



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN - 3 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Michael J. Dochniak
2653 Rice Creek Road, Apt. # 105
New Brighton, MN 55112

Re: TSCA Section 21 Petition Concerning *Hevea brasiliensis* Natural Rubber Latex Adhesives

Dear Mr. Dochniak:

The U.S. Environmental Protection Agency (EPA) has completed its review of your petition concerning *Hevea brasiliensis* natural rubber latex adhesives, which was filed under section 21 of the Toxic Substances Control Act (TSCA) on March 6, 2008.

EPA has reviewed the information submitted as part of the petition. EPA has also reviewed additional information already in EPA's possession or obtained by EPA and information submitted in public comments. Based on this review and a careful consideration of your specific request, EPA is denying the petition. The reasons for EPA's denial are set out in the enclosed, pre-publication copy of the notice that will be published in the *Federal Register* in a few days announcing EPA's decision.

Sincerely,

A handwritten signature in black ink that reads "James B. Gulliford".

James B. Gulliford
Assistant Administrator

PREPUBLICATION COPY NOTICE:

The Assistant Administrator for Prevention, Pesticides, and Toxic Substances signed the following *Federal Register* document on June 3, 2008:

Natural Rubber Latex Adhesives; Disposition of TSCA Section 21 Petition.

This is a prepublication version of the *Federal Register* document that EPA is submitting for publication in the *Federal Register*. While the Agency has taken steps to ensure the accuracy of this prepublication version of the document, it is not the official version of the document for purposes of public comment or judicial review. Please refer to the official version of the document that will appear in a forthcoming *Federal Register* publication, which is currently expected to occur within the next two weeks.

Once the official version of the document publishes in the *Federal Register*, you will also be able to access the on-line docket for this Federal Register document at <http://www.regulations.gov>, under Docket ID Number EPA-HQ-OPPT-2008-0273. You can then use EPA's electronic docket and comment system at www.regulations.gov, to access the index listing of the contents of the docket and to access those documents in the docket that are available electronically. For further information, please contact the person listed as the technical contact on the first page of the Federal Register document.

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2008-0273; FRL-8368-4]

Natural Rubber Latex Adhesives; Disposition of TSCA Section 21 Petition

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: On March 6, 2008, EPA received a petition from Michael J. Dochniak under section 21 of the Toxic Substances Control Act (TSCA) "to establish regulations prohibiting the use and distribution in commerce of *Hevea brasiliensis* [italics added] natural rubber latex adhesives having a total protein content greater than 200 micrograms per [gram] dry weight of latex based on the American Society for Testing and Materials method ASTM D1076-06 (Category 4)." The petition states: "Implementation of an EPA regulation that guides adhesive manufacturer's [sic] to use *Hevea [b]rasiliensis* [italics added] natural-rubber-latex that satisfy[ies] ASTM D1076-06 (Category 4) may affect the incidence and prevalence of latex allergy and allergy-induced autism in neonates." For the reasons set forth in this notice, EPA has denied the petitioner's request.

FOR FURTHER INFORMATION CONTACT: *For general information contact:* Colby Linter, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: *TSCA-Hotline@epa.gov*.

For technical information contact: Gerry Brown, Chemical Control Division (7405M), Office Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; telephone number: (202) 564-8086; e-mail address: *brown.gerry@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to you if you manufacture, process, import, or distribute in commerce *Hevea brasiliensis* (*Hevea*) natural rubber latex (NRL) adhesives. Potentially interested entities may include, but are not limited to:

- Adhesive manufacturing, NAICS code 325520.

08T-0835

- Other chemical and allied products merchant wholesalers, NAICS code 424690.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities that may be interested in this action. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might be of interest to certain entities. If you have any questions regarding this action, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPPT-2008-0273. All documents in the docket are listed in the docket's index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW, Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access docket ID number EPA-HQ-OPPT-2008-0273 at <http://www.regulations.gov>.

