



**H**alf a decade ago latex gloves were the hottest things in the rubber industry because of concern over the spread of AIDS. In advanced countries whole set of medical staff, military personnel and even super market workers have started using gloves as a protective measure against AIDS. Use of gloves in USA and North America became routine in mid 1988. All these created a world-wide boom in the market for gloves. Many investors in USA, China, Malaysia, Indonesia and Taiwan rushed their money for glove production. Price of gloves touched its peak level of 110 US dollars per 1000 pcs during that period. But in later

## AN ECONOMIC STUDY OF LATEX GLOVE INDUSTRY IN INDIA

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years ie; in 1989 and 90's the trend began to reverse due to overproduction and price of gloves fell in the range of 15-18 US dollars per 1000 pieces. Many latex gloves units in USA, China and other European countries have closed in 1990. This situation lead to healthy demand supply balance and finally the industry has revived and international price has improved to the range of 25 to 30 US dollars.

In India also more licences were issued to establish glove units. However only a few licensees have started production and other left the field. The units which started production faced teething troubles when the world glove market was gloomy. The Indian manufactures are still in dilemma though the units in Malaysia and Indonesia are setting for a take-off. In order to know about India's response to the changing situation and to examine the cause and significance of these upheavals a study was undertaken and the finding of the study are presented in this report.

### METHOD OF STUDY

Surgical gloves (sterile & non-sterile) disposable examination gloves, household gloves, industrial, electrical and postmortem gloves are the different types of gloves made from natural rubber. Of these examination and surgical gloves

are the most sophisticated and sensitive items. Demand is also more for these items not only in the world market but also in the domestic market. The units manufacturing examination gloves can also make surgical gloves with the same type of machinery and technology.

In India there are about 150 glove manufacturing units of which 47 are engaged in production of surgical and examination gloves. All these units are using automatic dipping plants whether imported or indigenously fabricated. Of these 47 units majority are concentrating in a single item ie., either surgical or examination gloves. However a few are producing both the items.

The present study is confined only to the surgical and examination glove manufacturing industry. All the required details were collected from the producers in a pre-tested questionnaire through interview method. Secondary details were collected from the periodicals and other published sources.

### GLOVE INDUSTRY - A WORLD SCENARIO

On the global scale Malaysia tops in the production taking a major share in the world market. It is reported that the total installed capacity of the country is about 15.5 billion gloves per year. More than 80 units have registered as members in the Malaysian Rubber Glove Manufactures Association

In addition some big and small units are also producing gloves. Production of rubber gloves in Malaysia for the year 1987 was 396.74 million pairs and this increased to 1345 million pairs in 1988, 1593 million pairs in 1989 and 1796 million pairs in 1990. In 1991 production was 2227 million pairs accounting 24% increase over the previous year's production. Export earnings of rubber gloves from Malaysia also increased from 848 million dollars in 1990 to 1033 million dollars in 1991 accounting 22% increase.

In Thailand about 50 units have started production though licences were given to 140 units to form latex glove plants. Total installed capacity of glove industry in Thailand is understood to be not less than 5.5 million. Installed capacity in Indonesia also rose from 0.4 billion in 1987 to 3.2 billion in 1988 and was expected to increase 9.8 billion in 1990. The installed capacity in Sri Lanka is limited to produce 400 million pieces of gloves per annum. Sri Lanka's export of rubber gloves jumped to 222 million pcs in 1991 from a mere 3.8 million pcs in 1990. Similar rates of growth have accrued in other key producing countries like Taiwan Philippines UK and China.

## GLOVE INDUSTRY IN INDIA

Government of India also issued more than 100 licences to establish glove units for export production. Of this about one third of the licences have established their factories. In addition some units in domestic tariff area (DTA) have also developed their capacities to produce gloves using automatic plants. The status of glove industry is given in table-1.

