

HP 00-2

Tuesday, January 18, 2000

CPSC/OFFICE OF THE SECRETARY

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Offices of the Secretary
Consumer Product Safety Commission
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Bethesda MD 20816
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CPSA 6 (b)(1) Cleared

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Citizen Petition

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

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

A. Action Requested

1. Amendment of sec. 1500.13, to add to list of "strong sensitizers, Natural Rubber Latex (NRL) and products containing NRL; and that said substance and products be labeled per sec. 1500.3(A)(2)(12),(13) and (14).
2. In accordance with sec. 1500(b)(15)(i), re: "Banned hazardous substances"; to require labeling of toys or other articles intended for use by children which may contain NRL under sec. 1500.3(b)(9).

B. Statement of grounds

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

2. The scientific findings described below, clearly contradict consensus re: NRL. When the list of "Strong sensitizers" in sec. 1500.13 was codified, per the attached page from a report, "Rubber sensitizers", by Susan E. Feinman, Ph.D., sent to Sandra Eberle, Chemical Hazards Program, OPM, on 29, December 1986. Introductory sub-paragraph (A), "Purpose of Report", states, "The purpose of this report is to evaluate whether certain rubber additives are bioavailable from consumer products in sufficient quantities to elicit

Latex Allergy News

allergic hypersensitivity responses and whether they should be labeled by the commission as strong sensitizers under the Federal Hazardous Substance Act. Subparagraph (c), "Rubber Sensitization, state, "Natural rubber poses no hazard as a contact allergen (Cronin, 1980)". The subparagraph concludes, "Thus consumers attributing allergic contact dermatitis to "rubber" are actually reacting to rubber additives".

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

4. The Journal of the Academy of Dermatology (Vol. 39, No. 1, July 1998) article, "Latex Allergy", summary states: "coined the next major health concern of the decade, allergy to natural rubber latex affects people routinely exposed to rubber products, groups at highest risk include health care workers, rubber industry workers, and persons who have undergone multiple surgical procedures, especially those with spina bifida. Allergy to latex is a type I, immediate, IgE - mediated reaction, which can lead to anaphylaxis and death. Much of latex research is published in allergy journals." The attached Journal article pages 1, 3, 5, 6 and 7, describe common nonmedical household products containing NRL; prevalence of latex allergy in the general and occupational populations; and allergy "risk factors", per attached with reference citation. The prevalence of latex in the general population is probably less than 2%. However, the accompanying Table IV list six authoritative sources for "% of positive", using different methods of testing, and the range from 08% to 7.9%. Pages 5 ad 6 and Table V cites studies reporting much higher latex sensitivity rates among certain populations. Children with Spina Bifida "currently 8 of 10 anaphylactic reaction occurring during surgery in all children are due to latex allergy". More recent studies are reporting the 65% of those children with Spina Bifida. Similar studies show the "up to 69%" of health care workers and 10% of hairdressers have been sensitized

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

6. The cover page of Mary Ann Henderson's letter mentions my name, Debi Adkins, in association with The Latex Allergy Information Service. I am Editor of "The Latex Allergy News", a newsletter with 10,000 subscribers and 942 daily visitors to its Web site: (one of five or ten latex allergy related web sites). However my interest in latex allergy is personal as well as professional. Briefly, I was a health care worker for 22 years, before I

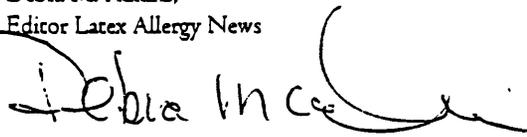
developed a life threatening latex allergy. I have very limited access to health care, and have to be very aware of latex products where ever I visit. That is why I have travel into New York City for any dental care, a distance of over 90 miles one way. Any and all of my physicians are made aware of the implications, and reactions and schedule any of my appointments for early in the day, to try to insure my safety.

