UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

VOTE SHEET

Date: OCT 10 2003 2003 OCT 16 A 9:21

TO : The Commission
Todd Stevenson, Secretary

FROM : W.H.DuRoss, III, General Counsel WHDIII
Stephen Lemberg, Assistant General Counsel SL
Patricia M. Pollitzer, Attorney PMP

SUBJECT : Petition HP 00-2 Requesting Rule Declaring Natural Rubber Latex to be a Strong Sensitizer

Attached is a briefing package from the staff concerning a petition submitted by Debi Adkins, editor of *Latex Allergy News*, requesting that the Commission declare natural rubber latex ("NRL") to be a strong sensitizer under the FHSA and that products containing NRL be labeled accordingly. The staff recommends that the Commission deny the petition.

Please indicate your vote on the following options.

I. Grant Petition HP 00-2.

_____ _____
Signature Date

II. Deny Petition HP 00-2 and direct the staff to prepare a letter of denial to the petitioner.

_____ _____
Signature Date

NOTE: This document has not been reviewed or accepted by the Commission.
Initial PMP **Date** 10/10/03

III. Defer decision on Petition HP 00-2.

Signature _____ Date _____

IV. Take other action (please specify):

_____

_____

_____

Signature _____ Date _____

BRIEFING PACKAGE

Petition Requesting That Natural Rubber Latex be Declared a Strong Sensitizer (HP00-2)

For Information Contact
Suzanne Barone, Ph.D.
Directorate for Health Sciences
(301) 504-7256

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Executive Summary

The U.S. Consumer Product Safety Commission (CPSC) received a petition from Debi Adkins, editor of *Latex Allergy News*, requesting that natural rubber latex (NRL) and products that contain NRL be added to the list of strong sensitizers under the Federal Hazardous Substances Act (FHSA) and be labeled accordingly. The petition also requests specifically that toys and other articles intended for use by children, which contain NRL, be labeled.

Before designating NRL as a strong sensitizer under the FHSA, the Commission must find that NRL has a significant potential for causing hypersensitivity. The Commission must consider the frequency of occurrence and severity of the reaction when making the decision to designate a substance as a strong sensitizer.

Hypersensitivity or allergy is a condition where an individual exhibits an "exaggerated" immune response to a normally innocuous agent. The development of an allergy is a two step process. In the first step an individual becomes "sensitized" after exposure to the agent in sufficient quantities to produce specific antibodies against the agent or allergen. Upon re-exposure to sufficient quantities, the allergen, or one structurally similar, can cause a response with clinical symptoms called allergy. Sensitization does not always lead to the development of an allergic reaction even if re-exposure occurs. While most allergic reactions involve minor symptoms (rash, nasal symptoms), anaphylactic reactions and death from NRL allergy have been documented.

The causal agent(s) in sensitization and allergy to NRL are naturally occurring proteins found in natural rubber. Several of these proteins have been characterized. However, the threshold levels of allergen needed for the development of sensitization and the development of clinical symptoms are not known.

NRL allergy has been associated with several specific populations including medical personnel who have high exposure to NRL-containing gloves, people who have had multiple surgeries that expose the mucous membranes directly to NRL, and atopic persons who are genetically more sensitive to many allergens.

Because NRL allergy in medical personnel and surgical patients has been associated with exposure to medical devices, the Food and Drug Administration (FDA) requires labeling of these products. Exposure of the general population to NRL is unknown. However, the prevalence of NRL allergy has remained at less than one percent in the general population. There are very few NRL-containing consumer products for which there are documented allergic reactions. In addition, the amounts and types of NRL allergens in NRL-containing consumer products are largely unknown. Thus, there is no way to correlate the allergen content of NRL-finished consumer products to the levels needed either to sensitize or to elicit clinical symptoms in sensitized individuals.

The available data do not support that NRL is a strong sensitizer according to the FHSA definition. Current scientific information about the development of NRL allergy from consumer products that contain NRL is limited and it does not appear that such information will be developed in the near future. Therefore, the staff recommends that the Commission deny the petition.

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: OCT 10 2003

TO : The Commission
Todd Stevenson, Secretary

THROUGH: W. H. DuRoss, III, General Counsel
Patricia Semple, Executive Director

FROM : Jacqueline Elder, Assistant Executive Director for Hazard Identification and Reduction
Suzanne Barone, Ph.D., Project Manager for Poison Prevention, Directorate for Health Sciences

SUBJECT : Petition on Natural Rubber Latex (HP 00-2)

This memorandum forwards the staff analysis of information related to petition HP 00-2, requesting that natural rubber latex (NRL) be added to the list of strong sensitizers under the Federal Hazardous Substances Act (FHSA). The staff recommendation to deny the petition is also discussed.

BACKGROUND

Petition HP 00-2

The U.S. Consumer Product Safety Commission (CPSC) received a petition from Debi Adkins, editor of *Latex Allergy News*, requesting that NRL and products that contain NRL be added to the list of strong sensitizers under the FHSA and be labeled accordingly. The petition also requests specifically that toys and other articles intended for use by children, which contain NRL, be labeled. A copy of the petition is at Tab A.

Before discussing the issue posed by the petitioner, it is important to understand the history of the FHSA related to strong sensitizers, the technical terminology used to define a strong sensitizer, and the activities that other government agencies have undertaken regarding NRL.

FHSA History and Requirements for Strong Sensitizers

The FHSA defines "strong sensitizer" as "*a substance which will cause on normal living tissue through an allergic or photodynamic process a hypersensitivity which becomes evident on reapplication of the same substance and which is designated as such by the [Commission]. Before designating any substance as a strong sensitizer,*

the [Commission], upon consideration of the frequency of occurrence and severity of the reaction, shall find that the substance has a significant potential for causing hypersensitivity" (15 U.S.C. §1261(k)). This definition is restated in the FHSA regulations at 16 CFR §1500.3(b)(9).

Currently, there are five substances identified in the FHSA regulations at 16 CFR § 1500.13, as "strong sensitizers." These include paraphenylenediamine and products containing it; powdered orris root; epoxy resins containing ethylenediamine, diethylenetriamine, and diglycidyl ethers of molecular weight of less than 200; formaldehyde and products containing 1 percent or more formaldehyde; and oil of bergamot and products containing 2 percent or more of oil of bergamot. These substances were determined to be strong sensitizers by the Food and Drug Administration (FDA) before the authority for the FHSA was transferred to CPSC in 1973. The CPSC has not declared any substances to be strong sensitizers.

The FHSA statutory definition of strong sensitizer was supplemented in the FHSA regulations by the FDA in 1961, to provide guidance on the interpretation of the statutory definition of strong sensitizer. In 1984, the Commission revoked these supplemental definitions for strong sensitizer because certain parts were found to be inconsistent with advances in the understanding of the basic principles involved in allergic hypersensitivity. In September 1984, the Commission established a Technical Advisory Panel on Allergic Sensitization (TAPAS) which helped the CPSC staff develop new supplemental definitions to clarify the interpretation of the statutory definition for strong sensitizer. On August 14, 1986, the Commission issued a rule supplementing the definition of strong sensitizer (51 FR 29094).

Effective September 15, 1986, the following definitions in 16 CFR §1500.3(c)(5) supplement the definition of sensitizer in 16 CFR §1500.3(b)(9).

Sensitizer: "A sensitizer is a substance that will induce an immunologically-mediated (allergic) response, including allergic photosensitivity. This allergic reaction will become evident upon reexposure to the same substance. Occasionally, a sensitizer will induce and elicit an allergic response on first exposure by virtue of active sensitization."

Strong: "In determining that a substance is a "strong" sensitizer, the Commission shall consider the available data for a number of factors. These factors should include any or all of the following (if available): Quantitative or qualitative risk assessment, frequency of occurrence and range of severity of reactions in healthy or susceptible populations, the result of experimental assays in animals or humans (considering dose-response factors), with human data taking precedence over animal data, other data on potency or bioavailability of sensitizers, data on reactions to a cross-reacting substance or to a chemical that metabolizes or degrades to form the same or a cross-reacting substance, the threshold of human sensitivity, epidemiological studies, case histories, occupational studies, and other appropriate *in vivo*[1] and *in vitro*[2] test studies."

[1] *in vivo* means in the living body
[2] *in vitro* refers to outside the body or in an artificial environment.

Severity of reaction: "The minimal severity of reaction for the purpose of designating a material as a "strong sensitizer" is a clinically important allergic reaction. For example, strong sensitizers may produce substantial illness, including any or all of the following: physical discomfort, distress, hardship, and functional or structural impairment. These may, but not necessarily, require medical treatment or produce loss of functional activities."

Significant potential for causing hypersensitivity: "Significant potential for causing hypersensitivity" is a relative determination that must be made separately for each substance. It may be based upon the chemical or functional properties of the substance, documented medical evidence of allergic reactions obtained from epidemiological surveys or individual case reports, controlled *in vitro* or *in vivo* experimental assays, or susceptibility profiles in normal or allergic subjects."

Normal living tissue: "The allergic hypersensitivity reaction occurs in normal living tissues, including the skin and other organ systems, such as the respiratory or gastrointestinal tract, either singularly or in combination, following sensitization by contact, ingestion, or inhalation."

These definitions identify the types of information that the Commission will consider when determining whether a substance is a strong sensitizer under the FHSA. For a product containing a strong sensitizer to be a hazardous substance and to require cautionary labeling under the FHSA, the product must be capable of causing substantial personal injury or substantial illness during or as a result of customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children (16 CFR §1500.3(b)(4)(i)). This requires consideration of the route and level of exposure that can be expected to be presented by the strong sensitizer as it exists in the particular household substance. Therefore, the determination of whether a cautionary label is required is made on a product-by-product basis and is not solely based on the presence of a strong sensitizer in a product.

If a household substance containing a strong sensitizer were determined to be a hazardous substance under the FHSA, cautionary labeling, including the signal words "Caution" or "Warning" would be required. However, if a toy or other article intended for use by children is a hazardous substance, then the product is banned unless specifically exempted (16 CFR §1500.3(b)(15)(i)).

These provisions do not apply to foods, drugs, and cosmetics regulated under the Federal Food, Drug, and Cosmetic Act.

Latex and Rubber Terminology

To avoid confusion about terminology associated with latex and products made from latex, the definitions to be used throughout this document will be the same as

those used by the FDA in its regulatory proceedings concerning medical devices containing latex (62 FR 51022).

Natural latex: is a milky fluid that consists of extremely small particles of rubber obtained from plants, principally from the *H. brasiliensis* tree, dispersed in an aqueous medium. It contains a variety of naturally occurring substances, including cis-1, 4-polyisoprene in a colloidal suspension, and plant proteins, which are believed to be the primary allergens.

Natural rubber (NR): includes all materials made from or containing natural latex. Products that contain natural rubber are made using two manufacturing processes: the natural rubber latex process and the dry natural rubber process.

Natural Rubber Latex (NRL): products that are manufactured from a process that uses natural latex in a concentrated colloidal suspension. The products are dipped, extruded, or coated. Examples of products are disposable gloves and balloons.

Dry Natural Rubber (DNR): products that are manufactured from a process that involves the use of coagulated natural latex in the form of dried or milled sheets. Products are made by either molding, extruding, or by converting the sheets into solution for dipping. Examples of products include tires, hoses, belts, and balls.

Other Federal Agency Activities Concerning NRL

Food and Drug Administration

The Food and Drug Administration (FDA) is the federal regulatory agency responsible for assuring the safety of many products including foods, drugs, cosmetics, and medical devices. Natural rubber is used either directly or indirectly in many products under the FDA's jurisdiction. The FDA is specifically reviewing the issue of potential NR allergy with respect to exposure to certain medical devices and foods.

Medical Devices

On September 30, 1997, in response to reports of severe allergic reactions and deaths related to medical devices containing NR, the FDA issued labeling requirements for medical devices containing NR in which the NR is intended to or likely to contact the user or patient (62 FR 51021). This rule requires NRL-containing medical devices to bear the label:

> **"Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions."**

Medical devices that contain DNR bear the label:

> **"This Product Contains Dry Natural Rubber."**

These FDA mandated labels also apply to packaging for medical devices that contain either NRL or DNR. This rule became effective on September 30, 1998. On April 1, 2003 the FDA issued a guidance document to help the industry with labeling for devices that contain NR.

