



Certificate of Analysis

Site / Address Almirall Hermal GmbH				Scholtzstrasse 3, 21465 Reinbek			
Product type Bulk		Product Code 98610501		Product Name Ecocel Lösung			
Batch number 98610501/02916		Batch size 497 KG		Certificate Number B-200708-76819		Manufacture Date 24/07/2020	

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: 12/09/2020

Result RELEASED	Approval Date 04/08/2020 16:34:12	Approved by Katrin Müller-Landré, QP Almirall Hermal GmbH
--------------------	--------------------------------------	--



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 60006002/029162	Batch size 68886 UN	Certificate Number B-200720-77237	Manufacture Date 24/07/2020

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	
Absence of Candida albicans	Absent in 1 g	Absent in 1 g	

Notes:

Expiry Date: 07.2023

Result RELEASED	Approval Date 17/08/2020 17:02:48	Approved by Katrin Müller-Landré, QP Almirall Hermal GmbH
--------------------	--------------------------------------	--