United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE: June, 2000

TO : HS

Through: Sadye E. Dunn, Secretary, OS

FROM : Martha A. Kosh, OS

SUBJECT: Petition Requesting Rule Declaring Natural Rubber Latex a Strong Sensitizer

ATTACHED ARE COMMENTS ON THE CP 00-2

COMMENT	DATE	SIGNED BY	AFFILIATION
CP 00-2-1	3/20/00	Regina Kellner RN, BSN	402 Grand Avenue Mukwonago, WI 53149
CP 00-2-2	3/25/00	Nancy Mauser	M235mauser@aol.com
CP 00-2-3	3/27/00	K. Bernard	kbernard@earthlink.net
CP 00-2-4	3/28/00	Richard Edlick Distinguished Professor of Plastic Surgery & Professor of Biomedical Engineering	University of Virginia Health Sciences Center Box 376 Charlottesville, VA 22908
CP 00-2-5	3/30/00	Lauri J. Harris RDH	733 Yorkshire Rd. Neenah, WI 54956
CP 00-2-6	4/28/00	Robert Hamilton Associate Prof. of Medicine and Pathology, Director DACI Reference Laboratory	The Johns Hopkins University School of Medicine
CP 00-2-7	5/02/00	Barbara Leather	220 W Sylvania Ave, #24 Neptune City, NJ 07753
CP 00-2-8	5/03/00	Colleen Baker BS, RN	39 Greenridge Crescent Hamlin, NY 14464

Petition Requesting Rule Declaring Natural Rubber Latex a Strong Sensitizer

CP 00-2-9	5/03/00	Kelly Clinton Ali Clinton Majica Alba Tammy Tahara Veronica Ramirez Sandra Carr	BrsBoots@aol.com
CP 00-2-10	5/11/00	Wayne Gainey	406 Drake Drive Dothan, AL 36305
CP 00-2-11	5/15/00	Anne Clark	118 Ashland Ave. River Forest, ILL 60305
CP 00-2-12	5/18/00	Patricia Szabo MHA, PT	159 Spook Rock Rd. Montebello, NY 10801
CP 00-2-13	5/18/00	Debbie Butler	111 Princeton Road Exton, PA 19341
CP 00-2-14	5/18/00	Kathleen Caleb	Kcaleb50@aol.com
CP 00-2-15	5/18/00	Bryan Lakin Vice President	Alcan Rubber & Chemical, Incorporated 29 Broadway New York, NY 10006
CP 00-2-16	5/19/00	Sam Heyman VP & General Manager	R Tape Corporation 6 Ingersoll Road CN 2002 South Plainfield, NJ 07080
CP 00-2-17	5/19/00	Brenda Ray M.S.N.	390 South Tyndall Pkwy PMB 228 Panama City, FL 32404
CP 00-2-18	5/19/00	Daniel Flynn Chairman	The Balloon Council 5000 E 29th St, N Wichita,KS 67220
CP 00-2-19	5/19/00	Jack Trautman Ph.D	Allergen Reduction, Inc 1202 Ann Street Madison, WI 53705
CP 00-2-20	5/18/00	Gail Rechowicz	GailRech@webtv.net
CP 00-2-21	5/19/00	Tan Choon CEO	Malaysian Rubber Export Promotion Council 11th Floor, Bangunan Getah Asli 148 Jalan Ampang 50450 Kuala Lumpur Malaysia

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CP 00-2-22	5/19/00	Lisa Kamenides	kamfam@mediaone.net
CP 00-2-23	5/19/00	John Friar II Owner	North American Rubber thread Co., Inc. 106 Ferry Street P.O. Box 1709 Fall river, MA 02722
CP 00-2-24	5/19/00	Richard Oldack President	Dyna-Tech Adhesives Incorporated P.O. Box 628 Country Club Road Grafton, WVA 26354
CP 00-2-25	5/20/00	Nancy Mitchell Michael Mitchell	3 Folsom's Pond Rd Wayland, MA 01778
CP 00-2-26	5/21/00	Marianne McAndrew	405 William Salesbury Dr Downingtown, PA 19335
CP 00-2-27	5/21/00	John Lancz Linda Lancz	LindaLancz@aol.com
CP 00-2-28	5/21/00	Marisa Mitchell RN	324 Goodlette Rd S. Naples, FL 34102
CP 00-2-29	5/21/00	Diana Cutright RN	4940 Deerfield Way, #101 Naples, FL 34110
CP 00-2-30	5/22/00	Rochelle Spiker Exec. Director	Potomac latex Allergy Association P.O. Box 52 Greenbelt, MD 20768
CP 00-2-31	5/22/00	Paula Wilkins	28 Wickliffe Drive Naples, FL 34110
CP 00-2-32	5/22/00	Roslyn Hamilton President	Oregon Ecobuilding Network P.O. Box 86444 Portland, OR 97286
CP 00-2-33	5/22/00	Anna Salanti	asalanti@worldnet.att.net
CP 00-2-34	5/22/00	Barbara Truitt	trukaras@expecpc.com
CP 00-2-35	5/22/00	Lise Borel DMD/Elastic Inc	P.O. Box 2228 West Chester, PA 19380

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CP 00-2-36	5/22/00	Tim Mulvihill	t.mulvihill@worldnet.att.net
CP 00-2-37	5/22/00	Lillie Thomas Vice President Of Quality Assurance	Custom Services International, Inc. 3111 West Post Rd Las Vegas, NV 89118
CP 00-2-38	5/22/00	Susan Lesica	337 East Capitol Drive Hartland, WI 53029
CP 00-2-39	5/22/00	Ursula Gregg	PMB # 117 303 91st Ave, NE, G701 Everett, WA 98205
CP 00-2-40	5/22/00	Tom Harrington Latex Chemist	2850 W. Bath Rd. Akron, OH 44333
CP 00-2-41	5/24/00	Lisa Butler	111 Princeton Road Exton, PA 19341
CP 00-2-42	5/24/00	Jean Mahoney Daniel Mahoney	omahoney@dellnet.com
CP 00-2-43	5/23/00	Diane Flanagan President	American Latex Allergy Association P.O. Box 13930 Milwaukee, WI 53213
CP 00-2-44	5/22/00	Robert Worthen President	Worthen Industries, Inc. 3 East Spit Brook Rd. Nashua, NH 03060
CP 00-2-45	5/25/00	Nancey Agard Assoc. Director Practice and Governmental Affairs	nancey.agard@nysna.org
CP 00-2-46	5/27/00	Dorcas Stein	cdstein@barrow.com
CP 00-2-47	5/27/00	Herbert Hoos RN	jem4141@msn.com

CP00-2-1

In regards to "Petition HP 00-2, Petition on Natural Rubber Latex "
[FR Doc **00-6874 Filed 3-20-00**; 8.45 am]

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

Dear Ms Dunn·

Please protect public health by requiring labeling of all products with Natural Latex Rubber (NRL) Natural Latex Rubber is a strong sensitizer. Many citizens have developed a life-threatening response to Natural Rubber Latex through frequent invasive exposures Routes of harm may include airborne NRL particles, injected, ingested, or contact Affected individuals have great difficulty protecting themselves from unlabeled products Parents cannot protect their children, if they are not aware of potential problems Labeling is the means to provide an adequate ability to avoid the hazard.

I would be happy to supply your office with any assistance you may require I would be able to help with current research or personal experiences with Natural Rubber Latex Allergy (NRLA)

Respectfully,

Regina Kellner, RN, BSN
402 Grand Avenue
Mukwonago, WI 53149
262-363-5800

CP00-2-2

Stevenson, Todd A

From: M235mauser@aol com
Sent: Saturday, March 25, 2000 4 49 PM
To: cpsc-os@cpsc gov
Subject: Petition HP 00-2, Petition on Natural Rubber Latex

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.

To Whom It May Concern:

I support the above petition. As a person with a severe type 1 latex allergy
and occupational asthma as a result of this allergy, I find it very difficult
obtaining information about the contents of consumer items. The FDA has

required labeling of NRL containing products, and it seems prudent that consumer items should also be labeled. Currently all purchases made by my
family must be thoroughly researched first to determine whether or not they
are safe for use around me. Calling a manufacturer is the only way to safely
obtain information about the contents of consumer items. Obtaining correct
information from manufacturers is very time consuming and not always reliable. I need this information to protect myself. If products were

appropriately labeled, it would make my life much safer. It also concerns me
that currently, the general public has little or no information about items
containing natural rubber latex which can sensitize and cause natural rubber
latex allergy. Warning labels, or content labels would at least provide the
information needed for the public to make an informed choice about the items
they use personally for themselves and their families. Currently estimates
are that apx. 6% of the general population may be affected by this allergy
which can progress to life threatening reactions with continued exposure to
the proteins in NRL. I am the moderator of an online support group for
approximately 100 people with latex allergy. Labeling of consumer products
would ease the burden that all of us have in protecting ourselves and/or

family members from a life threatening reaction.

Thank you for your consideration of this issue.

Nancy Mauser

Steve Gen Bd A. CP00-2-3

From: K. Bernard [kbernard@earthlink.net]
Sent: Monday, March 27, 2000 1.44 AM
To: cpsc-os@cpsc.gov
Subject: Petition HP 00-2, Petition on Natural Rubber Latex

To whom this may concern,

I am an ex- healthcare worker afflicted with latex allergy type I and IV. I fully support the labeling of all devices and products that contain NRL. How can you follow a physicians orders of strict avoidance of NRL, and not know if you are even being exposed by a product or food that has been prepared with latex gloves. Because my life could be in danger if I am exposed to NRL, and don't get immediate medical treatment, this information is detrimental to me. Thank you for your time.

Sincerely,

K.Bernard

CP00-2-4 Lgkd 04/3/00

UNIVERSITY OF VIRGINIA
HEALTH SCIENCES CENTER

DEPARTMENT OF PLASTIC SURGERY

March 28, 2000

Ms. Sadye E. Dunn, Secretary
Consumer Products Safety Commission
4330 East West Highway, Suite 502
Bethesda, MD 20814

Dear Ms. Dunn:

I strongly support the petition requesting that the Commission declare products containing natural rubber latex to be a strong sensitizer to human beings. In addition the cornstarch coating many natural rubber latex products is a vector for the sensitization. The cornstarch should be banned from use with latex glove products. I have enclosed with this letter a copy of my book Medicine's Deadly Dust that provides support for this recommendation, a report from public citizens to the Food and Drug Administration that recommends banning cornstarch on latex examination and surgical gloves, and a copy of a recent article "A Global Inventory of Hospitals Using Powder-Free Gloves: A Search for Principled Medical Leadership". If I can provide any further information, please do not hesitate to contact me.

Sincerely,

Richard F. Edlich

Distinguished Professor of Plastic Surgery
and Professor of Biomedical Engineering
(804)924-2085

Public Citizen

Jan. 7, 1998

POWDERED LATEX GLOVES POSE SERIOUS RISK TO PATIENTS AND HEALTH WORKERS

CALL FOR BAN ON DANGEROUS SURGICAL AND EXAMINATION GLOVES MANUFACTURED WITH CORNSTARCH POWDER COATING

Millions of patients and tens of thousands of health workers throughout the country are at serious risk from latex gloves powdered with cornstarch, said Public Citizen's Health Research Group in a petition to the Food and Drug Administration (FDA) today to ban such gloves.

