

TLT-info 1/2003

**Natural rubber allergen content of latex gloves.  
A market surveillance study.**



# GLOVE STUDY 2003

The National Agency for Medicines has conducted follow-up studies on the allergen contents of surgical and examination gloves made of latex for nearly ten years. The results of these market surveillance studies have been published in the TLT infos of the National Agency for Medicines. This study presents the allergen contents of latex gloves intended for medical use that were on the Finnish market in 2003. This study, as all the previous ones, was conducted jointly by the National Agency for Medicines, the Laboratory of Immunobiology of the Finnish National Public Health Institute and the Department of Dermatology of Tampere University Hospital.

## CONDUCT OF THE STUDY

The National Agency for Medicines collected samples of the glove types on the market in spring, 2003. The study was performed on gloves from 24 manufacturers, the number of samples was 78 in total. Of these, 35 were surgical and 43 examination or procedural gloves. The selection of powderless gloves has remained the same as the last time, there were 51 gloves of this type. It was not clear from all glove packages whether the gloves contained powder or not.

The samples were coded in the National Agency for Medicines, a standard extraction was made at Tampere University Hospital to produce the allergenic proteins in a soluble form, and extracts were dispatched to the Laboratory of Immunobiology of the Finnish National Public Health Institute, where the allergen contents were determined.

Two technologies were used for the survey. As in the five previous studies, the latex-IgE-ELISA inhibition method was applied for measuring the total allergen content of the glove-extracts (1). In addition, the contents of four clinically significant latex allergens (Hev b1, Hev b3, Hev b5 ja Hev b6.02) were determined using a commercial kit designed for the purpose (FITkit™). The Finnish research team has developed this method together with the biotechnology industry (FIT Biotech, Tampere). The dissolved allergens from the glove-extracts are captured onto the

ELISA plates by monoclonal antibodies and specifically identified with antibodies that react against other structures (epitopes) of the allergen molecule.

The method is quantitative, which means that the exact allergen contents can be found out. This new test has already been used in a few other studies and its behaviour was compared to the traditional ELISA inhibition in a recent report (2). This study showed highly significant correlation between the total allergenicity, skin prick test reactivity and the sum of the four studied latex allergens. The regulatory authorities have tested the new method both in the USA and in the work groups of the TC 205 committee of the European Committee for Standardization (CEN). The results are currently being evaluated by expert panels.

## RESULTS

The results of the study are presented in the attached table. The batch number of the studied glove and the name of the manufacturer are listed in connection with the glove brand. As in the previous studies, the gloves are grouped into four categories on the basis of their allergen content: 1) allergen content very low ( $<1$  AU/ml), low ( $\geq 1 < 10$  AU/ml), moderate ( $\geq 10 < 100$  AU/ml) and high ( $\geq 100$  AU/ml).

(The natural rubber latex standard preparation is assigned an arbitrary content of 100 000 AU/ml). The gloves in categories 'very low' and 'low' contain such low levels of the main natural rubber allergens that they are suitable not only for non-allergic persons but also for most of the sensitized users (3). However, careful follow-up in health care is needed, and if even the gloves with low- allergenicity cause symptoms, entirely latex-free gloves should be used.

High allergen contents, on the other hand, are a health risk, not only to the sensitised users and the patients but also to other persons exposed to these products (4).

When reviewing the results it should be considered that this study was conducted on one batch of a specific glove type. Therefore, the results do not necessarily indicate that the allergen contents of other batches of the same glove type would correspond to the results obtained here. The buyer should request the test results on the

allergenicity of the batch of the acquired gloves from the manufacturer when inviting tenders.

Six gloves (8%) of the 78 gloves studied in 2003 had total allergen contents exceeding 100 allergen units (AU) in one millilitre of extract (1:5), so these were ranked into the category of high allergenicity.

The content exceeded 10 AU/ml in 23 gloves (29%), in other words, the allergenicity of these gloves was classified as moderate.

