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BACKGROUND AND REQUIREMENTS

COSMETIC PRODUCTS – VERSION 1.0

ASTHMA ALLERGY NORDIC

Asthma Allergy Nordic

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Background and Requirements for Labelling of Cosmetic Products with Asthma Allergy Nordic

This document describes the background and requirements set for cosmetic products. 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 cosmetic products is that cosmetic products are in frequent or prolonged contact with the skin and despite the full declaration on the products, consumers may experience problems with cosmetic products in terms of skin allergy. The European legislation (Cosmetics Regulation 1223/2009/EC) aims at making the products safe to use. In this context, it generally does not refer to skin allergy, since skin allergy, in a regulatory context, is considered as an individual problem and as such not entirely included in the regulatory framework. The Cosmetics Regulation is usually only used in cases, where a cosmetic product is causing an epidemic of allergic reactions and not when it comes to individual experiences of skin allergy. Other markets may have corresponding legislations as well. Asthma Allergy Nordic aims to help consumers who are already sensitized or 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 respiratory system is minimised. Asthma Allergy Nordic has increased focus on asthma, where relevant, and people with hypersensitivity may feel, that labelled products help them, too.

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

- No fragrances
- No sensitizing preservatives (e.g., MIT)
- Full declaration on the product (including makeup)
- 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 sensitizing. **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. 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 and international dermatologists with expertise within the field. 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 be allergic towards the substance and may have an allergic reaction towards this.

Analysis: Methods and Results

There is now more focus on and specification of the documentation requirements in the criteria. This means that 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 choice of test and detection limits as well as on interpretation of test results and dialogue with the laboratories. Please, contact us early in the process, so that we might can be of help providing the necessary documentation. Contact information may be found on the Asthma Allergy Nordic website. [AAN website].

The *Retailers & Manufacturers Portal* provides a list of laboratories that have indicated that they may provide the service of testing according to the requirements in these criteria. [RMP]. The list is not

exhaustive and other laboratories may also be able to provide the service, but we encourage you to contact us prior to analysis if other laboratories are used.

Which Products May Be Labelled?

Products comprised by these criteria are cosmetic products as defined in the EU Cosmetics Regulation (1223/2009/EC) and similar products such as: products intended to be used on animals, wet wipes, and certain categories of medical equipment (see below). In addition, hand disinfectants are also included (see details in the section below).

Products Regulated under the Cosmetics Regulation

Products included under the EU Cosmetics Regulation such as personal care products (e.g., lotion, cream, soap), hair care products (e.g., shampoo, conditioner), personal hygiene products (e.g., toothpaste, shaving foam, intimate soap) and makeup (e.g., mascara, lipstick).

Products for animals

Products intended to be used on animals are not included in the EU Cosmetics Regulation but is considered a chemical product under the EU CLP Regulation (1272/2008/EC) and EU REACH Regulation (1907/2006/EC). These regulations have a different approach on consumer safety than the Cosmetics Regulation and the focus is mostly on information on hazards by classification and labelling of the chemical products and/or articles. To give consumers a minimised risk of developing skin allergy and having allergic reactions to the products when applied to animals, it is relevant that these products may obtain the Asthma Allergy Nordic label. The risk of allergy in the animals is not considered when assessing the products.

Wet wipes

Wet wipes are partly included in the Cosmetics Regulation since the cosmetic product (lotion/cream) that make the wet wipe moist is included. The wipe itself is not a cosmetic product but considered an article under the EU REACH Regulation. It is the experience of Asthma Allergy Nordic, that it is very relevant to look at the materials and process chemicals used in the production of the wipe, since there may be substances present that may cause allergic reactions in consumers.

Medical equipment

Medical equipment comprises a long line of products, where some might be similar in composition and use to other products included in these criteria. Examples include wet wipes for patients confined to the bed, products for treating lice or gels used at ultra-sonic scans. Medical equipment in Europe is regulated by 2017/745/EC.