The group, joined by co-petitioner Timothy Sullivan, MD, an allergist/immunologist from Emory University School of Medicine and an expert on latex allergy, called for an immediate ban by FDA on the use of cornstarch powder on latex surgical and examination gloves because of the serious dangers these gloves have caused medical personnel and patients. Cornstarch can inflame wounds and promote infection, and cornstarch-induced adhesions can produce intestinal obstruction, pelvic pain and infertility in patients operated on by medical personnel wearing cornstarch-powdered surgical gloves, said the group.

One of the most widespread dangers occurs because cornstarch also acts as a carrier for latex protein /allergens--these allergens becoming combined with the cornstarch during the manufacturing process. Well-documented and frequently reported adverse reactions to latex include rhinitis, asthma, and life-threatening anaphylactic shock, often caused by breathing in the cornstarch powder in the air. Many health care workers have experienced such serious reactions to latex they have been forced to give up work.

"These powdered latex gloves are a serious, unnecessary menace in hospitals and other health care facilities all over the country," said Dr. Sidney Wolfe MD, Director of Public Citizen's Health Research Group. "Safer alternatives such as powder-free gloves are easily and currently available, but too many hospitals are willing to cut corners and risk the health of their patients and employees. As of last year, 26% of surgical gloves used in the United States were powder-free proving that this safer alternative is quite feasible."

Labels warning that powdered gloves should be washed--to remove cornstarch-- before use are routinely ignored by the vast majority of health workers. A 1992 study found that only 17 % of surgeons washed their gloves after donning. Most emergency physicians use gloves lubricated with cornstarch during their wound closure techniques.

Several major hospitals have already switched to powder-free gloves, including Harvard's Brigham and Women's Hospital in Boston and Miami's Jackson Memorial Hospital. At the Brigham and Women's, one of the leading hospitals in the United States, as many as 12 to 14 operating room hospital workers a day were unable to work or had to be reassigned to desk jobs because of their allergic reactions. Jackson Memorial began experiencing problems with latex allergies in 1994 and, by May 1995, 95 employees had been treated for problems related to the gloves.

Between August 1996 and August 1997 alone the FDA received over 300 reports of allergic or anaphylactic reactions associated with latex gloves (it is estimated that at most one out of ten adverse reactions which actually occur are reported to the FDA so the number during that last year is likely in the thousands or more), and a 1997 study showed that up to 21% of hospital nursing staff were sensitized to latex.

Apart from the human cost, sticking with powdered latex gloves can be expensive for hospitals, says Public Citizen. Latex allergies tend to strike health care professionals with the most experience, leading to costly absences and compensatory claims. At Jackson Memorial Hospital, two workers compensation settlements exceeded $100,000 each, and the ongoing expense in one case has already cost over $370,000.

"These powdered gloves are expensive for hospitals, dangerous for their patients and a serious occupational hazard for their employees. The FDA should act immediately to prevent further damage to the public's health," said Dr. Wolfe. "The current FDA regulation, which went into effect on September 30, 1997, requires labels on all medical devices containing natural latex warning that the product contains latex 'Which may cause allergic reaction'. Whereas this is an admission of the problem, it is grossly inadequate compared with the additional action of banning powdered latex gloves which we are requesting today. If the FDA is to perform as a public health agency it must more definitively protect the millions of patients and tens of thousands of workers already allergic to latex. Unless definitive action is taken, not only will those people already allergic to latex continue to suffer serious, often life-threatening reactions, but the number of affected people will continue to rapidly increase as more and more exposure to airborne, latex-laden glove powder occurs."

You can view the petition, without attachments, on the Health Research Group site.

Complete copies of the petition to the FDA are available by calling 588-1000.

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HRG Publication 1432

Public Citizen

If you wish to support this petition, please write to FDA Deputy Commissioner Michael Friedman at the address below to urge a ban on powdered latex gloves. Send a copy to Dr. Sidney Wolfe, Public Citizen Health Research Group, 1600 20th St. NW, Washington, DC, 20009

Please note that the appendices referred to in this petition are not available online. If you would like to receive copies of the appendices, please call 202 588-1000

January 7, 1998

Michael Friedman, M.D.
Lead Deputy Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Petition to Ban Cornstarch Powder on Latex Gloves

Dear Dr. Friedman:

Public Citizen's Health Research Group and its Director, Sidney M. Wolfe, MD and Staff Researcher, Christine Dehlendorf, and Timothy Sullivan, MD, Professor of Medicine at Emory University School of Medicine and Head of the Subsection of Allergy and Immunology at the Emory Clinic hereby petition the Food and Administration (FDA) to immediately ban the use of cornstarch powder in the manufacture of latex surgical and examination gloves because of the serious and widespread dangers these gloves cause to medical personnel and to patients. An acceptable substitute, non-powdered gloves, is available and has already been implemented in many places. FDA's legal mandate to require such a ban is found in section 516 of the Food Drug and Cosmetic Act, 21USC 360(f). The continued use of powdered latex gloves is unacceptably harmful and the FDA must act to ban such dangerous products.

Introduction: Hospitals Which have Stopped Using Powdered Gloves

According to industry sales data, 26% of the U.S. surgical glove market is currently comprised of the sales of powder-free latex gloves.[1] Following are three examples of hospitals which switched from cornstarch powdered gloves to powder-free gloves.

In 1993, Brigham and Women's Hospital, a Harvard teaching hospital in Boston, experienced a mysterious epidemic among operating room personnel, in which 12 to 14 employees a day were unable to complete their typical duties due to allergic reactions. An internal investigation, followed by the hiring of an environmental consultant, identified the source of the epidemic to exposure to latex --

especially to aerosolized glove powder, which bound the latex proteins (Appendix A). Following this experience, the hospital became powder-free. In other words, they no longer used powdered latex surgical gloves.

In December of 1995, Jackson Memorial Hospital in Miami also chose to convert to low allergen, powder-free gloves, "after an epidemic of latex allergy, glove dermatitis and occupational asthma" (Appendix B). The number of complaints of reactions to latex plummeted after the switch was made.

Following the lead of these hospitals, Methodist Hospital in Indianapolis eliminated all powdered gloves from their facility in late 1995 and early 1996 after having more than 80 employees be identified as allergic to latex. As a result of the switch none of the allergic employees needed to leave their jobs (Appendix C).

The experiences of these hospitals are part of a rapidly growing recognition of problems with cornstarch powdered gloves. In addition to the link with latex allergies noted above, evidence also indicates that cornstarch causes surgical complications. In order to protect patients and health care workers from the risks of exposure to cornstarch, the FDA must follow the example of these hospitals by taking immediate action to ban its use as a lubricant for surgical and examination gloves.

In delineating the basis for urging the FDA to immediately implement this ban, this petition, following a brief discussion of the history of powdered gloves, details the serious medical problems associated with the use of cornstarch powder on surgical and examination gloves and addresses perceived barriers to the implementation of the proposed ban. This petition builds on Dr. Richard Edlich's (distinguished Professor of Plastic Surgery and Biomedical Engineering, University of Virginia School of Medicine) previous contacts with the FDA requesting a ban on cornstarch. On December 7 and 14th, 1995, Dr. Edlich sent letters to the FDA requesting a ban on cornstarch (Appendix D & E), and included in his letter scientific studies indicating that cornstarch-powdered gloves caused toxic reactions to tissues. Six months later, on June 3, 1996, Carol J. Shirk, Consumer Safety Officer of the FDA, responded to his letter, and informed Dr. Edlich that the FDA was extensively investigating his request and that he would be advised of the outcome of the review once a policy was determined regarding cornstarch powdered gloves (Appendix F). On July 15, 1997, he was informed by the FDA that they had made no final decision regarding this issue. We are therefore demanding that the FDA immediately take action to address this widespread public health problem. The FDA regulation, which went into effect September 30, 1997, requiring latex-containing medical devices such as gloves to contain a warning that the product contains latex "which may cause an allergic reaction" is appropriate for those products for which there is no safer substitute. But for powdered latex gloves, anything short of a ban--such as merely this label--is a dangerous insult to the millions of patients and tens of thousands of health care workers whose lives and health are jeopardized by the continued use in health care settings of these powdered gloves.

History of Medical Gloves

When surgical gloves were introduced at the turn of the century, they were sterilized by boiling and could only be donned by pulling the rubber gloves over wet hands. Because the wet hands of the surgical staff became macerated under the occlusive cover of the rubber glove, predisposing to severe dermatitis, surgeons searched for a dry lubricant that would facilitate donning and prevent the gloves from sticking together during the pressurized steam sterilization process (autoclaving). An early lubricant, a powder made of Lycopodium spores (club moss) was identified as causing foreign body

responses, including adhesions and granulomas. [2] Talcum powder (hydrous magnesium silicate), a non-absorbable lubricant, was also implicated in the production of granuloma in tissues and adhesion formation in the peritoneal cavity.[3,4] In the study in 1947,[4] Lee and Lehman, in addition to verifying the increasing evidence that talcum powder was a dangerous disease-promoting factor in human surgery, identified what appeared to be an acceptable alternative to talc -- cornstarch powder. They found that cornstarch powder was completely absorbed from the peritoneum (abdominal cavity) without any demonstrated inflammation and it produced no adhesions whatsoever. Because it was a cornstarch powder, it was taken up by the peritoneum and metabolized like any ingested starch.

By 1952 a sample survey indicated that cornstarch had replaced talc in 60% to 90% of hospitals in the U.S.,[5] and currently is found as the lubricant on most surgical and examination gloves used by health care workers. However, experimental and clinical studies in the last 50 years have continually documented dangerous side effects of this absorbable lubricant. There has also been increasing evidence of a link between cornstarch and latex allergies. Likely in response to concerns about adverse effects caused by cornstarch, in 1971 the FDA required that manufacturers place warning labels on the glove packages which stated that glove users should remove cornstarch from the glove surfaces by wiping the gloves with a wet sponge, towel, or by using another effective method.[6] In addition, realizing these serious dangers to the patients and health professionals, numerous manufacturers have developed powder-free surgical gloves, removing a barrier to the elimination of cornstarch powdered gloves. However, despite this recognition of the dangers of cornstarch and the existing technological advances in glove manufacturing, most hospitals continue to use powdered gloves.

