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Protecting our Workers: Natural Rubber Latex Gloves

A brief account of natural rubber latex, its related issues and manufacturing standards for use in medical gloves.

Natural rubber latex (NRL) gloves are still the most widely used NRL products in the world due to latex's unique abilities. Yet at the same time, gloves are considered to be one of the most controversial NRL products due to the adverse reactions that some individuals incur.

Use of NRL skyrocketed in the late 80s after the US Centre for Disease Control & Prevention first recommended NRL gloves for "universal protection" for healthcare workers (HCW) and facilities; protecting HCW and patients against potentially infectious materials and preventing the spread of bloodborne pathogens and HIV[i].

The increase in the use of NRL gloves led to a higher incidence of latex allergy especially among HCW. Latex sensitivity affects approximately 8 to 12% of HCW and 1 to 6% of the general population[ii]. Subsequent scientific studies also document that latex sensitivity to NRL proteins is triggered by a wide range of medical devices, and gloves are only one source of the allergy[iii].

There are other types of gloves made from non-NRL materials (such as synthetic rubbers and synthetic polymers) available in the market, but NRL is still recognized as the best overall material for barrier protection in health care settings. The ability of medical gloves to protect HCW against bloodborne pathogens remains a primary concern[iv].

This fact sheet covers:

- Related issues and injury risk
- Manufacturing standards

Injury

The three principal adverse reactions to NRL are: Immediate Type I hypersensitivity (Type I), Delayed Type IV hypersensitivity (Type IV) and Irritant Contact Dermatitis (ICD)[v]:

A Type I Reaction	A Type IV Allergy	ICD Reaction
A Type I reaction to residual proteins found in latex is immediate, typically occurring five to 30 minutes after initial contact. In some rare cases, symptoms of anaphylaxis can occur.	A Type IV allergy is a reaction to specific allergens such as chemical residues from the glove manufacturing process. The response is delayed rather than immediate, usually occurring six to 48 hours after initial contact albeit the symptoms can last for up to four days.	ICD is a non-immune reaction affecting a number of glove users and a condition affecting the skin and not an allergy.

Once a person is sensitized to latex, there is no permanent cure and any further exposure even at low levels may trigger a reaction. As such, Type I is considered to be more severe and of a major concern as compared to Type IV or ICD.

NRL Manufacturing Standards

Countries	Standards
US[vi]	ASTM D3578 - Powder-free and Powdered NRL gloves
European Union[vii]	EN455-3: Requirements and testing for biological evaluation
Canada[viii]	• ISO 10282:2014, Type 1 - Single-use sterile surgical rubber gloves • ISO 11193-1:2008, Type 1 - Single-use medical examination gloves
Australia & New Zealand[ix]	• AS/NZS 4179:2014 - Single-use sterile rubber surgical gloves • AS/NZS 4011.1:2014 - Single-use medical examination gloves
Malaysia[x & xi]	• MS 1155:2003 - Single-use medical examination gloves • MS 1291:2003 - Single-use sterile rubber surgical gloves • Standard Malaysian Glove (SMG) Type 1 (conforms to ASTM D3578) • SMG Type II (conforms to EN455)

In the US, the Food & Drug Administration (FDA) classifies NRL gloves as Class 1 medical devices. The FDA issued two rulings in September 1997[xii]:

1. A cautionary statement in bold print is required on all medical devices that contact humans and contain NRL – "Caution: This product contains natural latex rubber which may cause allergic reactions".
2. The labelling of medical devices that contain NRL shall not contain the term "hypoallergenic".

Take-Away

Based on the earlier mentioned standards, SMG (Type I and II), ASTM D3578 and EN455-3 appear to be the ideal manufacturing standards to follow/adopt for NRL gloves. The following table provides a comparison of the protein contents and powder levels between the standards[xiii]:

Property	SMG	ASTM D3578	EN455-3
Powder-free:			
Upper limit of protein	50 µg/dm^{2*}	200 µg/dm^2	50 µg/g*[xiv]
Upper limit of powder	2 mg/glove	2 mg/glove	2 mg/glove
Powdered:			
Upper limit of protein	200 µg/dm^{2*}	200 µg/dm^2	<100 µg/g^2 [xv]
Upper limit of powder	150 mg/glove	10 mg/glove	>2 mg/glove**

Notes:

* - 1 µg/dm^2 is roughly equivalent to 1 µg/g.

** - EN455-3 does not stipulated any upper limit of powder level for powdered gloves.

Conclusion

The aim of this article is to raise awareness of the related issues and industry risks, and manufacturing standards of using natural latex rubber gloves.

Generally speaking, unless a material that has the same properties as NRL but without any latex protein content is discovered or invented; NRL gloves, in particular the powder-free variety, are likely to remain as the most popular choice of medical gloves.

i https://academic.oup.com/labmed/article-pdf/29/5/278/24956961/labmed29-0278.pdf
ii https://www.cdc.gov/healthcommunication/toolstemplates/entertainmented/tips/LatexAllergy.html
iii https://www.tandfonline.com/doi/abs/10.1081/MC-120004763?scroll=top&needAccess=true&journalCode=lmsc19
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vi https://www.astm.org/DATABASE.CART/HISTORICAL/D3578-05.htm
vii https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en
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xi http://www.smgonline.biz/about.html
xii https://www.ncbi.nlm.nih.gov/pubmed/10175218
xiii http://www.smgonline.biz/PDF/SMGTYPE1.pdf
xiv http://dencor.ziltsysteem.nl/customers/dencor.ziltsysteem.nl/documents/HPC%20GN%2031.pdf
xv http://www.kanamlatex.com/surgicare_lowpro.html

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