INDUSTRIAL PRODUCTION OF LATEX POLYMERIZED
AND ITS DIPPING PRODUCTS IN INDONESIA

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ABSTRACT

INDUSTRIAL PRODUCTION OF LATEX POLYMERIZED AND ITS DIPPING PRODUCTS IN INDONESIA. Nine types of pre-vulcanized latex prepared by gamma rays of $^{60}$Co with the trade name of Latex Polymerized has been produced. The name of 9 types are: Type pre-vulcanized (PV) only 1 type, Type NR-g-styrene (KS) is four types, and type NR-g-methyl methacrylate (KM) is four types. The properties of Type PV such as DRC, TSC, KOH, VFA, and MST number are not only found to the requirement of the ISO 2004 standard but also the latex has low protein, lipid, and carbohydrate content. The physical and mechanical properties (tensile strength, modulus, and elongation at break) of rubber products such as condom, gloves, and sphygmomanometer are, and rubber foam are not only found to the requirement of ISO 4074, ISO 1028, and ANSI/AAMI SP-1994; ASTM D 1055-2005 standards, but also more hygienist such as is not allergy, and not carcinogenic.

Keywords: Latex polymerization, More hygienist

INTRODUCTION

Natural rubber latex (NRL) has a specific competitive against latex synthetic since it lower in price, renewable, good in wet strength and elastic as well as good in barrier properties, and it due widely used in medical devices such as for anesthesia (heating circuit, etc.) for dumb-bell (bite, block, dental dump, etc), for general medical (medical gloves, hot water bottle, blood pressure cuff etc.) , for surgical /urological (arterial and venous catheter, surgical gloves, etc.), and for various field such as : sealing compound adhesive, condom, sphygmomanometer and like [1-4].

The pre-dominant use of Latex Polymerized is in the production of dipped goods, where its superior film forming ability, excellent gel strength and high tensile strength and elongation required for the finish product are essential. How ever the incidence of latex allergy associated with water-extractable protein in gloves of Type I hyper-sensitivity has posed a serious challenge to latex dipping products manufactures [5].

The Indonesian Rel-ion sterilization Services Ltd. has established a commercial producing Latex Polymerized by gamma irradiation as a energy for vulcanization since 2008. This Latex Polymerization has been used for production of gloves, condom, and rubber for sphygmomanometer in factory scale.

This paper describes the production of Latex Polymerized and its rubber dipped product which has been carried out in factory scale in Rubber Industries. The purpose of this study is to prove that the production of Latex Polymerized and its rubber products can be produced in industrial scale, with good quality and more competitive compared with sulfur vulcanization method.
EXPERIMENTAL METHOD

Material

The raw material for producing Latex Polymerization is High Ammonia (HA) centrifuged natural rubber latex produced by Jalupang factory PTP VIII Subang, Bandung, West Java, Indonesia. The chemicals for producing Latex Polymerization such as: nonionic soap, Normal Butyl Acrylate (nBA), Methyl MethAcrylate (MMA), styrene were used as row materials. The chemical for producing condom sphygmomanometer gloves and rubber foam were prepared by industries.

Apparatus

The facilities of $^{60}$Co gamma rays with capacity 400 kCi which completed by the biological shield, the safety system, the source system, and conveyer system are installed at PT. Rel-ion Sterilization Services, Zone Industry Ganda Mekar, Cibitung Bekasi, Indonesia. The apparatus for producing gloves, condom, sphygmomanometer are prepared by rubber good industries. Apparatus for testing of allergic response, quality of latex and its rubber products are prepared by PT. Rel-ion Sterilization Services and Indonesia Government Institution.

Method

The procedure for production Latex Polymerized is described on Figure 1. From this figure it can be seen that the concentrated natural rubber latex from the drum A1 to be pure by pump A2 to the reaction mixture A3, then mixed with monomer emulsion. After mixing the latex pure into the drum A6 and irradiated by gamma $^{60}$Co (A7) at the dose of irradiation at 10, 15 or 30 depend on the Type of Latex Polymerized to be produced.

