Vytex™ Natural Rubber Latex: A Proposed Industry Standard for the Manufacture of Commercial Natural Rubber Products

Travis Honeycutt[a], Mark Swanson[b], William Doyle[a], Matthew Clark[a], and Russell Culp[a]

[a] Vystar Corporation, 3235 Satellite Boulevard, Building 400, Suite 290, Duluth, GA 30096
[b] Quan-Tec-Air, Inc., 2206 Deru Lane SW, Rochester, MN 55902

BIOGRAPHICAL NOTE

William R. Doyle is the President and Chief Operating Officer of Vystar Corporation and member of the Board of Directors. Mr. Doyle had most recently served as Vice President of Marketing, Women's Health for Matria Healthcare, Inc., a disease management company. Mr. Doyle spearheaded the initial branding efforts at Matria as well as held responsibility for sales development, training, public relations and marketing. He has worked in many aspects of the healthcare industry for over twenty years, encompassing manufacturing, sales, marketing and advertising. In addition to Matria, he has experience with such companies as Isolyser Company, Inc., McGaw, Inc., Lederle Laboratories (now Wyeth), and in an advertising capacity for Novartis Ophthalmics. He holds a Bachelor of Science in Biochemistry from Penn State University and a Master of Business Administration from Pepperdine University.

ABSTRACT

Vytex™ natural rubber latex (NRL) is a new product designed to offer a standardized source material for the production of natural rubber products using chemically modified NRL to reduce its allergenic properties. Vytex NRL is a commercially available latex source that is significantly reduced in the antigenic proteins that can cause latex allergy. It can be used in a wide array of commercial applications. The patent protected method of protein removal is achieved by the introduction of aluminum hydroxide, a well known protein binding chemical, to NRL source material. The result is Vytex NRL, a low antigen/protein product considered desirable for manufacture of items containing NRL. Integration of Vytex in an existing manufacturing environment without the need to invest in additional equipment is one of the advantages, which also include chemical and physical properties of Vytex products demonstrating similar or superior performance characteristics when compared to untreated NRL or synthetic products, respectively. Vytex is only slightly more expensive than traditional untreated NRL sources and is competitive with, and often less expensive than, many "natural rubber free" or synthetic alternative materials.

INTRODUCTION

Hevea brasiliensis natural rubber latex as a protective material has a long history of usage dating back to the 1800s. The widespread use of barrier NRL articles like gloves and condoms increased tremendously in the 1980s primarily due to the "universal precautions" policy outlined by the Centers for Disease Control. NRL's popularity and longevity can be attributed to several factors. The physical properties of NRL are superior to non-latex synthetic products. Field latex, the feedstock material for NRL that traditionally was sourced primarily in Malaysia and Thailand, is now available in several new regions around the world including India and China. NRL is significantly less expensive than most petroleum-based synthetic materials whose cost continues to rise and fluctuate with the rising cost of crude oil. The availability, ease of production and the performance of NRL products continue to make NRL the chosen material by manufacturers and users among industry and medical professionals. Today, there are over 40,000 commercially available products made from natural rubber latex.[1] A concern with NRL continues to be its potential involvement with adverse health effects due to the antigenicity of NRL products. An intuitive means of controlling this parameter in the NRL source material is by de-proteination / protein modification. Validation of this process can be achieved by specific methods of protein quantification.

Although the first description of an allergic reaction to latex gloves appeared in the American Literature in 1933[2] when usage was slight, the majority of latex allergic reactions were documented in the late 80s and throughout the 90s and 2000s. Published data indicate 17% of American healthcare workers and up to 73% or more of frequently exposed patients, such as those with spina bifida, were sensitized to latex proteins.[3,4]

Several attempts, including new source crops, synthetic lattices and various treatment methods, have been made to eliminate these problem proteins from *Hevea* NRL by biological, physical and / or chemical methods that affect the complex acid-base behavior of proteins. One approach has been to introduce the latex articles to multiple leaching steps and chlorination. This approach does reduce the protein levels in the finished product; however it weakens the latex film thus compromising the physical properties of the product.[5] Another attempt to reduce proteins in NRL is the use of proteolytic enzymes to degrade the proteins in the latex solution. The issue with this approach is the introduction of another protein (the enzyme) to the latex, which may itself be allergenic.[5] The most logical solution is the use of low-protein latex, such as Vytex as this approach will more than likely reduce the possibility for an allergic response in the end user of the finished product.[6] If high levels of protein are not present in the raw material they cannot appear in the manufactured product.[7]

