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BACKGROUND AND REQUIREMENTS

DETERGENTS – VERSION 1.1

ASTHMA ALLERGY NORDIC

Asthma Allergy Nordic

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Content

Background and Requirements for Labelling of Detergents with Asthma Allergy Nordic

This document describes the background and requirements set for detergents. In the document, each section will have a background text explaining, why the requirement is set and the reasoning behind the level of requirement. This is followed by the requirement itself and the accompanying documentation requirement; this is marked in a light blue box. A summary of the requirements can be found in Appendix 1. **Please note**, that all requirements relevant for the product type must be met in order to be recommended by Asthma Allergy Nordic. It is always required to fulfil the regulatory requirements of the laws governing the area of the market on 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 reason why criteria have been made for detergents is that detergents are frequently used and may be used in several ways that give rise to skin and/or airway exposure. Detergents for the European market are regulated under several different legislations namely the EU Detergent Regulation (648/2004/EC), the EU Classification, Labelling, and Packaging Regulation (1272/2008/EC), and the EU REACH Regulation (1907/2006/EC). The Detergent Regulation focuses on the environmental impact of surfactants and other select substances often present in detergents and also adds some requirements to product declaration, although full declaration is not required. The Classification, Labelling, and Packaging Regulation (CLP) focuses on product hazard labelling and the rules of classification on the product and how this shall be present on the product packaging. Finally, the REACH Regulation focus on the overall safety of human health and environment, however the specifics of the REACH Regulation is often not enough to prevent people with allergies from having allergic reactions to products on the market. Even though there are a lot of regulations for detergents none of them has special focus on allergies, asthma, or detailed consumer information. Asthma Allergy Nordic wish to add this aspect to detergent products with these criteria.

Asthma Allergy Nordic aims to help consumers who are already sensitized and consumers who want to be extra careful, by making it easy to choose a product where the risk of getting an allergic reaction on the skin and in the respiratory system is minimised. Asthma Allergy Nordic has increased focus on asthma, where relevant, and people with hypersensitivity (generally accepted non-allergic sensitivity) have experienced, that labelled products help them, too.

With *Asthma Allergy Nordic* label on detergents, you get:

- Minimal risk of allergies, asthma and/or generally accepted non-allergic sensitivity reactions
- No fragrance
- No sensitizing preservatives (e.g., methylisothiazolinone (MIT))

The definition of allergenic substances

Asthma Allergy Nordic requires that no substance present in the final product may be regarded as sensitizing. **Note**, that a substance is not considered to be present if the amount of the substance is below 0.1 ppm (0.00001%) in the final product (Lower Limit of Interest). **Also note**, that the lower limit of interest does not apply to fragrances, since the Odour Detection Threshold (ODT) for fragrances often are below 0.1 ppm and therefore present for the purpose they serve inherently. To assess whether a substance is considered an allergen, the following is taken into consideration:

- Is the substance classified as a sensitizer according to the EU CLP Regulation (1272/2008/EC)?
- Is there other documentation presented to prove the potential of the substance to sensitize the skin and/or mucous membranes? This could be the case if…:
    - There may be published articles on cases where allergic reactions have been reported over a period and where the clinical relevance has been established
    - There may be epidemics where a lot of cases are reported over a short period of time towards a specific substance
    - There may be substances where dermatologists experience allergic reactions in consumers towards a specific substance, and it is 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 number of consumers having a positive reaction when tested. This will be set in relation to the usage of the substance both in terms of amounts and groups of consumers.

These 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.

The definition on whether a substance is sensitizing or not is not well defined and grey zones may arise. In such cases, Asthma Allergy Nordic will consult data and assessments with a network of experts from the Nordic countries as well as international dermatologists with expertise within the fields, including clinical experience. The baseline for the label will be a cautious view of the substances with the balance between protecting consumers with contact allergy or respiratory issues and consumers who want to be extra careful. At the same time Asthma Allergy Nordic acknowledge 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 emphasize that even though a substance is not considered to be an allergen, there may be a minor group that are/might become allergic towards the substance and may have an allergic reaction towards this.

Which Products May Be Labelled?

Products comprised by these criteria are detergents as defined in the EU Detergent Regulation (648/2004/EC) and similar products such as cleaning wipes.

Products Regulated under the EU Detergent Regulation

Products included under the EU Detergent Regulation such as laundry detergents, all-purpose cleaners, sanitary cleaner, auxiliary washing products (e.g., pre-wash, stain remover, or bleaching products), and fabric softeners. This list is not exhaustive, but all products included under the EU Detergent Regulation, are also included under Asthma Allergy Nordic's criteria. [648/2004/EC].

Cleaning wipes

Cleaning wipes are not specifically included in the Detergent Regulation although the regulation mentions "*in any form*", however, cleaning wipes are products that consists of two different products a wipe and a detergent (or disinfectant). Since both the wipe and the detergent poses a potential risk for people with allergies, Asthma Allergy Nordic has included these products in the product group definition.

Criterion 1 – Information on Product Composition

To make an assessment of the product regarding allergy, Asthma Allergy Nordic needs the full composition of the product. The reason for this is that even very small amounts of a given substance may cause an allergic reaction to the skin. The full composition must contain all ingoing substances, including auxiliaries and impurities, present in the final product in amounts above 0.1 ppm. Substances are not considered present in the product if the amount is below 0.1 ppm. Should the INCI and cas-no. be insufficient to positively identify the ingoing substance, the chemical name of the substance must be stated. **Please note**, that the full composition required under this requirement can include substances not subject to the declaration as required by EU Detergent Regulation 648/2004/EC, appendix VII, D, as referred to in requirement 7.

Requirement 1

The full composition of the product must be provided. The full formulation must state the trade name of the product and (if applicable) formulation number or ID, trade name of raw materials, INCI of ingoing substances, cas-no., active amount of the substances in the finished product as well as function of each raw material. If no INCI name is available for the substance, the chemical name according to IUPAC nomenclature must be used instead.

The wipe material in cleaning wipes and the process chemicals used in the production process of the wipe must fulfil Asthma Allergy Nordic requirements (see criteria for Hygiene and Tissue Products). [AAN Hygiene and Tissue].

Documentation: Full formulation of the product including all ingoing substances (see definitions below). The formulation must contain information as described in the requirement. Safety data sheets and technical data sheets for the raw materials must be provided upon request. Safety data sheets and technical data sheets must always be provided for ingredients that require purification according to Asthma Allergy Nordic Customer Database [5].

Trade name is the name under which the product is sold to the consumers.

Formulation number is used by some producers to identify a specific product in the production. Information on formulation number 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 unique trade name under which a given raw material is sold from the supplier of the raw material. It must be provided since some raw materials need cleaning/purification and hence it is important to know precisely which raw material is used in the product formulation.

