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# BACKGROUND AND REQUIREMENTS

## DISPOSABLE NITRILE GLOVES – VERSION 1.0

ASTHMA ALLERGY NORDIC

# Asthma Allergy Nordic

*November 2024, version 1.0*

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## Background and Requirements for Labelling of Disposable Nitrile Gloves with the Allergy Label 'Asthma Allergy Nordic'

This document describes the background and requirements set for allergy labelling of disposable nitrile gloves (nitrile is also called synthetic latex) intended for personal use. In the document, each section will have a background text explaining, why the requirement is set and the reasoning for the level of requirement, followed by the requirement itself and the accompanying documentation requirement. All requirements and documentation are highlighted in a light blue box. A summary of the requirements can be found in Appendix 1. **Please note**, that all requirements relevant to the product type must be met in order to be recommended by Asthma Allergy Nordic. Products must always fulfil the regulatory requirements governing the market in which the product is sold. This will not be controlled by Asthma Allergy Nordic as part of the assessment for eligibility of the allergy label.

The criteria for disposable nitrile gloves apply to products intended for use or wear as a personal item, to provide coverage/shielding, or to function as a physical barrier. The products are in direct skin contact during use and possibly for a prolonged time. The materials used in the products may contain substances that can cause allergic skin reactions in people already sensitised.

Nitrile gloves sold on markets across the world may be regulated under different sets of legislations such as chemical regulations, medical device regulations, regulations for personal protection equipment etc. Even though there are several regulations for disposable gloves none of them has a special focus on allergies. Asthma Allergy Nordic wishes to address this aspect by setting criteria for disposable nitrile gloves to minimise the risk of allergies.

In general, Asthma Allergy Nordic aims to help consumers who are already sensitised, or consumers who want to be extra careful, by making it easy to choose a product in which the risk of getting an allergic skin reaction is minimised. In addition, Asthma Allergy Nordic has an increased focus on asthma, where relevant, and people with hypersensitivity may feel, that labelled products help them, too.

With the *Asthma Allergy Nordic* label on disposable nitrile gloves, you get:

- No fragrance
- No sensitising preservatives (e.g., MIT)
- No sensitising rubber chemicals
- Minimal risk of allergic reactions on the skin

### The Definition of Allergenic Substances

Asthma Allergy Nordic requires that no substance in direct contact with the skin and/or mucous membranes may be regarded as sensitising.

**Note**, that a substance is not considered to be present if the amount of the substance is below 0.1 ppm in the final product or component.

To assess whether a substance is considered an allergen, the following is taken into consideration:

- Is the substance harmonised classified as a skin sensitiser according to the EU CLP Regulation (1272/2008/EC)?
- Is there other documentation presented to establish the potential of the substance to sensitise the skin and/or mucous membranes? This could be the case if:
    - There may be published cases in which allergic reactions have been reported over a period and where the clinical relevance has been established.
    - There may be epidemics of allergic reactions towards a specific substance reported with a lot of cases over a short period of time.
    - There may be specific substances to which dermatologists experience allergic reactions in consumers, and it may be assumed that the actual number of cases is higher due to the substances not being in the baseline test series.
    - There may be a constant percentage of consumers having a positive allergic reaction towards a specific substance when tested. However, this will be considered in relation to the usage of the substance both in terms of amounts and groups of consumers.
    - The substance is notified through the European Chemicals Agency (ECHA) with classification as a skin sensitiser by several notifiers. [ECHA Inventory].

The above bullets will often – with the exception of a harmonised classification – have to be evaluated under more than one point to confirm the conclusion of the assessment.

How to establish whether a substance is sensitising or not is not well-defined and grey areas may arise. In such cases, Asthma Allergy Nordic will consult our network of experts from the Nordic countries and international dermatologists and allergists with expertise within the field. The baseline in the assessment of substances will be cautious to protect the majority of consumers with contact allergy or respiratory issues and also to help consumers who want to be extra careful. At the same time, Asthma Allergy Nordic acknowledges that for a small group of people, this will not be a guarantee against having an allergic reaction to a given product. It is important to emphasise that even though a substance is not considered to be an allergen, there may be a minority that is/might be allergic to the substance and may have an allergic reaction towards this.

