

Guayule

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Guayule (*Parthenium argentatum Gray*) is an alternative botanical source of high quality natural rubber. Guayule can be processed to produce a high quality latex suitable for the production of latex medical devices and consumer products using dipped, extruded and foamed processes. Guayule is a hard wood shrub native to the Chihuahuan Desert of northern Mexico and the Big Bend region of Texas. Although guayule rubber was commercially-produced in the early part of the last century, more recent efforts to reinstate production have not led to commercial success because the production costs of bulk rubber for tire manufacture were too high to permit direct competition with Hevea rubber. Guayule commercialization has been revitalized in recent years by use of the plant to produce low protein latex, that does cause reactions in Type I Hevea latex allergic people. This application allows a higher value rubber raw material and commercial competitiveness.

To produce guayule latex, the rubber particles must be removed intact from the ordinary bark cells in the stems and roots of the shrub (the bark parenchyma cells) while maintaining them in aqueous suspension. Thus, the shrub must remain in a hydrated condition through harvest, shipping and storage until ground up (homogenized) in an alkaline aqueous extraction medium. The rubber particles, which have a specific gravity of slightly less than 1, can then be purified from the homogenate using a series of centrifugation washing and concentration steps. This process is analogous to producing cream from milk. The process results in an artificially-produced natural rubber latex from which the cytoplasmic components, including all the soluble proteins have been removed. Extensive allergy testing using mice, rabbits and human subjects and a wide array of different test methods have clearly demonstrated that the latex contains very little protein, extremely low levels of soluble protein and no protein epitopes that cross-react with Type I latex allergy. Of course, if the proteins are not present in the latex, they cannot appear in the products manufactured from the latex.

The safety of guayule is now supported by industry, with the recently published ASTM D1076-06 standard (Standard Specification for Rubber ? Concentrated, Ammonia Preserved, Creamed, and Centrifuged Natural Latex), which has important and welcome ramifications for latex allergy sufferers and those seeking to reduce the incidence of latex allergy. It is the first time a major standards organization and the latex industry have come together to address the safety issue of natural rubber latex. The new ASTM standard in Category 4 is evidence that the industry is turning the corner and a new and safer era for latex allergy sufferers is underway. A Category 4 latex must contain a very low level of protein in the latex itself (less than 200 ug total protein/g dry weight latex) but that it also must have no cross-reactive proteins at all. This requirement specifically safeguards guayule latex and latex products from contamination with Hevea latex. Such contamination cannot be detected visually, and so the ASTM D6499 immunochemical test must be specifically applied.

The Category 4 low protein requirement provides the extra safety feature of very low protein exposure during product use, which should greatly reduce the chances of a user becoming allergic to guayule latex or latex products. It is clear that if high levels of protein are not present in the raw material they cannot appear in the manufactured product. At the present time, guayule latex, marketed as Yulex® latex through Centrotrade USA, is the only natural rubber latex that meets the new Category 4 standard, and, therefore, provides a new level of materials safety for medical product manufacturers. This cost-effective material is a clinically-proven solution to the serious health risks posed by tropical latex products while also being a renewable resource and superior in performance to synthetic petroleum-based latex products. Unlike synthetic alternatives, Yulex® latex does not require any sacrifice in critically important performance standards: it exceeds standard ISO & ASTM raw material tests for strength, flexibility, viral barrier protection and resistance to heat, moisture and deterioration.

Latex allergy sufferers should also take heart that material science innovators like Yulex Corporation are bringing to market such safe, natural solutions.

Guayule Latex FAQs

Answered by Dr. Katrina Cornish, Sr. Vice President, R&D, Yulex Corporation

I have a latex allergy is Guayule Latex safe for me to use?

The sera from over 400 Type I latex sensitive people have been tested against guayule latex ? no case of cross reactivity has been noted indicating that the material is safe for use by latex allergic people. Also, prick skin tests have been performed on some Type I patients, again with no adverse effect. Some latex allergic people have also worn guayule latex gloves multiple times without ill effect. In conclusion, guayule latex should be safe to use.

What products have Guayule latex in them?

At the moment no medical products are completed the approval processes needed before commercialization. Sue ? I am checking to see is a mattress by Perfosisem is now available.)

How do we find Guayule latex in products is there a label or icon to look for?

Labeling has not yet been finalized but watch out for Yulex® latex and ASTM D1076 Category 4 latex (no crossreactive proteins and very low total protein levels).

I am a manufacturer and I would like more information on how my product could use guayule latex?

Please contact Yulex Corporation (760) 476-0320) who will be happy to provide all the technical support you might need.

Natural rubber made from guayule for medical products

Guayule (*Parthenium argentatum Gray*) is a native desert plant used to produce high quality natural rubber for

medical devices and consumer products. A native desert plant to the southwestern U.S. and northern Mexico, guayule is a safe alternative for individuals allergic to *hevea* latex because it does not contain the same proteins as *hevea latex*, the latex derived from the Brazilian rubber tree.

In the 1990s, the U.S. Department of Agriculture's Agriculture Research Service launched a domestic rubber project, which, under the direction of Dr. Katrina Cornish, now senior vice president of Yulex Corporation, produced a patented process for extracting natural rubber latex from guayule. During this process, Dr. Cornish identified a unique benefit of the guayule plant -it was naturally circumallergenic because it was *hevea-latex* free and its proteins did not cross react with *hevea* latex proteins.

In clinical laboratory tests conducted through the Johns Hopkins University School of Medicine, no allergic reaction was detected when serum pools from severely latex allergic subjects were exposed to guayule.

The Yulex® natural rubber examination glove cleared in 2008 by the FDA is the first of many products to come from guayule. The material is a higher value rubber raw material because of its performance criteria such as elasticity, tensile strength, and durability. Unlike petroleum-based synthetics, the material is renewable and non-polluting.

Today, the market conditions for guayule rubber have changed in its favor as demand for safe alternatives to *hevea* latex rises, new bioscience practices improve its economics, and interest in renewable materials to replace petroleum-based products such as synthetic rubber grows.

Yulex natural rubber material is the only material to date to meet the ASTM standards for a new category of natural rubber latex that specifies safety and performance standards.

Balloon catheters, tracheal tubes and other medical devices are currently in development and/or production to provide hospitals and institutions becoming ?latex-safe? with alternative products.

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Guayule Latex FAQs

Answered by Dr. Katrina Cornish, Sr. Vice President, R&D, Yulex Corporation

Is Yulex natural rubber safe for hospitals going ?latex-safe??

Yulex natural rubber does not contain the proteins associated with *hevea* latex and is safer for people with Type I latex allergy. The material exceeds standard ISO and ASTM raw material tests for strength, flexibility, viral barrier protection and resistance to heat moisture and deterioration making it suitable for hospitals and institutions concerned about *hevea* latex.

What medical devices and products use Yulex natural rubber from guayule?

The Yulex natural rubber examination glove cleared in 2008 by the FDA is the first of many products to come from this material. Balloon catheter manufacturer Tech Device in Massachusetts is currently developing the first Yulex® rubber catheter product for FDA clearance, with other guayule-based medical device products also in development with the company's other manufacturing partners.

I am a manufacturer and I would like more information on how my product could use guayule latex?

To purchase Yulex natural rubber, contact Centrotrade at www.centrotrade.net [1].

For more information about Yulex Corporation, visit www.yulex.com [2].

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[1] <http://www.centrotrade.net>

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