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) according to the Cosmetic Regulation. INCI may be found on the European Commission website CosIng. [CosIng].

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

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 substances or groups of substances have multiple cas-no. and some cas-no. covers multiple substances. In many cases, cas-no. does help identifying substances and must therefore be stated on the formulation to avoid misinterpretations.

Active amount is the amount of the substances in a raw material or product excluding water. It may be referred to as active concentration as well.

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 as active substances and 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 is not considered as an ingoing substance since they are expected to be found with the active substance either because of the composition or the production process of raw material. Impurities may have different origins and may be the reason that a raw material cannot be accepted in products 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 are also part of the assessment regarding the risk of allergic reactions, see more of this under req. 2. Impurities migrating from packaging into the detergent product are also included in this definition. Impurities are not required to be declared on the product.

Criterion 2 – Specifically Limited or Excluded Substances

Some substances used in detergents may be problematic with regards to contact allergy or asthma. These substances need to be limited or excluded entirely.

Substances Classified Sensitizing to Skin, H317

Detergents may contain substances classified as sensitizing because legislation does not exclude the use of such substances, and the manufacturer has deemed them essential to the product. Since the aim of Asthma Allergy Nordic is to not only prevent induction of contact allergy but also minimise the risk that consumers already sensitized may elicit allergic reactions from using detergents, the use of these substances in products labelled with Asthma Allergy Nordic is excluded entirely – regardless of concentration; ***please note***, the defined lower limit of interest in 'The definition of allergenic substances'. This requirement includes all substances classified as sensitizing to skin (H317).

Substances Where Alternative Evidence of Contact Allergenic Potential Exists

Some substances are considered sensitizing by dermatologists even though the substances are not classified. These substances are considered the same way as substances with a harmonised classification (see above). Another way to qualify under this definition, would be the case, if the substance has a significant number of notifiers suggesting classification as sensitizing according to the ECHA Inventory. [ECHA Inventory]. The reason for this is that the process for classification of substances is long and the knowledge of the effects of the substances may be generally accepted long time before

the change of classification. Also see the definition of allergenic substances in the beginning of the document.

Irritants

Detergents can have a negative impact on the skin and mucous membranes because of their dehydrating, and irritant effects. Irritated or damaged skin is generally penetrated more easily by substances, and sensitizing substances may therefore cause allergic reactions to the skin more easily. In addition, consumers have come to expect that Asthma Allergy Nordic also consider irritation to the eyes as part of the product evaluation.

Everyone who is exposed to irritants is at risk of getting irritant contact dermatitis. People with sensitive skin are even more vulnerable and should therefore avoid being exposed to these types of products, and some consumers may benefit from advice as to use gloves when in direct skin contact with the in-use solution. This is addressed under req. 7.

Skin irritation may also arise from drying of the skin, e.g., due to high content of alcohol in the products. This will also be considered when assessing the product and its irritation potential.

Substances classified as skin irritants (H315), eye irritants (H319 or H318) or respiratory irritants (H335), or where alternative documentation for the irritating potential exists, may be present in the final product in limited amounts. How large a fraction of irritant substances that are allowed in the product depends on the composition of irritants in the product as well as the content of other substances that may increase or decrease the irritancy potential. Finally, the area of use of the product as well as the duration of use are included in the assessment. It is not just concentration of irritants in the in-use solution that matters, but a number of other factors that contribute. Intensive hand washing, wet work etc. can induce an irritating eczema no matter how low the levels of irritants are in the in-use solution. No exact limit is set for irritants. The product is assessed based on an in-depth knowledge of the product compositions and the inherent properties of the substances that it consists of combined with external factors such as in-use concentration of irritants and the intended use of the product.

If the concentration of irritating substances in the product is higher than accepted, a test may be performed to show that the product is not irritating to eyes or skin. The test may be part of European Centre Validating Alternative Methods (ECVAM's) validation program (e.g., HET-CAM and RBC). [ECVAM website]. Description of tests and explanation on abbreviations can be found on EVCAM's website. Alternatively, tests may be used, if they are commonly accepted (e.g., Zein) and not specifically dismissed by ECVAM, Scientific Committee on Consumer Safety (SCCS) or other scientific committees or bodies. [SCCS website]. The test conclusion must be provided. If the conclusion gives rise to any questions, the entire report may be requested.

Enzymes

Enzymes in detergents are potent respiratory sensitizers, and can if they become airborne, cause airway sensitization or asthma. The enzyme must therefore be in liquid form or encapsulated in granules and not prone to cause excessive dust formation when handled to prevent the risk of airway exposure. In liquid or encapsulated form enzymes are accepted and not limited by the lower limit of interest.

Fragrance

Fragrance allergy is of rising concern and correlates with exposure to fragrance substances. A general limitation in exposure may therefore help limiting the risk of developing fragrance allergy and people with hypersensitivity may feel the requirement help them too. Fragrance may not be part of the product or raw material.

It is a challenge to all that there is no generally accepted definition of perfume/fragrance. In the EU Cosmetics Regulation (1223/2009/EC), there is a need to actively consider if fragrance is present, if one wishes to use the claim "fragrance free", since a working group under the European Commission has made a technical document on cosmetic claims, addressing this claim, and they state that, "*The claim 'free from perfume' should not be used when a product contains an ingredient which exerts a perfuming function in the product, regardless of its other possible functions in the product.*" In light of this, a manufacturer must know if a fragrance substance is present, even if it is not used for fragrance purposes, and should such a substance be present, then the claim '*Fragrance free'* cannot be applied to the product. The intention of this requirement is, that the manufacturer must actively address this issue, and that the product should always comply to the Cosmetic Regulation's requirement for using the claim "perfume free" or "fragrance free". That amongst others means that the fragrances mentioned in the SCCS opinion SCCS/1459/11 are not allowed in the final product. [SCCS/1459/11].

Scent

Since smell or scent from a product may cause discomfort for people with sensitive airways, the smell/scent from ingredients other than fragrance materials shall be kept at a minimal level. Odours attributed to the final product and/or any of its raw materials should therefore be avoided, when they are described as strong and/or negative (e.g., intense, unpleasant, pungent, strong, and similar) according to EU REACH Regulation, annex II requirements for the compilation of safety data sheets.

Asthma Allergy Nordic is aware that this is a requirement with room for interpretation, but it holds a significant value to our target group and additionally has some significance to the requirement on fragrance. Asthma Allergy Nordic recognize this requirement poses a challenge to manufacturers. However, Asthma Allergy Nordic regards it as necessary as a strong scent may elicit a reaction in people who suffer from sensory hyperreactivity (SHR).

The assessment is intended to be made partly on the SDS where '*Odour*' has to be mentioned by the manufacturer combined with the possibility to have a product sample provided as supplement.