Two other non-*Hevea* NRL materials have been attempted to be commercialized in the US; guayule rubber latex and Taraxacum kok-saghyz, also known as the Russian dandelion. These materials are reported to be higher in cost compared to natural rubber and presently are available only in limited quantities. *Hevea* NRL has been around for more than a century and its antigenic proteins have been thoroughly researched. The allergenic properties and economic viability of latex from the guayule & Taraxacum kok-saghyz have yet to be scrutinized in the way that *Hevea* has been. Being natural products, both of these materials have their own unique set of proteins with potential allergenic behavior not yet understood.

VYTEX NATURAL RUBBER LATEX- A MODIFIED AND DEFINED NRL SOURCE

Vytex NRL is the result of rigorous research and development which began seven years ago and has resulted in two patents, with additional patent filings submitted and pending. Vytex NRL was first introduced at the International Latex Conference (ILC) in July, 2005 (Charlotte, NC), followed by presentations at Smithers Rapra's Latex and Synthetic Polymer Dispersions Conference, Latex 2006 in January (Frankfurt, Germany), and The Malaysian Rubber Glove Manufacturers' Association (MARGMA) in September, 2006 (Kuala Lumpur, Malaysia). Most recently, Vytex was featured in the Technology Trends section for Protein Issues as part of Revertex (Malaysia) Sdn Bhd presentation at ILC in August, 2007 (Las Vegas, NV).

The literature clearly describes the natural rubber latex proteins' affinity for USP absorbable dusting powder. Several papers have been presented on this subject confirming this interaction. The United States Food and Drug Administration (FDA) recognize this association and recommend a limit of powder and extractable protein per glove. Allergen-laden glove powder is implicated as a major contributor to the widespread sensitization to NRL and associated workplace symptoms wherein the powder acts as a vector to spread the proteins.[8] It is this powder/protein relationship that led to trials of the inclusion of insoluble aluminum hydroxide ($Al(OH)_3$) powder in the formula for Vytex production. It was hypothesized and later confirmed that under certain conditions, $Al(OH)_3$ produced protein complexes that could be removed from the Vytex NRL liquid solution using existing industry practices.

The production of Vytex NRL relies on the patent protected process involving the effective exchange of proteins from the field latex sap emulsion to $Al(OH)_3$. $Al(OH)_3$ is the most stable form of aluminum under normal conditions. It is commonly used as an absorbent, emulsifier, ion exchanger and antacid.[9] Aluminum hydroxide is used in the purification of water because it can form a jelly-like structure suspending any unwanted materials in water including bacteria.[10] $Al(OH)_3$ is an amphoteric substance, meaning it can react as either an acid or base and readily shares electrons with proteins.

As previously stated, Vytex NRL is created at the latex processor which takes place primarily in Southeast Asia and the surrounding regions. The crop flourishes in regions within about 5° to 10° of the equator and at moderate elevations.[11] The production of Vytex NRL can be easily integrated at the latex processor level without the capital need for any special or additional equipment. There are well over 6,000 processors of NRL worldwide with the majority located in SE Asia. Vystar is working with Revertex (Malaysia) Sdn Bhd, to introduce Vytex NRL commercially.

Products that can be made from Vytex NRL are expansive and include examination and surgical gloves, condoms, cold seal and pressure sensitive adhesives, breather bags, latex tubing and probe covers. Additional work is on-going to determine the benefits of using Vytex NRL in other medical and non-medical

products. Vytex NRL is only slightly more expensive than traditional NRL, and is priced comparable to, and in many cases less expensive than, nitrile synthetic alternative materials. Further, Vytex NRL provides significant cost value when compared to neoprene, guayule and synthetic poly-isoprene lattices. Prices for all the aforementioned materials are subject to change by market fluctuations

