



Certificate of Analysis

Site / Address Almirall Hermal GmbH		Scholtzstrasse 3, 21465 Reinbek	
Product type Bulk	Product Code 98610501	Product Name Ecocel Lösung	
Batch number 98610501/03917	Batch size 496 KG	Certificate Number B-200917-79126	Manufacture Date 01/10/2020

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	1.366	

Notes:

Valid to: 20/11/2020

Result RELEASED	Approval Date 19/10/2020 17:06:02	Approved by Katrin Müller-Landré, QP Almirall Hermal GmbH
--------------------	--------------------------------------	--

Certificate of Analysis

Analytical Laboratory Site
Almirall Hermal GmbH

Scholtzstrasse 3, 21465
Reinbek

Product type Drug Product	Product Code 60006002	Product Name Sililevo 5% Nail Lacq 3,3 ml DE	Sample S-201014-376966
Batch number 60006002/039173	Batch size 33086 UN	Certificate Number B-201014-80029	Manufacture Date 01/10/2020

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: 10.2023

Result Conforms	Approval Date 05/11/2020 06:56:39	Approved by Sandra Letters, Quality Control Manager QC-F
--------------------	--------------------------------------	---

Certificate of Analysis

Analytical Laboratory Site
Almirall Hermal GmbH

Scholtzstrasse 3, 21465
Reinbek

Product type Drug Product	Product Code 60006002	Product Name Sililevo 5% Nail Lacq 3,3 ml DE	Sample S-201014-376965
Batch number 60006002/039173	Batch size 33086 UN	Certificate Number B-201014-80029	Manufacture Date 01/10/2020

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	

Notes:

Expiry Date: 10.2023

Result Conforms	Approval Date 05/11/2020 06:56:39	Approved by Sandra Letters, Quality Control Manager QC-F
--------------------	--------------------------------------	---