



## Certificate of Analysis

Site / Address Almirall Hermal GmbH Scholtzstrasse 3, 21465 Reinbek			
Product type Bulk	Product Code 98610501	Product Name Ecocel Lösung	
Batch number 98610501/31325	Batch size 497 KG	Certificate Number B-230324-114479	Manufacture Date 31/03/2023

Parameter	Specification	Result	Units
Appearance	clear liquid	clear liquid	g/ml
Colour	pale yellow	pale yellow	
Odour	characteristic	characteristic	
Homogeneity	homogeneous	homogeneous	
Particulate matter in the solution	essentially free from particles (precipitates or others) that can be observed on visual inspection	essentially free from particles (precipitates or others) that can be observed on visual inspection	
Density	0.94 - 0.97 at 20°C	0.95	
Refractive index	1.360 - 1.370 at 20°C	1.367	

Notes:

Valid to: 20/05/2023

Result RELEASED	Approval Date 06/04/2023 10:11:17	Approved by Katrin Müller-Landré, QP Almirall Hermal GmbH
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## Certificate of Analysis

Site / Address Almirall Hermal GmbH Scholtzstrasse 3, 21465 Reinbek			
Product type Drug Product	Product Code 60006001	Product Name Sililevo 5% Nail Lacq 6,6 ml DE	
Batch number 60006001/313255	Batch size 48199 UN	Certificate Number B-230403-114851	Manufacture Date 31/03/2023

Parameter	Specification	Result	Units
Total aerobic micr. count (TAMC)	Not more than 10 <sup>2</sup> CFU / g	Not more than 10 <sup>2</sup> CFU / g	
Total yeast/mould count (TYMC)	Not more than 10 <sup>1</sup> CFU / g	Not more than 10 <sup>1</sup> CFU / g	
Absence of Staphylococcus aureus	Absent in 1 g	Absent in 1 g	
Absence of Pseudomonas aeruginosa	Absent in 1 g	Absent in 1 g	

Notes:

Expiry Date: 03.2026

Result	Approval Date	Approved by
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# Certificate of Analysis

Site / Address Almirall Hermal GmbH		Scholtzstrasse 3, 21465 Reinbek	
Product type Drug Product	Product Code 60006001	Product Name Sililevo 5% Nail Lacq 6,6 ml DE	
Batch number 60006001/313255	Batch size 48199 UN	Certificate Number B-230403-114851	Manufacture Date 31/03/2023

Parameter	Specification	Result	Units
Compliance with FPV	meets requirements	meets requirements	
Labeling / packaging	meets requirements	meets requirements	
Compliance with the reference sample	in compliance	in compliance	

Notes:

Expiry Date: 03.2026

Result	Approval Date	Approved by
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