bdh oc
6/22/00

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

MEMORANDUM

DATE: June 21, 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 CH 00-4

COMMENT	DATE	SIGNED BY	AFFILIATION
CH 00-4-1	6/20/00	Regina Kellner RN, BSN	402 Grand Avenue Mukwonago, WI 53149
CH 00-4-1a	6/20/00	Regina Kellner	address same as above
CH 00-4-2	3/25/00	Nancy Mauser	M235mauser@aol.com
CH 00-4-3	3/27/00	K. Bernard	kbernard@earthlink.net
CH 00-4-4	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
CH 00-4-5	3/30/00	Lauri J. Harris RDH	733 Yorkshire Rd. Neenah, WI 54956
CH 00-4-6	4/28/00	Robert Hamilton Associate Prof. of Medicine and Pathology, Dir. DACI Reference Laboratory	The Johns Hopkins University School of Medicine Room 1A20/5501 Hopkins Bayview Circle Baltimore, MD 21224
CH 00-4-7	5/02/00	Barbara Leather RT	220 W Sylvania Ave, #24 Neptune City, NJ 07753
CH 00-4-8	5/03/00	Colleen Baker BS, RN	39 Greenridge Crescent Hamlin, NY 14464

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CH 00-4-9	5/03/00	Kelly Clinton Ali Clinton Majica Alba Tammy Tahara Veronica Ramirez Sandra Carr	BrsBoots@aol.com
CH 00-4-10	5/11/00	Wayne Gainey	406 Drake Drive Dothan, AL 36305
CH 00-4-11	5/15/00	Anne Clark	118 Ashland Ave. River Forest, ILL 60305
CH 00-4-12	5/18/00	Patricia Szabo MHA, PT	159 Spook Rock Rd. Montebelio, NY 10801
CH 00-4-13	5/12/00	Debbie Butler	111 Princeton Road Exton, PA 19341
CH 00-4-14	5/18/00	Kathleen Caleb	Jordache Lane Spencerport, NY 14559
CH 00-4-15	5/18/00	Bryan Lakin Vice President	Alcan Rubber & Chemical, Incorporated 29 Broadway New York, NY 10006
CH 00-4-16	5/19/00	Sam Heyman VP & General Manager	R Tape Corporation 6 Ingersoll Road CN 2002 South Plainfield, NJ 07080
CH 00-4-17	5/19/00	Brenda Ray M.S.N.	390 South Tyndall Pkwy PMB 228 Panama City, FL 32404
CH 00-4-18	5/16/00	Daniel Flynn Chairman	The Balloon Council 5000 E 29th St, N Wichita,KS 67220
CH 00-4-19	5/19/00	Jack Trautman Ph.D	Allergen Reduction, Inc 1202 Ann Street Madison, WI 53705
CH 00-4-20	5/18/00	Gail Rechowicz	GailRech@webtv.net
CH 00-4-21	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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CH 00-4-22	5/19/00	Lisa Kamenides	kamfam@mediaone net
CH 00-4-23	5/19/00	John Friar II Owner	North American Rubber Thread Co., Inc 106 Ferry Street P.O. Box 1709 Fall river, MA 02722
CH 00-4-24	5/19/00	Richard Oldack President	Dyna-Tech Adhesives Incorporated P.O Box 628 Country Club Road Grafton, WVA 26354
CH 00-4-25	5/20/00	Nancy Mitchell Michael Mitchell	3 Folsom's Pond Rd Wayland, MA 01778
CH 00-4-26	5/21/00	Marianne McAndrew	405 William Salesbury Dr Downingtown, PA 19335
CH 00-4-27	5/21/00	Linda Shaw	107 Catherwood Pl Cary, NC 27511
CH 00-4-28	5/16/00	Marisa Mitchell RN	324 Goodlette Rd S Naples, FL 34102
CH 00-4-29	5/16/00	Diana Cutright RN	4940 Deerfield Way, #101 Naples, FL 34110
CH 00-4-30	5/22/00	Rochelle Spiker Exec. Director	Potomac latex Allergy Association P O Box 52 Greenbelt, MD 20768
CH 00-4-31	5/19/00	Paula Wilkins	28 Wickliffe Drive Naples, FL 34110
CH 00-4-32	5/22/00	Roslyn Hamilton President	Oregon Ecobuilding Network P.O. Box 86444 Portland, OR 97286
CH 00-4-33	5/22/00	Anna Salanti	asalanti@worldnet.att net
CH 00-4-34	5/22/00	Barbara Truitt	trukaras@expecpc com
CH 00-4-35	5/22/00	Lise Borel DMD/Elastic Inc	P.O. Box 2228 West Chester, PA 19380
CH 00-4-36	5/22/00	Tim Mulvihill	t.mulvihill@worldnet att net