Hand disinfectants

Hand disinfectants are a product group laying in a grey area between different legislations. However, it has recently been decided, that such products that fall under the EU Biocides Regulation (528/2018/EC), will be eligible for the Asthma Allergy Nordic label and is therefore included in these criteria.

Criterion 1 – Information on Product Composition

To make a risk 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. Should the INCI and cas-no. be insufficient to positively identify the ingoing substance, the chemical name of the substance must be stated.

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. It must be clearly stated in the formulation if an ingredient is originating from food allergens or not (cf. req. 5).

The wipe material in wet wipes and the process chemicals used in the production process of the wipe must also 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. (See Appendix 2). 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 Kemilex. [Kemilex].

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 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 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].

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. cover 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. There is no lower limit as to when a substance is ingoing as even very low amounts of a substance may cause allergic reactions to the skin in consumers with contact allergy to that specific substance.

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 cosmetic product are also included in this definition. Impurities from packaging will be handled in no other way than impurities from raw materials or production, but it is mentioned specifically to highlight, that these impurities are also included in the assessment. Impurities are not required to be declared on the product.

Criterion 2 – Specifically Limited or Excluded Substances

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

Substances Classified Sensitizing to Skin, H317

Legislation requires that cosmetic products must be safe to use. However, perfectly legal products may still contain substances classified as sensitizing because the substances are deemed safe to use. 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 cosmetics, the use of these substances in products labelled with Asthma Allergy Nordic is excluded entirely – regardless of

concentration. This requirement includes all substances classified as sensitizing to skin (H317). The reasons are also valid for other product types and segments not comprised by the Cosmetics Regulation but included under the scope of these criteria.

Substances Where Alternative Evidence of Contact Allergenic Potential Exists

Some substances are considered sensitizing by dermatologists even though the substances are not classified as such. 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.

Irritants

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 classified 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 in- 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.

If the amount 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 that are commonly accepted (e.g., Zein) and not specifically dismissed by ECVAM, Scientific Committee on Consumer Safety (SCCS) or other scientific committees or bodies may be used. [SCCS website]. The test conclusion must be provided. If the conclusion gives rise to any questions, the entire report may be requested.

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.

The reason for this requirement is that irritated or damaged skin generally is penetrated more easily by substances, and that sensitizing substances therefore may 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.

Fragrance

Fragrance may not be part of the product or raw material. That means that the product should always comply to the regulation's requirement for using the claim "perfume free" or "fragrance free". That among others means that the fragrances mentioned in the SCCS opinion SCCS/1459/11 are not allowed in the final product. [SCCS/1459/11]. 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.

Colourants

Colourants is not accepted in products with Asthma Allergy Nordic. This is because colourants are not regarded as essential for the function of the product on the body.

Exempted from this is decorative cosmetics (makeup), where colourants are essential for the function of the cosmetic product, see req. 6 for requirements on makeup.

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.

Only impurities that may be allergenic will be included in the assessment of the raw material. 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 Kemilex. [Kemilex]. Unless the raw material is certified and found in RawLex, documentation for purification must be provided once a year in order to assure that the requirements are met. [RawLex]. 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 Kemilex [Kemilex].

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 finished product causes irritation to the skin, eyes, or respiratory tract.
D. The product must be able to claim *Fragrance Free* according to the Cosmetics Regulation.
E. Colourants may not be part of the product or raw materials.

Exemption: colourants may be part of makeup, see req. 5

F. 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.

Criterion 3 – Natural Ingredients

Raw materials originating from nature is used more and more frequently in cosmetic products. When oils, waxes or other 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 opened the possibility of using 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 3.

Criterion 4 – Wet Wipes

Wet Wipes are products that comprise of two different components. One part, the lotion part, falls directly under the product definition of these criteria, whereas 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

Lotion 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 form food allergens in cosmetics. 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).

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. 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 the limit set. [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.

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.*

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.