**Table 1. Glove Units in India using automatic Dipping Plants**

Status	No. of Units	Total Installed Capacity	
		Examination Gloves (million pcs)	Surgical Gloves (million pairs)
FTZ	19	690	72
EOU	15	745	132
DTA	13	174	82
Total	47	1609	286

Though 47 units have started ventures (see table-1), all have not enjoyed the expected levels of business. Many units are closed or on the verge of closure due to the glut in the world market. A few have gone out of business. There was a major set back in the entire glove industry in 1989-90, 1990-91 and first half of 91-92. Recently the performance showed that the industry is well on the way to progress. Good inquiries are coming up from United States and European countries as the world glove market is picking up. Many units in India have got orders for the next one to two years. Those units who were in dilemma for the last two years have also started production.

During the period of study there are only 40 units actively engaged in production of gloves. Of these 26 are exclusively engaged in production of examination gloves 8 units on surgical gloves and the

remaining 6 are manufacturing both surgical and examination gloves. All these units have a total installed capacity for producing 1369 million pieces of examination gloves and 144 million pairs of surgical gloves. Summarised details of these units are given in table-2.

In addition to the existing units three more units are planning to start production by the end of 1992 with a capacity of 120 million pieces of examination gloves. Therefore the production capacity of examination gloves by the end of the year will be 1489 million pcs.

## PRODUCTION AND EXPORT

Production and export made by the units for the last 3 years are given in table-3. Table shows an upward trend in production indicating good progress in the

**Table 2. Summarised details of Glove Units**

Status	No. of Units	No. of Plants	Production Capacity	
			Examination Gloves (million nos.)	Surgical Gloves (million pairs)
FTZ	14	18	540	24
EOU	14	21	715	34
DTA	12	12	114	86
Total	40	51	1369	144

industry. 1991-92 production is more than doubled compared to the previous year's production. In this period seven units started production taking advantage of the market potential which collapsed earlier.

Regarding exports it is noted that major share of examination gloves produced is exported (98.4% in 1991-92) whereas surgical gloves are mainly marketed within the country. The export figure given in table-3 will not tally with the actual made as there are few more units in the small scale sector which are not covered in this study.

#### Underutilisation

Capacity utilisation of the industry is very low i.e. about 15% in examination gloves and 62% in surgical gloves. Low capacity utilisation which is common throughout the industry is mainly due to the surplus capacity available in general particularly in examination gloves. This underutilisation of capacity implies increased cost of production which make the glove industry incompetent in the world market. Therefore all units should increase their production, at least to cover the break even, so that they can compete with international giants in the world market.

#### MARKET FOR GLOVES

US Germany Canada UK South Africa and other European countries are the important marketing centres for gloves. The ANRPC reported that US itself requires up to 8,000 million pairs of gloves in a year.

According to the General Agreement on Trade and Tariffs

(GATT), the world import of rubber gloves is estimated to reach around 30 billion pcs per annum. Studies also projected that requirement of latex gloves in US will go up to 10 billion by the end of 1992 and global demand will go up to 35 billion pcs. Another projection made very recently showed that global market for gloves at the current period is estimated at around 9 billion pcs and it should cross to 10 billion pcs by 1994. The US market is all set to absorb 6.5 billion pcs in 1992 and is expected to stabilise at the range of 7.5 to 8 billion pcs by 1993-94. The requirement of latex gloves in Germany should also increase to 1.5 billion pcs by the later half of the Decade. Germany's import in 1991 was 955 million pcs of gloves. However, on contradictory to the expectation, import of gloves in these countries remained subdued for over one year particularly in 1989 due to over production and dumping of second quality gloves. But in later years import trend has improved when the world economy faced shortage of quality gloves with FDA regulation. The index of import of rubber gloves in USA Japan and EC have strengthened during this period. The US also imported 5975 million pcs of gloves in 1991 accounting an increase of 57.36% over the previous year's import of 3797 million pcs. In the first two months of 1992 US imported 1.67 billion pcs an increase of 176% over the same period in 1991. Table-4 gives country-wise import of rubber gloves in US for the years 1990 and 1991.

