

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

4. PETITION IS UNNECESSARY IN LIGHT OF EXISTING RECENT REGULATIONS

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

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

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

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

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "John Friar II".

John Friar II, Owner

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

May 19, 2000

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

“Petition HP 00-2, Petition on Natural Rubber Latex”

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

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

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

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

Sincerely,


Richard Oldack
President

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

~~Stevenson, Todd A.~~

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

Importance: High

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

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

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

Sincerely,

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

~~Stevenson, Todd~~

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

Dear Consumer Product Safety Commission:

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

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

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

Sincerely,

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

Lester 27

TO Sadye Dunn
Secretary to Consumer Safety Product Commission
Offices of the Secretary
Consumer Product Safety Commission
Mail Address Washington, DC 20207
Delivery Address Room 420
5401 Westbard Ave
Bethesda, MD 20816
Tel 301-504-0800
Fax. 301-504-0127

From Linda Shaw
107 Catherwood Pl
Cary, NC 27511

Re Position Statement/Comments on Citizen Petition HP-00-2 on Classifying Natural Rubber Latex as a Hazardous Substance, and requiring all substances and products Containing NRL be labeled

Please pass this petition.

My Son is a consumer in the United States of America. He is six years old. My Son is allergic to Natural Rubber Latex. This is my position on the Citizen Petition HP-00-2 on Classifying Natural Rubber Latex as a Hazardous Substance. This bill needs to be passed in order to save and protect millions of lives including children which have been needlessly exposed to the NRL protein that can cause hazardous risk of injury and/or death. Had this bill been presented and passed before 1993, my son would have been spared the horrible unreasonable injury and risk of death he now has to endure for the rest of his life. The manufacturers of Natural Rubber Latex have knowingly done a disservice to our American Citizens in the last several years and it is now time to correct this matter.

This is what my son's life is like. He came into our world in September of 1993 a healthy infant. The second he was pulled from the womb by Natural Rubber Latex gloves, he was exposed to the harmful Natural Rubber Latex proteins. Hereafter, I shall refer as NRL to abbreviate Natural Rubber Latex. The FDA knew in 1991 that the Natural Rubber Latex Proteins were a danger to the health of the American Citizens of these United States of America. Did they pull the plug on the manufacturers to protect innocent lives? If they had, then my Son would not have to be disabled at this point. Because of whatever reason, which, by the way, does not justify destroying any human right to good health, my Son is now, like millions of others disabled for the rest of his life. I plead to you, the Consumer Product Safety Commission to PASS the Citizen Petition HP-00-2 To require all products including general consumer use products to carry a warning label that the product contains Natural Rubber Latex, a hazardous substance, and that this product can be harmful to your health.

I also ask you to send a clear message back to all manufacturers of these products requiring that manufacturers be allowed to manufacture and sell only safe products. Require labeling these products clearly. Stating what active or non-active or supportive materials and the clear labeling of hazardous materials and their effect on the body, which will then in turn allow the consumer to make a knowledgeable decision as to whether or not to purchase the product based on what the label clearly states the product is made of. It is my understanding of the general knowledge that I was able to obtain from the Internet, that the manufacturers of Natural Rubber Latex stopped a crucial part of the manufacturing process that would have kept their product safe for the consumer. However, the manufacturers of the NRL products chose instead to sell out the safety of their product in favor of mass profits. The very act of doing this and not labeling the products that contained the hazardous NRL proteins made it impossible for me as a consumer to make a crucial decision in purchasing safe products for the sole purpose of caring for my son. The manufacturers of these products were solely interested in profits and not the safety of a parent's child's health. I, as a consumer was misled by their advertising and lack of labeling the products as potentially causing such a debilitating allergy to the consumers that these products are intended for.

Manufacturers of the products containing NRL proteins failed to properly advertise and label these NRL products and denied me the choice to consider purchasing or not purchasing a product that would affect the health of my child. The manufacturers of these NRL protein containing products made me believe that their product/s were safe for my child when in fact as it turns out they were not.

In fact the manufacturers knew that the product could harm my child consumer and did nothing to let me, a consumer know that the danger of NRL allergy could present itself with the use of these products. My son was diagnosed with NRL allergy in 1998. NRL causes unsafe and chronically life-threatening reactions due to repeated exposure. This is what I have been educated to know by the Doctors and general information that is available to the public on the Internet. I now have to view any and all products containing NRL proteins in this manner in caring for my son on a daily minute-by-minute basis, forever. My son will also have to for the rest of his precious life. These manufacturers of NRL gloves and NRL balloons must be held accountable for their gross exploitation of any human that they sell their dangerous and deadly products to. Why are the manufacturers of NRL containing products NOT made to adhere to the same safety policies as other manufacturers of other products?

I was very excited to learn of this citizen petition. Knowing that this citizen petition is being presented to protect lives is a wonderful thing.

The Consumer Product Safety Commission has in its power the immediate remedy to spare any other consumer the heartache, fear, stigma, and unreasonable disability and possible death due to harmful, and chronically deadly Natural Rubber Latex Proteins which can become aerosolized through exposure due to intimate contact due to touching of the skin, ingestion through the mouth, airways and waterborne activities.

Product recalls of products that could cause injuries and/or deaths, which were recalled by the Consumer Product Safety Commission which protects the public against unreasonable risks of injuries and/or death such as: Wooden Stacking Toys Recalled by Jack Rabbit Creations RELEASE #00-107B regarding a toy that presents a choking hazard to children, CPSC, Hangouts Recall Baby Hammocks RELEASE #00-107b these

baby hammocks can suddenly become twisted around children's necks and strangle them. These are just a couple of products which have been posted on the internet for recall, that can pose a danger yet as of the date posted had not caused any injuries or deaths. Why haven't the NRL Balloons, and NRL gloves been recalled? Why haven't the Koosh, and Dynaband Toys been recalled, why haven't any baby bottle NRL nipples been recalled or at the very least been required to completely covered and carry a warning label through packaging?

Simply labeling the product that it may cause a choking hazard isn't enough. It needs a warning along with further labeling that directly states that use of NRL products have been proven to cause life-threatening allergies that may cause an injury and/or death, NRL proteins are a hazardous substance.

Had all these products been labeled properly when I was out shopping, I would have been educated while I was considering purchasing these products and I would have been able to make crucial purchasing decisions in the products I was buying for my son. I would never have purchased these NRL containing products and my son would not have this awful NRL allergy today.

What makes the NRL balloons and NRL gloves so sacred that they are above safety, health provisions for safe products? My son is not merely a small number to be shadowed on a list of statistics. If products that present a safety and health danger to consumer/s are being recalled to prevent injuries and deaths, then why do the NRL Balloons and NRL gloves, toys, and other products stay on the market for consumer/s to purchase? Especially when there are documented cases of disabilities, deaths and harmed consumer/s from the use of these products. Don't we look to the health industry to tell us if a product is safe or a danger? There are numerous articles and lots of general information available for review that the health industry has noted that products containing NRL Proteins are a DANGER to the consumer/s health. With other safe products on the market which can be used in place of NRL products there seems to be no reason to keep these dangerous products on the market. ESPECIALLY WHEN THE MANUFACTURERS CAN AND KNOW HOW TO MAKE THEM SAFE FOR ALL CONSUMERS. I have often been told that my son represents a small portion of the population that could die from an exploded NRL balloon.

Is it that he is a small portion of consumers or is it that the profit made from selling dangerous NRL balloons and NRL gloves is so huge? If it is the case that he is a small number of consumer/s, where does the Consumer Product Safety Commission draw the line? How many Consumer/s have to be harmed, disabled and/or die before a product is rendered a candidate to be made safe for Consumer consumption and use? Why recall any product that is shown to cause harm and/or death but yet hasn't caused harm and/or death? The key word in The Consumer Product Safety Commission is CONSUMER, is it not? Are we coming into an era where we only consider a CONSUMER'S safety if it does not affect the stock market shares?

How were these products originally presented to the Consumer Product Safety Commission for approval? Had manufacturers changed the way they manufactured the product under the guidelines of which products are originally approved for manufacture? If so, then why haven't the products been recalled and fixed? It is not that the consumer/s that have been injured don't want the manufacturers to be able to produce products, but the consumer/s are entitled to have safe products. Especially when it has been

documented that the manufacturers originally made these products safe, yet after they were on the market, many believe, the manufacturers modified the process in which the product was manufactured which in turn has made these NRL containing products so dangerous and possibly deadly with repeated use. Perhaps to keep this from happening again, a new law could be instated requiring that any product that is remanufactured not using the same criteria for which it was originally approved, must be reapplied to the commission as a new product for approval.

A common practice of grocery stores is to give free NRL balloons to children of all ages to carry with them in the store and take home. Restaurants, Stores in Malls and Shopping Plazas give them out to children and display them regularly. Schools use them routinely. It is almost becoming impossible to go anywhere where these dangerous products aren't publicly everywhere.

