Paper presented at the Latex 2001 Conference Munich Germany 4-5 Dec 2001

Recent Advances in the Malaysia's Glove Industry in Meeting Today's healthcare Challenges

By
Dr Ong Eng Long

Abstract

Natural rubber medical gloves provide excellent barrier protection and offer unique flexibility, strength and elasticity are used to minimize healthcare workers exposure to contaminated blood and body fluids, as well as to reduce cross-infection during surgery. In recent years, however, the allergies of some individuals to the latex proteins in natural rubber gloves have caused concern to the medical professions and there is a shift in preference to more expensive powder-free latex gloves and gloves with low protein levels and also to synthetic gloves. Regulatory bodies are also imposing limits to the level of protein and powder in the gloves.

This paper reports some of the advances made by the Malaysian glove manufacturers in producing quality gloves that meet the requirements of the consumers. These include the use of specially enzymatic treated natural rubber latex as starting material, adopting newer processing technologies with effective pre- and post-curing leaching, the control of acidity in leaching water and the use of ultrasonic device in leaching to manufacture gloves with minimal protein content. Exploratory studies of using treated corn-starch to reduce the absorbent properties of powder in powdered natural rubber gloves also produced encouraging results. Improved processing technologies of on-line chlorination and from single-surface to both side polymer coating of gloves have enabled more efficient production of powder-free gloves. To meet the needs of users who are already sensitized to proteins and have been advised to avoid natural rubber latex gloves, some of the manufacturers have commenced producing and exporting quality nitrile and polyurethane gloves.

The introduction of a quality Standard Malaysian Glove scheme (SMG) for latex examination gloves (powdered and powder-free) with upper limits of protein and powder content is a major advancement to further minimise the risk of latex protein sensitisation.

Introduction

The phenomenal growth in the latex gloves industry in 1990s can be attributed to the AIDS outbreak and the 1987 'universal precautions' as mandated by the Centre for Disease Control and Prevention (CDC) of the U.S.A. when dealing with blood and bodily fluids. Healthcare institutions in the U.S. began demanding large quantities of latex medical gloves, which offered the best available protection, to those whose occupations necessitated exposure to and protection from pathogens. This had triggered a similar rapid increase in the consumption of latex for the manufacture of medical gloves in East Asia with the relocation of latex-based industry from the USA and Europe to natural rubber producing countries to take advantage of close proximity to latex supply, cheaper labour and attractive government incentives.

Malaysia is one of the producing countries which seized the opportunity to expand the latex based industry. In the early 1970's, Malaysia was the largest exporter of latex concentrate supplying about 80% of the total global needs while domestic consumption was as less than 5% of the local output. However by 1989, Malaysia became the world's largest user of latex concentrate.

Latex Glove Industry in Malaysia

Natural Rubber latex consumption in Malaysia increased gradually albeit at very low rates in the 1970s and first half of the 1980s. Statistics on natural rubber latex consumption by the various types of latex products showed that the uptake by the glove sub-sector registered the highest growth from a mere 18 178 tonnes in1987 to 201 478 tonnes in 1999 to register an eleven-fold growth and account for a 77.7 % of the sector's uptake and 54.2% of the industry total (Table 1). In 2000 the uptake dropped to 190 703 tonnes.

Another recent development in rubber consumption by the sector is the growing uptake of nitrile latex for the manufacture of gloves. Falling prices of latex gloves and rising demand for alternative gloves for protein-sensitised users have led to more manufacturers venturing into nitrile glove production. Consumption of the material by the sector had increased to almost 12 000 tonnes in 1999.

Table 1. Natural Rubber Consumption by Selected Latex Products Sub-sectors
(tonnes, dry weight)

Year	Gloves	Latex Thread	Catheters	Other Latex Products	Total
1987	18 178	n.a.	576	9 388	28 092
1988	31 945	n.a.	856	10 534	43 335
1989	47 342	n.a.	946	13 474	61 762
1990	62 972	n.a.	1 055	48 596	112 623
1991	78 142	56 742	1 157	3 332	139 373
1992	115 455	50 231	1 308	5 131	172 125
1993	152 383	31 925	1 370	5 616	191 294
1994	161871	43 570	1 410	6 477	213 328
1995	179 096	55 782	1 434	6 211	242 522
1996	191 770	73 709	1 374	5 557	272 410
1997	186 373	50 579	1 419	4 804	243 175
1998	204 131	52 353	1 296	4 888	262 668
1999	201 478	55 896	1 115	5 657	264 146
2000	190 703	60 853	1 409	6 301	259 266

Source: Department of Statistics, Malaysia;
Malaysian Rubber Board (MRB).

Table2. Output of Rubber Gloves, Catheters and Selected Rubber Products, 1993-2000

	1993	1994	1995	1996	1997	1998	1999	2000
Pneumatic tyres (all types, million units)	9.5	10.2	11.3	12.2	13.7	13.6	13.5	12.7
Inner tubes (all types, million units)	14.0	14.8	14.7	17.4	15.2	11.8	11.5	12.5
Rubber gloves (all types, billion pairs)	5.1	6.5	7.5	8.5	8.9	10.8	10.9	11.6
Catheters (million units)	65.3	78.5	79.2	87.3	89.2	75.9	94.6	91.0

Source: Department of Statistics, Malaysia; MRB

Table 3. Export of Rubber Goods
(Value in Million RM)

Year	1998	1999	2000
Latex gloves	4,132	3,659	3,332
All rubber products	6,491	6,029	5,698

Source: Department of Statistics, Malaysia;
MRB.

