Manufacturers balance cost, comfort and quality to meet changing glove market

By Bruce Flickinger

If you work in a critical manufacturing environment and use or specify the use of latex gloves, there’s a good probability that your company is being asked to bear some rather stiff increases in the cost of these most critical pieces of protective equipment.

This largely is because the costs of raw materials involved in making latex gloves have skyrocketed, increasing, by some accounts, as much as 350 percent in the past three years. There is simply a finite supply in the face of growing demand, and this does not appear to be a seasonal or temporary problem. Labor costs in the main glove-manufacturing countries are on the rise as well, so suppliers, already operating at or very near optimum efficiency, are being hard-pressed to absorb these increases internally.

“Many companies use latex because of its low cost, so the market traditionally has not been able to support significant price increases,” says Chris Heiland, director of sales with Value-Tek (Phoenix, Ariz.). “Glove makers can’t pass on these price increases, which is causing many of them to go out of business.”

Other glove manufacturers, or “dippers,” are converting their operations to production of nitrile gloves, the primary alternative to latex and increasingly the first choice for highly sensitive operations such as disk-drive manufacturing. Heiland, who is involved in his company’s product development efforts and recently returned from a tour of glove manufacturing operations in Malaysia, says that, compared to three years ago, there are about half as many latex glove dippers there.

Bob Clark, technical sales manager with Protective Industrial Products (Guilderland Center, N.Y.), says rising prices are expected across a range of raw materials. “Any time there are price increases, people start looking around at different materials,” he says. “Nitrile will be seeing price increases too due to increases in oil prices. It’s the nature of the industry when you’re dealing with petroleum- and rubber-based products.”

The upshot is a changing dynamic in the market for latex gloves and, by extension, for cleanroom gloves made of nitrile and other materials. Critical manufacturing companies in microelectronics, semiconductors and hard disk drives (HDD), along with FDA-regulated companies in pharmaceuticals and biotechnology, are more carefully evaluating their glove suppliers and glove usage decisions and, where necessary, undertaking the difficult process of changing the gloves their operators use.

“Gloves are probably the most important items of protective clothing in critical manufacturing because they come into direct contact with the products,” says Jason Baker, global technical program leader with Kimberly-Clark Professional, based in Roswell, Georgia. “Yield is the king in clean manufacturing, and gloves can affect yield. These are intensely competitive industries, and any change in glove use requires a careful assessment of costs, operator concerns, impact on yield, and a thorough qualification process.”

Reconsidering latex

Different end users place differing priorities on certain glove performance characteristics, and until recently, latex fulfilled most of these needs economically. In semiconductor and HDD manufacturing, microcontamination is the key concern, and low particulate, low ionic extractables, low out-gassing and good electrostatic discharge (ESD) protection are among the most critical elements of a glove. Conversely, the function of the gloves used in pharmaceutical manufacturing is to prevent product contamination from manufacturing personnel as well as to protect the personnel when handling the products. Here, the critical issues are bioburden and sterility, and pinholes are a particular worry because of the potential exposure to pathogens. Latex still is largely the material of choice for these companies, but even this is beginning to change.

“The primary reason people use latex is for its stretchability, and tactile feel and dexterity attributes,” Heiland says. “It feels good and affords the wearer a good grip. But just about every other attribute is negative when compared with the alternative.”

Carmen Castro, marketing and product development manager with MAPA AdvanTech Inc. (Columbia, Tenn.), says the company is still seeing a high level of use of latex gloves among semiconductor manufacturers. But, nitrile “is one of the toughest materials on the market when it comes to snag, puncture, abrasion and cut resistance, and offers a broad range of chemical protection,” she says. “It is a versatile polymer that handles the largest combination of physical and chemical hazards in a wide range of applications.”
Latex, or more precisely a polymer called polyisoprene, is a natural raw material and as such is subject to more variability when compared with petroleum-based nitrile. “The change in season, the nature of the soil and fertilizers used in the rubber plantation are some of the factors that can affect variables in the latex and therefore make consistent quality control of the gloves more challenging,” says S. K. Lau, vice president of Riverstone Resources Pte. Ltd.

Although many companies have manufacturing operations in Malaysia, Thailand or China, Riverstone is a Malaysian company with a network of international offices, including one in the U.S. (Gilbert, Arizona). Roughly 80 percent of its production is nitrile gloves, with the balance in natural rubber gloves. Lau says a further issue with latex gloves is that their surfaces are comparatively tackier due to the double-bond structure. They require higher use of calcium carbonate in production and stronger chlorination in postproduction, resulting in higher levels of particulates and ionic extractables.

Nitrile, a copolymer containing acrylonitrile, butadiene and methacrylic acid, is structurally different and presents fewer variables to the manufacturing team, Lau explains. Gloves manufactured using this material provide relatively fewer particulates, lower ionic extractables, better ESD protection and stronger resistance to chemicals. Essentially, these “are the performance characteristics of a glove required today in critical-environment manufacturing,” Lau says.