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CH 00-4-53	6/08/00	Carol Kuczora	P.O. Box 536 Grass Valley, CA 95945
CH 00-4-54	6/15/00	Anne Fehr	morefehr6@sprint.ca
CH 00-4-55	6/09/00	Gerald Mainman CEO	Northwest Coatings Corp 7221 South 10th St. Oak Creek, WI 53154
CH 00-4-56	6/16/00	Katy Wolf Exe. Director	Institute for Research and Technical Assistance 2800 Olympic Blvd., Suite 101 Santa Monica, CA 90404
CH 00-4-57	5/22/00	Dave Kinnaman	P.O Box 621 Vashon, WA 98070
CH 00-4-58	6/18/00	Cathy Cunningham	walc@lycosmail.com
CH 00-4-59	6/19/00	Bernie Liebler Director Technology and Regulatory Affairs	Health Industry Manufacturers Assoc. 1200 G St, NW Ste 400 Washington, DC 20005
CH 00-4-60	6/20/00	Thomas Tillotson Chairman/CEO	Tillotson Health Care Corporation TILLOTSON@thcnet.com
CH 00-4-61	6/16/00	Daniel McLain Director Becton Dickson Medical Toxicology	BDMT International Operations 21 Davis Drive P.O. Box 12016 Research Triangle Park NC 27709
CH 00-4-62	6/20/00	Michael Burnhill Vice President Medical Affairs	Planned Parenthood Federation of America, Inc. 810 Seventh Ave New York, NY 10019
CH 00-4-63	6/21/00	James Chatterton Vice President Regulatory	Ansell Perry 1875 Harsh Ave, SE Massillon, OH 44646
CH 00-4-64	6/20/00	Dr. Ong Englong Deputy Director General Malaysian Rubber Board	drong@pop.jaring.my

Petition Requesting Rule Declaring Natural Rubber Latex a Strong Sensitizer

CH 00-4-65	6/21/00	Kathryn Beaubien	Lindsay, Hart, Neil & Weigler, LLP 1275 Pennsylvania Ave, NW, Ninth Floor Washington, DC 20004
CH 00-4-66	6/21/00	Peter Friedmann Esq. On Behalf of Microflex Corporation	Address same above
CH 00-4-67	6/21/00	Tracey Norberg Director Environmental Affairs	Rubber Manufacturers 1400 K St., NW Washington, DC 20005
CH 00-4-68	6/21/00	Jan Amundson Vice President & General Counsel	National Association of Manufacturers 1331 Pennsylvania Ave, NW, Washington, DC 20004
CH 00-4-69	6/21/00	Ronald Johnson Associate Exe. Director	Gay Men's Health Crisis, Inc. 119 West 24 St. New York, NY 10011
CH 00-4-70	6/21/00	Sheila Millar Eric Singer Counsel for Bridgestone/ Firestone	Keller and Heckman, LLP 1001 G St, NW, Ste 500 W Washington, DC 20001
CH 00-4-71	6/21/00	Ethan Trull	Allegiance Healthcare Corporation 1430 Waukegan Rd. McGaw Park, IL 60085
CH 00-4-72	6/21/00	Ray Taylor Executive Vice President	Textile Rubber and Chemical Co. 1300 Tianco Dr., SW Dalton, GA 30720
CH 00-4-73	6/21/00	Rachel Subler	America Apparel Manufacturers Assoc 2500 Wilson Blvd. Suite 301 Arlington, VA 22201
CH 00-4-74	6/21/00	Joan Martellotto PhD, RN	1011 Delles Rd Wheaton, IL 60187

