

VYSTAR CORPORATION

Set to revolutionise the latex industry with Vytex NRL

Launching the superior Vytex Natural Rubber Latex (Vytex NRL) with protein levels minimised to undetectable levels with a revolutionary patented technology, this innovative company, headquartered in Duluth, Georgia, USA, is opening up the door for a new era of safer latex products

Bill Doyle, Vystar Corp. President and CEO, demonstrates the elastic quality and strength of Vytex NRL



It is indeed an exciting message that is being conveyed to the world by Vystar Corporation based in Duluth, Georgia, USA. Applying a revolutionary patented technology, the innovative company focussed on green technology has launched a novel form of natural raw material called Vytex NRL with protein levels minimised almost to

unperceivable levels. This is highly encouraging news for the NR latex products makers the world over, healthcare professionals and workers in particular, who have been confronted with the vexed issue of latex protein allergy. The creation of the innovative material is going to open up the door for a new era of safer latex products!

Latex sans problems

From its very inception in 2000 to 2007, Vystar has been focussing on the early stage research, development, testing and commercialisation of Vytex NRL which offers the best of latex sans its problems.

Explains William R. Doyle, (Bill Doyle, as he

is popularly called) Vystar's dynamic President & Chief Executive Officer, about the creation of Vytex NRL: "Through their research, Vystar scientists wanted to create a new form of latex that retained all of the positive qualities of latex while minimising its allergenic properties and offer an eco-friendly, raw material to manufacturers that



Vytex NRL: A natural raw material from the sap of the rubber tree

could easily be integrated into existing manufacturing processes with limited impact on the environment. The result was Vytex NRL, an eco-friendly, renewable latex material with virtually undetectable levels of the antigenic proteins that can cause latex allergy."

Allergy problem

Natural rubber latex (NRL) is used in more than 40,000 products. Valued for its desirable properties, it is used in numerous products in the medical industry (including gloves, catheters, adhesive bandages, surgical dressings, and breather bags), consumer products (condoms, balloons, toys) and home products (foam mattresses and pillows, latex backing on carpets and rugs), and elastic threads (clothing and textiles)."

Importantly, latex has been the very basic and integral part of the medical industry and is used in various medical devices. The most

commonly used latex medical device is the exam glove. The rise of the AIDS epidemic in the 1980s highlighted the widespread use of latex gloves to protect against infection. But, for many healthcare professionals, the increased exposure to latex led to allergic reactions. Symptoms ranged from watery and itchy eyes to red and irritated skin to trouble breathing and even life-threatening anaphylaxis. Healthcare professionals developed dangerous latex allergies that, in some cases, limited or ended their care-providing careers. Latex gloves were also negatively perceived because of the powder associated with the gloves that left residue on the users' hands and caused skin irritation.

Protein reducing process

"Vytex NRL applies green chemistry to treat NRL to significantly reduce its antigenic protein content," Bill Doyle said. After the liquid latex is collected from the *Hevea brasiliensis* tree, it is treated with a preservative, typically ammonia, to prevent coagulation and is transported to a processing facility for concentrating and compounding.

Natural rubber latex contains over 200 proteins, similar to other natural plant materials, of which 13 are known allergens. "The Vystar team has developed a patented method to remove virtually all the antigenic proteins found in natural rubber latex, while maintaining and improving upon its desirable qualities such as excellent barrier protection, tensile strength, tactile sensitivity, elasticity, memory and fit," he told *Rubber Asia*.

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. It can react as either an acid or base and readily share 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.

"The key benefit is that we are achieving these low protein levels in the raw material prior to production," according to Doyle. Additionally, manufacturers' efforts to reduce protein through the leaching process contribute to achieving our distinctively low levels. Vytex's low protein as the starting raw material coupled with good manufacturing practices ensures consumers have the safest natural rubber latex products on the market, he said. "However, there are a number of products using natural rubber latex that do not have the benefit of leaching in the manufacturing process to reduce the latex proteins, such as adhesives and foams. In these products, the low protein levels of the Vytex NRL raw

We will offer more innovative products in the future: Vystar Chief



Bill Doyle - Vystar Corp. President & CEO

Vystar has already established itself as an innovative company focussing on green technologies and providing manufacturers with a superior raw material and enhancing value through technical, regulatory, sales and marketing services.

At present, the strength of Vystar lies in its signature brand Vytex NRL, which can substitute traditional or synthetic latex in any product. Vystar, however, is looking forward to offering more innovative products in the future, said Bill Doyle, the President and CEO, in an interview to *Rubber Asia*. **Excerpts:**

Please tell us about the establishment of Vystar Corporation

Vystar® Corporation, established in 2000, was the brainchild of Travis Honeycutt, an inventor and chemist with extensive experience in the healthcare industry. Honeycutt and myself had worked together at Isolyser

Co., a company that specialised in infectious control products. It was Travis who personally financed the initial investment for Vystar.