Cornstarch-Induced Foreign Body Disease From Gloves

Most surgeons have an unfounded confidence in cornstarch and mistakenly believe that it is safe. Scientific experimental and clinical studies have confirmed that cornstarch promotes disease by two different mechanisms. First, it acts as a foreign body when deposited in the wound that elicits an exaggerated inflammatory response and interferes with the host's defenses against infection. When cornstarch contaminates soft tissues, it promotes the development of wound infection. The presence of small amounts of cornstarch promotes wound induration, bacterial growth, and wound infection.[7,8] When cornstarch gains access to the peritoneal cavity, it can cause granuloma formation, adhesion formation and peritonitis.[9,10,11,12] The development of cornstarch induced adhesions can produce intestinal obstruction, infertility, and pelvic pain. Other documented adverse reactions to cornstarch include endophthalmalitis,[13] post-thoracotomy syndrome,[14] meningismus after craniotomy,[15] retroperitoneal fibrosis,[16] and synovial inflammation.[17]

It is important to recognize that simply warning health care workers to wash the cornstarch off gloves prior to use does not prevent the adverse effects discussed above. Jagelman and Ellis[18] reported that washing with water reduced the number of starch granules, but left significant cornstarch on the glove that appeared to aggregate as clumps. They postulated that the development of clumps of cornstarch would promote a delay in absorption and an enhancement of the foreign-body reaction. In 1980, Tolbert and Brown[19] provided further evidence that glove washing with a saline solution left a portion of the cornstarch on the glove surface.

The most effective method of washing the cornstarch from the gloves involves a one minute cleansing with 10 mL of povidone-iodine followed by a 30 second rinse under sterile water.[20] This technique reduced the median number of starch granules per mm^2 of glove, as seen on microscopic examination,

from 2,720 (when no attempt to remove the powder was made) to 0 (when the povidone-iodine method was performed). However, this technique is time-consuming, costly, and burdensome to the clinical staff and can not ensure that all powder particles have been eliminated.

Even if these procedures were completely effective, it would still be necessary to ensure that health care workers adhere to the washing guidelines if the cornstarch powder is to be removed. In a study conducted by Fay and Dooher,[21] the surgical staff's compliance with glove washing to remove cornstarch lubricants was examined. Only 17% of the surgeons and 21% of the surgical nursing staff washed their gloves after donning. These investigators attributed the slightly higher levels of compliance among nurses to practices taught in nursing school and/or to references to the need for glove washing in nursing journals and textbooks. Information about glove washing might not be included in medical education.

It is also important to realize that some departments in the hospital use powdered surgical gloves in an environment in which they do not have easy access to sterile wash basins. For example, emergency physicians in Emergency Departments treat more than 10 million patients annually using sterile surgical gloves. During wound treatment, they usually do not have the benefit of a nursing assistant who prepares a sterile wash basin filled with sterile saline in which they can attempt to remove cornstarch from their gloves. Consequently, most emergency physicians use gloves lubricated with cornstarch during their wound closure techniques.

Cornstarch: Facilitator of Serious, Life-threatening Allergic Reactions to Latex

The second mechanism by which cornstarch on gloves causes disease is based on its role as a carrier for latex allergens. Reported reactions to latex include contact urticaria, rhinitis, asthma, and anaphylactic shock,[22,23,24,25,26,27,28,29,30,31] and the development of reactions to latex exposure has been linked to people's production of IgE antibodies to natural latex when exposed to the substance.[22-29] In 1992 the FDA identified more than 1,000 combined Medical Device Reporting Program and Product Problem Reporting Program reports of allergic or anaphlyactic reactions in conjunction with the use of plant-derived rubber or latex containing medical products.[32] (Note that there is some overlap between these two reporting programs). More recently, according to an official at the FDA (SF Dillard, Center for Devices and Radiological Health), **in the last year alone for which data are available (August 15, 1996-August 15, 1997), there were 305 reports to the FDA of allergic or anaphylactic reactions associated with the use of latex gloves.**

Health care workers are especially at risk for this allergy due to occupational exposure to latex. A 1992 study found that 8.8% of dentists in the U.S. Army Dental Corps self-reported histories consistent with latex allergy.[33] More recently, a 1996 study found that 5.5% of hospital personnel were positive for latex specific IgE antibody using a radioallergosorbent test.[34] Two other studies, published in 1997, reported that 12.1% of health care workers and 21% of hospital nursing staff were sensitized to latex, as determined by skin prick tests.[35,36]

This high prevalence of latex sensitization has staggering human costs, as trained health care workers who experience symptoms may require reassignment, or potentially can even need to discontinue their career in health care. Not only is this devastating to the individual, but society also loses the benefit of the training of these professionals.

A role of cornstarch in the development of latex allergy by health care workers was suggested by

Beezhold and Beck,[37] who identified a significant interaction between latex proteins and cornstarch powders. Further, Tomazic et al. showed that cornstarch binds latex proteins.[38] This interaction between cornstarch and latex has been implicated as the major cause of airborne latex, as evidenced by the fact that work areas which use only powder-free gloves have been shown to have low or undetectable amounts of latex aeroallergens.[39] These airborne cornstarch/latex particles have been shown to serve as an agent for exposure and sensitization of heath care workers to latex protein through the release of latex/cornstarch particles into the air.

First, Tomazic et al. demonstrated through competitive inhibition and direct binding immunoassays that the latex-protein/starch particles are allergenic proteins.[38] In addition, one study has demonstrated that sensitized people exhibit allergic symptoms such as rhinitis, cough, conjunctivitis or breathing problems when exposed only to airborne latex through the handling of cornstarch powdered latex gloves. Of 11 sensitized people, four developed shortness of breath, wheezing and had documented evidence of increased airway resistance.[40] Another study showed that four sensitized female nurses experienced immediate bronchoconstriction (increased airway resistance) when handling powdered latex surgical gloves and that bronchial challenges with powdered latex surgical glove extracts resulted in more severe reactions than challenges with non-powdered latex surgical glove extracts.[41] Therefore, the interaction between cornstarch and latex provides a route of exposure to the latex proteins which the absence of cornstarch would minimize.

Case reports in the literature support the role of cornstarch in latex allergy of health care workers. One hematology laboratory technician, who had experienced contact dermatitis, contact urticaria and anaphylaxis following contact with latex, continued to experience symptoms such as facial urticaria and rhinitis after she switched to vinyl gloves, and eventually stayed off work. She was able to return to work after her laboratory changed to powder-free gloves.[39] Another report involved an intensive care nurse who immediately had asthmatic symptoms when powdered latex gloves were manipulated in front of her, but had no reaction to vinyl gloves.[42]

The experiences of Jackson Memorial Hospital in Miami and Methodist Hospital in Indianapolis as well as the aforementioned situation at the Brigham and Women's Hospital in Boston also indicate the role of powdered gloves in the development of latex allergy, and the effectiveness of a switch to powder-free gloves for the protection of workers. All three hospitals made the switch to powder-free gloves after discovering that latex allergies were a substantial problem among their staff, and were able to adequately address the problem by implementing the ban.

For example, Methodist reported more than 80 employees diagnosed as latex allergic, with "most of these employees [having] 10-20+ years of service with Methodist Hospital ...[some] employees had such severe respiratory symptoms that they had to be removed from their current working environments until changes could be implemented." Having identified the primary source of exposure as powdered latex gloves, the hospital eliminated the "latex laden powder." As a result, none of the employees originally diagnosed as allergic was terminated. (Appendix C)

In 1994, Jackson Memorial also began having latex allergy problems, including "a clerk who was transferred from the gift shop to a lab clerk position, suffered anaphylactic shock and a full respiratory arrest after donning latex gloves...and was never able to work again" and "an OR tech who....began to have asthma attacks and hives every time she entered the operating room...She became so allergic she had reactions when she touched the phone, her underwear, the car steering wheel and even her child's school paper when she had used an eraser...She could not work at all for over a year and almost lost

her home." In the first five months of 1995, the hospital was receiving five new complaints a week of glove dermatitis or other symptoms, and. "by May, 1995, 95 employees had been treated for problems related to gloves...Each event required an average of two weeks off duty...many began to return with progressively more severe hives, facial edema and respiratory symptoms even though they were using non-latex gloves." Following the switch to powder-free gloves the number of complaints decreased to no more than two a month, with no new cases of occupational asthma or respiratory events related to glove use. (Appendix B)

The positive experiences of these hospitals with the elimination of powder-free gloves indicate that a commitment to eliminating cornstarch powder is an invaluable tool against the growing problem of latex allergy among health care workers.

The link between increased exposure of health care workers to latex proteins due to the use of cornstarch powder in gloves appears to be well established by the literature and case reports presented above. The National Institute for Occupational Safety and Health (NIOSH) has recognized this link, and the danger that the continued use of these gloves poses to workers. A safety alert report released in June 1997, entitled "Preventing Allergic Reactions to Natural Rubber Latex in the Workplace," not only alerted the public, employers, and safety and health officials to the increase in allergic reactions to latex, particularly among health care workers, but also recommended that "If latex gloves are chosen, provide reduced protein, powder-free gloves to protect workers from infectious materials".

Powder-Free Gloves are Effective and Cost-Efficient

According to IMS America, powder-free surgical gloves made up 26% of the surgical glove market in the second quarter of 1997.[1] This finding indicates that these gloves are being found to be acceptable by many surgeons. However, despite this and the developing understanding of the negative effects of the use of cornstarch powder on examination and surgical gloves, there is still resistance to the use of powder-free gloves based on questions about their ease of use and effectiveness, as well as about the cost of switching to powder-free alternatives. Below we will discuss the evidence regarding the use of powder-free gloves, as well as the experience of certain hospitals, all of which indicate powder-free gloves are in fact a viable alternative to cornstarch powdered gloves.

First, some surgeons are reluctant to use powder-free gloves because they perceive that they are more resistant to donning than powdered gloves. Dr. Edlich and his colleagues demonstrated that the glove-donning forces necessary for powder-free gloves and powdered gloves were comparable if the surgeon's hands were dry.[43] When donned with wet hands, one brand of powder-free gloves tore in all trials and the tested brand of powdered gloves tore in 6 of 14 trials, while a third powder-free brand could be donned without ripping. Another study demonstrated that many different brands of powder-free gloves exist with donning forces using dry hands which were comparable to those of the powder-free gloves tested in the original study. In this same study, 11 of 13 powder-free brands were donned using wet hands without tearing in all 13 trials.[44]

Concerns about the potential for leaks of powder-free gloves are addressed by the FDA's quality control testing of medical gloves. The FDA's guidance manual for manufacturers of medical gloves (issued in the December 12, 1990 Federal Register) describes in detail the water leak method of testing used to ensure that all medical glove manufacturer's meet a standard level of quality. Further, in contradiction to claims that powder-free gloves will be less effective than powdered gloves, polymer coated powder-free surgical gloves are particularly well suited for tape wound closure. The tested brand of powder-free gloves had adherence to wound closure tape which was comparable to that of

powdered gloves when unwashed, and was significantly less subject to adhesion after both brands of gloves had been washed and dried. In addition, adhesion of wound closure tape to powdered gloves decreased the tape's adhesion to skin by 61%, compared to only 28% with powder-free gloves.

One of the hospitals discussed above, Methodist Hospital, initially confronted resistance to the use of powder-free gloves due to concerns about effectiveness and ease of use. However, through providing a variety of gloves, the hospital succeeded in meeting the needs of its staff. This experience illustrates that with the increase in the variety of power-free gloves available, concern about the effectiveness and ease of use of powder-free gloves are not substantial enough to override the benefit of their use.