In July 1999, the FDA proposed to reclassify surgeon's and patient's examination gloves as Class II medical devices (64 FR 41710). Currently, gloves are Class I medical devices that must meet general controls that are applicable to all devices. Class II medical devices require special controls because the general controls are insufficient to provide reasonable assurance of safety.

In the 1999 proposal, the FDA recommended controls including limits on the amount of powder and protein per glove, and proposed new user label requirements. The FDA recommended that gloves contain no more than 1,200 micrograms (µg) of extractable protein per glove. The rationale for the limits on powder and protein is based on the presumption that lower levels would result in lower rates of sensitization. The limit of 1,200 µg/glove was based on technical considerations that would maintain glove integrity such as shelf life and barrier effectiveness. This is not necessarily a "safe" level of protein since the threshold levels of protein allergens for sensitization and symptom development are not known. The availability and cost of gloves that would meet this proposed standard were also considered. Manufacturers would be required to label gloves with the measured amount of protein per glove. The FDA is currently analyzing the comments that were received in response to this proposal.

Food

The FDA regulates substances that come in contact with food. Natural rubber gloves and other NR-containing utensils that come in contact with food are permitted as long as they do not contain any chemical that is prohibited by the regulations of the Federal Food, Drug, and Cosmetic Act (21 CFR § 177.2600). The FDA's Center for Food Safety and Applied Nutrition (CFSAN) is studying NRL allergies related to food handling.

The FDA submitted a report to Congress on food mediated latex allergic reactions in response to a Congressional request that the FDA study the incidence of latex allergies related to food handling and outline its plans to eliminate exposure from latex if the data warrants such a decision.[3] In the report, the FDA states that it will continue to gather information and monitor the incidence of food mediated latex allergic reactions. In order to get independent expert consideration of the issue, the FDA charged the CFSAN Food Advisory Committee to look at this issue.

The Additives and Ingredients Subcommittee of the Food Advisory Committee is gathering information and providing advice and recommendations to the FDA relating to

[3] Congressional Report on Food Mediated Latex Allergic Reactions, Senate Report 107-41 and Conference Action and Public Law 107-76, October 2002.

allergic reactions to food prepared by workers wearing NRL gloves (68 FR 44956). The Advisory Committee met to discuss these issues on August 26-28, 2003. The Committee concluded that there is the potential for a causative role for latex allergy resulting from food handling especially from certain types of gloves, but agreed that the existing evidence for the relationship was weak.[4]

National Institute for Occupational Safety and Health

The National Institute for Occupational Safety and Health (NIOSH) has published two documents about NRL allergy. A pamphlet entitled, *"Latex Allergy, A Prevention Guide"* recommends the use of non-latex gloves for activities that are not likely to involve contact with infectious materials such as food preparation or routine housekeeping (DHHS 98-113).

NIOSH also published an alert entitled, *"Preventing Allergic Reactions to Natural Rubber Latex in the Workplace"* (DHHS 97-135) in June 1997. This alert is intended for workers who may be exposed to NRL. It provides workplace recommendations for reducing exposures to NRL including providing non-NRL-containing gloves when appropriate. In addition, the alert contains general information about allergy to NRL.

Occupational Safety and Health Administration

The Occupational Safety and Health Administration (OSHA) issued a technical information bulletin entitled, *"Potential for Allergy to Natural Rubber Latex Gloves and Other Natural Rubber Products"* in April 1999. The intent of this bulletin was to alert OSHA field staff about latex allergy and the potential for allergic reactions to latex in the workplace.

REVIEW OF SENSITIZATION AND ALLERGIC POTENTIAL OF NRL

Background

Before declaring that a substance is a strong sensitizer, the FHSA requires the Commission to find that the substance has significant potential for causing hypersensitivity[5] based on the frequency of occurrence and the severity of the reaction. Since the petitioner specifically requested that NRL be declared a strong sensitizer, the review of the sensitization and allergic potential is focused on NRL. In addition, most data generated to date has focused on NRL and not DNR.

Products that contain NRL have been linked to two different immunologically mediated responses, IgE antibody mediated hypersensitivity (type I or IgE-mediated)

[4] Transcript from the FDA, Additives and Ingredients Subcommittee of the Food Advisory Committee on latex allergy, August 27, 2003.

[5] Hypersensitivity is a condition where an individual reacts with an exaggerated immune response (allergic symptoms) after exposure to a substance after previous exposure to the same substance. In this paper, the terms hypersensitivity and allergy will be used interchangeably.

and cell-mediated hypersensitivity (Type IV). The causal agent(s) in cell-mediated hypersensitivity are chemicals added to NRL during the manufacturing process. These chemicals are also found in consumer products not made of NRL. Therefore, the CPSC staff did not evaluate the potential of such additives for causing cell-mediated hypersensitivity as part of the review of NRL. The discussion of potential allergy to NRL is limited to IgE-mediated hypersensitivity.

Allergy is a condition where an individual exhibits an "exaggerated" immune response to a normally innocuous agent. The development of an allergy is a two step process. In the first step, called sensitization, an individual becomes "sensitized" after exposure to the agent in sufficient quantities to produce specific antibodies (called IgE antibodies) against the agent or allergen. Upon re-exposure to sufficient quantities, the allergen, or one structurally similar, can cause a response with clinical symptoms called "allergy." Sensitization does not always lead to the development of an allergic reaction even if re-exposure occurs. While most allergic reactions involve minor symptoms (rash, nasal symptoms), anaphylactic reactions and death from NRL allergy have been documented.

The causal agent(s) in IgE-mediated sensitization and allergy to NRL are naturally occurring proteins found in NR. Several of these proteins have been characterized. However, the threshold levels of allergen needed for the development of sensitization and the development of clinical symptoms are not known.

The severity, thresholds for development, and prevalence of sensitization and allergy to NRL are described below. Tab B contains a detailed discussion of each of these subjects.

Severity of Reactions

According to 16 CFR §1500.3(c)(5)(iii), the minimal severity for designating a substance as a strong sensitizer is a clinically important allergic reaction. Clinical symptoms of IgE-mediated reactions to NRL range from mild to severe. Most individuals with IgE-mediated reactions experience a mild rash or upper respiratory symptoms, but asthma, anaphylactic shock, and death also have been reported. Other clinical reactions include conjunctivitis, nausea, vomiting, shortness of breath, generalized swelling, swelling of the tongue and larynx, and rapid heart beat.

The number of individuals experiencing severe, potentially life threatening anaphylactic reactions, has remained relatively low. A comprehensive literature review of anaphylaxis in the general population of the United States determined that between 8.7 and 63 million individuals were at risk of an anaphylactic reaction from all causative agents studied (i.e., drugs, foods, insect stings, and NRL) with approximately 1,500 deaths per year. The FDA received a total of 1,100 reports of NRL-induced anaphylactic reactions between 1988 and 1993, 15 of which resulted in death.

While there is no doubt that NRL is capable of causing serious reactions, most incidents of NRL-induced anaphylaxis are associated with invasive surgical or other medical procedures which involve a subset of the population and not the population as a whole.

Threshold for Sensitization and Clinical Symptoms

As described above in the Severity of Reaction section, allergens elicit physiological responses in two stages, sensitization, and the allergic response. Therefore, there are two different thresholds, 1) the dose for sensitization and, 2) the dose that elicits an allergic response in a sensitized individual. It is probable that the threshold levels for the two stages are different. Determining the threshold level of NRL allergens necessary to sensitize an individual and the level of NRL allergen to elicit an allergic reaction upon re-exposure is complicated by several factors including the genetics of the individual, the route of exposure, and the quantity of allergen that is available.

While no threshold for the development of NRL-specific IgE sensitization or allergic reaction has been established, studies indicate the quantity of NRL allergens in products and the frequency of exposure influence the degree of the allergic reaction. However, a "safe" level of NRL protein has not been established. Sensitive, accurate, and reproducible methods for determining the biologically available NRL allergens in products are necessary to determine a threshold level that will elicit allergic reactions in sensitized individuals. There are limitations in the accuracy and sensitivity of current test methods.

Prevalence

The FHSA requires that the Commission consider the frequency of occurrence of the reaction in healthy or susceptible populations in order to make the finding that a substance has a significant potential for causing hypersensitivity. However, the identification and confirmation of NRL-sensitized or -allergic patients is complex due to limitations and differences in the various diagnostic procedures. Currently, there is no universally accepted standard approach for diagnosing NRL allergy. In the United States, a diagnosis of NRL allergy is based on patient history and *in vitro* testing[6]. In other countries, *in vivo* skin prick testing[7] is also used to make a diagnosis. Provocation testing[8] may be used if a patient's history and *in vitro* test results are discordant. These differences in approaches make the interpretation of epidemiological studies difficult because there are wide variations in the estimates of the prevalence of allergy to NRL.

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[6] *in vitro* tests quantify serum IgE antibodies.

[7] *in vivo* skin prick testing involves monitoring the reaction to a small amount of a preparation containing soluble NRL allergens introduced into the skin. Skin prick testing carries the risk of inducing anaphylaxis.

[8] Provocation testing places the individual in an NRL-containing environment or directly exposes them to an NRL-containing product. This carries the risk of inducing an anaphylactic reaction.

Many epidemiological studies have focused on worker populations with high potential exposure to NRL. Healthcare workers are a group with potential high exposure to NRL and therefore are at potential risk of developing an allergy to NRL. Most sensitized healthcare workers appear to develop NRL allergy due to exposure from the increased use of gloves and other medical devices made of or containing NRL. The powder used to aid in donning of the gloves may contribute to the development of NRL allergy by being an airborne carrier of protein allergens. The prevalence of NRL allergy in healthcare workers ranges from 2.2 to 17 percent as determined by various tests in various studies.

Other occupations have high exposure to NRL and are therefore identified as being at risk for developing sensitivity to NRL. These include workers in NRL-containing product manufacturing plants and laboratory workers.

Individuals undergoing multiple surgical procedures may have mucosal membrane and visceral exposure to NRL that can increase the risk of developing NRL sensitization and allergy. Children with spina bifida were one of the first groups established to be at risk for NRL sensitization and allergy. The prevalence of NRL sensitization in individuals with spina bifida ranges from 29 to 65 percent.

Atopic individuals, those who have a genetic hypersensitivity to allergens, are also at risk for developing symptoms to NRL. Reactions to NRL can be seen in people who are allergic to fruits and vegetables such as avocado, kiwi, and banana. More than 20 different foods, fruits, or plants have been identified as cross-reactive with NRL.

The prevalence of hypersensitivity to NRL in the general population is estimated to be below one percent. Higher estimates of the prevalence of NRL sensitization in the general population are cited in studies that solely measure NRL-specific IgE antibodies using serological assays. However, these assays may have low specificity and can generate false positive test results that lead to an overestimation of prevalence.

Incidents Reported to CPSC

The role of NRL-containing consumer products in the development of allergy to NRL is not known. The medical literature documents incidents of allergic reactions following exposure to NRL-containing consumer products such as balloons and household rubber gloves. While the circumstances of sensitization are seldom known, incidents confirming non-occupational allergic reactions to NRL-containing products are reported.

Staff reviewed four CPSC injury databases (IPII[9], NEISS[10], DTHS[11], and INDP[12]) for reports of hypersensitivity reactions associated with NRL. The staff reviewed all four databases for the time period between January 1997 and December 2002. Details of this review are in Tab B.

No cases of a hypersensitivity reaction to NRL-containing products were identified in either the DTHS file or INDP file. A review of NEISS identified 62 potential cases and a review of the IPII database identified 44 reports involving a variety of NRL products under CPSC's jurisdiction (e.g., Halloween masks, hair glue, liquid latex, swimming caps, and shower curtains). Reactions to gloves and balloons dominated the reports in both databases.

The type of reaction (non-immunologically related, cell-mediated, or IgE-mediated) could not be determined from the information provided in the cases. There was a lack of information regarding the individual's history relating to NRL and *in vitro* and/or *in vivo* test results confirming a diagnosis of NRL allergy. No conclusions regarding allergy to NRL can be derived from these data.