What are the services and technical support offered by Vystar?

In addition to offering our customers the best natural rubber latex source material on the market, Vystar also provides our customers with a customised level of support to help them achieve their business objectives and requirements. The Vystar Professional SupportSM (VPS) programme focusses on three core areas: Technical; regulatory & intellectual property, and marketing support.

Technical support is provided to assist our customers from initial evaluation and trials to full integration and commercialisation. Our global team of scientists, technicians and manufacturing specialists are available to meet our clients' diverse needs. Additionally, we are constantly investing in the future of Vytex NRL as the industry standard for natural rubber latex. These efforts include feature presentations and publications at key natural rubber latex conferences and also working with ASTM to establish a new category of latex that describes the low protein attributes of Vytex NRL.

Regulatory support is offered to our clients serving the medical community with their products made with Vytex NRL. Our staff has more than 20 years of regulatory experience in the healthcare and technology sectors and we assist our clients with testing, claims, filings and reporting for new medical device clearances and approvals.

"Intellectual property (IP) support is offered to all of our clients in order to help them create real asset value in their products "Made with Vytex". Using the Vytex NRL in their product often provides manufacturers a new product that creates real asset value for them, and the Vystar team, with more than 30 years collectively in developing new products and intellectual property, supports its customers by assisting with strategy, positioning and developing what is effectively a new intellectual property asset for these manufacturers."

Marketing support is designed to increase Vytex NRL visibility for our clients and their products "Made with

Vytex." We support our customers' marketing and advertising efforts through Website and search engine optimisation efforts (SEO), coverage on third-party websites (eg., Wikipedia), and affiliations with key organisations (eg., AID Atlanta and the American Latex Allergy Association). These awareness efforts aim to drive consumers towards products containing the label "Made with Vytex NRL."

The VPS programme, well received by our customers, was created to help them sell more products made with Vytex NRL, increase profits and grow market share.

Please tell us about US FDA clearance for products made with Vytex NRL.

U.S. FDA clearance is a requirement for medical devices, such as condoms, catheters and exam gloves. Vystar provides added value for manufacturers by assisting with regulatory submissions. FDA approval is not needed for consumer products such as mattresses, balloons or elastic threads.

In May 2009, Vystar and Alatech Healthcare LLC received 510(k) clearance from the FDA to market and sell the first product made with Vytex NRL, the new Envy™ condom. The Envy condom will carry labelling that will reflect the lowest antigenic protein content currently available in a natural rubber latex medical device in the US.

The Envy condom labelling notes the protein content at less than 2 micrograms/dm² of the antigenic proteins that can cause an allergic response. This is significant because Envy is the only product in the marketplace with this level of protein claim.

In July 2009, Vystar and Alatech received clearance from the FDA to market and sell an exam glove made with Vytex NRL, which is expected to be available in late 2009.

Which are the key export markets?

Latex as a raw material is a US\$ 2.5 billion industry worldwide. Our customers are located all over the globe. Our key markets include Southeast Asia – where the majority of latex manufacturing occurs – as well as Europe and North America, where many of the consumer and medical product manufacturing companies are based.

Please tell us about Vystar's marketing and distribution networks.

Centrotrade Minerals and Metals is the exclusive distributor of Vytex NRL in North America and Europe. Vystar benefits from Centrotrade's expertise in logistics and distribution. Currently, Vytex NRL is exported all over the world from Malaysia. For countries outside of North America and Europe, we address exporting Vytex NRL on a case by case basis.

As we saw exports grow to areas where tariffs were

cost-prohibitive, we have made the move to start development for those areas. Vystar currently works with Revertex Malaysia for the other areas.

Any plan to expand your company's presence in China and India?

Demand for latex is key in our expansion plans. Plans are being developed on how best we can service the local Indian markets by processing Vytex NRL in India. KA Prevulcanised Latex Pvt. Ltd. (KAPVL) is highly regarded for its latex processing capabilities and is well-established with local manufacturers, and we value our relationship with the company.

KAPVL is the Indian licensee for Revertex Prevulcanisation Technology. Furthermore, during the development phase Dr R.K. Matthan as Adviser to Revertex Sdn Bhd, Malaysia and Managing Director of Revertex - KA Prevulcanised Latex India Ltd (now KA Prevulcanised Latex P Ltd) played a key role in the scale up and debugging of the process to achieve viability on a plant scale operation. Dr Matthan, Vystar's Adviser for Latex Technology and R&D, Vystar Corporation and Joseph John, General Manager, KAPVL, a highly experienced plantation and latex processing specialist, are currently validating new process developments in India, so as to further enhance the quality and value of the Vytex Latexes for greater customer (processor) and end user (consumer) confidence.

About R&D at Vystar and the innovative areas of research?