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

C. Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Debra M. Adkins,
Editor Latex Allergy News





CONTINUING MEDICAL EDUCATION ART 105 98

Latex allergy

Erin M. Warshaw, MD *Minneapolis, Minnesota*

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

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

HISTORY OF RUBBER PRODUCTION

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

Unfortunately, early rubber products became brittle under cold conditions as well as sticky with age. These problems were solved in 1839 when Goodyear accidentally discovered vulcanization, a process that utilizes sulfur to stabilize the elastic

properties of rubber. Dunlop invented the inner tube and hollow tire in 1888,¹ and the first pair of rubber gloves was made by the Goodyear Rubber Company in 1890 at the request of William Stuart Halstead of breast surgery fame.² In 1850, Wickham, a British rubber planter in Brazil, introduced rubber seeds into Asia, now the major supplier of raw latex.³

HISTORY OF RUBBER ALLERGY

Two types of allergic reactions to rubber products are now known: type I (immediate-type) and type IV (delayed-type hypersensitivity [DTH]) (Table I). The first case of an immediate reaction to NRL was reported in 1927 by Stern⁴ who described severe generalized urticaria caused by a rubber dental prosthesis. Almost half a century later, Nutter⁵ reported the first glove-related case of an immediate-type reaction, contact urticaria. Soon after, several researchers⁶⁻¹⁰ established a link between NRL glove-induced symptoms and IgE mechanisms.

From *Dermatology*, University of Minnesota and the Veterans Affairs Medical Center.

Reprint requests: Erin M. Warshaw, MD, Dept. 111K Dermatology, VA Medical Center, 1 Veterans Dr., Minneapolis, MN 55417.

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

SEEKING PERMISSION 3/8/2000

Consumer Product Incident Report

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

YOUR NAME [REDACTED]

YOUR ADDRESS
CITY SAN DIEGO STATE CA ZIP 92111

YOUR TELEPHONE [REDACTED]

NAME OF VICTIM (IF DIFFERENT FROM ABOVE) SAME

ADDRESS
CITY STATE ZIP

TELEPHONE

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

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

DESCRIBE PRODUCT INVOLVED LATEX EXAM GLOVES

PRODUCT BRAND NAME/MANUFACTURER

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

WHEN WAS THE PRODUCT PURCHASED?

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



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Washington, DC 20207

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YOUR NAME

YOUR ADDRESS

CITY

STATE

ZIP

YOUR TELEPHONE

NAME OF VICTIM (IF DIFFERENT FROM ABOVE)

ADDRESS

CITY

STATE

ZIP

TELEPHONE

DESCRIBE THE INCIDENT OR HAZARD, INCLUDING DESCRIPTION OF INJURIES

Latex Balloons in hotels, restaurants sports arenas, grocery stores + florists shop cause ^{my} eyes to water + itch, and my throat to swell even after brief (2-3 minute) contact. MYLAR balloons are latex free + should be the only balloons used unless notice posted on the entrance.

VICTIM'S AGE

57

SEX

F

DATE OF INCIDENT

CONSTANT - multiple dates.

DESCRIBE PRODUCT INVOLVED

Latex balloons

PRODUCT BRAND NAME/MANUFACTURER

IS PRODUCT INVOLVED STILL AVAILABLE?

YES

NO

PRODUCT MODEL AND SERIAL NUMBER

WHEN WAS THE PRODUCT PURCHASED?

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Washington, DC 20207

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YOUR NAME

YOUR ADDRESS

CITY

STATE

ZIP

YOUR TELEPHONE

NAME OF VICTIM (IF DIFFERENT FROM ABOVE)

ADDRESS

CITY

STATE

ZIP

TELEPHONE

DESCRIBE THE INCIDENT OR HAZARD, INCLUDING DESCRIPTION OF INJURIES

Throat began swelling 1 hr after eating a hamburger at Burger King in Minnesota (no. Mankato?)

Also 2 Bar B Q restaurants in Kennville, + Comfort, TX - If gloves are mandatory in restaurants, vinyl (not latex) gloves should be used or a latex sign posted.

VICTIM'S AGE

57

SEX

F

DATE OF INCIDENT

May 98 + Feb 99

DESCRIBE PRODUCT INVOLVED

Latex gloves by food workers

PRODUCT BRAND NAME/MANUFACTURER

IS PRODUCT INVOLVED STILL AVAILABLE?

YES

NO

PRODUCT MODEL AND SERIAL NUMBER

WHEN WAS THE PRODUCT PURCHASED?

