Harry F. Bader

Standard for catheters – Finger holes – On-line chlorination

We are a leading manufacturer of Foley catheter having the following range of products a) female b) 2 way c) 3 way etc. We have our sister concern also in this business. This plant is two years old.

1. **Do you know the vendor who can supply us the precompounded latex which can be used for making Foleys in India?**
2. **Can you send us the following additives manufacturers' address? Casatab-T: We use it as an additive to the latex as thickening agent. GUM Adhesive: Using as in the dipping process with methylene chloride.**
3. **Can you suggest us the pigment, colour manufacturer for latex with which we can make the coloured catheter?**
4. **How temperature and factor humidity affect Foley catheter as a product and the latex? What should be the standards for the same?**
5. **What is yield for Foley catheter worldwide?**
6. **Is it necessary to jacket the tank with cold water or similar?**
7. **Can you suggest an alternative for methylene chloride which we are using along with GUM in the dipping process which insures that balloon is sealed properly?**
8. **Colour variation is observed after some period. Is there any storage standard for this dipped product to avoid colour change?**
9. **Can you send us the names of the books on Foley standards and latex testing and technology?**

G.P. Manjramkar
Manager Production
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Aurangabad 431 136

I'm not aware of a supplier of compounded latex in India. However, there are several suppliers of latex who advertise in *Rubber Asia*. I suggest you contact them for the names of compounding companies that supply latex.

2. "Casastab T" is now manufactured by, Swan Chemicals, Inc. 136 Ridge Road, Lyndhurst, NJ 07071. Tel: 201-729-1400. Fax: 201-729-0796 e-mail: swanchem@aol.com

GUM adhesive is available from Harwick Standard Distribution Corporation, P.O. Box 9360 Akron, OH 44305-0361. Tel: 330-798-9300 Fax: 330-798-451 e-mail: harwickstandard.com

3. Manufacturers of pigments are advertised in *Rubber Asia*.

4. The important thing to remember about temperature and humidity is that they should be kept constant day and night and every day. The process can be adjusted for virtually any reasonable level of temperature and humidity. However, it is impossible to keep changing the process to fit continuing changes in temperature and/or humidity.

5. This is a marketing-related question for which I have no answer.

6. Providing a cold water jacket for the latex tank is one way of overcoming changes in temperature in the factory.

7. There are other chlorinated solvents

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

which can substitute for methylene chloride. Your local pollution control agency can suggest acceptable alternatives.

8. There is no standard for storage conditions. However, while conducting a Shelf-Life Prediction Study or a Real-Time Storage Study, 25-30°C is generally used as normal storage temperature. There is no accepted relative humidity percentage. If you have to store your product in abnormal conditions, the packaging should be such that high humidity never reaches the product.

9. ASTM F 623 is the US standard for catheters. That provides testing methods. ISO 10933 provides information about required biocompatibility testing for medical devices. Also CFR 21 part of the US Federal Register provides information (mainly in section 177-2600) about material permissible in medical devices.

We are one of the leading manufacturers of latex-based surgical tubings in India.

By adding curatives at various proportions to the latex, the modulus and tensile properties are modified but the stiffness is unaltered.

Kindly advise us a latex compound with suitable stiffeners for increasing the stiffness and hardness of the finished product.

SISCO Latex Pvt. Ltd, .Gopalan Kadai Road, Kurumbapet, Pondicherry – 605 009

Increasing the zinc oxide level as well as the sulphur level should produce a tighter cure and less flexibility. This will also increase modulus and lower tensile strength.

The so-called stiffening agents are generally phenolic resins or high styrene resins. I'm sorry but I have no experience with these materials.

Harwick standard mentioned in the answer to question one above is listed as a supplier of these resins.

We are looking for consultancy for the production of polymer coated powder-free gloves (on line with low protein) by correspondence. We are in business for the last 11 years. Kindly give your proposal. I would like to get your valuable suggestion on the following:

We have five 90 meter production lines. In recent months I found a prominent problem with our gloves i.e. between finger holes. All other areas have no problem. The holes are not minute, but very big (say 1 mm size). This starts after cleaning of former, stays for 2 to 3 days and disappear. We are having the following recipe for production compounding:

Latex + all the V System + 0.1% KOH + 0.1% silicon based anti foam coagulant

Ca Co3 5 to 6% + nitrate 7 to 8% + 0.1% wetting agent.

This wetting agent is from a proprietary firm and we have been using this for the last so many years. Is the problem due to webbing? If so, the same latex is used in other lines. Single compound goes to all 5 lines.

Kindly give your valuable suggestion and help me.

Abraham

The fact that your problem of holes in the glove finger crotches occurs after the forms have been cleaned and then disappears after 2-3 days is a major clue.

I suggest you investigate the form cleaning operation.

A residue is likely remaining between the fingers after cleaning. After 2-3 days, this is washed away by the coagulant and the problem stops.

Wash away that residue from the forms before you put them back on line.

An article in *Rubber Asia* September/October 2000 mentioned on-line chlorination as one method used for glove chlorination. Can you give me some information on how this is done?

Anonymous

I also saw that article. There was no information given on methods of handling the chlorine gas that would be coming from the chlorine-water dip tank on an in-line system.

Chlorine is extremely corrosive, so all the line equipment and the conveying system must be protected from this corrosive action. Stainless steel does not work.

Chlorine is extremely toxic. In World War I it was the most effective war gas. Therefore, measures are needed to ensure gas coming from the tank is captured and neutralized before it gets to the manufacturing work force.

There are many safety and technical issues which must be addressed before on-line chlorination is attempted. I would strongly suggest not to consider it for an existing production facility. Designing a new facility including on-line chlorination would enable all those safety and technical issues to be handled prior to building the facility. ■