Between 1993 and 2000 the glove production had more than doubled to 11.6 billion pairs (Table 2). Malaysia has established itself as the leading producer and exported of latex gloves in the global market for more than a decade now. The dominance of the glove sector is underscored by its contribution of approximately 60% of the total export earnings from all rubber products in recent years. (Table 3) However, the last two years also witnessed a dropping of glove prices from one new low to another resulting in the decline in the export revenue. The country is also facing fierce competition from neighboring countries especially from Thailand with its abundant latex and labour force. In 1999 Malaysia occupied a dominant position capturing about 57% of US medical glove market, with Thailand at 26%, Indonesia 9%, China 4.6 and Sri Lanka 1.5%. Between 1995 and 1999, export from Thailand showed the most rapid growth from 2.2 billion pieces in 1995 increasing to 5.6 billion pieces in 1999. The predominant position of the glove industry in Malaysia now rests on its ability to confront several challenges, both current and foreseeable.

Issues and Challenges: *Latex Allergy*.

The underlying reason for the wide acceptance of natural rubber latex is attributed to its inherent superior properties such as unparalleled barrier performance, high wet gel, tensile and tear strengths, high elasticity and extreme softness coupled with its low cost and 'green' image. None of the synthetic rubber (SR) latices available in the market today could match natural rubber latex in the sum total of the aforesaid properties. However, the widespread negative and adverse publicity about latex protein allergy is directed at natural rubber latex gloves. This has clouded the consumers' mind with the misconception that natural rubber latex gloves are inferior.

The three types of adverse reactions associated with latex products are (a) Irritant contact dermatitis, non allergic, (b) Type IV - delayed hypersensitivity, cell mediated allergy and (c) Type I immediate hypersensitivity, IgE mediated allergy.

Irritant Contact Dermatitis

Irritant contact dermatitis (ICD) is not an allergic response and the irritation is actually a direct injury to the skin cells followed by local inflammation. The first symptoms of ICD are usually redness and swelling with associated itching and burning. Continual dermal insult results in lesion formation which often appear as dermal fissures, cracks and or papules (raised lesion or bump). With more chronic conditions, the fissures and cracks get deeper and wider and the skin become thickened, dry and scaly. ICD is brought by residual soaps, hand creams, powder, temperature and pH extreme, disinfectants and incomplete hand rinsing.

Type IV - Delayed Hypersensitivity

Type IV delayed hypersensitivity reaction is a cell mediated allergic response to specific chemicals commonly referred to as contact sensitisers and the symptoms will only be apparent after 48-96 hours after contact. This is allergic contact dermatitis and the symptoms are almost identical to those of the irritant reactions, except that they may not be restricted to the area of direct contact. Type IV hypersensitivity is non-life threatening. For the glove industry, the most common contact sensitisers are chemicals such as merceptobenzothiazole (MBT), thiurams and carbamates[1] that are used in manufacturing of latex and synthetic rubber gloves. Several approaches can be taken to address the problem associated with residual chemicals. These include reformulation, use of radiation-cured latex, optimisation of cure system and effective leaching or washing. The FDA has issued a guidance document on protocol for latex sensitivity test for medical gloves for a claim on reduced potential of chemical sensitisation or reduced reaction-inducing potential in allergic individuals[2]

Type I Immediate Hypersensitivity

Type I hypersensitivity reactions are mediated by the IgE immunoglobulin and the effect is immediate, generally producing some symptoms within minutes of exposure to the allergens. The symptoms include local urticaria, facial swelling, watery eyes, rhinitis, asthma and in extremely rare occasions, anaphylactic shock. Latex protein allergy is a form of the Type I allergy such as those caused by insect bites, plant pollens, penicillin and other drugs. This Type I hypersensitivity is attributed to residual extractable proteins found in natural rubber latex products[3-5]. However, Type I reaction has also been shown to be caused by various fruits and vegetables which contain naturally-occurred proteins. Furthermore, cross-reactions between latex sensitivity and fruits such as banana, avocado, chestnut, kiwi, pineapple, tomato and potato have also been reported[6,7].

Changes in requirements

As a result of widespread publicity over the years, healthcare institutions are more aware

of the problems posed by latex allergies. End-users are shifting their preference to higher-priced powder-free and gloves with low protein and low allergen content. Changes have been made by the latex industry to diversify their production of latex gloves to the needs of the customers.

The FDA proposed regulations to reclassify surgeon's and patient examination gloves as Class II medical devices involves changing the GMP requirements from general to special controls, which will have great significance to the manufacturers[8]. The objectives of reclassification were to reduce the adverse health effects due to allergic and foreign bodies reactions and defects in the barrier integrity and quality of gloves. The FDA proposal recommends that the powder limit for powdered and powder-free examination and surgical gloves to be respectively 120 mg and 2 mg per glove. For water-extractable protein, the maximum permissible limit will be 1200 μg per glove, irrespective of powdered or powder-free, has been proposed.