Colourants

Colourants are not regarded as essential for the function of the product. Therefore, colourants are not accepted in products with Asthma Allergy Nordic.

Purity of certain raw materials

Impurities may be part of raw materials whether these are of natural or synthetic origin. Common for the impurities are that they are mostly present due to natural content, process residual or the like, and thus is known for the specific raw material. This means that the impurities are a part of the assessment, when it is decided that the raw material may be accepted in products with Asthma Allergy Nordic. This is where the definition of "impurity" differs from "auxiliary". Still, impurities may vary, and it is always the responsibility of the applicant to notify Asthma Allergy Nordic of the impurities in the specific raw material. In the case of a raw material containing impurities that influence the assessment of the raw material, the acceptance of the raw material will be individual and based on the information submitted by the applicant. Examples can be found in the end of this section.

Asthma Allergy Nordic assess the raw materials and based on this assessment it is determined whether an impurity is acceptable, acceptable with limitations or unacceptable. The assessments are partly based on whether it is considered possible to clean up or purify the raw material (fully or partially), whether a safe limit may be established and whether a satisfactory test is available considering the chosen limits on content. In the cases where requirements are set, the requirement can be found in the Asthma Allergy Nordic Customer Database [5]. Unless the raw material is certified and found in the Asthma Allergy Nordic Customer Database, documentation for purification must be provided to assure that the requirements are met. Statements that the requirements are met will not be accepted without supporting documentation e.g., test results or the like.

Examples of impurities in raw materials

Note, that this list of examples is non-exhaustive and for illustrative purposes only. The specific limits can be found in the Asthma Allergy Nordic Customer Database [5].

Cocamidopropyl betaine contains the substances amidoamine (AA) and 3,3-dimethylamino-propylamine (DMAPA) that are substances originating from the production process. As part of the assessment of cocamidopropyl betaine it has been possible to set limits for the content of these impurities, and cocamidopropyl betaine may be accepted in products with Asthma Allergy Nordic if documentation for the amounts of AA and DMAPA meets the requirements in the specific raw material.

Aloe barbadensis contains substances called antraquinones that are a natural part of the aloe plant. *Aloe barbadensis* may be accepted if the level of antraquinones in the raw material meets the requirements.

Formaldehyde is a special case. Formaldehyde is classified as sensitizing to skin (H317). It may be added directly as an active substance or in-directly as formaldehyde releasers. In these forms, formaldehyde will not be accepted since formaldehyde is added intentionally to the product. Here formaldehyde is not an impurity. However, formaldehyde may also be present in the product unintentionally and unwanted. It may be because formaldehyde is formed in the product and cannot be traced to a raw material or a process. It may be due to impurities from the production process of the raw materials. In these cases, where formaldehyde is present unintentionally and unwanted, the raw material may be accepted, if it can be cleaned or purified. It will be a case-by-case assessment of the raw material whether purification is possible, or the raw material is rejected.

Requirement 2

A. Substances classified sensitizing with H317 may not be part of the product or raw materials.
B. Substances, where alternative evidence of sensitizing potential to the skin exists, may not be part of the product or raw materials.
C. Substances, classified as irritating to skin (H315), eyes (H319 or H318) or respiratory tract (H335), or where alternative evidence of irritating potential to skin or eye exists, may not be part of the product in amounts where the in-use concentration of the product causes irritation to the skin, eyes, or respiratory tract.

Exemption: Products intended to be used entirely without skin contact (e.g., toilet cleaners or scale removers) are exempted 2C.

D. Enzymes must be in liquid form or encapsuled in granules.
E. The product must be able to claim "*Fragrance Free"* according to the EU Cosmetics Regulation.
F. The product must not have a strong scent from chemicals.
G. Colourants must not be part of the product or raw materials.
H. Raw materials containing contaminants or impurities that may be sensitizing to the skin must be purified to an extent where the raw material, and hence the final product, do not cause allergic reactions to the skin.

Documentation: Full formulation cf. req. 1. *For point D*: Safety data sheet, technical data sheet, or specification showing the state of the enzyme raw material. *For point F*: Product safety data sheet; Asthma Allergy Nordic may ask for product samples to further support this requirement.

Criterion 3 – Natural Ingredients

Raw materials originating from nature may potentially be used in detergents. When oils, or extracts of natural origin are used, it will in most cases be a complex mixture of natural substances. Since Asthma Allergy Nordic requires knowledge of the full composition, there is a potential problem hidden here. At the same time, it is a wish from many consumers to be able to purchase products with natural ingredients and because of that, Asthma Allergy Nordic has allowed the possible use of these

ingredients. Often, however, the assessment of the natural raw materials will be as complex as the mixture of substances from which they are made. This may lead to limitations in the use. The limitation would be based on factors like use patterns and the amount of knowledge on the raw materials in question. These assessments will cause the raw materials to be placed in different categories. [AAN Natural Ingredients].

Requirement 3

Raw materials of natural origin may be used in products with the Asthma Allergy Nordic Label. The raw materials are assessed and based on the assessment, the raw materials are placed in categories and the use may be limited.

Details on grouping/categorisation and limits for each category can be found in Appendix 2.

Please note, that even though the appendix 2 is originally written for cosmetic products, the conclusions and means of assessment will be the same for detergents.

Criterion 4 – Cleaning Wipes

Cleaning wipes are products that comprise of two different components. One part, the detergent, falls directly under the product definition of these criteria, whereas the other part, the wipe material must meet the requirements set in Asthma Allergy Nordic's criteria for Hygiene and Tissue Products. [AAN Hygiene and Tissue].

Requirement 4

The detergent in the wet wipe must fulfil the requirements in this document. Besides this, the composition of the wipe material must be stated, and the wipe material must fulfil the criteria for Hygiene and Tissue Products under Asthma Allergy Nordic.

Documentation: Full formulation cf. req. 1. In addition, documentation that shows that the wipe material fulfils Asthma Allergy Nordic criteria for Hygiene and Tissue Products.

Criterion 5 – Food Allergens

Several studies, some very new, indicate that action towards food allergies caused by skin exposure could be relevant for allergy labelling. [Hsieh 2003], [Du Toit 2015], [Bøgh unpublished data]. On one hand, the scientific weight of evidence is not overwhelming, and the scope of the problem is not clear.

On the other hand, experts are concerned that this could be a rising problem, and there are indications that the link between skin exposure and food allergies does exist.

