Harry F. Bader

How to go about getting the FDA approval

We are an established latex examination and surgical manufacturer in Malaysia. Your company is referred to as one of the FDA-approved testing laboratories. Kindly advise us on the procedure and cost involved for FDA sampling. Could you tell us how soon we can get a test report?

Ms. Aziah Mahmud
Assistant Manager
Top Glove Sdn. Bhd.

I'm not sure what FDA sampling you need. If it is for 510k submission, the sampling and testing will be quite involved. If, however, you need water leakage testing by an independent laboratory to satisfy FDA detention requirements at a US port of entry, the procedure is quite simple.

We charge US $300 per glove tested. The number of gloves tested, if exam gloves, can be as few as 80 or as many as 560. If surgeon's gloves, that changes from 125 to as many as 875 gloves. This follows the requirements of FDA CFR 21, Part 800.

We will provide sampling instructions and proper forms to be filled in, to a third-party entity, so that they can collect samples to be forwarded to our lab in Akron, Ohio, USA. After testing, we will report the results to the FDA and to your company.

To begin this procedure we need FDA Notice of Detention, your packing list showing quantities and sizes of the gloves in question, the telephone/fax numbers, name of contact, and address of the third-party entity that will be sampling the gloves (or we can do the sampling for you), and, in the latter case, your purchase order authorizing us to proceed.

This is a typical service available from numerous laboratories. Some perform testing only, with you having the responsibility of reporting to the FDA. Some do both sampling and testing. Some do everything for you.

•••

I have heard about solvent dipping of butyl for making gloves. In the case of NR latex gloves, the coagulant (CaCO3 & CaNO3) itself acts as a stripping aid. But in the case of butyl solvent dipping, it is not possible. Can you suggest a stripping aid that is coated on the first, i.e. before solvent dipping, so that stripping becomes easier? Can we use any dewebbing agents for butyl dipping?

Sree Lakha

Many NR latex, nitrile latex and neoprene latex gloves are coagulant-dipped without using CaCO3 & CaNO3 as a stripping aid. In those cases, materials such as polyethylene glycol are added to the coagulant to facilitate easier stripping. As an alternative, wet stripping systems can be used.

If a 'straight' system is used, as in solvent dipping, wet stripping would be the preferred method. In this process on an automatic dipping line, the stripping solution would be 'flooded' onto the gloves as they pass by.

I have done this with NR latex on an automatic line and in the development lab for NR latex, butyl latex, and solvent solution

Harry F. Bader, Vice-President, Latex Services, Akron Rubber Development Laboratory, Akron, USA, and a world authority on latex, answers questions and doubts of readers on latex and latex products.

Send your questions to:

'The Latex Doctor'
Rubber Asia,
Dhanam House,
Cochin - 682 020,
Kerala, India
Fax: 94-484-317872

of NR. I would expect it to work equally as well with a solvent solution. For recommendations on dewebbing, contact Ms. Petra Vance at CrusaderCC@aol.com. Ms. Vance has international distribution of dewebbers and defoamers.

Crusader Chemical Company is an advertiser and Ms. Vance is a frequent writer of important articles in *Rubber Asia*.

•••

May I have some information about butyl latex. What type of latex is it? Anionic/cationic/artificial? Can it be used for making gloves? If so, what type of coacervantes can be used? Is it alkaline/acidic? Where is the latex available? Can butyl gloves be made by solvent dipping? Which is the current process of making butyl gloves?

Sree Jeeva

Solvent dipping of butyl is more likely than latex dipping. I believe most butyl gloves available today are solvent dipped. Butyl latex is available from Lord Corporation, Chemical Products Division, 2000 West Grandview Blvd, Erie, Pennsylvania 16514, USA (contact Victor Ferrell Tel: 814-868-3611).

They have butyl latex (BL-100) which I have found to be satisfactory for straight dipping. They claim coagulant dipping is possible. However, drying of thick butyl film is extremely difficult and also trapped bubbles are a big problem.

I suggest you contact them for their latest Technical Bulletin, which can answer many of your questions.

•••

My company is making flocked gloves using cotton flock. Flock does not stay well. We use Tensophine H-10 in the latex compound. What do you recommend as latex adhesive? Who makes that material?

Shukla Polymers

I'm not familiar with tensophine H-10, so I can't comment upon its use. For flock application, the following conditions are important:

Primarily, the latex film on which you are impregnating the flock must be wet. If it is wet, the latex will flow into the cotton fibres you are placing on its surface. The penetration of latex into the cotton fibre will ensure that it remains anchored to the glove. If the latex is not wet the flock won't stick.

To ensure that the latex is wet, the area around the dip tank and the flock both must be no less than 70% RH. If the air moisture content is lower, the latex dries too quickly.

The flock must be forcefully applied to the wet latex surface. This is usually done by having the application nozzle close to the gloves and having only enough air to move the flock forcefully but not so much air that it dries the latex.

The time from the forms clearing the latex to having the flock applied should be as short as possible, say seconds.

The per cent total solids of the latex compound should be somewhat less than what is used for the major glove dip and the pre-cure should be lower. Fresh latex compound with a chloroform pre-cure works best.

With a natural latex compound that is essentially a normal dipping compound with a lower per cent TSC and a low pre-cure. I've not found it necessary to use a tackifier.

Note: All the above are based upon a post-vulcanization system which tends to "tighten" the latex on to the cotton fibres. With a pre-vulcanization system a tackifier might be needed. While choosing a tackifier, care must be used to ensure that the glove does not remain tacky after stripping.

I am not familiar with suppliers in India; so I cannot give you any specific recommendation for a latex flock adhesive compound. However, I suggest you contact NR latex compound suppliers who advertise in *Rubber Asia*. I'm sure they can help. ■