The latex protein allergy issue also provides the market opportunity for the synthetic materials. The availability of thin-gauge nitrile latex gloves will provide an alternative to latex gloves, in additional to the other synthetic such as vinyl, polyurethane and thermoplastic gloves. In 1999, shipment of medical examination gloves to the US consisted of NR gloves (84%) and Synthetic gloves (16%). Frost and Sullivan forecasted that in year 2006 the figures would be 78% for latex and 22% for synthetics. Synthetic alternatives are not without health risks. Reports concerning contact dermatitis and contact urticaria from nitrile[8] and polyvinyl chloride[10] gloves have been published. PVC gloves have been banned in food-handling in Japan as a result of concern with the emission of toxic by-products from incomplete incineration and the leaching of harmful residues such as DEHP onto food.

These requirements have provided challenges to the glove manufacturers in Malaysia. Besides producing low protein low powder natural rubber latex gloves with all the superior barrier performance, they will also be eyeing the synthetic gloves market in order to maintain or enlarge the market share.

Residual Extractable Proteins

Like all plant materials, latex from Hevea Brasiliensis tree contains some proteins (1-5%) among other substances[11]. These proteins are present in the latex system as either soluble proteins in the serum phase or as surface-bound proteins on the rubber particles which comprise 30-40 % of the latex system. When the latex is processed into latex concentrate, with 60% dry rubber content, much of the soluble proteins would be removed and the amount of the extractable protein which remained in the concentrate would be very small. It is this small fraction that constitutes the residual extractable fraction of proteins which are implicated in the allergy issue.

To-date, a number of proteins have been identified as allergens in the latex, three of

which by the Rubber Research Institute of Malaysia, it is still not clear how many allergens are consistently present in the final gloves products since changes are likely to occur during processing. A recent study[12] was carried out by the researchers at the RRIM in collaboration with John Hopkins University to compare the contents of two latex allergens Hev b 2 and Hev b 3 in latex examination gloves, in fresh natural rubber latex and in ammoniated latex used in latex glove manufacture. The assay results showed that the amount of allergens present in the final product is very small in deed suggesting that the manufacturing process have removed most of the allergens present in the latex.

Proteins Quantification

Quantification of proteins in NR latex products is of great interest both to the glove manufacturers and users. The amount present is, however, very much influenced by the manufacturing process[13]. At the moment, measurement of total leachable protein of gloves by the modified Lowry tests[14-16] appears to be the best available method for manufacturers to monitor closely the quality of their gloves. The modified Lowry test however, can be susceptible to chemical interference such as the presence diphenyguadinine (DPG)[17]. For the detection of allergens, the radioallergiosorbent test with inhibition (RAST-inhibition) and the IgE antibody enzyme-linked immunosorbent assays with inhibition (IgE-ELISA inhibition) assays are available[18]. Efforts to standardise these assays have been slow because of lack of availability of standardised human antibodies and standardised allergens. It has been shown that measurements of total extractable protein using the modified Lowry methods correlate relatively well with the skin prick test (SPT) or the latex specific IgE ELISA-inhibition[18,19]. Malaysia is actively participating in the harmonization of protein quantification assays.

Protein Reduction

The reduction or removal of the undesirable residual extractable protein in gloves is of importance as it will reduce the risk of sensitization among the users. There are many ways of reducing the extractable protein (EP) level of natural rubber. It can be achieved by treating the latex, semi-finished, e.g., wet rubber gel, or finished latex products. Many of these methods have been investigated and reviewed[20-23]. Some of the more recent reports are briefly described here.

Enzymatic deprotenization

Enzymatic deprotenization and centrifugation of latex have been used to produce latex of low EP content[24,25]. Enzymatic deprotenization can also be used to treat latex products for the EP reduction[26,27]. In addition, treatment of latex with anion exchange resin has been reported to remove substantial amount of the proteins from the latex and latex products[28]. The removal of the proteins from the latex could be achieved by extracting the rubber with an organic solvent and re-dispersing it in water to form latex[29]. The

proteins could also be reduced by radiation vulcanization of the latex[30]. The addition of fumed silica to NR latex was reported to cause a reduction in the residual level of the EP[31,32]. The proteins could also be reduced to a level below the detection limit by adjusting the creaming process of the latex[33].

In enzymatic deproteinization the total proteins and allergenic proteins could be degraded and washed off the surface of NR latex film by a protease enzyme, Savinase NR[27]. Gloves washed with Savinase NR consistently give low extractable protein content of below 50 ppm and a low allergen level of less than 10 AU/ml (Tables 4,5). The Savinase NR wash is an environmentally friendly non-hazardous process with no deleterious effect on the gloves while the waste generated by the process could be regarded as biological waste[27].