Input from External Hearing

Based on the external hearing it has been clear, that this is a new area and how to address this has been challenging. Therefore, Asthma Allergy Nordic suggests the following steps when considering the requirement:

1. Determine what the origin of the ingredient is.
2. Check if the origin of the ingredient is considered a food allergen on Annex II (see appendix 5 of these criteria).
3. If the origin of the ingredient is **not** listed in Annex II, it is not included in this requirement.
4. If the ingredient (origin) is included in Annex II, documentation for the absence of proteins must be provided in order to have the raw material accepted for use in the certified product.

The dialogue with the hearing parties also showed that the assessment of some of the ingredients in use in today's products, was unclear, and based on the dialogue, some examples of ingredients and their assessment follow here.

Examples of assessment under requirement 5

The following is an assessment made on specific raw material sent in for pre-evaluation according to the new requirement 5. Other raw materials may have a different assessment based on the documentation provided for the individual raw material.

Butyrospermum parkii butter, Cetiol SB 45, BASF

The raw material originates from shea nuts according to the technical data sheet. Although nuts are included in the Annex II, only the nuts mentioned is included, and the list does not mention shea nuts. This means that shea nut is not considered a food allergen and butyrospermum parkii butter is not assessed under requirement 5.

Tochopherol, Dermofeel Toco 70, Evonik

The raw material originates from Soy Glycine according to the technical data sheet. Soy is mentioned as a food allergen in Annex II, but tocopherol is mentioned as an exemption in point 6b and is therefore not assessed under requirement 5.

If a tocopherol ingredient originates from another food allergen included in Annex II, this tocopherol ingredient will be assessed under requirement 5.

Lecithin, Metarin P TP, Cargill

The raw material originates from soy according to the technical data sheet. Soy is mentioned as a food allergen in Annex II, but soybean oil is mentioned as an exemption in point 6a provided the soybean oil is fully refined, and hence not assessed under requirement 5. Documentation for refinement of the soybean oil must be provided.

Should the lecithin ingredient not originate from fully refined soybean oil, or should the lecithin ingredient originate from any other food allergen included in Annex II, these will be assessed under requirement 5.

Criterion 6 – Makeup

Decorative cosmetics (makeup) are exempted requirement 2 regarding colourants since colourants serve an essential purpose for the function of these product types.

Asthma Allergy Nordic has done extensive research on the potential allergens in colourants used in makeup. The research shows that pigments in colourants may contain the allergenic metals nickel (Ni), cobalt (Co) and chromium (Cr). The same could also be the case for other minerals used in cosmetics. This will have to be addressed in allergy labelled makeup. The detailed discussion of the background may be found in Appendix 4.

Note, that colour-effect substances (e.g., mica) is also included in this requirement since they are also mostly of mineral origin and may likewise contain residual allergenic metals.

Summary and requirement level

On basis on the background and the knowledge collected during this work, it has been decided that the requirement at 1 ppm total-content per metal (Ni, Co, Cr) in the final product, is the right limit for Asthma Allergy Nordic, since the aim is to provide products tolerated by consumers with allergy. The assessment has been that the requirement may be hard to meet but there are currently products on the market that fulfil this criterion.

Documentation

This must be documented by a test of all products and colour variants that shall be approved. The test must measure the total content of the metals and the test must be made on three batches. At the point of application, one batch may be accepted as basis for approval if a test will be provided at the next-coming productions of the products. The metal content of all batches must fulfil the requirement. It is always the responsibility of the applicant that the requirements are met, and Asthma Allergy Nordic can request documentation for compliance with the requirements at any time – including the time after the approval of the product. However, this will only be relevant at most once a year or by suspicion of non-compliance. When documenting compliance after award of the approval (continuous control), only testing of one batch will be necessary.

Requirement 6

Makeup must fulfil the requirements in this document except for requirement 2 E. Instead, it must be documented that the final cosmetic product does not contain nickel (Ni), cobalt (Co) or chromium (Cr) in amounts above 1 ppm per metal.

Documentation: Full formulation cf. req. 1. In addition, a test report must be provided where the amount of the metals is measured on each of the products and each colour-variant for which approval is applied for. It must be measured as total content of the metals, and the test must be made on 3 different batches. The requirement must be documented continuously.