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YOUR NAME

YOUR ADDRESS

CITY

SOUTH EASTON

MASS

02375

STATE

ZIP

YOUR TELEPHONE

NAME OF VICTIM (IF DIFFERENT FROM ABOVE)

ADDRESS

CITY

STATE

ZIP

TELEPHONE

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

DESCRIBE THE INCIDENT OR HAZARD, INCLUDING DESCRIPTION OF INJURIES

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

VICTIM'S AGE

46

SEX

F

DATE OF INCIDENT

FIRST DIAGNOSED 6/94

DESCRIBE PRODUCT INVOLVED

LATEX GLOVES

PRODUCT BRAND NAME/MANUFACTURER

ALL BRANDS AND MANUFACTURERS

IS PRODUCT INVOLVED STILL AVAILABLE?

YES

NO

PRODUCT MODEL AND SERIAL NUMBER

WHEN WAS THE PRODUCT PURCHASED?

* IT IS NOW IMPERATIVE THAT I BE AWARE OF THE NATURAL RUBBER LATEX CONTENT IN ALL PRODUCTS.

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YOUR NAME (parents) _____

YOUR ADDRESS _____

Pittsburgh PA 15217
CITY STATE ZIP

NAME OF VICTIM (IF DIFFERENT FROM ABOVE) _____

same as above
ADDRESS _____

CITY STATE ZIP _____

TELEPHONE _____

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

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

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

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

DESCRIBE PRODUCT INVOLVED Latex gloves and balloons

PRODUCT BRAND NAME/MANUFACTURER _____

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

WHEN WAS THE PRODUCT PURCHASED? _____

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YOUR NAME

YOUR ADDRESS

CITY

STATE

ZIP

NAME OF VICTIM (IF DIFFERENT FROM ABOVE)

ADDRESS

CITY

STATE

ZIP

TELEPHONE

DESCRIBE THE INCIDENT OR HAZARD, INCLUDING DESCRIPTION OF INJURIES

Attended Springfield Mass. RV Show, walked in balloons every where, clown's w/balloons after 30 minutes difficulty breathing, throat sticking, took inhalers & ~~Med~~ put on respirator surgical mask, 30 more minutes later had to leave building, eyes burning, headache, difficulty breathing, ^{continues} ~~attach~~

VICTIM'S AGE

34

SEX

F

DATE OF INCIDENT

Approx wknd Feb. 20th, 1999.

DESCRIBE PRODUCT INVOLVED

Latex balloons

PRODUCT BRAND NAME/MANUFACTURER

IS PRODUCT INVOLVED STILL AVAILABLE?

YES

NO

PRODUCT MODEL AND SERIAL NUMBER

WHEN WAS THE PRODUCT PURCHASED?

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Incident continued:

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

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YOUR NAME

YOUR ADDRESS

CITY

STATE

ZIP

NAME OF VICTIM (IF DIFFERENT FROM ABOVE)

ADDRESS

CITY

STATE

ZIP

TELEPHONE

DESCRIBE THE INCIDENT OR HAZARD, INCLUDING DESCRIPTION OF INJURIES

Washed runner rugs with rubber backing - Took out of dryer 10:30pm - hands became extremely itchy, nose runny, sneezing - overwhelming tiredness. Woke up at 2:30am - felt like ~~the wire~~ ~~through~~ ~~to~~ chest; whole system ~~rotated~~ ~~with~~ wire brush, crushing chest pain - took 14 days for systems to return to normal

VICTIM'S AGE

34

SEX

F

DATE OF INCIDENT

2/3/99

DESCRIBE PRODUCT INVOLVED

Everyday - runner rug

PRODUCT BRAND NAME/MANUFACTURER

- bought at Walmart

IS PRODUCT INVOLVED STILL AVAILABLE?

YES

NO

PRODUCT MODEL AND SERIAL NUMBER

WHEN WAS THE PRODUCT PURCHASED?

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YOUR NAME [REDACTED]
YOUR ADDRESS [REDACTED]
New Hartford, CT 06057
CITY STATE ZIP
YOUR TELEPHONE [REDACTED]

NAME OF VICTIM (IF DIFFERENT FROM ABOVE)
Same
ADDRESS
CITY STATE ZIP
TELEPHONE

DESCRIBE THE INCIDENT OR HAZARD, INCLUDING DESCRIPTION OF INJURIES
My husband got new work boots 2 pairs, had very noticable strong glue smell. My nose started becoming congested, raw feeling. Approx 2 hrs later granular sputum coming up, difficulty breathing very tired - went to bed - all I could smell was shoe glue - got up - took offensive boots out onto porch. Fri 8/6/99 am upon waking nose is swollen, inside very raw, 2 days later granular sputum still coming up.
VICTIM'S AGE 34 SEX F DATE OF INCIDENT 8/5/99 am

