

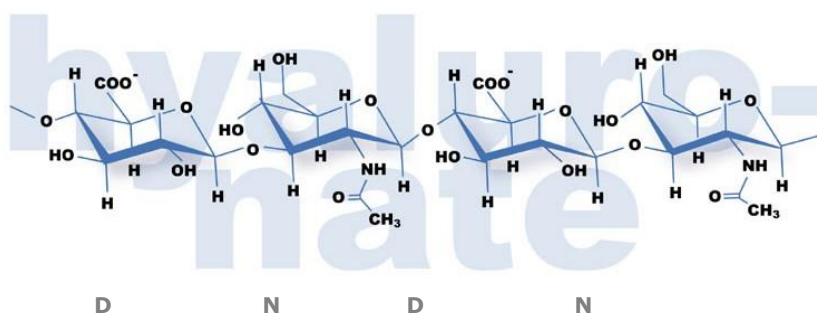
# Product Information Bulletin



## Ultra Pure Sodium Hyaluronates

Sodium Hyaluronate Pharma Grade is a highly purified and well-characterized sodium hyaluronate developed for use in biomedical and pharmaceutical applications. Sodium Hyaluronate Pharma Grade is manufactured at NovaMatrix' strategic partner Kikkoman Biochemifa Company (KBC)'s\*, state-of-the-art production facility in Kamogawa, Japan. The fermentation of ultra pure sodium hyaluronate is based on more than 10 years of experience and the plant is constructed and run in compliance with cGMP guidelines for bulk pharmaceuticals. The ultra pure sodium hyaluronates from KBC is described in a DMF submitted to the US FDA. In addition to sodium hyaluronate, NovaMatrix also provides ultra pure alginate and chitosan, poly-anionic and poly-cationic polymers, respectively, that can be used in combination with hyaluronan.

Sodium Hyaluronate, fermented from *Streptococcus zooepidemicus*, is a linear copolymer composed of (β-1,4)-linked D-glucuronate and (β-1,3)-N-acetyl-D-glucosamine (figure 1). Sodium Hyaluronate is an abundant glycosaminoglycan found in the extracellular matrix of skin, joints, eyes and most organs and tissues of all higher animals. It is the only non-sulfated glycosaminoglycan and forms highly viscous aqueous solutions.



Representative sequence of a hyaluronate molecule. D and N represent D-glucuronate and N-acetyl D-glucosamine, respectively.

The viscosity is a direct result of the polymer expanded random coil structure a consequence of strong hydrogen bonding. The coiled structure of hyaluronate can trap approximately 1000 times its weight in water. These characteristics give the molecule unique physicochemical properties as well as distinct biological functions and suggest it as an attractive building block for new biocompatible and biointeractive materials in drug delivery, tissue engineering and viscosupplementation.

Hyaluronic acid or hyaluronate is a natural component in mammalian organisms and will suffer from polymer chain enzymatic degradation by hyaluronidases. The half-life of hyaluronate in endothelial tissue is less than a day, and the natural turnover of the polymer in adults is approximately 7g a day. A mild to moderate covalent modification of hyaluronan will increase the *in vivo* stability and retention time from days up to months or year. The biomechanical properties of the polymer are also improved by covalent modification technologies. Current modifications are concentrated to the carboxyl group and hydroxyl group on the D and N monomer units respectively and polymer cross-linking technologies.

\* Kikkoman Biochemifa Company, formerly Kibun Foodchemifa

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#### **Patents**

NovaMatrix/FMC Corporation does not warrant against infringements of patents of third parties by reason of any uses made of the product in combination with other material or in the operation of any process, and purchasers assume all risks of patent infringement by reason of any such use, combination, or operation.

#### **Warranty**

Because of the numerous factors affecting results, NovaMatrix/FMC products are sold under the understanding that purchasers will make their own tests to determine the suitability of these products for their particular purpose. The several uses suggested by NovaMatrix/FMC Corporation are presented only to assist our customers in exploring possible applications. All information and data presented are believed to be accurate and reliable, but are presented without the assumption of any liability by NovaMatrix/FMC Corporation.

#### **Technical Service**

The information contained in this bulletin is intended to be general in nature. Techniques and data pertaining to specific uses for NovaMatrix/FMC products and new developments will be published periodically in the form of supplemental application bulletins. Our technical staff is ready to offer assistance in the use of NovaMatrix/FMC products.

#### **Regulatory Status**

Sodium Hyaluronate Pharma Grade meets the standards set forth in the current edition of the European Pharmacopoeia. Sodium Hyaluronate Pharma Grade satisfies the requirements for use in tissue-engineered medical products as set forth in ASTM F2347. Sodium Hyaluronate Pharma Grade is manufactured in compliance with current Good Manufacturing Practice and described in a DMF submitted to the US FDA.

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