## Analysis: Methods and Results

Some requirements must be documented by testing and not just by a statement. It is important to be aware that the choice of laboratory, test method as well as detection limits, will influence the outcome of the test/test results.

Asthma Allergy Nordic can be of assistance with guidance and dialogue both on the choice of test and detection limits as well as on the interpretation of test results and dialogue with the laboratories. Please, ensure the early involvement of Asthma Allergy Nordic to avoid unnecessary testing and to ensure the required documentation. Contact information may be found on the Asthma Allergy Nordic website. [AAN website].

We recommend that you do not test your product until you have had the formulation assessed by Asthma Allergy Nordic, as we often discover some hidden ingredients in the raw materials that may affect the outcome of the assessment.

## Which Products May Be Labelled?

Products covered by these criteria are disposable gloves made of nitrile (also referred to as "*synthetic latex*"), intended for personal use such as coverage, or barrier function. Such products aim at protecting the user from direct skin contact with chemical, biological, or otherwise potentially harmful substances or agents. It is the glove and its material that is assessed, not its performance.

### Products not Included in the Criteria

At present, only disposable nitrile gloves are included, which means that disposable gloves of other materials, such as natural rubber latex (NRL) or vinyl, are excluded from the product group. Other elastic products and materials are also not included at present.

## Requirement 1 – Information on Product Composition

Asthma Allergy Nordic needs the full chemical composition of the product as well as any process chemicals and finishing agents that may be present in the final product in order to properly assess the product's eligibility for the allergy label. The chemical composition of the product is expected to change during the manufacturing process from the ingoing ingredients to the final product. Therefore, both the ingoing ingredients and the composition of the finished ready-to-use product should be stated. In addition, all known residuals and impurities including, but not limited to, substances formed during vulcanisation are warranted.

Process chemicals may include treatment, finishing, donning, and storage aid (e.g., treatments and auxiliaries that help prevent mould/fungal growth and similar during storage/shipping/transport). The reason for this degree of detail is that even very small amounts of a given substance may cause an allergic reaction to the skin. To ensure easy identification, the substances should be stated with a clearly identifiable name such as INCI or chemical name and supplemented with the CAS number (CAS-no.). Should the composition of raw materials not be known to the applicant, the name of the raw material can be stated instead with a mention of the supplier's name. Subsequently, the necessary information will be obtained directly from the relevant supplier.

This information will be kept strictly confidential and will not be used for public declaration, but solely for assessing the product. Obtaining such information may be difficult for the manufacturer as the suppliers regard this information as confidential. Suppliers may send the information directly to Asthma Allergy Nordic and, if necessary, a confidentiality agreement will be signed with the suppliers and sub-suppliers. Asthma Allergy Nordic may help collect the required information. However, it is always the responsibility of the applicant to make sure all the necessary information is provided for the assessment and that this information is the correct information relating to the product application.

**Requirement 1**

The full composition of the product must be disclosed to Asthma Allergy Nordic including the name of the product and optionally product ID/composition ID. All ingoing chemicals and raw materials must be

stated in the composition, including residuals, impurities, auxiliaries, finishing agents, and process chemicals as well as the substances formed during manufacturing. In addition, the chemical composition of the final product must be stated.

- Single substances must be stated by chemical name (IUPAC)/INCI, cas-no., amount, and function.
- Raw materials must be stated by trade names, supplier name, amount, and function. The full composition of the raw material must be disclosed by the supplier. It is the responsibility of the applicant that the suppliers provide the necessary information on the raw material to Asthma Allergy Nordic.

*Ingoing substance/ingredient is defined as all substances/ingredients in the product/raw material stated down to 0.1 ppm in the final product or component.*

***Documentation***: Identification of all ingoing ingredients, process chemicals, and finishing agents as well as substances formed during manufacturing as mentioned above; In addition, the chemical composition of the final product.

**Note**, that it is the obligation of the applicant to inform of all aspects relevant for the assessment of the product, e.g., information on contaminants/impurities in raw materials and/or final product.

**Name of the product** is the name under which the final product is sold to the consumers.

**Product ID/Composition ID** is used by some manufacturers to identify a specific product in the production. Information on product ID/composition ID is not mandatory and should only be provided if the applicant believes it will ease identification and communication in the application process.