Table 4. Protein Content of Savinase NR Washed Gloves From Pilot Plant Trial

Glove treatment	EP-ASTM (ppm)	EP-RRIM (ppm)	Allergenic Protein (AU/ml)
Control	524	753	>1000
Water washed	50	60	149
Enzyme washed	50	29	8

Table 5. Protein Content of Savinase NR Washed Gloves in Commercial Production

Gloves	EP-RRIM(ppm	RAST inhibition (unit/g)	IgE-ELISA Inhibition (AU/ml)
NR glove 1	29	22	6.6
NR glove 2	24	20	5.9
NR glove 3	27	19	7.4
NR glove 4	23	18	NT
NR glove 5	26	22	NT
Control NR glove	500-1500	200.	>1000

Low Protein Latices

Several types of low protein latex are currently available in Malaysia. A low allergenic protein pre-vulcanized latex with low nitrosamines has been developed by the RRIM. The properties of the dipped films have high tensile strength values exceeding 25 MPa and low allergenic protein contents of less than 10 AU/ml. Recently SELATEX[34], a highly deproteinized and purified natural rubber latex prepared by using a proprietary enzyme and surfactant system was being promoted by the Sumirubber Industries in Malaysia. SELATEX has below 0.1 antigenic protein (LEAP assay) and the gloves derived have very low EP content (below 50 μg /g). Getahindus has also come out with a low protein latex concentrate G –TEX LPX[35] which is reported to produce gloves with consistently low EP level of less than 50 μg/g with physical properties well within the ASTM specification.

Thus it can be seen that low protein latices, characterized by reduced extractable proteins and low allergen contents, have been developed for the latex industry. However, the major obstacle to its wide acceptance by latex product manufacturers is the high premium of the latex and reluctance of consumers to pay for the extra effort taken by the suppliers.

Leaching

Leaching[36] with water can be a useful technique to remove the proteins as well as the residual chemicals both at the stage of semi-finished and finished products. The operation of leaching is performed on most latex dipped products. The purpose is to

remove water-soluble materials to improve film clarity, prevent surface blooms during storage and reduce water absorption. It is of particular importance in medical goods and electricians' gloves. The leaching process has become more important in recent years as a result of concern with allergic reactions associated with latex proteins.

Leaching operations are of two types viz. wet gel or dry film. Wet-gel leaching can only be carried out on-line and therefore requires the leaching facility to be built into the dipping line. Dry-film leaching is often carried out off-line as an extra-washing process, after striping the products from the formers. The best method of ensuring the lowest levels of water-soluble material in electrical, medical or food-related products is to carry out both the wet-gel and dry-film leaching.

Wet-gel leaching is carried out before drying with hot water at 60-80°C. Hot water also helps to consolidate the gel and to maintain the temperature of the gel and former. The time available for wet-gel leaching in a continuous dipping line is necessarily short to avoid undue lengthening of the production line, though this can be extended considerably in modern multi-tiered continuous dipping units. Dry-film leaching is carried out on the dried and vulcanised film and is relatively a slower process. The cleanliness of the leaching water is an important consideration and is maintained by continuously removing and replacing some of the water. The rate of replacement of the water for effective leaching depends on the volume of leaching water in relation to the weight of rubber passing through it.

Improved leaching protocol which incorporates 'post-cure' leaching stage is now being widely practised by the glove manufacturing industry[36]. Recently[37] the use of immersible transducer to generate ultrasonic waves in the dry-film leaching process has been reported to accelerate the reduction of extractable protein and allergenic protein contents of NR gloves. The optimum operating temperature for maximum rate of EP and AP reduction was found to be 55^{o}C.

Further study[37] on the effect of pH showed that dry-film leaching of NR gloves in mineral acids did not contribute to the reduction of EP and AP content. Dipping of gloves into ammonia solution after dry-film leaching was found to reduce the EP and AP contents of NR gloves. The greater EP and AP reduction could be due to the higher solubility of the proteins in ammonia.

Glove Powder

There were proposals from several states in the USA to ban the use of powdered gloves, though such a ban should be viewed as an over-reaction to the latex protein allergy problem. Glove lubricants for medical gloves are required to fulfill several roles. Firstly, lubricants function as mould-release on glove formers during latex glove manufacture. Secondly, they are used as de-tackifying agents to remove tack inherent in latex gloves. Thirdly, glove lubricants facilitate donning for use in medical and surgical procedures.

The first powder donning agent used for natural rubber latex gloves is Lycopodium spores, commonly known as club moss. This lubricant was later found to be toxic and became unacceptable for use as a glove lubricant. As a result, talcum powder or talc (hydrous magnesium silicate), a non-absorbable lubricant, was introduced as a replacement. As clinical complications with these agents were realised, an absorbable lubricant, a modified cornstarch was developed and replaced these agents. By the early 70s, many medical glove manufacturers replaced talc with the modified cornstarch The type of cornstarch powder currently used is that of a cross-linked product and is epichlorohydrin treated.

It has been suggested that all glove powders act as foreign bodies that elicit inflammatory responses in tissues[38] and it should be noted that the biologic responses to foreign bodies apply to both powdered natural rubber latex and synthetic gloves. The inflammatory responses to these powdered glove lubricants range from the formation of granulomas to the development of granulomatous peritonitis. In addition, cornstarch interferes with the host's defenses against infection and delays wound healing [39].

Respiratory problems and asthma-like attacks in hospital employees and patients have been ascribed to the inhalation of airborne natural latex allergen in the areas of heavy use of powdered gloves[40,41]. This is attributed to the propensity of cornstrach to bind natural latex proteins, which cannot be detached by simply washing the powder[42]. Recent findings indicated that the amount of protein bound is small with decreasing quantities of soluble proteins and powder present. Powdered gloves with very low EP contents are found to have very low allergenicity/allergen level, which is comparable to those of powder-free gloves. Recent studies at the RRIM showed that several modified donning powders have no affinity in binding latex proteins. In response to market demand, some of the manufacturers have been using an alternative powder, oat starch, which has been reported to be a suitable replacement for cornstarch as it does not bind to proteins[43,44].