II. Background

A. What Action is Requested Under this TSCA Section 21 Petition?

On March 6, 2008, EPA received a petition from Mr. Michael J. Dochniak under section 21 of TSCA "to establish regulations prohibiting the use and distribution in commerce of *Hevea brasiliensis* [italics added] natural rubber latex adhesives having a total protein content greater than 200 micrograms per [gram] dry weight of latex based on the American Society for Testing and Materials method ASTM

D1076-06 (Category 4).” The petition states: “Implementation of an EPA regulation that guides adhesive manufacturer’s [sic] to use *Hevea [b]brasiliensis* [italics added] natural-rubber-latex that satisfy[ies] ASTM D1076-06 (Category 4) may affect the incidence and prevalence of latex allergy and allergy-induced autism in neonates” (Ref. 1).

NRL is a naturally occurring polyisoprene elastomer obtained almost exclusively from the *Hevea* tree indigenous to South America but now grown for commercial purposes principally in Asia and Africa. NRL adhesives comprise a very small portion of the adhesives industry. They are grouped by the U.S. Census under the “natural base glues and adhesives” product category, which comprises the smallest share (< 3%) of the U.S. adhesive manufacturing industry. Adhesives manufacturers produce a wide range of products, including adhesives, caulks, lubricants, and sealants, and adhesives are used in a wide variety of industries. The U.S. adhesive industry is dominated by synthetic adhesives like acrylics, epoxide resins, vinyls, and synthetic rubbers such as polychloroprene and styrene-butadiene, the most common substitute for natural rubber adhesives. Most synthetic adhesives are derived from coal, natural gas, oil, or petroleum (Ref. 2).

ASTM D1076-06, Standard Specification for Rubber-Concentrated, Ammonia Preserved, Creamed, and Centrifuged Natural Latex, is a standard specification, not a method, although methods are referenced in the standard. ASTM International (ASTM), formerly the American Society for Testing and Materials, is a voluntary standards development organization, <http://www.astm.org/ABOUT/aboutASTM.html> (last visited April 28, 2008). ASTM D1076-06 covers requirements for four categories of “first grade concentrated natural rubber latex” (Ref. 3). Category 4, “Centrifuged, or centrifuged and creamed, guayule latex, or other natural rubber latex, containing less than 200 µg total protein per gram dry weight of latex, with ammonia or other hydroxide, with other necessary preservatives and stabilizers,” requires that the latex contain no more than 200 micrograms (µg) total protein per gram (dry weight) of latex utilizing ASTM Test Method D5712 and no detectable *Hevea* antigenic protein utilizing ASTM Test Method D6499-07 (Ref. 4). The latter test method, Standard Test Method for the Immunological Measurement of Antigenic Protein in Natural Rubber and Its Products, “covers an immunological method to determine the amount of antigenic protein in natural rubber and its products” (Ref. 4). According to ASTM, “[a]lthough this method detects antigenic proteins, it should not be considered as a measure of allergenic proteins,” because “[c]orrelation of protein/antigen levels with the level of allergenic proteins has not been fully established” (Ref. 4).

B. What Support Does the Petitioner Offer for this Request?

The petitioner provided the following exhibits to support his petition:

1. Exhibit A: Ylitalo, Leea. Natural Rubber Latex Allergy in Children. University of Tampere Medical School.

According to this study (abstract), the prevalence of NRL allergy in children admitted for inhalant or food testing (total number of children in the study, 3,269) was found to be 1%, based upon skin prick test analysis. EPA recognizes that latex protein can cause sensitization and allergic disease in certain children and adults, and epidemiological studies show varying rates of prevalence in adults and children.

2. Exhibit B: Blanco, Carlos, Latex-Fruit Syndrome, Current Allergy and Asthma Reports. 3:47-53. 2003.

This publication reviews evidence indicating that latex and food allergens cross react immunologically.

3. Exhibit C: Palomares, O. et al. 1,3 B-glucanases as candidates in latex-pollen-vegetable food cross-reactivity. Clinical and Experimental Allergy. 35:345. 2005.

This abstract also shows evidence of fruit, vegetables, and latex cross-reactivity.

4. Exhibit D: Latex in Food Packaging Risk. Available on-line at: <http://www.consumeraffairs.com/news04/2006/08/latex.html>.