CONSUMER PRODUCTS THAT CONTAIN NRL

A discussion of the market for NRL consumer products is at Tab C.

Natural rubber (NRL and DNR) is widely used. The most frequently cited estimate is that 40,000 different industrial, medical, and consumer products are made from NR. However, the identification of all consumer products that contain NR is extremely difficult. Tab C contains a list of household products and categories that may contain NR. It includes adhesives, balloons, elastic, pacifiers, as well as other possible NR-containing household consumer products. In several product categories, only some of the products may contain NRL. Latex adhesives may have applications in many product categories.

The manufacturing processes for DNR and NRL are different. If the NR is to be used for the manufacture of NRL products, the natural latex is concentrated and prevented from coagulating by adding a preservative such as ammonia. Other chemicals may be added to stabilize the NRL. Products are manufactured by dipping forms or molds into latex solution. The products then undergo further processing that may involve soaking, leaching, or rinsing in various substances such as water or

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[9] IPII is a compilation of incident reports of chronic, subchronic, and acute injuries from letters, hot line complaints, newspaper clippings, and other sources.

[10] NEISS is a nationally representative stratified probability sample of emergency room (ER) hospitals within the United States and its territories.

[11] The DTHS database consists of death certificates purchased according to certain external causes of death (Ecodes) likely to be associated with consumer products from all states, New York City, and the District of Columbia.

[12] The INDP database consists of in-depth investigations conducted by CPSC investigators of incidents reported to the CPSC.

cleaning solutions. In contrast, DNR is allowed to coagulate after it is collected. The coagulum is then crumbled and washed extensively before being pressed and dried at high temperatures.

The amounts of protein allergens in various natural rubber-containing products are generally not known. However, the processing of NR can change the protein profile. The profile of proteins varies greatly between DNR and NRL. The protein content of DNR-containing products tends to be lower than the protein content of NRL-containing products. This is probably due to the washing and high heat used in the DNR process.

Few studies have measured the protein or allergen content of non-medical NRL-containing products. However, the amount of protein and allergen appears to vary widely between product classes and within product classes made of NRL. Differences may be explained by variations in manufacturing processes. Longer periods of leaching or more extensive rinsing during the manufacture of the NRL products may remove more of the water-soluble proteins from the product. For example, the measured water-extractable protein content of 62 different NRL-containing products, including 21 different brands of gloves, balloons, mattress covers, and rubber tubing, varied from 5 micrograms per gram (µg/g) to 5,000 µg/g.[13] In another study, the measured allergen levels varied 3000-fold among powdered examination gloves from 10 different manufacturers.[14]

REMEDIATION

A detailed discussion is found at Tab B.

Since there is currently no "cure" for NRL allergy, avoidance of NRL-containing products or decreasing the levels of allergens in the products are the only ways to prevent clinical reactions in NRL allergic patients. Primary prevention programs that substitute low-protein powder-free NRL gloves, synthetic gloves, or both, for powdered NRL gloves appear to reduce the prevalence of NRL allergy in healthcare workers.

As described above, the way NRL is processed may affect the amount of protein and therefore, its allergenicity. Several processes may decrease the amount of protein or allergen. Water leaching of NRL products decreases the extractable protein content by decreasing the water-soluble components. Post-washing and chlorination of NRL products are two additional ways of reducing the amount of protein. Recently, it has been demonstrated that enzyme treatment of NRL reduces the antigenic protein in NRL without compromising the physical properties and performance of NRL products. The

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[13] Baur, X., Chen, Z., Raulf-Heimsoth, M., Degens, P. Protein and allergen content of various natural latex articles. Allergy 1997, 32:661-664.

[14] Yunginger, J.W., R.T. Jones, A.F. Franway, J.M. Kelso, M.A. Warner, and L.W. Hunt. Extractable latex allergens and proteins in medical gloves and other rubber products. J. Allergy Clin. Immunol. (1994). 93:836-841.

enzyme treatment cuts the NRL proteins into smaller non-antigenic proteins. Enzyme treatment is suitable for large-scale production of NRL gloves and can produce low allergen gloves with acceptable physical, aging, and barrier properties.

Although these methods are being developed to decrease the amount of protein or allergen in products, it is important to remember that the lowest level of NRL proteins necessary to elicit a response in an NRL allergic person is not defined. The various NRL proteins have different antigenic properties and responses by individuals may vary greatly depending on the content of individual antigens. Therefore, it is difficult to establish a correlation between 1) the total NRL protein concentration and the ability to sensitize, and 2) the total NRL protein concentration and the ability to elicit clinical symptoms in sensitized individuals. A "safe" level of NRL protein is not established.

SUMMARY

The petitioner requests that NRL be added to the list of strong sensitizers under the FHSA and that NRL-containing products be labeled accordingly. NRL products are manufactured from the milky fluid obtained from plants, principally from the *H. brasiliensis* tree, that consists of extremely small particles of rubber dispersed in a concentrated colloidal suspension.

Before designating NRL as a strong sensitizer, the Commission must find that NRL has a significant potential for causing hypersensitivity. The Commission must consider the frequency of occurrence and severity of the reaction when making the decision to designate a substance as a strong sensitizer. Sensitization and allergy to NRL have been documented. Naturally occurring proteins in NRL have been identified as the causal agents (allergens) in IgE-mediated sensitivity and allergy to NRL. However, the threshold levels of allergen necessary for the development of sensitization and the development of clinical symptoms are not known and are likely to vary among individuals. While most allergic reactions involve minor symptoms, anaphylactic reactions and death from NRL allergy have been documented.

NRL allergy has been associated with several specific populations including medical personnel who have high exposure to NRL-containing gloves, people who have had multiple surgeries that expose the mucous membranes directly to NRL, and atopic persons who are genetically more sensitive to many allergens.

Because NRL allergy in medical personnel and surgical patients has been associated with exposure to medical devices, the FDA requires labeling of these products. The FDA is considering whether to recommend specific levels of soluble protein and powder in gloves. However, these levels are not considered to be "safe" levels since the thresholds for sensitization and allergy development are not known.

While there has been an increase in reports of NRL allergies in medical personnel, the prevalence of NRL allergy in the general population has remained at less than one percent. Exposure of the general population to NRL is unknown. It is

estimated that there may be 40,000 products that contain NR. However, identification of all consumer products that contain NRL is very difficult. In addition, the levels of allergens in most NRL-containing products have not been measured and may vary depending on the manufacturing processes that are used.

RESPONSE TO COMMENTS

The Commission published a Federal Register notice on March 21, 2000 to inform the public about the petition from Ms. Adkins and to solicit comments concerning the petition (65 FR 15133). The Commission extended the comment period for an additional 30 days in response to seven requests for additional time to comment. The CPSC received 85 comments. The list of commenters is at Tab D. The comments are available for viewing at the CPSC website;
http://www.cpsc.gov/library/foia/foia00/pubcom/pubcom.html

Twenty-nine commenters support the petition that NRL should be declared a strong sensitizer. Forty-one commenters support either content or warning labeling of consumer products that contain NRL. Thirty-three of the commenters stated they do not support the petition. Thirty-one of the comments are from, or written on behalf of, people who claim to have NRL sensitivity or allergy. None of the commenters provided medical documentation. Twenty of the commenters are either product manufacturers or suppliers of NR. Eight commenters indicated that NRL does not meet the definition of a strong sensitizer.

The staff's responses to specific comments are detailed below.

Labeling Consumer Products that Contain NRL

The following comments deal with labeling issues. A more detailed response to labeling issues is at Tab E.

Comment: Since avoidance of NRL is the only current treatment for NRL allergy, many commenters requested labeling of consumer products to identify that they contain NRL.

Response: Under the FHSA, products require cautionary labeling if they are hazardous substances. The regulation requires the common name or the chemical name of the hazardous substance or each component which contributes substantially to its hazard be stated on the label of the product (16 CFR§1500.3(b)(14)). NRL-containing products would require cautionary labeling under the FHSA if: 1) NRL were declared a strong sensitizer, and 2) if the nature and level of exposure to the NRL-containing products were such that substantial personal injury or substantial illness could result during or as a result of customary or reasonably foreseeable handling or use. Therefore, if NRL were declared a strong sensitizer, only products found to be hazardous substances, i.e. meeting the second requirement, would require cautionary labeling. This would not necessarily result in the labeling of all products that contain NRL.

Aside from the question of the Commission's authority to require ingredient labeling or warning labels on all products that contain NRL, this approach raises many issues. Labeling of all NRL-containing products, as many of the commenters suggest, would be appropriate only if NRL in a particular product posed a hazard to sensitized individuals who needed to identify and avoid that product. However, there is currently no good basis for making a determination of the likelihood of an allergic reaction to a product because the NRL allergen levels that will trigger an allergic reaction are not known. It is not yet possible to distinguish consumer products which may contain hazardous levels of NRL allergens. Documented clinical reactions are limited to a small number of NRL-containing consumer products, such as balloons and gloves. These products are generally known to have NRL, therefore, labeling them would not provide consumers with any additional information.

Comment: Ten commenters indicated that declaring NRL to be a strong sensitizer and labeling consumer products could alarm or confuse consumers who are otherwise unaffected by NRL and discourage them from using beneficial products (CH00-4-18, 19,23,55,62,64,65,66,69,71).

Response: New labels could cause some concern or avoidance, however, those responses are likely to be the exception. Most consumers are not NRL allergic, and therefore have had no negative reactions to NRL. They are unlikely to perceive products containing NRL, such as balloons, as hazardous, and are unlikely to be concerned about the effects of using them. Therefore, a cautionary label about NRL would not be expected to change consumers' behavior, especially with familiar products that they perceive to be safe.

Comment: One commenter (CH00-4-56) requested that products that contain NRL be labeled only if the NRL is accessible. The commenter specifically requested that NRL adhesives used to bond foam in furniture be exempted from labeling because the adhesive is not accessible.

Response: If the Commission declares NRL to be a strong sensitizer, then the FHSA would require cautionary labeling when the nature and level of exposure to an NRL-containing product could result in substantial personal injury or substantial illness during or as a result of customary or reasonably foreseeable handling or use. If exposure to, and injury from, an NRL-containing product were not expected to occur because the strong sensitizer is inaccessible in the specific product, the product would not meet the definition of a hazardous substance, and would not require cautionary labeling under the FHSA.

Comment: One commenter (CH00-4-63) suggested that for non-medical products the need for cautionary or informational labeling should be made voluntarily by manufacturers on a product-by-product basis.

Response: Currently, there is nothing to prevent manufacturers from labeling NRL-containing products voluntarily and several companies have labeled their consumer-use

gloves. However, voluntary labeling of NRL-containing products is not the focus of the petition. The petitioner requested that NRL be declared a strong sensitizer under the FHSA and that products be labeled accordingly. If NRL were declared to be a strong sensitizer, the requirement for cautionary labeling for this hazard would depend on the product's potential, due to its NRL content, to cause substantial personal injury or illness during or as a result of exposure during use.

Comment: Three commenters (CH00-4-3, 31,75) requested labeling of prepackaged food that is exposed to any NRL. Commenters also requested identifying restaurants and other establishments where NRL-containing gloves are used.

Response: The labeling of prepackaged food or identification of restaurants requested by the commenters is not within CPSC's jurisdiction. The FDA is currently reviewing the incidence of NRL allergies related to food handling.

Comment: Seven comments specifically dealt with labeling clothing and shoes that contain NRL. Four commenters (CH00-4-28, 29,34,38) requested that all clothing and shoes that contain NRL be labeled. Three commenters (CH00-4-23, 73,77) stated that labeling clothing was not necessary because NRL is in low quantities in garments and garments are washed and the soluble protein allergens are removed.

Response: Clothing is a consumer product regulated by the CPSC and is therefore within the scope of the petition. If the Commission declared NRL to be a strong sensitizer, only NRL-containing clothing that may cause substantial personal injury or substantial illness during or as a result of customary or reasonably foreseeable handling or use would require cautionary labeling. This would not necessarily result in the cautionary labeling of all garments that contain NRL.

Comment: Six commenters requested that medical devices be exempt from FHSA jurisdiction because FDCA-required labeling was sufficient (CH00-4-59, 60,61,62,65, and 69).