Lau concurs that HDD manufacturing is becoming increasingly sensitive to contamination. “Natural rubber cleanroom gloves generally are no longer able to meet some of the specifications demanded from the end users,” he says. As a result, HDD manufacturers, including those subcontracting in components, “have replaced natural rubber gloves with nitrile cleanroom gloves in a majority of their production processes.”

Similarly, although microelectronic and semiconductor manufacturers largely use vinyl gloves because of their manufacturing requirements, “there has been a gradual migration to nitrile gloves in recent years,” driven mainly by the increasingly stringent manufacturing environment in this industry, Lau says.

**The making of a glove**

While their compositions differ, latex and nitrile gloves are made in roughly the same manner. The process is well-understood and generally a continuous industrial operation, but it’s not simple. Kimberly-Clark Professional, for example, has identified 65 critical parameters in its manufacturing processes. “You need to have a sturdy process with good quality systems in place,” Baker says.

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**Value-Tek’s nitrile cleanroom glove can be used in any critical application where ultralow particulate and extractables are required. Suitable for Class 1 [ISO 3] cleanrooms and above, the glove conforms to a number of test standards, including IES-RP-CC-005 and ASTM D3578-77, D412, D573 and D5151. Photo courtesy of Value-Tek.**

**Kimberly-Clark Professional SAFE-SKIN® Critical White Nitrile Ambidextrous Gloves for Cleanrooms are packaged in a Class 100 [ISO 5] cleanroom. The gloves are latex-free, have an AQL level of 1.5 for pinholes, and are static-dissipative in use. Photo courtesy of Kimberly-Clark Professional.**

**PIP Technical glove offerings include nitrile, latex, vinyl, copolymer vinyl and glove liners that are used in a variety of critical environment applications. Photo courtesy of Protective Industrial Products.**

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levels to synthetic-based alternatives. The company also offers fluoroelastomer gloves that provide resistance to aliphatic, aromatic and chlorinated solvents. “Fluoroelastomer is a weak polymer when it comes to mechanical properties, so we combine it with nitrile,” Castro says. “We put the fluoroelastomer on the outside layer for chemical resistance and nitrile on the inner layer for mechanical strength.”

On the downside, although inferior formulation materials present an initial cost savings, they are a poor investment over the long term, says Randy Kates, general manager, safety business, with Kimberly-Clark Professional. He says that some manufacturing operations, in order to contain costs, are looking for ways to shorten their process or use alternative materials, which may compromise glove quality. Another important point: “Users need to assess glove degradation after actual use in their processes, not just when they’re fresh from the factory,” Kates says.

In the manufacturing process, a mold form—essentially a hand model that is dipped into the liquid formulation—determines the glove size and the surface-texture design. For both latex and nitrile, the speed of the production line (the number of dips a mold form makes) determines the mil thickness and strength of the glove. The slower the mold runs through the vat and the more dips made, the thicker is the resultant glove. Durability, puncture resistance, pinhole reduction and chemical resistance all are affected to some degree by the thickness of the glove.

When the dip or forming process is completed, latex gloves are subjected to a vulcanization process to remove excess chemicals remaining from the mold process, to reduce odor and add elasticity to the latex. The gloves are then stripped from the mold formers and enter the final cleaning and treatment phase. Gloves destined for critical environments are chlorinated, which, while hardening the material and reducing shedding, can reduce the shelf life of the product.

Hydrolyzed cornstarch is often added to latex gloves, which makes donning easier and helps shorten the manufacturing process. However, studies show that the starch binds to the latex proteins and acts as a vector transfer of protein to the skin, contributing to much publicized problems with latex allergies.

Healthy hands

Skin health, along with protection of the process, is a major point of consideration with gloves. “You need to look at skin health, comfort and feel because cleanroom manufacturing operations are not like a healthcare setting where someone wears gloves for a short period and then removes them,” Baker says. “Operators wear them for much longer periods of time.”

The most common reaction associated with gloves is contact dermatitis, which can develop not only from glove use, but frequent and repeated use of hand hygiene products and exposure to chemicals. CDC classifies contact dermatitis as either irritant or allergic. Irritant contact dermatitis is common, nonallergic, and develops as dry, itchy, irritated areas on the skin around the area of contact.

By comparison, allergic contact dermatitis (Type IV hypersensitivity) often results from exposure to accelerators and other chemicals used in the manufacture of gloves. Allergic contact dermatitis manifests as a rash beginning hours after contact and, as with irritant dermatitis, is usually confined to the areas of contact.