Vystar maintains a very active R&D programme with focus on providing our customers with the best products possible. We are constantly working with our customers to try to understand their needs and requirements, and we work diligently with them to meet their needs. Additionally, we monitor consumer demand and trends to see how we can help offering solutions through our products and services.

What about Vystar's financial performance in 2008?

Vystar is in the process of filing financial documents with the US Securities and Exchange Commission (SEC) to become a public company. The company has filed documents with the SEC to meet regulatory standards and obtain a stock symbol.

Vystar started selling Vytex NRL in the third quarter of 2008. Audited numbers are not yet available.

What is your vision and how do you plan to achieve it?

The strength of Vystar is demonstrated in its signature brand, Vytex NRL. We've implemented a solid marketing campaign to increase awareness of Vytex NRL among key audiences and spread the message about its benefits. We look forward to offering more products in the future and increasing distribution to manufacturers in Asia and beyond.

material is even more critical in producing a product with low antigenic protein levels."

Testing process

After the latex is treated, samples are tested to ensure that 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 D6499-07. Both have been performed on many Vytex samples and products by Donald Guthrie Foundation for Education Research in Sayre, Pennsylvania, USA.

The Modified Lowry test is a chemical analysis test that is recognised 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 analysed 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: 1) Immediately after production, 2) after 21 days of



Envy condom carton: Envy™ is the first product made with Vytex NRL



Revertex Malaysia's manufacturing facility in Johor, Malaysia

Team Vystar: Experienced and dedicated

William Doyle: President and CEO

A dynamic entrepreneur and passionate supporter of innovation and green technologies, William R. Doyle (Bill Doyle, as he is popularly called), is President and Chief Executive Officer of Vystar Corporation. He oversees the operation and strategic vision for the company and is managing its transition from a privately-held company to a public one.

Doyle has co-authored and presented numerous papers about Vytex NRL and has made presentations at international conferences including the International Latex Conference, the Japan Rubber Association and the forthcoming Smithers-RAPRA Latex 2010 Conference in Amsterdam, Netherlands.

Doyle was originally part of the Vystar team where he served as Senior Vice President of Sales and Marketing and became CEO in 2008 when Honeycutt, who founded Vystar retired.

Prior to joining Vystar, Doyle was Vice President of Marketing, Women's Health for Matria Healthcare, Inc. (now Alere) where he spearheaded the initial branding efforts and held responsibility for sales development, training, public relations and marketing. He has worked in many aspects of healthcare for more than 25 years encompassing manufacturing, sales, marketing and advertising with such companies as Isolyser Company, Inc.; McGaw, Inc.; Lederle Laboratories (now Wyeth); and in an advertising capacity for Novartis Ophthalmics.

Doyle is a member of the Board of Directors of the Georgia Chapter of the March of Dimes where he is a past Chairman of the prematurity campaign. He holds a Bachelor of Science in Biochemistry from Penn State University and Master of Business Administration from Pepperdine University's Graziadio School of Business and Management.

Sandra Parker:

Executive Vice President, Marketing and Business Development

A healthcare industry professional with more than 25 years of sales and marketing management experience and a former nurse, Sandra Parker knows firsthand the wide applications for latex and the fears associated with latex allergy. She is responsible for business development, strategic planning, and marketing for Vystar. These duties include brand development and positioning, identification of new customers and markets, and creating channel strategies and relationships.

Parker has worked for leading medical companies such as McKesson, Teleflex and Kimberly-Clark and previously served as senior manager for Kimberly-Clark, where she managed the company's expansion into surgery centre, physician, dental, EMS, and other non-hospital markets. She is active in the industry organisation, Professional Women in Healthcare, and is a graduate of Jackson Memorial School of Nursing in Florida.

Matthew Clark: Vice President, Technical Sales

A dedicated professional who has been with the company since its inception, Matthew Clark brings a sharp, technical acumen, deep knowledge base and genuine energy to Vystar. As Vice President of Technical Sales, Clark is responsible for day-to-day Vystar operations as well as intellectual property, trademark and product development. He is a co-patent holder on the process to reduce the allergenicity of natural rubber latex prior to vulcanisation and an active participating member in ASTM D.11 on Rubber.

Clark is the primary contact for latex manufacturers and he oversees the technical, sales and customer service benefits for manufacturers. He is an active participant at international industry conferences and co-author of four technical papers on Vytex NRL. Prior to joining Vystar, Clark had supervisory roles at Isolyser, Globe Ticket and Label Company. He is a graduate of Gwinnett Technical Institute.

