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American Latex Allergy Association

THE ALERT Newsletter

Creating Awareness ~ Being Informed

Rubber Allergy Screening With T.R.U.E. TEST

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Contact allergies to rubber products are typically associated with chemicals used in the processing of both natural rubber latex (NRL) and synthetic rubbers (i.e. nitrile, neoprene). Most standard series of allergens contain numerous rubber chemicals. T.R.U.E. Test® (Allergen Patch Test) provides an excellent screening tool when "rubber contact allergy" is suspected and contains the following rubber-related chemical allergens:

Thiuram mix

Thiurams are rubber accelerators, which are the most common cause of rubber contact allergy. Hand contact dermatitis, due to NRL or synthetic gloves frequently caused by thiuram accelerators gloves used by health care workers is a common concern. Of the thiuram chemicals, the most frequently reported are tetramethylthiuram monosulfide (TMTM), tetramethylthiuram disulfide (TMD), dipentamethylenethiuram disulfide (PTD), and disulfiram all of which are contained within the T.R.U.E. Test Thiuram mix patch.

Thiuram sensitivity contributes to glove dermatitis, which is not limited to surgeons, surgical scrub nurses, and dentists, but may also be seen amongst housekeeping employees, food service workers, hairdressers, and homemakers. The eruption itself, while typically in a glove-type distribution, may occur on the feet and other areas of the skin, depending upon exposure. It may present in an airborne pattern, as thiurams are also used in agricultural chemicals (i.e. fungicides, spray-on wound dressing, and other uses). Thiuram sensitivity may be associated with photodermatitis perhaps as part of the extended antigen syndrome. It may also be seen as several forms of systemic contact dermatitis, including the administration of disulfiram (Antabuse) with a five-hour onset after the first dose of diffuse itching, swelling of the feet, and a vesicular eruption of the face, arms, feet and/or pompholyx, acute nummular dermatitis of the extremities, and dermatitis at an old scar site. Systemic disulfiram, which is often occupation-related, can also cause flushing with alcohol exposure. As with other rubber accelerators, reactions are sometimes from objects, which are non-occupation-related such as balloons, clothing, protective aprons, pillows, sponges, applicators, pesticides, putty, tires, rubber-bands, adhesives, plastic-treated seeds, fungicides, neoprene (chloroprene), germicides, insecticides, soluble oils, paints, animal repellants, soap, shampoo, finger cots, gaskets, and many other applications.

Mercaptobenzothiazole (MBT) and Mercapto mix

Mercaptobenzothiazole (MBT) is considered an accelerator, which is a chemical used in curing rubber. It is also categorized with other structurally similar chemicals known as benzothiazoles. Four of the five rubber antigens in the standard tray are tested as mixes which comprise three or four separate chemicals. MBT is an exception and is tested separately to allow use of a more optimal concentration, and to avoid irritant reactions. The remaining three structurally similar chemicals used in routine testing, make up Mercapto mix, allowing screening with a higher concentration of all four benzothiazole antigens. Although MBT is a potential sensitizer, it causes fewer cases of contact sensitivity than the thiurams. In the United States, the prevalence in a population tested for contact dermatitis is about 0.9-2%. The prevalence is greater in occupational contact dermatitis, however, sensitivity is not limited to that group, as it is also a common

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sensitizer in some pediatric populations.

Mercapto mix makes up three benzothiazole-related rubber chemicals: N-cyclohexyl-2-benzothiazolesulfenamide,dibenzothiazyl disulfide, and morpholinylmercaptobenzothiazol. N-cyclohexyl-2-benzothiazolesulfenamide is a benzothiazole accelerator sometimes used in manufacture of both natural and synthetic rubber tires, or it may be used to substitute for MBTS/DPG systems in other applications. Dibenzothiazyl disulfide is a dimer of 2-mercaptobenzothiazole. It is used as an accelerator for both natural and synthetic rubber, but in the latter it may be combined with a secondary accelerator. Dibenzothiazyl disulfide has been isolated from athletic shoes causing insole dermatitis along with MBT, but it is impossible to know whether it was used primarily or was formed chemically in the process from oxidative change. It may also be found in chloroprene rubber as a plasticiser.

Shoe dermatitis, such as insole dermatitis, is a typical presentation of sensitivity to MBT, and some such cases are occupational. Severity varies, likely due to both the level of sensitivity and the degree of exposure. The leading source is in shoes (and boots), and especially the insole area, where mercaptobenzothiazole is a most common allergen. Allergies to rubber chemicals in safety shoes (which is often due to dye and chromate sensitivity as rubber allergy) is often due to MBT.