HEVEA VS VYTEX™ NRL PROTEIN DETERMINATION

Hevea NRL proteins are measured by accredited test methods. The most frequently used test methods include the Modified Lowry ASTM D5712-05 (Lowry) and ELISA Inhibition ASTM D6499-03 (ELISA), both performed by Donald Guthrie Foundation for Education Research in Sayre, PA. These test methods have unique sensitivities and specificity. They measure total protein and antigenic protein, respectively.[12]

The Lowry test involves the reaction of latex proteins with an alkaline copper tartrate compound and the subsequent reaction of the protein-copper tartrate complex with Folin reagent, resulting in a blue color read using a spectrophotometer at 700 nm.[13] The Lowry test is subject to interference by chemical accelerators, such as carbamates, thiurams, benzothiazoles and guanidines, used in the production of latex gloves and phenolic chemicals naturally found in latex.[14,15,16] The Lowry test has been standardized as an ASTM test method D5712-05 for the analysis of protein in NRL and is recognized by the FDA for determination of protein levels in medical gloves.

The ELISA inhibition test measures NRL antigens by using latex-specific antibodies collected from hyperimmunized rabbits.[16] This immunochemical method is much more sensitive and reproducible than the Lowry test. It also does not suffer from the limitations of interferences as does the Lowry test. The FDA does not allow protein level claims below 50 micrograms per dm^2 of glove. This value has no established biological relevance but is used because of the reportable limit of detection of the Lowry method.

The ELISA test is designed and performed to quantify native NRL proteins in an ammoniated state. Vytex NRL film extracts consistently yield low total protein and antigenic protein content using the ASTM methods, however reproducibility issues and divergent values were commonly observed due to protein modification. The Lowry does not have the required sensitivity and the ELISA is prone to variable protein hydrolysis occurring during Vytex formulation which causes anomalies in antigenic protein detection. It is worth noting that donning powder can create false positives and interfere with enzyme assays (ELISA) to some degree in research laboratories.[17] Therefore, the Vystar Technical and Production Staff has devised a Standard Operating Procedure (SOP) that yields Vytex NRL with a negligible amount of $Al(OH)_3$ powder in the latex that can be used for the manufacturing of a wide variety of NRL products.

In an on-going effort to further describe Vytex NRL throughout its formulary process, we subjected several Vytex unleached film extracts to direct spectrophotometric testing at 280nm. At this wavelength, absorbed proteins can be read directly from the extract. This assessment of protein has the ability to measure all proteins including any morphed proteins no longer immuno-reactive (recognized by the ELISA antibodies). The utility of this method will rely on acceptable sensitivities and freedom from interferences. Preliminary 280nm data are consistent in a downward trend in measured protein content demonstrating reasonable reproducibility.

Table 1: Spectrophotometric testing of 280nm and antigenic protein in Vytex NRL films versus *Hevea* NRL films.

Sample ID	*Vytex A (aged for 1 month)*	*Vytex B (aged for 1 month)*	*Control*
ELISA ASTM D6499-03 (ug/ml)	1.97	1.27	11.2
ELISA ASTM D6499-03 (ug/g)	9.8	6.3	56.3
% Decrease vs. Control Avg of ug/ml & ug/g	83%	89%	n/a
O.D 280 nm (ug/g)	0.25	0.18	2.01
% Decrease vs. Control	88%	91%	n/a

(Results provided are an average of four test film samples)

MATERIALS AND METHODS

One metric ton each of two Vytex NRL variants was prepared at Revertex (Malaysia) Sdn Bhd using a scale-up process ready for commercialization and distributed to selected industrial working partners. Both Vytex NRL variants used for production included the same amount of $Al(OH)_3$ with the difference being fresh vs. aged and when $Al(OH)_3$ was added to the latex. These samples are designated as "Vytex A" & "Vytex B" respectively. It is important to note that Vytex was prepared on a commercial scale and was scrutinized against a double centrifuged *Hevea* NRL sample designated as "Control". The double centrifuge process is a popular approach taken by suppliers of latex rubber seeking to separate latex protein from latex rubber. This method is reported to reduce proteins levels by 50% compared to single centrifuged latex.[5] The double centrifuge process yields a highly purified *Hevea* latex concentrate prepared by re-centrifuging the first centrifuged latex which has been suitably diluted. Films prepared from double centrifuged latex typically exhibit excellent clarity, low water absorption and high dielectric properties[18]. The objective of this work is to examine and compare various types of products made from Vytex NRL to products made from twice centrifuged "purified" *Hevea* under the same processing conditions.