Response: The term, "hazardous substance" does not apply to foods, drugs, and cosmetics subject to the FDCA. However, medical devices are not specifically exempted from the jurisdiction of the FHSA (15 U.S.C §1261). If the Commission were to declare NRL a strong sensitizer, the Commission could defer any action regarding NRL-containing medical devices to the FDA. Currently, the FDA requires labeling of NRL- and DNR-containing medical devices.

Alternative to Labeling for Consumer Products

Comment: Two commenters (CH00-4-28, 31) specifically requested that latex balloons be banned.

Response: The petitioner requested that NRL be declared a strong sensitizer. If NRL is declared to be a strong sensitizer, products that contain NRL that cause substantial

personal injury or substantial illness during or as a result of customary or reasonably foreseeable handling or use would require cautionary labeling. However, as defined in the FHSA, if a toy or other product intended for use by children is determined to be a hazardous substance, or if a toy or other product intended for use by children contains a hazardous substance that is accessible to children, then the product would be banned, not labeled (16 CFR §1500.3(b)(15)(i)(A)).

Comment: Four comments were received related to the identification and removal of the components of NRL responsible for the reactions. One commenter (CH00-4-53) suggested that the toxic components of rubber be identified and removed. Two commenters (CH00-4-35, 40) requested standards for low levels of antigens in NRL products. Another commenter (CH00-4-19) described a test method for decreasing the amount of protein in NRL.

Response: As the commenters suggest, the best approach for limiting potential sensitization from NRL is to identify and remove the protein allergens. The identification of protein allergens responsible for the development of allergy to NRL is the focus of current research. Several of the protein structures have been characterized.

As discussed previously, the FDA has proposed recommending a limit on the amount of protein in NRL-containing gloves. The FDA recommends a limit of the total amount of protein to 1,200 µg/glove, based on considerations that would maintain glove integrity such as shelf life and barrier effectiveness, and the availability and cost of gloves. This is not necessarily a "safe" level of protein since the threshold levels of protein allergens for sensitization and symptom development are not known. Although, it is not known at this time what effect decreasing the level of protein to 1,200 µg/glove will have on the future development of allergy to NRL, it is presumed that lowering the amounts of protein will result in lower frequencies of sensitization and allergy.

Medical personnel are a high-risk group for the development of NRL allergy, primarily due to high exposure to NRL gloves. Given these circumstances, the approach taken by the FDA seems reasonable. This is not currently the case for consumer products that contain NRL. Documented cases of allergy from NRL-containing consumer products are few. The amounts of NRL allergenic proteins contained in the wide range of consumer products are either not known or vary greatly. Given the lack of available data on the allergenicity of NRL-containing consumer products, and the lack of data about a "safe" level of allergen protein, it is not currently feasible to set a level of protein or allergen content for NRL-containing consumer products that would be considered to have low or no sensitization potential.

Comment: Three commenters (CH00-4-4, 35,57) requested that the CPSC ban powdered gloves.

Response: The powder, used in gloves to facilitate donning them, binds protein allergens from NRL and is thought to contribute to the development of NRL allergy. In medical settings where many glove changes occur, high levels of powder in the air have

been measured. Therefore, the FDA has proposed to recommend a limit on the level of powder in medical gloves.

The petition to the CPSC requested that NRL be declared a strong sensitizer. If the Commission declared NRL to be a strong sensitizer and NRL-containing gloves for consumer use met the definition of a hazardous substance, those gloves would require cautionary labeling. In order to ban powered gloves for consumer use, the Commission would have to find that labeling was inadequate to address the risk of injury or illness from powdered gloves.

Comment: Two commenters (CH00-4-67, 85) suggested that NRL be considered separately from DNR because of the differences between these two products.

Response: The petition from Ms. Adkins requests specifically that NRL be declared a strong sensitizer. However, there is evidence that products made with DNR contain less protein than products made of NRL. Since the protein components and not the natural latex itself are the causal agents in the development of sensitivity and symptoms, it would be appropriate to consider NRL and DNR separately if it is determined that DNR does not contain enough protein to cause sensitization or subsequent allergy. However, the protein threshold levels are not known.

The FDA does not require a warning label on medical devices made of DNR. However, the FDA does require ingredient labeling of medical devices that contain DNR. This action was taken by the FDA because of reports of allergic reactions from DNR products. The allergy cases cited by the FDA followed the direct injection into the body of substances that were drawn through a vial with a DNR stopper or a syringe with a DNR plunger. This scenario does not exist with consumer products.

Latex Alternatives

Comment: Three commenters (CH00-4-40, 44,56) expressed concern about the use of more toxic or inferior replacements to NRL. One commenter (CH00-4-85) stated that there were no replacements for DNR.

Response: The commenters did not provide information to support their assertion that more toxic or inferior products would be used as replacements to NRL. The petitioner requested that NRL be added to the list of strong sensitizers under the FHSA and that NRL-containing products be labeled accordingly. The commenters imply that manufacturers would stop making products out of NRL or that consumers would stop buying products made of NRL if the Commission declared NRL to be a strong sensitizer. The staff has no information to verify these assertions.

Economic Impact

Comment: Two commenters (CH00-4-65, 68) stated that declaring NRL to be a strong sensitizer would have a cost impact associated with labeling. The commenters

speculated that a potential decrease in the use of NRL could have a serious impact on small businesses.

Response: The Commission is required by law to consider the impact of rulemaking on small businesses. This would be done as part of the rulemaking proceedings if the Commission grants the petition and initiates rulemaking to declare NRL a strong sensitizer.

OPTIONS

The Commission has three options:

1. If the Commission concludes that it is appropriate, the Commission could grant the petition and begin a proceeding to declare NRL to be a strong sensitizer.

2. If the Commission concludes that information is not available or likely to be developed to support the findings required by Section 2(k) of the FHSA and 16 CFR §1500.3(c)(5) of the FHSA regulations to declare NRL to be a strong sensitizer, the Commission could deny the petition.

3. If the Commission concludes that information is insufficient but is likely to be developed in a reasonable time to support the findings required by Section 2(k) of the FHSA and 16 CFR §1500.3(c)(5) of the FHSA regulations to declare NRL to be a strong sensitizer, the Commission could defer the petition.

RECOMMENDATION AND DISCUSSION

The petitioner requests that the Commission add NRL to the list of strong sensitizers under the FHSA and that products containing NRL be labeled accordingly. Before designating any substance as a strong sensitizer, the Commission must find that the substance has a significant potential for causing hypersensitivity. When making this decision, the Commission must consider the frequency of occurrence and severity of the reaction.

At this time, information about the development of NRL allergy from consumer products that contain NRL is limited and it does not appear that such information will be developed in the near future. The percent of NRL-allergic individuals in the general population has stayed relatively constant while increases in the number of NRL-allergic individuals are occurring in the occupational setting. The prevalence of NRL allergy in the general population is estimated to be less than one percent.

There is no doubt that certain NRL-derived proteins have been identified as allergens capable of causing sensitization and allergy. NRL allergy has been associated with a range of symptoms from mild to severe including anaphylaxis. Death from allergic reactions to NRL has been documented. However, the greatest risk of having a severe reaction has been associated with groups with high and frequent

exposure to NRL, such as occupationally or surgically exposed individuals or in atopic individuals who are genetically sensitive to many allergens.

Since medical personnel are a high-risk group for the development of NRL allergy mainly due to high exposure to gloves, the FDA has proposed to recommend a level of protein and powder for NRL gloves. This is not necessarily a "safe" level of protein since the threshold levels of protein allergens for sensitization and symptom development are not known. However, the rationale for the limits on powder and protein is based on the presumption that lower levels would result in lower rates of sensitization and allergy.

This is not currently the case for consumer products that contain NRL. There are very few NRL-containing consumer products for which there are documented allergic reactions. Currently, it is not possible to define threshold levels of NRL allergens that sensitize an individual or produce clinical symptoms in sensitized individuals. In addition, the amounts and types of NRL allergens in NRL-containing consumer products are largely unknown. Thus, there is currently no way to correlate the allergen content of NRL finished consumer products to the levels needed to either sensitize or to elicit clinical symptoms in sensitized individuals.

The staff recommends that the Commission deny the petition because the available data are insufficient to support that NRL is a strong sensitizer according to the FHSA definition. In addition, it should be noted, that even if the Commission found NRL to be a strong sensitizer, not all consumer products containing NRL would necessarily require cautionary labeling as the petitioner requested.

TAB A

HP 00-2

Latex Allergy New

Offices of the Secretary
Consumer Product Safety Commission
Mail Address: Washington DC 20207
Delivery Address: Room 420
5401 Westbard Ave.
Bethesda MD 20816
Tel. 301-504-0800
Fax. 301-504-0127

CPSA 6 (b)(1) Cleared #490
No. Misc. Prods.
Products Identified
Excepted by
Firms Notified
Comments Processed
WITH Comment
Notice Required.

Citizen Petition

The Undersigned submits this petition under CFR. Part 1051, "procedures for petitioning for rulemaking". Latex allergy is a progressive allergy that has been recognized in the last ten years. Prior to that it was thought that a very small percent of the population had any kind of reactions or sensitization to Natural Rubber Latex (NRL). With the advent of Universal Precautions by OSHA, and the CDCP, that changed. There were changes made to speed up the production of NRL products, and this lead to the sensitization of a large percentage of the population.

The FDA recognized that there was a problem, and issued an alert as early as 1991, and now requires labeling on all products that contain NRL. The FDA only mandates the Medical Products need to be labeled. This ruling went into effect in September 1998. There was some question about whether to include consumer products, and it was felt that that was outside the jurisdiction of the FDA. That puts this problem in the hands of the Consumer Products Safety Commission.

A. Action Requested

1. Amendment of sec.1500.13, to add to list of "strong sensitizers, Natural Rubber Latex (NRL) and products containing NRL; and that said substance and products be labeled per sec. 1500.3(A)(2)(12),(13) and (14).

2. In accordance with sec.1500(b)(15)(i), re: "Banned hazardous substances"; to require labeling of toys or other articles intended for use by children which may contain NRL under sec. 1500.3(b)(9).

B. Statement of grounds

1. Recent scientific findings indicate that NRL meets CFR criteria for a "hazardous substance" per sec. 1500.3(4)(i)(A); a "strong sensitizer" per sec. 1500.3(b)(9); a "banned hazardous substance" per sec. 1500.3(b)(15)(i) and sec. 1500.3(c)(5)(i) through (v); and sec. 1500.14(B)(9), that details the definition of sensitizers and strong sensitizers that qualify as hazardous substances.

2. The scientific findings described below, clearly contradict concensus re: NRL when the list of "Strong sensitizers" in sec. 1500.13 was codified, per the attached page from a report, "Rubber sensitizers", by Susan E. Feinman, Ph.D., sent to Sandra Eberle, Chemical Hazards Program, OPM, on 29, December 1986. Introductory sub-paragraph (A), "Purpose of Report", states, "The purpose of this report is to evaluate whether certain rubber additives are bioavailable from consumer products in sufficient quantities to elicit allergic hypersensitivity responses and whether they should be labeled by the commission as strong sensitizers under the Federal Hazardous Substance Act. Subparagraph (c), "Rubber Sensitization, states, "Natural rubber poses no hazard as a contact allergen (Cronin, 1980)". The subparagraph concludes, "Thus consumers attributing allergic contact dermatitis to "rubber" are actually reacting to rubber additives".

Latex Allergy News
www.latexallergynews.com
176 Roosevelt Ave.
Torrington, CT 06790
(860)482-6869
(860)482-2294 Fax
debulan1@jps.net

3. The above earlier conclusion re: NRL is obsoleted by the preponderance of reputable research and clinical studies cited in the Food and Drug Administration Final Rule, effective September 30, 1998, 21CFR Part 801, "Natural Rubber Containing Medical Devices: User Labeling" which according to the FDA, "scientific studies and case reports have documented sensitivity to natural latex proteins found in a wide range of medical devices". Re-labeling of "nonmedical NRL gloves and other consumer products that contain natural rubber", the Final Rule states, "The regulation of such products is beyond the scope of this rule. FDA's authority under the act to impose labeling requirements is restricted to products that meet the definition of foods, drugs, cosmetics, animal drugs, biologics, and devices, as those terms are defined under the act." The rules adds." FDA also does not agree with the suggestion that OTC Medical devices be exempted from the labeling".