In addition to concerns about the effectiveness of powder-free gloves, hospitals claim that making a switch to powder-free gloves would result in excessive costs, as the cost of one pair of surgical gloves purchased by a consumer in a pharmacy is around one and one-half to three fold greater than that of a glove lubricated with cornstarch. However, calculating the real cost of gloves is not as simple as comparing the cost of the two products.

First, it is important to realize that the purchasing power of the hospital is quite different from that of the individual consumer. In a wholesale marketplace, hospitals purchase so many thousands of surgical gloves that they can effectively barter regarding glove price. They can use a variety of innovative strategies to lower the purchase price of surgical gloves. For example, at the Mayo Clinic, a new innovative strategy to purchase gloves that markedly reduced the cost of powder-free gloves was developed. They used the research data of Dr. John Yunginger, an internationally recognized allergist at the Mayo Clinic, on the allergen protein content to select surgical gloves. Since December 1993, Mayo Clinic has only used gloves with a low-latex allergen protein content. From 15 to 16 different kinds of gloves, the Mayo Clinic now uses only 10 types from 5 manufacturers. The use of low latex allergen gloves has actually saved the Mayo Clinic money as they purchased only a few brands of gloves with low latex allergen content because, by buying from only a few manufacturers, they were able to negotiate for better prices. They also corrected inappropriate uses of the gloves.

In addition, related costs, such as the cost of extra equipment, worker's compensation and the loss of skilled workers must also be taken into account. The cost associated with washing procedures for cornstarch dusted gloves was determined by adding basin costs that contained the solution, solution cost, and unit wiping materials together and dividing by the number of team members. The direct cost of washing materials averaged $0.46 per glove with a range between $0.26 to $1.25 per glove, depending on the materials used and the level of washing required. [20]

The experiences of Jackson Memorial Hospital and Methodist Hospital indicate how important the cost of worker's compensation and the loss of skilled employees can be in choosing whether to use powder-free gloves. For example, Jackson Memorial Hospital reported four worker's compensation claims related to latex allergy, and two EEOC claims. Two workers compensation settlements alone exceeded $100,000 each, plus ongoing expenses (one of the cases has already cost at least $370,000). Further, the hospital notes that there were additional costs of replacing employees with overtime, and defending against the claims. Having compared these costs to estimates that having a powder-free facility would cost $300,000 a year, it was found that the actual increase was only $200,000 a year but that an additional $250,000 a year could be saved by other changes in glove utilization in the hospital. An administrator at the hospital stated that, although "It has not been easy going powder-free in today's economic environment....However, the satisfaction of seeing lives destroyed and then put back together...has been a rewarding experience. I would challenge any manager trying to make this difficult decision in today's medical financial arena to listen to the medical facts, talk to allergic

employees and remember why we are in the health care business. The answer will be obvious and cost justifiable." (Appendix B)

The OR project coordinator at Methodist Hospital reported similar findings with respect to the cost of switching to powder-free gloves, stating that "Latex allergies tend to strike the health care professionals with the most experience, and that is more costly than any additional expenses to a glove budget...For the price of commitment and persistence we were able to keep our tenured employees -- really a pretty good deal!" (Appendix C)

Conclusion

The evidence of the adverse effects of cornstarch and the growing problem of latex allergies, especially among health care professionals, indicate that the continued use of this powder on surgical and examination gloves is of major concern. It is clear that alternatives which are effective and well established in the market exist, and that, if the cost of powdered gloves are adjusted to include the cost of wash basins required to remove the powder, extra gloves, workers' compensation claims, and the loss of the experience of health care workers, there is no economic justification for failing to halt the use of cornstarch on gloves. We therefore urge the FDA to take immediate action to ban the use of surgical and examination gloves with cornstarch lubricants.

We expect a prompt response to this urgent petition.

Sincerely,

Sidney M. Wolfe, M.D.
Director

Christine Dehlendorf, Researcher
Public Citizen's Health Research Group

Timothy Sullivan, MD, Professor of Medicine,
Emory University School of Medicine
Head of the Subsection of Allergy and Immunology at the Emory Clinic

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Selected Topics Wound Care

A GLOBAL INVENTORY OF HOSPITALS USING POWDER-FREE GLOVES: A SEARCH FOR PRINCIPLED MEDICAL LEADERSHIP

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☐ **Abstract—Scientific experimental and clinical studies have demonstrated that cornstarch on surgical and examination gloves promotes disease by acting as a reactive foreign body in tissue and serving as a vector for latex allergy. Consequently, hospitals have selected an innovative glove selection program utilizing only powder-free gloves. Healthcare workers in emergency medical systems are now wearing powder-free, latex-free gloves to care for the growing number of patients sensitized to latex. A global Internet search has now identified 70 hospitals in the United States and three hospitals in Europe that use only powder-free gloves. © 2000 Elsevier Science Inc.**

☐ **Keywords—cornstarch; surgical gloves; examination gloves; powder-free gloves; latex allergy; internet search**

INTRODUCTION

Most physicians have an unfounded confidence in cornstarch and mistakenly believe that it is safe It is a substance recognized on the surface of examination and surgical gloves by all emergency physicians, surgeons, nurses, and hospital administrators Nevertheless, this familiar powder can cause a wide variety of sometimes deadly complications. While first used as a donning agent for gloves, recent technologic advances in glove manufacture have resulted in the development of inexpensive powder-free gloves with equal or superior performance characteristics to that of powdered gloves Today, cornstarch is a substance that has outlived its benefits Consequently, there are a growing number of hospitals that are using exclusively powder-free glove products

The purpose of this report is to first describe the mechanisms by which cornstarch elicits human disease Second, we describe a powder-free glove selection program for the hospital Finally, we enumerate the results of our global Internet search for hospitals using only powder-free gloves

Cornstarch-Induced Foreign Body Diseases

Scientific experimental and clinical studies have confirmed that cornstarch promotes disease by two different mechanisms First, it acts as a foreign body that causes a severe inflammatory response and interferes with the host's defenses against infection When cornstarch is deposited in soft tissues, it potentiates the development

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of wound infection (1,2) Small amounts of cornstarch encourages wound induration, bacterial growth, and infection Calcium carbonate has been recently introduced as a glove mold release agent to replace cornstarch A study has demonstrated that this new glove powder, calcium carbonate, is significantly more damaging to host wound defenses than cornstarch (3).

When cornstarch enters the peritoneal cavity, it can elicit granuloma formation, adhesion formation, and peritonitis (4–7) Cornstarch induced adhesions can cause intestinal obstruction, infertility, and pelvic pain It is interesting that the new surgical glove powder, calcium carbonate, promotes significantly more abdominal adhesions in experimental animals than does cornstarch (8) Scientists have reported numerous other adverse reactions to cornstarch that include endophthalmalitis, post-thoracotomy syndrome, meningismus after craniotomy, retroperitoneal fibrosis, and synovial inflammation (9–13)

It is important to understand that simply washing the cornstarch off gloves prior to use does not prevent the deleterious effects of cornstarch. Jagelman and Ellis show that washing with water decreases the number of starch particles, but leaves considerable cornstarch on the glove that aggregates as clumps (14) They suggest that cornstarch clumps would provoke a delay in absorption and an increase of the foreign-body reaction In 1980, the investigation by Tolbert and Brown provided further evidence that glove washing with a saline solution leaves residual cornstarch on the glove's surface (15)

Fraser found the most efficient method of washing the cornstarch from the gloves to be a one-minute cleansing with 10 mL of povidone-iodine followed by a 30-s rinse under sterile water (16). This technique decreases the median number of starch granules per mm^2 of glove, as seen on microscopic examination, from 2,720 (when no attempt to remove the powder is performed) to 0 (with the povidone-iodine method) However, this technique was time-consuming, costly, and burdensome to the clinical staff and did not ensure removal of all powder particles

Despite the effectiveness of these procedures, it would still be advisable that health care workers adhere to the washing guidelines if the cornstarch powder is to be removed completely In a later clinical trial, Fay and Dooher examined the surgical staff's compliance with glove washing to remove cornstarch lubricants They note that only 17% of the surgeons and 21% of the surgical nursing staff washed their gloves after donning (17)

It is also valuable to appreciate that healthcare workers in some hospital settings use powdered surgical gloves because they do not have easy access to sterile wash basins Emergency physicians in Emergency Departments (EDs) treat more than 10 million patients annually using sterile surgical gloves During wound care, they usually do not have the benefit of a nursing assistant who aseptically sets up a sterile wash basin filled with saline in which they can remove the cornstarch from their gloves Therefore, many emergency physicians resort to using gloves lubricated with cornstarch during wound treatments

Cornstarch as a Vector of Latex Allergies

The second mechanism by which cornstarch on gloves elicits disease is based on its role as a carrier for latex allergens Documented reactions to latex include contact urticaria, rhinitis, asthma, and anaphylactic shock (18–25) The development of reactions to latex exposure has been linked to the individual's production of IgE antibodies to natural latex when exposed to this substance (16–27) IgE mediated latex allergy has several presentations with symptoms varying from mild itching to severe anaphylaxis (28) Three clinical presentations are frequently seen. Glove induced local contact or irritant dermatitis may occur that may progress to contact urticaria, pruritus, erythema, and angioedema in the first group Some of these individuals may develop mucosal involvement with varying degrees of systemic allergic reactions ranging from hives, wheezing, to laryngeal edema to anaphylaxis The second group displays occupational disease of the lower or upper respiratory tract, or both, which includes rhinoconjunctivitis and bronchial asthma with or without skin reactions The third group develops anaphylaxis during a medical or surgical procedure

In 1992, the Food and Drug Administration reported more than 1,000 combined Medical Device Reporting Program and Product Problem Reporting Program reports of allergic or anaphylactic reactions in conjunction with the use of plant-derived rubber or latex containing medical products (29) It is important to realize that there is some overlap between these two reporting programs Recently, Dillard, an official in the Center for Devices and Radiological Health in the FDA, noted that there were 305 reports to the FDA of allergic or anaphylactic reactions associated with the use of latex gloves in the last year alone for which data are available (August 15, 1996–August 15, 1997) (29)

Health care workers are at high risk for this allergy due to occupational exposure to latex In 1992, Zoltan, Luciano, and James reported that 8 8% of dentists in the U S Army Dental Corp have self-reported histories consistent with latex allergy (30) Kaczmarek and colleagues in 1996 demonstrated that 5 5% of hospital personnel are positive for latex specific IgE antibody by employing a

radioallergosorbent test (31) Two other studies in 1997 indicated that 12 1% of health care workers and 21% of hospital nursing staff are sensitized to latex, as determined by skin prick tests (32,33)

This high incidence of latex sensitization has enormous human costs, as trained healthcare workers who have symptoms may require reassignment, or potentially can even need to discontinue their career in healthcare Not only is this devastating to the healthcare worker, society also loses the benefit of the training of these professionals A role of cornstarch in the development of latex allergy by health care workers is suggested by Beezhold and Beck, who found a significant interaction between latex proteins and cornstarch powders (34). In addition, Tomazic et al demonstrated that cornstarch binds latex proteins (35) This binding between cornstarch and latex has been implicated as the major cause of airborne latex. Tarlo and associates found low or undetectable latex aeroallergens in work areas where only powder-free gloves were used (36)