There was a time when I, like millions of other parents believed that NRL containing products were safe. Everybody said these are great products. Now I have been shocked to know that NRL containing products are not safe. NRL containing products can harm and kill. I always shopped thinking that the Consumer Product Safety Commission would not let products go on the shelves of stores and definitely would not allow dangerous products to remain on shelves for purchase if they were a danger to the consumer. I still have faith in the Consumer Product Safety Commission to protect my Self and my family by requiring that the NRL containing products will be labeled as hazardous and dangerous which after repeated exposure can cause NRL allergy and possible death. Had the manufacturers of these NRL containing products been required to label the NRL containing products as harmful substances that could cause allergy and/or death, I would have never allowed these products to come into contact with my son. Because the manufacturers allowed this to go on, every time we allowed our son to have one of these harmful and potentially deadly NRL balloons and other NRL containing products which were and still are advertised to the public as a "safe" products, we did NOT know that our son was being over exposed by the NRL balloons along with other products which were allowing the NRL proteins to aerosolize.

Every time he was fed with a baby bottle with the harmful NRL nipples. Every time he sucked on a NRL pacifier. Every time he played with a teething toy with NRL in it. Every time he played with children's toys with NRL in them. Every time he ate one of those cute little elastic candy beaded candies that so many parents put in goody bags, he was being overexposed. Every time his schools had him use those rubber foam things for art craft projects. Every time he helped me cut coupons and try to learn to read the newspaper that was dusted with the deadly NRL protein dust. Every time the daycare Personnel stamped his hand with the NRL stamps. He was being overexposed. Over and over and over continually he was being over exposed and we didn't know it. Then the day in the toy department of the department store, there he was, sitting on the fence, and we didn't know it. We had complete confidence in the Consumer Safety Product Commission that before toys came into the stores, they were approved for safety. We didn't know that unsafe toys were placed on the consumer shelves for the next kid at bat to be put at risk. Well, our son was and still is one. He chose A KOOSH toy, and that toy was like putting a loaded grenade in his hands. It went off and he, like many others is now on the other side of the fence. His health has been harmed in a horrible way.

The KOOSH BALL was not covered, had no warning label on it. The KOOSH BALL was cleverly marketed as a cute, fun safe toy with cool looking tag on it with a cheap price. My son has paid dearly for that. My son will continue to pay dearly for that. The KOOSH Toys have no place in a child's toy market. The one that my son purchased gave his ear a chemical like burn that damaged his skin. His skin on this ear, still today, is compromised in that it becomes easily chafed, blistered, and is very slow to heal. When a mosquito bites this area, it may become infected and is very slow to heal. A mosquito bite on any other part of his body heals in a normal way. These NRL balloons need to be banned from any public places, schools, entertainment facilities, and especially toy stores and the decoration department in any store. No consumer of any age should have to risk their life to buy food and other necessities just to live. No consumer of any age should become an outcast because of unsafe NRL containing products. Within our culture in any enclosed environmental setting. Whether that be an athletic, Sporting, Social, Eatery, Drama/Arts, Festival, any arena, or medical or just ANY enclosed setting.

I have read in my general research through general information made available to the public, which is out there available for anyone to see simply by accessing Internet, that the reason that reproductive devices such as the Natural Rubber Latex Condoms do not seem to cause allergic reactions is because the manufacturers still utilize the stricter original manufacturing methods. I invite The Consumer Product Safety Commission to look up these Latex Allergies, news releases and other general Latex product safety and health hazard/danger information available to the general population as I have. I know that you will be well educated as to the unreasonable risk of injury and possible death that can be sustained from the use of these Natural Rubber Latex Products which harm and can also sometimes kill, as in my son's case.

Please make the manufacturers of these NRL containing products recall and remake these NRL containing products in a completely safe manner that will not harm and/or kill any Consumer. The manufacturers of NRL containing products know how to make them safe without causing harm/or death. The manufacturers will still make a huge profit making completely safe NRL containing products.

Are not the car manufacturers required to make safe automobiles? It is almost as if the Manufacturers of NRL containing products are just waiting to see if you will discount and deny the consumer their right to SAFE products in the area of NRL gloves and NRL balloons, and other children's products because then the road will be paved for them to cut yet another very important life-saving manufacturing process to save production costs. And then, what is next? Millions and Millions of more consumer/s will pay the price of more cheap unsafe product/s that will pose unreasonable risk of injuries and/or death to the consumer/s. . . All this, just to put money in the pockets of manufacturers who, it appears don't hold the belief in the basic human right to good and decent health through the use of safe products. Otherwise, they would have always manufactured these products in a safe manner.

My son's health has been permanently damaged by the NRL KOOSH Toys, NRL balloons, and the UNSAFE NRL products marketed and sold to children when the Natural Rubber Latex Protein caused unnecessary harm that destroyed his right to good health in 1998. At the tender age of 4, he asked for some Swim goggles and a KOOSH Ball. Because there was no warning label on the products we purchased them for our son as pool toys, in the belief that if it was in the stores to be bought, then, we assumed that

the Consumer Product Safety Commission had passed these toys as, safe products for children. My son has paid dearly for this hazardous and deadly product. His Health is now disabled, and why? Because when he played with the KOOSH ball and Swim Goggles in the manner that most children play with, he broke out in Hives, Swelling on his face, and His ear actually got blistered up and exhibited the same redness and burning that you would get from a chemical burn. His face was completely swollen and red. He had difficulty breathing. It was horrible!

From that day, his life has completely changed. He can no longer be around NRL products. He can't be near or in the same confined area as a NRL balloon or come into contact with Natural Rubber Latex products. A NRL balloon can cause an asthmatic attack and death. That is an Unreasonable risk of injury and/or death.

He was tested through a blood test for Natural Rubber Latex allergies. He had a reaction while they were doing the test. What if this were your child or grandchild, or relative? We were informed that he became allergic to Natural Rubber Latex through overexposure to the protein. We were told that this is NOT a genetic tendency.

I asked myself over and over again. How? True, he has some food allergies, but would only four visits to the hospital in 4 years throw him over the fence? Was it the number of well visits to the doctor's office to get vaccinations that put him over the fence? It wasn't until I became pregnant with our 3rd child that I suddenly realized how this came to be. When I pulled out our baby equipment and baby supplies from the attic, it became very clear. My son that now is allergic to Natural Rubber Latex proteins was a daycare baby while I was working. He was exposed to the Natural Rubber Latex proteins found in pacifiers, baby toys, diapers on a daily basis. Then as he went on to daycare in his second year of life, he was again daily exposed to the Natural Rubber Latex proteins again through contact exposure from the cheap products manufactured such as these items which daycare and Preschool personnel love to use on, and I state ON children, stickers, stamps which they love to stamp the hands of children, and those Natural Rubber Foam things they use continually for projects and rewards. My son would come home complaining about his hands itching and sometimes it would take 2 or 3 days to get the stamp ink off his hands. His hands would get better over the weekend and then it would start all over again during the week. Because he had food allergies I thought that the other children were possibly eating peanuts and cross-contaminating the Rubber stamps. I pleaded with the daycare to stop stamping the tops of his hands as a reward incentive. The daycare gal told me I was nuts. I actually thought maybe I was. Last month I received a newsletter from THE ALERT NEWSLETTER, Volume 6, Number 1, with a report about a normal healthy Infant developing Natural Rubber Latex allergy in daycare.

How many more innocent children and families will the Consumer Product Safety Commission allow to become unreasonably put at risk of injury and chronic symptoms that can lead to death? Maybe instead of calling it Latex Allergies, a better name for this Latex allergy condition would be Latex Induced Allergy Syndrome.

Well, in 1998 that KOOSH product was just enough to put my son over the fence. Today, he is still having problems. He needs to be able to attend public school now in order to learn how to read and write. However, I have on more than one occasion had to remove my son from school due to the deadly Natural Rubber Latex Balloons, which by

the way, EACH balloon has 3,000 Hazardous Natural Rubber Latex Proteins. Each NRL glove contains 4,000 Hazardous Natural Rubber Latex Proteins.

The principal of his elementary school has told me that she plans on having NRL balloons in the school and we will be able to pull him out whenever they decide to have The NRL balloons. She says they use them for activities and teacher birthdays, and that The parents are allowed to bring them into the school to surprise their children for birthdays. There are approximately 600-700 children in his school. My son now has To risk his health/and life in order to obtain a vital education he needs. He needs to Be able to read labels to protect his life. Plainly stated, he needs to be able to read in Order to live by him self when he grows up. His school is placing party decorations above his civil right to a public education. His principal says that she can 't require his teacher to separate his NRL free learning materials from the NRL learning materials. (Even though my husband and myself have provided those NRL free learning materials at our cost.)

If my son is allergic to a specific food, I tell him, do not touch the food. The food can Be separated from him. How do I tell my son not to breathe unsafe hazardous Natural Rubber Latex Proteins that are in the air in a building he is in? How can you separate dust and air particles? Every time a teacher has a birthday, every time the Parent Teacher Association in school decides to have a fundraiser, luncheon, tea, whenever there is a class event, whenever a child's parent decides to bring a dangerous NRL balloon to school for their child to enjoy, my child along with every other student in his school, and in schools across America, is being unknowingly and over-exposed to these hazardous proteins. Every time each student/consumer is exposed, that puts that consumer on the fence.

This is a landmark decision that will be made by the Consumer Safety Product Commission. It will affect millions and millions of consumers who believe that The Consumer Product Safety Commission is acting on their behalf. You may well ask, why haven't more people come forth? The general public has not been educated about the dangers of NRL containing products. The general public believes that if a product exists on the store shelves, it is safe. That is what we believed. Now my family knows it is not true. My son and an estimated other 16 million consumers that are latex allergic also know this is not true.