4. The Journal of the Academy of Dermatology (Vol. 39, No. 1, July 1998) article, "Latex Allergy", summary states: "Coined the next major health concern of the decade, allergy to natural rubber latex affects people routinely exposed to rubber products. Groups at highest risk include health care workers, rubber industry workers, and persons who have undergone multiple surgical procedures, especially those with spina bifida. Allergy to latex is a type I, immediate, IgE - mediated reaction, which can lead to anaphylaxis and death. Much of latex research is published in allergy journals." The attached Journal article pages 1, 3, 5, 6 and 7, describe common nonmedical household products containing NRL; prevalence of latex allergy in the general and occupational populations; and allergy "risk factors", per attached with reference citation. The prevalence of latex in the general population is probably less than 2%. However, the accompanying Table IV lists six authoritative sources for "percent of positive", using different methods of testing, and the range from 0.8% to 7.9%. Pages 5 and 6 and Table V cite studies reporting much higher latex sensitivity rates among certain populations: "Children with Spina Bifida: Currently 8 of 10 anaphylactic reactions occurring during surgery in all children are due to latex allergy". It adds, "a recent study demonstrated a rate of 65%".

5. The enclosed CPSC Consumer Product Incident Reports, obtained under the FOIA and/or "copied" to the Latex Allergy News, detail the everyday experiences of latex allergy sufferers: including the newspaper article description of 13-year-old Denise Rae Odenbreit's fatal allergic reaction to toy balloons, (per her attending physician, Paul Kubic, MD. /. 612-220-6744, and her death certificate). The CPSC also received notice of the death of Sherry Fee Swineburg, 7/11/97, which was passed on to the FDA MedWatch system. (Rpt Page 562). Although there was no scientific evidence to link this event to latex allergy, it did mention that the patient had been diagnosed with a latex allergy, and the event did not have to be a work related death, the causative agent could have been a consumer product. The CPSC also released the enclosed Incident Report on the latex induced death of U.S. Navy Lt. Harold R. Henderson, as poignantly described by his mother, Mary Ann Henderson in her January 7, 1998 letter to the state of Wisconsin State Legislature.

6. The cover page of Mary Ann Henderson's letter mentions my name, Debra Adkins, in association with The Latex Allergy Information Service. I am Editor of "The Latex Allergy News", a newsletter with 10,000 subscribers and 942 daily visitors to its Web site: (one of five or ten latex allergy related web sites). However my interest in latex allergy is personal as well as professional. Briefly, I was a health care worker for 22 years, before I developed a life threatening latex allergy. I have very limited access to heath care, and have to be very aware of latex products wherever I visit. That is why I have to travel into New York City for any dental care, a distance of over 90 miles one way. Any and all of my physicians are made aware of the implications, and reactions and schedule any of my appointments for early in the day, to try to insure my safety.

There are so many products that contain NRL, but they may not be known. That is why we need the help of the CSPC. There is presently no "cure" for latex allergy; the only management is avoidance.

Latex Allergy New

C. Certification

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 are unfavorable to the petition 2/28/00

Sincerely

Debra M. Adkins

Latex Allergy News
176 Roosevelt Ave
Torrington CT. 06790
Tel. 860-482-6869
Fax. 860-482-2292

Date: 3

From: Debi Adkins Latex Allergy Information Service

To: Sandy Dunn Sec. to Comm.

Fax number:

301-504-0127

Comments:

No. of pages to Follow: 4

If any portion of this is transmittal is unclear please call 860-482-6869

This is an updated petition. There were a couple of typo's and one stat. was wrong it read 69% instead of 65%

I mailed it out on Feb 29, and it was returned - I give up -

Please respond by Fax

Thank you

178 Roosevelt Ave.
Torrington, Ct. 06790
(860) 482-6869
telefax 860-482-7640
CompuServe (76500,1452)

Secretary
Product Safety Commission
Office
Westboard Ave
MD

Journal of the
American Academy of
DERMATOLOGY
VOLUME 39 NUMBER 1 JULY 1998

CONTINUING MEDICAL EDUCATION ART 105 98

Latex allergy

Erin M. Warshaw, MD *Minneapolis, Minnesota*

Coined the next major health concern of the decade, allergy to natural rubber latex affects people routinely exposed to rubber products. Groups at highest risk include health care workers, rubber industry workers, and persons who have undergone multiple surgical procedures, especially those with spina bifida. Allergy to latex is a type I, immediate, IgE-mediated reaction, which can lead to anaphylaxis and death. Much of latex research is published in allergy journals. Dermatologists may not be aware of the prevalence, symptoms, risks, diagnosis, and treatment of latex allergy. These topics are the subject of this review. Research concerning antigenic proteins, as well as sources of latex alternatives, is also summarized. (J Am Acad Dermatol 1998;39:1-24.)

Learning objective: At the completion of this learning activity, participants should have a clear understanding of the history, biology, epidemiology, mechanism, clinical characteristics, diagnostic work-up, and treatment of latex allergy. Readers should also have a greater understanding of multiple potential allergenic latex proteins and their importance in preventing future latex-sensitization.

HISTORY OF RUBBER PRODUCTION

Pre-Columbian sketches depicting natural rubber religious offerings are probably the earliest documentation of the use of natural rubber latex (NRL). The first European explorers to visit Central America in the 15th century saw local people fashioning rubber shoes, balls, and bottles. Samples of these products were sent to Spain by the conquistadors. Rubber became an industrial product in Europe during the late 1700s after MacIntosh developed a waterproofing process.[1]

Unfortunately, early rubber products became brittle under cold conditions as well as sticky with age. These problems were solved in 1839 when Goodyear accidentally discovered vulcanization, a process that utilizes sulfur to stabilize the elastic properties of rubber. Dunlop invented the inner tube and hollow tire in 1888,[1] and the first pair of rubber gloves was made by the Goodyear Rubber Company in 1890 at the request of William Stuart Halstead of breast surgery fame.[2] In 1850, Wickham, a British rubber planter in Brazil, introduced rubber seeds into Asia, now the major supplier of raw latex.[3]

HISTORY OF RUBBER ALLERGY

Two types of allergic reactions to rubber products are now known: type I (immediate-type) and type IV (delayed-type hypersensitivity [DTH]) (Table I). The first case of an immediate reaction to NRL was reported in 1927 by Stern[4] who described severe generalized urticaria caused by a rubber dental prosthesis. Almost half a century later, Nutter[5] reported the first glove-related case of an immediate-type reaction, contact urticaria. Soon after, several researchers[6-10] established a link between NRL glove–induced symptoms and IgE mechanisms.

From Dermatology, University of Minnesota and the Veterans Affairs Medical Center.
Reprint requests: Erin M. Warshaw, MD, Dept. 111K Dermatology, VA Medical Center, 1 Veterans Dr., Minneapolis, MN 55417.

0190-9622/98/$5.00 + 0 16/2/90031

SEEKING PERMISSION 7/21/00

Consumer Product Incident Report

Please contact us about any injury or death involving consumer products. Call us toll free at: 1-800-638-8095. Visit our web site at www.cpsc.gov. Or, fill out the form below. send it to: U.S. Consumer Product Safety Commission/EHDS, Washington, DC 20207 or fax it to: 1-800-809-0924. We may contact you for further details. Please provide as much information as possible. Thank you.

[redacted]

YOUR NAME

[redacted]

YOUR ADDRESS

SAN DIEGO CA 92111

CITY STATE ZIP

[redacted]

YOUR TELEPHONE

SAME

NAME OF VICTIM (IF DIFFERENT FROM ABOVE)

ADDRESS

CITY STATE ZIP

TELEPHONE

DESCRIBE THE INCIDENT OR HAZARD, INCLUDING DESCRIPTION OF INJURIES LATEX ALLERGY AT WORK WITH RESPIRATORY PROBLEMS INCLUDING ASTHMA, ANAPHYLAXIS. I NOW HAVE REACTIVE AIRWAY DISEASE & HEART MURMUR. I AM UNABLE TO WORK WITHOUT REACTING WITHIN 10 MINUTES OF BEING WITHIN HOSPITAL. AM RN WORKING RECOVERY RM & OR.

VICTIM'S AGE 51 SEX F DATE OF INCIDENT 4/96

DESCRIBE PRODUCT INVOLVED LATEX EXAM GLOVES

PRODUCT BRAND NAME/MANUFACTURER

IS PRODUCT INVOLVED STILL AVAILABLE? ☐ YES ☐ NO PRODUCT MODEL AND SERIAL NUMBER

WHEN WAS THE PRODUCT PURCHASED?

This information is collected by authority of 15 U.S.C. 2054 and may be shared with product manufacturers, distributors, or retailers. No names or other personal information, however, will be disclosed without explicit permission.

U.S. Consumer Product Safety Commission
Washington, DC 20207

TC-49

PLEASE DUPLICATE THIS FORM FOR FUTURE USE. CPSC FORM 175A (6/96) OMB CLEARANCE NO.

Consumer Product Incident Report

Please contact us about any injury or death involving consumer products. Call us toll free at: 1-800-638-8095. Visit our web site at www.cpsc.gov. Or, fill out the form below. send it to: U.S. Consumer Product Safety Commission/EHDS, Washington, DC 20207 or fax it to: 1-800-809-0924. We may contact you for further details. Please provide as much information as possible. Thank you.

YOUR NAME

YOUR ADDRESS

CITY STATE ZIP

YOUR TEL

NAME OF VICTIM (IF DIFFERENT FROM ABOVE)

ADDRESS

CITY STATE ZIP

TELEPHONE

DESCRIBE THE INCIDENT OR HAZARD, INCLUDING DESCRIPTION OF INJURIES Latex Balloons in hotels, restaurants sports arenas, grocery stores + florists shop cause my eyes to water + itch, and my throat to swell even after brief (2-3 minute) contact. MYLAR balloons are latex free + should be the only balloons used unless notice posted on the entrance. '

VICTIM'S AGE 57 SEX F DATE OF INCIDENT CONSTANT - multiple dates.

DESCRIBE PRODUCT INVOLVED Latex balloons

PRODUCT BRAND NAME/MANUFACTURER

IS PRODUCT INVOLVED STILL AVAILABLE? ☒ YES ☐ NO PRODUCT MODEL AND SERIAL NUMBER

WHEN WAS THE PRODUCT PURCHASED?

This information is collected by authority of 15 U.S.C. 2054 and may be shared with product manufacturers, distributors, or retailers. No names or other personal information, however, will be disclosed without explicit permission.

U.S. Consumer Product Safety Commission
Washington, DC 20207

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Consumer Product Incident Report

Please contact us about any injury or death involving consumer products. Call us toll free at: 1-800-638-8095. Visit our web site at www.cpsc.gov. Or, fill out the form below. send it to: U.S. Consumer Product Safety Commission/EHDS, Washington, DC 20207 or fax it to: 1-800-809-0924. We may contact you for further details. Please provide as much information as possible. Thank you.

YOUR NAME

YOUR ADDRESS [redacted]

CITY STATE ZIP

YOUR TELEPHONE [redacted]

NAME OF VICTIM (IF DIFFERENT FROM ABOVE)

ADDRESS

CITY STATE ZIP

TELEPHONE

DESCRIBE THE INCIDENT OR HAZARD, INCLUDING DESCRIPTION OF INJURIES Throat began swelling 1 hr after eating a Hamburger at Burger King in Minnesota (No. Mankato?) Also 2 Bar B Q restaurants in Kerrville, + + Comfort, TX - If gloves are mandatory in restaurants, vinyl (not latex) gloves should be used or a latex sign posted.

VICTIM'S AGE 57 SEX F DATE OF INCIDENT May 98 + Feb 99

DESCRIBE PRODUCT INVOLVED Latex gloves by food workers

PRODUCT BRAND NAME/MANUFACTURER

IS PRODUCT INVOLVED STILL AVAILABLE? ☐ YES ☐ NO PRODUCT MODEL AND SERIAL NUMBER

WHEN WAS THE PRODUCT PURCHASED?