This is a news article reporting that consumer groups were calling for warning labels on food packaging containing latex.

5. Exhibit E: Dochniak, M.J. Autism spectrum disorders-Exogenous protein insult *Medical Hypothesis* (2007), doi:10.1016/j.mehy.2007.01.060.

This is an article written by the petitioner hypothesizing that increased latex allergen exposure may have affected the incidence of allergy-induced autism. The article presents only a hypothesis that is unsupported by any scientific study or data.

6. Exhibit F: U.S. Patent #7,784,281 (Ichikawa, et al.).

This patent discusses a method for reducing the allergenic protein content in *Hevea* NRL using digestive enzymes.

7. Exhibit G: Hayes, B. H. et al. Evaluation of Percutaneous Penetration of Natural Rubber Latex Proteins. *Toxicological Sciences*. 56, 262-270. 2000.

According to this article, the skin can be a plausible route for latex sensitization and a major exposure route when it is damaged (e.g., cuts and abrasion). Other routes would include contact via mucosal surfaces and inhalation exposure.

8. Exhibit H: H. B. Fuller Co. website literature on *Hevea brasiliensis* water based adhesives. Available on-line at: <http://www.hbfuller.com/adhesives/technologies/water/000525.shtml#NR>.

9. Exhibit I: Henkel Consumer adhesive literature. Natural rubber latex adhesive.

Both Exhibit H and Exhibit I show that at least some manufacturers do not display latex allergy protein warnings on their packaging.

10. Exhibit J: Niggeman, B. et al. Development of latex allergy in children up to 5 years of age—a retrospective analysis of risk factors. *Pediatric Allergy [and] Immunology*. 9:36–39. 1998 (International Standard Serial Number (Library of Congress) (ISSN): 0905–6157).

According to this study (abstract), besides the number of operations and an atopic disposition, there were no other definite factors for developing sensitization or allergy to latex in children up to 5 years of age. In general, risk groups for latex allergy are atopics and people frequently in contact with latex gloves, such as the medical profession and patients needing multiple surgeries.

C. What Are the Legal Standards Regarding TSCA Section 21 Petitions and TSCA Section 6 Rules?

Section 21(b)(1) of TSCA requires that the petition “set forth the facts which it is claimed establish that it is necessary” to issue the rule or order requested. 15 U.S.C. 2620(b)(1). Thus, TSCA section 21 implicitly incorporates the statutory standards that apply to the requested actions. In addition, TSCA section 21 establishes standards a court must use to decide whether to order EPA to initiate rulemaking in the event of a lawsuit filed by the petitioner after denial of a TSCA section 21 petition. 15 U.S.C. 2620(b)(4)(B). The petition does not state under which provision of TSCA the request would be satisfied, and only TSCA section 6 appears to be applicable. Accordingly, EPA has relied on the standards in TSCA section 21 and section 6 to evaluate this petition.

In order to promulgate a rule under TSCA section 6, the Administrator must find that “there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture . . . presents or will present an unreasonable risk of injury to health or the environment.” 15 U.S.C. 2605(a). This finding cannot be made considering risk alone. In promulgating any rule under TSCA section 6(a), the statute requires that the Administrator consider:

- The effects of such substance or mixture on health and the magnitude of the exposure of human beings to such substance or mixture.

- The effects of such substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture.
- The benefits of such substance or mixture for various uses and the availability of substitutes for such uses.
- The reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health. 15 U.S.C. 2605(c)(1).

Furthermore, the control measure adopted is to be the “least burdensome requirement” that adequately protects against the unreasonable risk. 15 U.S.C. 2605(a).

Section 21(b)(4)(B) of TSCA provides the standard for judicial review should EPA deny a request for rulemaking under TSCA section 6(a): “If the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that ... there is a reasonable basis to conclude that the issuance of such a rule ... is necessary to protect health or the environment against an unreasonable risk of injury,” the court shall order the Administrator to initiate the requested action. 15 U.S.C. 2620(b)(4)(B).