49 gloves (63%) had low allergenicity (below 10 AU/ml), which demonstrates that these days most of the gloves on the market belong to the category of low allergenicity. The number of gloves with 1-2 AU/ml was 8. This is slightly lower than in the previous study. 21 other gloves had allergenicity levels of 5- 9.9, which means that even these gloves can be classified as having low allergenicity.

10 gloves had very low allergenicity (< 1 AU/ml).

In the measurements of the four specific allergens it was found that four gloves contained measurable levels of Hev b1 and 17 gloves of Hev b3. These two belong to the hydrophobic allergens the amounts of which have usually been lower than the amounts of the two main hydrophilic allergens, Hev b5 and Hevb b6.02. Hev b5 could be detected in 46 gloves and the most important main natural rubber allergen, Hev b6.02, in 56 gloves. The sum of these four allergens correlated quite well with the total allergenicity measured by IgE determination ( $r= 0.78$ ), in other words, this concurred with previous study results.

Allergen determination methods based on human IgE are becoming obsolete since the research teams are running out of serums containing latex-specific IgE class antibodies. Therefore, it is important to introduce new determination methods not dependent on the use serums originating from humans (5). The results of this study will be compared with results in other material with the aim of drafting preliminary guidelines on the content levels of specific allergens that could be used as recommendations at a later stage. There is not yet enough information on the

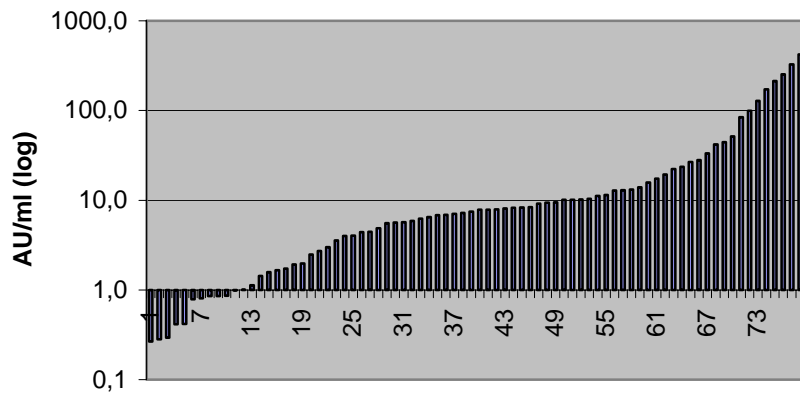
subject, so the interpretation of the results is currently based on the traditional low-moderate-high classification.

The market surveillance studies conducted in the previous years have indicated that the average allergen contents of natural rubber gloves on the market have decreased continuously, but the result this year indicates that this development has not continued as favourably as before. Nevertheless, the situation can still be considered very good from the point of view of the users, since there are several gloves with low allergenicity on the market.

The responsible researchers of the study group were Research Professor Timo Palosuo, Laboratory of Immunology of the National Public Health Institute (tel. 358-9-4744 8263) and Docent Kristiina Turjanmaa, Department of Dermatology, Tampere University Hospital (tel. 358-3-3116 5170). Additional information of the study may be obtained from the researchers and from the National Agency for Medicines from Senior Inspector Hely Reinikka-Railo (tel.358-9-4733 4245).

TLT-info (6) can be obtained from the department secretary of the National Agency for Medicines Medical Devices Centre (tel. 358-9-4733 4242).

