

Certificate of Analysis

Analytical Laboratory Site
Almirall Hermal GmbH

Scholtzstrasse 3, 21465
Reinbek

Product type Bulk	Product Code 98610501	Product Name Ecocel Lösung	Sample S-220825-476647
Batch number 98610501/23523	Batch size 499 KG	Certificate Number B-220825-105666	Manufacture Date 07/09/2022

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: 27/10/2022

Result Conforms	Approval Date 12/09/2022 07:53:48	Approved by Sandra Letters, Quality Control Manager QC-F
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Product type Drug Product	Product Code 60006001	Product Name Sililevo 5% Nail Lacq 6,6 ml DE	Sample S-220901-477555
Batch number 60006001/235233	Batch size 30030 UN	Certificate Number B-220901-105881	Manufacture Date 07/09/2022

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: 09.2025

Result Conforms	Approval Date 28/09/2022 15:27:10	Approved by Mark Kaebel, Quality Control Manager QC-F
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Product type Drug Product	Product Code 60006001	Product Name Sililevo 5% Nail Lacq 6,6 ml DE	Sample S-220901-477554
Batch number 60006001/235233	Batch size 30030 UN	Certificate Number B-220901-105881	Manufacture Date 07/09/2022

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: 09.2025

Result	Approval Date	Approved by
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