Powder-free gloves

There are several approaches designed to prevent the adverse effects of glove lubricants. The first is to remove all traces of powder lubricants from the surface of surgical gloves that comes into contact with the patient by washing off the powder before use. Unfortunately, this method of powder removal has been reported to be ineffective.

Polymer coating

The second approach is the development of a powder-free gloves based on polymer coating. Polymer coating, a process of laminating a layer of polymer or mixture of polymers, having low surface tack property onto the surfaces of NR gloves, is an alternative way of reducing the surface tackiness of NR gloves. Many polymers have

been reported to be used for this purpose and some of the more recent ones include combinations of polyurethane[45-47], polyacrylamide[45,47], polyacrylic acid/PMMA[45,47,48], polyvinyl acetate[46], carboxylated SBR[46], and caboxylated BR[46], polyacrylonitrile[47,48], PMMA-grafted NR[48], polysiloxane[49], polyether and polyeste[50]. Existing commercial polymer-coated gloves are normally made by coating the donning side of the glove with a polymer having good donning properties, and chlorinating the gripping side. Although the complete polymer coating of NR glove has been reported[51,52], there is little commercial uptake due to certain technological constraints with the coating of the gripping side being more difficult than the donning side of NR gloves during online production.

A new commercial process for the production of fully polymer coated NR gloves has been developed[53] which show no significant difference in the tensile properties of the glove before and after ageing test, carried out at 70^{o}C for 7 days, as shown in Table 6.

Table 6. Tensile Properties of Polymer Coated Gloves

Properties	Control (Powdered glove)		Polymer Coated	
	Unaged	Aged*	Unaged	Aged*
Tensile Strength (MPa)	25.2	26.5	25.0	24.9
Elongation Break (%)	910	980	900	960
M300% (MPa)	1.18	1.02	1.30	1.15
Max Load (N)	13.6	15.1	13.4	13.4

*At 70^{o}C for 7 days in oven

The gloves produced have good coefficient of friction (COF). The donning side of the glove has a low COF value which is good for donning and the gripping side of the glove, on the other hand, has a higher COF value which is good for gripping smooth object (Table 7). The fully polymer-coated glove was found to contain low extractable protein of 40 μg/g and allergen content of 10 AU/ml[53].

Table 7. Coefficient of Friction of Fully Polymer-coated Glove

Sample	Coefficient of friction
Present work: Donning side	0.42
Gripping side	1.17
Commercial: Donning side	0.38*
Gripping side	0.32**

Load: IN
Speed: 1mm/s
Temperature: room temperature
* Polymer-coated, silicone oil
** Chlorinated

Chlorination

The third approach is the tack removal by chlorination. Many latex products are chlorinated after production to reduce surface tack. Chlorination is used widely for the production of powder-free medical and clean-room gloves. The chlorine reacts with the rubber at the product surface, giving chlorinated rubber with a lower coefficient of friction . The chlorine is typically applied to rubber gloves at 600-2000 ppm, depending on the specific product.

Chlorination is accomplished using either sodium hypochlorite or chlorine gas. Chlorine gas is cheaper but more hazardous to store and use. Automatic mixing and metering units are often employed with chlorine gas. Sodium hypochlorite is available in different strength, the strength decays over time and is more expensive. Chlorination can be carried out off-line by a batch process in chlorinators or on-line in a continuous manner. The machine cycles for batch chlorination may vary from 20-90 minutes, depending on the process.

One significant drawback to the use of chlorinated gloves is deterioration of physical properties on thermal ageing and hence doubts on its long-term durability (shelf-life). Other disadvantages cited are the presence of strong odour, possible skin irritation and discolouration. Spontaneous combustion of chlorinated gloves during warehouse storage has also been reported[54]. Chlorinated latex gloves have extremely low extractable protein contents (0.01-0.02 mg/g, RRIM modified Lowry, BSA standard), but show poor ageing properties at 100°C[55]. This has been overcome by using modified cure systems of latex examination glove compounds by which the heat ageing resistance at 100°C of chlorinated gloves have been vastly improved[56].

Factory Technology Trends

Rising operating costs, and the lack of labour are becoming major concerns to the medical glove manufacturers in Malaysia. Many manufacturers have turned to automation as a cost cutting measure. Many of the about 75 latex glove manufacturing companies have gone for some form of automation especially auto-stripping. The automated systems of auto stripping and auto-packing of gloves, computer-controlled operations are to a greater extent manufactured locally. Many of these factories have incorporated several technological innovations into the locally designed and fabricated dipping lines. These include the on-line intermediate and post-leaching system, on-line chlorination and on-line polymer coating, and efficient on-line former washing system.