Allergen contents of latex gloves in 2003



<b>Allergen contents in the studied gloves</b>	
<b>Very low allergen content (&lt; 1 AU/ml)</b>	
<b>Glove (batch nr)</b>	<b>Manufacturer</b>
Arista Powder Free Latex Examination Glove (130302)	Arista Latindo Ind.
Arista Powder Free Super Grip Latex Examination Glove (110422)	Arista Latindo Ind.
Cision Powderfree Latex Surgeons Glove (47196501)	GMP (Health Line)
Glads Powder Free Procedure Glove (02H63-7571)	Mölnlycke Health Care
Glads Powderfree Procedure Glove (02L63-8719)	Mölnlycke Health Care
Glads Sterile Powderfree Latex Procedure Glove (02K30-H-8231)	Mölnlycke Health Care
Glads Sterile Powderfree Latex Procedure Glove (03A10-H-8913)	Mölnlycke Health Care
Ansell Gammex PF Surgical Glove Powder Free Latex (205460104)	Ansell Malaysia
No Powder Non-Sterile Latex Examination Glove SensiClean (301027204)	Ansell Malaysia
Soft line Surgical Latex Glove, powderfree (36.00/7.5.N)	Megro
<b>Low allergen content (<math>\geq 1 &lt; 10</math> AU/ml)</b>	
<b>Glove (batch nr)</b>	<b>Manufacturer</b>
Abena Sterile Powderfree Latex Examination Glove (0C 23502)	Saekko-Bambo Group
Ansell Medical Gammex Latex Surgical Glove Powdered (108483404)	Ansell Malaysia
Ansell Medical No Powder Sterile Latex Examination Glove (209200905)	Ansell Lanka (Pvt)
Ansell Medi-Grip PF Operation Glove Powderfree (207484804)	Ansell Malaysia
Ansell Micro-Thin Nu-Tex Powderfree Surgical Glove (206481504)	Ansell Malaysia
Ansell Nutex No Powder (302424804)	Ansell Malaysia
Biogel D Powder-free dental glove with biogel coating (01D9170)	Regent Medical
Biogel Indicator sterile powder-free latex surgical glove (02K4053)	Regent Medical
Biogel M sterile powder-free latex surgical glove (03A2677)	Regent Medical
Biogel Super-sensitive sterile powder-free latex surgical glove (02H0301)	Regent Medical
Conform + disposable latex glove, no powder (212003859)	Ansell
Conform Non-sterile Powdered Examination Glove (3014328)	Ansell (Thailand)
DermaClean Powderfree - Non sterile Latex Examination Glove (302524209)	Ansell (Ambi) Sdn Bhd
DermaGrip Examination Glove Powder Free - Polymer Coated (3022377203)	WRP Asia Pasific Sdn Phd
Eurotex SP Sterile surgical glove (41201)	Lab. Pharmaceutiques Euromedis
Everguard Latex examination glove powder free (1020621)	Selefatrade
Everguard Powder Free Latex Examination Glove (1030321)	Selefatrade
GN31 Powder Free Latex Examination Glove (47570812)	Health Line
Jin Xiang Latex Surgical Glove - Sterile (200104)	Jin Xiang Emulsion Production
Maxikleen Cleanroom NR Latex Glove (6018885)	WRP Sinetimed Sdn
Maxitex Duplex Dual Protection set, sterile surgical glove (2610)	Terang Nusa
Medigloves SensiSkin powder free medical examination glove (18.02/3.2.D H)	Medigloves Ltd
MedOla Blue Exclusive Undergloves Surgical Glove (30001)	Medigloves Ltd
MedOla Micro powder free surgical glove (3018515701)	WRP Asia Pasific Sdn Phd
MedOla Powder free surgical glove (19/02/5 A)	Medigloves Ltd
Micro-Touch Latex Surgical Glove (211042321)	Ansell Healthcare
Micro-Touch non-Chlorinated Powder Free Latex Medical Examination Glove (03022203 BF)	Ansell Healthcare
Powderfree Examination Glove (161 001 400 624)	Sänger Prima
Protegrity sterile Latex powder-free surgical glove (PS99L152)	Allegiance Healthcare Corp.
Safeskin Pfe Powder-Free Latex Exam Glove (3007T-5)	Kimberlye Clark

