

Latex Gloves Manufacturing / Allergen Information





pomona® 3 Hickory Ave Henderson Auckland 0612 ph: 0800 POMONA sales@pomona.co.nz www.pomona.co.nz



Important Facts About Latex and Latex Gloves

Natural rubber latex gloves - made from a renewable resource natural rubber are natural products. They are derived from natural rubber latex obtained from the Hevea Brasiliensis Tree when the bark is tapped (figure 1). This is unlike all synthetic gloves, which are made from Petroleum based chemicals.



Figure 1. Natural rubber latex collected in a cup after tapping of the bark of a hevea brasiliensis tree.

Raw Natural Rubber Latex

This is a milky fluid comprising 25%-40% of rubber hydrocarbon in the form of particles suspended in an aqueous serum together with a few percent of other non-rubber substances such as proteins, lipids, carbohydrates, sugars, some metals, fatty acids, and other substances, known as the non-rubber fraction. The remaining major component is water.

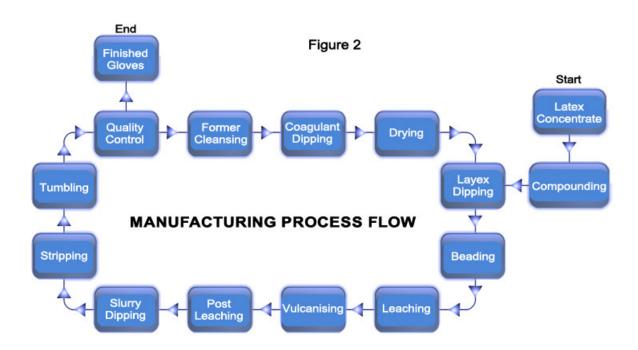
Natural Rubber Latex Concentrate

Latex collected from the tree after tapping is concentrated generally by centrifugation, to remove much of the aqueous components. The concentrated latex with about 60% dry rubber content (or drc) is then usually preserved with ammonia to combat bacterial growth. The resulting latex concentrate becomes the starting material for all natural rubber latex products, whether by dipping (for gloves, balloons, catheters, baby soothers, rubber tubing, toys and dental dams) or other processes such as foaming (for latex foam to sponge), or extrusion (for latex thread, more commonly known as "elastic").



Steps in the Manufacturing Process

The manufacture of most natural rubber latex gloves follow roughly the same sequence. However, many manufacturers include processing steps that reduce the level of protein in their gloves. The typical glove manufacturing process is as follows:



The salient features of the above manufacturing processes include the following:

Dipping: Liquid latex concentrate is mixed with various compounding chemicals and is introduced into one of the tanks in the processing line. Clean, dry formers in the shape of hands are immersed first in a coagulant and then in the latex mix for appropriate dwell time to give the desired latex film thickness. The coagulant is applied to facilitate the deposition of a layer of latex on the formers.

Wet-Gel Leaching and Beading: The thin latex film on each former is partially dried and leached briefly in clean water to remove the water-soluble materials. Beading also is introduced at this stage to give each glove a rolled bead or rim at the open end.

Drying and Curing: The gloves are then dried and vulcanized. drying and vulcanization or curing of the gloves are usually done in hot-air ovens, initially at lower temperatures of 80°-90°C, and then at higher temperatures of 100°-140°C where necessary.

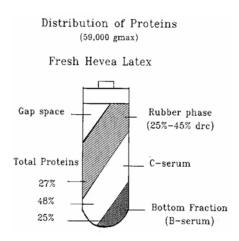
Post-Cure Leaching or Dry-Film Leaching: The cured gloves are immersed in clean water tanks to remove more water-soluble substances, particularly proteins on the surface of the gloves.



Powdered Gloves: The leached gloves are dipped into cornstarch powder slurry to pick up a coat of lubricant that makes them easier to don. They are then further dried.

Glove Stripping: This is the final operation on the production line - removal of gloves from the formers. This is often carried out manually, frequently with the assistance of compressed air, but an automatic stripping system is becoming more common.

Figure 3



When processed into latex concentrate, considerable amounts of the soluble proteins are removed. Further conversion of the latex concentrate into gloves removes more of these proteins through the leaching and washing steps. Therefore, the remaining levels of soluble proteins - or the residual extractable proteins implicated in allergic reactions - are markedly low. depending on which manufacturing process is used, the level of residual extractable protein can vary widely.

