

I n s p e c t i o n c e r t i f i c a t e
according to EN10204-3.1

Date: 08.03.2022

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Your order from 17.02.2022

Order No. : 201037606

Material No. : -147835

Delivery no./Pos. : 53269238 / 900002

Order : 15467482

Material : POLYGLYKOL 400 0220

Material-no. : 10031630233

Batch No. : DEG4585317

Quantity : 660 KG

Cont./Trailer - ID : slot 235686

On the batch, of which the consignment is a part, the following values were determined.

Inspection characteristic/-method	Specification	Result
Consistence at 20°C visual		Liquid
Transparency at 20°C visual		Clear
Solubility 25% a.i. in water visual		Clear
Hazen colour 25% a.i. in water EN 1557	<= 15	<= 5 [-]
pH value 5% in water USP-NF	4,5 - 7,0	6,8 [-]
Viscosity at 20°C DIN 51562	112 - 124	118 mPa·s
Viscosity at 98.9°C USP-NF	6,8 - 8,0	7,1 mm2/s
Water content Karl-Fischer DIN 51777	<= 1,00	0,03 %

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Inspection characteristic/-method	Specification	Result
Ethylene oxide Head-Space GC	<= 1	< 1 ppm
Dioxane content Head-Space GC	<= 1	<= 1 ppm
Reducing substances Ph. Eur.		Corresponding
OH value [mgKOH/g] DIN EN ISO 4629	267 - 295	282 [-]
Molar mass (calculated) of OH value	380 - 420	398 g/mol
Ethylene- and Diethyleneglycol Ph. Eur.	<= 0,20	0,03 %
Solidification point Ph. Eur.	4 - 8	5 °C
Acidity [ml0,1M NaOH/5g] Ph. Eur.	<= 0,1	<= 0,1 [-]
Sulphated ash Ph. Eur.	<= 0,1	<= 0,1 %
Formaldehyde Ph. Eur.	<= 15	2 ppm

Date of Manufacture: 08.02.2022

Recommended Retest Date: 08.02.2024

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Material : POLYGLYKOL 400 0220
Material No. : 10031630233
Batch No. : DEG4585317

Inspection characteristic/-method	Specification	Result
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Date of approval: 11.02.2022

Name of Authorized Person of Approval: Nicole Kraft

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Inspection characteristic/-method	Specification	Result
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This COA was released from a controlled electronic document management system.

The product comply with all specification requirements of the current version of the Ph. Eur., USP-NF and JP. Manufactured according to IPEC-IPEC-GMP (Excipients).

Sulphated Ash, Residue on ignition, Reducing Substances and Metal impurities according to ICH Q3D are tested in a skipped testing procedure. All other testing results given on the CoA are determined on every single batch or its precursor batch. Viscosity at 98,9°C is correlated from Viscosity at 20°C.

ICH-Guideline for Residual Solvents incl. Annex I (ICH/Q3C):
Ethylene oxide is used as a monomer for the production of the product. It is specified to have a residual level of 1 ppm in the final product. Only class 2 solvents 1.4-Dioxane and Ethylene glycol are likely to be present, due to the nature of the production process; all are below the Option 1 limit (1.4-Dioxane max. 1 ppm, Ethylene glycol max. 620 ppm). Annex I of the above mentioned ICH guideline is not applicable.

Metal impurities according to ICH Q3D "Metal impurities" have been evaluated for the Polyglykols in a risk assessment. A separate statement on ICH Q3D metal impurity limits is available on request.

Formaldehyde content may increase during storage.

Batch was produced and approved at Clariant Produkte (Deutschland) GmbH, D-84508 Burgkirchen.

The above particulars do not release the customer from the obligation to carry out an inspection of goods received.

Helmut Madl (inspection representative)

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This report does not require a signature.