

Data Sheet

Product:	CROSSLINKED HYALURONIC ACID POWDER
Description of product:	Crosslinked Hyaluronic Acid Sodium Salt, obtained by fermentation of Streptococcus Zooepidermicus, chemically crosslinked with 1-ethyl-3- (3-dimethylaminopropyl) carbodiimide hydrochloride (EDC) for topical use
Manufacturer:	Bioitech Italia
Code (Ref.):	B2OPH
Appearance:	White Powder
Solubility:	In water and in saline solutions
Glucuronic Acid Sodium Salt:	> 46.0 %
pH:	5.0 – 8.5 (0.5% in aqueous solution)
Viscosity :	4 – 14 cSt (0.05% in aqueous solution)
Residual Protein:	< 0.1%
Chlorides	< 0.5%
Arsenic	< 1.5 ppm
Cadmium	< 0.2 ppm
Cobalt	< 0.5 ppm
Total chromium	< 110 ppm
Iron	< 10 ppm
Mercury	< 0.3 ppm
Molybdenum	< 150 ppm
Nickel	< 2 ppm
Lead	< 0.5 ppm
Copper	< 30 ppm
Vanadium	< 1 ppm
Antimony	< 9 ppm
Lithium	< 25 ppm
Tin	< 60 ppm
Loss on drying	< 20.0%
Residual of Urea and N-ethyl-	< 300 PPM

N'-(dimethylaminopropyl) Urea:

Microbial Contamination:	< 100 CFU
TAMC	< 100
TYMC	< 100
Storage:	0°C - 25°C
Intended Use:	Ophthalmology and Cosmetics
Indications:	Treatment of Dry eye and eye disorders in general, keratitis, Xeroftalmia, keratoconjunctivitis, Sjogren syndrome and Stevens Johnson syndrome
Preparation Instructions:	Dissolve CrossYal in buffer solution at the desired concentration. Do not pre-filter. It can be heated up to 70 °C - 80 °C to dissolve the solution, if necessary. Sterilize by 0.2 micron filtration

- ✓ **Made in Italy - NOT irradiated**
- ✓ **NOT OGM**
- ✓ **Free of risk to BSE / TSE (non-animal biotechnology)**
- ✓ **It does not contain substances of animal origin**
- ✓ **Latex free**
- ✓ **It does not contain substances which are carcinogenic, mutagenic or toxic to reproduction (CMR), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council.**