The colloidal properties were tested on the freshly prepared Vytex NRL and the control *Hevea* NRL then again after the lattices had matured for 21 days. The results of Vytex A, Vytex B and the control are listed in Table 2.

Table 2: Colloidal properties on fresh and aged Vytex NRL and *Hevea* NRL.

Test parameter		*TSC (%)*	*NH_3 content (%)*	*VFA no.*	*Free Mg^{2+} (ppm)*	*Viscosity, cPs (sp 2/60)*	*MST (sec)*	*pH*	*Coagulum (mesh # 80/325) ppm*
	Initial Field Latex	37.57	0.36	0.021	145	n/a	n/a	10.47	n/a
Vytex A & B (Pilot Scale) (fresh)	Vytex A	61.52	0.73	0.017	nil	58	240	11.08	36 / 136
	Vytex B	61.48	0.71	0.018	nil	58	480	11.05	20 / 45
	Control	61.52	0.77	0.015	nil	87.5	300	11.01	8 / 31
Vytex A & B (Pilot Scale) (after 21 days maturation)	Vytex A	61.5	0.79	0.015	nil	56	2,160	11.32	18 / 89
	Vytex B	61.48	0.78	0.016	nil	66	2,627	11.4	12 / 91
	Control	61.52	0.75	0.015	nil	117.5	840	10.98	12 / 19

The colloidal property results from the Vytex NRL pilot trial were deemed acceptable by industry standards, and therefore the lattices were compounded by standard additives, which are commonly used to produce surgical gloves.

SURGICAL GLOVES MADE FROM VYTEX NRL

Surgical gloves were coagulant dipped at Revertex (Malaysia) Sdn Bhd Technical Center from all three compounds and were evaluated (Table 3) for physical property measurements according to ASTM standards.

Table 3: Physical properties of surgical gloves made from Vytex and *Hevea* NRL.

Test Parameter		*Vytex A*	*Vytex B*	*Control*
Unaged	Modulus @ 700% (Mpa)	13.1	11.8	15.6
	Tensile Strength (Mpa)	22.9	26.9	29.1
	Elongation @ Break (%)	834	878	845
Aged (100°C @ 22 hrs)	Modulus @ 700%	8.3	6.5	9.5
	Tensile Strength (Mpa)	27.4	25	24.2
	Elongation @ Break (%)	913	941	904

The physical properties of both Vytex A & B were within industry specifications. Vystar believes the reason why surgical gloves made from Vytex NRL demonstrate good stability upon aging is that the $Al(OH)_3$ removes and deactivates those molecular species vulnerable to free radical breakdown. Protein results listed below in Table 4 appear to support this theory.

Table 4: ELISA and Lowry test results for surgical gloves made from Vytex NRL versus *Hevea* NRL.

Sample ID	*ASTM D6499-03 ELISA (ug/ml)*	*ASTM D6499-03 ELISA (ug/g)*	*% Decrease vs. Control ELISA Avg. of ug/ml & ug/g*	*ASTM D5712-05 Lowry (ug/ml)*	*ASTM D5712-05 Lowry (ug/g)*	*% Decrease vs. Control Lowry Avg. of ug/ml & ug/g*
Vytex A-Unleached	1.1	5.7	91%	18	78	89%
Vytex A-Wet Leached	1.8	9.0	94%	24	110	82%
Vytex A-Post Leached	1.9	9.4	91%	21	100	87%
Vytex B-Unleached	1.7	8.7	87%	15	78	90%
Vytex B-Wet Leached	1.8	9.2	93%	14	68	89%
Vytex B-Post Leached	0.7	3.4	97%	<8.3	<42	>95%
Control-Unleached	13.1	65.7	n/a	157	770	n/a
Control- Wet Leached	28.1	140.6	n/a	126	645	n/a
Control-Post Leached	20.6	103.2	n/a	154	795	n/a

CONDOMS MADE FROM VYTEX NRL

Hevea NRL condoms are produced in very large numbers on highly automated production lines. This industry relies almost exclusively on *Hevea* natural rubber latex since its ability to form smooth, continuous films on drying and exhibits high strength and elasticity when vulcanized and leached. A straight dipped production process is typically used for the production of condoms where a suitably shaped former is immersed in a latex mix and withdrawn, usually twice dipped, to produce a uniform layer of latex on the former. The latex deposit is dried and vulcanized before removal from the former[19].