The studies include only some food allergens and only focus on allergy induced by proteins. Peanut and wheat are studied most extensively, and some articles are mentioning milk as cause of food allergic reactions due to skin exposure. [Du Toit, 2015], [Fukutomi 2014], [Bruusgaard-Mouritsen et al. 2020]. Experts also add that it cannot be ruled out that this will be valid for all proteins. [Bøgh unpublished data]. One of the studies also indicate that modified proteins seem more problematic than unmodified. Also, the way the modification is performed seems of importance – e.g., acidic hydrolysation or enzymatic hydrolysation. Yet another concern regarding the modified proteins is that it seems that the modification makes it possible to break an already established oral tolerance to the unmodified proteins. [Bøgh unpublished data]. The conclusion is that skin exposure to food proteins should be avoided in order to minimise the risk of inducing a food allergy through the skin.

Asthma Allergy Nordic finds enough reason for concern to address this issue in these criteria. Our purpose is to help preventing development of new allergies – both food allergy and contact allergy – and if an allergy is induced – to help allergic people choose products that minimise the risk of allergic reactions.

Based on this, Asthma Allergy Nordic has decided to take a cautious approach and set strict limits to proteins originating from food allergens in detergents. This is due to the fact, that detergents, like washing detergents and fabric softeners, are used on clothes and textiles that are in contact with the skin all the time, either as clothing or bedlinen. The clothes and bedlinen are used by all people regardless of age, which also means that even new-borns are exposed all the time. This exposure may pose a special concern when it comes to babies and new-borns since they have not yet developed a tolerance to the food proteins through digesting the proteins via food intake, and hence they may be more vulnerable to have a food allergy induced through the skin.

Even if the exposure scenario is not the same with detergents, other than washing detergents and fabric softeners, some skin contact may be considered, and hence the requirement is also valid for these products. Products that are used solely without skin exposure, e.g., toilet cleaners or machine dishwashing detergents, may be exempted from this criterion.

To define food allergens, we refer to the EU Regulation 1169/2011/EC Annex II. [Annex II]. Food allergens that are skin sensitisers are handled in the general requirement regarding sensitising substances (req. 2). The food allergens that are subject to declaration according to 1169/2011/EC is given in summary in appendix 3 of these criteria.

Ingredients from food allergens will be considered differently depending on whether purification is possible. This will be a case-by-case assessment based on the documentation available for the assessment of the ingredient. Ingredients, where documentation for the purification and hence the absence of proteins are provided will be accepted. Peanut oil, however, will not be accepted, as Asthma Allergy Nordic does not find that data support an acceptance of the use of peanut oil. Our interpretation of the SCCS Opinion on Peanut Oil is that there is not a scientific support of a limit.

[SCCS/1526/14]. The SCCS is saying that there is no known safe threshold defined for skin exposure of peanut proteins for peanut allergic people. Since this is an allergy with very serious complications if an allergic reaction occur, Asthma Allergy Nordic has decided to follow the cautious approach on this ingredient by not allowing peanut oil in products with the Asthma Allergy Nordic label.

For the definition of purification, Asthma Allergy Nordic defines that, ingredients are free from proteins, if the raw material does not contain peptides with a molecular weight above 3.5 kDa, determined with a detection limit of at most 0.5 ppm. This must be documented by specification of raw material or by batch analysis.

Note, that if the total amount of allergenic proteins is documented to be below 0.5 ppm in the finished product, then no further documentation is required under this requirement.

In the same way, raw materials with a content above 0.5 ppm proteins may be accepted but in amounts that limit the concentration of allergenic proteins in the final product to fulfil the limit of 0.5 ppm.

Requirement 5

All ingredients originating from food allergens* must be free from proteins.**

Peanut oil is not accepted.

** Food allergens as defined in the EU Regulation 1169/2011/EC Annex II.*

*** Ingredients used in products that are used solely without skin contact, e.g., toilet cleaners and machine dishwashing detergents, are not included in this criterion.*

Documentation: Full formulation cf. req. 1. It must be clearly stated in the formulation if an ingredient is originating from food allergens or not.

Specification of raw material, alternatively batch analysis providing documentation for the absence of proteins. Free from proteins means that the raw material does not contain peptides with a molecular weight above 3.5 kDa, determined with a detection limit of at most 0.5 ppm.

Criterion 6 – Spray Delivery Systems

Spray products may cause increased irritation of the mucous membranes and the respiratory tract and may cause discomfort for consumers with asthma or consumers with a sensitive respiratory system. [STAMI 2017]. Therefore, it is important that products that are dispensed by spray delivery systems have a particle size that prevents the product from reaching the deeper parts of the lungs. [CIR 2012], [SCCS/1539/14], [EUR 20268 EN (2002)], [Sherson 2017].

On the other hand, it is practical to use spray products to minimize the risk of contaminating the products during use as well as to ease the application of certain product. Therefore, Asthma Allergy Nordic allows spray products if the product is dispensed with a particle size that does not allow the

product to reach the deeper lung structures. Particles with an aerodynamic diameter larger than 10 µm will primarily stay in the upper parts of the lungs, while smaller particles may reach the deeper lung structures. [CIR 2012], [Sherson 2017].

It must be emphasized that the choice of packaging and dosing mechanism (dispenser system) will affect the assessment of the final product and product composition. Since the assessment of the product composition is the basis of an approval, the assessment also considers the exposure of the consumers as described in the section on irritants (req. 2). This means that the acceptable level of substances that are irritating to the respiratory tract will be higher in e.g., laundry capsules or dishwashing tablets than in hand dishwashing liquids. This also applies when assessing the product's risk of irritating the mucous membranes.

Asthma Allergy Nordic distinguish between the two different delivery systems: Mechanical pumps and delivery systems using aerosol propellants. Generally speaking, mechanical pumps generate larger particles than propellant sprays and hence, it is not necessary to document the particle size for products using a pump dispenser. It is, however, always the responsibility of applicant to guarantee that the product meets the requirements even though documentation is not required by Asthma Allergy Nordic. Asthma Allergy Nordic may at any time ask for documentation that the requirement is fulfilled and may always make external controls to see if the requirement is met.

Spray products using aerosol propellants can only be accepted, if the aerodynamic diameter of the particles is larger than 10 µm. Documentation for this must be a laboratory test conducted by an external laboratory under conditions representative for the use of the product by the consumers. An internal laboratory may be used for the test, if it can be shown that the laboratory has same competences as the external laboratories within the fields. The test conditions must be described in the test report. The requirement must be met for 99% of the particles of the product according to the test.

To further limit the risk of inhalation of the detergent particles, the products must have an advisory text on the product packaging, that urges the consumer to use the product at a minimum distance of 25 cm from the face.

Requirement 6

Spray products using aerosol propellants must disperse particles with an aerodynamic diameter larger than 10 µm.

Spray products must be labelled with the following text: "*People with sensitive airways, should only use spray products in a distance of at least 25 cm from the face and not directly pointed to the nose or mouth*" or equivalent.