There is considerable evidence that these airborne cornstarch-latex particles act as an agent for exposure and sensitization of healthcare workers to latex protein through the release of latex-cornstarch particles into the air First, latex-protein or starch particles are allergenic proteins (35) Sensitized people display allergic symptoms such as rhinitis, cough, conjunctivitis, or breathing problems when only exposed to airborne latex through the handling of cornstarch powdered latex gloves (37) Of 11 sensitized people, four developed shortness of breath, wheezing, and had evidence of enhanced airway resistance Four sensitized nurses experienced immediate bronchoconstriction when handling powdered latex surgical gloves and bronchial challenges with powdered latex surgical glove extracts resulted in more severe reactions than challenges with non-powdered latex surgical glove extracts (38) Consequently, it can be concluded that the interaction between cornstarch and latex provides a route of exposure to the latex proteins that the absence of cornstarch would minimize

Case reports in the literature provide further evidence for the role of cornstarch in latex allergy of healthcare workers. Tarlo and colleagues describe one hematology laboratory technician who had developed contact dermatitis, contact urticaria, and anaphylaxis following contact with latex She continued to experience symptoms, such as facial urticaria and rhinitis, after she switched to vinyl gloves, and eventually stayed home from work She was able to return to work after her laboratory changed to powder-free gloves (36) Lagier and associates examined an intensive care nurse who immediately had asthmatic symptoms when powdered latex gloves were manipulated in front of her, but had no reaction to vinyl gloves (39)

Jackson Memorial Hospital (Miami, FL), Methodist Hospital (Indianapolis, IN) and Brigham and Women's Hospital (Boston, MA) also found an important role of powdered gloves in the development of latex allergy. Their latex sensitized healthcare workers were able to continue work in a powder-free hospital environment (40) All three hospitals banned the use of powdered gloves, converting to powder-free gloves after discovering that latex allergies were a substantial problem among their staff. The favorable experiences of these hospitals with the elimination of powder-free gloves demonstrate that a commitment to eliminating cornstarch powder is a valuable tool against the growing problem of latex allergy among healthcare workers

This linkage between increased exposure of healthcare workers to latex proteins due to the use of cornstarch powder on gloves is now well documented by the literature The National Institute for Occupational Safety and Health (NIOSH) released a safety alert report in June 1997 entitled "Preventing Allergic Reactions to Natural Rubber Latex in the Workplace" (41) It alerted the public, employers, and safety and health officials to the increase in allergic reactions to latex, particularly among healthcare workers, but also recommended that "If latex gloves are chosen, provide reduced protein, powder-free gloves to protect workers from infectious materials."

Powder-Free Glove Selection Program for Hospitals

In the 1980's, manufacturers devised two different techniques to produce powder-free gloves. They used either a hydrogel polymer or surfactant as mold-release agents for latex gloves that allowed for the production of powder-free gloves in the absence of cornstarch The other approach involved chlorination of the powdered glove to remove surface glove powders resulting in a glove product with only small levels of residual cornstarch (42)

Biomechanical studies have demonstrated that the performance of powder-free latex gloves is remarkably similar to that of powdered latex gloves Cote and associates report that the forces required to don many manufactured powder-free latex examination gloves do not differ significantly from that encountered with powdered latex examination gloves (43) Similarly, Fisher and colleagues document that the glove donning forces for powder-free and powdered sterile latex surgical gloves do not differ significantly (44). Furthermore, the puncture resistance of powder-free and that of powdered latex surgical gloves are remarkably similar Pavlovich and colleagues note that powder-free latex gloves are especially suited for tape wound closure (45) They found that cornstarch powder bound to the microporous tapes and interfered with tape adhesion to skin In contrast, microporous

tapes handled with powder-free surgical latex gloves adhered aggressively to skin, facilitating wound approximation.

There have been major technologic advances in the design and manufacture of powder-free gloves. The surface of the fingertips of powder-free gloves has been textured to improve the physician's grasp of surgical instruments (46) In addition, a unique double glove puncture indication system has been designed for powder-free gloves (47) This puncture indication system consists of a double glove system with an inner glove uniformly colored green under a transparent outer glove When the outer glove is punctured, the green inner glove develops a dark patch under the puncture site, a warning to the physician to change the glove immediately The color change is an optical effect; it does not involve release of dye or any other material, but it works on the principle of capillary action. This double glove system has twice the resistance to puncture as a single glove

For healthcare environments managing latex sensitized patients, like ambulances and EDs, nitrile examination and surgical gloves are commonly used (48) Nitrile powder-free examination gloves that comply with the National Fire Protection Association Standards 1999 are especially suited for EMTS (48) The thickness of *nitrile gloves are half that of latex, enhancing the tactile* discrimination of the healthcare worker These thin nitrile gloves exhibit twice the puncture resistance of latex gloves The handling characteristics of the nitrile gloves are judged to be excellent with donning forces that are comparable to those encountered with latex gloves Another unique advantage of the nitrile gloves is that tape adhesive has limited adherence to the glove surface In contrast, tape adhesive aggressively adheres to latex gloves

These unique performance characteristics of nitrile examination gloves have been found useful in surgical gloves used in the ED (49) First, their thickness is significantly less than that of surgical latex gloves The puncture resistance of nitrile gloves is twice that of latex gloves Donning surgical nitrile gloves can be easily accomplished with either single or double gloves

Search for Hospitals Using Powder-Free Gloves

Since the advent of the latex allergy epidemic in healthcare workers and patients, many hospitals have implemented a comprehensive glove management program that involves the use of powder-free gloves To search for this principled medical leadership, we have devised an inventory of hospitals using only powder-free examination and surgical gloves throughout the world utilizing an Internet website (*www deadlydust com*) This site welcomes all hospitals using only powder-free examination and surgical gloves to be registered To date, 70 hospitals have registered on this website Twenty-one states have hospitals using only powder-free gloves (Table 1) Virginia [17] and Minnesota [11] have the highest number of registered hospitals. In June 2000, Kaiser Permanente managed care organizations will be listed on this website, including its 12 participating hospitals Three hospitals in Europe have taken a leadership role in banning the use of powdered gloves (Table 2)

Table 1. Hospitals Using Only Powder-Free Gloves in the United States

Arkansas	1	Missouri	1
California	1	Montana	3
Connecticut	3	North Carolina	2
Florida	1	Ohio	1
Indiana	1	Pennsylvania	4
Iowa	3	South Carolina	1
Louisiana	1	South Dakota	1
Maine	4	Vermont	1
Maryland	3	Virginia	17
Massachusetts	7	Wisconsin	3
Minnesota	11		

DISCUSSION

Despite overwhelming evidence of the dangers of powdered glove lubricants, many hospitals across the world continue to use powdered examination and surgical gloves During the last century, scientists repeatedly demonstrated that the powder on gloves causes serious disease requiring hospitalizations (50) Investigations also identified a latex allergy epidemic that threatens millions of healthcare workers and patients and pointed to the significant role of powdered glove lubricants in latex allergy (42) It must be particularly frustrating for *healthcare workers and patients, especially those sensi*tized to latex, to realize that this staggering problem has a simple, inexpensive solution powder-free gloves with low levels of latex allergens

In the absence of Food and Drug Administration (FDA) regulatory regulation, manufacturers are now pro-

Table 2. Hospitals Using Only Powder-Free Gloves in Europe

Scandinavia	
Hospital	Location
SOS Sodersjukhuset	Stockholm, Sweden
Orebro Region Hospital	Orebro, Sweden
United Kingdom	
Hospital	Location
Great Ormond Street Hospital	London, England

ducing a wide variety of effective and inexpensive powder-free latex and latex-free examination and surgical gloves using a variety of innovative techniques. Healthcare workers wearing powder-free glove products do not have to take the additional step of glove washing before usage With the advent of these innovative powder-free examination and surgical gloves, many hospitals now view the use of powdered gloves as an unacceptable and dangerous medical practice. Today, many hospitals throughout the country have displayed principled leadership in their announcement that they will use only powder-free gloves products. Seventy hospitals in the United States and three hospitals in Europe use only powder-free gloves Kaiser Permenente will declare that all of its hospitals would be using only powder-free gloves by June 2000

Unfortunately, this healthcare crisis ignited by glove powders has precipitated litigation across the country Howell Rosenberg, a partner with Brookman, Rosenberg, Brown & Sandler, a law firm in Philadelphia, estimated that about 250 cases against glove manufacturers have gone to Federal courts around the country, up from about 25 cases two and a half years ago. His office is handling a suit on behalf of all the Federal cases, roughly 12% of which are from New York Dozens more are being tried in state courts This litigious environment has not caused the FDA to ban the use of cornstarch on surgical and examination gloves Literally hundreds of letters have been sent to the Secretary of Health and Human Services, Donna Shalala, requesting that the FDA ban the use of cornstarch powdered gloves The citizen action group Public Citizen filed a petition to the FDA on January 7, 1998 requesting that cornstarch be banned from surgical and examination gloves (40) It is time for all hospitals in the United States to join this movement toward a powder-free healthcare environment with designated latex safe healthcare areas to protect their patients against the dangers of glove powders and the development of latex allergies

CONCLUSIONS

Cornstarch powder promotes disease by two different mechanisms It acts as a reactive foreign body in tissue, which results in a wide range of diseases, and serves as a vector for the latex allergy epidemic. A glove selection program for hospitals has been identified that utilizes only examination and surgical gloves without the cornstarch powder Powder-free, latex-free gloves are recommended for treatment areas caring for latex sensitized patients, especially the emergency medical system An Internet website has been developed as a global inventory for hospitals using only powder-free examination and surgical gloves Seventy hospitals in the United States and three hospitals in Europe are identified on the website This principled leadership displayed by a growing number of hospitals in the world should be a catalyst for the Food and Drug Administration to ban the use of cornstarch on examination and surgical gloves

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CP00-2-5

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

March 30, 2000

Consumer Product Safety Commission

I am responding to the petition you have received requesting the Commission to declare that natural rubber latex ("NRL") and products containing NRL are strong sensitizers under the Federal Hazardous Substance Act ("FHSA") and that products containing NRL must be labeled Our 11 year old son as well as myself have been diagnosed with natural rubber latex allergy approximately 6 years ago Our lives have changed tremendously since that diagnosis. Our son has had 2 anaphylactic reactions which required emergency treatment with epinephrine. Trying to make our daily environments "latex-free" and safe has been a challenge Ted is in 5th grade and next year will be starting a new school This is always a tremendous challenge as it requires many phone calls to manufacturers trying to verify whether or not their products contains NRL Just the daily battles of buying clothes, toys etc. and trying to make sure they are safe for our family is terrible Needless to say I urge you to grant this petition. Products must be labeled!! More and more people are becoming allergic to NRL Our environments must be kept safe. We should not have to spend hours on the phone trying to gather this information Thank you for your time and consideration in this matter

Sincerely,

Lauri J Harris

Lauri J Harris, RDH

Petition HP 00-2
Petition on natural rubber latex

THE JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE
REFERENCE LABORATORY FOR DERMATOLOGY, ALLERGY AND CLINICAL IMMUNOLOGY

CP00-2-6

DACI

April 28, 2000

2000 MAY -5 A 11:29

Mrs. Sadye E. Dunn
Office of the Secretary
Room 502
4330 East-West Highway
Bethesda, MD 20814
Fax 301-504-0127

RE: Comments on petition HP 00-2, Petition on Natural Rubber Latex

Dear Mrs. Dunn.

