DEVELOPMENTS IN LATEX PRODUCT INDUSTRIES AND CHALLENGES AHEAD FOR EXPORTERS OF LATEX PRODUCTS

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Introduction

Natural rubber latex is used to manufacture a number of products some of which are highly biologically sensitive. Human contact with latex film begins from the stage of child birth. The role of products like surgical gloves, hospital sheetings, pacifiers, soothers, nipples, balloons, condoms, catheters, foam rubber products and the extent of their contact with human body need no elaboration. With the extensive use of examination gloves in developed countries as a barrier against aids virus, the number of persons using rubber latex products went up enormously recently. The consumption of examination gloves in 1992 exceeded 10 billion pieces. The extensive use of rubber products in this magnitude has created some medical problems like sensitivity to its users for certain types of allergy. The reactions are asthmatic or anaphylactoid reactions and local eczema. Countries consuming rubber products are fully aware of these problems. To minimise incidence of allergy and related issues suitable acceptance procedures are evolved by importing countries of these products. These are known by different names like good manufacturing practice (Gmp), total quality management systems (TQMS), ISO-9000 etc. These are not specifications for the end products but systems and procedures to be followed by manufacturers. The details of the changing consumer needs and proposals for enabling manufacturers to meet these requirements are included in the paper.

Important rubber latex products and their manufacturing process

Dipped goods

Balloons, gloves, Catheters, nipples, Soothers, rubber bands, medical tubings etc. are manufactured by dipping appropriate formers in suitably compounded latex with or without coagulant dip. Almost sixty percent of natural rubber latex used in latex industry is in manufacture of dipped goods. In the process of manufacture, latex and the dry film come in contact with external ingredients like coagulants, antistick powders and compounding chemicals. If the process cycle is properly designed a sizeable portion of external additive can be removed by steps like leaching, washing and drying. There are also naturally occurring non-rubbers in latex, like proteins and resins. These are also found to

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create problems like allergy. In many small factories only the production of articles in large volume is considered important. When delicate products are to be exported the requirements of each product in the international market has to be assessed by the exporters and policies evolved to meet these requirements while the goods are produced.

Foam products

Both fibre foam and latex foam products are used in bedding and upholstery. In fibre foam the rubber content is around 30 percent. Foam products are exposed to prolonged contact with users and this long proximity can cause allergy and similar health complaints. In the production of foam rubber from latex a number of chemicals are added. In foam production there are stages for leaching the bed and removal of excess chemicals. If this is not done foam products may create problems like allergy. In fibre foam the treatment given to fibres should be such that no residual poisonous ingredient remain in fibres after its washing, leaching and drying. Use of antifungal agents like PCP is banned in many countries.

Latex thread

This product is used in manufacture of elastic under garments. Thus in products like underwears, brasiers and socks the extent of body exposure to latex thread is more than in many other products. Here also general ingredients are used in the production of thread. The effectiveness of the leaching step decides the trouble free performance of threads in under garments.

Cast toys

Cast toys are used mostly by children. Production of cast toys involves steps like compounding of latex, preparation of moulds for casting and casting of Toys from compounded latex. The ingredients for compounding should be selected carefully to avoid user complaints.

Status of latex industry in India

Although the number of latex based industries in the country is large, the volume of production of rubber products and the value of products is not commensurate with it. The export value of latex products from India is less than Rs. 25 crores per year whereas the value of latex products exported from Malaysia exceeds Rs. 1500 crores per year. Malaysia is world's biggest exporter of products like rubber threads, examination gloves and catheters. The consumption of concentrated latex in Malaysia exceed 1,00,000 tonnes per year. The consumption of latex by Indian product manufacturers is in the range 45000 tonnes per year. Most of the products manufactured are used within the country. Export of latex products is slowly gathering momentum in the country and the glove units established in the export zones and the condom units under public and private sector companies are taking a lead in this direction. There are also proposals for establishing

large rubber thread and catheter manufacturing units in the course of next two or three years.

Table 1 below gives the number of different types of latex product manufacturing units in the country.

