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CPSC/OFFICE OF
THE SECRETARY

2000 MAY 22 P 12 44

Office of the Secretary
Consumer Product Safety Commission
Room 502, 4330 East-West Highway
Bethesda
Maryland 20814
USA

19 May 2000

Re: PETITION HP 00-2 - "Petition on Natural Rubber Latex"

Comments by Malaysia on

The Petition Requesting Rule Declaring Natural Rubber Latex a Strong Sensitizer

With regards to the above mentioned petition from Debi Adkins, editor of Latex Allergy News, requesting that the Commission issue a rule declaring that natural rubber latex (NRL) and products containing NRL are strong sensitizers under the Federal Hazardous Substances Act (FHSA), Malaysia wishes to make the following comments

Natural Rubber Latex (NRL)

This raw material for the manufacture of many useful everyday products is first and foremost a green material, being produced by the Hevea trees. It is very environmentally friendly, unlike many raw materials for some other products such as those of synthetic rubber products.

Like all plant materials, it contains certain amount of proteins, which are essential substances involved in growth and metabolism of the plants. Some of these proteins may be allergic to certain individuals, as in the case of many other plant substances, such as bananas, kiwi, watermelon and potatoes. It is therefore illogical to classify it as a consumer product that is a strong sensitizer, especially when -

- a) natural rubber latex is **not** a consumer product, it is a raw material for the manufacture of consumer products. As such, it is highly unlikely that the general public would come in contact with it, except for workers in the latex / rubber industry which constitute an extremely small proportion of the general population, especially in the US.

- b) Even among the workers in the latex / rubber industry, prevalence of Type I hypersensitivity has been shown to be extremely low, as indicated by studies¹ conducted in Malaysia, one of the world's largest rubber producers and the world's largest latex glove manufacturing country

Products made from natural rubber latex

Latex First of all, we like to point out that the word "latex" is commonly defined as "a stable colloidal dispersion of a polymeric substance in a *liquid medium*" Once the raw latex is converted into its *solid products*, the liquid latex state of the polymeric material no longer exists Hence, it is incorrect to refer to products made from natural rubber latex as "products containing the latex"

Products As with regards to products made from natural rubber latex (or *Hevea* latex), there are two classes of product, namely, (i) latex products and (ii) raw dry rubber products

(i) *Latex products* are made from latex concentrate of 60% dry rubber content, prepared generally by centrifugation of the *Hevea* latex and preserved in ammonia to combat bacterial growth Products of this class consist of gloves, condoms, catheters, threads, balloons etc

(ii) *Dry rubber products* are made from raw natural rubber which is prepared by coagulation of the *Hevea* latex, followed by creping, crumbling and extensive washing of the coagulum before being dried at above 100°C Products of this class include tires, tubings, threads, bottle stoppers, automotive components, engineering parts, shoes, adhesives and some household appliances

It is undeniable that the onset of latex protein allergy problem has affected certain sensitive users of latex products particularly gloves, attributing to the presence of some residual water-extractable proteins A number of these cases have indeed been documented Malaysia is very sympathetic towards these allergy sufferers like Ms Adkins, who belong to less than 1% of the general population (an estimation by FDA) In addressing the problem, Malaysia has made great efforts to improve the quality of her products Like the FDA, Malaysia is also taking measures to enhance safety of all medical latex gloves aiming to reduce health risk among the users, particularly those in the healthcare sector Through new and improved technologies developed by the Rubber Research Institute of Malaysia (RRIM) in conjunction with the industry, latex gloves with low-powder, low-protein as well as powder-free latex gloves of low risk are now available Recently, Malaysia launched the Standard Malaysian Glove as a National Scheme to provide a minimum quality assurance, which is in line with the ASTM and FDA requirements

Thus far, the latex protein allergy is known to be associated mainly with latex medical products, especially gloves. Even then, according to a report by the FDA in 1997, "less than one allergic reaction of any kind was reported to the FDA for every 49 million gloves used". There are relatively very few incidences reported concerning the non-medical latex products and dry natural rubber products. There is a good reason for this. Let us take a look at some of these products that are commonly encountered.

Non-medical latex gloves Clean-room, household and industrial latex gloves belong to this category. Using the current technologies, these gloves are usually subjected to considerable washing followed by chlorination, a process used to remove tackiness of the gloves and also to facilitate easy donning. Chlorination of latex gloves is effective in reducing residual extractable proteins² implicated in the allergy reactions, therefore, these products have extremely low levels of residual proteins/allergens and low allergenicity, and hence are of low risk to the users, unless one is highly sensitive.

As for the use of other latex products such as toy balloons, adhesives and carpet backings, there is to our knowledge, no reported incidence of serious allergy reactions concerning them.

Dry natural rubber products These products are made from raw dry rubber via a completely different process from that of the latex products. While the starting material of the latter, the latex concentrate, may still retain certain amount of the soluble non-rubber substances from Hevea latex, most of these substances including proteins are removed during processing in the case of the raw dry rubber. Fabrication of rubber products at very high temperatures often renders the remaining proteins inactive or denatured. The extremely low residual extractable protein contents of not only the raw dry rubbers, but also their vulcanizates as well as their finished products have in fact been well demonstrated by Yip, Turjanmaa and Mäkinen-Kiljunen³. In addition, both their allergen contents, as assessed by the IgE latex specific RAST-inhibition test, and their allergenicity, as evaluated by the ability to elicit an allergic reaction in latex hypersensitive persons when subjected to the skin prick test, have also been shown to be extremely low. In the latter case, about 90% - 100% of the sensitive subjects tested showed no allergic response (a copy of the paper is attached for your information). Therefore, products made from raw dry rubber as stated above should not be a protein allergy problem for users, unless one is highly sensitive.

As with regards to reports that extracts of NR rubber tire fragments collected from the atmosphere contained residual extractable proteins which exhibited IgE binding activity⁴, we analyzed extracts of fragments from a number of new unused NR tires, and found that their residual extractable protein levels were so low that they were below the sensitivity limit of the testing method. It is therefore possible that fragments from the used tires reported were contaminated with other antigens picked up from the roads. The cross-activity of some plant antigens such as those from bananas, avocados, pears, papayas, chestnuts etc. has with latex proteins in demonstrating IgE binding is well documented⁵⁻⁸.

Malaysia therefore feels strongly that there is no justification for natural rubber/latex products to be labeled as strong sensitizers under the Federal Hazardous Substances Act on account of the protein allergy (Type I hypersensitivity) issue, and least of all for the raw material of natural rubber latex. As for the risk to Type IV allergy due to residual chemicals, it may well be pointed out that such risk should refer to all rubber products, be they natural or synthetic, since similar compounding ingredients are also employed in the manufacturing of synthetic products.

If natural rubber latex and its products were to be subsumed as hazardous materials to the consuming public, then one will have to include a host of many other similar materials and products. Some examples would include all vinyl products made from the carcinogenic vinyl chloride, all polyurethane products made from isocyanates known to be very toxic, all polychloroprene products from the toxic chloroprene as well as the new nitrile products, one of the raw materials being used is acrylonitrile which is a carcinogen.

In the case of natural rubber latex products, the FDA has already appropriately undertaken the necessary actions that are needed to safeguard the users of latex medical devices with regards to the latex protein allergy problem. Whether any other latex or rubber products need labeling would depend on whether or not users are generally at risk to serious adverse reactions. Presently there does not seem to be any compelling evidence to that effect. If CPSC is interested, Malaysia will be happy to collaborate in further studies concerning both the natural and synthetic products. The petition therefore seems to be an over reaction by certain latex hypersensitive individuals who lack proper understanding of the natural rubber latex and its products, and their benefits to mankind.



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References

- 1 Azizah M R , Shahnaz M , Hasma, H , Mok, K L Esah Yip and Nasuruddin B A (1997) Latex protein allergy: A prevalence study of factory workers *J nat Rubb Res* 11(4), 240
- 2 Nor Aisah Abd Aziz (1993) Chlorination of Gloves *Latex Proteins and Glove Industry*, Rubber Research Institute of Malaysia, 59
- 3 Esah Yip, Turjanmaa K. and Mäkinen-Kiljunen S (1995) The “non-allergenicity” of NR dry rubber products, with reference to type I protein allergy *Rubber Developments* 48(3/4), 48
- 4 Williams P B , Buhr M P *et al* (1995) Latex allergen in respirable particulate air pollution” *J Allergy & Clinical Immunology*, 95(Part 1) , 88
- 5 Rodriguez M , Vega F , Garcia K , Srenhardt G , William D and Slater J (1993) Hypersensitivity to latex , chestnut and banana *Ann Allergy*, 70, 31
- 6 Mäkinen-Kiljunen S (1994) Banana allergy in patients with immediate-type hypersensitivity to natural rubber latex characterization of cross-reacting antibodies and allergens *J Allergy Clin Immunol* 93, 990
- 7 Lavaud F , prevost A , Cossat C , Guerin L , Bernard J and Kochman S (1995) Allergy to latex, avocado, pear and banana – evidence for a 30 kd antigen in immunoblotting *J Allergy Clin Immunol* 95, 557
- 8 Baux X , Chen Z , Rozynek P , Duser M and Raulf-Heimsoth M (1995) Cross-reacting IgE antibodies recognizing latex allergens, including Hex b1, as well as papain *Allergy* , 50, 604

The 'non-allergenicity' of NR dry rubber products, with reference to type 1 protein allergy*

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Abstract

The protein allergy issue, associated with some natural rubber latex-dipped medical devices, has caused certain concern over the use of NR dry rubber products. A study was therefore carried out to evaluate a number of the commercially available dry rubber grades, both raw and vulcanized, and some dry rubber products. Their extractable protein contents, shown to be related to the allergenicity of the products, were measured by the RRM modified Lowry method, while their allergen activities, if any, were assessed by both the skin-prick test and the RAST-inhibition test.

Results revealed that NR dry rubbers and dry rubber products have not only extremely low extractable protein contents (often <20µg/g), but also very low or negligible allergenicity. Hence, it may be concluded that dry rubbers and dry rubber products are generally not affected by the protein allergy problem.

Introduction

NATURAL RUBBER PRODUCTS, from both latex and dry rubber, have been widely used all over the world for many years. Recently, the use of some latex-dipped articles, such as latex gloves, catheters and condoms, has been reported to have given rise to Type 1 hypersensitivity in some individuals.¹⁻⁴ Symptoms for this allergic reaction include urticaria, rhinitis, conjunctivitis, asthma and less frequently, anaphylaxis. The onset of this type of IgE-mediated allergy is believed to be due to a number of factors, one of which is the sudden demand in the late 1980s for latex products such as gloves and condoms, which are very good protective barriers against viral diseases, particularly AIDS. It is thought that the increased exposure to latex has resulted in sensitization of, especially, atopic individuals.¹

This allergic reaction has been shown to be due to a very small fraction of residual soluble proteins (EP) containing the allergens found in latex products.^{4,8} Research findings^{8,13} have shown that the amount of this protein fraction in different latex products prepared from the same latex source varies, depending on the processing procedure employed during their manufacturing. For example, it increases¹⁰ when latex is compounded, vulcanized or dried at an elevated temperature of 100°C. It decreases,^{9,11-13} on the other hand, when the products are washed/leached in water or chlorinated. The ability of the product to cause the allergic reaction, or its allergenicity, is very much influenced by the quantity of this protein fraction present, as shown by Yip *et al*¹⁴ who demonstrated that both the total residual extractable proteins and the allergenicity are well correlated, that is, high EP contents are always associated with positive allergic reaction when skin-tested on latex hypersensitive persons, and *vice versa*.

Although some inhibition activity of IgE binding was detected in extract of fragments from a worn tyre contaminated with road pollutants,¹⁵ there is however, no such allergy incidence reported involving the use of dry rubber products which are prepared somewhat differently from the latex-dipped goods. Nevertheless, it is learned that there is a certain 'fear campaign' launched against natural rubber threads, capitalizing on the latex protein issue. Work was therefore carried out to study the residual extractable proteins in NR dry rubbers and their products. Their allergen activity, as measured by a serological method, and their allergic responses, if any, elicited in latex protein hypersensitive subjects were investigated.

