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February 26, 2008

Director, Office of Pollution Prevention and Toxics  
Environmental Protection Agency – East  
Room 3166  
1201 Constitution Ave., NW  
Washington, D.C. 20460

Re: 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.

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Citizen Petition

The undersigned submits this petition to request the Director to issue a regulation.

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### Petition Request

Pursuant to Section 21 of the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2620, Michael J. Dochniak hereby petitions the Environmental Protection Agency (EPA) to establish regulations prohibiting the use and distribution in commerce of Hevea-Brasiliensis natural rubber latex adhesives having a total protein content greater than 200 micrograms per dry weight of latex based on *The American Society for Testing and Materials* method ASTM D1076-06 (Category 4).

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### Statement

Hevea-Brasiliensis natural rubber latex is a chemical substance that is not subject to regulation under TSCA.

It is well known that natural rubber latex adhesives, which are extracted from the rubber tree of Hevea Brasiliensis, contain antigenic proteins that may cause adverse immune responses in some individuals. Specifically, exposure to the proteins inherent in Hevea Brasiliensis (Hev-b) is known to cause an increased incidence of sensitization, adverse allergic reactions (i.e., latex allergy), and even death through anaphylactic shock.

Tapping a rubber tree involves cutting channels into the bark (controlled wounding) and bleeding out the milky white latex extract - The latex is produced by special cells called laticifers and is thought to be a defense against insect pathogens and possibly a site for the depositing of metabolic waste of the tree.

Hevea Brasiliensis latex contains about 2-5% by weight protein. Analysis indicates about 200 dissimilar proteins therein and about 50-60 are suspected allergens. The World Health Organization - International Union of Immunological Societies has assigned names to about 13 of these allergens (e.g., Hev-b 1-13).

A study showed that about 1% of children have latex allergy. (Exhibit A)

Other research indicates that an acquired immune response to the Hev-b proteins may be involved in the etiology of food allergies and allergy-induced-Autism. For example, it is well known that an acquired sensitization to the Hev-b proteins may affect the incidence and prevalence of IgE mediated reaction antibodies that can cross react with homologous proteins in fruits and vegetables. (Exhibit B and Exhibit C)

Consumer groups are calling for warning labels on food packaging containing latex, saying the substance poses a potential threat to people with allergic sensitivities. (Exhibit D)

Furthermore, it has been proposed in the Journal of Medical Hypotheses that increased Hev-b protein exposure may have affected the incidence of allergy induced autism. (Exhibit E)

It is generally known that the antigenic proteins inherent in Hevea Brasiliensis can be reduced. For example, aqueous washing procedures and/or digestive enzymes can be used to reduce the Hev-b protein content in Hevea Brasiliensis natural-rubber-latex. (Exhibit F)

Although “latex allergy” continues to be a serious health issue, the threshold of sensitivity to the Hev-b antigenic-proteins in Hevea Brasiliensis natural-rubber-latex is unknown.

A study that evaluated percutaneous penetration of natural rubber latex proteins concluded that the skin is not only a plausible route for latex sensitization but can be a major exposure route when the integument has been compromised. (Exhibit G)

Continued efforts in the United States have been undertaken to identify sources of Hevea Brasiliensis natural-rubber latex in order to minimize release into the environment. For example in the medical industry, efforts continue to substantially eliminate natural rubber latex in the health care environment. Specifically, John Hopkins Hospital recently announced in 2008 that it will no longer use nearly all medical natural-rubber latex products.

Manufacturer's that provide Hevea-Brasiliensis natural rubber latex adhesives do not display antigenic protein warnings (i.e., protein content information) on their packaging. (Exhibit H and Exhibit I)

Implementation of an EPA regulation that guides adhesive manufacturer's to use Hevea Brasiliensis natural-rubber-latex that satisfy ASTM D1076-06 (Category 4) may affect the incidence and prevalence of latex allergy and allergy-induced-autism in neonates.

In a study that evaluated the development of latex allergy in children up to 5 years of age, researchers concluded that besides the number of operations and an atopic predisposition – no other definite risk factor for developing sensitization or allergy to latex, such as everyday household objects, can be identified in children up to 5 years of age. (Exhibit J)

## Evidence Appendix

- Exhibit A: Leea Ylitalo, Natural Rubber Latex Allergy in Children, University Of Tampere Medical School.
- Exhibit B: Carlos Blanco, Latex-Fruit Syndrome, Current Allergy and Asthma Reports 2003, 3:47-53.
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- Exhibit C: Palomares O, Villalba M; Quiralte J, Polo F; Rodríguez R: 1,3-B glucanases as candidates in latex-pollen-vegetable food cross-reactivity; clinical Experimental allergy; vol. 35, pg. 345, march 2005.
- Exhibit D: Consumeraffairs.com: Latex In Food Packaging Poses Risk <http://www.consumeraffairs.com/news04/2006/08/latex.html>
- Exhibit E: Dochniak MJ, Autism spectrum disorders – Exogenous protein insult, Med Hypotheses (2007), Volume 69, Issue 3, page 545-549.
- Exhibit F: U.S. Patent 6,784,281 (Ichikawa, et al.)
- Exhibit G: Benjamin B. Hayes et al: Evaluation of Percutaneous Penetration of Natural Rubber Latex Proteins; Toxicological Sciences, 56, 262-270 (2000).
- Exhibit H: H.B.Fuller Company Website literature on Hevea-Brasiliensis water-based adhesives.  
<http://www.hbfuller.com/adhesives/technologies/water/000525.shtml#NR>
- Exhibit I: Henkel Consumer adhesive literature (i.e., TDS) – Natural rubber latex adhesive.
- Exhibit J: Niggemann B, Kulig M, Bergmann R, Wahn U: Development of latex allergy in children up to 5 years of age -- a retrospective analysis of risk factors; Pediatr Allergy Immunol. 1998, 9(1), 36-9 (ISSN: 0905-6157)

Declaration

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which is unfavorable to the petition.

 2/26/08  
Signature

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Michael J. Dochniak

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