To measure the dose absorbed, the first control is the cycle time setting, using an electric timer. It accuracy is checked and calibrated on periodic basis. The chromic film dosimeter is used to measure and determine of the dose adsorbed.

RESULT AND DISCUSSION

Production

Effect of ionizing radiation (gamma rays or electron beam) on polymeric materials has been studied since for over than 60 years ago by a number of investigators. It was reported that the effect on polymeric materials are degradation and cross-linking. Both degradation and cross-linking may occur simultaneously. In cross-linking occur at a high yield appear chain scission in the same polymer, the polymer is classified as a cross-linking polymer. On the other hand of the chain scission yield is higher than cross-linking in the same polymer, the polymer is classified as a degradable polymer. The effect of gamma irradiation on natural rubber latex is not only occur cross-link among cis 1,4 poly-isoprene, but also degradation on non rubber constituent [5].

Type of Latex Polymerized

Three grades of Rel-ion Natural Rubber Latex Polymerization namely; Type PV, Type KM, and Type KS. They are formulated specially for the manufacture of ultra-high clarity article by straight or coagulant dipping processes, with the most typical properties is shown on Table 1.

To measure the quality of rubber goods namely gloves, condom, and rubber for sphygmomanometer, used the procedure of ASTM, and ISO standard requirement [6-10].
Natural rubber latex polymerized no carcinogenic and allergenic protein. Natural rubber latex polymerized better latex stability in storage, natural rubber latex polymerized less environmental pollution, cleaner industry effluence and natural rubber latex polymerized has low protein, carbohydrate lipid content.

Dry Film Properties of Rel-ion Latex Polymerized

Dry Film Properties of Rel-ion Polymerized Latex such as transparency, water resistance, and safety are as follow.

Transparency

Rel-ion Natural Rubber Latex Polymerized contain a low proportion of non rubber, crosslink ingredients are reduce to a minimum, and no stabilizer, ensure the production of high transparent articles. These factor couple with simple drying treatment required

Water Resistance

The water resistance of Rel-ion Natural Rubber Latex Polymerization film is higher than that of the most compounded latex film because of the low non-rubber content and absence of added dispersing agents. Washing (leaching) of Rel-ion Polymerized Latex film will provide optimum water resistance.

Safety

The natural latex industry is facing a number of serious challenges such as carcinogenic and allergenic. Carcinogenic come from chemical to be used for producing the articles such as dithiocarbamate which can produce nitrosamine as carcinogenic materials, and allergenic comes from the latex protein content.

The quality of Latex Polymerized Type PV is shown on Table 2. It indicates that the TSC and DRC of Type I are higher than Type II, because for producing the Latex Polymerized Type I, the first step is to irradiate

### Table 1. Specification of rel-ion latex polymerized

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N.R. Latex Polymerization</th>
<th>ISO 2004 Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PV Type 1</td>
<td>Type 2</td>
</tr>
<tr>
<td>Total solid content (TSC), %.</td>
<td>61.5</td>
<td>58.5</td>
</tr>
<tr>
<td>Dry rubber content (DRC), %.</td>
<td>60.0</td>
<td>57.0</td>
</tr>
<tr>
<td>Non-rubber content (TSC-DRC)</td>
<td>1.5</td>
<td>1.5</td>
</tr>
<tr>
<td>Alkalinity (as NH₃), % on latex.</td>
<td>0.77</td>
<td>0.70</td>
</tr>
<tr>
<td>Mechanical stability time (MST), second.</td>
<td>1500</td>
<td>1500</td>
</tr>
<tr>
<td>Coagulum content, %.</td>
<td>0.04</td>
<td>0.04</td>
</tr>
<tr>
<td>Copper content, mg/kg.</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Magnesium content, mg/kg.</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Sludge content, %.</td>
<td>0.10</td>
<td>0.10</td>
</tr>
<tr>
<td>Volatile fatty acid number (VFA).</td>
<td>0.023</td>
<td>0.024</td>
</tr>
<tr>
<td>KOH number</td>
<td>0.8</td>
<td>0.8</td>
</tr>
<tr>
<td>Color on visual inspection</td>
<td>No pronounced blue/gray</td>
<td></td>
</tr>
<tr>
<td>Odor after neutralize with boric acid</td>
<td>No pronounced of pure active</td>
<td></td>
</tr>
</tbody>
</table>