III. Disposition of Petition

The petition does not set forth facts sufficient to establish that it is necessary to issue a rule prohibiting the use and distribution in commerce of *Hevea* NRL adhesives having greater than 200 µg total protein per gram of latex and no detectable *Hevea* antigenic protein. In particular, the petition does not set forth, as required by TSCA sections 6 and 21, facts sufficient to support a finding that *Hevea* NRL adhesives that do not meet the ASTM standard pose an unreasonable risk. The petition does not present facts establishing that latex adhesives containing any specific level of protein present an unreasonable risk. Nor does the petition set forth facts indicating that prohibiting *Hevea* NRL adhesives not meeting the ASTM standard would be effective in reducing the incidence of latex allergies, or that doing so would be the least burdensome requirement to protect against any unreasonable risk from latex.

While the petitioner provides some documentation to support the petition (see Unit II.B.), this documentation is minimal and insufficient to show a reasonable basis to find unreasonable risk. For example, while petition Exhibits A, G, and J seem to support the assertion that NRL latex sensitization and allergies occur in children, this information does not show that the NRL adhesives pose an unreasonable risk. Moreover, the petitioner only speculates that “[i]mplementation of an EPA regulation that guides adhesive manufacturers to use *Hevea [b]rasiliensis* [italics added] natural-rubber-latex that satisfy ASTM

D1076-06 (Category 4) may [emphasis added] affect the incidence and prevalence of latex allergy and allergy-induced-autism in neonates.” The only exhibit that purports to show a link between *Hevea* NRL and infant autism is an article that was written by the petitioner and published in *Medical Hypotheses* (Ref. 5). The article presents only a hypothesis that is unsupported by any scientific study or data. Moreover, neither this article nor any other factual information provided in the petition address the contribution of adhesives to any risk that might exist.

NRL allergies have been the subject of considerable Federal Government evaluation. In March 2000, for example, the U.S. Consumer Product Safety Commission (CPSC) received a petition requesting that the CPSC issue a rule declaring that NRL and products containing NRL are strong sensitizers under the Federal Hazardous Substances Act (FHSA) so that these products would require labeling. See the **Federal Register** issue of March 21, 2000 (65 FR 15133). The CPSC conducted an extensive review and issued a decision in June 2004 rejecting the petition (Ref. 6). Among other things, CPSC concluded that the incidence of NRL allergy in the general population was very low (below 1%), that many consumer products contain NRL, and that “in spite of the prevalence of NRL in consumer products, there are few documented cases of reactions to NRL-containing consumer products,” most of which involved medical devices¹ (The CPSC did not distinguish between *Hevea* and non-*Hevea* NRL, but nearly all commercial NRL is *Hevea*). The CPSC noted that the U.S. Food and Drug Administration (FDA) had issued rules requiring labeling for medical devices containing NRL, citing 21 CFR 801.437. FDA, however, has not limited protein content in, or prohibited, NRL (Ref. 7). See also the **Federal Register** issue of September 30, 1997 (62 FR 51021). In general, the CPSC concluded, most individuals only experience mild symptoms and “most incidents of life-threatening NRL-induced anaphylaxis are associated with invasive surgical or other medical procedures, not with consumer products” (Ref. 6). The CPSC determination suggests that the risks associated with NRL, principally *Hevea* NRL, are relatively insubstantial, and does not support a conclusion that any risk is unreasonable.

The petition provides little information on the factors that must be considered for a TSCA section 6 rulemaking. The petition does not explain why it specifically targets adhesives. The only documentation

¹ A substantial proportion, if not most, products of concern containing *Hevea* NRL may not be subject to TSCA. Among other things, medical devices, food, food additives, food packaging, and cosmetics do not fall within EPA’s authority under TSCA section 6. TSCA section 6 provides the authority to regulate chemical substances and mixtures. The term “chemical substance,” however, “does not include - ... (vi) any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.” 15 U.S.C. 2602(2)(B)(vi).

supporting the petition related to NRL adhesives was a product brochure and a Material Safety Data Sheet included as exhibits (petition Exhibits H and I) to show that two companies had not included antigenic protein warnings on their packaging. The petition does not discuss any special risks posed by NRL adhesives (in comparison to other NRL products or other adhesives), does not describe the contexts in which one might be exposed to NRL adhesives or why those exposures are of concern to the general population, and does not provide any other information on why adhesives are of particular concern.