Had the manufacturers of natural rubber latex products been required to label their hazardous products, these consumer/s would have been notified that these products could harm their health. Consumers could have been given the knowledge that would have allowed them to make an educated choice about these products.

Labeling of these hazardous NRL containing products will give my son and millions of others like him a chance NOT to be innocently harmed, damaged, or killed because of a manufacturer's unwillingness to produce a safe product for consumer use. Especially since the manufacturers know how to make NRL containing products safe for all consumers.

Labeling will educate the general public regarding the hazardous NRL containing products. Labeling the NRL containing products will warn unsuspecting consumers About the dangers of NRL containing products, and thereby may save other innocent children from the cruel and unreasonable health injury which my child has had to endure due to the exploitive manufacturing methods of the manufacturers of NRL containing products.

My son has to learn to live with Natural Rubber Latex Allergy. My son's childhood has been ruined by the hazardous Natural Rubber Latex Proteins. He is now six years old. He needs to attend public school in order to learn how to read and understand labels in order to avoid unnecessary risk of injury and/or death due to NRL Products. However, he has to put his health in danger just by attending school. When he is with a teacher that doesn't feel it is necessary to be diligent in keeping a dangerous NRL product separated from him, he has a reaction. He is made to feel so special that the other children tease him when his teacher tells him in front of the class that he can not attend a learning experience or celebration because the personnel staff feels it is more important to have a hazardous NRL balloon (a party decoration) in a room for display. If he becomes upset, he is then labeled immature and a discipline behavioral problem. He is six years old. How would any six-year-old react to this treatment by a teacher that is obviously not educated in this area? A teacher whom doesn't appear to want to be educated either.

I have witnessed myself a teacher allowing him to play with NRL balls and him having a reaction due to the NRL protein being rubbed on his face, only to listen to the teacher tell me that he "Sneaks the balls to play with when she isn't looking." And she then laughs in front of me. This teacher's behavior could be understandable were it not for the fact that at the beginning of the school year she was educated by the school Nurse how important it is to my son's health that he not have contact with NRL products. My husband and I have provided the school with Latex Free Safe products including balls. The teacher did not feel it was necessary to call and ask us for more balls when the NRL free balls needed to be replaced.

If the school has a social learning experience, or if the school decides to put balloons somewhere in the school, he is made to feel so special, that he is singled out and put somewhere else so that the other kids can enjoy these dangerous balloons without exposing him. One day after the principal of his school called to say that balloons had just been delivered to the library and I could pick my son up from school or if I chose the teacher would leave him in the classroom alone while the other kids went to the library. Not a pretty picture. Since he was eating lunch, I asked that he remain in the cafeteria, and I would pick him up. Do you think they could have let him sit at an empty table finishing his lunch? No. Do you think they could have sent him to the principal's office to wait? No. He was at the front of the cafeteria sitting alone. Bent over with his head in his hands. He is six years old. It was 10 minutes from the time the principal called my house and I arrived at the school. In that ten minutes, my son's entire self esteem was destroyed. His first grade teacher and assistant had gone to the library with the other kids. His first grade teacher had made a habit on un-inviting him to the school events because of NRL balloons. Yet, at the beginning of the year, this school had agreed NOT to have balloons in the school while he was present.

When we got into our van, my son wanted to know why balloons were more important than him. My son attends a public school that is funded by the consumer taxpayer. My son's right to a public education is being compromised because of dangerous NRL balloons! How is that justified? A consumer's right to public education denied due to a child's toy and/or party decoration. When did we put dangerous/deadly products above human rights?

We provided the school with NRL free safe gloves and volunteered to supply safe balloons. We also spent an estimated \$1,000.00 to retrofit his kindergarten class with safe products so he could participate. We felt the manufacturers had destroyed his physical health, but we had hoped to keep his self esteem intact. And still, it wasn't enough.

My son has to put his life in danger every day just to go to the grocery store, any social place, such as a restaurant, bowling alley, theatres, arenas, hospitals, you name it. I must place actual visits and contact personnel everywhere, before he steps foot anywhere. This is not right. This past weekend I had to spend time convincing the manager of a Chucky Cheese establishment not to have Natural Rubber Latex Balloons because he wanted to attend a friend's birthday party. They finally agreed, but not until I read them the disability form protecting Latex Allergic people. I observed children having a blast without the hazardous/deadly balloons.

Last year my son (5 at the time) was having a reaction to a food he was allergic to. While going to the hospital, we called ahead to let the hospital know he was Latex Allergic, we were told we would have to go to another hospital, because this Hospital was not set up. We prayed all the way to the other hospital that he would be okay. That is why we have to always carry more than one epi-pen for him. Because he may have to travel farther for medical care. Then when we get to medical personnel we have to carefully watch and make sure that none of the medical personnel uses NRL medical equipment on him.

How many other kids will end up like him? Over-exposed to these harmful products, how many other kids will grow up, pursue careers in the military, medical, teaching, or any other field only to learn that the first year in their Profession, they become latex allergic and can not do their chosen field?

If someone had told me that my Son's life would be severely compromised by a NRL balloon or NRL containing products five years ago, I would have burst out laughing. Now, I have to keep myself from bursting into tears every time I see him in tears because of children that are taught it is more important to have access to Hazardous NRL balloons instead of promoting human rights and the importance of developing strong friendships between peers.

Here are some other facts to consider
All of these came off the Internet as far as sources go

This: From the Archives Deseret News Archives, Friday, March 22, 1996
Latex Balloons, the rubbery kind that pop at the prick of a pin, are a danger to children. A child may die as a result, with a balloon or fragment of one lodged in the throat and blocking airways. The Heimlich maneuver often doesn't work with balloons because of the toy's stretch ability and ability to hold air. Patients and caregivers may be allergic to latex products, with reactions ranging from hives to respiratory distress. They pose a significant danger at home as well as in the hospital. More than 1,500 injuries are associated with balloons each year in the United States. Even pieces of popped balloons are dangerous. The balloons are the leading cause of pediatric choking caused children's products. According to Midget, infants as young as three months and children as old as 14 years have died of asphyxiation from balloons stuck in their throats.

Please, I beg you, don't let another child have to go through this. Please allow my child to walk into a store and pick up a product and know what is in it. Please allow all consumers to be able to know what materials (active and supportive) are in the products Consumers are interested in buying so they don't have an allergic and/or potentially fatal reaction to a product containing NRL proteins

Thank you

Linda Shaw
Fax 1-919-859-6527

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

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

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

Sincerely,

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

Marisa Mitchell RN

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

Latex 29

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

To Whom It May Concern:

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

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

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

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

Please push through legislation that requires product labeling.

Sincerely,



Diana Cutright



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

Office of the Secretary
Consumer Product Safety Commission
Room 502

May 22, 2000.

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

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

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

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

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


Rochelle D. Spiker, LCSW-C
Executive Director

31
Latex
OK
5/12/00

5-19-2000/OFFICE OF
THE SECRETARY

To: The Consumer Product Safety Commission,

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

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

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

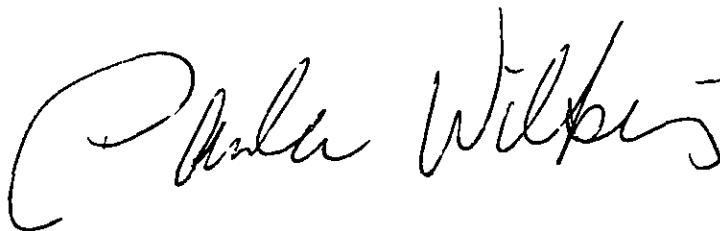
Gloves although necessary in certain situations should be monitored and limited. I have to drive out of the city where I live to get safe dental care. There are only three doctors in my city where I can seek safe medical care, an Obstetrician, Allergist and a General surgeon. Our counties hospitals have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

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

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

Thank-You!

Paula Wilkins
28 Wickliffe Drive
Naples,FL 34110

A handwritten signature in black ink that reads "Paula Wilkins". The signature is written in a cursive style with a large, looping initial "P" and a long horizontal stroke at the end.

**OREGON ECOBUILDING NETWORK**

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

*via fax (email as 5/22/00
not drawn)*

Page 1 of 1

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

To: Consumer Product Safety Commission

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

Sincerely, *Roslyn Hamilton*
Roslyn Hamilton, President

Stevenson, Todd A.

33

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

To Whom It May Concern:

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

Latex are strong sensistizers under the Federal hazardous Substances Act.

Sincerely,

Anna Salanti

asalanti@worldnet.att.net

Stevenson, Todd A.

Latex

34

From: Barbara Truitt [trukaras@execpc.com]
Sent: Monday, May 22, 2000 8.59 PM
To: cpsc-os@cpsc.gov
Subject: Petition HP 00-2, Petition on Natural Rubber Latex.

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

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

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

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

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

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

I hope that this proposal is given serious consideration and

implemented.

Stevenson, Todd A.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Stevenson, Todd A.

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

To Whom It May Concern:

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

Sincerely,

Tim Mulvihill

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May 22, 2000

Via Facsimile (301) 504-0800

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

Reference Petition HP 00-2 Petition on Natural Rubber Latex

Dear Gentlemen:

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

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

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

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

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

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

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

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

Sincerely,
CUSTOM SERVICES INTERNATIONAL INC.