Petition Requesting Rule Declaring Natural Rubber Latex a Strong Sensitizer

CH 00-4-75	6/21/00	Judith Herkimer RN	32 Warren Hill Rd Cornwall Bridge, CT 06754
CH 00-4-76	6/21/00	Leslie Gahagan	110 Amherst Ave, #D101 Sheboygan Falls, WI 533085
CH 00-4-77	6/20/00	Sid Smith President and CEO	The Hosiery Association 3623 Latrobe Dr. Suite 130 Charlotte, NC 28211
CH 00-4-78	6/21/00	Frederick Locker Atty	Locker Greenberg & Brainin, P.C. 420 Fifth Ave. New York, NY 10018
CH 00-4-79	6/21/00	Aaron Locker Atty	Locker Greenberg & Brainin, P.C. 420 Fifth Ave. New York, NY 10018

Petition Requesting Rule Declaring Natural Rubber Latex a Strong Sensitizer

CH 00-4-75	6/21/00	Judith Herkimer RN	32 Warren Hill Rd Cornwall Bridge, CT 06754
CH 00-4-76	6/21/00	Leslie Gahagan	110 Amherst Ave, #D101 Sheboygan Falls, WI 533085
CH 00-4-77	6/20/00	Sid Smith President and CEO	The Hosiery Association 3623 Latrobe Dr. Suite 130 Charlotte, NC 28211
CH 00-4-78	6/21/00	Frederick Locker Atty	Locker Greenberg & Brainin, P.C. 420 Fifth Ave. New York, NY 10018
CH 00-4-79	6/21/00	Aaron Locker Atty	Locker Greenberg & Brainin, P.C. 420 Fifth Ave. New York, NY 10018
CH 00-4-80	6/22/00	Ellen Meeropol Ms, RN, CS, PNP	Shriners Hospital for Children Springfield, MA
CH 00-4-81	6/22/00	Sandra Whitehouse	SandraWte@aol.com
CH 00-4-82	6/22/00	E.K. McIntosh Technical Dir.	The Carpet and Rug Institute 310 Holiday Ave. P.O. Box 2048 Dalton, GA 30722
CH 00-4-83	6/26/00	Maureen Glynn Assistant Atty General	150 South Main St. Providence, RI 02903
CH 00-4-84	6/29/00	Judith Weinstein Associate General Counsel	Geber Products Company 560 Morris Ave. Summit, NJ 07901

CH00-1
4

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

Stevenson, Todd A. CH00-4-1 latest 1a

From: Regina Kellner [beargoddus@hotmail com]
Sent: Tuesday, June 20, 2000 3 51 AM
To: cpsc-os@cpsc gov
Subject: Natural Rubber Latex Labeling Request/latex death

cpsc-os@cpsc.gov

Dear Office of the Secretary,

Enclosed is a news story reporting the tragic death of a young woman due to the use of natural rubber latex. An astute observer helped in determining the culprit in this death. This sad story emphasizes the need for consumer product labeling of natural rubber latex (NRL) containing materials.

Millions of people, myself included, must be allowed to protect ourselves from exposures to NRL. The lack of accurate labeling of deceivingly innocuous consumer products presents a persistent danger. Consumer product labeling would help to protect others and myself from a potential life threatening allergic reaction.

At one point in time many products were thought to be safe, but were found to be deadly. Products such as, radiation, asbestos, cigarettes, eventually were recognized for their lethal effects and appropriate use instructions were developed. Please provide the same labeling for consumer products continuing NRL.

Sincerely,

Regina Kellner, RN, BSN
402 Grand Avenue
Mukwonago, WI 53149

http://www.lineone.net/express/00/06/09/news/n1640-d.html
9 June, 2000
Fashion girl killed by her special hair fixing glue
BY MARTIN STOTE
A YOUNG fashion designer died after an allergic reaction to glue she was using to attach hair extensions. Nicola Faulkner, 28, who had been preparing for a dinner dance, collapsed in front of her boyfriend within minutes as her eyes, lips and tongue started to swell and she fought for breath, an inquest heard yesterday. Her scalp started to itch intensely, and a skin rash spread over her body after her cousin attached the weave to the back of her head with American-made Super Hair bonding. Her lungs collapsed and