A suitable mixture of compounding ingredients was used for all samples to ensure colloidal stability of the latex during processing. These properties are expressed in Table 5 below:

Table 5: Influence of compounding ingredients on Vytex NRL and *Hevea* NRL.

Test parameter	*Control Uncompounded*	*Control Compounded*	*Vytex A Uncompounded*	*Vytex A Compounded*	*Vytex B Uncompounded*	*Vytex B Compounded*
pH	10.82	11.24	11.43	11.05	11.22	10.77
Viscosity (cp)	69	94	70	18.5	68.5	20
MST (secs)	553	128	1,285	151	1,412	129
TS (%)	61.5	49.4	59.1	50.6	59.8	50.4
ZOV@60min. (cp)	268	NA	56	NA	56	NA

The production trial of condoms made from Vytex NRL was conducted at Alatech Healthcare, a large commercial manufacturer of condoms in the US with annual capacity exceeding $1 billion condoms. To prepare for dipping, the latex compounds were adjusted to 50% total solids. Using a clean straight wall condom former for two straight dips for each sample, the former was dipped into the respective latex compound and dried for 5 minutes @125° C. Next, the former was cooled at room temperature for 2 minutes then dipped again into the latex compound. This dip was followed by a drying time of 2 minutes @125° C then the bead was rolled. After drying, the new created condom was cured for 25 minutes @125° C. The leaching was performed in hot water (93° C) for 1 minute. After leaching, the condoms were dried for 3 minutes @125° C, then cooled at room temperature for a brief period. Next, the condoms were stripped from the former using dry starch powder. Finally the condoms were tested for physical performance (Table 6) and were packaged separately and sent to Guthrie for ELISA and Lowry protein testing with results expressed below in Table 7.

Table 6: Physical properties of condoms made from Vytex and *Hevea* NRL.

Test Parameter		*Vytex A*	*Vytex B*	*Control*
Unaged	Modulus @ 500% (Mpa)	1.4	1.4	1.5
	Tensile Strength (Mpa)	16.7	17.5	16.2
	Elongation @ Break (%)	887	864	846
Aged (100°C @ 22 hrs)	Modulus @ 500%	1.6	1.7	1.8
	Tensile Strength (Mpa)	19.4	18.9	13.5
	Elongation @ Break (%)	839	864	758

Table 6 illustrates that condoms made from Vytex NRL were 30% stronger than condoms made from *Hevea* NRL when aged and demonstrated much better resistance to aging compared to *Hevea* NRL condoms.

Table 7: ELISA and Lowry test results for condoms made from Vytex NRL versus *Hevea* NRL.

Sample ID	*ASTM D6499-03 ELISA (ug/ml)*	*ASTM D6499-03 ELISA (ug/g)*	*ASTM D5712-05 Lowry (ug/ml)*	*ASTM D5712-05 Lowry (ug/g)*
Vytex A	b.d (Below Detection)	<0.2	b.d (Below Detection)	<47
Vytex B	b.d. (Below Dection)	<0.2	b.d (Below Detection)	<47
Control	1.2	6.1	12	60

**The ELISA results indicate > 97% reduction in antigenic protein for the Vytex NRL condom sample*

ADHESIVES MADE FROM VYTEX NRL

Natural rubber latex was the first polymer to be used to produce pressure sensitive adhesives (PSA). NRL has inherent advantages when used in pressure sensitive and contact adhesive formulations. NRL has a very low glass transition temperature (Tg) and also low surface energy which enables it to flow over surfaces very effectively, a key attribute of PSA. Furthermore, NRL's extremely high molecular weight gives it high internal strength preventing it from splitting during removal. The high molecular weight of NRL makes it the only material that can function as a "cold seal" contact adhesive at room temperature. This is made possible because the low Tg and surface energy allow rubber films to flow cold very well while the mixing of the polymer chains is retarded by molecular weight.