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

[Federal Register: March 21, 2000 (Volume 65, Number 55)]

[Notices]

[Page 15133]

From the Federal Register Online via GPO Access [wais.access.gpo.gov]

[DOCID:fr21mr00-29]

CONSUMER PRODUCT SAFETY COMMISSION

Petition Requesting Rule Declaring Natural Rubber Latex a Strong Sensitizer

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

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

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

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

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

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

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

Dated: March 15, 2000.

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

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

Dear Commission Members,

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

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

Sincerely,

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

Latex

39

Stevenson, Todd A.

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

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

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

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

> > The text of the message follows:

> >
> > Subject: Petition HP-002
> > Date: Sun, 21 May 2000 21:35:17 -0700
> > From: "Ursula Gregg" <nolatem@earthlink.net>
> > To: cpssc.os@cpssc.gov

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

> > In September 1998 I was diagnosed with Type1 Latex Allergy. After
> > only 7
> > years of nursing I had to give up my career. Life has become very
> > complicated since acquiring this allergy. I constantly react in shoe
> > stores, the "fumes" from the natural rubber cause symptoms such as
> > nausea,
> > dizziness, coughing attack with shortness of breath. I now have to
> > order my
> > shoes through catalogs and have to make sure they do not contain any
> > natural rubber. Some companies are "costumer" oriented and will go
> > through
> > the trouble of finding out if their products contain natural rubber,
> > others
> > are not.

> > I recently had to leave during a family dinner at a restaurant due
> > to
> > latex
> > balloons. When I entered the restaurant with my family there were no
> > balloons present but a birthday party brought them in and they were
> > seated
> > below us. I did not know they were present when I started feeling
> > sick

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

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

PETITION HP 00-2

PETITION ON NATURAL RUBBER LATEX

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

Monday, May 15, 2000

40

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

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

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

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

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

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

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

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

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

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

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

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

Best Regards,

Tom Harrington
Latex Chemist

Stevenson, Todd A.

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



latex allergies2.doc

Please open file in excel.

111 Princeton Road
Exton, PA 19341
May 15, 2000

CPSC/OFFICE OF
THE SECRETARY

2000 MAY 24 A 8 54

Office of the Secretary
Consumer Product Safety Commission
Washington DC 20207

Dear secretary of the Consumer Product Safety Commission:

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


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

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

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

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

Respectfully,


Lisa Butler

42

~~Stevenson, Todd A.~~

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

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

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

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

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

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

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

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

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

Thank you for your time.

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

05/24/2000

Latex 43

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

American Latex Allergy Association

P.O. Box 13930

Milwaukee, WI 53213-0930

Telephone (888)972-5378

Fax (414)677-2808

E-mail: alert@execpc.com

May 22, 2000

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

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

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

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

We ask the CPSC to consider the following comments:

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

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

Sincerely,

Diane J. Flanagan

Diane J. Flanagan
President



Latex solvent 44

WORTHEN INDUSTRIES, INC.
3 EAST SPIT BROOK RD
NASHUA, NH 03060-5783
PHONE (603) 888-5443
FAX (603) 888-7945
EMail: info@worthenind.com

ROBERT F. WORTHEN
President

May 22, 2000

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

Dear Sir or Madam:

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

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

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

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

We strongly urge your office not to grant this petition.

Best regards,

A handwritten signature in black ink, appearing to read "R. F. Worthen", is written over the typed name "Robert F. Worthen". The signature is fluid and cursive, with a prominent initial "R".

RFW:j

Stevenson, Todd A.

45

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

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

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

Dear Secretary Dunn,

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

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

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

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

Sincerely,

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

~~Stevenson, Todd A.~~

Latex

46

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

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

I was recently diagnosed with NRL allergy. One of my biggest problems right now is not knowing what products I am being exposed to contain NRL; consequently my physical health seems to be getting worse, not better. PLEASE take this petition seriously. My type IV could possibly turn into a type 1 (anaphylactic) with constant exposure. I don't want that to happen.

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

Latex 47

Stevenson, Todd A.

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

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

Stevenson, Todd A.

Lantz
48

From: Rev Craig A Lantz [zionluth@nfdc net]
Sent: Tuesday, June 06, 2000 12:28 PM
To: cpssc-os@cpssc.gov
Subject: Petition HP 0072, Petition on Natural Rubber Latex.

RE: The request that the Commission declare that natural rubber latex ('NRL') and products containing NRL are strong sensitizers under the Federal Hazardous Substances Act ('FHSA') of FY 2000 so that these products would require labeling.

I strongly urge that the Commission NOT declare natural rubber latex ('NRL') to be a strong sensitizer. I believe that no significant increase in public safety would be realized if the Commission mad such a declaration, and that several business would be negatively affected by such a ruling.

Rational:

I agree that NRL does cause allergic reactions in some people. I have served as a hospital chaplain and have seen such reactions on occasion. These reactions are ones that typically develop over a extended period of exposure to NRL. They seem to develop more often if this exposure is during childhood. I have seldom seen these reactions develop in geriatric patients in the nursing homes that I work with.

I think that these reactions are generally rare and that most people who develop such allergic reactions are aware of their condition and thus can take steps to avoid NRL. The evidence seems to be that the primary reaction is respiratory distress caused by inhalation of NRL particles that are given off as new NRL items are opened and/or stretched for the first times. Other reactions are caused by direct contact with NRL. There seems to be little evidence that NRL that is contained or encased in other materials cause allergic reaction, since particles are not given off nor direct contact made with the NRL in most applications.

Practical consequences:

I believe that most people who have a sensitivity to NRL are aware of this condition and are able to easily identify objects made of NRL. I also believe that NRL that is "hidden" in other products does not present a significant threat since the NRL is normally enclosed and contact is thus prevented.

Because of this, I believe that labeling requirements would unnecessarily add to the cost of NRL products without gaining a significant increase in safety for the public.

Labeling requirements would also pose hardships upon certain users of
NRL
products without producing any significant increase in public safety.
Entertainers such as balloon decorators and sculptors would find it very
difficult to put warning labels on individual balloons for instance.
Labeling requirements would effectively put such people out of business
since there is currently no substitute for NRL in products such as
balloons.

Sincerely,

Rev. Craig A. Lantz
3312 Boose Rd
Glen Rock, PA 17327
(717) 428-1116

*Code 49
Latex*

Petition HP 00-2 Petition on NRL

June 8, 2000

Consumer Products Safety Commission
Rochelle Hammond
Office of the Secretary
Washington D C. 20207

Dear Ms Hammond,

I have been a practicing dentist for nearly thirty years I have recently retired, but I have mixed feelings about the state of my profession I had practiced for nearly twenty years when the concerns about infection pushed us towards regular use of latex rubber gloves My first months of wearing them caused severe papular lesions to form on the backs of my hands I tried numerous solutions, but the end result was that I would not wear latex rubber gloves

Subsequent to this I found my practice to be attractive to some very ill patients that were known to be latex allergic My initial attempts to rid my practice of latex products was very difficult The latex was used in approximately fifty everyday products that a dentist uses The resources that I turned to were helpful in my office becoming latex-free This was not an easy task five to eight years ago

I have also helped numerous patients have root canalled teeth removed from their mouths, due to the Gutta Percha that they are usually filled with This was confirmed by an Oral Pathologist, to be necessary due to the allergic manifestations around the tooth in tissue sections I soon found that there was extreme difficulty for these allergic patients to find dental offices that could even change enough to treat them

I believe that I have had enough experience to have extreme concern about my own health and the future of the patients, and practitioners in our society When I attempted to purchase products that were latex free, I had no easy way to find them or to be assured that they were indeed correctly labeled I will urge you to support our effort to have adequate labeling, by listing NRI products as strong sensitizers

The FHSA is there for that very reason, and I wish to go on record as being extremely concerned about Natural Rubber Latex We should all have choice and be able to buy products that are not harmful to ourselves an to others.

Yours in Better Health

LaVar H Riniker DDS
LaVar H Riniker DDS

Steph

50

Stevenson, Todd A.

From: JClarke345@aol.com
Sent: Tuesday, June 13, 2000 3:11 PM
To: cpsc-os@cpsc.gov
Subject: Natural Rubber Latex Labeling Request/latex death in England

<http://www.lineone.net/express/00/06/09/news/n1640-d.html>

Dear Office of the Secretary,
This tragic documented latex death is another opportunity to alert The Consumer Product Safety Commission of the importance of the need for consumer product labeling of natural rubber latex. Thank you for your attention to this serious public health matter to our family and millions of

Americans.
Anne Clark
118 Ashland Ave.
River Forest, IL 60305
JClarke345@aol.com

9 June, 2000 [back to news](#) [previous article](#) [next article](#) 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."

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~~Stevenson, Todd A.~~

Latex
51

From: mjb-pmb@webtv.net
Sent: Monday, June 12, 2000 7:58 PM
To: cpsc-os@cpsc.gov
Cc: dakmeb@northwinds.net
Subject: Latex Labeling

We urge you to take urgent action to mandate warning labels on all products containing natural rubber latex and related products. There is ample evidence of the life threatening nature of these products to those who are allergic and there is woefully little they can do to protect themselves without an appropriate warning. Please act now to save lives.

*Latex**52*
Stevenson, Todd A.