Table reveals that Malaysia's share in US market has increased from 63.05% in 1990 to 64.52%

in 1991. Thailand also has improved the position from 12.23% in 1990 to 14.33% in 1991. India's share in 1991 was doubled from the previous year's share of 0.59%.

#### Domestic Markets

Demand for latex gloves in India has also increased in view of the increasing incidence of AIDS in the country which has been realised by the medical profession recently. Experts in WHO argued that AIDS is spreading in India as quickly as in Africa and the country's situation is more complex. WHO conducted a survey which revealed that highest number of AIDS cases and zero-positivity rates have been reported from Bombay and Calcutta and the nation-wise average HIV prevalence rate has gone up from 0.2% in 1986 to 1.3% in 1990 accounting a seven-fold increase within the five years. The study also estimated that current infection in India varies between 3 lakh and 5 lakh this will go over one million by the turn of the Century. Considering this Union Cabinet has recently established a national AIDS Control Authority (NACA) for quick implementation of AIDS control programme.

As stated earlier gloves can also be applied in other areas like food, meat packing industry, laundry, catering etc...The rise of such industries in India should definitely give gloves a greater share in the domestic market. People engaged in chemical handling, food processing, automotive, hazardous waste and beauty parlour are often wearing surgical gloves which are costlier than examination gloves. Many of



these people are not aware of the availability of examination gloves. They simply buy gloves whatever is available in medical shops without considering its price and quality. They are also buying gloves from platform vendors who are trading second quality gloves and rejections made from the export trade.

All these shows that there is good market for examination gloves in India. The only thing is to exploit the market. For that, our manufactures should create an awareness among the consumers about the various applications of gloves and popularise its uses through proper media. Appendix-1 gives a rough idea of the market segment for gloves in India.

## PROSPECTS

Prospects of glove units in India looks bright. For surgical gloves market is very stable and demand is going up. Demand for examination-gloves is going up as the world market is now experiencing a shortage of quality product of new FDA regulation. Awareness of the continuing spread of AIDS and other lethal diseases has caused the world market for gloves to expand at the rate of about 10% per annum. Price realisation has also increased to the range of 25-30 US dollars (C.I.F.) as against 15-18 US dollars during the slump period. Quality of Indian gloves are noway inferior to gloves made from Malaysia and other key producing countries. However our manufacturers should take into account all the developments & regulations made in USA and other European countries on import of latex gloves.

**Table 3. Production and Export of Glove**

Year	Production		Export	
	Exam. Gloves (millionNos.)	Surgical Gloves (million pairs)	Examination Gloves (million nos)	Surgical Gloves (million pairs)
1989-90	56.086	9.749	19.098	2.846
1990-91	80.958	38.176	55.543	5.390
1991-92	208.470	89.442	205.132	33.081

## FDA Regulations on Latex Gloves

In the past US buyers were sticking on to ASTM standards and consignments that failed to meet ASTM specifications were rejected. Later, for assuring safety and effectiveness of medical gloves, the US FDA has reviewed the glove testing procedures. A more stringent leak testing methodology was introduced which differs from ASTM's testing methodology by adopting a 1000ml water test. According to the Federal Food, Drug and Cosmetic (FD and C) Act all medical gloves including patient examination and surgeon's gloves either produced domestically or

imported/traded in USA are subjected to the following controls.

### 1. Registration

the US glove manufacturers are required to register with FDA and foreign glove manufacturers are encouraged to do so.

### 2. Devise listing

all glove manufacturers are required to list with FDA by completing the medical devise listing form.

### 3. Pre-market Notification [510 (k)]

Manufacturers of gloves are required to submit a pre-market notification, also known as 510 (k),

**Table 4. Country-Wise Import of Rubber Gloves in US for the Years 1990 and 1991**

Country	Quantity Imported (million numbers)	
	1990	1991
Malaysia	2393.7 (63.05)	3855 (64.52)
Thailand	464.3 (12.23)	856 (14.33)
United Kingdom	395.5 (10.42)	NA
China	218.8 (5.76)	NA
Taiwan	136.8 (3.60)	NA
Indonesia	70.8 (1.86)	NA
India	22.6 (0.59)	64 (1.07)
Others	93.9 (2.47)	NA
Total	3796.4 (100.00)	5975 (100.00)

to the FDA indicating all details of gloves including the type and source of power or other donning lubricant used and its specification. A statement/summary of the safety and effectiveness information should also be submitted along with the 510(k).