Methods

Quantitation of extractable proteins - RRM modified Lowry method

Extraction of soluble proteins The NR dry rubber sample was cut into small pieces (of about 1mm³), which were extracted in 0.01M phosphate buffered saline at pH7 (5ml/g of rubber) at 23°C for 3 hours using a polypropylene container. The extract was centrifuged at 3000 x g for 15 minutes to remove any particular matter that might be present. The clear extract was then immediately subjected to protein precipitation.

Protein precipitation 6ml volume of the extract in a polypropylene tube was treated with 1ml trichloroacetic acid (35%, w/v) and 1ml phosphotungstic acid (1.6%, w/v). The content was mixed and allowed to stand for 20 minutes. The resulting precipitated proteins were

sedimented by centrifugation at 10 000 x g for 30 minutes, and were redissolved in 1ml of 0.2M sodium hydroxide

Colorimetric measurement Protein concentration was then determined using the RRIM modified Lowry microassay¹⁶. Procedures involved essentially the addition of 300µl of fresh mixture containing sodium carbonate (6%) and a solution of 1.5% copper sulphate in 3% sodium citrate (mixed in the ratio of 10:0:2) to 800µl of redissolved protein test sample. After standing for 10 minutes, a volume of 100µl Folin reagent (7.2%, Sigma Chemical) was introduced. Colour was allowed to develop at room temperature for 30 minutes. Absorbance readings at 750nm were recorded and read against a calibrated curve using bovine serum albumin (BSA) standard.

RAST-inhibition immunoassay

The total *in-vitro* allergenic protein activity was measured using the procedure according to Yman *et al*¹⁷.

Solid-phase allergens Activated paper discs (Immobilon Affinity Membrane[®], Millipore, Bedford, MA) were coupled with an optimal amount (1:100, v/v) of latex serum prepared by centrifuging non-ammoniated *Hevea* latex after freezing and thawing. The same latex serum was also used as a reference with a given arbitrary activity of 100 000 relative latex units (RLU/ml).

Latex-specific IgE antibodies The source of these antibodies was a pool of sera from more than 30 patients with confirmed allergy to latex and with a high latex specific IgE test results using RAST[®] (Pharmacia, Uppsala, Sweden). The patients concerned comprised children and adults, healthcare workers and lay people.

Inhibition immunoassay Each rubber sample was cut into pieces and extracted (1:5 weight per volume) in physiological saline in a shaker overnight. Several serial dilutions (1:2 or 1:10) were used from the reference and sample extracts. 30µl of each dilution was incubated with 20µl of the calibrated IgE serum pool in a tube for 3 hours in a shaker, after which one latex disc was added to each tube. Contents of the tubes were then allowed to incubate overnight. The tubes were washed three times and 50µl of a radio-labelled anti-IgE (Pharmacia, Uppsala, Sweden) was introduced to each tube. After an overnight incubation, the tubes were washed again, and the activity measured in a gamma-counter.

Percentage of inhibition was calculated from the control discs, one with no added inhibitor, and the other for background binding. The allergy activity of the sample was calculated relative to the reference using the parallel line assay method¹⁸. The sensitivity of the method is 0.1µg/ml protein as measured by the Lowry method, the inter-assay coefficient of variation is 20%.

Skin prick test:

The test solution was prepared by extracting 1g of the rubber test sample, cut in small pieces of about 1mm cubes, in 5ml of physiological saline (pH7) for 15 minutes at room temperature.

A drop of the test extract was first placed on the skin of the patient's forearm and pierced through the drop with the tiny one-mm peak of a sterile lancet, creating a small break

measured 15 minutes after application. A positive control using histamine dihydrochloride (10mg/ml) and a negative control with the physiological saline were also included in the test battery.

Test reactions or responses were evaluated in relation to the histamine wheal. Reaction size of twice that or more of the histamine control is a strong positive reaction and is denoted as 4+, same size as that of histamine control is 3+ (a clear positive), at least one-half of that of histamine is 2+ (a weak positive). Very small wheals were not considered to be positive.

Results

Residual extractable proteins (EP)

The preparations of dry rubbers and dry rubber products are different from those of latex-dipped products such as gloves. In the dipping process, the formers are usually first dipped in a coagulant such as calcium nitrate, and then in the compounded latex concentrate (derived from *Hevea* latex). The wet-gel gloves so formed are then leached in water for a few minutes, dipped in a cornstarch slurry, and finally vulcanized/dried at 100°-120°C. It may be mentioned that, depending on the extent of leaching, or if the gloves had been chlorinated or polymer coated, the EP content can vary from as high as more than 1000µg/g to as low as below 20µg/g.

The processing of dry rubber and products, on the other hand, takes a different route. Usually *Hevea* latex is converted directly into raw rubber by acid coagulation. After removal of the unwanted latex serum, the coagulated rubber is crumbled/creped and then dried. Except for drying, continuous washing with water is employed generously throughout the entire procedure. To fabricate into its products, the dry rubber is compounded and vulcanized, at temperatures sometimes as high as 160°C.

In view of the extensive washing employed during processing, it would not be surprising if most of the EP in the raw rubber has been removed. This is indeed found to be so when a total of twenty seven raw dry rubber samples from nine differently processed dry rubber grades were analysed. All the rubber grades were commercially produced, with the exception of the steam-coagulated rubber. Results, shown in Table 1, revealed that all samples have consistently very low EP contents of about 20µg/g of rubber and less, which are, in fact, at levels reaching the limit of measurements by the method used.

Subsequent vulcanization and fabrication processes of the dry rubber into its products, which often involve high temperatures, do not appear to have any adverse effect on the EP contents, which remain low. This is evident in Table 3, which shows EP levels of both raw and compounded rubbers as well as vulcanizates from five different grades and some final rubber products. In all cases, no values exceeded 35µg/g, which were extremely low. Such low EP levels have been indicated by Yip *et al*¹⁴ in the case of gloves, to elicit very little or no allergic response in latex hypersensitive persons when clinically tested. Therefore, dry rubbers and dry rubber products may be expected to display minimal or no allergic activity.

Allergenicity

To ascertain the very low or non-allergenicity of dry

technology

Table 1
Extractable protein contents of nine different dry rubber grades as determined by the RRIM modified Lowry method

Dry rubber sample	No of sources ^a	Mean protein level, µg/g (against BSA ^b)
1 SMR CV	5	<20
2 SMR L	6	<20
3 SMR 5	1	<20
4 SMR 10	5	<20
5 SMR 20	5	<20
6 RSS ^c	2	<20
7 Steam coagulated	1	<20
8 DPNR ^d (normal)	1	22
9 DPNR (food grade)	1	<20

a Samples of the same grade obtained from different producers b Bovine Serum Albumin protein calibration standard
c Ribbed smoked sheets d Deproteinized natural rubber, prepared by enzyme treatment of latex

Table 2
Latex allergen activity and extractable protein level of NR dry rubbers and dry rubber products

NR rubber sample	EP content, µg/g (RRIM-6 modified Lowry, against BSA)	Relative latex allergen activity, RLU/ml (RAST-inhibition)
SMR CV (raw)	<20	6
SMR CV (compounded)	<20	1
SMR L (raw)	<20	4
SMR L (compounded)	<20	3
SMR 20 (raw)	<20	2
SMR 20 (compounded)	<20	2
Cut-thread A	<20	<1
Cut-thread B	29	1
Cut-thread C	<20	4
Hot water bottle	<20	<1
Diver's flippers	34	2
Reference		
Non-ammoniated latex serum proteins		100 000
Control latex gloves X ^a	695	438
Control latex gloves Y ^a	689	431
Control vinyl gloves	-	<1

a Latex gloves X and Y were two latex glove samples shown to have positive allergenicity

Relative allergen activity 100 very high, 50-100 high, 0-50 median, 5-10 low, 5 very low or no activity

low EP contents, their allergen activity and allergic response, if any, elicited in latex protein hypersensitive patients, were investigated. While the allergen activity was measured using the *in-vitro* method of radioallergosorbent inhibition test (RAST-inhibition),¹⁷ the allergic response was assessed by the *in-vivo* skin-prick test,¹⁸ which is most commonly used for evaluating the Type 1 allergy of immediate hypersensitivity.²⁰

Radioimmunoassay of RAST-inhibition In this method, latex allergens were quantitated by allowing the soluble

sites of human IgE antibodies. The amount of latex specific antibodies bound to the solid phase was determined, and was inversely proportional to the quantity of latex allergens in the test sample. Using this technique, eleven dry rubber samples were examined. These included three commercial grades of SMR rubber (both raw and compounded), and five different rubber products. For controls, two samples of latex gloves known to show positive allergenicity and sample of vinyl non-NR gloves were also analysed.

Results in Table 2 showed that except for one sample which indicated a slightly higher value of 6 RLU/ml, all

Table 3
Residual extractable proteins (EP) of dry rubbers and products and allergic response elicited in latex hypersensitive persons

Sample	EP content, µg/g (against BSA)	Allergic response by skin-prick test, %		
		-ve	2+	3+/4+
SMR CV/raw	<20	100	0	0
SMR CV/compound mix	<20	100	0	0
SMR CV/vulcanizate	<20	100	0	0
SMR L/raw	<20	90	10	0
SMR L/compound mix	<20	100	0	0
SMR L/vulcanizate	22	100	0	0
SMR 10/vulcanizate	<20	100	0	0
SMR 20/raw	<20	90	10	0
SMR 20/compound mix	<20	100	0	0
SMR 20/vulcanizate	<20	100	0	0
RSS/raw	<20	88	0	12
RSS/vulcanizate	27	100	0	0
DPNR/normal grade/raw	22	90	10	0
DPNR/food grade/raw	<20	100	0	0
Cut-thread A	<20	100	0	0
Cut-thread B	29	90	10	0
Cut-thread C	<20	100	0	0
Hot water bottle	<20	100	0	0
Diver's flippers	34	100	0	0
Latex glove ^a	647	0	30	70
Latex glove ^a	655	0	23	77
Latex glove ^a	686	0	0	100

a Latex gloves known to show positive allergic responses

Compounded mix ACS 1 Vulcanizate with ACS 1 mix, cured at 140°C for 40 minutes

Allergic responses (4+) Strong positive reaction, (3+) Clear positive reaction, (2+) Weak positive reaction, (-ve) No positive reaction

or no allergen activity at all. Their EP contents were as anticipated, extremely low. These are in stark contrast with those of glove samples containing considerable quantities of EP (allergen activity 438 and 431 RLU/ml).

Skin-prick test This is a simple and rapid test of high sensitivity for IgE-mediated allergy. The allergic response to the allergens in the sensitized persons can be easily measured. Besides being used for identifying sensitized patients, the test is also used for detecting the presence of protein allergens in latex products.^{6,14}

Extracts from 14 dry rubber samples of various grades and five different rubber products with pre-determined EP contents, were skin-tested on latex protein hypersensitive subjects. The samples included both the raw and compounded (ACS 1 mix) rubbers, vulcanizates (with ACS 1 mix and cured at 140°C for 40 minutes) and rubber products such as cut threads, hot water bottles and diver's flippers. A total of 31 patients shown to be sensitive to latex proteins were clinically tested in three groups. Results are as shown in Table 3.

There was very little or no allergic response shown by the latex protein hypersensitive patients tested in all cases. These negative observations were substantiated by the

extracts from a certain brand of latex gloves known for their allergenicity.

Discussion

Although it is not possible to test all the dry rubber products available in the market, the present study has examined most of the major rubber grades used in the dry rubber product manufacturing industry, either in their raw, compounded or vulcanized forms, as well as several finished products. Findings have shown that in all cases, dry rubbers and their products have insignificant amounts of residual extractable protein fraction containing the allergens. Their removal apparently occurred mainly during processing of the raw rubbers, whereby these allergenic proteins were either rendered insoluble by the acid treatment or leached out by the extensive and continuous washing employed throughout the procedure. Subsequently processes converting them into products, such as compounding, vulcanization, and product fabrication, all of which were usually conducted in dry rubber state, did not induce any marked changes to either their low EP content or their 'non-allergenicity'. This is

'wet gel' gloves are vulcanized/dried at elevated temperature, due to migration of more soluble allergenic proteins along with considerable amounts of water to the surface of the latex film as it is being dried²¹

Assessments of both the *in-vitro* and *in-vivo* allergen activities of the test samples by the RAST-inhibition immunoassay and the skin-prick test respectively, have been shown to be consistent with the 'non-allergenicity' of these products as suggested by their remarkably low EP contents. It may be of interest to know that these two methods of assessment are very well correlated²². It is also noteworthy that these findings confirm the association of low EP contents with low allergen activity, and the near absence of allergen activity or non-allergenicity related to EP levels less than 100µg/g, as reported earlier¹⁴. However, it may be pointed out that there may be an extremely small number of individuals who are highly atopic, and who may develop sensitivity to a great number of things they come in contact with. Such people should be identified, treated specially, and allergen avoidance should be recommended.