From: Peter Donlon [p.donlon@worldnet.att.net]
Sent: Monday, June 05, 2000 10:12 PM
To: cpssc-os@cpssc.gov
Subject: NRL

Please pass petition to label all Natural Rubber Latex products. My son is 3 years old and was diagnosed with Latex Allergy at a month old. He developed it from latex nipples and pacifiers. It is extremely difficult to research each and every product we come across in our daily lives. We spend more time on the phone and computer researching latex content. There are so many people out there with NRL Allergy and this would save lives and reactions if we all knew what we were dealing with before opening a product.

Thank you,
Donna P. Donlon
Virginia Beach, VA 23455
757-363-0792

CPSC/OFC OF THE SECRETARY
FREEDOM OF INFORMATION

2000 JUN 14 A 11:19

Carol Kuczora
P O Box 536
Grass Valley
CA 95945
ew-tree@nccn.net

Latex 53

June 8, 2000

Office of the Secretary
Consumer Product Safety Commission
Washington, DC 20207
cpsc-os@cpsc.gov

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

Dear Commissioners

Processed rubber has long been known to contain toxic sensitizers. Indeed, today's rubber products are hazardous substances, and the public must be warned. This I know from first-hand experience.

Natural rubber latex has been harvested for a century. Cross-reactivity among toxic sensitizers has been known for almost all of that century (Landsteiner, 1918, 1945). Various synthetic rubbers have been in production for at least half of that century. Research warned us about the toxicity and sensitizing potential of rubber additives 30 years ago. The carcinogenicity of one synthetic rubber, butadiene, was finally confirmed a few years ago. The epidemic of hypersensitivity reactions to rubber has only been around for a decade. It is unlikely to be attributable to the vegetable product. It is much more likely to be caused by petroleum-derived additives or copolymers with petroleum derivatives, and/or by their oxidation products.

The term "natural" should therefore be deleted. It is too narrow. Indeed, it restricts the petition to the substance least likely to be a toxic sensitizer, excluding all the synthetic rubbers that are at least as likely to evoke hypersensitivity reactions, and excluding all the toxic additives that turn up in the substitutes for natural rubber as well as in rubber itself. So it's a diversion that will perpetuate the problem.

Likewise, the term "latex" is too broad, and also ambiguous. It doesn't necessarily mean rubber, even though the terms are often used interchangeably. The term really refers to the milky exudates of many different plants, including milkweed and opium poppies, as well as to rubber trees. Not all those plant latexes are sensitizers, and maybe none are. The term "latex" is also applied to paints with a milky texture that are primarily polyacrylate and contain neither plant material or protein, and certainly no rubber.

Rubber is the culprit here, and the rule declaring it a strong sensitizer should refer to "rubber," not to natural or latex.

As sensitizers go, it doesn't seem to be very "strong", unlike poison oak or DNCB, it requires chronic or massive exposure to develop hypersensitivity. But the reactions can be deadly.

What is rubber? It is an unsaturated hydrocarbon polymer. Strictly speaking, natural rubber is a polymer of isoprene. The plant *Hevea brasiliensis* is the source of natural cis-isoprene, and the plant gutta percha is the source of natural trans-isoprene. Isoprene can also be synthesized. Cis-isoprene is synthesized with a catalyst, and incredibly is legally termed "natural rubber." Moreover, toxic sensitizers such as acrylonitrile, a cyanide congener of the toxic sensitizer vinyl chloride, are used as additives in natural rubber.

However, there are many recipes for rubber -- both natural and synthetic -- and both pure and adulterated. They are not all equally toxic, and their toxicity varies with time, VOC's -- gases of monomer and additives and oxidation products -- escape from new product, and ozone and oxygen combine with old

product to break it down into airborne VOC's, which can be even worse. These fumes and dusts can enter the blood through the lungs and target any or every organ in the body.

Among synthetic rubbers are (a) GRS, a copolymer of butadiene and styrene, (b) Butene-Diene, a copolymer of isobutene and diene, (c) Neoprene, a copolymer of Chloroprene and Neoprene, (d) various copolymers of acrylonitrile and butadiene, both of which are both sensitizers and carcinogens, and (e) Thiokol, made of a dichloride and sodium polysulfide (Lange's *Handbook of Chemistry*, 11th ed., 1974)

Toxic additives are incorporated into natural and synthetic rubber products to start and stop chemical reactions, cross-link carbon chains, add plasticity, and slow oxidation. Eventually, these as well as the rubber all enter the air and are inhaled. Much research has been done in the past on contact dermatitis caused by rubber additives, and anything that can cause a rash externally can cause deadly havoc internally. Even the combustion products of poison oak or ivy can kill by its effects on the lungs. Consider what the following rubber additives can do when they enter the blood and organs through the lungs (Fisher, 1973)

Accelerators producing most cases of rubber dermatitis

- Mercaptobenzothiazole
- Tetramethylthiuram monosulfide
- Diphenylguanidine
- Hexamethylenetetramine (methenamine)

Antioxidants causing most cases of rubber dermatitis

- Monobenzylether of hydroquinone
- Phenyl-beta-naphthylamine
- n-Isopropyl-n-phenylparaphenylenediamine (IPDA)
- 4,4'-diaminodiphenyl methane

Chemicals used in both rubber and plastics

- Phenyl-alpha-naphthylamine
- Phenyl-beta-naphthylamine
- p-Hydroxyphenyl-beta-naphthylamine
- Aldol-alpha-naphthylamine
- n-Isopropyl-n'-phenyl-p-phenylenediamine
- Mercaptobenzimidazole
- 2,6-Di-tertiary butyl-4-methylphenol
- 2,6-Di(methylbenzyl)4-methylphenol
- Bis(5-methyl-3-tertiary butyl-2-hydroxyphenyl)monosulfide
- 2,5-Di-tertiary butylhydroquinone
- 2,5-Di-tertiary amylhydroquinone
- Tri(p-nonylphenyl)phosphate

"Rubber itself is not allergenic, it is the chemicals which are added to it during the manufacturing processes which sensitise, and, as these allergens are present in the finished product, both consumer and manufacturer are at risk of being sensitised" (Cronin, 1980)

Nevertheless, 20 years later, when sensitization became epidemic, "latex protein allergy" was blamed, "genetically predisposed individuals" and "atopic people" were blamed as if they were constitutionally inferior, and God was blamed. "Why did God put the proteins in the latex of the rubber tree? . . . Sometimes it gets so ridiculous that in the US we have got latex-free hospitals. With the skull and cross-bones and all. Latex-Free! Ridiculous!" (Dr. Lim Ken Yaik, Minister of Malaysia, the primary rubber-producing country, in a 1999 speech, reproduced at www.Immune.Com/rubber)

I fear that by trying to blame Nature by implicating natural rubber, manufacturers will flood the market with far more toxic synthetics, and won't even try to leave out the chemical sensitizers. I must use rubber gloves for dishwashing because my hands have become extremely sensitive to detergent. All the yellow gloves cause a lung and circulatory reaction. Last year I found one kind I could use without ill effect.

They were creamy colored and labeled "natural latex" When I tried to buy more, they had been taken off the market, and in their place were bright fucia gloves labeled as being from Malasia and reeking of moth balls -- much more toxic and reactive than any rubber Other new rubber products on the market substituting for natural rubber smell of perfume, vanilla, and chocolate, and they evoke a systemic reaction

Reseach is needed to determine what rubber, if any, is safe, which is the most hazardous, which components and additives are responsible for the toxicity, what parts of the molecules are the antigenic determinants, which route of exposure evokes the worst reactions, how to render it nonantigenic, if possible, etc, and, most importantly, get the real toxic components out

Another source of confusion is the nature of hypersensitivity or allergy Definitions seem fluid here, as allergists avoid getting involved in having to diagnose and treat toxic reactions to sensitizers, or implicate products, or document workers' compensation claims Sensitizers are nothing to sneeze at There is no system of the body that cannot be the target of a chemical sensitizer, and hypersensitivity is itself a type of toxic reaction (Casarett and Doull)

Hypersensitivity reactions are of many types They have been grouped into four types (Coombs and Gell).

- (I) IgE-mediated "allergy" to proteins or polysaccharides
- (II) cytotoxic, in which other antibodies attack cells such as red blood cells
- (III) antigen-antibody immune complex deposition in tissues with inflammation
- (IV) cell-mediated delayed hypersensitivity to haptten-protein conjugates of chemicals

I initially developed pulmonary and systemic reactions to the oxidation products of old foam rubber The cross-reactions were even worse In a chain-reaction I reacted to the VOC's of lots of other low-molecular-weight unsaturated hydrocarbons as well -- alkenes and terpenes -- such as vinyl chloride, vinyl cyanide (acrylonitrile, orlon, acrylics), vinyl acetate, vinyl acrylate, as well as to tires and shoe soles The one thing they all had in common is that they form epoxides That makes them all carcinogens as well as sensitizers The symptoms pointed to types II, III, and IV I had Reynauds pnenomenon, angioedema, hemolytic jaundice, arrythmias, metallic taste, miosis, tinnitus, scotoma, numb extremities Unfortunately, no test of hypersensitivity of other than type I seems to be available in this country anymore At least, not for humans. Consequently, there's no way to document such toxic exposure

I managed to get a test for Type I allergy to latex, which was negative. The test results included a note to the effect that it did not rule out the possibility of an anaphylactic reaction That tells me that anaphylactic reactions can be other than Type I During the first few years of my hypersensitivity, all my vital signs were extremely depressed, as if I were in a chronic state of partial clinical shock. On exposure to acrylic carpet and smog my heart kept stopping for several beats at a time, and I developed aortic stenosis

Many people sensitized to rubber cross-react with other airborne unsaturated hydrocarbons and their oxidation products, such as perfumes, diesel exhaust, plastics, paints, inks, and smog, with even more serious systemic reactions These pollutants are becoming increasingly difficult to avoid So this epidemic of hypersensitivity to rubber products is imprisoning people, and making it difficult to find safe air anywhere, indoor or out, that does not threaten to shorten their very life, as well as impair their quality of life

Incredibly, another experience many of us have in common is that when we present to our physicians with complaints of hypersensitivity to rubber we were initially told that it was all in our heads and sent to psychiatrists! It is as if propogandists for the chemical and rubber industry seek to add insult to injury by discounting and discrediting those who are already suffering physically from an exposure It has nothing to do with science and everything to do with money.