Documentation: The documentation must be a laboratory test performed by an external laboratory (see background text for dispensation option). The test must be performed under test conditions representative for the use of the product. The test conditions must be described in the test report. The requirement must be met for 99% of the dispersed particles 25 cm from the dispersing start. Documentation is not required for products using pump sprays; the requirement must, however, still be fulfilled at all times for all products.

Note, only products that will be dispensed by pump/propellants to form airborne particles is included in this requirement. Products that by pump or propellant dispenses as e.g., lotion, cream, foam, or mousse, is exempted this requirement.

Criterion 7 – 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 presented so correct usage can be verified.

In order for the recommended products to be used correctly, the consumer needs information and guidance that is clear and easy to understand. The information shall be easily accessed both when purchasing and when using the product.

Everyone who is exposed to irritants is at risk of getting irritant contact dermatitis. People with sensitive skin are even more vulnerable and should therefore avoid being exposed to these types of products. Detergents that are recommended by the Asthma Allergy Nordic shall therefore have instructions on the packaging recommending the consumer to use protective gloves during use such as hand washing dishes, using all-purpose cleaners, soaking, or hand washing textiles. The precise wording may be formulated appropriately according to the intended message. The recommendation must be found on products where there is a skin contact during use; the assessment will take into consideration the worst case in-use solution. This means that if the instruction on the product clearly states that the product is not suitable for use by hand (e.g., prewash, wash by hand, soaking) the recommendation may be omitted. Also, should the product have a very low content of irritants, the recommendation can likewise be omitted.

The EU Detergent Regulation requires the content of the detergents to be partially declared on the product and some ingredients must only be named by a group description e.g., anionic surfactant. The regulation requires a full declaration to be present on the company website instead. [648/2004/EC, appendix VII, D]. A full declaration is helpful for people with allergies or sensitivities to avoid certain substances or, in case of an allergic reaction, for the dermatologist to be able to identify possible culprits. Asthma Allergy Nordic therefore requires a reference to the full product declaration, as required by EU Detergent Regulation 648/2004/EC, appendix VII, D, to be present on the primary packaging of the product. This also applies for products intended for professional use.

A product sample may be required by Asthma Allergy Nordic to support the evaluation and for comparison in case of consumer complaints.

Claims on the product that address Asthma Allergy Nordic's allergy label must also be accepted.

Requirement 7

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

A description of how the product is to be used shall be placed on the packaging.

Recommendations for the consumers to use protective gloves when using the products shall be placed on the packaging where applicable (see background text above).

There must be a reference to the full product declaration, as required by EU Detergent Regulation 648/2004/EC, appendix VII, D, to be present on the primary packaging of the product.

This also applies for products intended for professional use.

Claims regarding Asthma Allergy Nordic's allergy label must be accepted.

Documentation: Artwork/label. A product sample may be required.

References

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[AAN Hygiene and Tissue]: Background and criteria for Labelling of Hygiene and Tissue Products with Asthma Allergy Nordic, Asthma Allergy Nordic 2020

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

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The Information Portal: asthmaallergynordic.org/infoportal/. Login required.

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[SCCS/1539/14]: *Opinion for clarification of the meaning of the term “sprayable applications/products” for the nano forms of Carbon Black CI 77266, Titanium Oxide and Zinc Oxide*, SCCS, second revision 25 June 2015

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[STAMI 2017]: STAMI-rapport Nr. 2, Årgang 18 (2017), *Rengjøringsmidler i sprayform – Frigir de helseskadelige stoffer til arbeidsatsmosfære som kan inhalers til lungene?*, Statens Arbeidsmiljøinstitutt, 2017

Appendix 1 – Criteria in Summery

Requirement 1

The full composition of the product must be provided. The full formulation must state the trade name of the product and (if applicable) formulation number or ID, trade name of raw materials, INCI of ingoing substances, cas-no., active amount of the substances in the finished product as well as function of each raw material. If no INCI name is available for the substance, the chemical name according to IUPAC nomenclature must be used instead.

The wipe material in cleaning wipes and the process chemicals used in the production process of the wipe must fulfil Asthma Allergy Nordic requirements (see criteria for Hygiene and Tissue Products). [AAN Hygiene and Tissue].

Documentation: Full formulation of the product including all ingoing substances (see definitions below). The formulation must contain information as described in the requirement. Safety data sheets and technical data sheets for the raw materials must be provided upon request. Safety data sheets and technical data sheets must always be provided for ingredients that require purification according to the Asthma Allergy Nordic Customer Database [5].

Requirement 2

A. Substances classified sensitizing with H317 may not be part of the product or raw materials.
B. Substances, where alternative evidence of sensitizing potential to the skin exists, may not be part of the product or raw materials.
C. Substances, classified as irritating to skin (H315), eyes (H319 or H318) or respiratory tract (H335), or where alternative evidence of irritating potential to skin or eye exists, may not be part of the product in amounts where the in-use concentration of the product causes irritation to the skin, eyes, or respiratory tract.
D. If the product is intended for – or has a reasonably foreseeable – use where the solution is in contact with the skin, the in-use solution shall have a pH-value of 5-8.

Exemption: Products intended to be used entirely without skin contact (e.g., toilet cleaners or scale removers) are exempted 2C and 2D.

E. Enzymes must be in liquid form or encapsuled in granules.
F. The product must be able to claim "*Fragrance Free"* according to the EU Cosmetics Regulation.
G. The product must not have a strong scent from chemicals.
H. Colourants must not be part of the product or raw materials.
I. Raw materials containing contaminants or impurities that may be sensitizing to the skin must be purified to an extent where the raw material, and hence the final product, do not cause allergic reactions to the skin.

Documentation: Full formulation cf. req. 1. *For point D*: Statement or calculation of the pH-value for the in-use solution. *For point E*: Safety data sheet, technical data sheet, or specification showing the state of the enzyme raw material. *For point G*: Product safety data sheet; Asthma Allergy Nordic may ask for product samples to further support this requirement.

Requirement 3

Raw materials of natural origin may be used in products with the Asthma Allergy Nordic Label. The raw materials are assessed and based on the assessment, the raw materials are placed in categories and the use may be limited.

Details on grouping/categorisation and limits for each category can be found in Appendix 2.

Requirement 4

The detergent in the wet wipe must fulfil the requirements in this document. Besides this, the composition of the wipe material must be stated, and the wipe material must fulfil the criteria for Hygiene and Tissue Products under Asthma Allergy Nordic.

Documentation: Full formulation cf. req. 1. In addition, documentation that shows that the wipe material fulfils Asthma Allergy Nordic criteria for Hygiene and Tissue Products.

Requirement 5

All ingredients originating from food allergens* must be free from proteins.**

Peanut oil is not accepted.