DESCRIBE PRODUCT INVOLVED Near Guard Hi-top leather work boot - steel toes
PRODUCT BRAND NAME/MANUFACTURER Near Guard

IS PRODUCT INVOLVED STILL AVAILABLE YES NO PRODUCT MODEL AND SERIAL NUMBER
WHEN WAS THE PRODUCT PURCHASED? 8/99 [REDACTED]

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CITY St. Peters MO STATE MO ZIP 63376
 ADDRESS _____
 CITY _____ STATE _____ ZIP _____

NAME OF VICTIM (IF DIFFERENT FROM ABOVE) _____
 ADDRESS _____
 CITY _____ STATE _____ ZIP _____
 TELEPHONE _____

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

VICTIM'S AGE 50 SEX F DATE OF INCIDENT _____

DESCRIBE PRODUCT INVOLVED linen, underwear, swimtrunks, slacks of latex allergy or that I had to give away many items I thought owned before learning
 PRODUCT BRAND NAME/MANUFACTURER Hanes, Platrix + others had thought were safe.

IS PRODUCT INVOLVED STILL AVAILABLE? YES NO PRODUCT MODEL AND SERIAL NUMBER _____
 WHEN WAS THE PRODUCT PURCHASED? _____

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Washington, DC 20207

EVENING TELEGRAM

SUPERIOR, WI
DAILY 12,661

SATURDAY
SEP 19 1992

BUBELLE'S

243
...en

TH

Area girl may have died from allergic reaction

By PEG LAMKIN
Telegram Correspondent

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

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

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

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

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

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

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

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

MINNESOTA DEPARTMENT OF HEALTH
Section of Vital Statistics
CERTIFICATE OF DEATH

LOCAL FILE NUMBER

STATE FILE NUMBER

1. DECEASED'S NAME (Last, first, middle) DENISE RAE OENBREIT		2. SEX Female		3. DATE OF DEATH (month, day, year) September 16, 1992		4. TIME OF DEATH 1300	
5. SOCIAL SECURITY NUMBER 394-84-9820		6. AGE (Last birthday observed) 13		7. MARRIAGE (1 YEAR) months days		8. DATE OF BIRTH (month, day, year) July 22, 1979	
9. BIRTHPLACE (city and state or foreign country) Rice Lake, Wisconsin		10. WAS INCIDENT EVER IN U.S. ARMED FORCES? (Specify year or year)		11. PLACE OF DEATH (check only one - see instructions on other side) <input checked="" type="checkbox"/> HOSPITAL <input type="checkbox"/> (X) Outpatient <input type="checkbox"/> OTHER <input type="checkbox"/> Nursing home <input type="checkbox"/> Residence <input type="checkbox"/> Inpatient <input type="checkbox"/> OGA <input type="checkbox"/> Other (specify)			
12. FACILITY NAME (if not institution, give street and number) United Hospital Childrens		13. CITY (if different from place) St. Paul		14. COUNTY OF DEATH Ramsey			
15. MARITAL STATUS - Married, Never Married, Widowed, Divorced (Specify) Never Married		16. SPOUSE - Name if wife, give maiden name		17. DECEASED'S USUAL OCCUPATION (give kind of work done during period of working life. Do not use retired) Student			
18. LEVEL OF EDUCATION Education		19. STATE OF BIRTH Wisconsin		20. COUNTY Barron		21. ZIP CODE 54822	
22. HOME ADDRESS (Specify street, city, state, zip code) 1908 10 1/2 Avenue Cameron, WI		23. WAS DECEASED IN FOREIGN BIRTH? (Specify year or years - if yes, specify Country, Province, Puerto Rican, etc.) <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		24. RACE (Leave instructions on other side) White			