Criterion 7 – Hand Disinfectants and Degreasing Products

Hand disinfectants and degreasing products may contain high amounts of substances that make the skin dry, especially when used in excessive amounts. In order to minimise skin irritation, it is required that substances are added to the product to counteract this effect. It must be clearly stated from the product formulation which substances are added to give skin conditioning effect and evidence showing that the substances have the wanted effect on the skin. An example of this could be glycerine added to a hand disinfectant as skin conditioner/humectant.

Requirement 7

Hand disinfectants and degreasing products must contain substances to counteract drying of the skin.

Documentation: Full formulation cf. req. 1. It must be stated in the formulation, which substances are added to meet this requirement and documentation that supports the claimed effect on the skin.

Criterion 8 – 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 minimise the risk of contaminating the products during use and to ease the application of certain products, if the product is provided with a spray delivery system. Therefore, Asthma Allergy Nordic allows spray products if the product is dispensed with a particle size that do 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., a foot cream than in a spray deodorant. 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.

Although Asthma Allergy Nordic accept spray products it does not mean that spray products will be the best choice for all the people that the label aims to protect. Therefore, Asthma Allergy Nordic require a text to be on the product label that advice consumers with sensitive airways on the use of spray products. The text may be re-phrased as long as the meaning is still the same.

Requirement 8

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 – or equivalent: "People with sensitive air ways, should only use spray products in a distance of at least 25 cm from the face and not directly pointed towards the nose or mouth".

Documentation: The documentation must be a laboratory test performed by an external laboratory (see background document 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 dispense as e.g., lotion, cream, foam, or mousse, are exempted this requirement.

Criterion 9 – 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.

Besides this, a full and unambiguous declaration, using INCI-nomenclature, of all ingoing substances (including auxiliaries and solvents) in the product is required and it must be placed on the primary packaging of product, so that the consumer have access to the declaration at any time. This also applies to products that are not included in the Cosmetics Regulation. With the term "unambiguous" is meant that the symbol "±" in front of colourants may *not* be used, but the specific colourants must be found on the relevant product.

The requirement is set to ensure that the consumers always know precisely what is in the product. Additionally, if a case of irritation or an allergic reaction to the skin should occur towards a substance in the product, full declaration may help increase the chance of identifying the substance. Asthma Allergy Nordic is, however, aware that it may be (graphically) challenging with a full declaration on very small products. In our opinion, the full declaration serves two purposes:

1. It provides the consumer with the opportunity to make an informed choice at the time of purchase.

2. It provides the consumer with the possibility of identifying substances towards which they have an allergic skin reaction, should such a situation arise.

With regards to point 1, this is handled by the Cosmetics Regulation. With regards to point 2, the optimal solution will be that the declaration is found on the primary packaging of the product and not on secondary packaging, which is often discarded by the consumers once the product is taken into use. For small sized products, this may be a challenge and Asthma Allergy Nordic may give acceptance to alternative methods of ensuring easy access to the declaration after purchase. An example of this could be placing of a QR-code on the primary packaging leading the consumer directly to a website, where the declaration for the specific product is found. The consumer must not have any doubts as to which declaration applies to the individual product.

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

Requirement 9

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

There must be a full and unambiguous declaration, using INCI-nomenclature, containing all ingoing substances on the primary packaging of the products (see above for dispensation options). By unambiguous declaration is meant that the symbol "±" may not be used in the declaration, but the specific colourants for the specific product must be stated.

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

Documentation: Artwork/label.

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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. It must be clearly stated in the formulation if an ingredient is originating from food allergens or not (cf. req. 5).

The wipe material in wet wipes and the process chemicals used in the production process of the wipe must also 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. (See Appendix 2). 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 Kemilex. [Kemilex].

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 finished product causes irritation to the skin, eyes, or respiratory tract.
D. The product must be able to claim *Fragrance Free* according to the Cosmetics Regulation.
E. Colourants may not be part of the product or raw materials.