The use of proper equipment design with special emphasis in form cleaning stations also have a direct impact on minimizing pinholes for gloves[57]. To meet the requirements of synthetic gloves, many of the Malaysian manufacturers are able to convert some of the existing lines to produce synthetic gloves such as nitrile and more recently polyurethane gloves [58] The manufacturers know that they will need to diversify and need a strong portfolio of products to survive in the industry. Frost and Sullivan projected that the the production of synthetic gloves will be increasing strongly and should contribute 30% of exports by 2007,

Standard Malaysian Gloves (SMG)

To further minimize the risk of latex protein sensitization, the Malaysian Rubber Glove Manufacturers' Association(MARGMA) and the Malaysian Rubber Board has recently introduced a quality Standard Malaysian Glove scheme[59] for quality latex examination gloves (powdered and powder-free). The introduction of the Standard Malaysian Glove (SMG) that limits the protein and powder levels is a major advancement in the development of superior quality latex examination gloves with technical specifications that are in compliance with the ASTM and FDA standards. The selection of the upper limits of protein and powder contents are reached after extensive research on the allergy and in-depth studies of consumers' requirements. Technical specifications are set up after much extensive R&D and after incorporating the views of not only glove manufacturers and consumers, but also of regulatory agencies such as the Food and Drug Administration (FDA) in the US and various government authorities, as well as testing laboratories.

The program also requires manufacturers to have in place a quality management system that meets with the requirements of ISO 9002 or its equivalent. Manufacturers' compliance with the requirements of the program is safeguarded by an independent Quality Inspectorate of the Malaysian Rubber Board (MRB) that conducts regular surveillance checking and testing to ensure that the technical specifications of the SMG are adhered to at all times. The objective of the SMG program is to provide a quality assurance and product guarantee by focusing on the 4Ps, i.e. Protein level, Powder content, Pinholes and Physical properties[60]. Currently a total of twenty-two glove manufacturers have been certified to be SMG producers representing about 50% of total glove production capacity in Malaysia. Every effort is being made to urge all glove manufacturers to adopt the SMG program so that Malaysia will continue to supply

quality gloves that meet today's healthcare challenges.

The Scheme identifies two categories of examination gloves: powdered and powder-free. Upper limits of residual extractable proteins specified for both types of gloves are based on collaborative scientific studies with dermatologists and immunologists who are active in the field of allergy research[19]. Other more demanding requirements are also seen in specifications of tensile properties and watertightness, to help to reduce the incidence of pinhole formation ensuring better glove performance (*Table 8*). The standards set represent the minimum requirements for quality gloves. Surveillance to ensure compliance is conducted by the Rubber Research Institute (RRIM) of the Malaysian Rubber Board. The Scheme is a dynamic one, and is subjected to periodic revision and up-grading upon careful consideration of the consumers' requirement and in consonance with standards set by the FDA.

With the establishment of SMG Scheme, Malaysia has taken an important step to make available medical gloves that are as safe as possible in relation to the latex protein allergy problem while ensuring that barrier protection against virus transmission will not be compromised.

Table 8: Technical Specifications of some glove parameters for the SMG Scheme

Parameter	**powdered**	**Powder-free**
Protein limit (μg/dm^2)	200	50
Powder limit (mg/glove)	150	2
Tensile strength: before ageing (MPa) min	21	
After ageing (MPa) min	16	
Elongation before ageing (%) min	700	
After ageing (%) min	500	
Length (mm) min	240	
Watertightness (AQL)	G1 1.5	

Conclusion

Natural rubber latex gloves are being used extensively world wide by healthcare workers as effective protection barrier to blood-bound pathogens. Malaysia is the world largest supplier of quality natural rubber latex examination gloves. However the use of these gloves has been challenged because of latex protein allergy issue. Over the years, Malaysia has undertaken a great deal of R & D activities aim at producing quality gloves that will meet the requirements of the users. Most local manufacturers have modified their lines to incorporate post-leaching, chlorination, enzyme treatment and polymer coating to produce low protein powder-free gloves, low-protein low powder gloves and even synthetic gloves. The quality Standard Malaysia Glove (SMG) scheme is to set a quality standard to meet the end-users requirement. This scheme is a testimony of quality assurance, and of the responsiveness of Malaysian manufacturers in addressing the latex protein allergy problem at source and at the same time upholding the superior barrier performance and other physical properties of natural rubber.

The changing requirements imposed by regulatory agencies on protein and powder levels, product labelling, and re-classification of medical gloves will subject immense pressure on latex industry to upgrade their manufacturing processes at additional costs. This should pose no problems to the SMG producers as the requirement of SMG specifications are in compliance with that of FDA.

The investments in automation and technology innovation have greatly contributed to the enhanced product quality and safety of gloves, thus meeting consumers' demand and regulatory requirements. The Malaysian glove manufacturers will continue to upgrade their operations and to adopt new technology in order to compete effectively in the global market. With the continuous R & D support from the Rubber Research Institute of Malaysia, the research arm of the Malaysian Rubber Board and the promotion of the SMG by the Malaysian Rubber Export Promotion Council, the glove industry in Malaysia should continue to maintain its position as a world leader in manufacturing quality gloves.