The petition does not provide any factual information on the magnitude of exposure to *Hevea* NRL or *Hevea* NRL adhesives that do not meet the ASTM standard or on the benefits of *Hevea* NRL or *Hevea* NRL adhesives that do not meet the ASTM standard for various uses. Other than noting the existence of substitutes, the petitioner provides no factual information on the availability of substitutes. The petitioner provides no factual information on the reasonably ascertainable economic consequences of prohibiting the use and distribution in commerce of *Hevea* NRL adhesives not meeting the ASTM standard. In particular, the petition contains little information on the relative importance of *Hevea* NRL adhesives as a source of infant exposure.

As for the regulation that the petition seeks (i.e., to prohibit the use and distribution in commerce of *Hevea* NRL adhesives that do not meet the ASTM Standard D1076-06 (Category 4)), the petition does not provide any evidence that ASTM Standard D1076-06 represents a safe or otherwise appropriate level of allergen in NRL. The threshold amount of NRL allergen needed to sensitize a person, or to produce an allergic reaction, is not known and, as ASTM Test Method D6499-07 states, antigenic proteins should not be considered a measure of allergenic proteins because a correlation between antigenic protein levels and the level of allergenic proteins has not been fully established (Refs. 4, 8, 9, and 10). In addition, each NRL protein has different antigenic properties, and individuals do not react uniformly to each allergenic protein (Ref. 12). As the CPSC has pointed out, without knowing the threshold amount, it is not possible to differentiate between products that would cause sensitization or allergic reaction and products that would not (Ref. 6). Moreover, it would be difficult for *Hevea* NRL adhesives products to meet the ASTM standard because the referenced test method for detecting antigenic *Hevea* proteins is very sensitive and it is difficult to prepare *Hevea* NRL such that the level of antigenic protein would be low enough to be undetectable by the referenced method (Ref. 13). In addition, the petitioner has not provided evidence showing that prohibiting *Hevea* NRL that did not meet this standard would be the least burdensome requirement.

In addition, a regulation requiring reduced protein content in *Hevea* NRL adhesives is unlikely to significantly contribute to reducing *Hevea* NRL allergy in the general population. The groups considered

most at risk for *Hevea* NRL allergy are atopic individuals (who have a genetic predisposition to allergies), individuals with certain food allergies, and medical professionals and patients who undergo multiple surgeries (who come into repeated contact with latex gloves or other latex medical equipment) (Refs. 8, 9, 11, and 12).

Another factor to consider for a TSCA section 6 rulemaking is the availability of substitutes. Petitioner has requested that EPA ban products that do not meet the ASTM standard. Although, for some products, there are substitutes to *Hevea* NRL that do meet the ASTM standard, the petition does not present facts establishing that substitutes of NRL meeting this standard are technically feasible to use with or as adhesives, that they are safer than *Hevea* NRL, or that the substitutes are effective or economical for use in or as adhesives. The petitioner mentions in the petition that procedures, such as aqueous washing or treatment with digestive enzymes can be used to reduce the antigenic protein content in *Hevea* NRL (see Exhibit F). This washing or treatment could be a substitute to *Hevea* NRL that does not meet the ASTM standard, but these methods can be expensive, may produce latex with inferior physical, chemical, or mechanical properties, or significant quantities of proteins may still remain in the latex (Ref. 14). As for other substitutes (that do not involve procedures for reducing protein content), sources other than *Hevea* trees can be used to make NRL. For example, NRL can be obtained from the guayule plant (*Parthenium argentatum*). Petitioner has provided no information on the cost or feasibility of producing guayule NRL. In addition, guayule NRL may not be a satisfactory substitute for *Hevea* NRL for purposes of reducing the incidences of allergic reactions. Although, the proteins present in guayule NRL may not cross-react with IgE antibodies from subjects allergic to NRL obtained from *Hevea* NRL, there is still some concern that the proteins present in guayule NRL could also sensitize some individuals and cause allergic reactions (Refs. 15 and 16). Finally, latex-free synthetic alternatives are also available, but these alternatives are more expensive and may not perform as well as *Hevea* NRL (Ref. 14). As evidence that substitutes may create their own risks, many synthetic elastomers contain traces of carcinogens, and the production of vinyl gloves, a major substitute for latex gloves, increases the risk of dioxin releases into the atmosphere (Ref. 2).