#### 4. Labelling

display of written, printed or graphic matter upon the immediate container of glove is strictly required. Name and places of business, statements of identity and net quantity content, country of origin, lot number & expiry date, donning powder identification and caution, adequate direction for use etc.... are important to be noted in labelling.

#### 5. Good Manufacturing Practices (GMP)

Manufacturers of medical gloves are required to meet the current GMP regulations for medical devices. The GMP regulation requires that every finished glove manufacturer shall prepare and implement a Quality Assurance (QA) Programme which should include the following:

- adequate organisation and sufficient trained personnel
- formal and documented QA Programme
- designated QA management
- review of all records
- approval or rejection of materials, components and finished products
- adequate and controlled equipment, environment and facilities

-assure adequate and correct quality assurance checks

-identification of QA problems and corrective actions

-periodic audits with corrective actions.

All these five regulations are common to both patient examination and surgical gloves. However in the case of marketing surgical gloves in USA, FDA requires a few more restrictions. They are,

1. Supply data on skin irritation and Dermal Sensitization studies of surgeon's gloves.
2. Dusting power used for surgeon's gloves must be cleared for marketing by the Pre-market Approval (PMA) process and this should meet the specifications of absorbable powder (made from cornstarch) in United States Pharmacopeia (U.S.P).
3. A sterility assurance level (SAL) of  $10^{-6}$  is also required for surgeon's gloves. That is the sterilization process designed so that the probability of a glove being non-sterile is 1 in one million even if the gloves originally contained highly resistant micro-organisms<sup>8</sup>.

Recently it is found that the use of latex containing medical devices caused various allergic reactions resulting in death, urticaria, rhinitis and respiratory symptoms such as asthma<sup>9</sup>. The American College of Allergy and Immunology in May 1992 provided a board list of recommendations of latex allergy. since most of the allergic reactions are caused by extractable proteins that occur in latex, FDA has instructed to make protein levels in latex

medical devices as low as possible. FDA also published an advisory document to all manufacturers of latex devices suggesting various steps to minimize the leachable proteins. A brief review of FDA's suggestions are given below<sup>10</sup>.

#### 1. Leaching

removal of as much of water soluble proteins as possible from latex devices by controlling leaching process.

#### 2. Post cure Processing

off-line washing of latex devices with hot water after completion of curing process and surface treatment of the cured device with chlorine or other agents.

#### 3. Latex Specification

manufacturers should specify the water soluble protein content of the raw latex to be purchased which can be reduced by centrifugation and other techniques.

#### 4. Manufacturing and Quality Assurance Process Validation

the process for measuring proteins must be validated and documented and assure that the leaching, cleaning or treating process being used adequately reduce water soluble proteins to or below the level in the company's specification.

#### PROBLEMS AND SUGGESTIONS

One of the important problems faced by the Indian Glove industry is low price realisation. It is reported that Malaysian gloves are sold at higher prices because of the goodwill and govt. support

they earned. The price they get is about 4000 US dollars (10-15%) more than what we get per million pcs. Beside market information is provided by the Trade Attaches of the Malaysian Embassies in Europe and USA which enable the Malaysian glove manufacturers to take part directly in tenders. Since these facilities are not available to the Indian glove manufacturers, it is suggested that, the Indian Embassies attached to European