** Food allergens as defined in the EU Regulation 1169/2011/EC Annex II.*

*** Ingredients used in products that are used solely without skin contact, e.g., toilet cleaners and machine dishwashing detergents, are not included in this criterion.*

Documentation: Full formulation cf. req. 1. It must be clearly stated in the formulation if an ingredient is originating from food allergens or not. Specification of raw material, alternatively batch analysis providing documentation for the absence of proteins. Free from proteins means that the raw material does not contain peptides with a molecular weight above 3.5 kDa, determined with a detection limit of at most 0.5 ppm.

Requirement 6

Spray products using aerosol propellants must disperse particles with an aerodynamic diameter larger than 10 µm.

Spray products must be labelled with the following text: "*People with sensitive airways, should only use spray products in a distance of at least 25 cm from the face and not directly pointed to the nose or mouth*" or equivalent.

Documentation: The documentation must be a laboratory test performed by an external laboratory (see background text for dispensation option). The test must be performed under test conditions representative for the use of the product. The test conditions must be described in the test report. The requirement must be met for 99% of the dispersed particles 25 cm from the dispersing start. Documentation is not required for products using pump sprays; the requirement must, however, still be fulfilled at all times for all products.

Requirement 7

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

A description of how the product is to be used shall be placed on the packaging.

Recommendations for the consumers to use protective gloves when using the products shall be placed on the packaging where applicable (see background text above).

There must be a reference to the full product declaration, as required by EU Detergent Regulation 648/2004/EC, appendix VII, D , to be present on the primary packaging of the product.

This also applies for products intended for professional use.

Claims regarding Asthma Allergy Nordic's allergy label must be accepted.

Documentation: Artwork/label. A product sample may be required.

Appendix 2 – Requirements on Natural Ingredients

1. Purpose

In many markets there is a growing demand for the use of natural ingredients. The consumers have changed their habits, and they are increasingly focusing on the natural aspects when purchasing cosmetics and personal care products.

With Asthma Allergy Nordic, there is an opportunity to offer a wider selection of products to consumers handling the issues set up in *Criteria for labelling of cosmetic products.*

Compared with other cosmetic ingredients, natural ingredients are usually very complex composites. They consist of several hundred different components, known as well as unknown substances. Furthermore, the composition may vary from batch to batch. This is a major challenge for the risk assessment, since it usually requires full knowledge of all the ingredients if a product should be recommended by Asthma Allergy Nordic.

To address this challenge of unknowns, requirements for natural ingredients in cosmetics are presented. The requirements are to be used together with the *Criteria for labelling of cosmetic products* [1,2].

2. What is meant by natural ingredients?

There are several different definitions of natural ingredients both nationally and internationally. There are, therefore, different perceptions of what natural ingredients are, and so far, a regulatory definition does not exist. In our context cosmetic ingredients are divided into four groups, the first is considered as natural ingredients, the second as naturally derived substances, the third as nature-identical substances, and the fourth as synthetic substances.

2.1 Natural ingredients

Natural ingredients are substance mixtures/single substances extracted from plants (including algae), fungi, animals, inorganic minerals, and microorganisms, either by physical processes, natural fermentation, or other extraction methods (e.g. solvent extraction) [3]. The ingredients may be *chemically unmodified*, i.e., the raw materials have not undergone further processing after extraction or *chemically modified/processed* in a laboratory, where the raw material undergoes several process steps to improve the quality and appearance of the raw materials as well as to purify it. Thus, the term ‘natural ingredients’ is broad and covers the following groups:

G1 Vegetable oils, including butters
G2 Essential/ethereal oils
G3 Waxes from vegetable, animal, and mineral origin
G4 Plant, algal and flower extracts (dry matter)
G5 Plant, algal and flower extracts (juice/sap)

G6 Tinctures
G7 Substances extracted from microorganisms and fungi
G8 Inorganic substances of mineral origin

The requirements in section 4 are only applicable for ingredients defined in G1 to G7.

2.2 Naturally derived substances

Naturally derived substances (G9) are single substances/substance mixtures manufactured from isolated ingredients extracted from nature. The substances in this group are therefore always manufactured from a natural starting material (as described in section 2.1), such as fats, oils, waxes, saccharides, lecithins and proteins, with the aim of, e.g. derivation and/or concentration of specific substances. Glycerine is an example of a naturally derived substance. The substance is often generated by hydrolysis of vegetable oils such as coconut oil or palm oil, where triglycerides are converted into glycerine and fatty acid, or as a by-product in the manufacture of biodiesel (transesterification of vegetable oils). Other examples of naturally derived substances are shown in annex 1.

Naturally derived substances are not considered to be natural ingredients in this context. Asthma-Allergy Nordic expects that the manufacturers use naturally derived substances with highest purity, and that the 'natural' composition is minimal/non-existing in the raw materials used. It is the producer's obligation and responsibility always to inform about the purity and the composition of the raw material. This is described in more details in the *Criteria for labelling of cosmetic products* [1,2].

Substances in this group should therefore only comply with the requirements described in the *Criteria for labelling of cosmetic products* [1,2].

2.3 Nature-identical substances

Nature-identical substances (G10) are single substances originally found in nature, but which are reproduced synthetically in a laboratory. The group includes, among other things, inorganic pigments/minerals, and preservatives. Benzoic acid is an example of a nature-identical substance. The substance is e.g. found in the resin from *Styrax Benzoin* (benzoestyrax). However, commercial benzoic acid is most commonly produced synthetically by oxidation of toluene. Other examples of natural-identical substances are shown in annex 1.

Nature-identical substances are not defined as natural ingredients, as the substances are synthetically produced. The use of these substances should therefore only comply with the requirements described in the *Criteria for labelling of cosmetic products* [1,2].

2.4 Synthetic substances

Synthetic substances (G11) are single substances, which are not found in nature, and which are solely produced synthetically in a laboratory. The use of synthetic substances should therefore only comply with the requirements described in the *Criteria for labelling of cosmetic products* [1,2].

3. Assessment of allergy risk

When evaluating the allergy risk, the natural ingredient as a whole and not only its individual main components is assessed. In some cases, there may descriptions in the literature of impurities or substances in the raw material with an allergenic potential. These components will be assessed, and in these cases, a specific concentration limit and/or requirement for purification may be set, if possible (see section 5.1.2 and 5.1.3).

Some of the vegetable oils are made from plant material, which is known and highly potent food allergens (e.g. soya and peanuts). It therefore seems reasonable to adopt a sceptical opinion towards these oils for use in cosmetics. The concern is especially related to the protein content of the oils, as it is here, the allergy risk is found. The sensitisation potential of vegetable oils is generally poor, though, and reactions are seldom seen in individuals allergic to food, particularly if the oil has undergone a refining process, whereby the protein fraction is removed [4]. Therefor in some cases a requirement for refining of vegetable oils may be relevant, particularly if the starting material is a known food allergen (see section 5.1.2).