IV. Comments Received

EPA published a notice in the **Federal Register** announcing receipt of this TSCA section 21 petition and inviting public comment on or before May 12, 2008 (Ref. 17). EPA received seven timely comments. Of the seven comments received, two were from trade groups, three were from manufacturers, one was from ASTM International, and one from an individual.

One brief comment, from a manufacturer of latex and latex-free bandages, supported the petition "because it would go a long way in

preventing allergic reactions that have become more common among health care workers,” but did not provide any additional information (Ref. 18).

Another comment, from a manufacturer of guayule natural rubber latex products, commented that it is presently not possible for *Hevea* NRL to meet the ASTM D1076–06 Category 4 standard, that only guayule can meet the standard, and that, even if the total protein present in *Hevea* NRL could be reduced to the level in the Category 4 standard, remaining proteins could still present a risk of allergic reaction to the final product. The commenter suggested that a ban is, therefore, not practical and that any proposed ban should, at least, be phased in to permit time for development of substitutes and/or only target adhesives to which children are exposed (Ref. 19).

The other five comments opposed the petitioned action and/or discussed the inappropriateness of the ASTM standard for addressing the concerns stated in the petition.

The comment from ASTM International (from the Chairman of the subcommittee that maintains ASTM D1076–06), for example, noted that the Category 4 standard specified in the petition was added for NRL from botanical sources other than *Hevea* and that ASTM D1076–06 does not apply to “compounded latex concentrates,” such as adhesives (Ref. 20).

The Pressure Sensitive Tape Council noted many of the same issues discussed in this unit, including concerns similar to ASTM’s regarding the appropriateness of the standard, the lack of facts supporting the petitioner’s autism hypothesis, and the unexplained focus on *Hevea* NRL adhesives as opposed to the many other uses of *Hevea* NRL (gloves, sports equipment, carpet backing, balloons, rubber bands, handles on tools, and clothing elastics) (Ref. 21).

The Rubber Manufacturers Association (RMA) noted the lack of evidence of a link between *Hevea* NRL exposure and autism, commenting that in the long history of NRL harvest and use, and in the course of multiple government inquiries into latex allergy, no one had observed a link between NRL and autism. The RMA also commented that the petition did not cite any evidence that allergens in NRL adhesives are being transported to the human body and described differences in exposure potential between dipped latex products (such as medical gloves, balloons, and condoms) and dry rubber products (such as tires, hoses, belts, and balls). The RMA also commented that the primary route of consumer exposure to adhesives would be through medical bandages, which, as a medical device, would fall under the jurisdiction of FDA. Finally, the RMA criticized the use of some of the references in petitioner’s *Medical Hypotheses* paper, commenting that several references did not in fact support the petitioner’s hypothesis (Ref. 22).