pockets of air bubbled under the skin. Coroner Selena Lynch recorded a verdict of death by misadventure after hearing that Nicola had suffered an extreme reaction to the latex in the bonding and gone into anaphylactic shock. Nicola's uncle Lloyd Miller said she had a history of allergic reactions to food which contained nuts, and was "fastidious" about checking the labels of cooking ingredients. Nicola's mother Delores wept as she told how her daughter's cousin Sandra Vassell telephoned from her home in Sydenham, South-east London, to alert her. "She said Nicola had had an attack and that an ambulance was there and that she had no idea what was going on," said Mrs Faulkner. "Sandra told me, 'I had fixed the extension weave to the back of her head but I left her to check the dinner. I was only down there for five minutes when she called me and said please remove the bonding weave because I am itching.'" Nicola had thrown open the windows in a desperate attempt to get some fresh air, but collapsed as she turned back to her cousin. Paramedics arrived and she was taken to hospital. Mrs Faulkner travelled from her home in Nottingham to Sydenham to find out what had happened to her daughter. She rummaged through rubbish bins and found the bottle of glue. "I looked around the house and in the bathroom," she said. "There was a chair in front of the mirror where Nicola had been sitting. "I saw two strands of the weaving extensions, and in the bin there was a bottle of bonding glue used to put the extensions in your hair. I saw this container of glue. It was partly used." Mrs Vassell, a former hairdresser, also wept as she told how Nicola had been set to attend a dinner dance that night and had asked for her hair to be styled in a "longish bob". She thought initially that the itching was due to the extensions touching the nape of her neck. Mrs Vassell said she told her cousin: "You'll have to get used to this hair hanging down, girl." Dr Jane Norton, a pathologist from University Hospital, Lewisham, said the reaction to the latex had probably triggered a massive asthma attack.Nicola had used the glue once before without problems. "The first time the specified product is used there is no reaction," said Dr Norton. "It is only the second time that you use the product that you react severely." Coroner Mrs Lynch said: "What a tragic case."

CH00-4-2

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

~~Stevenson, Todd A.~~ CH00-4-3

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

CH00-4-4 Lab 04/3/00

UNIVERSITY OF VIRGINIA
HEALTH SCIENCES CENTER

OFFICE OF THE SECRETARY

DEPARTMENT OF PLASTIC SURGERY

2000 APR -3 A 10:31

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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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

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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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 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

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

1. Kaczmarek, RG, BG Silverman, TP Gross, RG Hamilton, E Kessler, JT Arrowsmith-Lowe, RM Moore Jr. Rubber latex-specific IgE antibodies among emergency room workers Results of a multi-center prevalence study. *Ann Allergy Asthma and Immunol.* 76:51-56, 1996.
2. Amin BV, Bewtra AK, Case report of latex allergy in a healthy infant. J Allergy Clin. Immunol 104:S245, (Abst 726), 2000

Stevenson, Todd A.

Latex comment 7

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

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.~~ 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

Late Comment

Stevenson, Todd A.

From: Majica Alba [majicasonrisa@yahoo.com]
Sent: Wednesday, May 03, 2000 9:22 PM
To: cpsc-os@cpsc.gov
Subject: RE: Petition HP 00-2, Petition on Natural Rubber

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,

Majica Alba

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
>
> >>
>
>

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, bacteria, 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.

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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

12 Later comment ok 5/18/00

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

SECRETARY
2000 MAY 18 A 11: 0

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

6.VP okg 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
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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

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Letter 16

1ST Choice for Quality and Value

TAPE

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

17 Lwb 5/19/00

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

THE BALLOON COUNCIL

Affirming America's Ongoing Love Affair With Balloons

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.

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

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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) 5/19/00

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

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

DATE: 5/19/00

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 Rechowicz

6-62 Sprtd 21

Malaysian Rubber Export Promotion Council
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148 Jalan Ampang
50450 Kuala Lumpur
Malaysia
Tel 603 – 21669918 Fax 603 - 21668018

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

19 May 2000

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

Comments by Malaysia on

The Petition Requesting Rule Declaring Natural Rubber Latex a Strong Sensitizer

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

Natural Rubber Latex (NRL)

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

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

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

b) Even among the workers in the latex / rubber industry, prevalence of Type I hypersensitivity has been shown to be extremely low, as indicated by studies[1] conducted in Malaysia, one of the world's largest rubber producers and the world's largest latex glove manufacturing country.

