specifications of following monographs:

"Propylene Glycol" of USP-NF2022, Issue 1

"Propylenglycole" of European Pharmacopoeia 10th edition

Manufacturer: BASF SE

Carl-Bosch-Str.38

67056 Ludwigshafen

Germany

QC-Reference-No.

22C09358

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10560.000 KG

Total

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AM576NS

220KG Plastic drums

Purchase order/Customer material

306/2022

Production date (YYYY-MM-DD) 2022-07-19

Release date (YYYY-MM-DD) 2022-07-22

Best before (YYYY-MM-DD) 2024-07-18

BASF SE

Quality Assurance - Release

sig. Fr. Surdmann

QA-Representative

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