Eco-Friendly Alternative to Traditional Latex

William Doyle

Latex is a preferred material for thousands of products. However, prolonged exposure has revealed concerns with allergies that cause reactions ranging from mild itching to troubled breathing. A company has developed a new material that is a modified version of the latex which addresses these concerns. This article showcases this material and its potential applications.

William Doyle is president and CEO of Vystar Corp. The company is the exclusive creator of Vytex Natural Rubber Latex–a patented, eco-friendly natural latex raw material with ultra-low levels of antigenic proteins. Doyle can be reached at 770-965-0383 or wdoyle@vytex.com [1].

Natural rubber latex has long been a staple in hospitals, medical clinics, and dentists' offices. Valued for its desirable properties, such as excellent barrier protection, strength, and elasticity, latex is used in thousands of medical devices. The rise of the AIDS epidemic in the 1980s spurred the widespread use of latex gloves to protect against infection. But for many healthcare professionals, the increased exposure to latex led to allergic reactions ranging from watery and itchy eyes to red and irritated skin to troubled breathing. They developed dangerous latex allergies that, in some cases, limited or ended their care-providing careers.

Latex allergies affect up to 17% of healthcare workers and 1% of the general population–three million people–according to the American Latex Allergy Association. This number, however, can be as high as 10% among condom-users. In addition to healthcare professionals, food service workers, hairdressers, janitors, and people who have undergone multiple surgeries are also at a higher risk for developing latex allergies.

The prevalence of sensitivities and allergies to latex among employees and patients prompted many healthcare facilities to switch to synthetic materials, including nitrile, polyurethane, polyvinyl chloride (PVC), neoprene, and vinyl, for gloves and

other products in an effort to become "latex-free" environments. However, these synthetic alternatives are petroleum-based products, and some have been shown to contain carcinogenic chemicals and are not as breathable as natural rubber latex. For example, foam mattresses made of polyurethane off-gas toxic substances that can lead to asthma-like symptoms.

Latex is used in thousands of products, such as condoms, catheters, foam mattresses, and balloons, and is more desirable and commonly preferred to synthetics because of its elasticity, strength, and pliability.

An Ultralow Protein Alternative

Vystar Corp. created a latex raw material called Vytex Natural Rubber Latex (NRL) that not only retains the eco-friendly nature of NRL, but significantly reduces the antigenic proteins found in natural rubber latex–the reason why some healthcare workers and others have moved away from latex to the more carcinogenic synthetics, losing the eco-friendly status of the product. Vystar is working with numerous manufacturers worldwide to conduct trials in which Vytex NRL is substituted for traditional latex or synthetic materials in products such as exam and surgical gloves, catheters, adhesive bandages, condoms, probe covers, blood pressure cuffs, IV tubing, stethoscopes and breather bags. The first products made with Vytex NRL–a condom and exam glove–are expected to be available this year.

The Vytex technology has been issued multiple U.S. and international patents covering the reduction of allergenicity prior to vulcanization, and has several others pending.

Vystar's patented technology removes virtually all the antigenic proteins found in natural rubber latex, while maintaining and improving upon its desirable qualities, including excellent barrier protection, tensile strength, tactile sensitivity, elasticity, memory and fit. Vytex NRL is made from natural rubber latex, an organic substance harvested from the sap in *Hevea brasiliensis* rubber trees. Unlike synthetic materials such as vinyl, which are derived from petroleum by-products, Vytex NRL is a natural and renewable resource and contains no known or suspected human carcinogens. An additional benefit over all other NRL formulations is the clarity and odor-free qualities of Vytex. Further, because Vytex is made from a natural raw material, it is biodegradable and will decompose. Latex scraps can even be repurposed for use in the rubber soles of shoes.

As hospitals look for more ways to be environmentally conscious and use products that emphasize patient safety, glove manufacturers are uniquely positioned to utilize innovative materials such as Vytex NRL in their production lines. Focus groups conducted by Vystar revealed that OR nurses and other healthcare workers expressed extreme dissatisfaction with gloves made of synthetic substitutes, citing poor elasticity and fit, frequent tearing, odor, and higher cost as drawbacks. They described their "perfect" glove as a powder-free, ultra low protein natural rubber latex option.