the field latex, then the irradiated field latex was concentrated by centrifugation machine. This procedure is quite the with the convention procedure for producing HA concentrated latex which has standardized by ISO 2404, where the standard TSC of ISO is 61.5%. So Total solid content of Latex Polymerization Type PV I is quite the same with the quality of ISO standard. But for producing Latex Polymerized Type II the first step is to irradiate the HA concentrated latex with the TSC 55%.

If the Latex Polymerized compared with sulfur compound, it indicates that key feature of Latex Polymerized is absence of accelerators, zinc oxide and amine-based accelerator, which can produce nitrosamine, with generic form may be represented by the structure as Equation (1) [4]:

\[ R_1 \begin{align*} \text{N} & \text{= N} = \text{O} \end{align*} \]

where:
- \( R_1 \) and \( R_2 \) = Methylene function group
- \( N \) = Nitrogen
- \( O \) = Oxygen

It has been reported that the special formulation for Rel-ion Polymerized Latex is no contain of sulfur vulcanization ingredient such as sulfur, dithiocarbamate material. The test results by independent laboratory in specializing analysis of nitrosamine showed that no nitrosamine were detected in pre-vulcanized NRL Latex film. It means that rubber film is not content of carcinogenic materials, because nitrosamines has been shown to be a potent carcinogen in animal tests producing liver, kidney and lung cancer.

Absence of the conventional sulfur compound latex accelerators (dithio carbamates and thiazoles) sulfur from Latex Polymerized ensure that products made from Latex Polymerized will not caused any dermatitis / allergic reaction associated with these chemicals. Dermatitis (irritation of the skin) from the accelerators, zinc oxide and amine-based accelerator, may be responsible for much of the tissue irritation experienced by patients who have latex urinary catheters implanted for long periods.

The absence of zinc and zinc-bearing accelerators eliminates the problem associated with minimizing zinc contents in order to meet regulatory limits for zinc in babies bottle teats, and soothers.

The absence of zinc also removes the possibility of trace contamination by lead and cadmium often found from Latex Polymerized on factory scale. in teats and soothers, and the absence of amine-based accelerators further means that the possibility of forming nitrosamines during the process production is eliminated.

The low modulus of Latex Polymerization film is some advantage for articles such as gloves and toy balloons, where high modulus is not desirable. However, the cross-link density will need to be sufficient to prevent distortion of the product on removal from the former.

Product from Latex Polymerized should have high transparency, due to the absence of curing ingredients, and this is desirable for products such as teats and soothers and some catheters. Additionally, their should be very pole since they do not need of heated to high temperature for further vulcanization. Also product form Latex Polymerized should be totally free of the “bloom” problem that are often encountered in conventionally vulcanized, because these blooms are normally the results of excessive level of accelerator or sulfur in the formulation.

Compared with sulfur vulcanization it indicates that Latex Polymerized have low protein, lipids and carbohydrate content to ensure that the finished articles have the minimal amount of residual protein containing the allergens and safe for using.

From these advantages characteristic of Latex Polymerized, it can be recommended that the potential application of Latex Polymerized are good for production of medical products such as condom, teats, balloons, and gloves for food contact

**DIPING PRODUCT FROM LATEX POLYMERIZED**

Three kind of dipping products namely condom, gloves, and sphygmomanometer has been carried out, with the details information are as follows.

