Vytex® Natural Rubber Latex: An Eco-Friendly Alternative Raw Material

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ABSTRACT

Vytex® Natural Rubber Latex (NRL), harvested from the *Hevea brasiliensis* tree, has transformed latex using a patented process for the production of an ultra low antigenic protein natural rubber latex raw material. The science and applied technology behind its creation is multi-faceted and includes the use of insoluble aluminum hydroxide ($Al(OH)_3$), well known for its protein binding characteristics, in a proprietary blend.

The colloidal and physical properties of this $Al(OH)_3$ treated latex are presented and compared with standard CL60 lattices. Extensive field, laboratory and end-product manufacturer evaluations have been conducted globally leading to multiple United States Food and Drug Administration (USFDA) 510(k) filings for selected products. Of those submissions, US FDA clearance has been granted for the Envy™ condom, made with Vytex NRL and manufactured by Alatech Healthcare, Eufaula, Alabama. The condom will be available for retail sale in the fall of 2009.

Specific data presented here includes an assessment of total and antigenic protein concentrations at various stages of manufacturing and the attributes of products made with low antigenic protein NRL. Furthermore, the data suggests that manufacturers seeking to provide ultra low protein products can do so while minimizing the costs involved with protein removal through leach tank washing or post-dip processing.

Vytex NRL is currently processed in Malaysia and can be obtained for commercial use or approved field evaluations through Centrotrade Minerals and Metals, Inc., Chesapeake, Virginia, or Vystar Corporation.

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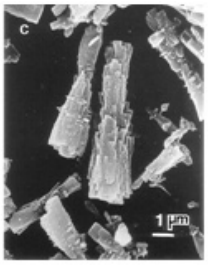
INTRODUCTION

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 protein contents of certain identified proteins. An intuitive means of controlling this parameter in the NRL source material is by de-proteination/protein modification. Quantitative validation of any of these protein removal processes can be achieved by specific methods of protein quantification. Several attempts, including new source crops, synthetic lattices and various treatment methods, have been made to eliminate the proteins from *Hevea* NRL. Biological, physical and/or chemical methods that affect the complex acid-base protein interactions have been evaluated.[2]

One approach is to introduce latex articles to multiple leaching steps and chlorination. This method does reduce the protein levels in the finished product; however it can weaken the latex film, compromising the physical properties of the product.[3] Another method 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) into the latex, which itself may be allergenic.[3] The most practical solution for manufacturers is the use of low antigenic protein latex that will not affect the latex properties, such as $Al(OH)_3$ treated latex. This approach will reduce the potential for an allergic response to the finished product without additional rinsing or leaching or the introduction of outside proteins.

VYTEX NRL TECHNOLOGY

Production relies on the effective exchange of proteins from the field latex sap emulsion to insoluble aluminum hydroxide. $Al(OH)_3$ is commonly used as an absorbent, emulsifier, ion exchanger and antacid.[4] Additionally, it is used in the purification of water because it can form a jelly-like structure suspending any unwanted materials in water, including bacteria.[5] Moreover, $Al(OH)_3$, a well-known protein binding additive, is the most stable form of aluminum under normal conditions. It is an amphoteric substance, capable of reacting as either an acid or base, and thus available for sharing electrons with proteins.[2]



Aluminum hydroxide is mixed into a slurry and strategically introduced into the field latex solution. $Al(OH)_3$ has a very unique and reactive surface area which is full of nooks and crevices. This irregular surface area allows for the effective exchange of proteins and other particulates from the field latex solution to the insoluble aluminum hydroxide crystals which then are removed by filtration and/or centrifugation. This results in a much cleaner latex compound containing significantly fewer latex proteins and impurities. A scanning electron microscopy image of an aluminum hydroxide crystal generated in water is illustrated.[6]

NEW GENERATION FOR NRL PRODUCT CREATION

Vystar's $Al(OH)_3$ treated ultra low antigenic protein latex has undergone more than 50 commercial evaluations in a wide array of products across many different industries. Today it is being used in adhesive and condom applications. Initially, product development efforts were focused on the latex protein allergy issue, however subsequent efforts have yielded a cleaner NRL raw material leading to improved product safety and customer satisfaction as desired outcomes.

