

## BEYOND ENZYMES

# THE BIRTH OF A NEW BIOBASED INDUSTRY

The face of the chemical industry is changing with help from Novozymes. One of the new business areas within BioBusiness is the conversion of renewable resources into chemicals. Though Novozymes will not produce chemicals itself, it will use its biotechnology to help other companies produce chemicals.

Cargill is a good example, being a leading player in the conversion of renewables to chemicals. In January 2008, Cargill and Novozymes announced a joint agreement to develop technology enabling the production of acrylic acid via 3-hydroxypropionic acid (3-HPA) from renewable raw materials. The project is supported by a USD 1.5 million matching cooperative agreement from the US Department of Energy.

Novozymes and Cargill will develop a process to convert glucose or another carbohydrate source into 3-HPA by fermentation. This conversion is a multi-step enzymatic reaction within the cells of a microorganism. Using Novozymes' unique technology platform in protein and pathway engineering, the natural biosynthetic pathways of the microorganism will be changed so that it begins to produce the desired molecules in high amounts. 3-HPA produced from the fermentation can then be recovered and

transformed into chemical derivatives such as acrylic acid.

At present, most acrylic acid results from the oxidation of propylene, a petrochemical industry product from the refining of crude oil. Almost half of the 3.1 million tons of crude acrylic acid produced annually (2005) is used to make glacial acrylic acid for superabsorbents. Their major use is in personal care items such as diapers (more than 1 million tons annually). The remainder is used to produce acrylates that are components of acrylic fibers, coatings, paints, and inks.

"Due to increasing oil prices, the conversion of renewable raw materials into chemicals is becoming economically viable and holds significant commercial potential," says Executive Vice President Thomas Videbæk. "This strongly positions Novozymes to put its bioinnovation capabilities to work towards our vision of a 'biobased economy' where biomaterials will supplement many of the petroleum-based products we know today. The collaboration with Cargill is a good example of how we leverage and build upon our technology base to expand the business into new areas. We are building on existing technology and on our existing relationships."



New biotechnology could help to keep babies dry using renewable resources.

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# IDENTICAL TO HUMAN SERUM ALBUMIN, JUST BETTER!

Novozymes Biopharma is the result of a number of acquisitions in the last few years, including Delta Biotechnology Ltd in the UK and GroPep in Australia. The synergies between the various activities in Novozymes Biopharma and also with Enzyme Business are now beginning to show in terms of an attractive product portfolio of animal-free ingredients for cell culture media and other areas in biopharmaceutical production.

Just like enzyme products, the pharmaceutical ingredients sold by Novozymes Biopharma are made by microorganisms. The advantage of microbially produced ingredients is that they come from an identified, controlled, nonanimal, and nonhuman source and can be made consistently to recognized quality standards. The disadvantage of using raw materials from an animal or a human source is that they must be assessed for the presence of viral or other potentially pathogenic organisms.

One example is human serum albumin (HSA), naturally produced by the liver and found in blood plasma. It is extracted from human or animal blood and has played an important role

in the development of a wide range of biopharmaceutical products and as a nutrient in cell culture media. However, with concerns about animal-derived materials, the regulatory authorities are now strongly recommending that drug and device manufacturers seek alternatives to all components of animal origin.

Recombunin® from Novozymes is the world's first and only animal-free recombinant HSA on the market approved for use in the manufacture of human therapeutics. Recombunin is produced by the yeast microorganism *Saccharomyces cerevisiae* (baker's yeast). It is structurally identical and comparable in safety and tolerability to human serum albumin (HSA). The first commercial approval for the use of Recombunin was in 2005 for the manufacture of the childhood vaccine M-M-R® II by Merck & Co.

Another development of interest to pharmaceutical companies is albumin fusion technology that can considerably extend the half-life of drugs by fusing albumin and the active pharmaceutical ingredient together, leading to fewer side effects, better tolerance, and less frequent injec-

tions. This technology is being licensed out by Novozymes Biopharma to pharmaceutical companies, and a number of drugs manufactured using this technology are presently undergoing late-phase clinical trials.

Apart from biopharmaceutical ingredients and technology, Novozymes Biopharma also offers customized pharmaceutical-grade contract manufacturing services at its production facilities in Lund, Sweden. ▶▶



Recombunin® is an excipient used to replace human serum albumin in protein drug formulations.