25. DECEASED'S EDUCATION (Specify only highest grade completed: Elementary/Secondary 0-12; College 13-16 or 17-19)		26. FATHER'S NAME (First, middle, last) Gari Donald Odenbreit		27. FATHER'S BIRTH ADDRESS (Street and Number or Rural Route Number, City, State, Zip Code) 2348 4 1/2 Avenue Chetek, Wisconsin 54728			
28. DECEASED'S NAME (First, middle, maiden surname) Catherine Mae Metz		29. DECEASED'S NAME (Last, first, middle) Gari Donald Odenbreit		30. MANNER OF DEPOSITION <input checked="" type="checkbox"/> Burial <input type="checkbox"/> Cremation <input type="checkbox"/> Burial then stone <input type="checkbox"/> Donation <input type="checkbox"/> Other (specify)			
31. PLACE OF DEPOSITION (Name of cemetery, crematory, or other place) Pine Grove Cemetery		32. LOCATION - City or Township, State Cameron, Wisconsin		33. SIGNATURE OF FUNERAL DIRECTOR OR PHYSICIAN <i>[Signature]</i> 2855			
34. LICENSE NUMBER (of Funeral Establishment) 0383		35. NAME AND ADDRESS OF FUNERAL ESTABLISHMENT O.E. Larson-Osborne Mortuary 2301 Central Avenue NE, Minneapolis, MN 55418		36. CERTIFICATION PHYSICIAN I attended the decedent from _____ to _____ on _____ day year _____ on _____ day year _____ and last saw her/him on _____ on _____ day year _____ <input checked="" type="checkbox"/> And will view the body after death.			
37. SIGNATURE (Physician, Medical Examiner, or Coroner) <i>[Signature]</i>		38. LICENSE NUMBER (of physician) 0244921		39. DATE SIGNED (month, day, year) 10-7-92		40. REGISTERED DEATH <i>[Signature]</i> Deputy DATE FILED (month, day, year) OCT 13 1992	
41. NAME AND ADDRESS OF <input type="checkbox"/> PHYSICIAN <input checked="" type="checkbox"/> MEDICAL EXAMINER OR CORONER MICHAEL B. MCGEE, M.D. 155 HILL ST. ST. PAUL, MN 55102		42. CAUSE OF DEATH (List the Sequence, manner or complications that caused the death. Do not enter the mode of dying, such as cardiac or respiratory arrest, shock, or brain failure. List only one cause on each line.) ANOXIC ENCEPHALOPATHY due to or as a consequence of: RESPIRATORY ARREST due to or as a consequence of: PROBABLE STATUS ASTHMATICUS		43. I Express deferred <input type="checkbox"/> death toll		Approximate interval between onset and death	
44. SPECIFIC CAUSE (List disease or condition resulting in death) Specify immediately (or conditions, if any, leading to immediate cause from WHICH THIS CAUSE ISSUES or injury that initiated events resulting in death) LAST		45. PART 2. OTHER SIGNIFICANT CONDITIONS contributing to death but not resulting in the underlying cause given in Part 1		46. WAS CASE REFERRED TO MEDICAL EXAMINER OR CORONER? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		47. WAS AN AUTOPSY PERFORMED? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
48. WERE AUTOPSY FINDINGS AVAILABLE PRIOR TO COMPLETION OF CAUSE OF DEATH? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		49. DATE OF DEATH (month, day, year)		50. TIME OF DEATH		51. PLACE OF DEATH - At home, farm, street, factory, office building, etc. (Specify)	
52. MANNER OF DEATH <input checked="" type="checkbox"/> Natural <input type="checkbox"/> Accident <input type="checkbox"/> Suicide <input type="checkbox"/> Homicide <input type="checkbox"/> Pending investigation <input type="checkbox"/> Could not be determined		53. PLACE OF BIRTH (At home, farm, street, factory, office building, etc. (Specify))		54. LOCATION - Street and number		55. CITY or Township, State	

STATE OF MINNESOTA
RAMSEY COUNTY

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

(Signed) *[Signature]*, this 3rd day of April 1992
Deputy Registrar, Vital Statistics