Exemption: colourants may be part of makeup, see req. 5

F. 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.

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 3.

Requirement 4

Lotion 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.*

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

Makeup must fulfil the requirements in this document except for requirement 2 E. Instead, it must be documented that the final cosmetic product does not contain nickel (Ni), cobalt (Co) or chromium (Cr) in amounts above 1 ppm per metal.

Documentation: Full formulation cf. req. 1. In addition, a test report must be provided where the amount of the metals is measured on each of the products and each colour-variant for which approval is applied for. It must be measured as total content of the metals, and the test must be made on 3 different batches. The requirement must be documented continuously.

Requirement 7

Hand disinfectants and degreasing products must contain substances to counteract drying of the skin.

Documentation: Full formulation cf. req. 1. It must be stated in the formulation, which substances are added to meet this requirement and documentation that supports the claimed effect on the skin.

Requirement 8

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 – or equivalent: "People with sensitive air ways, should only use spray products in a distance of at least 25 cm from the face and not directly pointed towards the nose or mouth".

Documentation: The documentation must be a laboratory test performed by an external laboratory (see background document 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 9

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

There must be a full and unambiguous declaration, using INCI-nomenclature, containing all ingoing substances on the primary packaging of the products (see above for dispensation options). By unambiguous declaration is meant that the symbol "±" may not be used in the declaration, but the specific colourants for the specific product must be stated.

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

Documentation: Artwork/label.

Appendix 2 – Help Form for Manufacturers of Cosmetic Products

The help form in its entirety can be found on the on the Retailers and Manufacturers Information Portal [RMP]. The help form is meant as an example of the way to present the documentation under Criterion 1.

Please list the full composition of the final product stating all the ingoing substances[1] including all ingredients in the raw materials used. For raw materials always state the trade name and the supplier. The composition must sum to 100%.

It is important for you to know that we need information about all ingredients, regardless of amount in the raw material, including any impurities[2]. If you use a raw material where you don't know the exact composition or ingredients, we must have this information from your supplier.

Type/function	INCI	CAS no.	Full trade name of raw material	Supplier	Amount (%)	$	Full composition of raw material[3]	#
						☐	☐	
						☐	☐	
						☐	☐	
						☐	☐	
						☐	☐	
						☐	☐	
						☐	☐	
						☐	☐	
						☐	☐	
						☐	☐	
				Sum				

[1] **Ingoing substance** is defined as all substances present in the product in the form of active substances and auxiliaries, solvents and the like. Substances present in amounts under 0.1 ppm is considered to be under the Lower Limit of Interest (LLoI).

[2] **Impurities** are not subject to declaration, but information on them is needed for evaluation of the product. They are not regarded as ingoing substances, as they are expected to be found with the active substance either due to the composition of the ingredient or the production process of the raw material.

[$] Mark **colour** or **colour-effect substance**

[3] The **full composition** of mentioned raw material is known to you and stated in this document. Please note, that information solely derived from MSDS not necessarily comprise the full composition as confidential information and non-classified substances are not stated here. This is therefore not regarded as a sufficient level of information.

[#] State **origin of ingredient**, synthetic, natural, food allergen

Appendix 3 – 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 be 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 Kemilex [5] under "Other properties". 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 Kemilex [5] and information will be sent to the relevant producers and entered on Asthma-Allergy Denmark's web portal for producers 'Retailer & Manufacturers Portal'.

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[4]. 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 Kemilex [5] under "Other properties".

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.

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 Kemilex [5] under "Other properties".

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.

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

- **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 once a year. 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 raw material database 'RawLex', 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 Kemilex, 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] Kemilex: http://www.astma-allergi.dk/kemilex

Annex 1. 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 4 – Detailed Background on Requirements on Metals in Makeup

Which substances should be considered?

During the task of making criteria for makeup, Asthma Allergy Nordic has reviewed literature and has had a dialogue with Scandinavian and international experts in the field. [Thyssen 2017], [Lidén 2017], [Basketter 2017]. Also, an independent report has been produced from Technological Institute, where studies of impurities in makeup is reviewed with focus on the allergenic potential of the impurities. [Teknologisk 2016].