The active substances of natural ingredients may vary depending on extraction method, parts of the plant used, and in which region the plant is grown. Different types of refining methods may remove part of the active substances, but nevertheless natural ingredients are immensely complex composites and may consist of several hundred different chemical substances (hereinafter referred to as 'the unknown content'). This is a challenge when assessing if a product may obtain Asthma Allergy Nordic, where full knowledge of all the ingredients is required. Asthma-Allergy Nordic handles this challenge by distinguishing between natural ingredients that are well documented, and natural ingredients that are not well documented (see section 4 and 5). The fact that an ingredient has been used for many years and in many products, is considered as part of a documentation for a possible non-allergic effect, assuming that allergic reactions from the ingredient in question would be thoroughly described in the literature, if such reactions had been seen. Moreover, it is the specific raw material that is accepted.

4. Categorisation of natural ingredients

Asthma-Allergy Nordic has defined three categories where cat. 1 are natural ingredients that are well documented in the literature, cat. 2 are natural ingredients with limited documentation, and cat. 3 are natural ingredients that are not permitted in products with Asthma Allergy Nordic. The categorisation of natural ingredients can be found in the Asthma Allergy Nordic Customer Database [5]. The definition of whether a substance is considered allergenic follows the definition described in the *Criteria for labelling of cosmetic products* [1,2].

Cat. 1 natural ingredients

- Ingredients that are well documented in the literature and/or widely used. The ingredients are not considered to cause contact allergy.

Cat. 2 natural ingredients

- Ingredients that are not considered to cause contact allergy, but with limited documentation and use.

Cat. 3 natural ingredients

- Ingredients that are considered to cause contact allergy, including:
    - Ingredients that contain fragrance substances, which cannot be purified.
    - Ingredients that contain other allergenic substances, which cannot be purified.
    - Ingredients with scents, even if the ingredient could otherwise fit into the definition of cat. 1 or cat. 2. This includes fragrant ingredients that through the application may scent the product, even if it has been added with a different function.

A substance in cat. 2 may increase to cat. 1, if the use of the substance increases significantly, and/or if new documentation shows that the substance does not cause contact allergy. On the other hand, ingredients in cat. 1 and cat. 2 may decrease to cat. 3, if, for example, new documentation shows that the ingredients have allergenic properties. Changes in classification can be found in the Asthma Allergy Nordic Customer Database [5] and information will be sent to the relevant producers and entered on Asthma-Allergy Denmark's web portal for producers 'The Information Portal' [6].

5. Requirements for natural ingredients (requirement 1-2)

Annex 1 shows an overview of the requirements for the use of natural ingredients in cosmetic products as well as the categorisation of the ingredients.

For all-natural ingredients an evaluation is done, and in some cases, there may be a requirement for purification of known allergens in the raw material, including refining of oil/butter/wax. This is described in more detail below.

With the objective to minimize 'the unknown content', concentration limitation is only imposed on ingredients in cat. 2. 'the unknown content' is weighted less in cat. 1 ingredients where it is assumed that 'the unknown content' is not relevant to contact allergy, as allergic reactions from the ingredient in question would have been thoroughly described in the literature, if such reactions had been seen.

5.1 Permitted natural ingredients (requirement 1)

The following natural ingredients are permitted in products with Asthma Allergy Nordic:

- **G1 Vegetable oils/butter.**
    a. Cat. 1 - no concentration limit
    b. Cat. 2 - maximum 20% of the ingredient in the final cosmetic product
- **G3 Wax from vegetable, animal, and mineral origin**
    a. Cat. 1 - no concentration limit
    b. Cat. 2 - maximum 20% of the ingredient in the final cosmetic product
- **G4.1 Plant, algal and flower extracts (dry matter)**
    a. Cat. 1 - no concentration limit

b. Cat. 2 - maximum 0.01% of the ingredient in the final cosmetic product

- **G5.1 plant, algal and flower extracts (juice/sap)**
  a. Cat. 1 - no concentration limit
  b. Cat. 2 - maximum 1% of the ingredient in the final cosmetic product
- **G7 Substances extracted from micro-organisms and fungi**
  a. Cat. 1 - no concentration limit
  b. Cat. 2 - maximum 20% of the ingredient in the final cosmetic product

5.1.1 The sum of natural ingredients in category 2 at product evaluation

At a specific product evaluation, the sum of the ingredients in cat. 2 and within the same group of ingredients must not exceed the maximum concentration specified in annex 3. E.g. this means that if two different vegetable oils are used in cat. 2, the total sum of both ingredients can be maximum 20%. If a vegetable oil in cat. 2 and a flower extract (juice) in cat. 2 are used; the maximum concentration of the flower extract must be 1 % and the sum of the two ingredients must not exceed 20% in the product.

5.1.2 Purification of allergenic substances and refining

Natural ingredients may contain known allergenic substances or impurities, which need to be purified before the raw material can be used in cosmetic products. The threshold depends on the individual allergenic substances or impurities, and the quantity of the substances must be documented by a laboratory analysis (see section 6.2).

In general, Asthma Allergy Nordic does not focus directly on allergens inducing type 1 allergies[1]. However, there may be cases where the proteins in a vegetable oil/butter have allergenic properties, which after cosmetic use are considered to cause allergic skin reactions. To minimize the protein content, such cases will require refining of the oil. There are no requirements to the actual refining method, but the producer must document (by laboratory analysis) that the protein content in the raw material is limited (see section 6.2). Here, the threshold value will also depend on the individual allergenic oil/butter.

Information on requirement for purification/refining of a raw material can be seen in the Asthma Allergy Nordic Customer Database [5].

5.1.3 Metal contamination in natural ingredients

Contamination with the metals nickel (Ni), cobalt (Co) and chromium (Cr) may occur in some natural ingredients, especially in ingredients under G1, G3, G4 and G5. These three metals are among the substances most frequently seen in connection with contact allergy. Asthma-Allergy Nordic therefore considers that it is essential to include these metals in the requirement for the natural ingredients, which may potentially be contaminated.

[1] This is also called an immediate reaction, where symptoms typically appear within a few minutes or hours.

Asthma-Allergy Nordic requires that products with certain natural ingredients should not contain more than 1 ppm of total metal content for each of the metals Ni, Co, and Cr. The requirement is documented by submitting test results for either the product or the raw materials (see section 6.3) to be approved. If the test result for the raw material is submitted, it must be documented by calculation that the product meets the requirement.

Information on the requirement for metal contamination can be seen in the Asthma Allergy Nordic Customer Database [5].

For more information on the background and the requirements concerning metal contaminants please refer to the *Criteria for labelling of cosmetic products* [1,2].

