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SPECIFICATION DATA SHEET

PrincipHYAL® Cube³

EU and US INCI name	Chinese (IECIC) INCI name	CAS and EC nr. according to REACH regulation	CAS and EC nr. associated to the INCI name*
Sodium Hyaluronate	Sodium Hyaluronate	CAS: 9067-32-7 EC: (polymer)	CAS: 9067-32-7 EC: (polymer)

^{*}found in International Cosmetic Ingredient Dictionary and Handbook, published by PCPC

ANALYTICAL SPECIFICATION						
Parameter	Unit	Requirement	Method			
PHYSICAL-CHEMICAL						
Appearance	-	Powder	IO 07-06A			
Color	-	White	IO 07-06A			
Odor	-	Characteristic	IO 07-06A			
Molecular weight	kDa	50 – 3.000	IO 07-06AA			
Limiting viscosity	dl/g	≤ 30	IO 07-06BU			
pH (0.1% solution)		6,0 - 8,0	IO 07-06B			
Transparency (0.1% solution,550 nm)	%	≥ 99	Ph.Eur. 2.2.25			
Loss on drying (105°C)	%	≤ 10	IO 07-06K			
Proteins	%	≤ 0,10	S.H. Ph.Eur. Monograph			
Sodium Hyaluronate assay	%	≥ 93	S.H. Ph.Eur. Monograph			
Glucuronic acid assay	%	44 – 50	S.H. Ph.Eur. Monograph			
EFFICACY						
Elastin synthesis (fibroblasts, 24h, 1%)	μg	≥ 110,00	IO 07-06CA			



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MICROBIOLOGICAL					
Total bacterial count	CFU/g	≤ 100*	Ph.Eur. 2.6.12 / USP (current edition)		
Total yeast and mould count	CFU/g	≤ 100*	Ph.Eur. 2.6.12 / USP (current edition)		
Staphylococcus aureus	g	Absence	Ph.Eur. 2.6.13 / USP (current edition)		
Pseudomonas aeruginosa	g	Absence	Ph.Eur. 2.6.13 / USP (current edition)		
Candida albicans	g	Absence	Ph.Eur. 2.6.13 / USP (current edition)		
Escherichia coli	g	Absence	Ph.Eur. 2.6.13 / USP (current edition)		

^{*2}x (as per Ph. Eur. 2.6.12)

Storage: keep the product in the original container, well closed. Store in a cool and dry place (15°C - 30°C), protected from humidity, light or heat sources.

<u>Period of best use</u>: 36 months from production date, in the sealed original container, if stored as described above.

Roelmi HPC Technical Department

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