



Certificate of Analysis

Site / Address Almirall Hermal GmbH				Scholtzstrasse 3, 21465 Reinbek			
Product type Bulk		Product Code 98610501		Product Name Ecocel Lösung			
Batch number 98610501/10418		Batch size 500 KG		Certificate Number B-210118-83082		Manufacture Date 27/01/2021	

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	1.366	

Notes:

Valid to: 18/03/2021

Result RELEASED	Approval Date 05/02/2021 16:06:20	Approved by Katrin Müller-Landré, QP Almirall Hermal GmbH
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Certificate of Analysis

Analytical Laboratory Site
Almirall Hermal GmbH

Scholtzstrasse 3, 21465
Reinbek

Product type Drug Product	Product Code 60006001	Product Name Sililevo 5% Nail Lacq 6,6 ml DE	Sample S-210216-394067
Batch number 60006001/104186	Batch size 38868 UN	Certificate Number B-210216-84334	Manufacture Date 27/01/2021

Parameter	Specification	Result	Units
Total aerobic micr. count (TAMC)	Not more than 10^2 CFU / g	Not more than 10^2 CFU / g	
Total yeast/mould count (TYMC)	Not more than 10^1 CFU / g	Not more than 10^1 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: 01.2024

Result Conforms	Approval Date 15/03/2021 17:13:55	Approved by Sandra Letters, Quality Control Manager QC-F
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Certificate of Analysis

Analytical Laboratory Site
Almirall Hermal GmbH

Scholtzstrasse 3, 21465
Reinbek

Product type Drug Product	Product Code 60006001	Product Name Sililevo 5% Nail Lacq 6,6 ml DE	Sample S-210216-394066
Batch number 60006001/104186	Batch size 38868 UN	Certificate Number B-210216-84334	Manufacture Date 27/01/2021
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: 01.2024

Result Conforms	Approval Date 15/03/2021 17:13:55	Approved by Sandra Letters, Quality Control Manager QC-F
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