Table 1 **Latex product Manufacturing Units**

Nature of the unit	*No of units*
1. Feeding bottle nipples	47
2. Balloons	87
3. Rubber bands	200
4. Electrician's gloves	3
5. Household gloves	32
6. Industrial gloves	32
7. Surgical gloves	47
8. Examination gloves	31
9. Finger stalls	21
10. Condoms	4
11. Foam products	348
12. Elastic thread	65
13. Latex based Adhesives	98

Thus the number of units engaged in manufacture of products from latex exceed one thousand. Most of these units operate in small scale sector and the quality of goods produced needs substantial improvement if they are to compete effectively in the international market.

Challenges to be faced by latex product manufacturers in global market

Indian industry is exposed to international competition with the adoption of liberalised economic policy by the Govt. of India. Many products originated from the small scale sector are likely to find stiff competition with quality products from overseas countries. Also an expanding industry will have to find new markets for its products both within the country and outside. This is possible only when the industry can design products as per requirements of the users. Manufacturers of products like examination gloves, catheters, rubber threads, pacifiers, soothers, nipples, balloons and medical sundries are likely to face this problems more seriously. Most of these products are exported to developed countries like USA, Germany and other European nations. The main defects noticed by the Buyers in developed countries on latex products are listed under.

1. Presence of nitrosamines

For vulcanisation of rubber latex, amine based accelerators are used. These accelerators produce nitrosamine a carcinogenic substance during vulcanisation. Presence of nitrosamines at extremely low concentrations, of the order of ppb (Parts per billion) is not acceptable to many buyers in the West. Tolerance limits are specified in the national standards of rubber latex products by major importing countries. The producing countries will have to evolve suitable technology to produce latex products that meet such stringent tolerant limits for nitrosamines. There are also difficulties in arriving suitable extraction and estimation procedures for nitrosamine. Some use synthetic saliva for extraction of nitrosamines, yet others use chloroform for extraction. Even before these are standardised

and approved by international standards organisation, tolerant limits are prescribed by some countries importing latex products. The limits of nitrosamines prescribed by Germany for latex teats and soothers is 30 ppb and for nitrosatable ammines 500 ppb. Conventional latex accelerator ZDEC (Zinc Diethyl Dithio Carbamate) used for producing latex products like teaths is found to yield upto 400 ppb nitosoluble amines. Therefore the latex product manufacturers have to select accelerators which will not produce such high values of nitrosatables. Thiurams and Thiagole accelerators were found to give vulcanisates with low values of nitrosamines and nitrosatables. Leaching of latex products and washing it in sodium sulphite solution is found to reduce levels of nitrosamines. So product manufacturers will have to take additional measures for quality conformity and to that extent its cost will increase.

Zinc oxide toxicity

Limits are prescribed for the Zinc content in products like baby feeding bottle nipples and soothers. In all conventional Sulphur vulcanising systems zinc is an essential ingredient. Product users in developed countries prefer to get delicate rubber products without zinc. The absence of Zinc in products also eliminates trace contamination by lead and Cadmium. The two elements are already banned from soothers and nipples.

Allergic reactions of latex products

Reports are appearing from countries with large volume consumption of rubber products on the allergic reaction of these products to certain sensitive persons. Two types of allergic reactions are reported. The first type is a transient condition of the skin, usually caused by an allergic reaction and characterised by pale, irregular, elevated patches and severe itching. Highly sensitised persons will show Anaphylaxis, a condition of increased susceptibility to foreign proteins resulting from previous exposure to it. It is believed that these reactions are caused by the proteins naturally present in latex. This is categorised as Type -1 allergy.

Certain class of residual compounding ingredients in latex products found to give itching, redness, swelling etc. to users, a few hours after contact with it. This is described as Type IV allergy.

Type 1 allergy has following features

a) It occurs quickly on contact with rubber products.

b) It produces redness, wheals and flares at the contact site or elsewhere.

c) It can produce anaphylactic reactions. It is caused by the proteins in latex and not by compounding ingredients. Some of the reported effects arising out of anaphylaxis are breathing difficulty, speeding of heart rate, fluid release in the tissues and unconsciousness. In isolated cases these reactions have proved fatal to the affected person. Considering the strong consumer protections movements in developed countries the risk and challenges to manufacturers of latex products is thus evident.

