

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

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 inspectionessentially free from particles
(precipitates or others) that can be
observed on visual inspection

Density

0.94 - 0.97 at 20°C

0.95

g/ml

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 60006001		Product Name Sililevo 5% Nail Lacq 6,6 ml DE			
Batch number 60006001/029161		Batch size 32560 UN		Certificate Number B-200720-77236		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 19/08/2020 09:11:56	Approved by Katrin Müller-Landré, QP Almirall Hermal GmbH
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