This information is collected by authority of 15 U.S.C. 2054 and may be shared with product manufacturers, distributors, or retailers. No names or other personal information, however, will be disclosed without explicit permission.

U.S. Consumer Product Safety Commission
Washington, DC 20207

PLEASE DUPLICATE THIS FORM FOR FUTURE USE.

CPSC FORM 175A (6/96) OMB CLEARANCE NO 3041-0029

Consumer Product Incident Report

Please contact us about any injury or death involving consumer products. Call us toll free at: 1-800-638-8095. Visit our web site at www.cpsc.gov. Or, fill out the form below, send it to: U.S. Consumer Product Safety Commission/EHDS, Washington, DC 20207 or fax it to: 1-800-809-0924. We may contact you for further details. Please provide as much information as possible. Thank you.

YOUR NAME [redacted]

YOUR ADDRESS [redacted]

CITY SOUTH EASTON STATE MASS ZIP 02375

YOUR TELEPHONE [redacted]

NAME OF VICTIM (IF DIFFERENT FROM ABOVE)

ADDRESS

CITY STATE ZIP

TELEPHONE

* NATURAL RUBBER LATEX IS NOW A HAZARDOUS SUBSTANCE TO ME.

DESCRIBE THE INCIDENT OR HAZARD, INCLUDING DESCRIPTION OF INJURIES I DEVELOPED AN ALLERGY TO NATURAL RUBBER LATEX AS A RESULT OF MY USE OF LATEX GLOVES WHILE WORKING AS A NURSE. I NOW HAVE A LIFE LONG TYPE I- ALLERGY WHICH CAN CAUSE ANAPHYLAXIS AND DEATH. I MUST AVOID ALL EXPOSURE TO NATURAL RUBBER LATEX IN ALL MY MEDICAL & DENTAL CARE AND IN MY PERSONAL LIFE.

VICTIM'S AGE 46 SEX F DATE OF INCIDENT FIRST DIAGNOSED 6/94

DESCRIBE PRODUCT INVOLVED LATEX GLOVES

PRODUCT BRAND NAME/MANUFACTURER ALL BRANDS AND MANUFACTURERS

IS PRODUCT INVOLVED STILL AVAILABLE? ☒YES ☐NO PRODUCT MODEL AND SERIAL NUMBER

WHERE WAS THE PRODUCT PURCHASED? * IT IS NOW IMPERATIVE THAT I BE AWARE OF THE NATURAL RUBBER LATEX CONTENT IN ALL PRODUCTS.

This information is collected by authority of 15 U.S.C. 2054 and may be shared with product manufacturers, distributors, or retailers. No names or other personal information, however, will be disclosed without explicit permission.

U.S. Consumer Product Safety Commission
Washington, DC 20207

PLEASE DUPLICATE THIS FORM FOR FUTURE USE.

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[redacted] (parents)

YOUR NAME

[redacted]

YOUR ADDRESS

Pittsburgh PA 15217

CITY STATE ZIP

[redacted]

YOUR PHONE

NAME OF VICTIM IF DIFFERENT FROM ABOVE

same as above

ADDRESS

CITY STATE ZIP

TELEPHONE

DESCRIBE THE INCIDENT OR HAZARD, INCLUDING DESCRIPTION OF INJURIES ANAPHYLAXIS, EDEMA, URTICARIA, HIVES

Adam experienced an anaphylactic reaction in a restaurant at the age of three. Latex gloves were utilized in the restaurant. The other above described symptoms/reactions were the result of his prescence in a room where balloons existed or had been blown up.. Latex gloves and balloons are the scariest items for his allergy. We would like to see all latex balloons come with a strict warning. Obviously we feel the same way about latex gloves. **BAN LATEX GLOVES & PRODUCTS IT KILLS!**

Adam's allergy has been confirmed by blood tests which are performed annually at the direction of his allergist.

VICTIM'S AGE 6 SEX M DATE OF INCIDENT Anaphylaxis on September 1996

DESCRIBE PRODUCT INVOLVED Latex gloves and balloons

PRODUCT BRAND NAME/MANUFACTURER

IS PRODUCT INVOLVED STILL AVAILABLE? ☒YES ☐NO PRODUCT MODEL AND SERIAL NUMBER

WHEN WAS THE PRODUCT PURCHASED?

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U.S. Consumer Product Safety Commission
Washington, DC 20207

PLEASE INDICATE THIS FORM FOR FUTURE USE CPSC FORM 1753 (10/94) OMB CLEARANCE NO. 3041-0038

Consumer Product Incident Report

Please contact us about any injury or death involving consumer products. Call us toll free at: 1-800-638-8095. Visit our web site at www.cpsc.gov. Or, fill out the form below. send it to: U.S. Consumer Product Safety Commission/EHDS, Washington, DC 20207 or fax it to: 1-800-809-0924. We may contact you for further details. Please provide as much information as possible. Thank you.

YOUR NAME [redacted]

YOUR ADDRESS [redacted]

CITY [redacted] STATE CT ZIP 06057

YOUR PHONE [redacted]

NAME OF VICTIM (IF DIFFERENT FROM ABOVE)

Same

ADDRESS

CITY STATE ZIP

TELEPHONE

DESCRIBE THE INCIDENT OR HAZARD, INCLUDING DESCRIPTION OF INJURIES Attended Springfield Mass. TV Show, Walked in balloons every where, clowns w/balloons. After 30 minutes difficulty breathing, throat sticking, took inhalers & theraflu (2) put on respirator surgical mask, 30 more minutes later ± had to leave building, eyes burning, headache, difficulty breathing, continues attacks

VICTIM'S AGE 34 SEX F DATE OF INCIDENT Approx Wknd Feb. 20th, 1999.

DESCRIBE PRODUCT INVOLVED Latex balloons

PRODUCT BRAND NAME/MANUFACTURER

IS PRODUCT INVOLVED STILL AVAILABLE? X YES ☐ NO PRODUCT MODEL AND SERIAL NUMBER

WHEN WAS THE PRODUCT PURCHASED?

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U.S. Consumer Product Safety Commission
Washington, DC 20207

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CPSC FORM 175A (6/90) OMB CLEARANCE NO. 3041-0029

[redacted]

Incident continued:

felt extremely tired(suddenly), took week + 1/2 to return to normal breathing and feeling - not being tired out.

Consumer Product Incident Report

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YOUR NAME [redacted]

YOUR ADDRESS [redacted]

CITY New Hartford STATE CT ZIP 06057

YOUR PHONE [redacted]

NAME OF VICTIM (IF DIFFERENT FROM ABOVE)

ADDRESS Same.

CITY STATE ZIP

TELEPHONE

DESCRIBE THE INCIDENT OR HAZARD, INCLUDING DESCRIPTION OF INJURIES Washed runner rugs with rubber backing - Took out of dryer 10:30pm - hands became extreme itchy, nose runny, sneezing - over whelming tiredness. Woke up at 2:30am - felt like more than to chest, whole system contracted with wire brush, crushing chest pain - took 14 days for systems to return to norm

VICTIM'S AGE 34 SEX F DATE OF INCIDENT 2/3/99

DESCRIBE PRODUCT INVOLVED Everyday - Runner Rug - Bought at Walmart.

PRODUCT BRAND NAME/MANUFACTURER

IS PRODUCT INVOLVED STILL AVAILABLE? ☒ YES ☐ NO PRODUCT MODEL AND SERIAL NUMBER

WHEN WAS THE PRODUCT PURCHASED?

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Washington, DC 20207

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YOUR NAME [redacted]

YOUR ADDRESS [redacted]

CITY New Hartford STATE CT ZIP 06057

YOUR TELEPHONE [redacted]

NAME OF VICTIM (IF DIFFERENT FROM ABOVE)

Same.

ADDRESS

CITY STATE ZIP

TELEPHONE

DESCRIBE THE INCIDENT OR HAZARD, INCLUDING DESCRIPTION OF INJURIES My husband got new work boots 2 pairs, I had very noticable strong glue smell. My nose started becoming congested, raw feeling. Approx 2 hrs later granular sputum coming up, difficulty breathing. Very tired - went to bed - all I could smell was like glue - got up - took offensive boots out onto porch. Fri 8/6/99 am upon waking. Nose is swollen, inside very raw, 2 days later granular sputum still coming up.

VICTIM'S AGE 34 SEX F DATE OF INCIDENT 8/5/99 pm

DESCRIBE PRODUCT INVOLVED Wear Guard Hi-top leather work boot - steel toes.

PRODUCT BRAND NAME/MANUFACTURER Wear Guard

IS PRODUCT INVOLVED STILL AVAILABLE? ☒ YES ☐ NO PRODUCT MODEL AND SERIAL NUMBER [redacted]

WHEN WAS THE PRODUCT PURCHASED? 8/99

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U.S. Consumer Product Safety Commission
Washington, DC 20207

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CPSC FORM 175A (6/96) OMB CLEARANCE NO. 3041-0029

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[redacted]

YOUR ADDRESS

St. Peters MO 63376
CITY STATE ZIP

[redacted]

YOUR TELEPHONE

NAME OF VICTIM (IF DIFFERENT FROM ABOVE)

ADDRESS

CITY STATE ZIP

TELEPHONE

DESCRIBE THE INCIDENT OR HAZARD, INCLUDING DESCRIPTION OF INJURIES Use of latex elastic causes me to develop severe eczema. Since clothing is not labeled to indicate latex is used, I have no way of knowing if an article of clothing is safe for me. At present, I have had to make my own undergarments (or purchase custom made - very expensive). I have also had to give away many items I thought owned before learning of latex allergy or that I had thought were safe.

VICTIM'S AGE 50 SEX F DATE OF INCIDENT

DESCRIBE PRODUCT INVOLVED bras, underwear, swimsuits, slacks

PRODUCT BRAND NAME/MANUFACTURER Hanes, Platex & others

IS PRODUCT INVOLVED STILL AVAILABLE? ☑YES ☐NO PRODUCT MODEL AND SERIAL NUMBER

WHEN WAS THE PRODUCT PURCHASED?

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U.S. Consumer Product Safety Commission
Washington, DC 20207

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CPSC FORM 175A (a/96) OMB CLEARANCE NO. 3041-0029

EVENING TELEGRAM

SUPERIOR, WI
DAILY 12,661

SATURDAY
SEP 19 1992

BURRELLE'S

243
...edn TH

Area girl may have died from allergic reaction

By PEG LAMKIN
Telegram Correspondent

RICE LAKE – A 13-year-old rural Cameron girl may have died Wednesday from an allergic reaction to latex, after blowing up balloons in bath water, according to a St. Paul, Minn., doctor.

Denise Odenbrelt, daughter of Gary Odenbrelt, New Auburn, and Cathy Buckwalter, Cameron, was taken to a Rice Lake hospital Sunday morning after she was found unconscious and not breathing on a bathroom floor. She died at 12:50 p.m. Wednesday in Children's Hospital, St. Paul, where she had been transferred by helicopter.

Dr. Paul Kubic, pulmonologist at Children's Hospital, said the child is believed to have died of anaphylactic shock (an extreme allergic reaction), and an allergy to latex was "probably No. 1 of the diagnosis possibilities." Results of biochemical tests were not yet available.

Kubic said Denise and her family had a history of allergies, and she may have become sensitized to the substances during a recent hospital stay. She had been hospitalized with asthma and pneumonia within the past month, but had returned home and was said to be "feeling fine" in the day or so before her death, according to Kubic.

"It's something parents should take note of, especially if there is a strong family history of allergies," Kubic said. "Hidden allergens may be found anywhere in the environment, and latex allergies are well-known today."

He said many people become sensitized to latex during surgery, where they have contact with surgical gloves.

Buckwalter said her daughter had been playing with balloons in the bathtub, and while hospitalized earlier, had been blowing up surgical gloves.