Therefore, please declare rubber a toxic sensitizer, but do not blame Nature by calling it "natural," or confuse the issue by calling it "latex." Thank you.

*Remember nitrosamines
in pacifiers?
To prevent illness, it
is necessary to identify*

*Sincerely,
Caral Kujawa
... other products!*

Latex 54

Stevenson, Todd A.

From: Anne Fehr [morefehr6@sprint ca]
Sent: Thursday, June 15, 2000 8.28 AM
To: cpsc-os@cpsc gov
Subject: CONSUMER LABELING - LATEX

As a sister to a wonderful 37 year old mother of three young daughters, who is allergic to latex after over exposure from being a nurse, I beg of you to please address the issue of CONSUMER LABELING for products containing LATEX

This is a most dangerous and fatal, and proven health threat If you feel you must list fat content in food items for those who are simply dieting . then please also concentrate on more serious issues

WE MUST ENACT CONSUMER LABELING FOR PRODUCTS CONTAINING ** LATEX **

Anne Fehr
morefehr6@sprint.ca



Northwest Coatings Corp.

7221 South 10th Street • Oak Creek, Wisconsin 53154
Telephone (414) 762-3330 Telefax (414) 762-9132

Latex 55

June 9, 2000

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

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

Dear Secretary:

Northwest Coatings has, since 1970, manufactured products that incorporate natural rubber latex as a raw material. We do not manufacture finished products that a consumer would use. Rather, we modify natural rubber latex with a variety of additives that provide the performance required by the ultimate end use.

Our products, which are shipped in liquid form, are converted into finished goods by our customers. The ultimate uses of the products we supply fall into two classes:

1. Medical devices, which are already regulated by the Food and Drug Administration.
2. Adhesives, which are used in printing and packaging applications.

We empathize with those who are allergic to natural rubber latex, seafood or any other substance that impacts their health. However, in our opinion the petitioner's proposals, to designate natural rubber latex a "strong sensitizer" and to require labeling on all products that contain natural rubber latex, are an overreaction. We are of this opinion for four reasons:

1. Over the past thirty years our company has processed tens of millions of pounds of latex and has not had a single employee affected by contact with natural rubber latex.
2. Many uses of adhesives in the packaging industry do not involve contact by consumers. To require that a package be labeled to alert the consumer to the presence of latex could unnecessarily alarm the consumer. This could lead the manufacturer of the package (and the manufacturer of the product that goes into the package) to discontinue the use of adhesives that are based on natural rubber latex. This could result in defacto banning of a raw material (natural rubber latex) that provides desired performance at competitive costs.

– ISO 9001 Registered –

internet address: www.northwestcoatings.com
E-mail address: nwc@northwestcoatings.com



3. Applications such as a self-sealing envelope adhesive involve only incidental, if any, contact by consumers. In order to use a self-sealing envelope that utilizes natural rubber based adhesive the consumer removes a protective strip that releases from the adhesive and closes the envelope flap. Typically the consumer does not touch the tacky adhesive. If incidental contact does occur, it is minor compared to wearing rubber latex gloves. To legislate that the envelope flap be labeled to alert the user to the presence of natural rubber latex is an onerous, unnecessary requirement.
4. Some applications for adhesives that are based on natural rubber latex do involve contact by workers and/or consumers. For example, natural rubber latex is often used in the adhesive that bonds film or paper to plastic, wood or metal objects such as furniture to provide protection while the object is being manufactured or shipped. With furniture, for example, the consumer would peel off the protective film or paper and dispose of it when the furniture is delivered.

Although we do not manufacture the protective film or paper for this application, we are not aware of cases of allergic reaction when the edge of the protective film or paper is grasped to remove it from the surface that it is protecting. Is the petitioner of Petition HP 00-2 aware of consumers that have suffered allergic reaction when they removed a protective tape from an object that they purchased?

Once again, to require that such protective tapes be labeled to indicate that the adhesive contains natural rubber latex could unnecessarily prompt the manufacturers of such tapes to discontinue the use of natural rubber based adhesive.

We ask that a reasoned, practical approach be taken to any change in:

- A. The designation of natural rubber latex.
- B. The requirements for new labeling of products that incorporate natural rubber latex.

We invite you to contact Northwest Coatings for additional information on the use of natural rubber latex in the adhesives industry.

Yours truly,

Gerald E. Mainman
CEO

**Institute for Research and
Technical Assistance**
a nonprofit organization



Post-it [®] Fax Note	7671	Date	6/16/00	# of pages	2
To	Office of the Secretary		From	Kathy Wolf	
Co./Dept.	Consumer Prod Safety		Co.	IRTA	
Phone #	301 504 0800		Phone #	310 453 0450	
Fax #	301 504 0127		Fax #	310 453 2660	

June 16, 2000

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

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

To Whom It May Concern:

I am writing with comments on the petition from Debi Adkins requesting that the Consumer Products Safety Commission (CPSC) issue a rule declaring that natural rubber latex (NRL) and products containing NRL are strong sensitizers and that labeling of these products should be required. I am requesting that you limit the labeling requirement to NRL adhesives products that are available for human uptake.

I am Director of the Institute for Research and Technical Assistance (IRTA), a nonprofit organization. IRTA works with companies to assist them in converting to low- or non-solvent technologies in cleaning, printing, coating, paint stripping, dry cleaning and adhesives applications. IRTA also performs test and demonstration projects on new and emerging low- or non-solvent technologies.

IRTA is currently conducting a project sponsored by the Environmental Protection Agency (EPA) to investigate alternative adhesives for foam fabricators, upholstered furniture manufacturers and mattress manufacturers. The adhesives used in these industries are referred to as porous substrate bonding adhesives because they are used to bond various types of porous substrates like foam, fiber, fabric and wood.

For several years, the adhesives used by these industries were solvent-based adhesives that relied on 1,1,1-trichloroethane (TCA) as the solvent carrier. TCA production was banned in the U.S. in 1996 because the chemical contributes to stratospheric ozone depletion. Although TCA inventory was still available after 1996, the price of the chemical increased substantially because of a Congressional tax. The adhesive formulators, at that stage, began reformulating the adhesives with methylene chloride (METH).

In January 1997, the Occupational Safety and Health Administration (OSHA) finalized a regulation that lowered the Permissible Exposure Level (PEL) of METH from 500 ppm to 25 ppm. An action level of 12.5 ppm was also established. Companies with exposures above the action level were required to implement exposure monitoring and a medical surveillance program. It is unlikely that the new OSHA exposure levels can be met by most companies using adhesives.

The EPA sponsored project IRTA is conducting was designed to evaluate alternative adhesives for these industries that used TCA or METH adhesives. Alternatives that have emerged include acetone-based adhesives, n-propyl bromide-based adhesives, water-based adhesives and hot melts. Acetone is low in toxicity but has a very low flash point. n-Propyl bromide is a new chemical that may have toxicity problems; OSHA and NIOSH have nominated the chemical for toxicity testing. The best alternatives that minimize the human health and environmental problems associated with adhesive use are water-based adhesives and hot melts. Hot melts, which are 100 percent solids, are applicable for some

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upholstered and office furniture manufacturing but are not appropriate for foam fabrication operations. Water-based adhesives can be used by foam fabricators, furniture manufacturers and mattress manufacturers. The water-based adhesives used by these industries generally contain NRL.

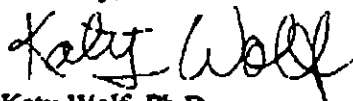
Foam fabricators use adhesives to bond foam-to-foam and foam-to-fiber. The foam is cut and bonded to achieve a particular shape and feel that are appropriate for different parts of furniture. Water is the carrier in the latex-based adhesives. The latex hardens to form the bond between the substrates. Foam fabricators sell the bonded products to upholstered furniture and mattress manufacturers. Upholstered furniture manufacturers use the foam in furniture like chairs and sofas and mattress manufacturers use the bonded foam in mattresses. Many upholstered furniture and mattress manufacturers also use adhesive to bond foam-to-foam, foam-to-fabric and foam-to-wood. The furniture is covered with fabric during manufacture. Once the bonded foam is part of the furniture, it is virtually inaccessible for human exposure. Even if the fabric of the piece of furniture is ripped, the solid latex could only be accessed by ripping apart the foam. Even if this were to occur, the solid latex is not in an available form.