**Name of raw material** is the trade name under which a given raw material is sold from the supplier of the raw material. It must be provided since additional information may be needed for some raw materials. Hence, it is important to know precisely which raw materials are used in the manufacturing process.

**IUPAC** is an abbreviation for *International Union of Pure and Applied Chemistry,* and it has a standardised nomenclature for naming chemical substances.

**INCI** is an abbreviation for *International Nomenclature of Cosmetic Ingredients* and is the name of the ingoing substances that must be in the product declaration (ingredient list) of cosmetic products according to the Cosmetic Regulation. INCI may be found on the European Commission website CosIng. [CosIng].

**CAS-no.** is an abbreviation for *Chemical Abstract Service Number* and is a way of identifying substances. Cas-no. should be a unique identifier for a substance, but this is not always the case. Some groups of substances have multiple CAS-no.'s, and some CAS-no.'s cover multiple substances. In many cases, a CAS-no. does help identify substances and must therefore be stated in the composition to avoid misinterpretations.

**Function** is the purpose for which a substance or raw material is present in the product.

**Ingoing substance** is defined as all the substances present in the product such as active substances, auxiliaries, solvents, and the like, but not impurities in the raw materials. A substance is considered not to be present if the amount is below 0.1 ppm in the final product.

**Auxiliaries and solvents** are considered as ingoing substances since they may vary from raw material to raw material and therefore cannot be expected or predicted in a specific raw material.

**Impurities** are part of the assessment regarding the risk of allergic reactions, see more of this under req. 2. Impurities are not considered as ingoing substances. However, they may occur in the final product due to content in ingoing substances and raw materials, from process chemicals, or from the manufacturing process of the product. Impurities may have different origins and may be the reason that a raw material cannot be accepted in products labelled with Asthma Allergy Nordic. It will always be the responsibility of the applicant to inform of a known content of impurities in the raw materials, even though they are not considered as ingoing substances. Impurities migrating from packaging into the product are also included in this definition.

**Process chemicals** are substances or mixtures used during the manufacturing process. These substances may be "used" or "consumed" during the production leaving only traces or residuals. However, many substances that are sensitising cause sensitisation even in very low amounts, and even trace levels may be relevant when considering exposure of individuals with an allergy to those substances. Process chemicals are therefore assessed as an ingoing substance in the evaluation of the product.

**Finishing agents** may be added during the manufacturing process or as a separate process after production. Finishing agents may serve different functions, e.g., ease separation of the gloves from each other. Finishing agents are considered as a part of the final product.

## Requirement 2 – Specifically Limited or Excluded Substances

The aim of Asthma Allergy Nordic is not only to prevent the induction of contact allergy but also minimise the risk to consumers already sensitised from getting allergic reactions when using disposable nitrile gloves.

Some substances used in disposable nitrile gloves may be problematic with regard to contact allergy. These substances need to be limited or excluded entirely.

### A. Substances Harmonised Classified Sensitising to Skin, H317

The use of sensitising substances in products labelled with Asthma Allergy Nordic is excluded entirely – regardless of concentration (***note***, the defined lower limit of interest in "The definition of allergenic substances"). This requirement includes all substances with a harmonised classification as skin sensitisation (H317).

### B. Substances Where Alternative Evidence of Contact Allergenic Potential Exists

Some substances are considered sensitising by dermatologists even though the substances are not classified as such. Other ways to qualify as alternative evidence of contact allergenic potential, are described in more detail in the introduction section “The Definition of Allergenic Substances”. All these substances are considered the same way as substances with a harmonised classification (see above).

The Asthma Allergy Nordic Customer Database contains assessments regarding skin sensitisation of many substances. [AAN Database]. If a specific substance is not present, it is possible to ask Asthma Allergy Nordic to assess that substance.

