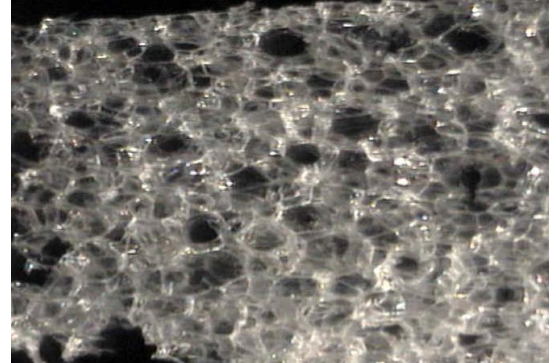


alginate

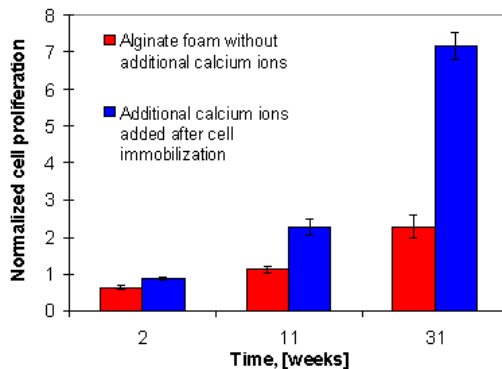
Alginate Foam

There are numerous biomedical uses for biomaterials made in the form of films, fibers, foams and gels. It is highly desirable that these materials exhibit biocompatibility and controlled biodegradability. One such material is alginate. Of particular interest recently are alginate foams. Alginate foams offer many new possibilities for overcoming today's bio-medical challenges in areas such as: tissue engineering, wound management, anti-adhesion, *in vivo/in vitro* cell support, medical implants, and controlled drug release *in situ*.

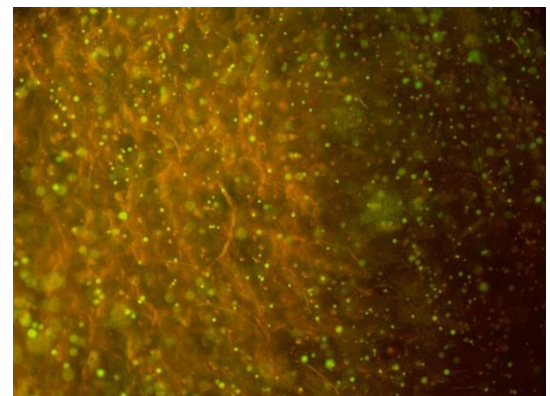


The proprietary ultra-pure alginate foams developed by NovaMatrix, are flexible and pliable, yet can be engineered to provide structural integrity, and tensile strength if required. Unlike other foams, alginate foams are biocompatible, are easily handled, and can be manufactured without the need for expensive freeze drying. Endotoxin levels are low, and the foam may be sterilized using common sterilization techniques.

For example, the alginate foams have several benefits as immobilization matrices. Materials such as drugs, particulates, living cells, etc. can be immobilized within the pores of the foam. For cell immobilization this is a quick and gentle technique; the living cells are immobilized from the start in a three dimensional network. As such, they tend to readily proliferate in three dimensions within the foam matrix. To imitate the natural environment for differentiated cells, the elasticity/stiffness of the foam can be modified. The cells can also be readily harvested later for further study, by using chelating agents to dissolve the foam.



Cell proliferation normalized to initial number of cells seeded onto the alginate foam as a function of time.



Human Chondrocytes immobilized in alginate foam for 31 weeks. Cells are stained with use of a Live/Dead Viability/Cytotoxicity Kit and the viable cells confirmed by green fluorescence in a fluorescence light microscope

At NovaMatrix we recognize that with such diversity of possible applications, no one foam formulation would be sufficient, nor practical. However, there is high formulation flexibility of our alginate foams and they can be engineered to meet the requirements of specific applications. Among the physical foam properties that can be controlled are pore size, strength, degradation rate, absorption rate, absorption capacity and density. NovaMatrix is capable of working with you to develop an alginate based foam tailored to your specific interest, and application requirements. NovaMatrix foam technology is available for use under license.

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

PRONOVA™ sodium alginate meets the standards set forth in the current editions of the United States Pharmacopeia/National Formulary and European Pharmacopoeia. PRONOVA™ sodium alginate satisfies ASTM F 2064 for use in tissue engineered medical products (TEMPs). PRONOVA™ sodium alginate is manufactured in compliance with Good Manufacturing Practice and described in a DMF submitted to the US FDA.

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