



Harry F. Bader

## Particle count testing for vinyl gloves

Could you let me know about the particle count testing of vinyl gloves for a Cleanroom Class 10K Standard?

Ningsih Dharmawijaya

Fed. Std. 209E, "Airborne Particulate Classes for Cleanrooms and Clean Zones" is the controlling document. This provides the allowable particulate count and total particulate area for all cleanroom levels.

The control is on the particles in the room and not on the individual protective gear in the room. However, steps are taken to reduce particulates by choosing low-particulate protective garments and devices.

IES-RP-CC005.2: "Gloves and Finger Cots Used in Cleanrooms and Other Controlled Environments" is available from the Institute of Environmental Sciences, 940 E. Northwest Highway, Prospect, IL. 60056 USA.

*NOTE: It's quite expensive for non-members.*

Test methods which would apply to gloves are:

ASTM F 24-00: "Standard Method for Measuring and Counting Particulate Contamination on Surfaces".

ASTM E 1731-01: "Standard Test Method for Gravimetric Determination of Non-volatile Residues from Cleanroom Gloves"

ASTM D 6124-01: "Powder Content of Powder-Free Gloves".

The testing requirements should be part of the purchasing agreement between the manufacturer and the customer.

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I am a toxicologist in a contract laboratory. Traditionally, for cytotoxicity assays (as required by ISO/USP biocompatibility testing), we have been using a latex glove formulation as a positive control. Our current lot of gloves was validated several years ago and we are running low on the remaining supply. I have ordered several different latex gloves from different manufacturers to revalidate but cannot find any that will give a positive response.

I was wondering if there was any way we could purchase a low-grade latex formulation that would not meet the standards required for human-use products. I need a product that will consistently yield failing (grade 3 or higher) results in agar overlay cytotoxicity testing. Any suggestions, please?

Annetta Herrington  
STS duoTEK, Inc.

This is an interesting question. It seems that general glove quality has improved and it is no longer common for NR latex gloves to cause positive cytotoxic reactions. There is no good reason why that did not happen at least 15 years ago.

I made some film for Ms.

*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'  
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Herrington from a popular commercial pre-vulcanized NR latex compound. I did no leaching or washing. I followed a very simple process.

- \* Coagulant dip, dry 20 minutes at 50°C.
- \* Latex dip, dry 1 ½ hours at 50°C.
- \* Powder with CaCO<sub>3</sub>, strip

Samples were sent to Ms. Herrington, she reported "no positive reaction". Which means accelerator residues are present insufficiently to cause a positive reaction.

I later made a post-vulcanization compound with moderately high carbamate and thiazole accelerator content. This was processed without leaching or washing and did provide the desired "positive control" Ms. Herrington needed for her testing.

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We make surgeon's gloves (powdered) with coagulant dipping process. Please suggest some cleaning solutions for online ceramic mould cleaning, after stripping? (We now use imported ceramic mould cleaner CMC3 & CMC2 from Malaysia. Now, our dealer is unable to supply the same) Awaiting for your valuable reply.

K. Muralidharan,  
for TTK Healthcare Ltd.

If your coagulant contains calcium carbonate as the powder for ease of stripping and as the basic powder for the glove, your former cleaner should be an acid. So it will react with the CaCO<sub>3</sub>.

If the CMC3 and CMC2 materials worked well for you, why not send samples of them to a laboratory for analysis?

That would provide a formula for you to make up your own equivalent of the CMC3 and CMC2. If you cannot locate a local lab to do that work, contact [harryb@ardl.com](mailto:harryb@ardl.com).

An alternative is a dipping former cleaner from Oakite Products, Inc., 50 Valley Road, Berkeley Hts., New Jersey 07922-2712; Telephone 908-464-6900.

Fax: 908-464-4658; Website: [www.oakite.com](http://www.oakite.com)

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We are planning to put up a surgical gloves plant in India. So we are in search of machinery manufacturers. Since, you are the expert, please suggest which type from which manufacturer is cheap and best to suit Indian conditions. If you have any information, please send details through e-mail.

Address not mentioned

ACC Automation is the logical choice. Their equipment can be tailored to your individual needs. They can provide engineered drawings only, or they can provide a full turnkey plant. It is your decision.

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A question came up at our Latex Safety Meeting about whether items in the patients' rooms were latex-free. There was concern about the reusable blood pressure cuffs and the black-extension blood pressure tubing. I know the replacement items in our warehouse are latex-free, but I am not sure what the old items in the room are. Most of these older items are not marked. Is there any simple method to determine if an item contains latex — a chemical test of some type that could be performed in a patient's room?

Charles Platt,  
Medical Center of Central Georgia.

There is no simple test for natural rubber latex protein content. The tests in common use are destructive for the item being tested.

In today's litigious climate, I can understand the concern about latex allergy lawsuits. For peace of mind, I suggest you replace the items about which you have concerns. ■

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