To date, well over 500 samples have been analyzed for latex proteins utilizing both the ELISA (ASTM D6499-07) protein method for antigenic proteins and Modified Lowry (ASTM D5712-05) for total extractable protein determination. Results from these tests confirm that the process reduces proteins to levels considered acceptable by the Association of Operating Room Nurses (AORN) and the Malaysian Rubber Board's Standard Malaysian Glove (SMG) program. To further quantify the low antigenic protein content, a revision to ASTM D-1076 test method has been proposed. The proposal includes a new category of *Hevea* natural rubber latex that contains less than 200 $\mu g/dm^2$ of total protein and less than 10 $\mu g/dm^2$ of antigenic protein. Voting on this proposal by ASTM membership is currently in process.

Results from manufacturer's field evaluations revealed $Al(OH)_3$ treated latex was much more than another low protein NRL source material. For instance, while it is absolutely necessary to start with a low protein latex to produce low protein adhesives due to the absence of post leaching, adhesive manufacturers have noted the low odor from products made with ultra low antigenic protein latex. Additionally, due to the removal of proteins and other unwanted impurities inherently present in latex, this treated latex coats more evenly and smoothly compared to *Hevea* NRL. In addition, when sprayed, does not clog the spray heads as standard *Hevea* latex has a tendency to do leading to manufacturing deficiencies and equipment downtime.

Foam and bedding manufacturers have consistently noted the low odor and whiteness of foam products made with $Al(OH)_3$ treated latex. Both of these properties are considered key attributes in most foam production environments. Glove manufacturers have focused their evaluation efforts on testing low antigenic protein latex for protein content at several stages of production. Most notably, gloves made with $Al(OH)_3$ treated natural rubber latex achieve low protein content, even with minimum post leaching. This is important since the majority of the non-raw material costs associated with the production of latex gloves occur from the post dip processes, including post-leaching. The dipping process is extremely automated and requires few employee hours until the gloves are stripped, unlike many post dip processes.

The opportunities for glove manufacturers using ultra low protein latex are the reduced costs in leach water temperature and the cost of potable water. The post dip process removes some proteins but its major function is to remove the unreacted chemicals from the vulcanization process. The potential energy cost savings and water reduction is under investigation by several key glove manufacturers and successful implementation into their processes will allow them cost savings as well as reducing their environmental impact. These key attributes are important and suggest that ultra

low protein latex is the ideal solution not just because of the low protein attributes but also because of its superior line and product performance.

ENVIRONMENTAL IMPACT OF $Al(OH)_3$ TREATED LATEX COMPARED TO SYNTHETIC ALTERNATIVES

Natural rubber latex is an organic substance primarily extracted from *Hevea brasiliensis* rubber trees and can be produced by over 2,000 plant species having a main constituent of poly (cis-1,4-isoprene) a highly unsaturated hydrocarbon.[7] It is well known that natural rubber latex is biodegradable, as is $Al(OH)_3$ treated latex, and can return to nature in as little time as 6 months for a balloon or the time required for an oak leaf to biodegrade in nature.[8] This represents a stark contrast to frequently used synthetic alternative materials made from petroleum derivatives found in many industries today.

Alternative materials to natural rubber latex are available in many forms including polyvinyl acetate and styrene for adhesive applications and polyvinyl chloride, nitrile, chloroprene and polyisoprene used in surgical and exam gloves. Petroleum based synthetic alternative materials are not biodegradable and disposal by incineration releases dioxin, cyanide, vinyl chlorides, hydrogen chloride and other harmful and toxic substances.[9] It has been reported by the Malaysian Rubber Export Council that large-scale use and disposal of synthetic gloves would have an adverse environmental impact.[10] Furthermore, synthetic elastomers used in adhesives contain trace amounts of monomer that releases into the atmosphere as a volatile organic compound (VOC). The availability and usage of synthetic alternative materials directly depends on the availability of petrochemicals such as petroleum, coal, oil and natural gas. The production of natural rubber uses one-tenth of the fossil fuels required to produce synthetic rubbers.[11]

In contrast, $Al(OH)_3$ treated NRL is all natural, biodegradable and renewable, contains no VOCs, is free of known or suspected carcinogens and non-toxic. The process to obtain ultra low protein NRL does not require a large quantity of chemicals for manufacturing and is essentially a pure hydrocarbon material whereby disposal by incineration produces only water and CO_2.

