

ANSELL WHITE PAPER ON GLOVES NRL ALLERGEN CONTENTS

To date, 13 allergenic proteins have been identified by the scientific world.

The allergens showing the highest “potential” (type I allergies) are the following : Hev b1, Hev b3, Hev b5 and Hev b6.02

Producing low allergen gloves has always been at one of Ansell’s top priorities and thanks to the company’s unique manufacturing process, this goal has been achieved

over the past years, helping Ansell to produce top quality low proteins state-of-the-art surgical gloves.

In order to identify the allergens mentioned above within “common production”, a specific latex allergens precise detection / quantification method was necessary.

The FITKIT™, developed by the company FIT BIOTECH (www.fitbiotech.com) in partnership with leading scientists, consists

of monoclonal antibodies acting against four clinically relevant latex allergens (Hev b1, Hev b3, Hev b5 and Hev b6.02) present in NRL gloves.

In order to benchmark **Ansell High Temperature Post Washing Process** versus DPNR (Deproteinised and purified natural rubber latex), the FITKIT™ reliable immunological test has been used. Results are as follows:

Latex Type	Glove Type	Normal processing method	Ansell High Temp. Post Washing Process	Hev b1 µg/ml	Hev b3 µg/ml	Hev b5 µg/ml	Hev b6.02 µg/ml	Sum of 4 µg/g	Total Allergens AU/ml (allergen units)
High Ammonia Latex (Ansell)	Powder-free	Yes	Yes	ND	ND	ND	ND	ND	0.2
High Ammonia Latex (Ansell)	Powder	Yes	Yes	ND	ND	ND	ND	ND	0.7
DPNR supplier 1	Powder-free	Yes	No	ND	ND	ND	ND	ND	19
DPNR supplier 2	Powder-free	Yes	No	ND	ND	ND	0.07	0.07	21

Fig 1 : Ansell High Temperature Post Washing Process versus Deproteinized Latex

Important note: "ND" = non-detectable. Used when ...

- Concentration of Hev b1 and/or Hev b3 are < 0,050 µg/g
- Concentration of Hev b5 and/or Hev b6,02 are < 0,025 µg/g
- Concentration for the Sum of 4 allergen is below 0,15 µ/g

These results support the **Ansell** approach and confirm the quality of the **Ansell** High Temperature Post Washing Process, which gives better results than DPNR... at a reasonable price!

The above test results show that the **Ansell** High Temperature Post Washing Process reduces the NRL allergen content of NRL gloves more

than 20 times more than DPNR and therefore prove that the **Ansell** High Temperature Post Washing Process remains one of the most effective ways to reduce the NRL allergen content of NRL gloves.

Manufacturers have developed technologies that allow them to produce low allergen gloves as well as synthetic gloves.

High Temperature Post Washing Process remains the most effective way to reduce the NRL allergen content of NRL gloves.

Providing low allergen powder free gloves and synthetic alternatives, to healthcare workers significantly reduces the risk of sensitization.

Hev b1, Hev b3, Hev b5 and Hev b6.02 concentration levels in some Ansell PF gloves via FITKIT™

	Hev b1 µg/ml	Hev b3 µg/ml	Hev b5 µg/ml	Hev b6.02 µg/ml	Sum of 4 µg/g
Gammex PF	ND	ND	ND	ND	ND
Gammex PF HydraSoft	ND	ND	ND	ND	ND
Micro-Thin PF	ND	ND	0.03	ND	0.03
MediGrip PF	0.14	ND	ND	ND	0.14
Encore Orthopaedic	ND	ND	0.08	0.07	0.15
Encore MicrOptic PF	ND	ND	0.10	0.24	0.34
Micro-Thin Nutex	ND	0.42	0.05	ND	0.47
MTPF ²	ND	ND	0.14	0.57	0.71
Encore Acclaim PF	ND	0.12	0.07	0.84	1.03

Fig 2 : Ansell PF gloves allergens contents via FITKIT™

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- Concentration for the Sum of 4 allergen is below 0,15 µ/g

Conclusion:

Ansell High Temperature Post Washing Process has been and is still one of the most efficient methods to decrease the level of allergising proteins coming from NRL, as proved by the results obtained by Ansell high quality gloves.

Attachments:

- “Natural rubber allergen content of latex gloves – A market surveillance study”
Allergen contents of 78 (35 surgical – 43 procedure or examination) gloves present in 2003 on the Finnish market have been compared.
- “Developments in natural rubber latex management and

manufacturing” – World Allergy Congress – June 2005, Paul Cacioli, Ph. D., Lai Hee Meng - Ansell Healthcare

This article demonstrates the advantage of Temperature Post Washing Process – available for a long time by **Ansell** – compared to DPNR latex

- FITKIT™ brochure