### *Rubber Chemicals*

A specific group of substances used in disposable gloves are known to cause allergic reactions in sensitised people. These are generally referred to as “*rubber chemicals*” and are used as accelerators, antioxidants, stabilizers etc. in the manufacturing process. Not all these substances are classified as skin sensitisers and will therefore not fall under the criterion excluding classified substances. However, for some of the rubber chemicals there is alternative documentation available identifying them as allergens. Below, you will find examples of rubber chemicals that do not have a harmonised skin sensitisation classification. However, they have already been assessed by Asthma Allergy Nordic and are excluded in disposable nitrile gloves labelled with the Asthma Allergy Nordic label (see the Asthma Allergy Nordic Customer Database for the conclusion):

- 1,3-diphenylguanidine (DPG) (102-06-7)
- dimethylthiocarbamylbenzothiazole sulfide (DMTBS) (3432-25-5)
- diethylthiocarbamylbenzothiazole sulfide (DETBS) (95-30-7)
- p-tertiary butyl catechol (TBC) (98-29-3)

Other rubber chemicals may also be excluded after a thorough assessment of available information.

## C. Fragrance

Fragrance allergy is a frequent allergy and correlates with exposure to fragrance substances. A general limitation in exposure may therefore reduce the risk of developing fragrance allergy and help those who are already suffering from fragrance allergy. In addition, people with hypersensitivity may feel the requirement help them too. The “No fragrance” claim is a hallmark of the allergy label, and it is therefore very important that fragrances are not present at all in allergy labelled products.

However, managing this requirement in practice is complicated as there is no precise definition of “fragrances” or “fragrance substances”. Published reports may help identify fragrances, but they are not exhaustive. When assessing disposable nitrile gloves, Asthma Allergy Nordic will make assessments of each ingoing substance and decide if a substance is considered a fragrance or fragrance substance. The applicant must also take this into consideration when stating the function of the ingoing substances.

So, even if the requirement itself is very simple, the documentation and assessment may be complicated. It may help applicants to check their potential fragrances against the references mentioned here: [SCCS/1459/11], [de Grout 2019], [The Complete IFRA Standards, 2022]. This will not necessarily be sufficient, but it may give an indication. It is also possible to have Asthma Allergy Nordic

assess a specific substance if an assessment should not already be available in the Asthma Allergy Nordic Customer Database.

## D. Residual monomers

Nitrile polymers may contain residuals of acrylonitrile, which is the monomer used for building the polymer. Acrylonitrile is harmonised classified as a skin sensitiser, and as such unwanted in the allergy labelled product and excluded according to requirement 2A. However, avoiding residual monomers may be close to impossible [Wakui et al 2001], and instead a very limited amount of monomer may be accepted, since it is assumed that the monomer is mostly locked/bound inside the polymer matrix and therefore not poses a high risk of causing allergic skin reactions.

The tolerated level of residual acrylonitrile is based on several considerations. One being a comparison to the accepted level of sensitising monomers in allergy labelled paint, in which monomers are accepted up to 100 ppm. However, the fact that paint is not intended for skin contact was taken into account when setting this limit. In contrast, nitrile gloves are in skin contact for a considerable length of time as well as creating an environment for the skin that is challenging due to raised levels of heat and moisture. Another consideration is, that [Wakui et al 2001] have investigated the level of residual acrylonitrile in nitrile gloves and found it generally lies below 1 ppm. Finally, [Aerts et al 2023], tested an individual with a known allergy to acrylonitrile and found that the individual had no allergic reactions to a concentration of 0,001% (10 ppm) acrylonitrile.

Based on these considerations, a content of residual acrylonitrile below 1 ppm (< 1 ppm) in the final product is accepted as it lies below the assumed amount causing allergic reactions in a sensitised individual.

These considerations are extrapolated in the way that the requirement is applicable for residuals of all skin sensitising monomers.

The requirement must be documented by a test of the final product. The test must be made on three different batches and must be documented continuously. This means that Asthma Allergy Nordic may ask for documentation that the requirement is met even after awarding the certification. This may be part of the continuous compliance control or based on suspicion of non-compliance.

## E. Impurities

Impurities, other than residual monomers, may be part of raw materials or formed during the manufacturing process. Since these impurities/residuals are present in the final product they may be cause for concern should the substances be known to be skin sensitisers. It is therefore vital that applicants inform of all known impurities and residuals in the product as part of the product composition, cf. req. 1, regardless of whether they originate from raw materials or the manufacturing process.