Environmental initiatives to use “Green” products with reduced hazardous ingredients are gaining momentum globally. The State of California Environmental Protection Agency (EPA) enacted Proposition 65 in 1986 requiring public disclosure of chemicals known to the State to cause cancer or reproductive toxicity. The list of chemicals covered under Proposition 65 has grown to approximately 775 chemicals since its inception, including many of the synthetics in use today.

$Al(OH)_3$ treated latex is Proposition 65 compliant, accomplishes green initiatives and provides a healthier environment for workers and consumers. The company’s green process produces an $Al(OH)_3$ treated natural rubber latex substantially free of proteins while retaining all the positive attributes of natural rubber latex thus making it the eco-friendly material of choice over *Hevea brasiliensis* and synthetic alternative materials.

PROTEIN MEASUREMENTS OF NRL SOURCE MATERIALS

Various methods have evolved to estimate the quantity of allergenic proteins in latex materials. Today no assay for allergenic proteins is as sensitive as a highly allergic human. Since all allergens in latex are proteins, there is a relatively strong correlation between the quantity of residual protein in latex and its allergenic potential as noted by the limits imposed by the Malaysian Rubber Board in its SMG program. National standards organizations have developed standardized methods for measuring proteins in latex. Ultra low antigenic protein NRL and products made with this material have been analyzed for protein using the recommended methods and the quantity of residual protein is routinely below the detection limit of the current total extractable protein assay. A limitation of protein assays for natural rubber latex is that while all allergens are proteins, not all proteins are allergens. It is therefore possible to have relatively high levels of non-allergenic proteins with low levels of allergenic or antigenic proteins in a latex preparation and, in such cases; there can be discrepancies between measures of allergenicity and protein content.

The subject $Al(OH)_3$ treated natural latex is the only chemically modified and commercially available NRL source material and, therefore, requires close attention to detail when describing its low protein properties. Since a residual amount of modified protein remains present after processing, it is important to precisely describe the modified nature of these proteins (peptides). The $Al(OH)_3$ treated latex has been tested throughout its development primarily using the ELISA test method (ASTM D6499-07) and the Modified Lowry test method (ASTM D5712-05). Protein testing has been performed by the LEAP Testing Service, Donald Guthrie Foundation for Education Research, an independent testing facility located in Sayre, PA.[2] In addition, several manufacturers currently evaluating Vystar's ultra low antigenic protein NRL have performed their own in-house versions of these ASTM test methods with similar results.

The Modified 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.[12] The Modified 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.[13,14,15] The Modified Lowry 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 sensitivity of the Lowry is roughly 8.3 µg/ml of total protein.

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 Modified Lowry test and does not suffer from the limitations of the Modified Lowry test. The FDA currently does not allow protein level claims below 50 micrograms per dm^2 of total extractable protein in medical gloves. This value has no established biological relevance but is used because of the reportable limit of detection of the Modified Lowry method. The sensitivity of the ELISA is roughly 0.03 µg/ml of antigenic protein in currently available products.

In an effort to further describe $Al(OH)_3$ treated natural rubber latex throughout its production process, we subjected several $Al(OH)_3$ treated latex unleached film extracts to direct spectrophotometric testing @ 280nm at Quan-Tec-Air (QTA), Inc. located in Rochester, Minnesota. 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).[2] The utility of this method relies on acceptable sensitivity and freedom from interference. These data demonstrate a downward trend in measured protein content and reasonable reproducibility. The method is fast, reliable, cost effective and meets the requirements of specificity for total protein measurement and the sensitivity for analytical protein measurement as low as 1µg.