I am writing you to strongly support the labeling of natural rubber latex containing consumer products as "containing natural rubber latex" In an 1996 prevalence study that we performed together with members of the Consumer Product Safety Commission (ref 1), we showed that the prevalence of latex sensitization (latex-specific IgE antibodies) among hospital personnel is appreciable and that their health care providers should be made aware of latex allergy Subsequent to this it has been shown in some studies that over 50% of children with spina bifida and from 1 to 6% of the non-healthcare workers general public have become sensitized (IgE antibody positive) to natural rubber latex.

In a presentation at the Academy of Asthma, Allergy and Immunology meeting this year in San Diego, a group from Creighton University in Omaha NE reported on a 7 month old infant without any congenital deformities that developed a latex allergy from apparent normal use of rubber toys, pacifiers, nipples and disposable diapers (ref 2). This is the youngest infant to be reported with a latex allergy. Exposure was not through surgeries but rather through the use of standard consumer products containing natural rubber latex. This makes the important case for labeling natural rubber-containing consumer products.

The only method of we have of insuring that the public does not become sensitized and develop a potentially life-threatening latex allergy is avoidance. However, one must know that the product contains natural rubber latex to avoid exposure. While not all rubber-containing consumer products release the same levels of latex allergen, it is currently not possible to identify those consumer products that place latex allergic individuals at high risk for symptoms as a result of simply their use. It is important that all rubber-containing consumer products be clearly labeled as containing natural rubber latex so that sensitized individuals can more easily identify and avoid rubber latex allergen exposure Knowledge (about rubber content of products) is strength (in promoting avoidance therapy)

Sincerely yours,

Robert G. Hamilton, Ph.D., D ABMLI
Associate Professor of Medicine and Pathology
Director, DACI Reference Laboratory

References

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Stevenson, Todd A.

Late comment

From: BROKENBONES@aol com
Sent: Tuesday, May 02, 2000 11 37 AM
To: cpsc-os@cpsc gov
Subject: Petition HP 00-2 Petition on Natural Rubber Latex

I would like to see that Natural Rubber Latex and products containing NRL be
> declared "strong sensitizers" under the Federal Hazardous Substances Act.
> I unfortunately have been sensitized through my 18 year career as a Radiology
> Technologist, and have now developed a Type I Hypersensitivity to NRL. I
have
> lost my career to this Hypersensitivity, and have faced many other difficult
> health and financial problems. This is now permanent and life long for me,
> and I am only 37 years old.
> The reason I am a Type I hypersensitive person, is because I was a hard
> worker, and followed the rules that mandated that I was to wear protective
> gear while handling body fluids, etc.
> The "gear" that was supplied to me by my Employer was powdered NRL gloves, I
> never thought that my career choice as a Radiology Technologist could
> possibly cost me my livelihood, let alone my life! I now have to carry
> epinephrine with me at all times, for the rest of my life, as well as wearing
> an identification, bracelet and necklace stating that I have an allergy to
> latex.
> I do not want anyone else to be needlessly sensitized, this is something
that
> can be stopped There is no cure for those of us who have been sensitized,
> but there is a cure for those who have not been sensitized, that cure would
> be removing the NRL from the medical community, and from standard household
> items, toys and sporting goods.
> There are many things that can replace latex, but nothing can replace my
life
> I urge you to please act upon the rule Declaring Natural Rubber Latex a
> Strong Sensitizer, please protect all of the innocent people who may
> unknowingly become sensitized, if more is not done about this.
> Sincerely Yours,
> Barbara Leather RT(R)
> 220 West Sylvania Ave #24
> Neptune City NJ 07753-6253

CP00-2-8

Colleen M. Baker BS, RN.
39 Greenridge Crescent
Hamlin, NY 14464
716 964-3502
May 2000

Office Of The Secretary
Consumer Product Safety Commission
Washington, DC 20814

I am writing regarding petition # HP 00-2, petition on Natural Rubber Latex.

I strongly encourage the CPSC to declare that natural rubber latex (NRL) and products containing natural rubber latex are strong sensitizers under the Federal Hazardous Substance Act (FHSA).

I was exposed to NRL and have a severe life-threatening, occupationally acquired latex sensitivity The research clearly shows that only those with exposure to NRL products can develop a type I life-threatening allergy. Therefore, these products should be listed under the FHSA, they are very hazardous.

My life since developing NRL allergy has been drastically altered and difficult There are thousands of consumer products that are made of, or contain NRL and are not labeled as such. This makes it most difficult for the millions of people who are now trying to live with latex allergy to function daily, when we are trying to avoid and decipher if regular products such as pencil erasers, glue, gardening supplies, clothing, shoes, baby products, gloves, envelopes, and kitchen utensils do or do not contain any NRL. We must repeatedly contact manufactures to see if we can touch or even be near these products before use.

The requiring of labels for all NRL products would be most beneficial for those of us already suffering with this totally preventable illness, as well as serve to warn other consumers to the dangers of NRL products.

Thank you for allowing comments on this topic.

Sincerely,

Colleen M. Baker, BS, RN.

Stevenson, Todd A.

From: Colleen M Baker [CMBaker@frontiernet net]
Sent: Wednesday, May 03, 2000 2:05 PM
To: cpsc-os@cpsc gov
Subject: HP OO-2 Natural Rubber latex

Please see attached Natural Rubber latex Document.

Colleen M. Baker, BS, RN
Latex Allergy Association of NY
cmbaker@frontiernet net
http //www frontiernet net/~cmbaker -LAANY

Stevenson, Todd A. CP00-2-9

From: BRsBoots@aol com
Sent: Wednesday, May 03, 2000 12:50 PM
To: cpsc-os@cpsc gov
Subject: Petition HP 00-2, Petition on Natural Rubber Latex

May 3, 2000

Consumer Product Safety Commission
Washington, DC 20207

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

Dear Sirs/Ladies

I would like to add my voice of support to Debi Adkins, editor of Latex Allergy News, on her request to declare that natural rubber latex ("NRL") and products containing NRL as strong sensitizers under the Federal Hazardous Substances Act ("FHSA").

As a person who suffers from Type 1 Latex Allergy I can confirm that this substance has almost ended my life on two occasions and that it has seriously incapacitated me. This substance is a KNOWN health hazard that has not been taken seriously. I sincerely hope you will help to stop the needless sensitization of more people Together we can halt this destructive force!!

Thank you for your time and consideration in this matter.

Sincerely,

Kelly J Clinton

Stevenson, Todd A.

From: alikat [alikat@neo rr com]
Sent: Wednesday, May 03, 2000 4 44 PM
To: cpsc-os@cpsc gov
Subject: Petition HP 00-2, Petition on Natural Rubber Latex

In a message dated 5/3/00 9·50 06 AM Pacific Daylight Time, BRsBoots writes·

<< May 3, 2000

Consumer Product Safety Commission
Washington, DC 20207

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

Dear Sirs/Ladies·

I would like to add my voice of support to Debi Adkins, editor of Latex Allergy News, on her request to declare that natural rubber latex ("NRL") and products containing NRL as strong sensitizers under the Federal Hazardous Substances Act ("FHSA")

As a person who suffers from Type 1 Latex Allergy I can confirm that this substance has almost ended my life on two occasions and that it has seriously incapacitated me This substance is a KNOWN health hazard that has not been taken seriously I sincerely hope you will help to stop the needless sensitization of more people Together we can halt this destructive force!!

Thank you for your time and consideration in this matter

Sincerely,

Kelly J Clinton
Ali Clinton

Stevenson, Todd A.

From: Tammy_Tahara@monterey edu
Sent: Wednesday, May 03, 2000 1 16 PM
To: cpsc-os@cpsc gov
Cc: brsboots@aol com
Subject: Petition HP 00-2, Petition on Natural Rubber Latex

May 3, 2000

Consumer Product Safety Commission
Washington, DC 20207

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

Dear Sirs/Ladies

I would like to add my voice of support to Debi Adkins, editor of Latex Allergy News, on her request to declare that natural rubber latex ("NRL") and products containing NRL as strong sensitizers under the Federal Hazardous Substances Act ("FHSA").

As a person who suffers from Type 1 Latex Allergy I can confirm that this substance has almost ended my life on two occasions and that it has seriously incapacitated me. This substance is a KNOWN health hazard that has not been taken seriously. I sincerely hope you will help to stop the needless *sensitization of more people Together we can halt this destructive* force''

Thank you for your time and consideration in this matter

Sincerely,

Kelly J Clinton

Dear Gentlepeople,
I am sending you this letter in support of my daughter, Kelly J Clinton, who suffers from Type 1 Latex Allergy. Please give very serious consideration to declaring natural rubber latex (NLR) and products containing NLR as strong sensitizers under the Federal Hazardaous Substances Act (FHSA).

Thank you

Sincerely,

Tammy Tahara

Late comment

Stevenson, Todd A

From: DulceLimon@aol com
Sent: Friday, May 05, 2000 11.10 PM
To: cpsc-os@cpsc gov
Subject: Petition on Natural Rubber Latex

May 5, 2000

Consumer Product Safety Commission
Washington, DC 20207

RE· Petition HP 00-2, Petition on Natural Rubber Latex

Dear Sirs/Ladies

I would like to add my voice of support to Debi Adkins, editor of Latex Allergy News, on her request to declare that natural rubber latex ("NRL") and products containing NRL as strong sensitizers under the Federal Hazardous Substances Act ("FHSA").

As a person who knows someone who suffers from Type 1 Latex Allergy I can confirm that this substance has almost ended my life on two occasions and that it has seriously incapacitated me. This substance is a KNOWN health hazard that has not been taken seriously. I sincerely hope you will help to stop the needless sensitization of more people. Together we can halt this destructive force!!

Thank you for your time and consideration in this matter.

Sincerely,

Veronica Ramirez

Stevenson, Todd A.