CONSUMER PRODUCT INCIDENT REPORT

1. NAME OF RESPONDENT Mary Ann Henderson		2. TELEPHONE NO. (Home) (Work) 816-619-2933	
3. STREET ADDRESS 205 S. Main, Apt. B P.O. Box 446		4. CITY STATE ZIP CODE Drexel MO 64742	
5. DESCRIBE ACCIDENT SITUATION OR HAZARD, INCLUDING DATA ON INJURIES. (Use second page if necessary.) My son NAVY Lt. Harold R. Henderson, died on August 29, 1997 due to complication from Latex poisoning.			
6. DATE OF INCIDENT(S) 8/29/97	7. IF INJURY OR NEAR MISS, OBTAIN AGE <u>40</u> SEX <u>Male</u> AND DESCRIBE INJURY <u>latex poisoning</u>	8. IF VICTIM DIFFERENT FROM RESPONDENT, PROVIDE NAME <u>Lt. Harold R. Henderson</u> RELATIONSHIP <u>Son</u>	
9. DESCRIPTION OF PRODUCT Use of latex rubber gloves		10. BRAND NAME See attached sheet	
11. MANUFACTURER/DISTRIBUTOR NAME, ADDRESS & PHONE See attached sheet		12. MODEL, SERIAL NO.'S 13. DEALER'S NAME, ADDRESS & PHONE See attached sheet	
14. WAS THE PRODUCT DAMAGED, REPAIRED OR MODIFIED? YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> IF YES, BEFORE OR AFTER THE INCIDENT? <u>Trying to make changes</u> Describe <u>DEAD!! From effects of latex poisoning</u>		15. PRODUCT PURCHASED NEW <input type="checkbox"/> USED <input type="checkbox"/> DATE PURCHASED _____ AGE _____	
17. HAVE YOU CONTACTED THE MANUFACTURER? YES _____ NO <input checked="" type="checkbox"/> IF NOT, DO YOU PLAN TO CONTACT THEM? YES <input checked="" type="checkbox"/> NO _____ OTHER _____		18. IS THE PRODUCT STILL AVAILABLE? YES <input checked="" type="checkbox"/> NO _____ IF NOT, ITS DISPOSITION _____	19. MAY WE USE YOUR NAME WITH THIS REPORT? YES <input checked="" type="checkbox"/> NO _____
FOR ADMINISTRATION USE			
20. DATE RECEIVED	21. RECEIVED BY (Name & Office)	22. DOCUMENT NO. X9832148	
23. FOLLOW-UP ACTION		24. PRODUCT CODE(S)	
25. DISTRIBUTION		26. ENDORSER'S NAME & TITLE	

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

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

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

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

When I went to San Diego, California the end of July 1996 to attend my sons beautiful wedding the beginning of August to his wonderful lady Christine, I saw how his 6' 7 1/2" body had gone down hill. We had to all most hold him up for the

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

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

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

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

potential for progression of this Condition!

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

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

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

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

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

He leaves many friends both in nursing and outside world.

To the Wisconsin legislation, thanks for caring.

Sincerely,

Mary Ann Henderson

205 E. Main, Apt. B

P.O. Box 246

DREXEL, Missouri
64742

Phone:

1-816-619-2933

CONSUMER PRODUCT INCIDENT REPORT

1. NAME OF RESPONDENT Mary Ann Henderson		2. TELEPHONE NO. (Home) (Work) 816-619-2933		
3. STREET ADDRESS 205 E. Main, Apt. B P.O. Box #16		4. CITY Drexel	STATE MO	ZIP CODE 64742
5. DESCRIBE ACCIDENT SITUATION OR HAZARD, INCLUDING DATA ON INJURIES. (Use second page if necessary.) My son Navy Lt. Harold R. Henderson, died on August 29, 1997 due to complication from Latex poisoning.				
6. DATE OF INCIDENT(S) 8/29/97	7. IF INJURY OR NEAR MISS, OBTAIN AGE <u>40</u> SEX <u>Male</u> AND DESCRIBE INJURY <u>latex poisoning</u>	8. IF VICTIM DIFFERENT FROM RESPONDENT, PROVIDE NAME <u>Lt. Harold R. Henderson</u> RELATIONSHIP <u>Son</u>		
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14. WAS THE PRODUCT DAMAGED, REPAIRED OR MODIFIED? YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> IF YES, BEFORE OR AFTER THE INCIDENT? <u>Trying to make changes</u> Describe <u>DEAD!! From effects of latex poisoning</u>		15. PRODUCT PURCHASED NEW <input type="checkbox"/> USED <input type="checkbox"/> DATE PURCHASED _____ AGE _____ 16. DOES PRODUCT HAVE WARNING LABELS? IF SO, NOTE: <u>NO</u> _____ _____ NO NO NO		
17. HAVE YOU CONTACTED THE MANUFACTURER? YES _____ NO <input checked="" type="checkbox"/> IF NOT, DO YOU PLAN TO CONTACT THEM? YES <input checked="" type="checkbox"/> NO _____ OTHER _____	18. IS THE PRODUCT STILL AVAILABLE? YES <input checked="" type="checkbox"/> NO _____ IF NOT, ITS DISPOSITION _____	19. MAY I USE YOUR NAME WITH THIS REPORT? YES <input checked="" type="checkbox"/> NO _____		
FOR ADMINISTRATION USE				
20. DATE RECEIVED	21. RECEIVED BY (Name & Office)	22. DOCUMENT NO. X983248		
23. FOLLOW-UP ACTION		24. PRODUCT CODE(S)		
25. DISTRIBUTION		26. ENCLASER'S NAME & TITLE		