It may be of interest to mention that the inhibition of IgE binding to latex proteins reported for extract of fragments from a worn and contaminated tyre,¹⁵ may not necessarily be due to latex antigens. The possibility of some other antigens in the extract effecting such an interaction due to cross-reaction^{23, 24} cannot be excluded.

It is hence reasonable to conclude that, as tested by the best methods available, dry rubbers and dry rubber products have not only extremely low residual extractable protein contents, but also very low or negligible allergenicity. This is not withstanding the fact that there are relatively fewer dry rubber products used in the healthcare sector where prevalence of Type 1 hypersensitivity has been reported. Furthermore, products such as the cut threads which are often used as medical bandages, are not likely to pose any problem since they are generally covered by fabric thereby minimising any contact with the human skin. Therefore NR dry rubbers and dry rubber products are essentially not affected by the protein allergy.

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References

- 1 Nutter, A F, Contact urticaria to rubber, *Br J Dermatol*, 1979, 101, 597-598
- 2 Forström, L, Contact urticaria from latex surgical gloves, *Contact Dermatitis*, 1980, 6, 33-34
- 3 Ownby, D R, Tomlanovich, M, Sammons, N and McCullough, J, Anaphylaxis associated with allergy during barium enema examinations, *J Allergy Clin Immunol*, 1991, 156, 903-908
- 4 Proc 'International latex conference Sensitivity to latex medical devices' 1992 Baltimore USA

- Rubber contact urticaria Allergenic properties of 19 brands of gloves, *Contact Dermatitis*, 1988 19, 362-367
- 6 Slater, J E and Chhabra, S K, Latex antigens, *J Allergy Clin Immunol*, 1992, 84, 673-678
- 7 Alenius H, Turjanmaa, K, Mäkinen-Kiljunen S, Reunala, T and Palosuo T, IgE immune response to rubber proteins in adult patients with latex allergy, *J Allergy Clin Immunol*, 1994, 93, 859-863
- 8 Alenius, H, Yip, E, Turjanmaa, K, Reunala, T, Mäkinen-Kiljunen, S and Palosuo, T, Distribution of allergenic proteins between fractions of natural rubber latex (NRL) separated by ultracentrifugation, *XV Int Congr Allergol Clin Immunol EAACI Stockholm*, 1994, Abstract 344
- 9 Dalrymple, S J and Audley, B G, Allergenic proteins in dipped products extractable protein levels, *Rubber Developments*, 1992, 45(2/3), 51-60
- 10 Hashim A, Effect of leaching on extractable protein content, *Proc Int Rubb Technol Conf Workshop on Latex Proteins*, Kuala Lumpur, 1993, 27-31
- 11 Subramanian, A, Yip E Ng, K P and Mok, K L, Extractable protein content of gloves from prevulcanized natural rubber latex, *Proc Int Rubb Technol Conf Workshop on 'Latex Proteins'*, Kuala Lumpur, 1993, 76-80
- 12 Nor Aisah Abd Aziz, Chlorination of gloves, *Proc Int Rubb Technol Conf Workshop on 'Latex Proteins'* Kuala Lumpur, 1993, 59-69
- 13 Yip, Esah, Determination of extractable proteins in natural rubber products by high performance liquid chromatography (HPLC) *Proc Int Rubb Technol Conf Workshop on 'Latex Proteins'* Kuala Lumpur, 1993 41-50
- 14 Yip, Esah, Turjanmaa K, Ng, K P and Mok K L, Residual extractable proteins and allergenicity of natural rubber products, *Proc Int Conf on Latex Protein Allergy the latest position*, Paris, 1995, 33-40
- 15 Williams *et al*, Latex allergen in respirable particulate air pollution *J Allergy Clin Immunol* 1995 95(1), 88-95
- 16 Yusof, Faridah and Yeang, H Y, Quantitation of proteins from natural rubber latex gloves, *Journal of Natural Rubber Research*, 1992, 7(3), 206-218
- 17 Yman, L, Ponterius, G and Brandt, R, RAST-based allergen assay methods *Dev Biol Stand* 1975, 29, 151-165
- 18 Anderson, M C, Baer, H and Rastogi, S, RAST inhibition procedure Allergic Product Branch, Bureau of Biologics, Food and Drug Administration Bethesda, Maryland, USA, 1981
- 19 Dreborg, S, Skin test used in Tyre 1 allergy testing Position Paper, *Allergy*, 1989, 44, Suppl 10, 22-30
- 20 Levy, D, Measurement of hypersensitivity to latex allergen activity from *in-vivo* and *in-vitro* testing, *Proc Int Conf on 'Latex Protein Allergy the latest position'*, Paris, 1995, 1-6
- 21 Shamsul A R, Samsidar Hamzah, Hafsa Md Ghazaly and Yeang H Y, Latex Allergy Studies Location of soluble proteins in latex examination gloves, *Journal of Natural Rubber Research*, 1993, 8(4), 299-307
- 22 Mäkinen-Kiljunen, S and Turjanmaa, K, Correlation of latex allergen activity from *in-vivo* and *in-vitro* testing, *Proc 'Latex Allergy Symposium'* Toronto, Canada, 1994, Abstract, 35
- 23 Kurup, V P, Kelly, T, Elms, N Kelly, K and Fink, J, Cross reactivity of Food Allergen in Latex Allergy, *Allergy Proc*, 1994, 15(4), 211-216
- 24 Hasma, H, Inhibition of IgE binding to latex proteins by antigens other than those of latex *Rubber Research Institute*

Stevenson, Todd A.

From: KamFam [kamfam@mediaone.net]
Sent: Friday, May 19, 2000 10 05 AM
To: cpssc-os@cpssc.gov
Cc: KamFam
Subject: Petition HP 00-2, Petition on Natural Rubber Latex

To Whom It may Concern.

I am writing to you today in an effort to ask that the Commission issue a ruling declaring that natural rubber latex ("NRL") and products containing NRL are strong sensitizers under the Federal Hazardous Substances Act ("FHSA"). I am a disabled RN with Type 1 Natural Rubber Latex Allergy. As disheartening as it is that my career has ended in a field that I loved most dearly, my concerns lie with children who are developing this potentially fatal allergy, my son included.

A brief history of my son's own exposure to Natural Rubber Latex will show that NRL (Natural Rubber Latex) IS a Hazardous Substance! My son was premature at 32 weeks. The exposure to all medical supplies that contain Natural rubber latex while hospitalized for 12 days prior to coming home put him at risk for developing this potentially fatal allergy! At 9 months of age he had a bilateral Hernia Repair with again more exposure to NRL during his day surgery procedure in the hospital. For the simple fact that I myself was diagnosed with this allergy in 1991 my son's exposure after these exposures were greatly eliminated because of myself also having the allergy i.e. (Our home is safe, Our vehicles are safe, we limited our exposures)

Today my son is a healthy, active, bright, and extremely knowledgeable on Natural Rubber Latex Allergy. You may wonder what it is like to live with this allergy. Well from a kid's perspective it's scary! Think of all the places and things that have natural rubber in, on, or around that could potentially lead to anaphylaxis for a child.

I would ask on behalf of my son and myself that the Commission think about what a person lives with in a day with a natural Rubber latex allergy. It just seems so simple a resolution- get rid of it now and stop the sensitizing before it stops more of our children.

Thank you for your time,

Lisa Kamenides Disabled RN with Type 1 Natural Rubber Latex Allergy, son age 6 with type 1 NRLA

North American
Rubber Thread Co., Inc.

106 Ferry Street, P O Box 1709
Fall River, MA 02722
Sales (508) 673-1444
Telephone (508) 677-3334
International (508) 675-0181
FAX (508) 677-0293

93
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out
5/16/00

May 16, 2000

Office of the Secretary
Consumer Product Safety Commission
Washington, DC 20207
(deliver to
Room 302
4330 East-West Highway
Bethesda, MD 20814)

OFFICE OF THE SECRETARY
FEDERAL BUREAU OF INVESTIGATION
2000 MAY 18 P 3:30

[Re Petition HP 00-2, Petition on Natural Rubber Latex]

Dear Madam Secretary

North American Rubber Thread wishes to **OPPOSE** the captioned petition submitted by Debi Adkins, editor of Latex Allergy News, which requests classification of natural rubber latex and products made therefrom as "strong sensitizers" under the Federal Hazardous Substances Act, 15 USC 1261-1277

We applaud Ms Adkins effort to continue to highlight the issue of "latex allergy" to a public awareness, but we believe that adoption of the recommendation would constitute an egregious **ERROR** which would cause 1 unjustifiable alarm to consumers, 2 unjustifiable harm to consumers, and 3 unjustifiable, indiscriminate harm to a large number of industries, and the manufacturers therein Point 4 is that existing regulations offer the correct level of intervention based on available information

1 ADOPTION OF THE PETITION WOULD CAUSE UNJUSTIFIABLE ALARM TO CONSUMERS

Would you, as an individual, continue to buy the undergarments you are wearing as you read this letter, if it contained a warning saying they contained a "strong sensitizer"? Petitioner would have you do that, because virtually every undergarment produced and sold in the United States contains natural rubber thread made from latex

We submit that people around us are not experiencing the effects that a "strong sensitizer" would produce if it were present in their undergarments Telling them that this would happen when it won't would cause unjustified alarm

Furthermore, the alternatives do not offer comfort 1) go back to using drawstrings, or 2) convert to synthetic elastomers made from Diisocyanates and Substituted Amines, chemical families that truly are strong sensitizers, or use elastomers containing chloroprene or isoprene, possible carcinogens

2 ADOPTION OF THE PETITION WOULD CAUSE UNJUSTIFIABLE HARM TO CONSUMERS

Products made from natural rubber latex perform functions that science or the marketplace has determined to be helpful These uses cover such a broad spectrum as to be practically innumerable, but some of them are lifesaving We believe it is inappropriate to dissuade people from using them, because the risk-to-benefit ratio is overwhelmingly in favor of these products

That a segment of the population may have at least a mild negative reaction to chemicals or protein found in compounds of latex natural rubber is out of dispute. However, many people now sensitized developed their sensitivity from products made before awareness of the issue developed. Manufacturers now produce articles less prone to initiating new cases of sensitization. Our Company has ongoing programs in this regard. It seems incorrect to steer the general population away from these improved products based on POTENTIAL negative aspect of them by declaring ALL to be "strong sensitizers". It is simply not the case for most people, any more than it is for bananas or peanuts.

3 ADOPTION OF THE PETITION WOULD CAUSE UNJUSTIFIABLE HARM TO A LARGE NUMBER OF INDUSTRIES, AND MANUFACTURERS THEREIN

We believe it to be self-evident that producers of products made from natural rubber latex would be hurt if the petition were adopted. They would be harmed both because of the shift away from their products, as well as increased cost generated in the workplace for new measures likely required for worker safety. The question, then, is whether such harm is justifiable.

We have personal experience as a chemist, engineer, and manufacturer of rubber articles from latex for more than 30 years, in several countries from Brazil to Southeast Asia. Once every few years, an individual will exhibit a Type IV (rash) reaction to some substance in the factory. Most frequently it is to the cardboard boxes made from Kraft paper. Sometimes it can be traced to a chemical, usually an accelerator used in the rubber cure system. In all cases the symptom is a rash that goes away when contact with the sensitizing material is eliminated. But, we have never seen, nor are we aware of, one human being at any level of any manufacturing or processing company that has ever exhibited a type I allergic reaction to any substance within the rubber manufacturing environment.