From: Sandra Kilogan [kilogan1@redshift com]
Sent: Thursday, May 04, 2000 11 05 AM
To: cpsc-os@cpsc.gov
Subject: Fw Petition HP 00-2, Petition on Natural Rubber Latex

Petition HP 00-2, Petition on

Consumer Product Safety Commission

> Washington, DC 20207
>
> RE Petition HP 00-2, Petition on Natural Rubber Latex
>
> Dear Sirs/Ladies
>
> I would like to add my voice of support to Debi Adkins, editor of Latex
> Allergy News, on her request to declare that natural rubber latex ("NRL") and
> products containing NRL as strong sensitizers under the Federal Hazardous
> Substances Act ("FHSA").
>
> As a person who suffers from Type 1 Latex Allergy I can confirm that this
> substance has almost ended my life on two occasions and that it has seriously
> incapacitated me. This substance is a KNOWN health hazard that has not been
> taken seriously. I sincerely hope you will help to stop the needless
> sensitization of more people. Together we can halt this destructive force''
>
> Thank you for your time and consideration in this matter
>
> Sincerely,
>
Sandra Carr
>
> >>
>
>

CP00-2-10

11 May 2000

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

Fax: (301) 504-0127

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

The subject item is an issue that carries more emotion than substance. How many people do genuinely have an allergic reaction to latex? Statistics in the last 10 years have ranged from less than 0.1% population up to 3+%. Regardless the percentage of potential reactions are infinitesimally small. Albeit, if a person is allergic then the reaction can be quite severe. Conversely, consider the protection granted to large portions/percentages of the population from diseases, bactena, germs etc afforded by gloves of all types in a broad scope of industries. And yes, there are alternatives to natural latex gloves, but there are significant unknowns relative to substitutes. And how about the toys, etc used by children around the world containing natural rubber for generations now with little if any problems. But the good accomplished is often overlooked for the "politically-correct", "legally armed", loudest critics and then the general population suffers deficient products at higher costs and the regulatory bureaucrats applaud themselves for having implemented rules, regulations and policies that rather than accomplish good for the masses seemingly offer protection for a very small minority of the population

Respectfully submitted

Wayne L Gainey
406 Drake Drive
Dothan, AL 36305

I am NOT a disinterested party I have been involved in producing condoms, gloves, balloons, finger cots and catheters for over 30 years. I've even thought that our products were of great use and benefit.

CP00-2-11

Petition HP 00-2, Petition on Natural Rubber Latex

May 15, 2000

Submitted to:
cpsc-os@cpsc.gov
Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207
(301)504-0800
Office of the Secretary, Room 502, 4330 East-West Highway, Bethesda, Maryland 20814. Fax (301) 504-0127

Submitted by:
Anne Clark
118 Ashland Ave.
River Forest, Ill 60305

To Whom It May Concern:

I appreciate the opportunity to comment on the citizen's petition on Natural Rubber Latex submitted by Debi Adkins. My son, James, has latex allergy. Everyday we are faced with the daunting task of attempting to eliminate his exposure to natural rubber latex while at the same time keeping him involved in as "normal" a life as possible. Casual contact with balls, art materials, liners of food products, bike handles have all posed varying degrees of health risks for him. His chances of not dying or being seriously injured from consumer products made from natural rubber latex would be greatly improved if consumer products were labeled as such. Our family supports the recommendations made by The American College of Allergy, Asthma and Immunology contained in "Latex allergy: an Emerging Health care Problem. Endorsed by the board of Regents, April 1995. Published in Annals of Allergy, Asthma & Immunology 1995; 75:19-21.

"The American College Of Allergy, Asthma and Immunology suggest that following proposals be addressed immediately:
2. Content labeling of consumer goods. Consumer goods may contain sufficient quantities of latex to elicit severe reaction. A requirement for latex content labeling of consumer goods phased in over 1-2 years should increase consumer safety with minimal market disruption."

Given the current 21 deaths from natural rubber latex reported to the FDA, these labeling recommendations are clearly needed and long over due. It is our hope that this petition will prompt the Consumer Product Safety Commission to seriously address and correct this oversight of labeling.

Thank you,

Anne Clark

Anne Clark

Later comment ok 5/18/00 G

Patricia Joanne Szabo MHA, PT
159 Spook Rock Rd.
Montebello NY 10901

May 18, 2000

Office of the Secretary
Consumer Product Safety Commission
Washington, DC 20207
RE: Petition HP 00-2 Petition on Natural Rubber Latex
Via telefacsimile @ 301-504-0127

Dear Sir or Madam

Products containing natural rubber latex (NRL) are strong sensitizers and should be labeled as such I know; I have been sensitized. Since my sensitization, I lost my job working in a hospital as a physical therapist. Sadly, I also lost my freedom. If I am unexpectedly exposed to a product that contains NRL, I take a handful of pills and use an inhaler to try to stop my allergic reaction I carry auto-injectable epinephrine to treat myself in case of an emergency I have also been hospitalized

To try to prevent such reactions, on a daily basis I have to monitor the contents of what I touch, breathe, eat, and wear Now that I have been sensitized by the unsafe levels of latex protein in the NRL gloves I wore at work, any NRL product could cause me to have a reaction—a potentially life-threatening reaction This is scary when you consider how many thousands of items now contain NRL, most of which are not labeled. In addition, it is not easy to tell when a product does contain NRL because it comes in many different forms

I know there is nothing you can do to change my condition now that I have been sensitized to NRL but you can make it safer for me to live. You can decrease my risk of anaphylaxis and prevent my health from deteriorating further due to inadvertent NRL product exposure I speak for all latex-allergy sufferers Please help us fight this disease. Give us a better way to help ourselves. Please support this petition so that latex products can be easily and properly identified. For latex sensitive individuals, this is a matter of life and death

Sincerely,

Patricia Joanne Szabo MHA, PT

111 Princeton Road
Exton, PA 19341

May 12, 2000

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.

My 16 year old daughter and I do not match the risk profile of many individuals with a natural rubber latex allergy. Our background does not include any employment as healthcare workers or as staff who must wear latex gloves. We have never been employed in any industry where natural rubber is part of the manufacturing process. Hospital stays, thankfully, have been limited for both of us. We have, instead, become sensitized to natural rubber latex through exposure in everyday situations involving a variety of products including latex gloves, latex balloons, several different adhesives, new carpet and upholstery, clothing, and a number of other consumer goods where we can only guess at the natural rubber latex content.

Our quality of daily life has been negatively impacted by this development. There is always the need to be prepared to deal with an allergic reaction and its aftermath which may include itching eyes and skin (with or without blisters), dizziness, prolonged headache, blood pressure changes, and breathing difficulties. If we are to avoid latex, we are no longer free to go where we please or do what we want to do. Numerous choices of ours are limited by this constraint. What classes to take (what classroom environments to avoid), where to worship, what kind of transportation to use, where to shop and what to buy, what doctors and hospitals to use for care, how to bandage an injury, what clothes to buy and wear, what social events to attend, and where and what to eat must all be evaluated based on the ongoing need to avoid natural rubber latex.

A rule under the Federal Hazardous Substances Act stating that products containing natural rubber latex are strong sensitizers would reflect the truth as we have experienced it. By requiring all products containing natural rubber latex to be labeled accordingly, many of these threats to our health and well-being could be eliminated in the future. People everywhere (the newly diagnosed latex sensitive and their doctors, purchasers, end-users, caregivers, building contractors, restaurant owners, etc) would be empowered to know what was dangerous to a latex sensitive individual and what wasn't. We and our school system, our healthcare providers, businesses we frequent, building contractors, and others could be assured before purchasing a product that latex was not present and that people like us were not being further endangered.

Please accept this testimony and rule that natural rubber latex is a strong sensitizer. My hope is that this will spare others from the exposure that has so altered our lives.

Sincerely,

Debbie Lynn Butler

(Mrs.)Debbie Lynn Butler

Stevenson, Todd A.

14

From: KCaleb50@aol.com
Sent: Thursday, May 18, 2000 1.10 PM
To: cpsc-os@cpsc.gov
Subject: Re.petition # HP 00-2, petition on Natural Rubber Latex

Office Of The Secretary
Consumer Product Safety Commission
Washington, DC 20814

I am writing regarding petition # HP 00-2, petition on natural Rubber Latex.

I strongly encourage the CPSC to decalre that natural rubber latex (NRL) and products containing natural rubber latex are strong sensitizers under the Federal Haxardous Substance Act (FHSA).

I have a severe life-threatening occupationally acquired latex sensitivity as a result of being exposed to NRL while working in the nursing field. The research clearly shows that only those with exposure to NRL products can develop a type I life threatening allergy, and therefore these products should be listed underhe FHSA.

Since developing NRL allergy my life has been drastically altered and difficult. There are thousands of consumer products that are made of, or contain NRL and are not labeled as such, makes it most difficult for me and the millions of other people who are also trying to live with latex allergy to function on a daily basis when one has to avoid natural rubber latex.

Avoiding contact with natural rubber latex at present is the only treatment for a person who is allergic to natural rubber latex. We must contact manufactures repeatedly to see if we can touch or even be near products before use.

I strongly believe the requiring of labels for all NRL products would be most beneficial for those of us already suffering with this totally preventable illness, as well as serve to warn other consumers to the dangers of NRL products before they too are extensively exposed and unnecessarily sensitized.

Thank you for allowing comments on this topic.

Sincerely,

Kathleen
R. Caleb

141

Jordache Lane

Spencerport, NY 14559

given OK'd 15

ALCAN RUBBER & CHEMICAL, INC.

May 18, 2000

Sadye E. Dunn
Secretary
Office of the Secretary
Room 502
U.S. Consumer Product Safety Commission
4330 East-West Highway
Bethesda, MD 20814
Fax 301-504-0127

RE: Petition HP 00-2, Petition Requesting Rule Declaring Natural Rubber Latex A Strong Sensitizer

Dear Madam Secretary:

Alcan Rubber & Chemical, Inc. ("Alcan" hereinafter) sells natural rubber latex to a variety of customers throughout the United States. As the Commission is well aware, natural rubber latex has many valuable uses in both the medical and consumer fields. Futhermore, natural rubber latex is widely accepted as the premier virus barrier, outperforming other materials. In addition, natural rubber latex is significantly less expensive than other alternatives.

Alcan submits there are many differing opinions regarding human sensitivity to natural rubber latex. Given this ambiguity, it is not appropriate, in our view, to require labeling of natural rubber latex as a strong sensitizer.

Alcan strongly recommends that prior to adopting any rule requiring labeling for natural rubber latex, that a detailed cost/benefit analysis be conducted. Prior to acting in this matter, the Commission should be certain that there are no unintended consequences that may cause harm to consumers, or may result in additional expense for consumers.

Thank you for the opportunity to comment.

Sincerely,

Bryan Lakin
Vice President

29 Broadway
New York, NY 10006
Telephone (212) 952-9230
Fax (212) 422-0059

ALCAN RUBBER & CHEMICAL, INC.

2 pages including cover sheet

To: U.S. Consumer Product Safety Commission
Bethesda, Maryland
Fax 301-504-0127

May 18, 2000

Please deliver this letter as addressed.

Thank you.