Products made from natural rubber latex

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

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

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

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

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

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

Non-medical latex gloves Clean-room, household and industrial latex gloves belong to this category. Using the current technologies, these gloves are usually subjected to considerable washing followed by chlorination, a process used to remove tackiness of the gloves and also to facilitate easy donning. Chlorination of latex gloves is effective in reducing residual extractable proteins[2] implicated in the allergy reactions, therefore, these products have extremely low levels of residual proteins/allergens and low allergenicity, and hence are of low risk to the users, unless one is highly sensitive.

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

Dry natural rubber products These products are made from raw dry rubber via a completely different process from that of the latex products. While the starting material of the latter, the latex concentrate, may still retain certain amount of the soluble non-rubber substances from Hevea latex, most of these substances including proteins are removed during processing in the case of the raw dry rubber Fabrication of rubber products at very high temperatures often renders the remaining proteins inactive or denatured. The extremely low residual extractable protein contents of not only the raw dry rubbers, but also their vulcanizates as well as their finished products have in fact been well demonstrated by Yip, Turjanmaa and Makinen-Kiljunin[3]. In addition, both their allergen contents, as assessed by the IgE latex specific RAST-inhibition test, and their allergenicity, as evaluated by the ability to elicit an allergic reaction in latex hypersensitive persons when subjected to the skin prick test, have also been shown to be extremely low. In the latter case, about 90% - 100% of the sensitive subjects tested showed no allergic response (a copy of the paper is attached for your information) Therefore, products made from raw dry rubber as stated above should not be a protein allergy problem for users, unless one is highly sensitive.

As with regards to reports that extracts of NR rubber tire fragments collected from the atmosphere contained residual extractable proteins which exhibited IgE binding activity[4], we analyzed extracts of fragments from a number of new unused NR tires, and found that their residual extractable protein levels were so low that they were below the sensitivity limit of the testing method. It is therefore possible that fragments from the used tires reported were contaminated with other antigens picked up from the roads. The cross-activity of some plant antigens such as those from bananas, avocados, pears, papayas, chestnuts etc. has with latex proteins in demonstrating IgE binding is well documented[5-8].

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

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

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

Tan Sri Wong Kum Choon
Chief Executive Officer
Malaysian Rubber Export Promotion Council (MREPC)

References

1. Azizah M.R , Shahnaz M., Hasma, H., Mok, K L Esah Yip and Nasuruddin B A (1997). Latex protein allergy· A prevalence study of factory workers. *J nat Rubb Res* **11(4)**, 240.

2. Nor Aisah Abd. Aziz (1993) Chlorination of Gloves. *Latex Proteins and Glove Industry,* Rubber Research Institute of Malaysia, 59.

3. Esah Yıp, Turjanmaa K. and Mäkinen-Kiljunın S (1995) The "non-allergenicity" of NR dry rubber products, with reference to type I protein allergy *Rubber Developments* **48(3/4)**, 48.

4. Williams P.B , Buhr M.P. *et al* (1995) Latex allergen ın respırable partıculate air pollutıon" *J Allergy & Clınical Immunology*, **95(Part 1)** , 88.

5. Rodriguez M , Vega F., Garcia K., Sreinhardt G , Wılliam D and Slater J. (1993). Hypersensitivity to latex , chestnut and banana *Ann Allergy*, **70**, 31

6. Makınen-Kıljunin S (1994) Banana allergy in patients with ımmediate-type hypersensitivity to natural rubber latex characterızatıon of cross-reactıng antıbodies and allergens *J Allergy Clın Immunol* **93**, 990.

7. Lavaud F., prevost A., Cossart C , Guerın L., Bernard J and Kochman S (1995) Allergy to latex, avocado, pear and banana – evidence for a 30 kd antigen ın immunoblotting. *J/ Allergy Clın Immunol* **95**, 557.

8. Baux X., Chen Z., Rozynek P , Duser M. and Raulf-Heimsoth M (1995) Cross-reacting IgE antıbodies recognizing latex allergens, ıncludıng Hex b1, as well as papain. *Allergy* , **50**, 604.