Safeskin Satin Plus Latex Exam Glove (2158T4)	Safeskin Corp
Safeskin Satin Plus Powder-Free Latex Exam Glove (1237T-4)	Kimberley-Clark Corp.
Sempercure edition - inner coated - natural latex - examinations gloves (30030003)	Semperit Technische Produkte
Sempermed Powder free examination glove - Natural latex (52 550 174)	Semperit Technische Produkte
Sempermed powder free examination glove - Natural (TAG2 52280109)	Semperit Austria
Sempermed supreme Surgeons' glove latex powderfree (01D 344)	Semperit Technische Produkte
Sempermed supreme surgical glove-Late-powder-free (03 E 28)	Semperit Technische Produkte
Sensiflex Plus Latex Surgical Glove, powderfree (2610)	Terang Nusa
Soft line Surgical Latex Glove, powderfree (6062656-2F)	Saekko-Bambo Group
<b>Moderate allergen content (<math>\geq 10 &lt; 100</math> AU/ml)</b>	
<b>Glove (batch nr)</b>	<b>Manufacturer</b>
Safeskin LPE Lightly Powdered Latex Exam Glove (2162T-2)	Kimberley-Clark Corp.
Arista Pre-Powdered Latex Examination Glove (70322)	Arista Latindo Ind.
Biogel sterile powder-free latex surgical glove (02H2268)	Regent Medical
Biogel sterile powder-free latex surgical glove (02J1212)	Regent Medical
Biogel Super-sensitive sterile powder-free latex surgical glove optifit (02L2151)	Regent Medical
Engångshandskar av naturlatex (20848017)	Seleftrade
Everguard Latex examination glove Pre-powdered non-sterile (20948020)	Seleftrade
Glads White Procedure Glove , pre-powdered (03C62142A)	Mölnlycke Health Care
Golden Hand Latex Examination Glove, pre-powdered, non sterile (11248017)	Seleftrade
Latex Examination glove powder free (56 510 036)	VWR Int.
MedOla Premium powder free surgical glove (212875070)	WRP Asia Pacific Sdn Bhd
Micro-Touch Latex Medical Examination Glove (105082721)	Ansell Healthcare
Micro-Touch PF2 Latex Surgical Glove - Powder Free (206043921)	Ansell
Protegrity Micro powder-free surgical glove (PSOOP260)	Allegiance Healthcare Corp.
Protegrity Micro SMT Technology Powder-free Surgical glove (TSO210471)	Allegiance Healthcare Corp.
Protegrity SMT sterile latex powder-free surgical glove (TSO209303)	Allegiance Healthcare Corp.
Safeskin PF Powder-Free Latex Surgical Glove (54470)	Kimberley-Clark Corp.
Safeskin LPE Lightly Powdered Natural Ruber Latex Exam Glove (3002T-2)	Kimberley-Clark
Safeskin PF powder-free Latex Surgical glove (2354S-18V)	Kimberley-Clark
Safeskin PFE Powder-Free Latex Exam Glove (2285T-5)	Kimberley-Clark Corp.
Sempercure latex examination glove powdered (12 200256 140 035)	Semperit Technische Produkte
Sempermed supreme surgical glove sterile - latex - powder-free (02C1155)	Semperit Technische Produkte
Triflex Sterile Latex Surgical glove (TSO206062)	Allegiance Healthcare Corp.
<b>High allergen content (<math>\geq 100</math> AU/ml)</b>	
<b>Glove (batch nr)</b>	<b>Manufacturer</b>
Tod Dent Latex Glove (85015680)	Hammasväline Oriola Oy
Sempermed Derma plus Surgical glove Latex powdered (02 H 551)	Semperit Technische Produkte
Latex Glove (6062902-2)	Saekko-Bambo Group
MedOla Basic powder free surgical glove (31501023)	TG Medical Sdn. Bhd.
Sempermed DERMA plus surgical glove - latex -powdered (02K880)	Semperit Technische Produkte
Sempermed derma plus Surgical glove - latex - powdered (02N5 77)	Semperit Technische Produkte

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