References:

1. Feinman S.E. (1987), Sensitivity to Rubber Chemicals, *J. Toxicol. - Cut. & Oculat Toxicol*, **6(2)**, 117-153.
2. FDA (1999), Premarket Notification [510(k)] Submissions for Testing for Skin Sensitisation To Chemicals In Natural Rubber Products, Jan 13, 1999,
3. Leynadier F and Dry J. (1991), Allergy to latex, *Clinical Reviews in Allergy*, Volume 9, 317-377.
4. Turjanmaa K. (1994), *Protective Gloves for Occupational Use, ed. by Gunh,*

Mellstrom, Jan E. Wahberg, Howard I. Maibach, CRC Press Inc., Chapter 17. Contact Urticaria from Latex Gloves, 241-254

5. Hamann, C.P. (1993), Natural rubber latex protein sensitivity in review, *Amer. J. Cont. Derma*., 4, 4-21.
6. Rodriguez, M., Vega, F., Garcia, M.T., Panizo, C., Laffond, C., Montalvo, A. and Cuevas, M. (1993), Hypersensitivity to latex, chestnut and banana, *Ann Allergy*, 70, 31-34.
7. Sussman G.L. and Beezhold D.H. (1994), Hypersensitivity to potato and tomato in latex allergic patients, *Latex Allergy Symposium*, Toronto, Canada, September, 19.
8. FDA (1999), 21 CFR Parts 801, 878, and 880 Surgeon's and Patient Examination Gloves: Reclassification and Medical Glove Guidance Manual Availability; Proposed Rule and Notice, *Federal Register, Vol 64, No. 146, July 30, 1999, 41710-41745*
9. Brehler, R (1996), Contact Urticaria caused by Latex-free Nitrile Gloves, *Contact Dermatitis* 34(4), 296
10. Ritsuko Hayakawa et al, (2000), *Source to Surgery*, *AnsellCare Newsletter*, Vol 8, Issue3, November 2000
11. Ong E.L., Eng A.H. (2001)Natural Rubber Polymer Handbook Second Edition 2001 .
12. Yeang H.Y., Lau C H., Arif S A M., Loke Y.H., Hamzah S., and Hamilton R.G. Hev b 2 and Hev b 3 Content in Natural Rubber Latex and Latex gloves Paper Presented at the AAAAI Conference USA 2001
13. Turjanmaa K and Renunala, T (1989). Condoms as a Source of Latex Allergen and Cause of Contact Urticaria, Contact Dermatitis, **20**, 360-364, 1989
14. Department of Standards Malaysia (1998), Test Method for the Analysis of Extractable Proteins in Natural Rubber Products *MS 1392:98*.
15. American Society for Testing and Materials (1999), Standard Test Method for the Analysis of Protein in Natural Rubber and its Products D 5712-99.
16. CEN (1999), Medical Gloves for Single Use. Part 3: Requirements and Testing for Biological Evaluation. EN 455-3, Centre Europeen de Normalisation (European Committee for Standardisation), Brussels, Belgium.
17. S.F. Chen, Teoh SC, Porter M (1997). False Positive Results with the American Society for Testing and Materials D5712-95 Test Method for Protein given by a Common Vulcanisation Accelerator. J. Allergy Cli Immunol 100, 713-714.
18. Palosuo, T., Makinen-Kiljunen,S., Alenius,H., Yip,E. and Turjanmaa,K. (1998) Measurement of Natural Rubber Latex Allergen Levels in Medical Gloves by Allergen-specific IgE-ELISA Inhibition, RAST Inhibition, and Skin Prick Test. *Allergy* **,** 53, p.59-67.
19. Yip, E., Palosuo, T, Alenius, H. and Turjanmaa, K. (1997) Correlation between Total Extractable Proteins and Allergen Levels of Natural Rubber Latex Gloves, J. nat Rubb. Res. 12(2), 120-130.
20. Barclay, L.M.(l995) Developments in Low Protein/Low Allergen Prevulcanized Natural Rubber. MARGMA Newsletter, 1st Quarter, 5-11.
21. Dalrymple, S.J. and Audley, B.G. (1992) Allergenic Proteins in Dipped

Products: Factors Influencing Extractable Proteins Levels. Rubb. Devlop., 45, 51-60.

22. Sebastian, M.S.(2000) Latex Protein Allergy. *Rubb. India*. May Issue, 11-16.
23. Jose, P.M.(2000) Protein Allergy in NR Latex Products. *Rubb. India*. July Issue, 11-15.
24. Trautman, J.C.(l998) The Method of Neutralising Protein Allergens in Natural Rubber Latex Product formed thereby. *US Patent No.5777004 A 19980707.*
25. Nakade, S., Hayashi, M., Okada, J., Tanaka, Y., Ichihashi, M. (1998) Studies of High Purity Natural Rubber V. Provisional Guidelines on the Design of Latex Allergy Free NRL Products. *Int. Polym. Sci. Technol*. 25, p. T29-32.
26. Elvig, No. (1992) Treatment of latex. *Res. Discl*., 223, 335102.
27. Heng, K.C., Amir Hashim, M.Y. and Hasma, H. (1999) Enzyme Treatment of Rubber Gloves. *Seminar Latex-Based Industry into the Next Millennium – Critical Challenges Ahead., Hyatt Saujana, Subang, November 1999.* Paper 7.
28. Beezhold, D.H.(1996) Methods to remove proteins from natural rubber latex. *U.S. Patent 5, 563, 241.*
29. Schloman, W.W. and Mcintyre, D.(2000) Hypoallergenic Natural Rubber Latex and Process for Making the Same. *US Patent No.6054525 A1 20000425*.
30. Varghese, S., Katsumura, Y., Makuuch, K. and Yoshii, F.(2000) Production of Soluble Protein Free Latex by Radiation Process. *Rubb. Chem. Technol*., 73, 80-88.
31. Anand J. and Morris, M.D. (1997) Reinforcement of Latex with Fumed Silica's. *Rubb. Plast. News*, 26, 16-19.
32. Amdur, S. (1999) Removing Natural Latex from Dipped Rubber Goods with Fumed Silica Additives. *Prep. 156 ACS Rubb. Div. Meeting – Fall 1999 Orlando, USA.* Paper 80.
33. Lewis and Peat Rubber Limited (1999) Zero Protein Cream Latex. p.2.
34. Hamada A., (2001) SELATEX, Highly Deproteinized and Purified Natural Rubber Latex Paper presented at Latex-based insustry Seminar, Subang Malaysia Feb 2001
35. Tan S H, Ng L F, Mok L S, Shum K C, Choon K M and Lim B T (2001) A New Material for Glove Paper presented at Latex-based insustry Seminar, Subang Malaysia Feb 2001
36. Ng K.P., Yip, E. and Mok K.L. (1994) Production of Natural Rubber Latex Gloves with Low Extractable Protein Content: Some Practical Recommendations *J. nat. Rubb. Res.,* 9(2) 87-95.
37. Eng A.H, Hasma H, Mok KL.and Lai PF. (2001), Int Latex Conf, July, 2001, Akron, Ohio.
38. Woods, J.A. et al. (1997), Surgical Glove Lubricants; From Toxicity to