Table 1: Spectrophotometric Testing A_{280}; *Hevea* NRL Films vs. Vytex NRL Films

Sample ID	% Protein Reduction Compared to *Hevea* Control	% Protein Reduction Compared to Prevulcanized *Hevea*
Vytex Lot A	88%	61%
Vytex Lot B	92%	72%

The issues of latex allergy have been addressed in part through education, the use of non-latex alternative materials and by changes in the manufacturing of certain products, i.e. improved leaching conditions for dipped goods. However, natural rubber latex has many unique properties that make it more desirable than the substitutes for many applications, especially for barrier protection from potentially infectious materials. A new raw material with little if any allergen content can potentially reduce the risk of sensitization for individuals using products made with ultra low antigenic protein latex, thereby offering better products for future generations while reducing energy and natural resource consumption.

GLOVES MADE WITH VARIOUS SOURCE MATERIALS

Glove manufacturers are looking at new lattices not only for low protein content but also for the enhanced performance characteristics resulting from ultra low protein latex and the potential cost savings by reduced leaching. Several manufacturers have performed testing at various stages of production including those who perform their own in-house Modified Lowry protein testing to determine how $Al(OH)_3$ treated latex compares with their current NRL source materials. All samples were tested under the same conditions.

Table 2: Asian Glove Manufacturers' Protein Comparison of Incoming Liquid Latex

Source of Current Concentrated NRL	% Extractable Protein (EP) Raw Material
Supplier- A	3.60
Supplier- B	2.82
Supplier- C	2.31
Vytex NRL	1.33

During the 1980s, the incidence of latex allergies in healthcare workers was exacerbated by inadequate leaching whereby today these issues are managed by improved leaching processes and techniques by today's glove manufacturers. Leaching is the process where hydrophilic materials in latex products, such as excess calcium nitrate, fatty acid soaps, other surfactants and water soluble proteins, are removed.[17] Leaching times may last from as little as 10 minutes for thin films on formers (wet gel leaching) to longer time periods up to several hours for gloves washed off the former (post-dipped leaching).[18] Not surprisingly, this time consuming process generates additional manufacturing expense and continues to be investigated by manufacturers seeking to reduce their production costs.

These efforts directed at minimizing production costs and environmental impact have glove manufacturers evaluating $Al(OH)_3$ treated latex at various stages of production to determine if reduced leaching conditions are possible using $Al(OH)_3$ treated latex as the starting feedstock material. It is important to note that these trials were conducted independently at various manufacturing facilities under conditions specific to that particular manufacturer.

Table 3: Asian Glove Manufacturers' Protein Comparison of Vytex and *Hevea* at Various Stages of Production with Different Donning Agents

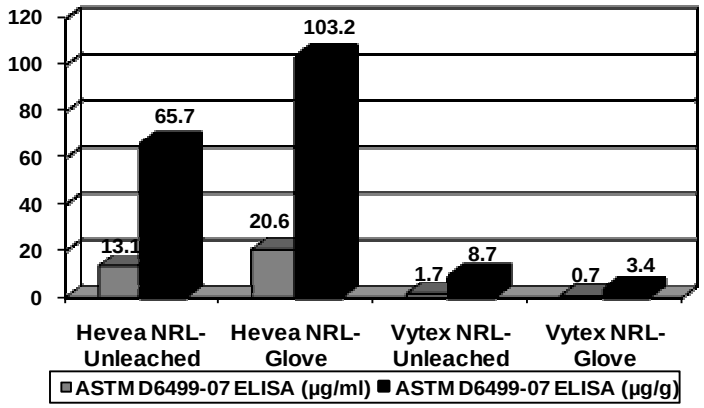
Powdered			
Condition	**Vytex NRL (Powder) (µg/g)**	***Hevea* (Powder) Regular (µg/g)**	**% of Protein Reduction**
Pre & Post Leaching	32.9	180.8	82%
Synthetic Polymer Coated			
Condition	**Vytex NRL (µg/g)**	***Hevea* (µg/g)**	**% of Protein Reduction**
Pre & Post Leaching	71.9	173.6	59%
Post Leaching	96.5	389.3	75%
Pre Leaching	173.1	472.1	63%
Unleached	326.7	665.9	51%
On Line Chlorinated			
Condition	**Vytex NRL (µg/g)**	***Hevea* (µg/g)**	**% of Protein Reduction**
Pre & Post Leaching	42.3	80.9	48%
Post Leaching	88.5	260	67%
Pre Leaching	43.1	156.9	73%
Unleached	86.1	323.9	73%