Dr. Paul Kubic
Childrens Hosp St. Paul, MN
612-220-6744

MINNESOTA DEPARTMENT OF HEALTH
Section of Vital Statistics

CERTIFICATE OF DEATH

LOCAL FILE NUMBER

STATE FILE NUMBER

1. DECEDENT'S NAME (First)	(Middle)	(Last)	2. SEX	3. DATE OF DEATH (Month, day, year)	4. TIME OF DEATH
DENISE	RAE	ODENBREIT	Female	September 16, 1992	1300

5. SOCIAL SECURITY NUMBER	6a. AGE (Last Birthday) (Years)	6b. UNDER 1 YEAR (Months / Days)	6c. UNDER 1 DAY (Hours / Minutes)	7. DATE OF BIRTH (Month, day, year)
394-84-9820	13			July 22, 1979

8. BIRTHPLACE (City and State or Foreign Country)	9. WAS DECEDENT EVER IN U.S. ARMED FORCES? (Specify yes or no)	10a. PLACE OF DEATH (Check only one; give name of hospital or other location)
Rice Lake, Wisconsin	No	☒ HOSPITAL ☐ Inpatient ☐ ER/Outpatient ☐ DOA ☐ OTHER ☐ Nursing home ☐ Residence ☐ Other (Specify)

10b. FACILITY NAME (If not institution, give street and number)	10c. CITY OR TOWN OF DEATH	10d. COUNTY OF DEATH
United Hospital Childrens	St. Paul	Ramsey

11. MARITAL STATUS (Married, Never Married, Widowed, Divorced, Unknown)	12. SPOUSE (If wife, give maiden name)	13a. DECEDENT'S USUAL OCCUPATION (Give kind of work done during most of working life. Do not use retired)
Never Married		Student

13b. KIND OF BUSINESS/INDUSTRY	14a. RESIDENCE - State	14b. COUNTY	14c. CITY OR TOWN
Education	Wisconsin	Barron	Prairie Lake Township

14d. STREET AND NUMBER	14e. INSIDE CITY LIMITS? (Specify yes or no)	14f. ZIP CODE	15. WAS DECEDENT OF HISPANIC ORIGIN? (Specify yes or no — if yes, specify Cuban, Mexican, Puerto Rican, etc.)
1908 10½ Avenue Cameron, WI	No	54822	☐ Yes ☒ No

16. RACE (Give instructions or other info)	17. DECEDENT'S EDUCATION (Specify only highest grade completed) Elementary/Secondary (0-12) College (1-4 or 1+)	18. FATHER'S NAME (First, Middle, Last)
White	6	Gari Donald Odenbreit

19. MOTHER'S NAME (First, Middle, Maiden surname)	20a. INFORMANT'S NAME (Type/print)	20b. INFORMANT'S MAILING ADDRESS (Street and Number or Rural Route Number, City, State, Zip Code)
Catherine Mae Metz	Gari Donald Odenbreit	2348 4½ Avenue Chetek, Wisconsin 54728

21a. METHOD OF DISPOSITION					
☒ Burial	☐ Cremation	☐ Removal from state	☐ Donation	☐ Other (Specify)	

21b. PLACE OF DISPOSITION (Name of cemetery, crematory, or other place)	21c. LOCATION - City or Township, State	21d. SIGNATURE OF FUNERAL DIRECTOR OR AUTHORIZED AGENT
Pine Grove Cemetery	Cameron, Wisconsin	Lynette Kuhnert 2555

21e. LICENSE NUMBER (of Funeral Establishment)	21f. NAME AND ADDRESS OF FUNERAL ESTABLISHMENT	22a. CERTIFICATION-PHYSICIAN
0383	O.E. Larson-Osborne Mortuary 2301 Central Avenue NE, Minneapolis, MN 55418	I attended the deceased from ____ to ____ (mo. day year) (mo. day year) and last saw him/her on ____ (mo. day year) ☐ Did not view the body after death.

22b. SIGNATURE (Physician, Medical Examiner or Coroner)	22c. LICENSE (Medical) NUMBER	22d. DATE SIGNED (Month, day, year)
	0244921	10-7-92

23. NAME AND ADDRESS OF ☐ EMPLOYER ☒ MEDICAL EXAMINER OR CORONER	24. ACCEPTANT SIGNATURE	25. DATE FILED (Month, day, year)
MICHAEL B. MCGEE, M.D. 155 HILL ST. ST. PAUL, MN 55102	Therese Koch Deputy	OCT 13 1992

26. CAUSE OF DEATH

Part I. Enter the diseases, injuries or complications that caused the death. Do not enter the mode of dying, such as cardiac or respiratory arrest, shock, or heart failure. List only one cause on each line.

IMMEDIATE CAUSE (Final disease or condition resulting in death)	a. ANOXIC ENCEPHALOPATHY	
Sequentially list conditions, if any, leading to immediate cause. Enter UNDERLYING CAUSE (disease or injury that initiated events resulting in death) LAST	b. due to or as a consequence of: RESPIRATORY ARREST	
	c. due to or as a consequence of: PROBABLE STATUS ASTHMATICUS	

Part II. Other significant conditions contributing to death but not resulting in the underlying cause given in Part I

27. WAS CASE REFERRED TO MEDICAL EXAMINER/CORONER?	28. WAS AN AUTOPSY PERFORMED?	29. WERE AUTOPSY FINDINGS AVAILABLE PRIOR TO COMPLETION OF CAUSE OF DEATH?
☒ Yes ☐ No	☒ Yes ☐ No	☒ Yes ☐ No

30. MANNER OF DEATH						30a. DATE OF INJURY (Month, day, year)	30b. TIME OF INJURY
☒ Natural	☐ Accident	☐ Suicide	☐ Homicide	☐ Pending investigation	☐ Could not be determined		

31. PLACE OF INJURY	31a. DESCRIBE HOW INJURY OCCURRED
☐ Yes ☐ No	

31b. PLACE OF INJURY - At home, farm, street, factory, office building, etc. (Specify)	31c. LOCATION - Street and number (City or Township, State)

MS 4804 (Rev. 11-88) NCHS

STATE OF MINNESOTA
RAMSEY COUNTY

I hereby certify that the above is a true and correct copy of the record on file with the Vital Statistics Registry of Saint Paul - Ramsey County Department of Public Health, City of Saint Paul, Minnesota.

(Signed) _____, this 3rd day of April 1998

Deputy Registrar, Vital Statistics

CONSUMER PRODUCT INCIDENT REPORT

1. NAME OF RESPONDENT	2. TELEPHONE NO. (Home) (Work)
Mary Ann Henderson	816-619-2933
3. STREET ADDRESS	**4. CITY / STATE / ZIP CODE**
205 E. Main, Apt. B P.O. Box 146	Drexel MO 64742

5. DESCRIBE ACCIDENT SITUATION OR HAZARD, INCLUDING DATA ON INJURIES. (Use second page if necessary.)

My son Navy Lt. Harold R. Henderson, died on August 29, 1997 due to cumplacation from Latex poisoning.

6. DATE OF INCIDENT(S)	7. IF INJURY OR NEAR MISS, OBTAIN	8. IF VICTIM DIFFERENT FROM RESPONDENT, PROVIDE
8/29/97	AGE 40 SEX Male AND DESCRIBE INJURY latex poisoning	NAME Lt. Harold R. Henderson RELATIONSHIP Son

9. DESCRIPTION OF PRODUCT	10. BRAND NAME
Use of latex rubber gloves	See attached sheet
11. MANUFACTURER/DISTRIBUTOR NAME, ADDRESS & PHONE	**12. MODEL, SERIAL NO.'S**
See attached sheet	
	13. DEALER'S NAME, ADDRESS & PHONE
	See attached sheet

14. WAS THE PRODUCT DAMAGED, REPAIRED OR MODIFIED?	15. PRODUCT PURCHASED NEW ____ USED ____
YES X NO ____ IF YES, BEFORE OR AFTER THE INCIDENT? Trying to make changes Describe DEAD!! From effects of latex poisoning	DATE PURCHASED ____ AGE ____ 16. DOES PRODUCT HAVE WARNING LABELS? IF SO, NOTE: NO NO NO NO

17. HAVE YOU CONTACTED THE MANUFACTURER?	18. IS THE PRODUCT STILL AVAILABLE?	19. MAY WE USE YOUR NAME WITH THIS REPORT?
YES ____ NO X IF NOT, DO YOU PLAN TO CONTACT THEM? YES X NO ____ OTHER ____	YES X NO ____ IF NOT, ITS DISPOSITION ____	YES X NO ____

FOR ADMINISTRATION USE

20. DATE RECEIVED	21. RECEIVED BY (Name & Office)	22. DOCUMENT NO.
		X983248
23. FOLLOW-UP ACTION		**24. PRODUCT CODE(S)**
25. DISTRIBUTION	**26. ENDORSER'S NAME & TITLE**	

CPSC FORM 175 (9/89)

T-23

If you have any changes, additions, or comments you wish to make concerning your attached report, please make them in the space below.

See attached sheet.

I confirm that the information in the attached report (including any changes, additions, or comments I have made) is accurate to the best of my knowledge and belief.

Mary Ann Henderson 3-21-98
Signature Date

☐ I request that you do not release my name.

☐ You may release my name to the manufacturer but I request that you not release it to the general public.

☒ You may release my name to the manufacturer and to the public.

X9832148

T-23

Consumer Product Incident Report

By filling out the form below and then submitting it, you can report any injury or death involving consumer products to us, or report an unsafe product to us. We may contact you by mail or by telephone (not via internet) for further details or to confirm the information you sent. Please provide as much information as possible. Your name, address, and telephone number are optional, but we can't contact you without that information. You can also report an incident or unsafe product by calling toll-free at 1-800-638-2772.

When filling out the form, use the <TAB> key or your mouse to go to the next data area. Use the scroll bar to scroll down the form.

Your name: MARY Ann Henderson

Your address: 205 E. Main, P.O. Box 246

X983-2148

City: Drexel

ISSUE 23

State: Mo

MAR 0 2 1998

E-mail address:

Zip code: 64742

Your telephone: 816-619-2933

Name of victim (if different from above): LT. Harold R. Henderson, U.S. Navy

Victim address: 3162 Pageant Ave.

City: San Diego

State: CA

Zip code: 92129

Victim telephone: 1-619-538-3405

Describe the incident or hazard, including description of injuries

This was My son's address & phone No. at Time of his death, Aug. 29, 1997. Please read all enclosed information which will explain. I'm Working very hard for Debi Adkins & Lisa C. Borel at LATEX ALLERGY Information Service, in behalf of My Son.

1710

Thank You,
Mary Ann Henderson

Victim's Age: 40

Victim's sex
- ○ Female
- ✓ Male

Date of Incident: Aug 29, 1997

Describe product involved:
Read enclosed material

Product Brand Name/Manufacturer:

Is product involved still available?
- ✓ Yes
- ○ No

Product model and serial number:

When was the product purchased?

Send to CPSC | Clear Form

This information is collected by authority of 15 U.S.C. 2054 and will be entered into a database by a Consumer Product Safety Commission contractor. The information may be shared with product manufacturers, distributors, or retailers. However, no names or other personal information will be disclosed without explicit permission.

OMB Control Number 3041-0029

January 7, 1998

To whom it may Concern:

In regards to an Act to create 146.49 of the statutes: relating to prohibiting the use of Certain latex products by health Care providers and granting rule making Authority by the Wisconsin legislation.

Let me first introduce myself, I am Mary Ann Henderson, the mother of the late Lieutenant Harold R. (Hal) Henderson, RN, BSN, CEN, TNCC, NC, USN/Ret., Age 40 years of San Diego, California, who died Friday, August 29, 1997, at the Balboa Naval Hospital.

My son had been in very ill health for some time as the result by respiratory and Cardiac Complications associated with Latex allergy, he suffered a massive healt attack. Full life support was removed at 2:15pm. Pacific Time, August 29, 1997.

Now I ask your indulgence as I go back a few years, so that everyone understands my sons great love of the medical field. He was interested in the medical field about the fifth grade and he was able to attend Vocational Tec. School half days when he was a Junior in high school.

He was a member of ROTC in high school and towards the end of his Junior school year he told me he was going down to talk with the Navy Recruiter. Hal did this and signed a Contract to become a Navy Corpsman and join the Navy at the end of his senior year of high school in 1975, he could then persue his dream of becoming a Navy Trama Nurse. He achieved that dream from Navy Corpsman to Lieutenant Navy Nurse.

