



U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

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June 4, 2004

Ms. Debra M. Adkins
Roosevelt Ave.
Torrington, CT 06790

Dear Ms. Adkins:

The Commission has considered your petition, HP 00-2, requesting that the Commission issue a rule declaring natural rubber latex ("NRL") to be a strong sensitizer under the Federal Hazardous Substances Act ("FHSA"). In your petition you requested that the Commission issue a rule adding NRL to the list of strong sensitizers at 16 C.F.R. § 1500.13, and that consumer products containing NRL, including children's products, be labeled. The Commission has considered the information that you provided, comments on the petition by interested persons, a package of written materials prepared by the staff, and information from the Commission's December 10, 2003 briefing and public hearing. Based on its review of these materials, and for the reasons discussed below, the Commission voted unanimously to deny the petition.¹

For the Commission to add a substance to the regulatory list of strong sensitizers, it must find that the substance meets the definition of "strong sensitizer" in the FHSA. Section 2(k) of the FHSA defines the term "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 the Commission declares to be a strong sensitizer. 15 U.S.C. § 1261(k). The definition further states that before making such a declaration, and "upon consideration of the frequency of occurrence and severity of the reaction, [the Commission] shall find that the substance has a significant potential for causing hypersensitivity." *Id.*² Thus, to declare NRL a strong sensitizer, the Commission would have to find that NRL has a significant potential to cause hypersensitivity. In making that determination, the Commission must consider how frequently a reaction to the substance occurs and how severe the reaction is.

¹ Commissioner Thomas H. Moore filed a statement with his vote. A copy of his statement is enclosed.

² The Commission also has regulations that supplement the statutory definition of "strong sensitizer." 16 C.F.R. § 1500.13.

There are many consumer products that contain some amount of NRL. Such products include adhesives, balloons, elastic, and pacifiers. Some of these products, such as adhesives and elastic, may be in many types of consumer goods and contain varying levels of latex proteins. Yet, in spite of the prevalence of NRL in consumer products, there are few documented cases of reactions to NRL-containing consumer products. Most incidents involve medical devices. As you know, the Food and Drug Administration ("FDA") has issued rules requiring labeling for medical devices containing NRL (and dry natural rubber as well). See 21 C.F.R. § 801.437.

Most individuals who have a reaction to NRL experience a mild rash or upper respiratory symptoms. More severe reactions such as asthma, anaphylactic shock and death have also been reported. However, most incidents of life-threatening NRL-induced anaphylaxis are associated with invasive surgical or other medical procedures, not with consumer products. The Commission's regulations concerning severity of reaction to a strong sensitizer state that the minimal severity of reaction for purposes of designating a substance a strong sensitizer is "a clinically sensitive reaction." 16 C.F.R. § 1500.3(c)(5)(iii). Reported reactions to NRL do seem to meet this regulatory definition.

Determining the frequency of reaction is difficult. Currently, there is no universally accepted standard approach for diagnosing NRL allergy. Most of the epidemiological studies have focused on specific populations with high levels of exposure to NRL, such as health care workers or children with spina bifida. Studies estimate the prevalence of NRL allergies in healthcare workers in the range of 2.2 to 17 percent. The prevalence of NRL sensitization in individuals with spina bifida ranges from 29 to 65 percent. Studies indicate that allergy to NRL in the general population is estimated to be below 1 percent.

The Commission must consider a substance's potential for causing allergic reactions based on reactions to the substance's presence in consumer products. However, with the current level of information, it is difficult to determine the degree of involvement of consumer products in NRL reactions. Most reported incidents involve medical devices rather than consumer products. Most studies concern populations who are exposed to NRL in their occupation or during medical procedures. There have been some cases reported to CPSC's National Electronic Injury Surveillance System ("NEISS") and the Injury or Potential Injury Incident Database ("IPII") databases that involved NRL-containing consumer products and could involve allergic reactions to NRL.³ Most of these incidents involved gloves and balloons. However, these incident reports do not provide information about the individual's history related to NRL, so one cannot determine if these incidents were the result of NRL sensitization.

Moreover, based on current scientific knowledge, it is impossible for the Commission to determine a level of NRL proteins that would cause neither sensitization nor subsequent reaction. Without such threshold levels, one cannot differentiate between products which would cause sensitization or reaction and those which would not. This is particularly important because the Commission's declaration that a substance is a strong

³ The staff identified 62 potential cases in the NEISS database and 44 potential cases in the IPII database.

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sensitizer does not necessarily mean that the substance, or a product containing it, must be labeled. Under the FHSA, labeling is only required if an item is or contains a "hazardous substance." For an item to be a "hazardous substance" the substance must be a strong sensitizer and be able to cause substantial injury or illness through reasonably foreseeable handling or use. 15 U.S.C. § 1261(f)(1)(A).⁴ Given the current state of the science, it would be very difficult for a manufacturer of a product that contains NRL to determine that his/her product could cause substantial injury or illness due to the presence of NRL.

Conclusion

For the reasons explained above, the Commission concluded that the information currently available is not sufficient to begin a rulemaking proceeding to declare NRL a strong sensitizer. Available information indicates that the frequency of NRL allergies associated with consumer products is low. Currently, many scientific uncertainties exist about the levels of NRL proteins in consumer products and what the threshold levels for sensitization and allergy to these proteins might be. Accordingly, Petition HP 00-2 is denied.

Sincerely,

A handwritten signature in black ink, appearing to read "Todd Stevenson", written over a large, stylized, triangular-shaped graphic element.