A positive patch test to 2-MBT may be evidence for occupationally-induced contact dermatitis when there is relevant occupational exposure, such as reactions in "elastic thread" workers, cement tube workers, workers exposed to a conveyer belt, postal clerks in contact with rubber bands and workers using rubber bank-note counters or finger cots. However, reactions are often caused by non-occupational exposure to a wide variety of rubber products. Reported examples include brassiere cups, condoms, rubber swim caps and face masks, a Foley catheter, medical prostheses, elastic bandages, rubber stoppers in medical syringes, shoes, and baby bottle nipples. It has also been found in non-rubber sources such as an anticorrosive agent, an antifreeze mixture, veterinary medications, soluble oils, clothing, tools, cements adhesives, cleansers detergents, paints, fungicides, slimicides, greases, and insecticides.

Black rubber mix

Black Rubber mix contains certain chemicals used in the processing of rubber to make the product more resistant to breakdown, cracking, and crumbling. Antidegradants help prevent damage in rubber products from oxygen and ozone and to provide protection from flex cracking and heat aging. Black Rubber mix contains the antioxidant and antiozonate chemicals N-isopropyl-N'-phenyl paraphenylenediamine, N-cyclohexyl-N'-phenyl paraphenylenediamine and N, N'-diphenyl paraphenylenediamine. The components of Black Rubber mix are used in both natural and synthetic products. While mostly used in tires, these antioxidants are found in almost all black rubber products, such as tires, handles, and hoses.

Patients with sensitivity to the p-phenylenediamine (PPD) derivatives may or may not be sensitive to other rubber chemicals. Hand dermatitis is a common allergy related to PPD derivatives, especially in individuals who handle automotive parts (i.e. tires, hoses); mechanics and body shop employees, salvage workers, automobile sales persons, automotive parts clerks, tire fitters, tire salesmen, are at risk. Service station, garage and parking attendants, car washers, drivers, and truckers are also exposed. Some occupations pose exposure that is not as apparent such as military personnel operating radarscopes, scuba divers (business or pleasure), motorcyclists(includingpolicemen), hospital employees, electrical workers (who handle insulated wire/cable), and repairmen. Bank tellers and postal workers, and florists may use elastic bands which sometimes contain these chemicals. Dairy farmers may break out to black rubber components of automatic milking machines. Contact of the hands and face may also increase exposure (i.e. cane handle, escalator handrail, stapler base).

Carba mix

Carba mix comprises three rubber chemicals: two carbamate activators and/or accelerators (zincdibutyldithiocarbamateandzincdiethyldithiocarbamate) and diphenylguanidine in equal parts. Carbamates are found in a wide variety of

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rubber products and commonly found in both natural and synthetic rubber gloves. They are also used as agricultural chemicals, and may be found in anti-nematode preparations and soil fumigants, which can represent a source of sensitivity in agricultural workers and florists. Because of the structural similarity between these two groups (thiurams and carbamates) and their mutual use in some products, concomitant sensitization or cross reactions between the thiurams and carbamates are common.

p-phenylenediamine (PPD)
Another antigen available on T.R.U.E. Test is PPD. This is sometimes confused with the Black Rubber mix antioxidants. Although this dye is found most often in permanent and semi-permanent hair dyes about 1/3 of persons allergic to Black-Rubber mix will also react to the test to PPD.

p-tert-Butylphenol Formaldehyde Resin
p-tert-Butylphenol formaldehyde resin is used to formulate many waterproof glues used in the manufacturing of rubber products, leather goods, furniture, and shoe industries. Many adhesive formulations, including those with p-tert-Butylphenol formaldehyde resin are used in rubber manufacturing to provide durability, heat resistance, elasticity, and rubber-related reactions have been reported from exposure to neoprene wet suits and shoes.

Despite the fact that many of these sensitizing chemicals decompose or are leached from the product during manufacturing, significant residual amounts may remain. A combination of factors such as the cumulative effect of repeat exposure, hydration either by hydration or perspiration, variation in the amount of residual chemicals within the same product type, as well as enhanced skin penetration due to lipophilic properties of the chemicals, may all be significant and contribute to sensitization.

T.R.U.E. Test® (Allergen Patch Test) provides an excellent screening tool when "rubber contact allergy" is suspected and contains the rubber-related chemicals: Thiuram mix, MBT, Mercapto mix, Black rubber mix, Carba mix, PPD, and p-tert-Butylphenol formaldehyde resin. The accelerators in these chemicals are often responsible for most cases of rubber contact allergy. T.R.U.E. Test provides the core set of chemicals to diagnose and treat contact allergies that can arise from these rubber-related chemicals.

Ask The Expert ? ? ?

Here is your chance. You ask the questions -
We get you the answers.
Send to: alert@latexallergyresources.org

I have been diagnosed with a Natural Rubber Latex Allergy. I have been changing my products to the synthetics rubber latex products and/or alternatives. But why am I reacting to these products that are not made of natural rubber latex?

