

**CERTIFICATE OF MANUFACTURE / COMPLIANCE****Product Identification Number :** 60006002**Product Name :** Sililevo 5% Nail Lacq 3,3 ml DE**Importing Country :** Germany**Date of Manufacture :** 07/2023**Date of Expiry :** 07/2026**Strength/Potency :** N/A**Batch Number :** 329263**Formulation No. :** 98610501**Batch size (units) :** 109904 UN**Marketing  
Authorisation No :** ---**Manufacturing  
Authorisation No :** DE\_SH\_01\_MIA\_2023-0001**Name and Address of  
Manufacturer :** Almirall Hermal GmbH  
Scholtzstrasse 3, 21465  
Reinbek

*I hereby certify that the above information is authentic and accurate. This batch of product has been fabricated/manufactured, including packaging and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processings, packaging and analysis records were reviewed and found to be in compliance with GMP.*

**Position of Authorised Person :** QP Almirall Hermal GmbH/QA Manager**Signature of Authorised Person :** Julia Grewe Borrás**Date Certificate Issued :** Aug.25.2023

## 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 329263	Batch size 109904 UN	Certificate Number B-230804-120148	Manufacture Date 07/2023

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	1.367	
Compliance with FPV	meets requirements	meets requirements	
Compliance with the reference sample	in compliance	in compliance	
Labeling / packaging	meets requirements	meets requirements	
Total aerobic micr. count (TAMC)	Not more than 10 <sup>2</sup> CFU / g	Not more than 10 <sup>2</sup> CFU / g	
Total yeast/mould count (TYMC)	Not more than 10 <sup>1</sup> CFU / g	Not more than 10 <sup>1</sup> 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: 07/2026

Result RELEASED	Approval Date 25/08/2023 14:10:39	Approved by Julia Grewe Borrás, QP Almirall Hermal GmbH/QA Manager Sandra Letters, Quality Control Manager QC-F
--------------------	--------------------------------------	---