Vytex NRL integrates seamlessly into manufacturing operations that currently use traditional latex or synthetic substitutes without additional capital investment or equipment. In some cases, glove manufacturers using Vytex NRL achieved low antigenic protein levels even before normal washing and post-leaching. This is significant because much of the non-raw material costs associated with latex glove production are attributed to the post dip processes, including leaching. Furthermore, these enhanced processes can significantly reduce manufacturer water and energy consumption, thus reducing overall environmental impact.

Product Applications

Vystar is working with U.S. manufacturer Alatech Healthcare LLC, which received 510(k) clearance from the FDA to market and sell the first condom and exam glove made with Vytex NRL. The new Envy condom will carry labeling that will reflect the lowest antigenic protein content currently available in a natural rubber latex medical device in the U.S. The Envy condom labeling notes the protein content at less than 2 micrograms/dm^2 of the antigenic proteins that can cause an allergic response. The glove and condom products are expected to be available in late 2009.

The Science Behind Vytex NRL

Natural rubber latex is a cloudy white liquid, collected by cutting a thin strip of bark from the *Hevea brasiliensis* tree and allowing the latex to be secreted into a collection cup over a period of several hours. After collection, the latex is treated with a preservative, typically ammonia, to prevent coagulation and is transported to a processing facility for concentrating and compounding.

Vytex NRL applies green chemistry to treat NRL to significantly reduce its antigenic protein content, which could prevent latex allergies from developing. Natural rubber latex contains over 200 proteins, similar to other natural plant materials, of which 13 are known allergens. The Vytex NRL process was created to significantly reduce these known proteins.

The patented protein removal process involves adding aluminum hydroxide–$Al(OH)_3$–a well-known protein binding chemical, to latex while it is still in liquid form. $Al(OH)_3$ is an amphoteric substance, meaning it can react as either an acid or base and readily shares electrons with proteins. This compound acts as a binding agent to the latex and produces protein complexes that are removed from the Vytex NRL solution using existing industry practices.

After the latex is treated, samples are tested to ensure the protein levels are at the low levels required by Vystar's standards using the industry-standard tests. The most frequently used testing methodologies to measure protein content are the Modified Lowry American Society for Testing and Materials (ASTM) D5712-05 and ELISA Inhibition ASTM D6499-03. Both have been performed on many Vytex

samples and products by Donald Guthrie Foundation for Education Research.

The Modified Lowry test is a chemical analysis test that is recognized as a national standard for measuring total extractable proteins in NRL (ASTM D5712). The ELISA Inhibition assay is a method used to test for antigenic latex proteins.

Un-leached film samples of Vytex NRL have been thoroughly analyzed during the development phase. Over 500 sample films and products made with Vytex NRL have been independently tested for protein levels. Protein testing using the Modified Lowry and ELISA methods occurred at three time intervals: immediately after production, after 21 days of storage, and after six months of storage.

Test results during all phases of protein testing generated less than 10 ug/g of antigenic protein using the ELISA protein test method for un-leached film samples. Products made from Vytex NRL under similar conditions used for *Hevea* natural rubber latex production frequently exhibit less than 0.2 ug/g of antigenic protein–below detection for a wide variety of medical devices, including exam gloves, condoms, surgical gloves, probe covers, and breather bags. Overall, Vytex NRL typically has 90% fewer antigenic proteins than untreated *Hevea* natural rubber latex.

Vystar is working with the ASTM Natural Rubber Subcommittee to establish a new category of ultra low Hevea protein natural rubber latex that describes the attributes of Vytex NRL under ASTM guidelines.

Online

For additional information on the technologies and products discussed in this article, see *MDT* online at www.mdtmag.com [2] and the following websites:
- www.vytex.com [3]
- www.alatechhealthcare.com [4]
- www.astm.org [5]
- www.guthrie.org [6]

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