Some disadvantages of NRL are its ability to oxidize and become embrittled, loosing its tack and adhesion properties over time and its ability to "sensitize" skin as a result of allergic reactions. Oxidation is dealt with through use of anti-oxidants. Sensitization can be overcome with the use of a low protein starting NRL such as Vytex NRL, as it is understood that if high levels of protein are not present in the raw material they cannot appear in the manufactured product.[7]

The objective of this phase of testing was to formulate cold seal (contact) and pressure sensitive adhesives using Vytex NRL and a *Hevea* natural rubber latex sample formulated for an adhesive compound and to conduct appropriate comparative testing for each sample. Testing was performed at National Polymer Laboratory, a custom manufacturing company focusing on polymeric materials in the fields of adhesives, coatings and nanocomposites. Test results are expressed in Table 8.

During the formulary process, one particular observation regarding Vytex NRL and the *Hevea* control NRL samples was the smoothness of the Vytex NRL sample, which is attributed to improved stability. This can eliminate the need for filtering during compounding and assist in the adhesive coating process downstream.

Table 8: Physical properties of cold seal and pressure sensitive adhesives made from Vytex and *Hevea* NRL.

Test Parameter	*Cold Seal Control*	*Cold Seal Vytex A*	*Cold Seal Vytex B*	*PSA Control*	*PSA Vytex A*	*PSA Vytex B*
Brookfield Viscosity centipoise (cps)	1,200	1,200	1,400	2,600	2,200	2,400
Coat Weight (grams per $in.^2$)	24.8	36.4	35.0	38.0	35.8	25.9
Thickness (mils)	1.0	1.4	1.4	1.5	1.4	1.0
pH	10	10	10	9	9	9
T-Peel ASTM D-1876 (Avg) units: (# / lineal in.)	1.0	1.0	0.9	n/a	n/a	n/a
(Standard Deviation) (σ) 1 min. Substrate: Face to Face*	0.4	0.4	0.2	n/a	n/a	n/a
Peel Adhesion ASTM D-3330 (Average) units: (# / lineal in.)	n/a	n/a	n/a	3.3	5.2	4.0
(Standard Deviation) (σ) 180^o Peel 1 min. Substrate: Stainless Steel	n/a	n/a	n/a	0.3	0.1	0.3
Loop Tack ASTM D-6195 (Average) units: (# / in^2.)	2.7	n/a	3.3	37.5	n/a	36.8
(Standard Deviation) (σ) Substrate: Stainless Steel	0.4	n/a	1.6	3.4	n/a	3.5
Shear (minutes) ASTM D-3654 (Average) units: (minutes)	n/a	n/a	n/a	>10,080	n/a	>10,080
Storage Modulus @-120°C (Mpa)	2,175	n/a	2,085	2,683	n/a	2,959
Onset Tg°C	-71.82	n/a	-73.66	-64.41	n/a	-64.06
Peak Tg°C	-66.20	n/a	-65.37	-53.09	n/a	-58.07

**Face to Face= Adhesive to Adhesive*

It is concluded that low protein Vytex NRL can be substituted for versions of untreated *Hevea* NRL weather treated or not in the production of cold seal and pressure sensitive adhesives without compromising the physical performance of the resultant products. The use of the low protein NRL for adhesive applications is of particular importance because post leaching techniques commonly used for the removal of water soluble materials are not applicable for these product applications.

BREATHER BAGS, TUBING AND PROBE COVERS MADE FROM VYTEX NRL

Several additional medical products have been produced from Vytex NRL. The aim of this work was to coagulant dip breather bags and tubing and to straight dip probe covers using Vytex NRL under manufacturing conditions used to produce products made from *Hevea* NRL. This work was performed by Diptech Systems, Inc. The protein results are illustrated below in Table 9.

Table 9: ELISA and Lowry test results for products made from Vytex NRL.