T-23

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

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

I'm starting my next line of work in the name of my son to contact as many latex manufacturers that I can. And relate what their product can cause.

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

Mary Ann Henderson March 16, 1998
Signature Data

I request that you do not release my name.

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

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

I-23

X9832145

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

See attached sheet.

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

Mary Ann Henderson
Signature 3-21-98
Date

I request that you do not release my name.

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

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

X9832148

I-23

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Page 7

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He leaves many friends both in nursing and outside world.

To the Wisconsin Legislature, thanks for caring.

Sincerely,

Mary Ann Henderson

205 E. Main, Apt. B

P.O. Box 246

DREXEL, Missouri
64442

Phone:

1-816-619-2933

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

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

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

Senators

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

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

Missouri State House

District 31st.
Harold L. Casbey
Room 320
State Capital
Jefferson City, Mo. 65102

SKELTON
DANCE BUILDING
20515-2504
225-2878

514-B N.W. SEVEN HIGHWAY
BLUE SPRING, MO 64014-2731
(816) 228-4242

1818 INDUSTRIAL DRIVE
JEFFERSON CITY, MO 65109-144
(573) 635-3499

219 NORTH ADAMS STREET
LEBANON, MO 65536-3000
(417) 532-7964

319 SOUTH LAMME
FEDERAL BUILDING
SEDALIA, MO 65301-4593
(816) 826-2675

Congress of the United States

House of Representatives

Washington, DC 20515-2504

January 22, 1998

Mary Ann Henderson
E Main, #B
Box 246
Kel, MO 64742

Dear Ms. Henderson:

Thank you for writing to me with your concerns regarding latex allergies. I appreciate hearing from you on this issue.

I regret that you have had such a devastating experience. I am pleased that you have the time to share the tributes to your son as well as the information on latex allergies. Although no legislation preventing the use of latex products by health care providers is before Congress at this time, rest assured that I will keep you and your son in mind and should related legislation come to the House floor in the days ahead.

Again, thank you for getting in touch with me. Please do not hesitate to contact me in the future. With best regards, I remain

Very truly yours,



IKE SKELTON
Member of Congress

United States Senate

WASHINGTON, DC 20510-2504

January 15, 1998

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

Dear Mary:

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

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

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

Sincerely,



John Ashcroft
United States Senate

JDA:sem

Obituaries

Lieutenant Harold R. "Hal" Henderson

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

Lieutenant Henderson, who had worked at Balboa Medical Center as an intensive care and emergency nurse, served in Desert Storm and was recently accepted into a master's program for nursing and community health at San Diego State University. Hal is survived by his mother Mary Ann Henderson and wife, Christine. The couple's first year anniversary was August 4, 1997. He leaves his children, Cara Jo, Brandon Paul and

Harold R. Henderson Jr., as well as step-children: Nathaniel and Matthew Davis. Sadly, Lt. Hal Henderson died on Hal Jr.'s 9th birthday.

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

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

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

Hal's many successes will continue to receive attention, his spirit of public service is one to be admired and emulated. He wanted so much to prevent others from having to go

through the same needless loss of career, health and self-esteem, that he did. Hal, the members of ELASTIC, trust your wish; to prevent others

from suffering from latex allergy, as you have, will be granted. It is our pledge to continue your work, to continue to increase awareness, inform and educate. Perhaps your tragic and needless death will open the eyes of those who doubt, maybe this new-found awareness and a nudge from an angel or two, will allow your wish to be become reality.

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

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

A Tribute to a Fallen Comrade

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

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

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

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

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

Hal Henderson died August 29, 1997.
He was the Military advisor for

ELASTIC.
He may be gone from our sights
but never our hearts and minds.
In Memory—Pat Lawson, CST