

SPECIFICATION DATA SHEET

Sodium Hyaluronate MW 1%

EU INCI name	US INCI name	CAS n.	EC n.	RANGE
Sodium Hyaluronate	Sodium Hyaluronate	9067-32-7	---- (polymer)	1%
Aqua	Water	7732-18-5	231-791-2	94%
Pentylene glycol	Pentylene glycol	5343-92-0	226-285-3	4.5%
Sodium benzoate	Sodium benzoate	532-32-1	208-534-8	0.5%

ANALYTICAL SPECIFICATION			
Parameter	Unit	Requirement	Method
PHYSICAL-CHEMICAL			
Appearance	-	Clear to slightly opalescent, viscous solution	Internal method (comparison with the standard)
Color	-	Colorless to pale yellow	Internal method (comparison with the standard)
Odor	-	Characteristic	Internal method (comparison with the standard)
pH (0.1% solution)	i.u.	4.0 – 6.0	Ph.Eur. 2.2.3
Viscosity (Brookfield DV-E S03 5 rpm, 25°C)	mPas	5,000 – 15,000	Ph. Eur. 2.2.10
MICROBIOLOGICAL			
Total bacteria count	CFU/g	≤ 100	Ph.Eur. 2.6.12
Yeasts & Moulds	CFU/g	≤ 100	Ph.Eur. 2.6.12
<i>Staphylococcus aureus</i>	g	Absent	Ph.Eur. 2.6.13
<i>Pseudomonas aeruginosa</i>	g	Absent	Ph.Eur. 2.6.13
<i>Candida albicans</i>	g	Absent	Ph.Eur. 2.6.13

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OTHER DATA NOT SUBJECTED TO ANALYTICAL CERTIFICATION			
Parameter	Unit	Typical result	Method
Dry residue (160°C)	%	1.4 – 1.6	Ph. Eur. 2.2.32
Glucuronic acid assay	%	≥ 0.46	S.H. Ph.Eur. Monograph
Sodium Hyaluronate assay	%	≥ 0.95	S.H. Ph.Eur. Monograph
Heavy metals (sum expressed as Pb)	ppm	≤ 10	Ph.Eur. 2.4.8

ADDITIONAL INFORMATION		
The product contains 1% Sodium Hyaluronate with the following features:		
Parameter	Unit	Requirement
Limiting weight	KDa	1,000 – 1,800
Transparency (0.1% solution)	%	≥ 99.0
Protein content	%	≤ 0.05

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: 24 months from production date, in sealed original container, if stored as described above.

Roelmi HPC Technical Department

The information included in this Specification Data Sheet does not discharge you from the control of the product before the use. Roelmi HPC SRL does not take liability for any damage to people or property for improper use. The current Specification Sheet Data replaces and cancels every previous version.