**Production of Condom**

Straight dipping for production of condom is the simplest type of dipping process. The thickness of the rubber deposit obtained by this method is around 40-60 \( \mu \) dependent on the total solid content of the latex and its viscosity. The clean former of condoms immersed into the Latex Polymerized compound. The deposit is dried, then immersed again into the second Latex Polymerized, dried again, then stripped from the former with wet stripping method. The wet condoms are leached, dehydrated, dried in tumble, dried in air condition, pine

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**Table 3. Summary of skin-prick test (SPT), from 11 patients the allergic response by latex hypersensitive individual [5].**

<table>
<thead>
<tr>
<th>Samples</th>
<th>EPC, ( \mu g )</th>
<th>Individuals hypersensitive SPT, number of patient</th>
<th>Average, Au.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>no data</td>
<td>0 0 0 0 0 0 0 0 0 0 1</td>
<td>0.1</td>
</tr>
<tr>
<td>Standard hypersensitivity latex</td>
<td>no data</td>
<td>2 2 2 2 2 2 2 2 2 3 2</td>
<td>2.1</td>
</tr>
<tr>
<td>Condom from sulfur vulcanization</td>
<td>115</td>
<td>2 0 1 0 0 0 0 0 0 1 0</td>
<td>0.4</td>
</tr>
<tr>
<td>Condom from irradiated natural rubber latex</td>
<td>116</td>
<td>0 0 0 0 0 0 0 0 0 0 0</td>
<td>0</td>
</tr>
</tbody>
</table>

EPC = Extractable protein content, Maximum the allergic level response = 4 Au/g. Au = allergy unit.
hole test, selection, lubrication and then packaged. It indicates that for obtaining thickness of condom 40-60 μ, the total solid content should be around 51%.

Condom from Latex Polymerized produced in factory scale with extractable protein content 116 μg/g showed to give negative response (Table 3). The negative response to Skin-Prick Test of condom prepared from Latex Polymerized due to the degradation of non rubber content such as extractable protein by gamma radiation.

Production of Surgical Gloves

The gloves former after leaching and heating is dipped into a solution of CaNO₃ as coagulant agent. The coated former then dipped into the latex. On coming into contact with the coagulant, the latex is gelled and diffuses away from the former the gelled layer becomes thicker. The thickness of rubber film produce therefore depends on the dwell time in the latex, concentration and viscosity of coagulant used as well as on the rubber content and viscosity of the latex. The effect of leaching on the extractable protein content in gloves is showed on Figure 2.

It is indicated that the extractable protein content of gloves after leaching with cationic soap (C) is lesser than the other treatments. It means that the polarity of cationic soap is better than water (W) or ammonia (A) as the leaching solvent. So that the solubility of extractable protein in cationic soap is better than water and ammonia, hence the residue of extractable protein in gloves after leaching with cationic soap is lesser. Figure 2 shows that by increasing the curing time from 3 to 10 minutes, the tensile strength of gloves increases, then after 15 minutes the tensile strength of gloves is quite the same. So it can be concluded that the optimum time of curing is 10 minutes.

Production of Rubber for Sphygmomanometer

There are three kinds of rubber sphygmomanometer has been prepared, namely: bulb, bladder, and tube. The procedure for production of the rubber for sphygmomanometer is coagulant dipping method with two time of dipping in coagulant, and in latex. The thickness of rubber deposit depends on the dipping time and concentration of coagulant of the second coagulant. The factors such as heating time and leaching of the products has been carried out. Figure 3 (c) shows the effect of curing time of Latex Polymerized and sulfur vulcanization against tensile strength. There are two points which can be seen from
Industrial Production of Latex Polymerized and its Dipping Products in Indonesia

Table 4. The quality of condom, surgical gloves, and rubber for sphygmomanometer from INRL produced in factory scale