It was concluded by this manufacturer that examination gloves made with $Al(OH)_3$ treated latex contained significantly fewer proteins when compared to *Hevea* control gloves made under similar conditions at all various stages of production.

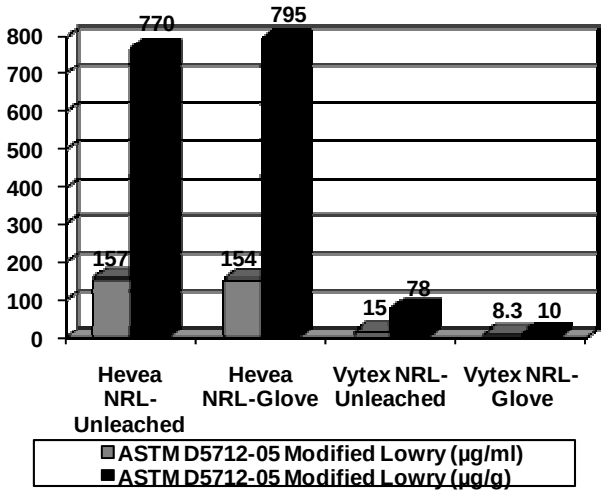
In an attempt to demonstrate the repeatability of achieving low protein gloves at various stages of production, graphs 1-4 below illustrate and suggest that ultra low antigenic protein latex will also achieve low protein content for surgical gloves at various stages of manufacturing.

Surgical Gloves Made from Vytex NRL (Lab Samples)
Total Protein Results for ELISA and Modified Lowry Test

Graph 1: ELISA



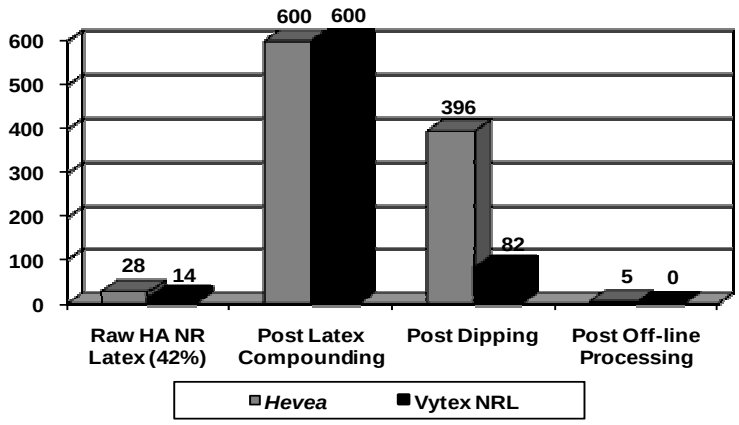
Graph 2: Modified Lowry



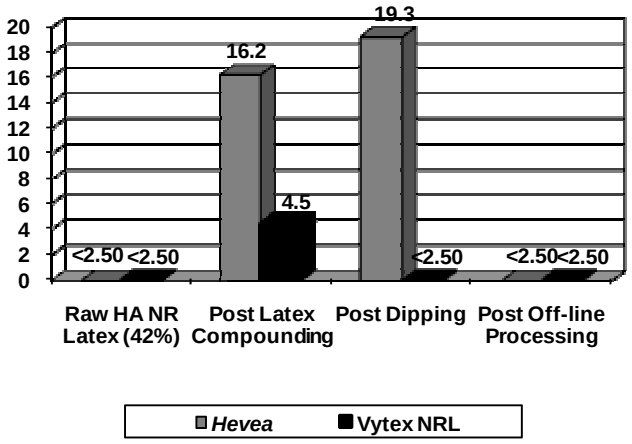
Note: Protein results illustrated in graphs 1 and 2 confirm low protein gloves made with $Al(OH)_3$ treated latex favorably compare to *Hevea* NRL gloves made under similar conditions at various stages of production.