Measures adopted by importing countries for quality regulations

ISO - 9000 and its relevance to exporters of products

Quantity systems is a modern concept enabling manufacturers to produce goods or render services meeting the stated requirements of the customer. The standards on quality systems give assurance to customers at various stages through out the life of a contract or supply. There are several components in a quality management system. Most important among it is Management responsibitlity for quality. The company should have a quality policy, which takes care of matters like product design as per needs of customer, proper vender selection for raw material, proper procedures and systems for manufacture, Sound market intelligence for product improvement and design changes as per needs of customers. Exporters of products will have to get accreditation under ISO - 9000 for getting access to markets in developed countries. Only the high quality conscious and efficient manufacturers can meet the strict requirements under this system. Buyers in Europe are more inclined to buy products from sources with ISO - 9000 accreditation.

Good manufacturing practices and FDA approval

Manufacturers exporting latex devices to USA are required to meet the Good Manufacturing Practices (GMP) regulation for medical devices. The GMP regulation requires that every manufacturer shall prepare and implement a quality assurance programme. The GMPP regulations are administered by the Food and Drug Administration (FDA) of USA. Exporters of latex products to USA will have to register with FDA and cover the inspections and regulatory procedures for getting approval. For ensuring approval the manufacturers should have proper planning from the initial stages of production. All components and manufacturing materials used must have specifications. Proper components for manufacture is an important step in producing high quality products. When a Device Master Record (DMR) is prepared, component specifications, acceptance procedures, storage and handling system, processing procedures testing of products, packing procedures etc. are included in it.

In essence the GMP and its regulations are similar to the systems and procedures of ISO - 9000. In both cases quality assurance systems are to be properly documented covering all stages of production. A strict implementation of the systems envisaged under these will help manufacturers to produce good quality products without rejections and wastage.

Product specific problems and remedies

Examination gloves

The most important natural rubber latex product of the century is examination gloves. It is estimated that around 40 per cent of the latex used globally by product manufacturers is con-

sumed by this product. Consumption of latex in this product in 1991 was estimated to be around 135000 tonnes.

Most Important problems faced by product manufacturers is the allergic reactions reported by users of the product. Although the incidence of fatal reactions reported are negligibly small, the existence of this reaction is considered to be a factor inhibiting its expanded use. Manufacturers of examination gloves have to take proper steps to minimise extractable proteins in their product. For this use of low protein latex in production process, proper leaching procedures, steps for elimination of dusting powders etc. are considered useful. Individual manufacturers will have to standardise and evolve their own procedures for getting products of desired properties.

Nipples, pacifiers, soothers and balloons

The products are mostly used by children and considerable oral contact of the product occurs during use. The medical purity of the products are therefore highly desirable. The important contaminations reported on these products are nitosammines and nitrosatable amines. There is good demand for products which meet specifications in international market. The nitrosamines originate from accelerators used in vulcanisation. A permanent solution to the problem is to use non-Sulphur vulcanised lattices in production of these products. Radiation vulcanised natural rubber latex (RVNRL) is supposed to be most suitable for this.

Condoms and Catheters

Both the products are to remain exposed to sensitive internal organs and can cause type-IV allergy in isolated cases. Chances of allergy is more in Catheters considering its complicated fabrication procedure, involving multiple dips. condoms are thin walled products and leaching it in on line process may be adequate in many cases. In Catheters it is desirable to give proper hot water leaching and a coating on the tubes to minimize skin irritation problems.

Summary and conclusions

Natural rubber latex based products have good domestic and overseas market. Labour intensive dipped rubber products can be produced advantageously in developing countries. The manufacturers of these products have to study consumer needs in different importing countries and evolve proper strategies for making products meeting such requirements. In international market quality is more important than price and so the manufacturers will have to make suitable additional investments to produce goods acceptable in global market.