My Son was so very proud to serve his Country and was on the front lines in Desert Storm.

Hal loved working in the ER and ICU and because of this he

developed latex allergy from his occupational exposure to latex products. He began having life threatening reactions. At this time my son and I began having many long distance phone calls over the next couple of years. You see my son died because after years of medical apathy and their disbelief that an innocent balloon or a latex glove could cause a life-threatening reaction, because the very people treating him failed to give his Allergy and it's potential to be a progressive Condition, proper attention the attacks became more frequent and his strong body slowly died.

My son would call me hardly able to breath or sounded just so weak to talk. He would tell me how the doctors at the very hospital he worked at would treat him in the ER with such disrespect, Contempt, And tell him that it was all in his head. He told me the Navy Head Brass were putting pressure on him to retire and give up his

Career in nursing and the Navy. He loved his service to the military. Each time he was rushed to the ER he said they treated him with such apathy that he said his self-esteem went to an all time low. He said they would even come in the ER or his room wearing powdered latex gloves. My son died in a hospital that still used products knowing full well that they caused serious, systemic life-threatening allergic reactions and death, and on these products were no warning labels.

Each phone call from my son in California to me here in Missouri, would tell me how he was going down hill, a mother can tell even over the phone.

When I went to San Diego, California the end of July 1996 to attend my sons beautiful wedding the begining of August to his wonderful lady Christine, I saw how his 6' 7½" body had gone down hill. We had to all most hold him up for the

Ceremony, but Hal loved Christine so much, and he had told me that week before, "What ever it takes mom get me to the Alter on time". Even as ill as he was they shared together many happy memories in their one short year together.

My gut feeling when I flew home after the wedding that he was in very bad medical shape, and failing fast.

My Son remained optimistic after he was forced to give up his Career in nursing and his service to the military, that he could prevent others from becoming latex allergic, and to prevent others having to go through his great loss of Career, health, self-esteem that he had suffered

After retiring Hal began Working tirelessly as a military liaison for ELASTIC Inc., He worked tirelessly with California Congressmen Randy "Duke" Cunningham (51st District) and Bob Filner (50th District) which resulted in a awareness of the seriousness and the

potential for progression of this Condition.

To my son, my new Angel with God, I have made a promise to continue to make others aware, inform and just keep talking. Perhaps my burying my 40 year old son before me, whose needless death should not have happen will keep me pushing for new awareness and will help me and ELASTIC Inc. and other State legislator to do his wishes saving lives and safe guarding the health of Countless people.

There is such a big hole in my heart, that will never be filled but by doing my sons work it will help.

I am sending to my Missouri legislators of my home state your proposal and all added information on latex allergy, imploring them to join my band wagon against latex allergy & product usage with latex

Thank You for allowing me to relate to everyone my feelings about this very life-threatening problem of latex allergy that is effecting so many people.

My son left behind myself, his Wonderful wife Christine, Children Cara Jo, Brandon Paul, and Hal Jr. who turned 9 the day his father died and step-children Nathaniel and Matthew.

He leaves many friends both in nursing and outside world.

To the Wisconsin Legislation, thanks for Caring.

Sincerely,

Mary Ann Henderson
205 E. Main, Apt. B
P.O. Box 246
DREXEL, Missouri
64742

Phone:
1-816-619-2933

CONSUMER PRODUCT INCIDENT REPORT

1. NAME OF RESPONDENT	2. TELEPHONE NO. (Home) (Work)
Mary Ann Henderson	816-619-2933
3. STREET ADDRESS	**4. CITY / STATE / ZIP CODE**
205 E. Main, Apt. B P.O. Box 116	Drexel MO 64742

5. DESCRIBE ACCIDENT SITUATION OR HAZARD, INCLUDING DATA ON INJURIES. (Use second page if necessary.)

My son Navy Lt. Harold R. Henderson, died on August 29, 1997 due to complacation from Latex poisoning.

6. DATE OF INCIDENT(S)	7. IF INJURY OR NEAR MISS, OBTAIN	8. IF VICTIM DIFFERENT FROM RESPONDENT, PROVIDE
8/29/97	AGE 40 SEX ~~Male~~ AND DESCRIBE INJURY ~~latex poisoning~~	NAME ~~Lt. Harold R. Henderson~~ RELATIONSHIP ~~Son~~

9. DESCRIPTION OF PRODUCT	10. BRAND NAME
Use of latex rubber gloves	See attached sheet
11. MANUFACTURER/DISTRIBUTOR NAME, ADDRESS & PHONE	**12. MODEL, SERIAL NO.'S**
See attached sheet	
	13. DEALER'S NAME, ADDRESS & PHONE
	See attached sheet

14. WAS THE PRODUCT DAMAGED, REPAIRED OR MODIFIED?	15. PRODUCT PURCHASED NEW ____ USED ____
YES X NO ____ IF YES, BEFORE OR AFTER THE INCIDENT? ~~Trying to make changes~~ Describe ~~DEAD!! From effects of latex poisoning~~	DATE PURCHASED ____ AGE ____
	16. DOES PRODUCT HAVE WARNING LABELS? IF SO, NOTE: NO NO NO NO

17. HAVE YOU CONTACTED THE MANUFACTURER?	18. IS THE PRODUCT STILL AVAILABLE?	19. MAY WE USE YOUR NAME WITH THIS REPORT?
YES ____ NO X IF NOT, DO YOU PLAN TO CONTACT THEM? YES X NO ____ OTHER ____	YES X NO ____ IF NOT, ITS DISPOSITION ____	YES X NO ____

FOR ADMINISTRATION USE

20. DATE RECEIVED	21. RECEIVED BY (Name & Office)	22. DOCUMENT NO.
		X983248
23. FOLLOW-UP ACTION		**24. PRODUCT CODE(S)**
25. DISTRIBUTION	**26. ENCORSER'S NAME & TITLE**	

CPSC FORM 175 (5/89)

If you have any changes, additions, or comments you wish to make concerning your attached report, please make them in the space below.

I want all manufactures of any. latex products to made aware of the dangers to others. In my case the death of my son, Lt Harold Hal" R. Henderson USN. Ret. age 40.

I'm starting my next line of work in the name of my son to contact as many latex Manufactures that I can. and relate what their products can Cause.

I confirm that the information in the attached report (including any changes, additions, or comments I have made) is accurate to the best of my knowledge and belief.

Mary Ann Henderson
Signature

March 16, 1998
Date

☐ I request that you do not release my name.

☐ You may release my name to the manufacturer but I request that you not release it to the general public.

☑ You may release my name to the manufacturer and to the public.

I-23
X9832145

Ike, Skelton (Fourth Dist.)
2227 Rayburn House Office Building
Washington, D.C. 20515-2504

Richard A. Gephardt (Third Dist.)
1226 Longworth House Office Building
Washington, D.C. 20515-2503

Karen McCarthy (Fifth Dist.)
1232 Longworth House Office Building
Washington, D.C. 20515

Senators

Christopher S. (Kit) Bond
274 Russell Senate Office Building
Washington, D.C. 20510-2503

John David Ashcroft
316 Hart Senate Office Building
Washington, D.C. 20510-2502

Missouri State House

District 31st.
Harold L. Cushey
Room 320
State Capitol
Jefferson City, Mo. 65102

JOHN ASHCROFT
MISSOURI

United States Senate

WASHINGTON, DC 20510-2504

January 15, 1998

Ms. Mary Ann Henderson
P.O. Box 246
Drexel, Missouri 64742

Dear Mary:

Thank you for contacting my office and relating your concerns regarding latex allergies. Hearing your opinions on important issues facing the Congress and the country is necessary for me to make good decisions about the future of our nation.

I appreciate the opportunity to serve you in the U.S. Senate and to help change the way Washington does business. The ideas and opinions you have sent me will be a great help as this Congress formulates new policies for our country. Your information will help me understand how the issues facing America affect Missourians and all citizens. I will keep your views in mind as this issue comes before the Congress.

Thanks again for your interest in latex allergies. If you have any further questions or concerns please feel free to contact me.

Sincerely,

John Ashcroft

John Ashcroft
United States Senate

JDA:sem

Obituaries

Lieutenant Harold R. "Hal" Henderson

Lieutenant Harold R. "Hal" Henderson,RN, BSN, CEN, TNCC, NC USN/RET, 40, of San Diego, California, died Friday, August 29, 1997, at the Balboa Naval Hospital. Lieutenant Henderson, who had been in ill health for some time as the result of respiratory and cardiac complications associated with latex allergy, suffered a massive heart attack. Full life support was removed at 2:15 p.m. Pacific Time.

Lieutenant Henderson, who had worked at Balboa Medical Center as an intensive care and emergency nurse, served in Desert Storm and was recently accepted into a master's program for nursing and community health at San Diego State University. Hal is survived by his mother Mary Ann Henderson and wife, Christine. The couple's first year anniversary was August 4, 1997. He leaves his children, Cara Jo, Brandon Paul and Harold R. Henderson Jr., as well as step-children: Nathaniel and Matthew Davis. Sadly, Lt. Hal Henderson died on Hal Jr.'s 9th birthday.

A good soldier, a wonderful man, a loving husband died on Friday, August 29, 1997. Lt. Hal Henderson, a 40 year old newly married, ER nurse, retired Naval Corp Officer had served with Desert Storm. Hal died because he had developed latex allergy from occupational exposure to latex products. Frequent exposure to latex containing products, especially powdered latex gloves, is causing more and more people to become allergic to latex and many to go on to develop disabling and potentially life-threatening chronic asthma. Hal died in a hospital that still used products known to cause serious, systemic, life-threatening allergic reactions and death, yet most of these items do not carry a warning or product content label.

Lt. Henderson died from respiratory and cardiac complications that can be part of latex allergy. Hal died because after years of medical apathy and disbelief that something as simple and seemingly innocent as a balloon or a latex glove could cause a life-threatening reaction, because some of those treating him failed to give this allergy and it's potential to be a progressive condition, proper attention, his once strong, military-honed body had had enough.

Lt. Henderson had been forced to give up his career in nursing, was unable to continue his service to the military, but remained optimistic that he could prevent others from becoming latex allergic. Hal worked tirelessly as a military liaison for ELASTIC Inc. His members of the California Congress, Randy "Duke" Cunningham (51st District) and Bob Filner (50th District) resulted in a new awareness of the seriousness and the potential for progression of this condition.

Hal's many successes will continue to receive attention, his spirit of public service is one to be admired and emulated. He wanted so much to prevent others from having to go through the same needless loss of career, health and self-steem, that he did. Hal, the members of ELASTIC, trust your wish; to prevent others from suffering from latex allergy, as you have, will be granted. It is our pledge to continue your work, to continue to increase awareness, inform and educate. Perhaps your tragic and needless death will open the eyes of those who doubt, maybe this new-found awareness and a nudge from an angel or two, will allow your wish to be become reality.

Lieutenant Henderson, a soldier on earth, now a soldier of God. Hal Henderson, son to Mary Ann, loving husband to Christine, devoted father to Cara Jo, Brandon Paul and Hal Jr., step-father to Nathaniel and Matthew, steadfast friend to so many, ER and ICU nurse; saving lives and safeguarding the health of countless patients, now a guardian angel, watching from the heavens.

Hal, you are sorely missed, but your spirit and light will always be present in our hearts.

A Tribute to a Fallen Comrade

His was just a name to me,
for we never did formally meet.
Our goal in life was to teach the world
and this allergy we would beat.

But as time went on he became so ill
there wasn't too much hope.
His heart was weak, his lungs weren't strong
his body just couldn't cope.

A bright light went out-a candle dimmed
we lost a comrade and guide.
But as we work toward latex safe
He'll always be by our side.

A good friend we lost--
a husband, a father, a son.
He taught us well, this gentle man
Our battle will eventually be won.

Here's to you, Hal Henderson,
a nurse, a leader, a friend.
This makes us, the surviving ones,
work harder for an end.

Hal Henderson died August 29, 1997.
He was the Military advisor for
E.L.A.S.T.I.C.
He may be gone from our sights
but never our hearts and minds.
In Memory--Pat Lawson, CST