Sample ID	*ASTM D6499-03 ELISA (ug/ml)*	*ASTM D6499-03 ELISA (ug/g)*	*ASTM D5712-05 Lowry (ug/ml)*	*ASTM D5712-05 Lowry (ug/g)*
Breather bags made from Vytex NRL	b.d (Below Detection)	<0.2	b.d (Below Detection)	<42
Tubing made from Vytex NRL	b.d (Below Detection)	<0.2	b.d (Below Detection)	<42
Probe covers made from Vytex NRL	0.1	0.4	b.d (Below Detection)	<42

CONCLUSION

Suppliers and manufacturers of natural rubber latex have acknowledged the need and importance of reducing the antigenic properties of NRL products. Recognizing this need and understanding NRL proteins' affinity to powder, Vystar Corporation patented a process that introduces insoluble aluminum hydroxide powder into liquid latex that complex and removes proteins and unwanted impurities thus creating Vytex, a low protein chemically-modified NRL source material. Vytex NRL has been produced at the latex processor's manufacturing environment and can be easily intergraded into the current processing scheme without the capital need to acquire additional equipment. Since a significant amount of proteins are removed during Vytex processing, manufacturers seeking to reduce their protein leaching times now have a viable option to do so with the use of low protein Vytex NRL. This is of particular importance in the production of adhesive materials where post leaching techniques are not available.

Vytex NRL has been used to make a wide array of medical and non-medical products and continues to be trialed by several specialized manufacturing companies. Resultant products made from Vytex NRL demonstrate excellent resistance to aging compared to control *Hevea* NRL samples due to the removal of species vulnerable to free radical breakdown confirming that Vytex NRL can be substituted for *Hevea* NRL or synthetic alternative materials when reduced antigenic proteins and good aging characteristics are essential.

Film samples and products made from Vytex NRL have been thoroughly tested using accredited protein testing methods. While results consistently demonstrate significant reduction in protein for products made from Vytex NRL, Vystar Corporation and its Technical Advisors will continue to further validate the low antigenic properties of Vytex NRL to help ensure the advantages of products made from Vytex NRL.

REFERENCES

1. Infection Control Today Magazine, www.infectioncontroltoday.com/articles/051feat2.html
2. Downing J. Dermatis from rubber gloves. N Engl J Med 1933;208:196-8
3. Yassin MS, Lierl MB, Fisher TJ, et al. Latex allergy in hospital employees. Ann Allergy 1994;72:245-9
4. Kelly KI, Pearson ML Kurup VP, et al. A cluster of anaphylactic reactions in spina bifida during general anesthesia. J Allergy Clin Immunol 1994;94:53-61
5. Beezhold D. Methods to remove proteins from natural rubber latex, US Patent 5563241
6. Lovell CR. Relation between Protein Level and Allergic Response. Conference on Latex Protein Allergy, Dec. 6 1993, Amsterdam
7. Cornish K, McMahan C, Xie, W, Williams J, Nguyen K, Kostyal D, Horton K, Marsh T, ASTM D1076 Category 4 Latex and Quantifying Guayule (NRG) and Hevea (NR) Latex Protein.
8. Swanson MC, Olson D, Latex allergen affinity for starch powders applied to natural rubber gloves and released as an aerosol: From dust to don. CND J Allergy & Clinical Immunology Vol. 5, No 8, 2000
9. www.en.wikipedia.org/wiki/aluminum_hydroxide
10. Holtzclaw HF, Robinson WR, Nebergall WH. General Chemistry (7th edition). D.C. HEATH and Company 1984;884-5.
11. Everything Heava Brasiliensis, www.everything2.com/index.pl?node=heava%20brasiliensis Oct.11, 2001
12. Tillotson™ Healthcare Corporation, Technicare™ Bulletin, ELISA- Inhibition Testing of Latex Glove Protein Antigens
13. ASTM Designation D5712-99: Standard Test Method for Analysis of Protein in Natural Rubber and its Products, published September 1999.
14. Interference by detergents, chelating agents, and buffers with the Lowry protein determination. Anal. Biochem. 1973;52:517-521
15. Bensadoun A. Weinstein D.; Assay of Proteins in the Presence of Interfering Materials. Anal. Biochem. 1976;70:241-250
16. ASTM: Standard Test Method for the Immunological Measurement of Antigenic Protein in Natural Rubber and its Products, approved December 1999
17. Kimberly-Clark: Medical Gloves- Powder-Associated Issues- History of Glove Powder
18. http://www.inpol.es/ingles/latex_cn.asp
19. Ir H. Naus, F. Collard, H. te Winkel, Dipping- Production of condoms and gloves, “Information Center for Natural Rubber www.rubber-stiching.info/art7-1nr17.html