

SPECIFICATION DATA SHEET

PrincipHYAL (10)

EU INCI name	US INCI name	CAS n.	EC n.
Sodium Hyaluronate	Sodium Hyaluronate	9067-32-7	---- (polymer)

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	< 10	IO 07-06AA
Limiting viscosity	dl/g	< 0,5	S.H. Ph.Eur.Monograph
pH (0.1% solution)	i.u.	6,0 – 8,0	Ph.Eur. 2.2.3
Transparency (0.1% solution,550 nm)	%	≥99	Ph.Eur. 2.2.25
Loss on drying (105°C)	%	≤ 10	Ph.Eur. 2.2.32
Proteins	%	≤ 0,10	S.H. Ph.Eur.Monograph
Sodium Hyaluronate assay	%	≥ 95	S.H. Ph.Eur.Monograph
Glucuronic acid assay	%	≥ 46	S.H. Ph.Eur.Monograph
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)

ROELMI HPC srl

Via Celeste Milani, 24/26
21040 Origgio (VA) Italia
VAT: IT 09553280968
REA: VA-361664

T. +39 02 3351 0150
F. +39 02 3354 9210
roelmi.hpc@legalmail.it
Capitale sociale Euro 120.000 i.v.

info@roelmihpc.com
www.roelmihpc.com



SPECIFICATION DATA SHEET

PrincipHYAL (10)

<i>Staphylococcus aureus</i>	g	Absent	Ph.Eur. 2.6.13 / USP (current edition)
<i>Pseudomonas aeruginosa</i>	g	Absent	Ph.Eur. 2.6.13 / USP (current edition)
<i>Candida albicans</i>	g	Absent	Ph.Eur. 2.6.13 / USP (current edition)
<i>Escherichia coli</i>	g	Absent	Ph.Eur. 2.6.13 / USP (current edition)

OTHER DATA NOT SUBJECTED TO ANALYTICAL CERTIFICATION

Parameter	Unit	Typical result	Method
Total heavy metals (Nichel, cadmium, lead, arsenic, cobalt, chromium, mercury, antimony)	ppm	≤10	AAS/ ICP-MS
Residual solvents (ethanol)	%	≤ 0,5	GC

Storage: keep the product in the original container well closed in fresh and dry place, repaired from humidity, light or heat sources.

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

Roelmi HPC Technical Department

THE INFORMATION CONTAINED IN THIS DOCUMENT ARE BASED ON OUR CURRENT SCIENTIFIC KNOWLEDGE AND DOES NOT DISCHARGE THE USER FROM THE CONTROL OF THE PRODUCT BEFORE THE USE. THE INFORMATION ARE CAREFUL AND RELIABLE BUT IT SHOULD NOT BE TAKEN AS EXPRESSING OR IMPLYING ANY WARRANTY CONCERNING THE PRODUCT CHARACTERISTICS. THE USER, UNDER HIS OWN RESPONSIBILITY, MUST RESPECT THE RULES AND LAWS IN FORCE. ROELMI HPC SRL DOES NOT TAKE LIABILITY FOR ANY DAMAGE TO PEOPLE OR PROPERTY FOR IMPROPER USE AND DECLINES ANY RESPONSABILITY IN CASE THE USE OF THE PRODUCT INFORMATION MIGHT TAKE TO PATENT INFRINGEMENT OF THIRD PARTIES.

THE PRESENT DOCUMENT SUBSTITUTES AND CANCELS THE PREVIOUS VERSION.

ROELMI HPC srl

Via Celeste Milani, 24/26 T. +39 02 3351 0150

21040 Origgio (VA) Italia F. +39 02 3354 9210

VAT: IT 09553280968 roelmi.hpc@legalmail.it

REA: VA-361664

Capitale sociale Euro 120.000 i.v.

info@roelmihpc.com

www.roelmihpc.com