Many companies are already using water-based and hot melt products. IRTA is working with several solvent-based adhesive users and is encouraging them to convert to water-based and hot melt products. I am concerned that a labeling requirement for the foam, the furniture or the mattresses would cause industrial firms involved in foam fabrication and furniture or mattress manufacturing to convert away from the water-based latex adhesives to solvent-based products. I am also concerned that companies that are using the solvent-based adhesives would be unwilling to consider converting to the water-based adhesives if their products required labeling. From an overall human health and environmental standpoint, it would not be good public policy to discourage the use of a safer product by requiring products containing it to be labeled.

It might be appropriate to require labeling for the latex adhesive used in foam fabrication, upholstered furniture manufacture and mattress manufacture. I am requesting that you not require labeling for products containing latex-based adhesive used for bonding. The latex is not available for human exposure in these products.

I appreciate the opportunity to comment on your proposal. If you have questions about the industries that use latex adhesives or about any of the points mentioned here, please call me at (310) 453-0450.

Sincerely,



Katy Wolf, Ph.D.
Executive Director

May 22, 2000

Office of the Secretary
Consumer Product Safety Commission
Washington, District of Columbia USA
20207

Telephone (301) 504-0800
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Office of the Secretary
Consumer Product Safety Commission
Room 502
4330 East-West Highway
Bethesda, Maryland USA
20814

Dear Ms. Brown, Ms. Gall, and Mr. Brown; Madam or Sir,

As a citizen, I hereby petition the US Consumer Product Safety Commission (hereafter "Commission") to classify the primary physical offender in the cause of natural rubber latex (NRL) allergy sensitization, the allergen-protein-laden lubricant known as "USP absorbable dusting powder" (on NRL gloves and other NRL products) as a "strong sensitizer" under 15 U.S.C. 1261-1277, the Federal Hazardous Substances Act (FHSA).

The Commission has already properly labeled epichlorohydrin as a strong sensitizer under the FHSA. Now therefore be it known that the strong sensitizer epichlorohydrin is commonly (perhaps universally) required in the manufacture of the subject of this present petition: "USP absorbable dusting powder." This petition, therefore, requests that the Commission extend also to "USP absorbable dusting powder" the label "strong sensitizer" - a label that is already properly applied to one of the manufacturing precursors of "USP absorbable dusting powder," itself.

This petition to the Commission is based on well know, proven, reliable, valid, published scientific facts cited throughout. I assert, based on these facts, that the cornstarch lubricant "USP absorbable dusting powder" on NRL gloves, under current and ordinary manufacturing procedures, when aerosolized in ordinary use, is well known to sensitize life-threatening NRL allergy in individuals (both customers and workers).

A decade ago, well after the advent of near universal application of "USP absorbable dusting powder" lubrication on NRL products, the US Food and Drug Administration (FDA) recognized the dangers that NRL allergy poses, when FDA "sent a letter to manufacturers in May 1991 advising them of allergenic problems with latex devices."¹

Further, the "USP absorbable dusting powder" lubricant on NRL gloves, under current manufacturing procedures, when aerosolized in ordinary use, is known to be a serious threat to individuals already sensitized to NRL allergy, because the "USP absorbable dusting powder" carries significant amounts of NRL allergen proteins, causing serious and life-threatening allergic reactions if sensitized individuals breathe the allergen-protein-laden "USP absorbable dusting powder" into their lungs or when the "USP absorbable dusting powder" otherwise comes into contact with mucosal tissues of these already sensitized individuals.

In order to carry out its proper duty to the public to improve and maintain public safety, I request that the Commission urgently act to declare the allergen-protein-laden lubricant "USP absorbable dusting powder," when combined with NRL products, is a strong sensitizer under the FHSA and therefore explicitly label the allergen-protein-laden "USP absorbable dusting powder" on natural rubber latex gloves, and "USP absorbable dusting powder" on all other NRL products under the Commission's jurisdiction, as a "strong sensitizer" under the FHSA.

Counter-Arguments

While some insist that NRL products (themselves, alone) are most dangerous, I instead submit that the "USP absorbable dusting powder" lubricant cornstarch powder on NRL products is the far greater danger, directly responsible for causing untold sensitization, financial loss, career loss, health loss, disability and even death through NRL allergy. I recently addressed the FDA with similar concerns, and I am attaching those comments for your information.

Other arguments commonly put forward are that latex allergy concerns should be addressed by use of alternative (synthetic) materials, or by eliminating the cornstarch lubricant powder altogether. On the other hand, synthetic gloves are implicated in Type 4 allergic sensitization to manufacturing chemicals and synthetic gloves may be more costly and much more dangerous to dispose of than natural rubber latex gloves. Similarly, elimination of "USP absorbable dusting powder" cornstarch, if not replaced with an inexpensive, effective lubricant (silicone, hydrogel, oat starch, or otherwise), may undesirably lead to consumers and workers applying talc or other more dangerous lubricants at the time of glove donning.

Many Products Affected

Consumer products that may contain allergen-protein-laden lubricant "USP absorbable dusting powder" which are under the Commission's jurisdiction include "industrial" latex gloves (gloves used in food service, janitorial, automobile maintenance, toll-taking, gardening, retail food preparation, other uses, and in homes by ordinary consumers) and other NRL products that concomitantly include the accused strong sensitizer NRL-allergen-protein-laden "USP absorbable dusting powder." "USP absorbable dusting powder" may also be in other consumer NRL products such as balloons, pacifiers, and many other products.

USP Absorbable Dusting Powder

I assert that "USP absorbable dusting powder" (when in ordinary manufactured NRL products, used in commonplace and ordinary ways) can and does cause NRL allergic sensitization which, in turn, can and does result in serious allergic reactions, even death. This information is well known to glove experts. For example, on March 25, 1988, Dr. Elizabeth D. Jacobson of the FDA testified to Congress that, "FDA also has significant concerns about the role of glove donning powder (typically cornstarch) in the sensitization and reaction to natural latex. Natural latex allergens have been shown to bind to cornstarch. The dispersal into the air of glove powder carrying latex proteins may be a significant agent for sensitizing non-allergic individuals who breathe in the powder."²

Seventeen months previously, in September 1987, the FDA said, "Experimental and clinical data demonstrate that: natural latex proteins are allergenic, natural latex proteins bind to cornstarch, aerosolized powder on NRL gloves is allergenic and can cause respiratory allergic reactions. These published studies support the conclusion that airborne glove powder represents a threat to individuals allergic to natural rubber latex and may represent an important agent for sensitizing non-allergic individuals," and "... studies clearly demonstrate that cornstarch indeed binds allergenic proteins, which can not be detached by simply washing the powder. These findings support the

causal relationship between asthmatic reactions in individuals with natural latex allergy and the exposure to airborne particles from NRL products."³

These findings were also well known and stressed by the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, in their consumer-oriented pamphlet "Latex Allergy: A Prevention Guide" in 1997, saying "Is skin contact the only type of latex exposure? No. Latex proteins become fastened to the lubricant powder used in some gloves. When workers change gloves, the protein/powder particles become airborne and can be inhaled."⁴

Also in 1997, the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention said, "The proteins responsible for latex allergies have been shown to fasten to powder that is used on some latex gloves. When powdered gloves are worn, more latex protein reaches the skin. Also, when gloves are changed, latex protein/powder particles get into the air, where they can be inhaled and contact body membranes..."⁵

Again, in the Federal Register: July 30, 1999 (Volume 64, Number 146) the US FDA restated the danger, "FDA has significant concerns about the role of glove powder as a carrier of airborne allergens, because NL allergens have been shown to bind to cornstarch."⁶

Also in 1998, the US Department of Labor, Occupational Safety and Health Administration stated, "Studies have indicated that corn starch powder, added to gloves to facilitate donning and removal, can serve as a carrier for the allergenic proteins from the NRL."⁷

These statements by scientists in authority in the US government are widely reported and have been published and publicly available on the internet, making this information "well known" by most definitions.

Prevent Improper Consumer Diversion of Rejected "Medical" Gloves

In order to reduce and prevent the incidence of future NRL allergic sensitization, the Commission should act to declare the dangerous NRL-allergen-protein-laden lubricant "USP absorbable dusting powder" is a strong sensitizer. The Commission should also do everything in its power to appropriately limit the improper diversion into any and all consumer uses of all NRL-allergen-protein-laden "USP absorbable dusting powder," especially in products originally labeled for medical use (e.g., patient examination gloves) and subsequently rejected (detained at port of entry) by the FDA. FDA officials have communicated their disposition to cooperate in this matter in private conversations with me.

Prevalence Of Latex Allergy

Currently NRL allergically-sensitized individuals (estimated between 1% and 6% of the general population, and over 50% of spina bifida patients) must avoid all contact with NRL, including and especially "USP absorbable dusting powder" which contains and carries NRL-allergen-proteins.^{8, 9} Commission action to label "USP absorbable dusting powder" may assist these currently (already) sensitized individuals to avoid NRL allergic reactions. Commission action to label "USP absorbable dusting powder" can also possibly assist already sensitized individuals in avoiding worsening (progression) of their NRL allergic symptoms, because allergy and allergic symptoms are caused by repeated exposure to an allergen. The requested labeling can assist sensitized individuals to avoid repeated exposure to the allergens which cause their allergic symptoms and that can cause the worsening of their allergy.