Opportunity, J Emerg Med**.,** 15(2), 209-220
39. Brett C.O. et al. (1998) Influence of Absorbable Dusting Powders on Wound Infection, J Emerg Med., 16(6), 875-879
40. Swanson M.C. et al (1995), Quantification of Occupational Latex Aeroallergens in a Medical Center, J Allergy Clin Immunol 94:445-51
41. Allmers, H et al (1998), Reduction of Latex Aeroallergens and Latex-Specific IgE Antibodies in Sensitised Workers after Removal of Powdered Natural Rubber Latex Gloves in a Hospital, J Allergy Clin Immunol, 102(5) , 841-846
42. Tomazic V.J., Shampaine E.L., Lamanna A., Withrow T.R., Adkinson N.F. and Hamilton R.G. (1994), Cornstarch Powder on Latex Products is an Allergen Carrier, J. Allergy Clin Immunol 93:751-758.
43. Ostar Oat Powder, Ultravena Industries.
44. Swanson M C, (2000) Latex Allergen Affinity for Starch Powders Applied to Natural Rubber Gloves and Released as an Aerosol: From Dust to Don Canadian J ACI 5(8) 328, 2000
45. W.N. Haung, N.R. Manwill, A. Muschelewicz, F.B. Chen (1997). Flexible Rubber Articles and Method of Making. U.S. Patent, No.5,601,870
46. M.C. Chen (1994) Process for forming Powder-free Medical Glove. U.S. Patent, No.5, 284,607.
47. C.W. Ansell, N. Nedcalf, P.W. Williams (1992) Gloves. U.S. Patent, No.5 088,125.
48. A.D.T. Gorton (1996) Coating Compositions Method of Using it and Article Coated with Same. U.S. Patent, No.5,571,219
49. E.G. Puig, J.S. Bosch, J.C. Figueras (1997) Composition for Coating Rubber of Latex Articles. U.S. Patent, 5,674,818.
50. J.G. Nile, S.J. Gromelski, A.A. Brain, S.T. Hardwick (l993) Rubber Articles Having a Modified Polymer Layer of Ether and Ester Units. WIPO Patent Corporation Treaty. No.WO 93/06996.

51. P.E. Esemplare (1991) Articles Having Improved Slip Coatings. U.S. Patent No.5,069,965.
52. K.F. Gazeley (1993) Treatment of Rubber Articles. Eur. Pat. Appl., No.594,410 A2.
53. Eng A H, Lai P F (2000) Recent Studies on Polymer Coating of NR Latex Gloves Paper presented at MARGMA Seminar Subang 2000
54. FDA, (1996), Potential Risk of Spontaneous Combustion in Large Quantities of Patient Examination Gloves, Public Health Advisory, June 27, 1996.
55. Nor Aisah Ab Aziz (1993) Chlorination of Gloves, *Proc. IRTC'93 Wkshop on Latex Proteins*, Kuala Lumpur, Malaysia, 59-67
56. Nor Aisah Ab Aziz (1994) Formulations for Heat Resistant Chlorinated Natural Rubber Latex Films, *J. Nat. Rubb. Res.*, 9(2) 109-120
57. Jeff Charlton, Pinhole Reduction Techniques for Unsupported Gloves Paper presented at MARGMA's seminar July 2000, Malaysia
58. William L Howe, Medical Glove Market Remains Tight Rubber Asia Jan-Feb 2000
59. Ong E.L and Chew,C.S.(1998), Implementation of the Standard Malaysia Glove

Scheme, Malaysian Rubber Seminar (France, Germany and United Kingdom), Sept 25-Oct 7, 1998.
60. Ong E :L, Lai P F, Lim C L and Ng K P (2001) Standard Malaysian Glove Scheme: Technical requirements Asian Gloves and Dipped Goods Directory Rubber Asia Publication p59 2001