The same can be said of manufacturers of elastic web in the textile industry who use our product, and the final consumer, the American public. In fact, one would be hard-pressed to find a product that elicits fewer complaints than narrow elastic fabric containing rubber thread from latex. We believe that the reason for this is that it is a SAFE, BIOLOGICALLY INERT, (and environmentally "green") product. The only requirement we would like to see (with pride) is the listing of natural rubber thread along with the rest of the ingredients, such as cotton or polyester, on the regular label of an article.

As further argument against classifying natural rubber thread in textiles as a "strong sensitizer", it is to be noted that most people WASH their clothes, and in doing so, remove soluble protein present.

[This is not to say that there is no problem with latex protein. We are aware of the cases in the health care field of the specific barium enema deaths, and the more widespread sensitizations to examination gloves. From the toy industry, one instance was reported to us of a strong reaction to natural rubber thread that occurred in the early 1990's. A child with Spina Bifida, and on several medications, had to be taken to an emergency room for treatment after having drooled onto a toy while cuddling it to his face and sleeping on it. But we are also aware of the improvements developed to diminish the problem. It is our further belief that those who experienced allergic reactions had not previously experienced them while wearing undergarments that contained natural rubber thread from latex.]

Seventy-five years of safe use of natural rubber latex-based extruded rubber thread in the textile industry provides compelling evidence that petitioner's proposal to classify all products from natural

rubber latex as strong sensitizers is extreme, unwarranted, counterproductive, and unjustified. It should be rejected.

4 PETITION IS UNNECESSARY IN LIGHT OF EXISTING RECENT REGULATIONS

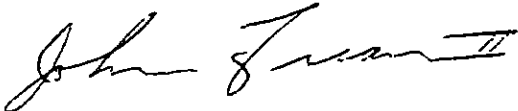
In June of 1997, NIOSH published recommendations containing ways to reduce exposure to latex allergens in the medical care industry and other workplaces.

In October of that same year, the Food and Drug Administration issued a rule requiring that, as of October 1, 1998, medical devices containing rubber from natural latex be so labeled (a requirement we supported).

These two steps covered those most at risk: workers in the health care industry and their patients. They also provided impetus for workers and manufacturers in latex-related industries to improve processes, procedures and products, resulting in the chance that fewer people will become sensitized in the future.

THIS CEMENTS THE CASE FOR REJECTION OF THE PETITION at this time in the general case of latex, and especially for the specific case of natural rubber thread for narrow elastic fabric for the textile industry. We ask that you agree with our position.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John Friar II". The signature is fluid and cursive, with a long horizontal stroke at the end.

John Friar II, Owner

24

6/19
01/20/00
S/1/2/00

**>> DYNA-TECH ADHESIVES INCORPORATED
NEW TECHNOLOGY IN ADHESIVES FOR THE PSA INDUSTRY**

May 19, 2000

Office of the Secretary
Consumer Product Safety Commission
Washington, DC 20207

"Petition HP 00-2, Petition on Natural Rubber Latex"

The management and staff at Dyna-Tech Adhesives, Inc request that Petition HP 00-2, to have natural rubber latex and products containing natural rubber latex declared as a strong sensitizer, be disallowed. As a leader in the production of adhesives containing natural rubber latex for the water based pressure sensitive adhesives industry our experience supports no reason to take this action. We have been producing adhesive for the label and tape industry for 19 years, and a segment of our product line contains natural rubber latex as critical component for certain adhesive applications. During our history we have encountered less than five complaints concerning any sensitivity to our adhesives and upon investigation determined that these complaints were either not due to contact with the adhesive or involved a product that did not even contain natural rubber latex. In addition we have been involved in the processing of millions of pounds of natural rubber latex through our operation and the operations of our customers. There has never been a problem with natural rubber latex sensitivity with any of our employees or the employees of any of our customers.

The subject petition requesting that natural rubber latex and all products containing natural rubber latex be classified as a strong sensitizer is an extreme overreaction. Many products containing natural latex do not even come into contact with humans as latex gloves do. For example, such a ruling will cause undue alarm with the final consumer of products that contain our adhesives. The chance that the adhesive will come in contact with the consumer is remote because it is between the label and the product being labeled. This fact coupled with the very small percentage of the population that has become sensitized to natural rubber latex results in a chance of a problem arising being virtually non-existent.

If this action is taken, the unnecessary alarm that it will no doubt create will cause sever damage to us in the form of lost business. Furthermore, whatever natural rubber latex related business that is not devastated by this action will become far more costly due to the requirement of labeling all products containing natural rubber latex.

In summary we are again strongly requesting those products containing natural rubber latex not be declared as strong sensitizer based on our experience which proves that in our industry it most definitely is not.

Sincerely,


Richard Oldack
President

**>> DYNA-TECH ADHESIVES INCORPORATED
NEW TECHNOLOGY IN ADHESIVES FOR THE PSA INDUSTRY**

May 19, 2000

Office of the Secretary
Consumer Product Safety Commission
Washington, DC 20207

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In summary we are again strongly requesting those products containing natural rubber latex not be declared as strong sensitizer based on our experience which proves that in our industry it most definitely is not.

Sincerely,

Richard Oldack
President

P O BOX 628 • COUNTRY CLUB ROAD • GRAFTON, WEST VIRGINIA 26354 • (304) 265-5200

Stevenson, Todd A.

From: jmpaine@uhl.wa.gov
Sent: Friday, May 19, 2000 4:52 PM
To: cpssc-os@cpssc.gov
Subject: CPSC FOIA Request DOC



CPSC FOIA Request.DOC

Please see attached FOIA request.

<<CPSCFOIA Request.DOC>>

"WorldSecure <uhl.wa.gov>" made the following annotations on 05/19/00 15:53:58

Information contained in this email transmission is privileged and confidential. If you are not the intended recipient, do not read, distribute or reproduce this transmission (including any attachments). If you have received this email in error, please notify the sender by email reply.

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~~Stevenson, Todd A.~~

2.5

From: Nancy Mitchell [nam1@ix.netcom.com]
Sent: Saturday, May 20, 2000 5:25 PM
To: cpsc-os@cpsc.gov
Subject: Petition HP 00-2, Petition on Natural Rubber Latex

Importance: High

Re: Petition HP 00-2, Petition on Natural Rubber Latex
Date: May 20, 2000
To: Office of the Secretary, Consumer Product Safety Commission

Our son, Sean, was diagnosed seven years ago with a severe latex allergy. His allergist has advised us to keep him away from natural rubber latex (NRL) in order to prevent allergic reactions. Allergic reactions to this potent allergen can be life-threatening. Reportedly, NRL is in some 40,000 consumer products. Identifying what products do or do not contain NRL has been a very difficult and frustrating task. Trying to obtain accurate information from manufacturers has consumed a great deal of our time. Often we are unable to get a satisfying or straight answer from them regarding the NRL content of their products.

The Food and Drug Administration currently requires that NRL-containing medical devices be labeled. Since this ruling went into effect, avoiding NRL, particularly in the health care setting, has been a great deal easier. However, it only applies to medical devices. We need to have consumer products likewise labeled. Our son continues to have allergic reactions and often we are at a loss to determine what products in our everyday lives are triggering these reactions. We urge the Consumer Product Safety Commission to declare NRL a strong sensitizer and require labeling of NRL-containing consumer products. Thank you for allowing us to comment on this important matter.

Sincerely,

Nancy A. and Michael J. Mitchell
3 Folsom's Pond Road
Wayland, MA 01778
508.358.5979

~~Stevenson, Todd~~

26

From: PMMMMC@aol.com
Sent: Sunday, May 21, 2000 9 47 PM
To: cpsc-os@cpsc.gov
Subject: "Petition HP 00-2, Petition on Natural Rubber Latex "

Dear Consumer Product Safety Commission:

I am writing to you to request that you consider labeling of consumer products with regards to the presence of natural rubber latex in the product.

The prevalence of latex allergy has increased in the past several years, to the extent that some researchers have stated that it is in epidemic proportions. Because your Commission has the task of promoting product safety in the United States, I ask that you seriously consider the labeling of products that contain natural rubber latex. The prevalence of latex allergy with children with spina bifida is 65-70%; healthcare workers up to 17% and the general population, 6%. These numbers are increasing day to day with continued products of natural rubber latex. Latex allergy is a condition in which frequent exposure increases the risk for development of the allergy. I ask your commission to be proactive for the safety of consumers in labeling products which contain natural rubber latex. Medical devices must be labeled regarding this content, and some US manufacturers have already been proactive with labeling of their consumer products.

I ask you to please take this petition seriously and vote to make all consumer products to be labeled as to the presence of natural rubber latex.

Sincerely,

Marianne G. McAndrew, RN,BSN,CDE
610-518-3373
405 William Salesbury Drive
Downingtown, PA 19335

Stevenson, Todd A.

27

From: LindaLancz@aol.com
Sent: Sunday, May 21, 2000 4 40 PM
To: cpssc-os@cpssc.gov
Subject: No Subject

To: cpssc-os@cpssc.gov
Regarding - HP 00-3--Ban Candle Wicks Containing Lead.''

To reduce the risk of hazardous exposure to lead, we request manufacturers to eliminate the use of lead candle wicks that may be accessible to children from products used in or around households, schools, or in recreation. We also recommend that, before purchasing products for resale, importers, distributors, and retailers obtain assurances from manufacturers that those products do not contain lead that may be accessible to children.

The adverse health effects of lead poisoning in children are well-documented and may have long-lasting or permanent consequences. These effects include neurological damage, delayed mental and physical development, attention and learning deficiencies, and hearing problems. Because lead accumulates in the body, even exposures to small amounts of lead can contribute to the overall level of lead in the blood and to the subsequent risk of adverse health effects. Therefore, any unnecessary exposure of children or adults to lead should be avoided."

This entire controversy could have an immediate, cost effective and easily enforceable remedy - eliminate metal core wicks all together ...there's no expensive testing, no wiggle room, no guessing...in my opinion it's the only responsible and enforceable thing to do. It is totally irresponsible to allow this practice to continue when we know as much as we do about the effects of lead.

We all pay the price for lead exposures since research has shown what only a few years ago used to be considered slight or permissible exposures can rob children of their learning potential & the hope of what "might have been," increased health care costs from treating the myriad of health complications from lead exposures and as a society we pay the price in drop out rates, increased crime, aggressive behavior and domestic violence...all of

which

studies have shown are influenced by lead & other heavy metal uptake.

Rev. John and Linda Lancz

28

Ms Rockelle Hammond
Office of the Secretary
Consumer Product Safety Commission
Washington, DC 20207

5/16/00

Dear Ms. Hammond,

I am a 41 year old RN with latex allergy. This diagnosis has changed my life in many ways.

First of all it is difficult to access health care in the hospital setting. The hospitals are a dangerous place to be. Though they are trying to be low allergen it still isn't safe for me. I often wonder what will happen if I need emergency care. Will I die?

I lost the career I worked so hard for. Sometimes it seems like a bad dream. Working as an OB nurse was rewarding and fulfilling. I miss it!

It seems every where I go there is that enemy LATEX!! I can't eat out anymore. My kids wanted to take me to a special restaurant for my birthday but after calling the restaurant I discovered they used powdered latex gloves for food preparation. How disappointed I was and so sad were my lovely children who now were stuck with a mom allergic to latex. Come to find out most of the restaurants in town use either latex or powdered latex gloves. I can't order out lunch at work I have to bring my own food. Restaurants don't seem to care or want to listen about the dangers of using latex gloves not only for people who patronize them but also for their own workers. Stores

From K-mart, Wal-Mart and Target have now become a battle zone for me. No more can I go shopping in these stores. I have to monitor all of the toys my kids have or get to make sure they are safe

I have had to stop going to Birthday parties with my kids because they always have balloons. It causes my kids to have anxiety and me to become hoarse and develop anaphylactic symptoms. Balloons are like grenades and they are everywhere. Sea World balloon toss, outing for my son had a balloon tent with balloons popping, dinner function balloon bouquets on table, water balloon toss at schools, neighbors, parties, Balloons at grocery store, church, Mall, and banks. They seem to be everywhere.

Lets talk about clothes. No bathing suits, bras, and underwear. The special order ones are very expensive so I have no suit, no bra, no underwear and a few pairs of socks. My wardrobe is very limited. Why, because most clothing contains latex and they don't label any clothing that contains it so you never know. Other allergies have labels on if allergic to peanuts many foods are labeled. Why not something that can kill us!!!