Bryan Lakin

29 Broadway
New York, NY 10006
Telephone (212) 952 9230
Fax (212) 422-0059

Late 5/22/00 16

TAPE

1ST Choice for Quality and Value

CPSC/OFFICE OF
THE SECRETARY

2000 MAY 22 P 12:43

May 19, 2000

Ms. Sadye E Dunn
Secretary
Office of the Secretary
Room 502
US Consumer Product Safety Commission
4330 East-West Highway
Bethesda, MD 20814

Re: Petition HP 00-2:
Petition Requesting Rule Declaring Natural Rubber Latex (NRL) a Strong Sensitizer

Dear Madam Secretary·

We are shocked at the ease of how a poorly-informed person or group can threaten an entire industry by requesting legislative or commission action to warn consumers of unsubstantiated claims.

Thousands of working taxpayers in this country are employed by producers of latex products made with imported latex Our tape industry has existed for decades without being suddenly labeled as "hazardous to one's health."

There appears to be a movement in this country, which rewards people who cause destruction to our industrial and manufacturing base through their means and background of approaching governing bodies with semi-truthful, to absolutely untruthful and unfounded accusations. These people create the opportunity for litigious actions by the legal profession, which has no regard for the truth nor the havoc created through their long term law suits and group legal actions, which few industries can afford to defend against

We have been a producer of tape products, which employ latex adhesive systems for twenty years, during which time have not had one single incident of allergic reaction to our products, nor medical confirmation from any employee regarding sensitivity to the product we produce or the raw materials used

Allergy symptoms are rampant in the United States ranging from contact to grass, animals, air we breathe, food we ingest, and clothes we wear Now, we are faced with the outlandish claim by some sponsor-person or group alleging without hard, exact evidence that we are dealing with and providing in the form of a product, a hazardous material

It is time for our government to take action against such self interest groups to protect the manufacturing base in this country from these irresponsible actions designed not for the publics' welfare, but for their own personal interest.

The industrial and consumer-oriented employers of labor, in the United States, should not be harassed by the personal greed of self-serving individuals or groups Proof of claim well beyond, "suspicion," possibilities," or "conjecture," must be the basis of any such action

In our experience, Natural Rubber Latex is not a strong sensitizer and products containing NRL should not be labeled as such.

Respectfully,

Sam Heyman
VP & General Manager

cc. Bryan Lakin, VP Alcan Rubber & Chemical, Inc

SGIA
Screenprinting & Graphic Imaging Association International

R Tape Corporation
6 Ingersoll Road • CN 2002 • South Plainfield, NJ 07080
908-753-5570 • Fax 908-753-5014 • 800-440-1250

MEMBER
ISA
INTERNATIONAL SIGN ASSOCIATION

bob 5/11/00 16

TAPE

1ST Choice for Quality and Value

May 19, 2000

Ms. Sadye E. Dunn
Secretary
Office of the Secretary
Room 502
US Consumer Product Safety Commission
4330 East-West Highway
Bethesda, MD 20814

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Respectfully,

Sam Heyman
VP & General Manager

cc: Bryan Lakin, VP Alcan Rubber & Chemical, Inc.

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6 Ingersoll Road • CN 2002 • South Plainfield NJ 07080
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MEMBER ISA INTERNATIONAL SIGN ASSOCIATION

17

Petition HP 00-2, Petition on Natural Rubber Latex

To: Office of the Secretary, Sadye E. Dunn
Consumer Product Safety Commission
Washington, DC 20207

Comments of: Brenda K. Ray, M.S.N.
390 South Tyndall Parkway, PMB 228
Panama City, FL 32404-6724
(850) 874-0413

To Whom It May Concern:

In 1996 I was diagnosed with Type-I latex allergy. At the time, I was working as a nurse-midwife, having completed my master's training the previous year. In my ignorance, I continued working (I was not warned to avoid *inhaled* NRL dust from medical gloves). I did switch to synthetic medical gloves immediately. A year later I anaphylaxed. My much-loved career ended that day. Little did I know how natural rubber latex (NRL) would impact my life.

In addition to complete financial ruin, loss of our home, my job and career, I also lost my health. I now have lung damage, much like that of silicosis or other occupational dust lung disease. I cannot think of one area of my life that NRL has not altered for the worse.

I won't list the areas of my life in which many of the estimated 40,000 NRL-containing products have impacted my daily life. Whether it's to enjoy our area beaches or go to the mall, I rarely venture out of my home without being reminded of my sensitization to NRL. Latex balloons can be found everywhere. Symbolic of festivity and fun, businesses use them for any special occasion. For me, it ends my fun as I have to remove myself (and my family) from any area where a balloon might burst. As benign as it may sound to you, purchasing a squeeze toy for the family pet could be deadly for me.

I adjure you to list NRL as a "strong sensitizer" so that labeling will be required. Some things in life are beyond our control, but this is not. Please make these petitioned changes; save lives as you also raise the quality of life for many Americans.

Sincerely,

Brenda Ray, M.S.N.

Brenda Ray, M.S.N.

18 bkh 04/19/00

Affirming America's Ongoing Love Affair With Balloons

THE BALLOON COUNCIL

PUBLIC AFFAIRS DIRECTOR
Dale Florio
Princeton House
160 West State Street
Trenton NJ 08608
(800) 233 8887
Fax (609) 989 7491

PUBLIC INFORMATION DIRECTOR
Patricia Barlo
PO Box 176
St Michaels MD 21663
(410) 745-3494
Fax (410) 745 6448

May 16, 2000

2000 MAY 19 A 10:58

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

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

This letter is in response to the Consumer Product Safety Commission's request for comments on a petition to declare products containing natural rubber latex as "strong sensitizers" under the Federal Hazardous Substances Act ("FHSA") The Balloon Council believes that this measure is unwarranted and may indeed needlessly confuse the great majority of the population that is not affected by the issue while not providing any meaningful benefit to that very small percentage of the population for which latex allergies do indeed present a moderate to serious health risk

Latex is and has been used widely in everyday items in the United States for decades and yet has only been associated with allergic reactions in the past ten or so years Latex is a natural product—like bee sting venom, poison ivy, peanuts, or many other such organic substances—and can therefore cause allergy problems ranging from minor skin irritation to reactions that require immediate emergency medical treatment

According to the FDA and the Journal of the American Association of Nurse Anesthetists, at least 94 percent of the population will never have any allergic reaction to latex Today, health care experts driving the anti-latex issue estimate that one to six percent of the general population is sensitive to latex—comparable to the rate for bee venom, peanuts, grass and animal hair Those most at risk of having an allergic reaction to latex are healthcare workers, such as doctors and nurses or spina bifida patients who have had extensive contact with latex through multiple surgeries Within the health care industry population segment there is a dramatic surge above the norm, with sensitivity rates ranging from 8 to 14 percent Further, there is evidence indicating that these people have been sensitized over long periods of protracted skin contact, which generally does not occur from many of the products that would be covered by this regulation, but which does occur from medical protective products already covered by FDA labeling requirements Citing the increased risk for allergic reaction posed by latex products for these workers, in 1998 the FDA required that all latex products carry warning labels to that effect.

May 16, 2000

However, the general public stands a significantly lower likelihood of a reaction than health care workers and thus labeling latex products as "strong sensitizers" may cause unnecessary confusion and alarm among consumers There is little (if any) evidence to support claims that the casual contact with latex products such as balloons will sensitize a person to latex. In fact, tens of thousands of workers who have had close contact with the product for years present evidence to the contrary

Further, there is increasing evidence that estimates of the size of the sensitized population may be greatly overstated Articles in several leading peer-reviewed medical publications suggest that the number of people who actually have an allergic reaction to latex may be less than half (and maybe less than 10%) the commonly-sited "statistics " (Reference citations attached.)

The balloon industry is intent on providing products that are fun and safe for everyone In recent years The Balloon Council has taken numerous steps to educate consumers on the responsible use and disposal of balloons so as to prevent injury and protect the environment Among its many initiatives, The Balloon Council provides balloon retailers and distributors with up-to-date accurate information on latex allergies for them to pass on to consumers This educational approach offers a more meaningful picture to consumers than mandatory labeling

We feel that the scientific evidence does not support mandatory labeling, and that such labeling would not benefit consumers and would indeed harm many people in the latex industry by needlessly frightening consumers We encourage you to not support such labeling

Thank you for the opportunity to provide you with this information

Sincerely,

Daniel A Flynn
Chairman

Enclosure

Recent Articles on Size of Latex Sensitized Population

1. Hamilton, R.G. and N.F. Adkinson. Diagnosis of natural rubber latex allergy: multicenter latex skin testing efficacy study: Journal of Allergy and Clinical Immunology. 1998 Sep;102 (3):482-90.

2. Kim, K.T., E.K. Wellmeyer, and K.V. Miller. Minimum prevalence of latex hypersensitivity in health care workers: Allergy and Asthma Proceedings 1999 Nov-Dec; 20 (6) : 387-90

3. Blanco, C., N. Ortega, M. Alvarez, C. Dominguez, and R. Castillo. Comparison of skin-prick test and specific serum IgE determination for the diagnosis of latex allergy: Clinical and Experimental Allergy 1998 Aug; 28 (8) : 971-6

4. Liss, G.M. and G.L. Sussman. Latex sensitization: occupational versus general population prevalence rates: American Journal of Industrial Medicine 1999 Feb; 35 (2) : 196-200

(1 of 2) 19 5/19/00 2

ALLERGEN REDUCTION, INC.

1202 Ann Street-Madison, WI 53705
Phone 608-257-1330
FAX 608-251-3007

FACSIMILE

TO: Office of the Secretary
COMPANY: Consumer Product Safety Commission, Washington D.C.
FAX NO: 301-504-0127
DATE: 5/19/00

FROM: Jack Trautman, Ph.D.
FAX NO: 608-251-3007
TEL NO: 608-257-1330
Pages: 1

MESSAGE

PETITION HP 00-2

This is to advise you that several latex products have been manufactured from 60% latex emulsion by the technology in our U. S. Patent 5,777,004 and tested (RAST and ELISA assays) for Type I allergens. All have been at or below the detection limits (5 ppm) as determined by an independent testing laboratory. We are in discussions with the major latex product manufacturers to get this technology into production channels.

We do have some significant concerns if the Consumer Product Safety Commission approves this Petition. What kind of labelling would be required or approved for latex products which have no detectable allergens by ASTM testing procedures?

If approved, this type of labelling would have a very serious impact on the consumer confidence of non-detectable allergen latex products. In fact, we believe the availability of non-allergenic products would be materially retarded and have the effect of: 1. slowing the accessibility of these products to those individuals most in need of them, i.e. those whose careers and lives are threatened. 2. increasing the total number of people who will be latex sensitized in the absence of these products in the market place. We feel the most logical solution would be to postpone the labelling deadline a) for a sufficient period to enable this technology to be implemented, and b) provide a labelling catagory for non-detectable allergen products.

Stevenson, Todd A. 20

From: GailRech@webtv net
Sent: Thursday, May 18, 2000 10 15 PM
To: cpsc-os@cpsc.gov
Subject: Petition HP00-2 Petition on Natural Rubber Latex

I would like to see a rule issued declaring that natural rubber latex (NRL), and products containing NRL, are strong sensitizers under the Federal Hazardous Substances Act. (FHSA)
Thank You,
Gail Reshowicz