Both the internal review and the external report from Technological Institute points to three metals: nickel (Ni), cobalt (Co) and chromium (Cr) that could be relevant to consider when making requirements to allergy-labelled makeup. [Teknologisk 2016].

Quote from the summary of the report from Technological Institute: "*According to the conducted literature study, it is found well-documented that nickel (Ni), cobalt (Co) and chromium (Cr) may be found in cosmetic products and that the metals may cause allergic contact dermatitis*.". [Teknologisk 2016].

The three metals are known to cause allergic contact dermatitis. In a large European study from 2016, the following was found in the general population: "*The most frequent contact allergy was diagnosed against metals (nickel sulfate (Ni), cobalt chloride (Co), potassium dichromate (Cr)), followed by preservatives*". [BJD 2016]. The frequency was found to be 14.5% for nickel, 2.2% for cobalt and 0.8% for chromium. In comparison the frequency for fragrance mix and the allergenic colourant PPD was found to be 0.9% for fragrance mix I, 1.9% for fragrance mix II and 1.0% for PPD.

On this basis, the three metals are considered relevant to include in the requirements for allergy-labelled makeup, if the aim is to help consumers with allergic contact dermatitis.

Which content should be tested and what limit should be set?

In the work of setting limits for the three metals, it has been considered, that the aim for the allergy-label Asthma Allergy Nordic is both to help consumers who wish to prevent allergy and consumers who has one or more allergies. In addition, it should be noted, that the metals are not subject to declaration on the products, which means that consumers cannot make informed choices *not* to be exposed to these substances.

When setting the limits for metals, it must be assessed what the consumers are exposed to – called the *bio-available amount* (or content). Knowledge on bioavailability is limited. When analysing, two concepts are used: the sweat-soluble content and the total-content. The bio-available content lies somewhere in-between these two, but it is not determined where. From an allergy point of view, it is the most principal

factor to avoid allergenic substances. In this context, it means that looking at the total content of the metals is the most precautionary and sensible approach in order to protect allergic consumers.

On top of this, Asthma Allergy Nordic has been in dialogue with several laboratories regarding the choice of method and they question the suitability of the sweat-soluble content when testing makeup. [ALS 2017], [Teknologisk Institut 2017], [Eurofins 2017]. They point out that the test methods for sweat-soluble content is specially unsuited for powdered products and that the method will under-estimate the content of metal in comparison to the real content. One laboratory states that they do not perform test of the sweat-soluble metal content in cosmetic products. It is the conviction of Asthma Allergy Nordic that the requirement based on the total-content of the metals, is the only right choice, when it comes to protecting consumers.

As to the limit value, it is not possible to set requirements where all allergic people avoid discomforts, but literature shows that a limit of 1 ppm total-content for each of the metals is a sensible limit. Asthma Allergy Nordic has been in dialogue with leading Scandinavian and international experts within this area, and they support this limit. It is pointed out by the experts that there is no exact limit, but 1 ppm is both sensible and reasonable, when the criteria aims to protect sensitive individuals. [Thyssen 2017], [Lidén 2017], [Basketter 2017].

Can any products meet the requirements?

Asthma Allergy Nordic has included in the work with the criteria an assessment whether any products currently on the market may fulfil the criteria set for metals. This information was solely with the purpose of advising clients and give a sense of applicability – not to find the level of requirement. The assessment was based on laboratory tests of approx. 50 products on the Danish market – both international brands, popular brands and brands marketing themselves as skin/health/allergy friendly. Approximately 30% of the tested products met the criteria for metals.

Also, the report from Technological Institute lists in tables different levels of the three metals found through studies. [Teknologisk 2016]. These levels are very widespread, but it also shows that some products contain less than 1 ppm of each of the metal.

The conclusion has therefore been, that though the requirement is strict, there are products currently on the market, that meet the criteria of 1 ppm per metal in the final product.

Appendix 5 – 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