I have to be careful because some prepackaged foods are packaged on a line that uses powdered latex gloves. So I am careful not to eat just anything. It is very boring.

As you can see this allergy affects all aspects of my life eating, clothing, health care, job, and shopping. I would like to not become sicker from this allergy and by having everything labeled latex free would be a great accomplishment for all of us afflicted with this allergy and I think banning latex balloons is mandatory. They can kill us!!!!!!!

Sincerely,

A handwritten signature in black ink that reads "Marisa Mitchell RN". The signature is written in a cursive, flowing style.

Marisa Mitchell RN

4940 Deerfield Way, #101
Naples, Fl 34110
May 16, 2000

Letter 29

Consumer Product Safety Commission
Office of the Secretary
Room 502
4330 East-West Highway
Bethesda, Maryland 20814

To Whom It May Concern:

I am a Registered Nurse who has a Type 1 latex allergy. This has changed my life and my professional career. It started with an allergic reaction to my hands and to my eyes, but has progressed to affect my entire system.

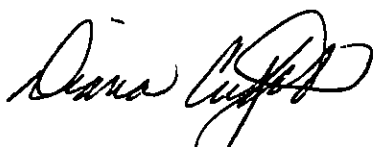
I support any legislation that would require product labeling and changes in the law that would protect those who are allergic to latex and also the public from becoming allergic to latex.

I have had reactions to: gloves, Band-Aids, tape, elastic in waistbands of clothes, clothes made of stretchy material, tires, glue used in laying carpets, food eaten in restaurants that prepare food using latex gloves, balloons, swimsuits, pool water from a wellness center that had a floor made of old tires, rubber handles on exercise equipment, and EKG electrodes. There are many products that I no longer buy because I do not know their latex status.

These products are life-threatening to anyone who has a Type 1 latex allergy. They can cause skin rashes, asthma, hypotension, cardiac arrhythmias, and anaphylactic shock.

Please push through legislation that requires product labeling.

Sincerely,



Diana Cutright



POTOMAC LATEX ALLERGY ASSOCIATION
P.O. Box 52
GREENBELT, MD 20768
301-345-0966
POTOMACLAA@AOL.COM

Office of the Secretary
- Consumer Product Safety Commission
Room 502

May 22, 2000.

**Comments Regarding Petition HP002
Petition On Natural Rubber Latex**

Natural Rubber Latex is a substance found in some 40,000 different items. It has traditionally been regarded as a very useful and inert substance, and has been touted repeatedly as the most reliable barrier against AIDS. Indeed, the advent of Universal Precautions, which mandated the use of barrier protection for healthcare workers, guaranteed that natural rubber would find widespread usage in the form of medical gloves, with glove numbers now in the billions yearly for the United States alone. With this widespread usage of latex has emerged an unplanned-for consequence, natural rubber latex allergy. Medical evidence indicates that latex allergy is an acquired allergy, requiring exposure to develop. Persons especially at risk are those who have received the most exposure to this substance, as indicated in the percentage of healthcare workers, spina bifida patients, and other persons with a history of multiple surgeries now being affected.

The passage of this petition is of extreme importance for the health and safety of the American public and those already affected by latex allergy. The public needs to be made aware that natural rubber is a strong sensitizer and that usage of the product may place them at risk of developing latex allergy. Furthermore consumers need to be aware that usage of latex may be hazardous to the growing numbers of person with latex allergy, and that the indiscriminate public display and usage of this product may prove harmful to unsuspecting passersby with latex allergy.

The Anaphylaxis Campaign, Merck Manual, and National Jewish Medical and Research Center recognize latex as one of the four major trigger groups for anaphylaxis, the other 3 being foods such as shellfish, drugs such as penicillin, and bees/wasp stings. We wouldn't dare let a hive of bees loose in a shopping mall, yet how often do we see shopping malls filled with balloons? How frequently are babies given a latex pacifier to suckle on? How often are latex gloves used in food service? The list of examples are lengthy, but public protection and education are nearly non-existent.

The public needs to be made aware that natural rubber latex is indeed a strong sensitizer, and those already with latex allergy need to be protected from the indiscriminate and uneducated usage of this product.


Rochelle D. Spiker, LCSW-C
Executive Director

**POTOMAC LATEX ALLERGY ASSOCIATION
FAX TRANSMISSION RECORD**

DATE: 5/22/2000

**TO: Office of the Secretary
FAX NUMBER: 301-504-0127**

**FROM: ROCHELLE D. SPIKER, MSW, LCSW-C
EXECUTIVE DIRECTOR
FAX NUMBER: 301-345-0966**

NUMBER OF PAGES: 1

TIME OF TRANSMISSION: 12:25 pm

MESSAGE: Comments in support of petition HP002-Petition on Natural Rubber Latex

31

Latex
OK
5/19/00

5-19-2000/OFFICE OF
THE SECRETARY

To: The Consumer Product Safety Commission,

I strongly believe that all products that contain natural rubber latex should be labeled, including foods that have been handled by latex products. I have had varying degrees of reactions to many products; gloves, balloons, from touching a new vacuum cleaner filter that was bordered with a soft rubber seal, hives from using a new shower head that had a rubber seal, a rubber hose on a new dishwasher, from a pre filled syringe after a procedure, clothing, shoes, bandaids, EKG patches and prepackaged food handled with latex or processed in a warehouse that uses powdered latex gloves. I'm sure there are many that I am forgetting.

I now order all of my clothing and shoes from catalogs or have someone get them for me and there are many clothes and shoes that I just do not purchase simply because they are not labeled or the materials are not listed in the catalog description. There are other items that I either only have 1 or 2 of, or do not have any because they are either not available without elastic or the specialty catalogs where they are sold are so very expensive. Bathing suits, bras and underwear will typically list the cloths but leave out what materials the straps, decorations, and elastic in the legs is made from.

If I go anywhere it is essential that I call ahead to make sure that the environment is safe. From experience I have learned that one must ask for a manager or the information is often inaccurate. I usually have to ask that they get the box of gloves that they use and read it to me, and if on rare occasion they are not latex, I then have to ask about balloons being in the environment and how recent it has been. Balloons and gloves are by far the largest danger to me and prevent me from going many places, Walmart, Target, Fast food and regular restaurants, Sams Club, bowling allies, grocery stores, hairdressers, day care centers, automotive centers, Weddings, churches, and ceremonies because the whole world believes that balloons and gloves are benign and so they are EVERYWHERE! I have even heard of teachers and girl scout leaders using them for craft projects with children, this is not only dangerous but their parents have no idea what their children were exposed to that day, or why their child had an asthma attack that day. There are warning signs to alert those with pacemakers about microwave ovens but there are never balloon warnings and even if there were we still couldn't go there. Balloons should be removed from the market, they are NOT necessary for ANYTHING and there are alternatives available. They might be CUTE but they cause asthma, latex allergy, choking, and deaths.

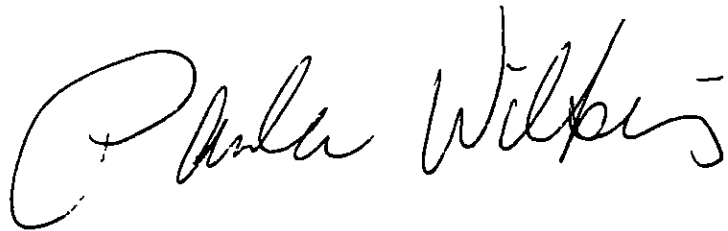
Gloves although necessary in certain situations should be monitored and limited. I have to drive out of the city where I live to get safe dental care. There are only three doctors in my city where I can seek safe medical care, an Obstitritian, Allergist and a General surgeon. Our counties hospitals have made improvements but they are still not safe for anyone with a severe latex allergy and they are still putting those less severe at risk for progressing. My physician wanted me to get a cardiac workup several weeks ago, I am still attempting to find a safe doctor that I can go to and a safe place to be tested. If one finds a safe place out of the city that they live in, it then becomes a battle with the insurance companies on why you must go "out of the network" and is usually not approved.

The hospitals are beginning to educate, however it is either not enough or people are not listening. My latex allergic coworker was recently in our hospital for some tests and although they have a "latex safe room" it was in use so she waited in the powder filled lobby while they took latex supplies out of another room that was probably not cleaned appropriately. This caused her to have to use her inhalers, she was lucky that this is all she needed this time. Who

knows what this unnecessary exposure will cause her in the future Then all of the lab personnel kept coming into her labeled room with latex gloves already on and would argue with her about it. What will it take? more dedicated people loosing the careers that they loved? influential persons acquiring the allergy? more deaths? how unfortunate. There are varying degrees of severity with this allergy from fairly mild to very severe or even deadly but the hospital personnel treat all as though they are mild instead of how it should be, that they are all assumed severe. I feel that we definatly do not have the same rights as all other patients, the right to safe and competent care in an environment that has safe air for us to breathe. Please begin to pass legislation that will help us to remain at least as healthy as we are now and not progress.

Thank-You!

Paula Wilkins
28 Wickliffe Drive
Naples,FL 34110

A handwritten signature in black ink that reads "Paula Wilkins". The signature is written in a cursive style with a large, looping initial "P".

**OREGON ECOBUILDING NETWORK**

P.O. Box 86444
Portland, OR 97286
Phone or Fax (503) 760-2092
E-mail: oebn@teleport.com
website: www.pnf.org/oebn

*via fax (email as stated
not withdrawn)*

Page 1 of 1

From: oebn <oebn@teleport.com>
To: cosc-os@cpsc.gov <cosc-os@cpsc.gov>
Date: Monday, May 22, 2000 7:56 PM
Subject: HP 00-2: Petition Natural Rubber Latex

To: Consumer Product Safety Commission

We appreciate the opportunity to comment on this Petition HP 00-2: Natural Rubber Latex. On behalf of members and friends of Oregon Ecobuilding Network, we state YES unequivocally for the necessity of labeling and warning consumers on the use of Natural Rubber Latex in many products. The asthmatic, hives and other reactions that are reported to our network are very severe and can be fatal from Latex exposure. The seriousness of accumulative exposure to Latex including toxic ingredients of carbamates, benzo-thiozals, thiurams and mercaptins cannot be overemphasized. Our network is a charitable 501(c)(3) with a focus on healthier buildings education and advocacy for chemically injured. There is a growing public awareness of the importance of clean and safe products, with non-toxic or low-toxic ingredients. We recently spoke at a mothers group, called "Formerly Employed Moms at the Leading Edge". They were shocked to hear of Latex use in children's pacifiers; this is so incredibly irresponsible of the manufacturers. We encourage you to take this issue very seriously, as the impact of accumulative Latex exposure in the workplace, food handling, and in many products has become a serious threat to human health.

Sincerely, *Roslyn Hamilton*
Roslyn Hamilton, President

Cathey

33

Stevenson, Todd A.

From: Anna Salanti [asalanti@worldnet.att net]
Sent: Monday, May 22, 2000 4 14 PM
To: cpsc-os@cpsc.gov
Subject: Petition Hp 00-2 Petition on Natural Rubber Latex

To Whom It May Concern:

I am writing to urge you to advocate the use of non-latex medical equipment and supplies, including gloves. Non-powdered glove use is not a sufficient safeguard in prevention of latex allergy. I have converted from Type 4 to Type 1 latex allergy by using hypoallergenic, powder free gloves. I was employed as an RN for twenty years. I developed a latex allergy by wearing latex gloves throughout my workday, complying with current, OSHA mandated universal precautions. Doing so caused the loss of my career as well as the deterioration of my health. When I come in contact with latex, my eyes become itchy and watery. I have generalized itching and hives. My skin becomes flushed. I start to cough. As my throat begins to swell, I become dizzy and short of breath. My heart races and my blood pressure falls. This becomes a serious situation and unless I receive emergency care, the end result could be death. My last life-threatening experience occurred at a restaurant, after eating food that had been prepared by someone wearing latex gloves. This was the most severe anaphylactic reaction I have ever experienced. Immediately after this experience, I became reactive to many of the cross-reactive foods. I could not have contact with any clothing having latex or accelerators in the elastic or fabric. I could not wear any shoes containing latex, nor could I come in contact with glues, make-up, computer mice (the list of latex containing items is endless) without having a reaction. I could not enter a hospital, clinic or physician's or dentist's office that uses non-powdered latex gloves without having an allergic reaction due to the airborne latex particles and to the transfer of latex allergens on office equipment. I urge you to recommend the use of non-latex medical equipment and supplies. It is also imperative that latex gloves be prohibited from being used in handling of foods and in the food service industry. This will prevent the further sensitization of workers and the general public. As a consumer, my life depends on appropriate labeling of all items containing natural rubber latex. I urge that the Commission issue a rule declaring that natural rubber latex and products containing Natural Rubber

Latex are strong sensistizers under the Federal hazardous Substances Act.