<table>
<thead>
<tr>
<th>Properties</th>
<th>Treatment</th>
<th>Condom ISO 4074-9</th>
<th>INRL</th>
<th>Surgical gloves Type I ISO 4074-9</th>
<th>Type II ISO 4074-9</th>
<th>Sphygmomanometer bulb ANSI</th>
<th>INRL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tensile strength, MPa.</td>
<td>A</td>
<td>20</td>
<td>22</td>
<td>23</td>
<td>17</td>
<td>Nr 25</td>
<td>22</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>17*</td>
<td>18</td>
<td>17</td>
<td>12</td>
<td>Nr 20</td>
<td>19</td>
</tr>
<tr>
<td>Elongation at break, %</td>
<td>A</td>
<td>750*</td>
<td>1000</td>
<td>700*</td>
<td>550*</td>
<td>900</td>
<td>Nr 1000</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>650*</td>
<td>900</td>
<td>560*</td>
<td>490*</td>
<td>900</td>
<td>Nr 1000</td>
</tr>
<tr>
<td>Modulus 500%, MPa.</td>
<td>A</td>
<td>-</td>
<td>-</td>
<td>3**</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Bursting strength, liter.</td>
<td>A</td>
<td>20*</td>
<td>25</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Response against Type I</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>allergic by ELISA test.</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Response against Type I</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>allergic by SPT test.</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

A = before aging, B = after aging 70°C/7 days, * minimum, ** maximum, Nr = no requirement,

this figure: (1) By increasing the tensile strength increases which means the vulcanization occur, but after the over vulcanization the tensile strength decrease. The time which can produce the maximum tensile strength is called optimum cure time such as the optimum cure time of Latex Polymerized is 15 minutes, but for the sulfur vulcanization is around 24 minutes. (2) The optimum cure vulcanization of Latex Polymerized is 15 minutes, while the optimum vulcanization of sulfur vulcanization is 24 minutes mean that the in Latex Polymerized is a pre-vulcanized latex, but in sulfur vulcanization there is not pre-vulcanization So the time for vulcanization of sulfur vulcanization need more longer time than Latex Polymerized (Figure 3(a)).

The effect of leaching time on the residue of extractable content and total protein content of bulb sphygmomanometer not leaching (a) and after leaching in water for 6 hour (b), for 24 hour (c) and leaching in 1% ammonia or KOH for 24 hour are shown on Figures 3(a) and 3(b). The results showed that the leaching time agent of ammonia, for production of rubber (bulb, bladder, and rubber tube) is 1% of soup solution (Figure 3(a)), the extractable and total protein content decrease (Figures 3(a) and 3(b)). It indicates that by increasing of leaching time from 6 to 24 hour in water, the extractable content and total protein content decreases. It means that during prolongation of leaching time, the solubility of protein is running well. Then if the bulb is leached by the 1% ammonia or KOH for 24 hour, the extractable protein content decreases from 662 to 72 µg/g, it means that the polarity of extractable protein content in ammonia or KOH is better then water.

The Quality of Rubber Product from Latex Polymerized Type PV

The quality and mechanical of condom, surgical gloves, and sphygmomanometer produced in factory scale are shown Table 4. They indicate that the quality of condom, surgical gloves, and sphygmomanometer are not only found to the requirement of ISO 4074-9, ISO 4074-9, and ANSI/AAMI SP-1994 standards, but also the allergic response tested clinical latex sensitive protein allergen by ELISA test on gloves, and by SPT test on condom are found to be negative. Its means that condom, gloves, and rubber for sphygmomanometer are safe for user.

CONCLUSION

From these information it can be concluded that the production of Latex Polymerized and its rubber products in industrial scale has been carried out. The quality of polymerized latex is not only found to requirements of ISO 2004, but also have low protein, lipid and carbohydrate. The quality of rubber products from Latex Polymerization such as condom, gloves, and rubber for sphygmomanometer are not only found to requirement of ISO 40074, ISO 10282, and ANSI/AAMI SP-1994 standards, but also free from nitrosamines and protein allergen

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