The more serious systemic allergic re-action is latex allergy, or Type I hypersensitivity to latex proteins. It usually begins within minutes of exposure but sometimes can occur hours later. It produces varied symptoms; these commonly include runny nose, sneezing, itchy eyes, scratchy throat, hives and itchy burning sensations. Though uncommon, more severe symptoms can manifest, including difficulty breathing, coughing spells, and wheezing, cardiovascular and gastrointestinal ailments, and in rare cases, anaphylaxis and death.

Additionally, because cleanroom gloves are worn for extended periods—up to two hours in some operations—they can have a deleterious effect on the process as well as the wearer’s hands. “Gloves will degrade over extended wearing periods primarily due to oils and sweat from the hands,” Baker says. “Inferior formulations can show significant degradation after two-hour use; our research has shown some gloves can contain as much as 60 percent pinholes” after two hours of wear.

Heiland sounds a related note of caution regarding changes in glove supply, even from the same glove manufacturer, noting that product batches coming from different production facilities technically should be requalified but often aren’t. “A lot of glove manufacturers are outsourcing parts of their operations, using different formers or dippers,” he explains. “Savvy customers are aware of these types of changes, which glove manufacturers must make to remain competitive, but which also need to be considered.”

Assessing quality

Gloves used in cleanroom environments are subject to a number of testing standards depending upon the application for which they are used. Testing performed on MAPA Critical Environment gloves, for example, consists of particle, extractables and NVR using IEST-RP-CC005.3, along with ASTM D739 and ASTM D471 to test for chemical permeation and degradation, and EN 388 for mechanical properties. Additionally, MAPA latex gloves are tested for natural rubber protein
levels using ELISA (enzyme-linked immunosorbent assay) ASTM D6499. Castro adds that over and above ASTM testing, the company performs light air inflation tests on chemical-resistant gloves to detect pinholes and defects.

Qualifying gloves, particularly when changing to a new material or formulation, is a critical and demanding process for both end users and their suppliers. The gloving industry is “very competitive and the greatest challenge is complacency—getting a company to consider changing its glove supplier,” Heiland says. PIP’s Clark adds that, “Larger companies require more technical data before even evaluating any type of glove change. With smaller companies it really comes down to price.”

Aside from cost and material performance issues, gloves are probably the most intimate piece of protective clothing, subject to wide variation in fit, feel and comfort. Heiland says some companies use a quality investigation to drive their glove-use decision, while others are more operator-sensitive and, here, it is “hard to get a consensus” on glove type. Heiland says. K-C’s Kates adds, “Customers have a feel for their gloves. They know what they need.”

According to Clark, for operators, “the issue is strictly comfort. If someone has been wearing latex gloves for 20 years, it’s hard to get them to agree to a change. Nitrile provides the closest fit and feel to latex, so it’s easier to go from latex to nitrile than to vinyl as long as certain chemicals aren’t involved. Many companies already have both latex and nitrile gloves due to the allergy issue.”

Most customers want to see evidence of process control in the manufacture of the gloves, and new customers typically will audit the manufacturing facility, Kates says. They’ll then perform a trial with a population of their users, and when a comfort level is reached, they’ll request batch certificates of analysis that give detailed lot information about particle shedding, extractables, pinholes and other quality data.

For its part, Value-Tek offers test data on the Internet for every product lot produced, and works with an accredited university that provides independent testing of product lots every 90 days, which allows current and prospective clients to do quality trending.

Baker says Kimberly-Clark Professional provides customers with product specifications and independent test data, followed by production samples for performing their own analytical testing. Customers will then perform a small-line trial, looking for changes in yield as well as negative feedback from operators. An extensive cost analysis will be conducted before the full implementation. “The entire process can take from two to six months,” Baker says.

Heiland notes that the electronics industry, in particular, is very mature, marked by high levels of consolidation and educated customers. “Global electronics companies, although they currently are somewhat fragmented, are moving toward achieving consistency across all their sites. They want to use the same product and pay the same costs.”

Riverstone supplies products to global locations for its customers; Lau says, along with cost, choosing products from the same manufacturer across operations is a quality control measure for consistency. Even subcontractors are often required to use gloves from the same manufacturer as the parent company.
A Class 10 (ISO 4) packaging room for testing and packaging cleanroom nitrile gloves at Value-Tek’s facility in Kuala Lumpur, Malaysia. Photo courtesy of Value-Tek.

Summary

While quality is obviously of key importance, the cost component also factors prominently into most glove-use decisions. Glove manufacturers and end users alike are finding they have to do some recalculating due to recent changes in the cost structure of raw materials.

Regardless of the long-term import of this situation for glove manufacturers, other materials that are proven, perform well and meet demands for cleanliness are available for end users. Manufacturers are endeavoring to meet these needs, which grow ever more exacting as manufacturing processes aim to conform to higher performance standards.

So while cost always affects a purchasing decision, it should not be considered singularly. “Product cost must be supported by consistent product quality and customer services,” Lau says. “The management team, technical knowledge and R&D activity of the company are other factors that need to be taken into account.”

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