Dalrymple S.J. and Audley G.B. "Allergenic proteins in dipped products: factors influencing extractable protein levels," rubber developments, 1992; 45(2/3):51 Yunginger J.W., Jones R.T., Fransway A.F., et al. "Extractable proteins in disposable medical gloves and other rubber products," J. Allergy Clin. Immunol. 1994; 93: 836-842) Ng K.P., Yip e., Mok k.l. "Production of natural rubber latex gloves with low extractable protein content: Some practical recommendations," J. Nat. Rubber Research, 1994; 9:87-95.

Latex Allergens

Not all proteins in the residual extractable fraction cause the allergic reaction. Although to date 13 proteins (mostly soluble) in raw hevea latex have been reported to be possible allergens as defined by their display of IGE antibody binding activities, it is unlikely that all of them would be present in the finished products after processing.

Alenius H., Turjanmaa K. and Palosuo t. "Natural rubber latex allergy," occup. environ, med, 2002; 59: 419-424; Yeang H.Y. "Natural rubber latex allergens: new developments," curr opin allergy clin. immunol. 2004; 4: 99-104),



Cross Reactivity

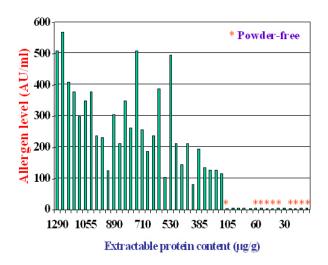
It is noteworthy that individuals with sera showing binding of IGE to latex proteins are not necessarily latex allergic. The binding could be due to cross-reactivity with other plant proteins with certain similarities, suggesting shared or common antigenic components among proteins from latex and foods. A study of binding patterns of IGE antibodies from the sera of individuals who were not latex allergic but who had reactions to fruits supported this. The findings also showed that multiple bindings occurred between latex serum proteins and IGE from many who reacted to extracts of fruits but not to latex gloves. On the other hand, more specific and fewer bindings to latex protein by those who skin tested positive to latex glove extracts were generally observed.

hasma h., shahnaz m., yip e., azizsah m., mok k.l. and nasuruddin b.a. "binding patterns of ige antibodies in sera of rubber tappers to fresh hevea latex serum proteins," j. rubber research, 1998; 1(3): 146-153

Allergenicity of Latex Gloves

The allergenic potential of latex gloves can be measured in-vivo by skin-prick testing (SPT) on latex-allergic subjects, or in-vitro by specific ige antibody-inhibition immunoassays. The SPT method is known to be more specific and more sensitive than the IGE binding techniques. However, all of these methods are relatively sophisticated, and require further improvements, and they are also expensive to perform. The presently preferred method is the quantification of total proteins using the modified lowry micro-assay, which is technically easy and possible to standardize as well as cost effective. however, the test is not allergen specific. Nevertheless, significant correlations between residual total extractable protein content and the allergen levels of extracts of nr latex gloves based on both serological ige specific inhibition immunoassays, and the SPT testing, have been established. Latex gloves with high residual extractable protein contents are associated with positive SPT or high allergen contents. Latex gloves with very low residual extractable proteins, on the other hand, tend to have very low or negligible spt reactions by latex sensitive subjects.

Figure 4. Total extractable protein content (as measured by modified lowry assay) of latex gloves and percentage negative skin prick test response shown by latex sensitive subjects. (ref: Yip E., Turjanmaa K., Ng K.P. and Mok K.L. "Residual extractable proteins and allergenicity of natural rubber products," J. Nat. Rubber research, 1994; 9: 79-86;)



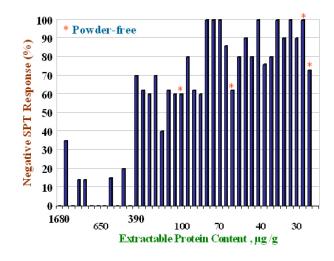


Figure 5. Total extractable protein content and allergen level of 46 lots of latex gloves, as determined by modified lowry test and ige latex specific elisa-inhibition respectively. (Ref: Yip E., Palosuo T., Alenius H., and Turjanmaa K. "Correlations between total extractable proteins and allergen levels of natural rubber latex gloves," J. Nat. Rubber research, 1997; 12: 120-130)