Dr.R.K.Matthan:

Technology and R&D Advisor

Dr. Matthan has worked with leading latex companies and research institutions in Asia, especially Malaysia. He is also associated with latex companies in C.America and Korea. His current work on the pressurised incorporation of inline deagglomerated nano chemical dispersions into latex has shown promise in the significant improvement of barrier and strength characteristics of very thin latex films for medical devices. He serves on the Research Advisory bodies of leading Institutions in India engaged in rubber research and innovation



Bill Doyle shows some of the locations in a world map where Vystar is conducting manufacturing trials



Vytex glove: The first glove made with Vytex NRL

storage and 3) after 6 months of storage.

Positive results

Vystar is working with two top-tier American medical schools to conduct an accredited, scientific human skin study to test the effect of Vytex NRL on latex-allergic patients (Type 1 – Immediate or IgE antibody-mediated allergic reactions) and the allergenic potency of raw ammoniated natural rubber latex and Vytex NRL in latex-sensitive individuals.

"We are also 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," Vystar President told *Rubber Asia*.

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 frequently exhibited 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.

Tie-up with Revertex

Vystar has a non-exclusive toll manufacturing agreement with Revertex Malaysia for the commercial production of Vytex NRL. "Revertex is the world's largest producer of pre-vulcanised rubber latices and post-vulcanisable latex compounds and is well-known for producing high quality latex compounds. We value the company's knowledge, expertise and technical support," Doyle said.

"Revertex has sufficient processing capacity to meet our current production needs. As the worldwide demand continues to grow, Revertex has the ability and has committed to grow with us to ensure product demand is met. Vytex NRL is derived from natural rubber latex, so as long as NRL is processed, Vytex NRL is available for processing," he added.

New Vytex NRL grades

Vytex NRL is commercially available in both high and low ammonia grades. "We work closely with our customers to ensure their specific needs and requirements are met," he said. Vytex NRL has many outstanding features in addition to having significantly fewer proteins. For example, condoms and adhesives made with Vytex are whiter than non-Vytex NRL condoms. Foams made with Vytex are virtually odour-free compared to foam made with non-Vytex *Hevea* NRL. Vytex NRL has been designed as a "drop in" material for traditional latex or synthetic



Revertex is a division of Yule Catto & Company and is the world's largest producer of prevulcanised rubber latices

Milestones of growth

- 2000 : Vystar Corporation founded by Travis Honeycutt.
- December 2005 : William Doyle named President of Vystar.
- June 2006 : Vystar awarded U.S. patent #7,056,970 for Vytex technology.
- March 2007 : Vystar named a "Top 10 Technology Company" by the Technology Association of Georgia.
- April 2008 : Vystar Corporation signed agreement with Revertex Malaysia to produce Vytex NRL. William Doyle becomes CEO of Vystar.
- October 2008 : Vystar completed its third round of funding with investments coming primarily from physicians.
- November 2008 : Vystar filed initial S-1 documents with SEC to begin public listing process.
- January 2009 : Vystar signed agreement with Centrotech Minerals and Metals, Inc. and Centrotech Deutschland, GmbH, to distribute Vytex NRL to manufacturers in North America and Europe.
- May 2009 : Vystar Corporation and Alatech Healthcare, LLC received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market and sell Alatech's Envy™ condom manufactured with Vytex NRL.
- July 2009 : Vystar Corporation and Alatech Healthcare, LLC received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market and sell the first exam glove manufactured with Vytex NRL.
- October 2009 : Envy condom is launched to consumers and distributed to thousands of participants at the Atlanta AIDS Walk.
- November 2009 : Alatech plans to launch exam glove made with Vytex NRL.

substitutes, so manufacturers upgrading to Vytex find it easy to work with and enjoy a point of differentiation due to reduced allergenic properties and the opportunity to "ingredient brand" their products with the "Made with Vytex" claim.

"We are also actively researching several prevulcanised versions of Vytex NRL," the President added

FDA nod for products

Vystar and Alatech Healthcare LLC are introducing the first consumer product made with Vytex NRL: the Envy™ condom. Vystar and Alatech distributed thousands of condoms at the Atlanta AIDS Walk in October and donated more than 10,000 condoms to AID Atlanta, a non-profit organisation that provides educational programmes and resources on HIV/AIDS and is one of the largest AIDS service organisations in the United States.

The Envy condom is available for purchase online at Condomania.com and will soon be available in select retail locations.

Vystar and Alatech received 510(k) clearance from the U.S. FDA to market and sell the first exam glove made with Vytex NRL. Both the Envy condom and the exam glove are manufactured by Alatech Healthcare LLC in Eufaula, Alabama.

In addition, Vystar has more than 55 manufacturing trials worldwide for numerous products, including condoms; catheters; foam mattresses and pillows, elastic threads for use in clothing and textiles, balloons, surgical gloves, exam gloves, adhesives used in food packaging and envelopes, adhesive bandages and surgical dressings.

The Vytex technology has been issued multiple US and international patents covering the reduction of allergenicity prior to vulcanisation, and has several others pending, according to Bill Doyle. ■