Surgical Gloves Made from Vytex NRL (Glove Production Line)
Total Protein Results for ELISA and Modified Lowry Test

Graph 3: Modified Lowry



Graph 4: ELISA



The production conditions for each trial were unique to each manufacturer. Variables included the compounding ingredients, leach time, water and vulcanization temperatures. Each of these variables can influence the finished glove protein values. Both examination and surgical gloves made with $Al(OH)_3$ treated latex in all manufacturer trials contained significantly fewer proteins than *Hevea* control gloves. This indicates that glove manufacturers using an ultra low antigenic protein latex as their raw feedstock can be within ASTM glove protein compliance with only pre-leaching

thus offering gloves with acceptable protein levels and potentially reducing production costs as well.

Proteins in typical *Hevea* NRL are available at the surface of a glove or film upon drying. The $Al(OH)_3$ treated latex manufacturing process ensures that the majority of the proteins have been aggregated and removed during the production process. This greatly reduces film surface protein availability in gloves made with $Al(OH)_3$ treated latex. This overall protein reduction in the primary source material and throughout all phases of glove production suggests that manufacturers desiring to lessen energy and water usage through reduced leaching can do so.

As a next step to the implementation process, one manufacturer has successfully completed the required biocompatibility testing for a US FDA 510(k) application for a glove made with $Al(OH)_3$ treated latex. It is well known that traditionally compounded latex products cannot pass cytotoxicity testing believed to be due to the presence of high levels of protein. The gloves submitted passed cytotoxicity and other biocompatibility testing required to receive FDA 510(k) clearance. Biocompatibility testing was performed at NAMSA, an independent laboratory located in California.

ADHESIVES MADE WITH $Al(OH)_3$ TREATED LATEX

Natural rubber is generally noted for its excellent flexibility and resiliency making it a valuable natural component in cold seal, shoe, contact and foam fabricating adhesives. Water-based adhesives using *Hevea brasiliensis* natural rubber latex, available commercially at approximately 60% total solids, are widely used for bakery and confectionary packaging, specialty envelopes and labels, and paper banding. The natural latex adhesive is commonly formulated with thickeners, such as cellulose or polyvinyl alcohol, tackifiers, such as aqueous dispersions of hydrocarbon tackifiers or high boiling hydrocarbon solvents, inorganic fillers, and alkali viscosity stabilizers. Additionally, fungicides are frequently included to prevent bacterial attack. $Al(OH)_3$ treated latex has been widely accepted as an eco-friendly source material, containing virtually undetectable levels of proteins for the adhesive market.

Advantages when used for adhesives include:

- Outperforms *Hevea* NRL in cold seal applications
- Improved stability, compoundability, and coating characteristics
- Very low odor
- Higher clarity and whiteness
- Superior aging and shelf stability
- 100% natural
- Biodegradable

Ultra low antigenic protein latex is extremely important in adhesive applications due to the absence of secondary post leaching techniques commonly used in other applications for the reduction of proteins. If high levels of protein are not present in the raw material they cannot appear in the manufactured end product.[19] This benefit has led to multiple trials and evaluations by the leading global adhesive manufacturers to

support the growing need for lower protein levels in adhesive applications. A comparison of $Al(OH)_3$ treated latex and standard *Hevea* latex unformulated cold seal characteristics are illustrated below:

Table 4: Unformulated Cold Seal Characteristics

Test Parameters	Vytex NRL	*Hevea* NRL
T-Peel	0.88 lbs/in	0.88 lbs/in
PAFT	185	204
SAFT	218	252
ASTM D5712-05	<200 µg/dm^2	600 µg/dm^2
ASTM D6499-07	<10 µg/dm^2	55 µg/dm^2

$Al(OH)_3$ treated latex has been used in medical dressing and bandage applications, Part of the evaluation process for a major manufacturer was biocompatibility testing was performed on cohesive bandages made with ultra low antigenic protein latex. The manufacturer concluded that cohesive bandages produced with $Al(OH)_3$ treated latex do not induce skin irritations and cause no sensitization dermal reactions. Protein testing conducted by the same manufacturer verified the low protein status of subject NRL in finished products while retaining the positive benefits of natural rubber latex.

Another adhesive manufacturer performed a wide variety of tests specific to their end product using adhesives made with $Al(OH)_3$ treated latex. This latex was substituted for *Hevea* NRL in two dissimilar cold-seal adhesive applications and evaluated for one month cling values and bond strength. The test parameters were a coat weight of three pounds per ream and samples conditioned at room temperature and 120°F. Cling and cold seal bond strength was gathered after 1 month aging. It was concluded that both cold seal formulations had the desired cling values on both metalized OPP and cavitated OPP less than 100 grams per linear inch and met all manufacturer requirements. Furthermore, cold seal formulations had the desired bond strength on both metalized OPP and cavitated OPP greater than 300 grams per linear inch. These independent test results again confirm that ultra low antigenic protein latex can be substituted for *Hevea* NRL without compromising the physical performance attributes. Adhesives made with $Al(OH)_3$ treated latex are undergoing end-user review and commercial availability is expected in the fall of 2009.

CONDOMS MADE WITH $Al(OH)_3$ TREATED LATEX

Condoms made with $Al(OH)_3$ treated latex offers users a choice to overcome irritation issues and still have the ultimate protection material. $Al(OH)_3$ treated latex is currently being evaluated by three large manufacturers to determine utility in condom applications. Natural rubber latex is the preferred material for condoms due to its well known liquid barrier protection, elasticity and fit.

Vytex NRL, highly purified double centrifuged *Hevea* latex and regular *Hevea* natural rubber latex were evaluated by a large European condom manufacturer. The evaluation included a comparison of the incoming feedstock materials, including the extrapolation of conductivity testing as a measurement of protein.

Table 5: Comparison of Vytex, Double Centrifuged and High Ammonia *Hevea*

Characteristic	Vytex NRL	Double Centrifuged *Hevea*	High Ammonia *Hevea*
TSC [%]	59.7	60.3	61.5
pH	10.81	10.2	10.3 - 11
KOH #	0.29	0.36	0.5 - 0.7
Conductivity @ 25°C (mS/cm)	1.93	2.29	3.0 - 5.0

It is understood that the higher the protein content, the quicker the rate of hydration. This property is related to the ability of the hydrated product to allow for electrical conductance, also known as conductivity. It was concluded that the low conductive value in the $Al(OH)_3$ treated latex is a result of the absence of water soluble proteins in condoms made with source material.

In another evaluation, a large Asian condom manufacturer evaluated $Al(OH)_3$ treated latex against their *Hevea* source material for protein content and physical performance.

Table 6: Asian Manufacturer Property Analysis of Vytex NRL and *Hevea* NRL

Property	Specification	Vytex NRL	*Hevea* NRL
Solid Density (%)	>61.5	60.3	61.6
Viscosity (mPa)	<80	61.6	66.4
pH	10 - 11.5	11.1	11.2
Magnesium Density (ppm)	<10	4.1	5.1
Compounded Property			
Solid Density (%)	N/A	54	54
Viscosity (mPa)	N/A	29	39
pH	N/A	10.4	10.4
Magnesium Density (ppm)	N/A	263	305
Physical Property			
Pulling Strength (mPa)	N/A	33.2	31.8
Stretch (%)	N/A	890	885
100% Modulus (mPa)	N/A	0.63	0.71
300% Modulus (mPa)	N/A	1.12	1.39
Protein %	N/A	0.17	0.45

In addition to a 62% reduction in protein compared to the *Hevea* source material, condoms made with Vytex NRL had a higher pulling strength and stretch with lower modulus. This observation has been reported by several manufacturers currently using ultra low antigenic protein latex in dipped applications. This is a result of the absence of proteins and other unwanted impurities inherently present in natural rubber latex that are prone to breakdown.