Todd Stevenson
Secretary

Enclosure: Statement of Commissioner Moore of April 30, 2004

⁴ If a substance (or product) meets both of the prongs of this definition it is a hazardous substance and must be labeled in compliance with section 2(p) or it would be "misbranded" and in violation of the FHSA. Id. § 1261(p).

STATEMENT OF THE HONORABLE THOMAS H. MOORE
ON Petition HP 00-2 Requesting a Rule Declaring Natural Rubber Latex to be a Strong
Sensitizer
April 30, 2004

Sometimes our laws fail us. This may be one of those times. Neither the Consumer Product Safety Commission (CPSC), nor any other federal agency, has the authority to require "ingredient labeling" on non-medical, non-textile consumer products. In the medical device area, the Food and Drug Administration (FDA) has broad statutory authority. It was able to require warning labels on medical products containing latex by finding that products that contained latex failed to reveal facts that were material with respect to the consequences which may result from the use of that article. In that case, the consequences were the allergic reactions that some people have to natural rubber latex (NRL).

In order to require warning labels on consumer products, CPSC has to make very specific findings about the nature of the substance under review. We must find that a substance in the product is a strong sensitizer as defined by the Federal Hazardous Substances Act. That definition states, in part, that a substance is a strong sensitizer if it causes "on normal living tissue through an allergic or photodynamic process a hypersensitivity which becomes evident on reapplication of the same substance...." This suggests that the substance must be both the initial cause of the hypersensitization and the trigger for the subsequent allergic reactions. Our staff *did* conclude that the symptoms of IgE-mediated reaction to NRL would be severe enough to meet the test for designating a substance a strong sensitizer. However, in most of the documented cases we have seen, the initial sensitization has been from a medical device. Our staff found that there is no data currently available that confirms that specific natural rubber latex consumer products are responsible for natural rubber latex sensitization. They stated that "the reports do not or cannot identify the initiating event resulting in sensitization." The requirement that the substance be the cause of the initial sensitization is a major barrier to our ability to make the necessary findings on this substance.

To designate a substance a strong sensitizer, the Commission also must find that the substance has a "significant potential for causing hypersensitivity." To make this finding, in addition to considering the severity of the reaction, CPSC is also required to take into account the frequency of occurrence of such reaction. Based on the best available data, it appears that the prevalence of NRL allergy in the general population is less than one percent. Of that, some substantially smaller amount of the general population experience the more severe symptoms, such as anaphylaxis. Nearly all of the cases involving anaphylaxis have been associated with invasive surgical or other medical procedures.

When people's health and quality of life are at stake, I do not like having to decide how many allergic reactions are enough for us to take action. While the number of people that experience the more severe symptoms is relatively low, for those people who have severe reactions from exposure to NRL, this can be literally a life or death issue. And those who have milder symptoms never know when their symptoms may become more severe. A number of

commenters argued that those most at risk from NRL—health care professionals, people who have had multiple surgeries, etc.—are already protected by the FDA’s action. However, the FDA’s action only protects them from contact with medical devices, not from all the other products that contain latex. For those that are already sensitized and have developed an allergy, they are at risk everywhere they go.

Our staff is correct that putting a warning label on a product will not protect a consumer who has not yet had an allergic reaction to NRL and who therefore does not know to avoid it. They are also correct that persons who know they are allergic will avoid products that they know contain latex. However, while some latex-containing products, such as balloons, are obvious, there are many products that contain latex that are not so obvious. Even more than a warning label, what consumers need is information. People with latex allergies are desperate for information about the materials in the products they buy. The issue for them is not so much about alerting the general population, but about protecting themselves. If our statute gave us the authority, I would vote to require product manufacturers to indicate prominently on their product packaging, product inserts, and, if feasible, on the products themselves, that the product contains latex.

While NRL allergy affects a small percentage of the population at this time, if that percentage were to increase, and if we learn more about NRL allergy as it relates to consumer products, we may at some point want to take another look at whether NRL meets the statutory criteria for a strong sensitizer. We are seeing an increase in certain food allergies in this country. A recent report found a doubling of peanut allergies in children over just a five-year period. And our staff found that the prevalence of NRL allergy has increased during the past five years, especially in the occupational setting and that there is “no conclusive explanation at the present time” for this apparent increase. With the change in the composition of medical gloves and other medical devices due to FDA actions, we may see a decline in the prevalence of NRL allergy in the future. Nevertheless, it would behoove manufacturers of NRL to take steps to reduce the level of proteins that consumers can come into contact with, whether or not the end product is a medical device. Some companies have indicated that, regardless of what CPSC does in this proceeding, they intend to label their non-medical latex products, such as gloves, with the same cautionary language that FDA has required them to put on their medical products. In addition, some manufacturers of consumer products are already providing information to consumers about the existence or nonexistence of latex in their products. I hope that more and more companies start taking this responsible, customer-oriented approach.

Besides the statutory constraints, we also have data limitations. There is no reliable, national, annual estimate of the frequency and severity of allergic reactions to NRL products. I imagine that is true for many substances that initiate allergic reactions, due in part to the difficulty of diagnosing the cause of the symptoms. I am not sure if there is any feasible, cost-effective way to capture this information but to the extent we can, we should be vigilant in looking for consumer product-related NRL reactions in the future, about which we have so little information.

While I would like to be able to require manufacturers to tell consumers when their products contain NRL, CPSC does not have the authority to do that. And the state of medical science and research on NRL allergy has not developed to the point where we can make the currently-

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required statutory findings. Given the inability to link the products we regulate with NRL allergy, the low prevalence of hypersensitivity to NRL in the general population, and the even smaller percentage of people who have serious reactions, I must reluctantly agree with our staff's recommendation that we deny this petition.