

PT IMCD Indonesia
Blugreen-Boutique Office
Tower C-D, 3rd Floor
Jl. Lingkar Luar Barat Kav 88
11610 JAKARTA, KEMBANGAN UTARA, KEMBANGAN
INDONESIA

Inspection certificate
according to EN10204-3.1

Date: 27.04.2023
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Your order from 04.04.2023

Order No. : 13671 OP
Delivery no./Pos. : 53768237 / 900001
Order : 15808179
Material : POLYGLYKOL 6000 P
Material-no. : 10792616889
Batch No. : DEG4619558
Quantity : 4.000 KG

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		Powder
Solubility 25% a.i. in water visual		Clear
Hazen colour 25% a.i. in water EN 1557	<= 30	<= 5 [-]
pH value 5% in water USP-NF	4,5 - 7,5	6,9 [-]
Viscosity at 20°C of 50% solution DIN 51562	210 - 262	228 mPa·s
Viscosity at 98.9°C USP-NF	250 - 390	328 mm2/s
Water content Karl-Fischer DIN 51777	<= 1,00	0,07 %
Ethylen oxide content Head-Space GC	<= 1	< 1 ppm

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Inspection characteristic/-method	Specification	Result
Dioxane content Head-Space GC	≤ 1	< 1 ppm
Reducing substances Ph. Eur.		Corresponding
OH value [mgKOH/g] DIN EN ISO 4629	17 - 20	18 [-]
Molar mass (calculated) of OH value	5600 - 6600	6098 g/mol
Ethylene- and Diethyleneglycol Ph. Eur.	$\leq 0,20$	$\leq 0,01$ %
Solidification point Ph. Eur.	55 - 60	58 °C
Acidity [ml0,1M NaOH/5g] Ph. Eur.	$\leq 0,1$	$\leq 0,1$ [-]
Sulphated ash Ph. Eur.	$\leq 0,1$	$\leq 0,1$ %
Formaldehyde Ph. Eur.	≤ 15	< 1 ppm

Date of Manufacture: 25.01.2023

Recommended Retest Date: 24.01.2025

Date of approval: 15.02.2023

Name of Authorized Person of Approval: Sergej Dzevlan



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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. and USP-NF. Manufactured according to 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 of 50% solution.

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 milled at Linus GmbH; D-53340 Meckenheim.

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