



Certificate of Analysis

Site / Address Almirall Hermal GmbH		Scholtzstrasse 3, 21465 Reinbek	
Product type Bulk	Product Code 98610501	Product Name Ecocel Lösung	
Batch number 98610501/12319	Batch size 498 KG	Certificate Number B-210607-88433	Manufacture Date 29/06/2021

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	1.368	

Notes:

Valid to: 18/08/2021

Result RELEASED	Approval Date 02/07/2021 14:43:28	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 60006002	Product Name Sililevo 5% Nail Lacq 3,3 ml DE	
Batch number 60006002/123195	Batch size 27846 UN	Certificate Number B-210802-90368	Manufacture Date 29/06/2021

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	
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: Released by the responsible person for medical devices on 17-Aug-2021

Expiry Date: 06.2024

Result RELEASED	Approval Date 17/08/2021 08:39:27	Approved by Katrin Müller-Landré, QP Almirall Hermal GmbH
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