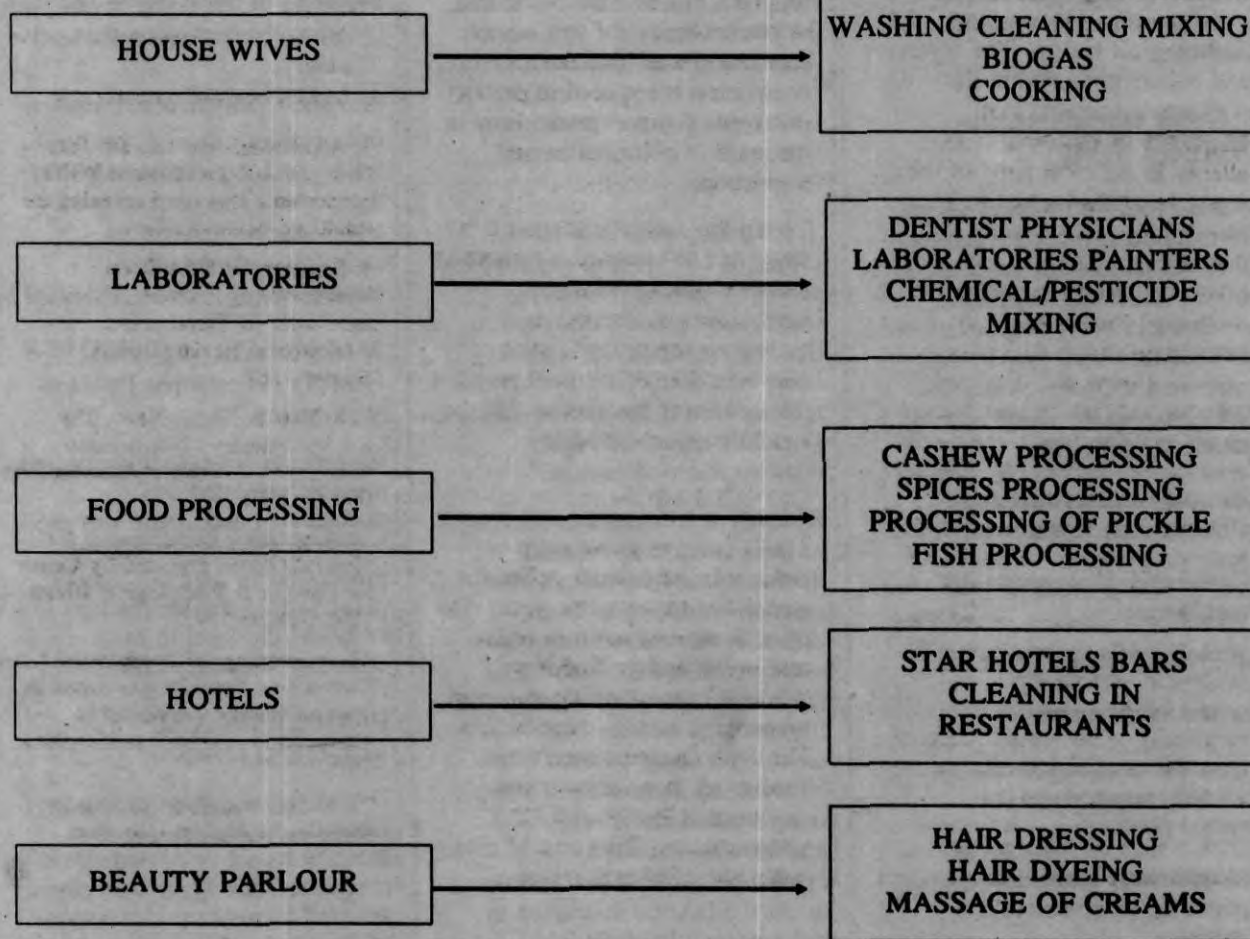
countries should collect market information and pass on to the manufacturers. A consortium of manufacturers should also be set up in US or Canada to organise marketing of Indian gloves. This consortium should collect international prices of gloves and on that basis fix lowest price for Indian gloves below which no manufacturer should sell and higher price should be targetted on the basis of quality. Similarly trade mission, trade expositions

and individual visits are also useful for making trade relations. Lack of collective marketing is another limitation. As the manufacturers in Malaysia & Indonesia have established a joint marketing agency, our manufacturers should also work collectively forgetting best prices so that they can win larger share in the world market.