V. References

1. Dochniak, Michael J. Citizen Petition under TSCA to prohibit the use of *Hevea-Brasiliensis* natural rubber latex adhesives in the United States, wherein said adhesives have a protein content greater than 200 micrograms per dry weight of latex. February 26, 2008.
2. EPA, OPPT, Economics, Exposure and Technology Division (EETD). Profile: Natural Rubber Latex Adhesives. May 7, 2008.
3. ASTM. ASTM D1076-06. Standard Specification for Rubber-Concentrated, Ammonia Preserved, Creamed, and Centrifuged Natural Latex. June 2006.
4. ASTM. Active Standard: D6499-07. Standard Test Method for the Immunological Measurement of Antigenic Protein in Natural Rubber and Its Products. Available on-line at: http://enterprise.astm.org/REDLINE_PAGES/D6499.htm (last visited May 13, 2008).
5. Dochniak, Michael J. Autism spectrum disorders-Exogenous protein insult, *Medical Hypotheses* (2007), doi:10.1016/j.mehy.2007.01.060.
6. CPSC. Letter from Todd Stevenson, Secretary, U.S. Consumer Product Safety Commission, to Debra Adkins, responding to her petition HP 00-2 requesting CPSC to issue a rule adding NRL to the list of strong sensitizers. June 4, 2004.
7. FDA. FDA Clears Glove Made from New Type of Latex. *FDA News*. April 23, 2008.
8. National Institute of Occupational Safety and Health (NIOSH), NIOSH Publication No. 97-135: Preventing Allergic Reactions to Natural Rubber Latex in the Workplace (June 1997).
9. Center for Food Safety and Applied Nutrition, Food Advisory Committee Meeting, Additives and Ingredients Subcommittee. Latex Glove Background Report. August 2003.
10. Northwestern University, Office for Research Safety, Laboratory Safety, Office of the Vice President for Research. Allergic Reactions to Latex Gloves. Available on-line at: <http://www.research.northwestern.edu/ors/labsafe/latex.htm> (last visited May 13, 2008).
11. CPSC. Memorandum from Jacqueline Elder, Assistant Executive Director for Hazard Identification and Reduction, to Todd Stevenson, Secretary, re: Additional Information on Petition on the Natural Rubber Latex (HP 00-2). April 1, 2004.
12. CPSC. Briefing Package, Petition Requesting that Natural Rubber latex be declared a Strong Sensitizer (HP00-2). October 2003.

13. European Commission, Scientific Committee on Medicinal Products and Medical Devices. Opinion on natural rubber latex allergy. June 2000.

14. U S. Patent #5,741,885.

15. Siler, D.J.; Cornish, K.; and Hamilton, R.G. Absence of cross-reactivity of IgE antibodies from subjects allergic to *Hevea brasiliensis* latex with a new source of natural rubber latex from guayule (*Parthenium argentatum*). *Journal of Allergy Clinical Immunology*. 98: 895–902. 1996.

16. U.S. Patent #6,054,525.

17. EPA. *Hevea brasiliensis* Natural Rubber Latex Adhesives; TSCA Section 21 Petition; Notice of Receipt. **Federal Register** (73 FR 22368, April 25, 2008) (FRL–8361–3). Available on-line at: <http://www.epa.gov/fedrgstr>.

18. Comment from Andover Healthcare, Inc. May 12, 2008.

19. Letter from the Yulex Corp. May 7, 2008.

20. Letter from ASTM International. May 7, 2008.


21. Letter from the Pressure Sensitive Tape Council. May 9, 2008.

22. Letter from the Rubber Manufacturers Association. May 12, 2008.

List of Subjects

Environmental protection, Antigenic proteins, Asperger syndrome, Autism, Health, *Hevea brasiliensis* natural rubber latex adhesives, Infants and children.

Dated: 6/3/08

A handwritten signature in cursive script, appearing to read "James B. Sheldahl", is written over a horizontal line.

Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

[FR Doc. 08-?????? Filed ??-??-08; 8:45 am]

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4a Express Package Service
FedEx Priority Overnight
FedEx Standard Overnight
FedEx 2Day
FedEx 2Day Freight
FedEx 3Day Freight
FedEx 3Day Overnight

4b Express Freight Service
FedEx 1Day Freight
FedEx 2Day Freight
FedEx 3Day Freight
FedEx 3Day Overnight

5 Packaging
FedEx Envelope
FedEx Pak
FedEx Tube
FedEx Box
FedEx Other

6 Special Handling
SATURDAY Delivery
HOLD Saturday at FedEx Location
HOLD Saturday at FedEx Location
HOLD Saturday at FedEx Location

7 Payment
Bill to: Sender, Recipient, Third Party, Credit Card, Cash/Check
Total Packages, Total Weight, Total Declared Value

8 NEW Residential Delivery Signature Options
No Signature Required, Direct Signature, Indirect Signature

Form ID No. 0215

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1797-1398-5

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PULL AND RETAIN THIS COPY BEFORE AFFIXING TO THE PACKAGE. NO POUCH NEEDED.