This question comes up often so we went to the Experts at SmartPractice to have it answered. We have used their answer in the feature article.

Convincing the FDA to ban the Dangerous Cornstarch Powder on Medical Gloves

Because of the dangers to patients and health care professionals from cornstarch powder, numerous manufacturers have developed powder-free latex and synthetic surgical examination and surgical gloves.1 It has been well documented that the cornstarch powder on medical gloves presents health hazards to patients and health care workers by four different mechanisms.2 First, the cornstarch powder on gloves has documented detrimental effects on wound closure techniques.3 Second, this powder potentiates wound infection.4 Third, cornstarch induces peritoneal adhesion formation and granulomatous peritonitis.5,6 Finally, these powders serve as carriers of latex allergen reaction to sensitized patients.7 These well-documented hazards have caused the United Kingdom and Germany to ban cornstarch powder on medical gloves approximately 10 years ago.8,9

Realizing the documented dangers of cornstarch powder listed above, on September 24, 2008, Edlich and eleven health care professionals submitted a Citizen's Petition to the Food and Drug Administration (FDA) to ban immediately the use of cornstarch powder in the manufacture of surgical and examination gloves.10 Because of the dangers of this dangerous powder on medical gloves, many manufacturers have introduced a large supply of powder-free, high-quality, inexpensive, easily donned, natural rubber latex and synthetic gloves since 1998.

On Monday, November 8, 2010, Edlich received a telephone call from Mr. Paul Gadiock of Regulatory Affairs of the FDA regarding the Petition to ban cornstarch on medical gloves. Gadiock indicated that in one to two months, the FDA would be publishing a notice in the Federal Register requesting health care professionals and companies to submit comments or provide any scientific documentation that cornstarch powder on medical gloves is safe and can be used without any damaging effects on patients or health care professionals.11

On February 5-April 25, 2011, the Federal Register was open for comments from healthcare professionals and glove manufacturers regarding the risks and benefits of cornstarch powder on medical gloves.12 Of the 280 comments posted on the Federal Register, all comments focused on the benefits of banning cornstarch on medical gloves in the United States. They also emphasized that warning labels on medical glove packages that contain medical gloves coated with cornstarch were of no value because most health care professionals do not have the opportunity to ever read them. On May 31, 2011, the Pharmaceutical & Medical Packaging News.com wrote an article regarding banning powdered latex gloves. In this report, it was pointed out that almost no health care professionals use powdered medical gloves in our country.13 "A report by Global Industry Analysts, Inc. of San Jose on the disposable glove market in 2010 found that only 7% of gloves in the U.S. market were powdered. Some 92% of exam gloves were powder free and 94% of surgical gloves were powder free. Despite the increase cost of powder free gloves, the report says, Global Industry Analysts Inc. predicts further reduction in the use of powder gloves by 2015".

After the FDA received comments from the Federal Register, Mr. Gadiock contacted Dr. Edlich and indicated that the FDA would announce its final decision on banning cornstarch on medical gloves in either April or May of 2012. He also noted that the decision would be a favorable one. Because of the delay in hearing the final decision of the FDA, Dr. Edlich teamed up with two gifted research assistants, Julie A. Garrison and Heather N. Smith, to write a comprehensive review of the academic journey to ban the deadly cornstarch powder on medical gloves. Their review of the subject was published in the book "Deadly Powder on Medical Gloves—a Wake-up Call to the Food and Drug Administration". The publisher of the book, IUniverse, Inc., made the book available for marketing through their own website as well as Amazon.com and Barnes and Noble online. The co-authors of this article, along with Sue Lockwood of the American Latex Allergy Association, submitted a petition on Change.org to have a petition submitted to the FDA to ban cornstarch powder from medical

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gloves. At the present time, 250 individuals have signed the petition. It's important to emphasize that one of the co-authors of this report, Danielle D. Phelps, played a leadership role in developing a brochure that facilitated the process of how to sign on to the petition. We will wait impatiently to learn of the decision of the FDA.

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Utilizing Innovative Technologies and Other Conditions of Safe Use To Expand Access to Nonprescription

The FDA is requesting comments about moving medication to nonprescription status. If you think asthma or anaphylaxis should not be self-diagnosed or treated, please submit comments to the FDA.
http://www.fda.gov/Drugs/NewsEvents/ucm289290.htm

Your help is needed to continue to pressure the FDA to ban cornstarch powder on medical gloves. Dr. Richard F. Edlich is now submitting a petition to Change.org, requesting the FDA bans cornstarch powder on medical gloves. If you would like to sign the petition all you have to do is go onto the website - http://www.change.org/petitions#search/Deadly Powder on Medical Gloves