5.2 Not permitted natural ingredients (requirement 2)

The following natural ingredients are not permitted in products with Asthma Allergy Nordic:

- **G2 Essential/ethereal oils.** Due to the content of fragrance substances.
- **G4.2/G5.2 Extracts of flowers and plants with fragrance.** Due to the content of fragrance substances or ingredients with a scent.
- **G6 Tinctures.** Due to lack of processing/refining as well as the risk of content of fragrance substances.
- **Other ingredients** that are rejected as cat. 1 or cat. 2 ingredients.

6. Documentation (requirement 3)

Asthma-Allergy Nordic must approve all-natural raw materials to be used in products labelled with Asthma Allergy Nordic. This section describes the specific documentation requirements applicable for raw materials with natural ingredients.

6.1 Documents

For natural ingredients, documentation is required in the form of safety data sheets, technical data sheets and flow charts of the manufacturing process. If the ingredients manufacturing process is well-known by Asthma-Allergy Nordic, there will not be a requirement for information about the manufacturing process. This is the case for some of the vegetable oils. In some cases, additional documentation may be required for the raw material, such as product documentation/toxicological dossier.

6.2 Requirements for purification of allergenic substances and refining

It is required that a laboratory analysis is performed on three different batches the first time an application is made for a raw material; this must subsequently be documented on request. The documentation includes an indication of the quantity of relevant substances, the applied test method,

and the detection limit. If the quantity of the relevant substance appears in the supplier's raw material specification, this is deemed to be sufficient documentation. However, inquiries may take place about documentation for the raw material specification.

The applicant does not need to submit documentation, if the raw material is already found in the Asthma Allergy Nordic Customer Database [5] as the requirement for continuous documentation is subject to the raw material supplier.

6.3 Requirements for metal contamination in products with natural ingredients

The requirement is only applying for those ingredients listed in the Asthma Allergy Nordic Customer Database [5], having a specific requirement for documentation for metal contamination.

A laboratory analysis is performed on the final cosmetic product. Measurements are to be taken on the total content of the metals. The test must be carried out on three different batches the first time an application is made. Subsequently, the compliance with the requirement must be documented once a year. The documentation includes an indication of the quantity of the metals Ni, Cr and Co, the applied test method, and the detection limit.

Alternatively, the raw material used in the products may be tested for all three metals. If the quantity of the metals appears in the supplier's raw material specification, this is deemed to be sufficient documentation. A calculation must be included to show that the final product complies with the requirement (see *Criteria for labelling of cosmetic products*) [1,2].

For more information on the documentation requirement concerning metal contamination please refer to the *Criteria for labelling of cosmetic products* [1,2].

7. References

[1] Criteria for cosmetic products for Asthma Allergy Nordic

[2] Background to the requirements for labelling of cosmetic products with Asthma Allergy Nordic

[3] ISO16128-1:2016. Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products – part 1: definitions for ingredients

[4] Plant-Derived Fatty Acid Oils as Used in Cosmetics, Cosmetic Ingredient Review 2011

[5] The Asthma Allergy Nordic Customer Database: astma-allergi-webcustomer.onteamshare.com/Identity/Account/Login

[6] Information portal: asthmaallergynordic.org/infoportal/

Appendix 2. Overview of requirements applicable to natural ingredients

Ingredient group	Requirement for application	Category	Limitation
G1 Vegetable oils/butter.	Purification/refining of possible allergens	1	No limitation
		2	Max. 20%
G2 Essential/ethereal oils	Not permitted due to the content of fragrance substances	3	Not permitted
G3 Waxes from vegetable, animal, and mineral origin	Purification/refining of possible allergens	1	No limitation
		2	Max. 20%
G4 plant, algal and flower extracts (dry matter)	***G4.1 Extracts without fragrance*** Purification of possible allergens	1	No limitation
		2	Max. 0.01%[1]
	G4.2 Extracts with fragrance Scented or content of fragrance substances	3	Not permitted
G5 plant, algal and flower extracts (juice/sap)	***G5.1 Extracts without fragrance*** Purification of possible allergens	1	No limitation
		2	Max. 1%
	G5.2 Extracts with fragrance Scented or content of fragrance substances	3	Not permitted
G6 Tinctures	Not permitted due to lack of processing/refining/purification	3	Not permitted
G7 Substances extracted from microorganisms and fungi	Purification of possible allergens	1	No limitation
		2	Max. 20%
G8 Inorganic substances of mineral origin	Not subject to the requirements for natural ingredients		
G9 Natural derivatives	Not subject to the requirements for natural ingredients		
G10 Nature-identical substances	Not subject to the requirements for natural ingredients		
G11 Synthetic substances	Not subject to the requirements for natural ingredients		

[1] Alternatively, max. 1% of the hydrated form.

NB! At a specific product evaluation, the sum of the ingredients in cat. 2 and within the same group of ingredients must not exceed the maximum concentration specified in the table. E.g., this means that if two different vegetable oils are used in cat. 2, the maximum total quantity of both ingredients can be 20%.

Appendix 3 – Allergens as Listed in Annex II of EU Regulation 1169/2011/EC

The list of allergens is copied from EU Regulation 1169/2011/EC on the provision of food information to consumers.

Note, that in the case of cereals and nuts, only those listed in the annex are included in the regulation. Other species of cereals and nuts are not included in the regulation and hence not included in requirement 5 of this criteria document.

Note, the "…"-exemptions are not mentioned in this appendix as AAN has considered them not relevant for cosmetic ingredients.

1. Cereals: wheat, rye, barley, oat, spelt, kamut or their hybridised strains and products thereof, except:
    a. Wheat-based glucose syrups including dextrose
    b. Wheat-based maltodextrins
    c. Glucose syrups based on barley
    d. …
2. Crustaceans and products thereof
3. Eggs and products thereof
4. Fish and products thereof, except:
    a. Fish gelatine used as a carrier for vitamin or carotenoid preparations
    b. …
5. Peanuts and products thereof
6. Soybeans and products thereof, except:
    a. Fully refined soybean oil and fats
    b. Natural mixed tocopherols (E306), natural D-alpha-tocopherol, natural D-alpha-tocopherol acetate, natural D-alpha-tocopherol succinate from soybean sources
    c. Vegetable oils derived phytosterols and phytosterol esters from soybean sources
    d. Plant stanol ester produced from vegetable oil sterols from soybean sources
7. Milk and products thereof including lactose, except:
    a. …
    b. Lactitol
8. Nuts: almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia or Queensland nuts and products thereof
9. Celery and products thereof
10. Mustard and products thereof
11. Sesame seeds and products thereof
12. Sulphur dioxide and sulphites [above a specific limit and other detailed requirements]
13. Lupin and products thereof
14. Molluscs and products thereof