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

Esah Yip (Rubber Research Institute of Malaysia), Kristiina Turjanmaa (Tampere University Hospital, Finland) and Soili Mäkinen-Kiljunen (Helsinki University Central Hospital, Finland)

Abstract

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

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

Introduction

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

This allergic reaction has been shown to be due to a very small fraction of residual soluble proteins (EP) containing the allergens found in latex products.[4-8] Research findings[9-13] have shown that the amount of this protein fraction in different latex products prepared from the same latex source varies, depending on the processing procedure employed during their manufacturing For example, it increases[10] when latex is compounded, vulcanized or dried at an elevated temperature of 100°C. It decreases,[9,11-13] on the other hand, when the products are washed/leached in water or chlorinated. The ability of the product to cause the allergic reaction, or its allergenicity, is very much influenced by the quantity of this protein fraction present, as shown by Yip *et al*[14] who demonstrated that both the total residual extractable proteins and the allergenicity are well correlated, that is, high EP contents are always associated with positive allergic reaction when skin-tested on latex hypersensitive persons, and *vice versa*.

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

Methods

Quantitation of extractable proteins – RRIM modified Lowry method

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

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

*Part of this work was presented at the Latex Protein Allergy Conference in Paris 1995

sedimented by centrifugation at 10 000 x g for 30 minutes, and were redissolved in 1ml of 0 2M sodium hydroxide.

Colorimetric measurement: Protein concentration was then determined using the RRIM modified Lowry microassay [16] Procedures involved essentially the addition of 300µl of fresh mixture containing sodium carbonate (6%) and a solution of 1 5% copper sulphate in 3% sodium citrate (mixed in the ratio of 10.0.0.2) to 800µl of redissolved protein test sample After standing for 10 minutes, a volume of 100µl Folin reagent (72%, Sigma Chemical) was introduced. Colour was allowed to develop at room temperature for 30 minutes. Absorbance readings at 750nm were recorded and read against a calibrated curve using bovine serum albumin (BSA) standard.

RAST-inhibition immunoassay:

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

Solid-phase allergens Activated paper discs (Immobilon Affinity Membrane^R, Millipore, Bedford, MA) were coupled with an optimal amount (1.100, v/v) of latex serum prepared by centrifuging non-ammoniated *Hevea* latex after freezing and thawing. The same latex serum was also used as a reference with a given arbitrary activity of 100 000 relative latex units (RLU/ml).

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

Inhibition immunoassay Each rubber sample was cut into pieces and extracted (1:5 weight per volume) in physiological saline in a shaker overnight. Several serial dilutions (1.2 or 1:10) were used from the reference and sample extracts. 30µl of each dilution was incubated with 20µl of the calibrated IgE serum pool in a tube for 3 hours in a shaker, after which one latex disc was added to each tube Contents of the tubes were then allowed to incubate overnight The tubes were washed three times and 50µl of a radio-labelled anti-IgE (Pharmacia, Uppsala, Sweden) was introduced to each tube. After an overnight incubation, the tubes were washed again, and the activity measured in a gamma-counter.

Percentage of inhibition was calculated from the control discs, one with no added inhibitor, and the other for background binding. The allergy activity of the sample was calculated relative to the reference using the parallel line assay method [18] The sensitivity of the method is 0.1µg/ml protein as measured by the Lowry method; the inter-assay coefficient of variation is 20%.

Skin prick test:

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

A drop of the test extract was first placed on the skin of the patient's forearm and pierced through the drop with the tiny one-mm peak of a sterile lancet, creating a small break in the epidermis The size of the wheal developed was measured 15 minutes after application A positive control using histamine dihydrochloride (10mg/ml) and a negative control with the physiological saline were also included in the test battery

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

Results

Residual extractable proteins (EP)

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

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

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

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

Allergenicity

To ascertain the very low or non-allergenicity of dry rubbers and their products, as suggested by their extremely

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

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

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

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

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

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

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

low EP contents, their allergen activity and allergic response, if any, elicited in latex protein hypersensitive patients, were investigated. While the allergen activity was measured using the *in-vitro* method of radioallergosorbent inhibition test (RAST-inhibition),[17] the allergic response was assessed by the *in-vivo* skin-prick test,[19] which is most commonly used for evaluating the Type 1 allergy of immediate hypersensitivity.[20]