Sincerely,

Anna Salanti

asalanti@worldnet.att.net

Latex

34

Stevenson, Todd A.

From: Barbara Truitt [trukaras@execpc.com]
Sent: Monday, May 22, 2000 8 59 PM
To: cpsc-os@cpsc.gov
Subject: Petition HP 00-2, Petition on Natural Rubber Latex

It has been almost 9 years since my diagnosis with latex allergy. I still have problems purchasing consumer products safely. In order to contact the manufacturer, you have to know the exact product name/number. For some items, this is relatively easy. For clothing, it is almost impossible. The current rules for clothing requires only that if a substance is more the 5% of the content that it be labeled, exclusive of trim. Natural rubber is most frequently found in trim and so is a hidden substance. I have reacted strongly to natural rubber hidden in clothes. I have learned to err on the side of safety and not buy clothes unless I can have the elastic removed and replaced with a non natural rubber material. I do this even though not all elastic contains natural rubber.

When I was trying to purchase a computer, the company was not able to tell me if the keyboard contained any natural rubber. They contacted their supplier and could not get a guarantee from their supplier. I went to a computer store and took apart a keyboard so that I could see what was used. I purchased one which used springs rather than a rubber substance of unknown and seemingly unknowable content.

There have been times when I've copied down a product number and information, contacted the company and never heard back from them.

One shoe company suggested looking at the way that their shoes were made because the same style was made in two different countries, one with natural rubber adhesive and one without natural rubber' I don't think that the shoe store would allow me to tear apart one shoe in order to see how it had been made.

I've had a customer service representative of a company suggest that I try their product and that they would refund my money if it didn't work out. I explained that I react with anaphylaxis, putting my life in danger if I were to try out a product that turned out to have natural rubber. I didn't buy that product.

It would certainly make it easier and safer to purchase consumer products if they were labeled as to natural rubber content.

I hope that this proposal is given serious consideration and

implemented.

Stevenson, Todd A.

From: Lise C. Borel DMD [ELASTIC@latex-allergy org]
Sent: Monday, May 22, 2000 5.13 PM
To: cpssc-os@cpssc.gov
Cc: Lise C Borel
Subject: Petition HP 00-2, Petition on Natural Rubber Latex.

Petition HP 00-2, Petition on Natural Rubber Latex.

Natural rubber latex is used to manufacture thousands of products used by Americans for both medical and consumer purposes. Since the late 1980's there has been a dramatic and alarming increase in the number of people adversely affected by latex allergy

Consumer issues regarding latex allergy include but are not restricted to:

- ❖ Patient rights – universal access to safe health care and public facilities
- ❖ Consumer product labeling.
- ❖ The need for consumer awareness and education
- ❖ Lack of industry standards pertaining to allergenic content of consumer products.
- ❖ Powdered latex products – aerosolization of potent allergenic latex proteins – “second-hand latex”
- ❖ Non-medical use of latex gloves including:
 1. Disposable latex (*Hevea brasiliensis* natural rubber latex) glove use by food handlers is a direct source of food adulteration caused by the migration of allergenic proteins from the glove surface to food products.
 2. Latex glove by non-medical personnel including day care workers, auto mechanics, housekeepers, beauty salon workers and in classroom settings by teachers and students

“The U.S. Food and Drug Administration, Center for Devices and Radiological Health reports that scientific and clinical data demonstrate that certain proteins found in natural rubber latex harvested from the rubber tree *Hevea brasiliensis* are allergenic and cause severe allergic reactions. In addition, cornstarch powder, used as a lubricant, is a vehicle for latex proteins, increasing exposure and the potential for severe allergic reactions, by carrying them into the environment” (September 1997 Medical Glove Powder Report)

In a 1991 Medical Alert “Allergic Reactions to Latex-Containing Medical Devices”, the FDA notified health care professionals and medical device manufacturers of increasing reports of severe allergic reactions and deaths associated with medical devices made from or containing natural rubber latex.

While thousands of products are made from natural rubber latex, in terms of frequency of use and bio-available latex allergens, latex gloves have been identified as the primary source of exposure to latex allergens in health care settings. Frequent latex glove use by consumers in non-medical settings, needlessly subjects the general public to the very same exposure risk factors as health care workers and patients in the medical setting.

Historically, medical latex gloves have been regulated as Class I medical devices and have been subject to the least regulatory control. Due to the potential of these products to cause life-threatening and fatal reactions and the increasing number of glove-related reports to the FDA MedWatch Reporting Program, including 5 deaths associated with latex gloves, the FDA is in the process of reclassifying medical gloves from Class I to Class II devices. Class II devices are

those for which general controls alone are not enough and are subject to special controls including special labeling requirements, mandatory performance standards and post market surveillance

Based on the reclassification of medical exam latex gloves to Class II devices with stricter regulatory control, consumer use of latex gloves – with no regulatory controls, should be eliminated. The safety issues are the same, the products are the same – only the user setting is different

According to the American Academy of Allergy Asthma and Immunology and the American College of Allergy Asthma and Immunology. "Allergic sensitization to constituent latex rubber proteins is linked to exposure to latex allergens in the vast majority of cases. Direct exposure to latex allergens results from either contact exposures to medical devices and latex gloves or from respiratory exposure to latex aeroallergen carried by donning glove powders.

Latex occupational asthma may result from inhalation of latex rubber proteins carried on glove powder from latex gloves. Asthma caused by occupational exposure may continue and lead to persistent impairment, and rarely, to disability."

Compared with other allergenic substances, management of latex allergy presents many challenges. Historically, the cornerstone of allergic disease management has been avoidance of the offending allergen(s). This strategy is hardly effective when applied to natural rubber latex due to the prevalence of latex and latex-containing products in today's society

The Food and Drug Administration states: Avoidance of use of natural latex products by such (latex allergic) individuals may provide insufficient protection from natural latex proteins if they are in the environment of powdered glove use. The use of powdered latex gloves and balloons in consumer settings creates a hidden environmental hazard to anyone who has developed latex allergy.

The use of powdered latex products and prevalent latex glove use in many non-medical settings including food service, hair salons, classrooms and day care, generates increased risk of exposure to latex allergens for the general public

Due to the lack of consumer product labeling, the potential for natural rubber latex exposure and subsequent reactions is a daily threat for latex allergic individuals. Consumer product labeling would enable the general public to make educated purchasing decisions

Additionally – in the event of a medical emergency, such as one that results from an exposure to latex balloons or non-medical use of latex gloves, Emergency Medical Services are often unprepared, in terms of awareness and appropriate non-latex product availability, to safely treat latex-allergic patients

"The abrupt transformation of latex into a potent antigenic protein has been a source of considerable consternation and doubt. However, the broad scope of this problem (latex allergy) is documented and beyond contradiction. In children with spina bifida or other conditions who undergo early, frequent instrumentation, latex allergy has reached epidemic levels. Studies of exposed health care workers from several different countries are remarkably consistent in finding between 8 and 17 percent who are at risk for allergic reactions. The frequency of reports of severe and anaphylactic reactions occurring during skin testing, during medical procedures and with inadvertent contact outside of the medical setting all suggest an unusual propensity of this antigen to evoke potentially catastrophic responses." (Charous BL. - Latex allergy: a new and common problem. Am Fam Physician. 1998 Jan 1; 57(1): 42.)

A review of governmental and professional organizational (Centers for Disease Control and Prevention, CDC National Institute of Occupational Safety and Health, Occupational Safety and Health Administration, American Academy of Allergy, Asthma and Immunology, and the American College of Allergy, Asthma and Immunology) latex allergy risk reduction, management and prevention strategy recommendations include:

- The curtailment of significant exposure to latex rubber proteins.
- Production and proper use of appropriate non-latex alternative products.
- Latex gloves should be used only as mandated by accepted Universal Precautions standards. The routine use of non-latex gloves by food handlers, housekeeping, transport and medical personnel in low risk situations (e.g. food

- handling, bed transport, routine physical examination, consumer use)
- If latex gloves are selected, only low-allergen, powder-free latex gloves should be purchased and used
 - Labeling of all latex products.
 - Education and increased awareness of the public and healthcare field regarding symptoms, risk factors, emergency management, risk reduction and prevention strategies.
 - Research in all areas of latex allergy including pathophysiology, causative factors, diagnostics, immunotherapy, treatment standards and prevention strategies as well as natural rubber latex product standards resulting in products with virtually undetectable levels of allergenic proteins, alternative barrier materials, educational and awareness programs and campaigns to and provide a forum for presentation of that research.
 - Availability and awareness of reliable diagnostic tests.

The CPSC should act to reduce the risk of injuries and deaths associated with natural rubber latex-containing consumer products:

- Mandate content and warning statements on consumer products that contain or have packaging that contains natural rubber latex
- Increase national awareness of latex allergy as public health issue by informing and educating consumers through the media, state and local governments, private organizations, and by responding to consumer inquiries
- Phase-out non-medical use of natural rubber latex gloves.
- Phase-out all powdered natural rubber latex consumer products
- Developing product standards with industry to manufacture products with virtually undetectable levels of allergenic proteins.
- Issuing and enforcing mandatory product standards, banning natural rubber latex consumer products if no feasible standard is acceptable
- Conduct research on potential product hazards associated with natural rubber latex consumer products

Thank you for the opportunity to comment on this serious public health issue.

Lise C. Borel DMD / ELASTIC Inc.
P.O. Box 2228
West Chester, PA 19380
610-436-4801 / 610-436-1198 Fax
ELASTIC@latex-allergy.org
www.latex-allergy.org
<http://latexallergylinks.tripod.com>

Stevenson, Todd A.

From: Tim Mulvihill [t.mulvihill@worldnet.att.net]
Sent: Monday, May 22, 2000 9:07 PM
To: cpsc-os@cpsc.gov
Subject: Latex Labeling

To Whom It May Concern,

I believe government warnings on all latex products is a very good idea. Latex can truly be a hazardous material. My mother has had serious problems in the past with latex. After working in a hospital for 20 years, using latex daily she developed an allergy to it. In recent years she has had numerous instances where she had an allergic reaction which among other things included severely unpaired breathing. One instance occurred after eating in a restaurant where the food was prepared by someone wearing latex gloves. Since my mother has developed the allergy I have heard of many other individuals with similar problems who have had experiences similar to the restaurant one, some have even scarier stories to tell. I am completely convinced that the latex allergy issue is no joke and should be of serious concern labeling products that contain latex or come into contact with latex is an excellent idea. Also since there is a possible link to long term use of the product and the allergy, people who use the product often should be made aware of possible long term effects. Thank you for your time.

Sincerely,

Tim Mulvihill



May 22, 2000

Via Facsimile (301) 504-0800

Office of the Secretary
Consumer Product Safety Commission
4330 East-West Highway
Room 502
Bethesda, MD 20814

Reference: Petition HP 00-2 Petition on Natural Rubber Latex

Dear Gentlemen

These comments are written in response to the above referenced petition. In the medical literature, of the general population only 1% of the consumers are potentially allergic to natural rubber latex ("NRL").¹ The American College of Allergy and Asthma has projected that as many as 18 million Americans could be affected.² Even assuming this is a worse case, this is less than 7% of the U.S. population, a large percentage of which are health care workers

There is no dispute that in the course of their employment, as a part of "Universal Precautions" or OSHA "Bloodborne Pathogens" regulations health care workers have been significantly exposed to NRL. As a result of this exposure, many have developed sensitivities to NRL. It is not, however, necessary to label NRL as a "strong sensitizer" as requested by the above referenced petition. Instead, responsible use and monitoring would be appropriate for health care workers, and since latex avoidance is the method used to control an existing allergy, labeling already required by the FDA on medical devices would be appropriate for inclusion on consumer labels. Most manufacturers (this company being one) have already taken the responsibility to inform its consumers that there is a potential for developing an allergy to NRL and if symptoms result, the use of the product should be discontinued.

