



CERTIFICATE OF ANALYSIS

SPECIFEEL EM

Batch n.	24B220
Production date	JANUARY 2025
Period of best use	JULY 2026

Parameter	Unit	Requirement	Method	Result
Appearance	-	Yellow clear viscous fluid	IO 07-06A	Yellow clear viscous fluid
Odour	-	Characteristic	IO 07-06A	Characteristic
Colour	GARDNER	1 max	ASTM D 1544	Complies
Solubility	-	Soluble in water	Preface Ph. Eur.	Soluble in water
Active substance	%	31 - 38	Internal Method*	Complies
pH (20% water solution)	-	8,5 - 9,5	Ph.Eur.2.2.3	9,4
Viscosity (Brookfield DV-LV, s= 63 - 20 RPM)	cps	1300 - 6000	Ph.Eur.2.2.10	1408
Solids (130 °C)	%	34 - 40	Ph.Eur.2.2.32	39
Sodium Chloride	%	4 max	UNI 26015:1993	Complies
MICROBIOLOGICAL				
Total bacterial count	CFU/g	≤ 100	Ph. Eur. 2.6.12/ USP current edition	<10
Total yeast and mould count	CFU/g	≤ 100	Ph. Eur. 2.6.12/ USP current edition	<10
<i>Staphylococcus aureus</i>	g	Absence	Ph. Eur. 2.6.13/ USP current edition	Absence
<i>Pseudomonas aeruginosa</i>	g	Absence	Ph. Eur. 2.6.13/ USP current edition	Absence
<i>Candida albicans</i>	g	Absence	Ph. Eur. 2.6.13/ USP current edition	Absence

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<i>Escherichia coli</i>	g	Absence	Ph. Eur. 2.6.13/ USP current edition	Absence
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*Difference between the "Solids" and "Sodium Chloride" parameters.

Date: 21th February 2025

Roelmi HPC Technical Department

The analyses are performed on a representative sample and are referred to the product at the time of release. The information included in this Certificate of Analysis does not discharge the user from the control of the product before the use. Roelmi HPC SRL does not take liability for any damage due to improper use. This document refers to the latest version of the specification data sheet and it has been prepared by electronic processing not requiring signature and the traceability to the original signature is managed by internal quality assurance system.

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