Radioimmunoassay of RAST-inhibition In this method, latex allergens were quantitated by allowing the soluble latex allergens in the sample extract to compete with a reference allergen mixture on a solid phase for the binding sites of human IgE antibodies The amount of latex specific antibodies bound to the solid phase was determined, and was inversely proportional to the quantity of latex allergens in the test sample Using this technique, eleven dry rubber samples were examined These included three commercial grades of SMR rubber (both raw and compounded), and five different rubber products. For controls, two samples of latex gloves known to show positive allergenicity and sample of vinyl non-NR gloves were also analysed.

Results in Table 2 showed that except for one sample which indicated a slightly higher value of 6 RUL/ml, all others gave values less than 5 RLU/ml, showing very low

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

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

a. Latex gloves known to show positive allergic responses.

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

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

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

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

Extracts from 14 dry rubber samples of various grades and five different rubber products with pre-determined EP contents, were skin-tested on latex protein hypersensitive subjects. The samples included both the raw and compounded (ACS1 mix) rubbers, vulcanizates (with ACS1 mix and cured at 140°C for 40 minutes) and rubber products such as cut threads, hot water bottles and diver's flippers A total of 31 patients shown to be sensitive to latex proteins were clinically tested in three groups. Results are as shown in Table 3.

There was very little or no allergic response shown by the latex protein hypersensitive patients tested in all cases. These negative observations were substantiated by the strong positive reactions elicited in the same patients by extracts from a certain brand of latex gloves known for their allergenicity

Discussion

Although it is not possible to test all the dry rubber products available in the market, the present study has examined most of the major rubber grades used in the dry rubber product manufacturing industry, either in their raw, compounded or vulcanized forms, as well as several finished products Findings have shown that in all cases, dry rubbers and their products have insignificant amounts of residual extractable protein fraction containing the allergens. Their removal apparently occurred mainly during processing of the raw rubbers, whereby these allergenic proteins were either rendered insoluble by the acid treatment or leached out by the extensive and continuous washing employed throughout the procedure. Subsequently processes converting them into products, such as compounding, vulcanization, and product fabrication, all of which were usually conducted in dry rubber state, did not induce any marked changes to either their low EP content or their 'non-allergenicity'. This is unlike the latex gloves, where their EP increases[9] when the

'wet gel' gloves are vulcanized/dried at elevated temperature, due to migration of more soluble allergenic proteins along with considerable amounts of water to the surface of the latex film as it is being dried [21]

Assessments of both the *in-vitro* and *in-vivo* allergen activities of the test samples by the RAST-inhibition immunoassay and the skin-prick test respectively, have been shown to be consistent with the 'non-allergenicity' of these products as suggested by their remarkably low EP contents It may be of interest to know that these two methods of assessment are very well correlated.[22] It is also noteworthy that these findings confirm the association of low EP contents with low allergen activity, and the near absence of allergen activity or non-allergenicity related to EP levels less than 100µg/g, as reported earlier [14] However, it may be pointed out that there may be an extremely small number of individuals who are highly atopic, and who may develop sensitivity to a great number of things they come in contact with Such people should be identified, treated specially, and allergen avoidance should be recommended

It may be of interest to mention that the inhibition of IgE binding to latex proteins reported for extract of fragments from a worn and contaminated tyre,[13] may not necessarily be due to latex antigens The possibility of some other antigens in the extract effecting such an interaction due to cross-reaction[23] [24] cannot be excluded

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

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Stevenson, Todd A.

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

To Whom It may Concern:

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

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

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

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

Thank you for your time,

Lisa Kamenides Disabled RN with Type 1 *N*atural *R*ubber *L*atex *A*llergy, son age 6 with type 1 *NRLA*

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May 16, 2000

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

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

Dear Madam Secretary:

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

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

1 ADOPTION OF THE PETITION WOULD CAUSE UNJUSTIFIABLE ALARM TO CONSUMERS

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

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

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

2. ADOPTION OF THE PETITION WOULD CAUSE UNJUSTIFIABLE HARM TO CONSUMERS

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

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

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

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

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

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

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

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

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