¹ Nightingale, S L., et al., "New regulations to improve the quality of medical gloves" JAMA 1991; 265:1229

² "Health Policy Issues" AORN Journal 1997 Jul, 66(1)

Under the law referenced by the petition, most of the uses for NRL are in fact regulated by the FDA either as a food contact surface (e.g. gloves, utensils, packaging used in food service and baby nipples), or as a medical device (all medical uses). These applications would be exempt by law. This does leave many applications for NRL in consumer products which may not be labeled.

Under the basis argued by the petitioner, it is asserted that NRL is a "toxic substance" NRL would not be subject as a toxic substance as it is defined in FHSA since it has been recognized as safe by the FDA for ingestion (See 21 CFR 177) and also accepted as safe for contact with food stuffs (See 21 CFR 177.2600) The determination of "toxic as defined in FHSA is determined by the FDA as the methods of determining toxicity fall within the ambit of FDA regulatory power. FDA has rule making in progress concerning this, and it would be premature to preempt this process.

NRL further does not meet the definition of the term "hazardous substance" as that is defined by FHSA. The first requirement is that the substance be "toxic" (15 USC 1261 (f)(1)(a)(i)). NRL does not meet that definition as it has been recognized as a GRAS substance by the FDA. The second requirement is that the substance be "corrosive" (15 USC 1261 (f)(1)(a)(ii)) NRL does not meet this definition because by definition it is not corrosive and is suitable for human contact. The third requirement is that the substance be an "irritant". (15 USC 1261 (f)(1)(a)(iii)) NRL is not an irritant, instead it is a potential allergen in populations which are susceptible and overexposed. The largest risk factor for an allergy to NRL is heredity and this cannot be controlled. For those who receive skin irritation, there are other materials which can be chosen which provide similar protection. This irritation is often masked by users who prefer NRL with lotions which may amplify conditions. This is not the result of NRL, but the over use of NRL as gloves. The fourth requirement is that it is "flammable" or "combustible". NRL does not meet this definition. The final requirement is that it decomposes or is dangerous if ingested by children. As NRL has been recognized as generally safe for ingestion by the FDA, it does not meet this definition.

The appropriate response to this petition referenced above is a requirement that consumer products be labeled for content, so that those with NRL have a choice to avoid contact. All medical devices currently bear a label clause that states: "Warning: This product contains natural rubber latex which may cause allergies." That will provide the necessary protection that this petition seeks. Further regulatory requirements are unwarranted. NRL should not be labeled as a "strong sensitizer" as requested by the petition as it does not rise to the level contemplated by the referenced law and is generally safe for consumers. NRL has been in use for over 100 years with minimal effects and should continue to be a choice as currently labeled (with the proposed addition consistent with the FDA requirement)

Sincerely,
CUSTOM SERVICES INTERNATIONAL INC.



Lillie C. Thomas, M.S.
Vice President of Quality Assurance

[Federal Register: March 21, 2000 (Volume 65, Number 55)]
[Notices]
[Page 15133]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr21mr00-29]

CONSUMER PRODUCT SAFETY COMMISSION

Petition Requesting Rule Declaring Natural Rubber Latex a Strong Sensitizer

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: The Commission has received a petition from Debi Adkins, editor of Latex Allergy News, requesting that the Commission issue a rule declaring that natural rubber latex (''NRL'') and products containing NRL are strong sensitizers under the Federal Hazardous Substances Act (''FHSA''). The Commission solicits written comments concerning the petition.

DATES: The Office of the Secretary should receive comments on the petition by May 22, 2000.

ADDRESSES: Comments, preferably in five copies, on the petition should be mailed to the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207, telephone (301) 504-0800, or delivered to the Office of the Secretary, Room 502, 4330 East-West Highway, Bethesda, Maryland 20814. Comments may also be filed by telefacsimile to (301) 504-0127 or by email to cpsc-os@cpsc.gov. Comments should be captioned ''Petition HP 00-2, Petition on Natural Rubber Latex.'' A copy of the petition is available for inspection at the Commission's Public Reading Room, Room 419, 4330 East-West Highway, Bethesda, Maryland.

FOR FURTHER INFORMATION CONTACT: Rockelle Hammond, Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504-0800, ext. 1232.

SUPPLEMENTARY INFORMATION: The Commission has received correspondence from Debi Adkins, editor of Latex Allergy News, that requests the Commission to declare that natural rubber latex (''NRL'') and products containing NRL are strong sensitizers under the Federal Hazardous Substances Act (''FHSA''). The petitioner asserts that a portion of the population has developed an allergy to NRL that can cause serious allergic reactions, even death. NRL may be in such consumer products as gloves, adhesives, shoes, balloons, pacifiers, and carpet backing, as well as many medical products. Ms. Adkins asks the Commission to add NRL and products containing NRL to its list of strong sensitizers so that these products would require labeling. The Commission is docketing the correspondence as a petition under provisions of the FHSA, 15 U.S.C. 1261-1277.

Interested parties may obtain a copy of the petition by writing or calling the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504-0800. A copy of the petition is also available for inspection from 8:30 a.m. to 5 p.m., Monday through Friday, in the Commission's Public Reading Room, Room 419, 4330 East-West Highway, Bethesda, Maryland.

Dated: March 15, 2000.

Sadye E. Dunn,
Secretary, Consumer Product Safety Commission.
(FR Doc. 00-6874 Filed 3-20-00; 8:45 am)
BILLING CODE 6355-01-P

Comments to: The Consumer Product Safety Commission on "Petition
HP 00-2, Petition on Natural Rubber Latex

Dear Commission Members,

I'm writing to you on behalf of my thirteen year old daughter and myself. We have both been diagnosed with an allergy to Hevea natural rubber latex (HNRL). We have had reactions that involve both hives and life threatening asthma. In the past four years since our diagnosis we have had many difficulties with consumer products containing HNRL. Both of us have searched for undergarments which don't contain HNRL, with little success. Unfortunately, we both have suffered allergic reactions to bras, underpants and socks which consisted of a hive reaction which continued for weeks. This has happened more than one time to both of us. Recently I invested \$45 in a "Speedo" swimsuit which listed it's "Lycra" content but no other elastomer. I washed the suit and then wore it for two days at which time I broke out in hives around the arms. My daughter has had hive reactions to the swim aid called "noodles" which resulted in inch size hives on her legs. . In my daughter's school environment we have had to find HNRL free pencil erasers, paints, glues, gym balls and rubber band replacements, to list a few. I have spent large amounts of time calling companies to see if their products contain HNRL. This is the only way in which we can protect ourselves from potentially life threatening allergic reactions to HNRL.

This may seem like just a nuisance to you but to us it is a matter of life or death. We need consumer products labeled with their NRL content in order to live a safe and healthy life.

Sincerely,

Susan Lesica
337 East Capitol Drive
Hartland, WI 53029
(262)367-8912

Latex

Stevenson, Todd A.

From: Ursula Gregg [nolatex@earthlink net]
Sent: Monday, May 22, 2000 4.00 AM
To: cpssc-os@cpssc.gov
Subject: Petition HP-002

> [Original Message]
> From: Murray S. Cohn <mcohn@cpssc.gov>
> To: <nolatex@earthlink.net>
> Date: 05/22/2000 5:23:34 AM
> Subject: Re: Failed mail: unknown user

> pls send this to cpssc-os@cpssc.gov
> - postmaster at cpssc.gov

> -----
> > The requested destination was:
> > cpssc.os@cpssc.gov

> > The text of the message follows:

> > Subject: Petition HP-002
> > Date: Sun, 21 May 2000 21:35.17 -0700
> > From "Ursula Gregg" <nolatex@earthlink.net>
> > To: cpssc.os@cpssc.gov

> > RE: Requesting Rule Declaring Natural Rubber Latex Strong Sensitizer

> > In September 1998 I was diagnosed with Type1 Latex Allergy. After only 7

> > years of nursing I had to give up my career. Life has become very
> > complicated since acquiring this allergy. I constantly react in shoe
> > stores, the "fumes" from the natural rubber cause symptoms such as
> > nausea,

> > dizziness, coughing attack with shortness of breath. I now have to
> > order my

> > shoes through catalogs and have to make sure they do not contain any
> > natural rubber. Some companies are "costumer" oriented and will go
> > through

> > the trouble of finding out if their products contain natural rubber,
> > others

> > are not.

> > I recently had to leave during a family dinner at a restaurant due
> > to
> > latex

> > balloons. When I entered the restaurant with my family there were no
> > balloons present but a birthday party brought them in and they were
> > seated

> > below us. I did not know they were present when I started feeling
> > sick

> > because our view was blocked. My symptoms included, red face,
coughing
> > attack, shortness of breath, rapid heart beat and dizziness.
> >
> > I also react in carpet stores and order any rugs, mats I need from
catalogs
> > or stores that are willing to deliver. After carefully searching for
a
new
> > living room rug (replaced wall to wall carpet with hard wood
floor)and
> > being reassured by the store employee that the backing was NOT
natural
> > rubber latex I ordered the rug. After I received the rug I removed
the
> > wrapping and I immediately had a reaction, nausea, dizziness,
coughing,
> > shortness of breath. The employee was mistaken and the backing was
made
of
> > natural rubber latex. The employee stated he had "asked around" and
was
> > told by others that the backing was not natural rubber latex. He
even
said,
> > "too bad they don't write it on the label"
> >
> > There are many other consumer products that I've reacted to which
could've
> > been avoided, would I have known they contain natural rubber latex.
> >
> > Thank you for considering this Request.
> >
> > Sincerely,
> >
> > Ursula L Gregg
> > PMB # 117
> > 303 91st Ave NE, G701
> > Everett WA 98205-1541
> >
> > phone: (425) 335-4898
> > fax: (425) 397-9186
> >
> > e-mail: nolatex@earthlink.net
>

--- Ursula Gregg
--- nolatex@earthlink.net
--- EarthLink: It's your Internet.

PETITION HP 00-2

PETITION ON NATURAL RUBBER LATEX

Tom Harrington. 2850 W. Bath Rd. Akron, Ohio 44333

Monday, May 15, 2000

40

Latex allergies have become a significant problem to the health care industry over the last ten years. One problem is that people can become sensitized to natural rubber latex (NRL) and the other is a small number of people have developed a severe allergy to NRL.

In regards to the problem of sensitization, the health care and latex industry along with the FDA have done much to begin the reduction of latex sensitization in the health care industry. More needs to be done to eliminate the problem, but I don't believe the answer is to list NRL as a strong sensitizer.

It is my goal to give the Consumer Product Safety Council insight into the latex allergy problem and to show why I believe the solution is being pursued scientifically and is nearly in our grasp

Thirteen years ago I began my career in NRL. I saw that NRL was used in a variety of markets due to its' unique combination of properties. One very important property was its compatibility with human skin and tissue I learned how to formulate from recipes that had been proven successful in industry decades before I mixed up my first batch I began to formulate nrl batches new and old I served the glove, condom, dental, and medical tube markets all without incidence of latex allergies Then suddenly in 1991-1992, fourteen deaths were linked to one specific NRL part, manufactured by one company Government and industry raced to answer the questions "why?" and "what to do?" Did medical grade NRL compounds suddenly become deadly? No Was the problem due to poorly manufactured NRL enema bags? Or was the problem specific to spina bifida patients that were in contact with NRL most of their lives? I may have answered, "yes" to those questions five years ago but not today

I believe some truths have been made clear and I wish to share them with you.

- We know the water-soluble proteins in NRL cause latex allergies and latex sensitization The combination of three criteria control the rate of sensitization.
 - 1) Protein concentration
 - 2) The amount of skin surface that is in contact with the rubber
 - 3) The duration of contact
- These proteins can be washed out of the rubber part to very low levels
- An effective test is available to measure these protein levels (LEAP assay)

It is clear to me that regulating NRL is not going to stop sensitization but rather the regulation of the amount of protein in NRL can stop the sensitization process

The FDA and industry is currently working toward the goal of minimizing allergenic proteins in latex products to a safe level in two ways:

- 1) Changing NRL gloves status from a level I medical device to a Level II. This will force all foreign and domestic gloves to meet more stringent production procedures. This will help bring down protein levels
- 2) Declaring a safe level of allergenic protein in NRL products.