International buyers are still worried about the quality of

#### Annexure. I

### DOMESTIC MARKET FOR SURGICAL/EXAM GLOVES





Indian gloves to FDA rules. Therefore to challenge the new FDA regulations, it is necessary to create an awareness among the Indian manufacturers of FDA rules and GMP.

Efforts should be made to provide a forum for the latex glove manufacturers in India to exchange knowledge and views developed in advanced countries about the allergic reaction of latex medical devices and its hazards to the medical community. Here it is worthwhile to mention the "International Latex Conference conducted in the first week of November 1992 in USA which was mainly sponsored by the Food & Drug Administration and the Center for Devices and Radiological Health. The reports and papers presented in the conference revealed that frequency of reporting latex allergy in different parts of the world has been increasing in recent years. Considering this manufacturers in Malaysia reviewed various methods for reducing protein during the production of medical devices such as gloves and condoms. It is reported that the typical "on-line or off-line leaching" treatments removes approximately 50% of the water extractable protein. Chlorination, Steam Sterilisation, Enzyme treatment of latex and use of barrier coatings have also been found effective in reducing protein levels or denaturing the protein as part of the manufacturing process. The level of protein in the serum phase of latex can also be reduced through double centrifugation."

FDA's alert on latex allergy incited many glove manufacturers

in USA to produce TPE gloves (Thermoplastic Elastomer Gloves) which are reported to be free from NR latex skin irritants<sup>12</sup>. They also started to produce Powderfree Gloves and Clean Room Gloves as the demand for these items has considerably increased in the international market. It is estimated that the use of powderfree gloves may grow from the current estimated 150 million pcs to around 1000 million pcs in the next two to three years. This type of gloves also fetch a better price of atleast 8 to 12 US dollars per 1000 pieces extra than the price for examination gloves. India can produce powderfree gloves economically than Malaysia and Indonesia because of less labour cost in India as high labour component is required to produce this type of gloves particularly in the stage of chlorination and inspection.

To tap the domestic market it is suggested to establish a marketing network with individuals approaching the important marketing segments. Gloves can also be marketed in small pouches through super markets so that they can be popularised easily.

## CONCLUSION

The success of glove units in India is beyond doubt optimistic atleast for the next few years. The price is moving towards better realisation and profitability. Practical convertability of export proceeds is also favourable factor. The manufacturers should take heed of all these aspects and co-operate closely with FDA administration. They should also make liberal advertisement

campaign to establish an image for Indian gloves in abroad so that they can develop good trade relations in the international market.

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## RRIMFLOW: A PROMISING RADICAL METHOD OF CROP PRODUCTION IN *Hevea*

**T**he current scenario in the natural rubber industry in Malaysia dictates the necessity for radical technologies of crop production in *Hevea*. These techniques should have attributes which could overcome several constraints associated with existing conventional exploitation systems and contribute to higher labour and tree productivity. This will ensure that the returns per unit area are more remunerative, with improved man/land ratios that are comparable to other plantation crops.

It is generally known that processes occurring in latex vessels following excision tapping and the activity of bark coagulants on latex as it flows down the tapping cut contribute to cessation of flow, 2-3 h after tapping. Although the flow time is enhanced by several hours in stimulated trees, it is, however, confined to the initial few tappings after application of stimulants. It is obvious that much higher yields with long hours of latex flow can only be achieved if

methods could be developed to circumvent these restrictive mechanisms on latex flow.

The RRIM has, therefore, developed a novel and radical technique of exploitation of *Hevea* known as 'RRIMFLOW'. This technique, which is an incision method, is combined with application of a potent stimulant which keeps the latex vessels unplugged for considerable length of time over an extensive area of bark on the panel. The latex is extracted in a closed system into



Figure 1a. Components of RRIMFLOW - a PVC applicator for stimulant application, with LIL.ECS sets for collection of latex in a sealed container, which in this case is a polybag.



Figure 1b. Extraction of latex through a plastic tubing (2mm diameter x 60mm length), with one end fitted into the puncture and the other end leading into the sealed polybag through a 2mm aperture.