Therefore, I request the Commission to urgently add "USP absorbable dusting powder" in NRL products to the list of strong sensitizers so that without delay all NRL consumer products under the Commission's purview containing

8 - Latex Allergy in Pediatric Spina Bifida Patients: Incidence and Surgical Implications
<http://www.aaco.org/word/html/anmaet183/scipro/ppr074.htm>

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FDA should rapidly acknowledge and encourage alternative glove lubrication methods, and FDA should rapidly acknowledge and encourage alternative donning powders.

A move to phase in lower levels of NRL protein in the glove itself, while probably helpful, is less important than the immediate cessation of the FDA required USP Absorbable Dusting Powder vector in surgical gloves, *because* the current donning powder binds with and carries NRL proteins.

Individuals allergic to natural rubber latex must continue to struggle with their disease – the least that they should be provided is access to safe and appropriate emergency medical care, and venues for safe and proper routine health care. Unless airborne USP Absorbable Dusting Powder is eliminated or repaired, the latex allergic cannot safely approach typical health care facilities.

Consequently, all proposed NRL protein limits must apply to, and must include, the NRL protein inadvertently now included in medical glove donning powder.

Protein limits must be stated either for the glove and for the donning powder, or for the both glove and donning powder devices together. Equivocation on this matter has already caused too much confusion and misinformation. The donning powder now carries significant amounts of NRL-protein, and it should not.

The proposed labeling is not adequate because it does not quantify the extractable NRL protein bound to and therefore in the donning powder. The NRL protein content of the glove is false, misleading and understated *unless* the protein content in the primary airborne NRL-protein delivery vehicle, the lubricating/donning powder, is clearly identified and reported to the consumer.

Gloves in Kits

Again, I applaud the FDA for requiring gloves in kits to be precisely and accurately labeled. For public safety, all natural rubber latex items in kits, including catheters and tubes, should be labeled for NRL protein and powder content. Additionally, labeling of these devices should especially also include the NRL protein and powder content of the gloves in the kit.

So-called "Lightly Powdered" Gloves

FDA has too long ignored the widespread misbranding of "lightly powdered" labeling. Lack of enforcement of this misbranding has sown confusion and misinformation among patients, medical glove users, distributors, and manufacturers.

FDA should immediately use its enforcement powers to stop this widespread, false marketing claim ("Lightly Powdered"). Lax FDA enforcement in this matter has already caused much confusion and misinformation.

1. *FDA requests comments on the timeframe for implementation of the proposed rule considering the need for changes in production, technology, and labeling, as well as the immediate need to address adverse health concerns associated with medical gloves. Although FDA prefers a 1-year effective date, FDA is proposing a 2-year effective date based on indications from industry that the necessary changes could not be made in 1 year and that a shortage of medical gloves could result.*

FDA should implement the proposed rule immediately. Implementation without readiness to enforce, however, would be a sham. If enforcement is not promptly forthcoming, implementation should be cancelled, and the proposal should be shelved.

2. *In the proposed guidance document, FDA recommends a limit of no more than 120 mg powder per powdered glove, regardless of size, as the maximum level in order to reduce exposure to particulates and airborne allergens. FDA requests comments on the recommended limit with regard to the minimum level of powder needed for adequate donning of gloves.*

Assumptions In FDA Proposal

The proposed limit of 120 mg powder per glove assumes that glove donning powders are a NRL-protein (antigen) carrier, causing latex allergy incidents in those already sensitized, and causing new allergic sensitization to occur.

However, there is no evidence that any specific level (lower or higher than 120 mg.) of NRL protein or protein-bound USP Absorbable Dusting Powder will protect workers or patients from sensitization or reactions. There is no known "safe" level.

Because there is no known safe level of exposure, it is all the more important to identify and label accurately and completely the actual level of NRL protein exposure caused with each glove use. The NRL-protein exposure is understated and false unless the NRL-protein bound to the USP Absorbable Dusting Powder is measured and included in the labeling.

False FDA Assumption

However, the ASSUMPTION that glove powder is the culprit, while initially satisfying, hides the further assumption that alternative glove powders are unavailable. This hidden, FALSE assumption is very dangerous.

The assumption that alternative glove powders are unavailable has clouded the air for several years now, while alternative glove powders languish in disuse. FDA has disregarded alternative lubricants and lubricating methods at great loss.

FDA Therefore Again At Fault

Everyone knows that the USP Absorbable Dusting Powder, when bound to NRL protein, is dangerous beyond words, yet FDA continues to demand USP Absorbable Dusting Powder in every surgical glove. This damaging requirement should be rescinded immediately.

FDA should sponsor research to identify alternative, safer donning powders. FDA should carefully investigate alternative lubrication methods and alternative donning powders. FDA should not force medical glove users, and those who inadvertently breathe the NRL-protein-laden USP Absorbable Dusting Powder vector, to continue to use dangerous powders that bind with and carry NRL proteins. FDA should sponsor research to repair this serious and perilous flaw in USP Absorbable Dusting Powder.

- 3. FDA requests comments on the feasibility and desirability of additional labeling requiring manufacturers to state the primary ingredients in glove powder in the product labeling.*

Specific Labeling Is an Improvement

Increased labeling requirements have been a step in the right direction. Product labeling should respond clearly and directly to specific health and safety concerns. Accurate labels help to enable latex allergic individuals to protect themselves.

Accurate labels may also help enable others to avoid needless allergic sensitization, and to otherwise identify possible irritants and chemical allergens.

Accurate labeling (on primary packaging) of NRL protein content for both the glove and the donning powder, and nothing less, is required for public safety.

All labeling should be clearly visible and easy to read.

Necessary Labeling Includes

3A. No ingredients in the glove package should be optional in labeling. Donning powder now appears to be optional in labeling requirements, and donning powder **SHOULD NOT BE OPTIONAL**.

3B. All ingredients having recognized potential to sensitize ANY allergy MUST be labeled on the consumer glove box.

3C. All ingredients that have recognized potential to irritate or disable human beings should be labeled on the consumer glove box. Health care and other workers, and their patients and consumers, require the FDA to exercise this power to protect and serve the public.

3D. Specifically, the presence of these ingredients or residues MUST be labeled:

- ionically bound USP Absorbable Dusting Powder-natural-rubber-latex-protein
- magnesium oxide
- **specific chemical accelerators MUST be labeled**
- carba mix
- black rubber mix (BRM)
- quaternium-15
- mercaptobenzothiazole (MBT)
- mercapto mix
- thimerosal
- thiurams

3E. Labeling of glove donning powder as "USP absorbable dusting powder" is NOT acceptable. The actual ingredients of the powder, including the NRL protein content, magnesium oxide, etc., MUST be revealed to the consumer on the primary packaging.

Trade secret and proprietary ingredient mixes, and related manufacturing concerns, should never be allowed to prevent FDA from doing its solemn duty to protect public safety.

The proposed labeling is not adequate because it does not quantify the extractable NRL protein bound to and present in the donning powder. The NRL protein content of the glove is false, misleading and understated *unless* the protein content in the primary NRL-protein delivery vehicle, the lubricating/donning powder, is clearly identified and reported to the consumer.

4. In the proposed guidance document, FDA is recommending no more than 2 mg powder per glove, regardless of size, as the recommended powder level for those surgeon's and patient examination gloves labeled "powder-free." FDA requests comments on the proposed limit. FDA is also seeking comments on the possible impact of this powder limit on barrier properties and shelf-life of NL gloves.

FDA must enforce the rule on all manufacturers, for the rule to be meaningful.

5. *FDA is also considering a future requirement that all surgeon's and patient examination gloves marketed in the United States be powder-free. FDA requests comments as to whether a continued need for powdered gloves exists, and, if so, the reason for this need. Comments on the feasibility of such restrictions.*

Alternative gloves have not been accepted rapidly in the marketplace. "Old style" USP Absorbable Dusting Powdered gloves have largely remained the market mainstay over the past several years. FDA may be unable to enforce any such dramatic shift as a proposed "powder-free" initiative.

6. *FDA considered restrictions on the sale (advertising), distribution, and use of powdered surgeon's and patient examination gloves. FDA is seeking comments on the feasibility of such restrictions.*

Banning USP Absorbable Dusting [cornstarch] Powder is appropriate and necessary because of USP Absorbable Dusting [cornstarch] Powder's proven propensity to bind with and carry NRL proteins. Banning alternative, non-cornstarch donning powders and other lubrication methods (not so indicted) would be rash and inappropriate.

7. *In the proposed guidance document, FDA is recommending an upper limit of no more than 1,200 μ g protein per NL glove, regardless of size, as the maximum level for NL surgeon's and patient examination gloves. FDA is seeking comments on the proposed recommended limit.*

This rule will be meaningless unless FDA has the ability to enforce it. Will a proposed enforcement procedure promptly go into effect?

8. *FDA's objectives in this proposed rulemaking are to reduce adverse health effects from allergic reactions and foreign body reactions by controlling the levels of water-extractable protein and glove powder on NL gloves. FDA requests comments as to whether there are feasible alternative approaches to achieve these objectives. If other alternatives or data submitted present feasible methods to protect the public health or suggest that different powder or protein levels are adequate to protect the public health, FDA may incorporate such data or approaches in a final rule.*

As emphasized throughout these comments, removing or repairing the USP Absorbable Dusting Powder donning powder is the single most promising alternative now available. Other proposed methods rely on estimates of future price economics, questionable assumptions, and social engineering. Non-cornstarch alternative lubricating powders can be much safer, equally effective in donning lubrication, and are already immediately available.