There is no cure for this allergy that I am aware of. The people that have been affected have lost a great deal. But I do not believe declaring NRL a strong sensitizer benefits the majority of people Below I list my thoughts;

- NRL products help many more people than they hurt. As with penicillin many people are allergic to it, but the multitudes of benefits insure its continued use.
- I believe labeling will not help people that have developed latex allergies. The possibility the patient may not see the label always exists The patient must be educated by their doctor on which products to steer clear of as is done with bananas, kiwi or other foods.
- It has the potential to damage latex markets that have been incident free. NRL offer healthcare workers in many cases the best material for the job. Listing it as a strong sensitizer will push producers into introducing unproven materials of containing lower barrier properties.

I hope that my comments will be of help to the CPSC in deciding on the nrl petition. If you wish to contact me please do not hesitate. I can be reached at the address listed in the header.

Best Regards,

Tom Harrington
Latex Chemist

Stevenson, Todd A.

From: AnnAndy@aol.com
Sent: Monday, May 22, 2000 5:11 PM
To: cpssc-os@cpssc.gov
Subject: PETITION HP 00-2 COMMENTS



latex allergies2.doc

Please open file in excel.

111 Princeton Road
Exton, PA 19341
May 15, 2000

CPSC/OFFICE OF
THE SECRETARY

2000 MAY 24 A 8:54

Office of the Secretary
Consumer Product Safety Commission
Washington DC 20207

Dear secretary of the Consumer Product Safety Commission


I am writing concerning Petition HP 00-2, Petition on Natural Rubber Latex

I am a 16-year-old trying to lead a normal life, but I have a latex allergy. Unlike the people who typically develop latex allergies, I have never worked as a food handler or in the healthcare field so I have not worn latex gloves on a daily basis, yet I have still been sensitized to natural rubber latex. The sensitivity was developed through everyday items such as latex balloons, erasers, latex gloves at the doctor's and dentist's, glue and other adhesives, new carpet and upholstery, clothing with spandex, rubber gym floors, and numerous other items that do not have an advertised latex content.

The quality of my daily life has been turned upside-down by living with the diagnosis of my allergy. There is always the fear that I will have an allergic reaction, which could encompass symptoms such as unsightly hives and red splotches, burning blood-shot eyes, dizziness, prolonged migraine headaches, and breathing difficulties. If I was able to avoid latex, I would not have to cope with this added stress. (High school is stressful enough.) Many choices in my life are limited by the presence of latex. I have to think twice before I shop or buy clothes!!!, choose classes (many classrooms have a dangerous environment due to latex), buy a car!!!, go to any kind of medical facility, make my weekend plans, and go to church. All of the places mentioned above have the potential to be latex polluted spots.

A rule under the Federal Hazardous Substances Act stating that products containing natural rubber latex are strong sensitizers would mirror my experiences. By requiring all products containing natural rubber latex to be labeled accordingly, many threats to my health and happiness could be eliminated in the future. People acquainted with me (doctors, principals, teachers, employers, shop owners, friends, friend's parents, etc.) would have the information (on the label) to know what could be really bad for my health .. or kill me. People should be assured before purchasing a product that latex is not present; this would make the world a better place for hundreds of thousands of people who are, or will be in the future, sensitive to latex.

Please accept my letter as a testimony and rule that NATURAL RUBBER LATEX IS A STRONG SENSITIZER. I hope that no other teenager will have to live in fear of a latex allergic reaction and be deprived the chance of living a stereotypical teenage life.

Respectfully,

Lisa Butler

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~~Stevenson, Todd A.~~

From: DANIEL MAHONEY [omahoney@dellnet.com]
Sent: Tuesday, May 23, 2000 11 01 PM
To: cpsc-os@cpsc.gov
Subject: Petition HP 00-2 , Petition on Natural Rubber Latex

"Petition HP 00-2, Petition on Natural Rubber Latex "

Office of the Secretary
May 22, 2000
Consumer Product Safety Commission

I am writing to you regarding an important public health issue, Natural Rubber Latex and its associated health risks. It has been well documented in the scientific literature for over a decade that repeated exposure to the proteins in Natural Rubber Latex can result in sensitization to these proteins. Once sensitized to NRL (natural rubber latex) individuals are at grave risk for increasingly severe reactions. Reactions may vary in severity from localized rash, hives, asthma, wheezing, edema, anaphylactic shock and death. To date there have been 23 deaths associated with life-threatening reactions to NRL. At present there is no known cure for Natural Rubber Latex Allergy. Current treatment includes medication to help reduce the allergic response and relieve symptomatology as well as avoidance of Natural Rubber Latex Proteins.

The advent of Universal Precautions has caused widespread and indiscriminate use of latex products, particularly latex gloves. Individuals at increased risk for developing latex allergy are healthcare workers, spinal bifida patients, individuals with history of multiple surgeries/catheterizations and other individuals that have repeated latex protein exposure via their occupation or hobbies.

Several products contain NRL proteins including: medical equipment, balloons, condoms, baby bottle nipples, pacifiers, erasers, rubberbands, Band-Aids etc., the list is endless.

The passage of this petition is imperative to protect the safety of the public and those already affected by latex allergy. It is incumbent on the CPSC to inform the American public that they are being exposed to a potentially dangerous and strong sensitizer: Natural Rubber Latex Proteins. Consumers need to be made aware that indiscriminate usage of latex products, i.e., gloves in food service, and balloon decorations may be harmful or deadly to those already affected with latex allergy.

Labeling of products containing latex proteins is as important and prudent as listing food allergen ingredients on food product labels to prevent unnecessary allergic reactions.

As a medical professional and citizen, I urge the CPSC to expedite passage of this petition to prevent morbidity and mortality related to NRL protein exposure.

Thank you for your time.

Respectfully submitted, Jean Carazza-Mahoney RN
Member of the NY State Nurses Association
Member of the American Association of Occupational Health Nurses

05/24/2000

Latex 43

A.L.E.R.T., Inc.

American Latex Allergy Association
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E-mail. alert@execpc.com

May 22, 2000

Office of the Secretary
Consumer Product Safety Commission
Washington, DC 20207

**Subject: Petition Requesting Rule Declaring Natural Rubber Latex a Strong Sensitizer
Petition Number HP 00-2, Petition on Natural Rubber Latex**

A L E R T , Inc is a not-for-profit national organization whose mission is to create awareness of latex allergy through education and to provide support to individuals who have been diagnosed with latex allergy

A.L.E.R.T , Inc supports the work the Consumer Product Safety Commission is doing to improve the safety of consumer products We believe that the evidence provided in the original petition by Debi Atkins is valid and persuasive. Based on the information provided by Ms. Atkins, a declaration by the CPSC that declares natural rubber latex as a strong sensitizer is warranted.

We ask the CPSC to consider the following comments

1. It is estimated that over 3 million people in the United States have developed an allergy to natural rubber latex.
2. The only treatment for the latex allergic individual is avoidance of products containing natural rubber latex. Latex allergic individuals can experience severe and possibly life threatening allergic reactions to consumer products that contain natural rubber latex. Labeling of natural rubber latex consumer products will assist the allergic individual with avoiding natural rubber latex.
3. A declaration of natural rubber latex as a strong sensitizer will allow the CPSC to create uniform labeling. At the present time some manufacturers of consumer products have labeled their products in a variety of ways to indicate whether the product does or does not contain natural rubber latex. These inconsistencies can be misleading, confusing and potentially dangerous to the consumer.
4. Labeling of natural rubber latex consumer products will be beneficial to all consumers.

We thank the members of the CPSC for consideration of this petition and appreciate the opportunity to provide comment.

Sincerely,

Diane J. Flanagan

Diane J. Flanagan
President

*Letter
Comet
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ROBERT F WORTHEN
President

May 22, 2000

Office of the Secretary
Consumer Product Safety Commission
Washington, DC 20207

Dear Sir or Madam:

UPACO Adhesives, a division of Worthen Industries, Inc., is a manufacturer of industrial adhesives. For the past eight years, we have been working with the furniture industry to convert them from VOC and HAP solvent-based adhesives to water-based adhesives. These conversions have been in conjunction with rulings to this effect from the EPA and OSHA trying to reduce the use of these solvents.

To date, the products we have been most successful with have been based on natural latex. These products offer the performance characteristics that our customers want at a price that they can afford. Products based on synthetic latex cost three times as much and do not adequately perform a major function they need which is bonding foam to fiber.

If furniture manufacturers have to label their products with a warning that they contain natural rubber, they will quit using these water-based products and revert to solvent products. This will increase the emissions of pollutants and greenhouse gases and undermines the work of the past eight years in trying to reduce these emissions.

While we are aware that there are people who exhibit severe allergic reactions to natural latex, we are also aware that the percentage is very small. In the eight years of marketing our products and the thousands of individuals who have used them every day, we have never had a major allergic reaction. The most severe reaction we have seen is minor cases of contact dermatitis.

We strongly urge your office not to grant this petition.

Best regards,

RFW J

Stevenson, Todd A.

From: nancey agard@nysna.org
Sent: Thursday, May 25, 2000 3:47 PM
To: cpssc-os@cpssc.gov
Subject: Petition HP 00-2, Petition on Natural Rubber Latex

Sadye E. Dunn, Secretary
Consumer Product Safety Commission
Washington, DC 20207

Re: Petition HP 00-2, Petition on Natural Rubber Latex

Dear Secretary Dunn,

The New York State Nurses Association supports the petition of Debra Atkins requesting the Commission issue a rule declaring that natural rubber latex (NRL) and products containing NRL strong sensitizers under the Federal Hazardous Substances Act.

The public believes NRL and NRL products are harmless. The public, infants, children and adults, are exposed to NRL all the time. Because there is no education or public acknowledgment that NRL could be harmful to certain individuals, exposure, sensitization and allergy to NRL continues to occur each day, each hour of each day to the citizen of the United States. New York nurses and other health care providers have recognized the dangers associated with NRL and are making moves, taking action to reduce exposures to latex that occurs within organized health care.

Often times, patients enter the health care system and they are unaware of their sensitivity or allergy to NRL. Since it is practically impossible to make the health care delivery system latex free, their treatment may include exposure to varying amounts of NRL. Those patients may go on to experience life threatening health problems because we, the health care practitioners, did not know that the patient was allergic to NRL. Patients have died of anaphylactic reactions to NRL without health care practitioners knowing what they were allergic to and that their care was contributing to the allergic reaction. If people were made aware of the potential hazards associated with exposure to NRL and products containing it in everyday life, it is likely that fewer people would become sensitized or allergic to NRL. Their quality of life and ability to obtain safe health care would be greatly enhanced.

NY nurses and the NYSNA urges the Commission to issue a ruling declaring NRL and products containing it as strong sensitizers so the public can become informed as to the hazards associated with NRL and unnecessary disease and disability can be avoided.

Sincerely,

Nancey P Agard, MS, RN
Associate Director
Practice & Governmental Affairs

Latex

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~~Stevenson, Todd A.~~

From: Dorcas Stein [cdstein@barrow.com]
Sent: Saturday, May 27, 2000 6:58 PM
To: cpsc-os@cpsc.gov
Subject: Petition HP00-2 on Natural Rubber Latex

I am strongly in favor of this petition requesting that Natural Rubber Latex be declared a strong sensitizer and that any product sold to consumers require a label indicating that it contains natural rubber latex.

I was recently diagnosed with NRL allergy. One of my biggest problems right now is not knowing what products I am being exposed to contain NRL;

consequently my physical health seems to be getting worse, not better. PLEASE take this petition seriously. My type IV could possibly turn into a type I (anaphylactic) with constant exposure. I don't want that to happen.

Thank you /s/ Dorcas Itta Stein at cdstein@barrow.com

Latex

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Stevenson, Todd A.

From: jem4141 [jem4141@msn.com]
Sent: Saturday, May 27, 2000 1:30 PM
To: - cpsc-os@cpsc.gov
Subject: petition on Natural Rubber Latex

Hello I am an RN Disabled by NRLA I am one who would like to see th CPSC declare Natural Rubber Latex as a strong sensitizer You May add My name to the petition
Thank you Herbert J Hoos RN