Asthma Allergy Nordic assesses the full composition of the final product and as part of this assessment, the presence of impurities will be evaluated. Sensitising impurities are unwanted in line with all other

sensitising substances, but in some cases, it is impossible to avoid a certain impurity in specific products. In such cases, it will be considered if an acceptable limit may be established for the presence of the impurity. In addition, full or partial purification of the raw material or product may be a solution. General statements that the requirements are met will not be accepted without supporting documentation e.g., test results or the like.

*Example of impurity*

The substance 2-cyanoethyl dimethyldithiocarbamate, CEDMC, has been found as an impurity in nitrile gloves. [Silic et al. 2024]. It is formed during the vulcanisation process from the monomer, acetonitrile, and from dimethyl amine, and carbon sulfide. CEDMC has been shown to cause allergic reactions to the skin, and structurally it resembles other known sensitisers used in gloves of the family, dithiocarbamates. CEDMC is an unwanted impurity due to its sensitising properties, and as such must not be present in the final product (see definition under "The Definition of Allergenic Substances").

**Requirement 2**

A. Substances harmonised classified as skin sensitising (H317) may not be part of the product or raw materials.
B. Substances, where alternative evidence of sensitising potential to the skin exists, may not be part of the product or raw materials.
C. Substances considered as fragrances may not be part of the product or raw materials.
D. The final product must contain less than 1 ppm (< 1 ppm) of monomers that are considered sensitising.
E. Sensitising impurities and contaminants must be below 0.1 ppm in the final product, unless otherwise stated.

***Documentation***: Full formulation cf. req. 1.
*Especially for req. 2D*: this must be documented by an appropriate test made by an accredited laboratory using a suitable method. **Note**, that the detection limit used must be relevant for the requirement set.

## Requirement 3 – Finishing Agents

Finishing agents may have different functions, e.g., separating gloves from each other, and may be applied after or during production. Finishing agents used on the interior of the glove, is not accepted, since this will lead to an increased exposure of the user to chemical substances or mixtures and hence pose a risk of causing allergy or allergic reactions.

Finishing agents may be used on the exterior of the glove. If a powder is used on the exterior, the glove must be able to claim "powder free" according to EN455-3, to ensure that the amount of powder used is as low as possible.

**Requirement 3**

Finishing agents may be used only on the exterior of the glove. The product must be able to claim "powder free" according to EN455-3.

***Documentation***: Full formulation cf. req. 1. If powder is used as a finishing agent, the amount used must be stated in the product composition.

## Requirement 4 – Functional Additives

Disposable gloves may have additives in the form of lotions or powders or the like. Such additives may serve different functions, e.g., donning agent. These substances or mixtures will often occur on the inside of the glove in direct skin contact during use. This means that the user is exposed to the additive during every usage, regardless of whether the additive is needed or wanted by the user.

Generally, it is advisable to minimise the contact of chemical substances in order to minimise the risk of inducing or eliciting allergic reactions. Therefore, such functional additives are not accepted in products certified by Asthma Allergy Nordic.

**Requirement 4**

Lotion or powder are not accepted in the final products.

***Documentation***: Full formulation cf. req. 1.

## Requirement 5 – Artwork/label

The use of the Asthma Allergy Nordic logo is subject to the requirements of the Logo Manual. [AAN Logo Manual]. Artwork/label must be submitted in order to verify correct use of the Asthma Allergy Nordic label.

Claims on the product artwork/packaging within the area of interest of Asthma Allergy Nordic must also be approved. Artwork changes that concern areas not related to the logo, and our organisation, do not require prior approval. However, Asthma Allergy Nordic must always be supplied with the current artwork to ensure traceability when communicating with both consumers and the manufacturer as well as inspecting certified products.

**Requirement 5**

Artwork/label must be approved. The Asthma Allergy Nordic logo must be designed in accordance with the guidelines in the Logo Manual.

Claims within the area of interest of Asthma Allergy Nordic must also be approved.