Another evaluation was conducted by a large US condom manufacturer. After performing initial QA/QC and the appropriate lab trials, this manufacturer proceeded with performing the required biocompatibility testing to submit a US FDA 510(k) application. The FDA has granted a 510(k) clearance for the first commercially available product made with Vytex NRL. The Envy™ condom, manufactured by Alatech Healthcare, LLC, Eufaula, AL, will be the first product available in the U.S. containing a label claim of "less than 2 µg/dm^2 of antigenic protein". The stringent requirements to achieve this clearance and label claim included biocompatibility testing and comprehensive protein testing to support the claim. The Envy condom will be marketed and sold by Alatech Healthcare and will be available for sale in the third quarter 2009.

COLLOIDAL PROPERTIES

Every batch of Vytex NRL produced is tested to confirm low protein content and colloidal properties according to International Organization for Standardization (ISO) standards to ensure compliance with ISO specifications and manufacturers expectations. The table below lists the typical colloidal properties of $Al(OH)_3$ treated latex. These properties are included on the Certificate of Analysis (COA) accompanying each shipment.

Table 7: Colloidal Properties of Vytex NRL

Property	Specifications (HA)	Typical Vytex NRL (HA)	Specifications (LA)	Typical Vytex LA	ISO Standard
Viscosity cps (sp 2/60)	20 - 100	81	20 - 100	92	1652
TSC (%)	60.0 - 61.5	60.88	60.0 - 61.5	60.34	124
Alkalinity (%)	0.65 - 0.8	0.71	0.20 - 0.29	0.24	125
VFA no.	0.07 max.	0.018	0.07 max.	0.019	506
Mechanical Stability	650 Seconds min.	1860	650 Seconds min.	1870	35
Coagulum (mesh# 80) ppm	100 max.	23	100 max.	19	706
pH	10.5 - 11.5	10.87	9.5 - 10.5	9.89	976

Manufacturers require that the colloidal properties are within a specific range and the $Al(OH)_3$ protein removal process conforms to ISO specifications. Additionally, Vytex NRL has greater mechanical stability compared to standard *Hevea* NRL which is attributed to the protein removal process. NRL stability is desired in several applications which suggest that $Al(OH)_3$ treated latex can be substituted for *Hevea* a wide array of end product applications. Several trials using this new raw material are currently ongoing including tubing, catheters, balloons, gloves and various other industries seeking an ultra low protein alternative material.

CONCLUSION

Suppliers and manufacturers of natural rubber latex and its many products continue to acknowledge the need and importance of reducing the allergenic properties of NRL. While recognizing this need, consideration for processes and products that minimize the environmental impact and maximize the health and safety and economic benefits are critical to the sustainability of the latex industry.

Ultra low protein levels antigenic protein natural latex achieves these objectives as an eco-friendly alternative source material for over 40,000 products.

$Al(OH)_3$ treated latex is environmentally friendly, a natural and renewable resource with no known human carcinogens or VOCs. Many independent manufacturer evaluations have demonstrated $Al(OH)_3$ treated latex significantly reduces protein levels, minimizes the need for extensive leaching processes in dipped goods and potentially reduces energy, water and production consumption and costs. This benefit is of particular importance in the production of adhesives where leaching the proteins is not possible. Products made from $Al(OH)_3$ treated latex demonstrate excellent physical properties and improved resistance to aging due to the removal of proteins and other microbial food sources, enhancing the protective characteristics of NRL .

By offering ultra low antigenic protein latex products that have been $Al(OH)_3$ treated, future sensitization could be overcome altogether.

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