***Documentation***: Current artwork/label.

# References


[AAN Database]: Asthma Allergy Nordic Customer Database, https://www.asthmaallergynordic.org/infoportal/guidance-for-digital-tools/ (Requires customer profile for login)

[AAN Logo Manual]: *Logo Manual*, Asthma Allergy Nordic

[AAN website]: https://www.asthmaallergynordic.com/

[Aerts et al 2023]: *Occupational allergic contact dermatitis from acrylonitrile, a highly toxic industrial chemical*. O. Aerts, D. Mortelmans, A. Bracke, E. Romaen & E. Dendooven, Contact Dermatitis 88(6), 493-494, 2023

[de Grout 2019]: *MONOGRAPHS IN CONTACT ALLERGY VOLUME 2* – FRAGRANCES AND ESSENTIAL OILS, Anton C. de Grout, CRC Press 2019

[ECHA Inventory]: https://echa.europa.eu/en/information-on-chemicals/cl-inventory-database

[IFRA 2022]: *The Complete IFRA Standards*, 2022, https://ifrafragrance.org/docs/default-source/ifra-code-of-practice-and-standards/ifra-standards---50th-amendment/standards-compiled.pdf?sfvrsn=87deb890_4 (11.05.2023)

[SCCS/1459/11]: *Opinion on Fragrance Allergens in Cosmetic Products*, SCCS, 13-14 December 2011, https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_073.pdf

[Silic et al. 2024*]: 2-Cyanoethyl dimethyldithiocarbmate, new contact allergen found in accelerator-free nitrile gloves*, Silic L. L., Persson C., Pesonen M., Suuronen K., Svedman C. & Bergendorf O., Contact Dermatitis 2024;1-9, 2024

[Wakui et al 2001]: *Migrants from disposable gloves and residual acrylonitrile*, Wakui C, Kawamura Y, Maitani T. Shokuhin Eiseigaku Zasshi Oct, 42(5):322-8. 2001. doi: 10.3358/shokueishi.42.322. PMID: 11775358.

# Appendix 1 – Criteria in Summary

**Requirement 1**

The full composition of the product must be disclosed to Asthma Allergy Nordic including the name of the product and optionally product ID/composition ID. All ingoing chemicals and raw materials must be stated in the composition, including residuals, impurities, auxiliaries, finishing agents, and process chemicals as well as the substances formed during manufacturing. In addition, the chemical composition of the final product must be stated.

- Single substances must be stated by chemical name (IUPAC)/INCI, cas-no., amount, and function.
- Raw materials must be stated by trade names, supplier name, amount, and function. The full composition of the raw material must be disclosed by the supplier. It is the responsibility of the applicant that the suppliers provide the necessary information on the raw material to Asthma Allergy Nordic.

*Ingoing substance/ingredient is defined as all substances/ingredients in the product/raw material stated down to 0.1 ppm in the final product or component.*

***Documentation***: Identification of all ingoing ingredients, process chemicals, and finishing agents as well as substances formed during manufacturing as mentioned above; In addition, the chemical composition of the final product.

**Requirement 2**

A. Substances harmonised classified as skin sensitising (H317) may not be part of the product or raw materials.
B. Substances, where alternative evidence of sensitising potential to the skin exists, may not be part of the product or raw materials.
C. Substances considered as fragrances may not be part of the product or raw materials.
D. The final product must contain less than 1 ppm (< 1 ppm) of monomers that are considered sensitising.
E. Sensitising impurities and contaminants must be below 0.1 ppm in the final product, unless otherwise stated.

***Documentation***: Full formulation cf. req. 1.
*Especially for req. 2D*: this must be documented by an appropriate test made by an accredited laboratory using a suitable method. **Note**, that the detection limit used must be relevant for the requirement set.

**Requirement 3**

Finishing agents may be used only on the exterior of the glove. The product must be able to claim "powder free" according to EN455-3.

***Documentation***: Full formulation cf. req. 1. If powder is used as a finishing agent, the amount used must be stated in the product composition.

**Requirement 4**

Lotion or powder are not accepted in the final products.

***Documentation***: Full formulation cf. req. 1.

**Requirement 5**

Artwork/label must be approved. The Asthma Allergy Nordic logo must be designed in accordance with the guidelines in the Logo Manual.

Claims within the area of interest of Asthma Allergy Nordic must also be approved.

***Documentation***: Current artwork/label.