Asthma-Allergy Denmark

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Background for Requirements for Labelling of Cosmetic Products with The Blue Label

This document states the background for the requirements set for cosmetic products. Cosmetic products include a long line of products types such as personal care, toothpaste, shaving foam, makeup and wet wipes.

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. The legislation (Cosmetics Regulation 1223/2009/EC) aims at making the products safe to use. In this context, it means that consumers may not develop contact dermatitis by using cosmetics. Besides, contact allergy is in a regular context, considered as an individual problem and as such not entirely included in the regulatory framework. The Blue Label 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 allergic reaction to the skin is minimised.

At present, the Blue Label does not include requirements on packaging, only to the cosmetic product itself.

The definition of allergenic substances

The Blue Label requires that no substances in direct contact with the skin, may be regarded as sensitizing. To assess whether a substance is considered an allergen, the following is taken into consideration:

- Are the substances classified as sensitizers?
- Is there other documentation presented to prove the substances' potential to sensitize the skin? This could be the case if…:
    - There may be published several articles on cases where allergic reactions have been reported over a period of time 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 standard test series
    - There may be a constant number of consumers having a positive reaction when tested (as a rule of thumb 2% of the subjects tested having positive reaction towards the substance)

The definition on whether a substance is sensitizing or not is not complete, and grey zones may arise. In such cases, Asthma-Allergy Denmark will consult data and assessments with a network of dermatologists such as experts from the National Allergy Research Centre, the University of Southern Denmark and foreign 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 and consumers who want to be extra careful. At the same time Asthma-Allergy Denmark acknowledge that not all people will be guaranteed not to have an allergic reaction to any given product. It is important to emphasize that even though a substance is not considered to be an allergen, there may be consumers that are 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 a statement. When choosing a laboratory, a test method and detection limits – and interpretation of the results; the choices influence the outcome of the test.

Asthma-Allergy Denmark can be of assistance with guidance and dialogue both on choice of test and detection limits as well as interpretation of test results and dialogue with the laboratories. Please, contact us early in the process, so that we might help provide the necessary documentation.

In the near future, the *Retailers & Manufacturers Portal* will provide a list of laboratories, that has indicated that they may provide the service of testing according to the requirements in these criteria.

Which Products May Be Labelled?

Products comprised by these criteria are cosmetic products as defined in the Cosmetics Regulation (1223/2009/EC) and similar product 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).

The reason why these products may be labelled with The Blue Label is that although the Cosmetics Regulation requires all products must be safe to use, this safety primarily focus on the development of allergic contact dermatitis (induction) and do not equally focus on allergic reactions in individuals already sensitized (elicitation). Also, contact allergy is in the context of regulation, considered as an individual problem, and as such not included in the regulatory framework.

Products intended to be used on animals are not included in the Cosmetics Regulation but is considered a chemical product under the CLP Regulation (1272/2008/EC) and 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 contact dermatitis and having allergic reactions to the

products, when the products are applied to the animals, Asthma-Allergy Denmark finds it relevant that these products may obtain The Blue Label. The risk of allergy in the animals is not considered when assessing the products.

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

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 is regulated by 1046/2002/EEC and the Danish Executive Order 1264 of 15 December 2008.

Hand disinfectants is a product group laying in a grey area between different legislations. The active substance itself, i.e. the substance giving the product its disinfecting properties, will be regulated under the Biocide Regulation (528/2012/EC) as soon as it is approved according to the regulation. Products approved under the Biocide regulation will not be eligible for The Blue Label. But, as there can be a period where the active substances are not yet approved under the Biocide Regulation, hand disinfectants may be labelled with The Blue Label until an approval is decided. The reason for labelling these products with The Blue label is, that they may contain substances that may cause allergic reactions to the skin. In addition, the products may have a drying effect on the skin, and The Blue Label sets requirements to counter this effect in the products.

Information on Product Composition (requirement 1)

To make a risk assessment of the product regarding allergy, Asthma-Allergy Denmark needs the full composition of the product. The reason for this is that even very small amounts of a given substance may cause allergic contact dermatitis.

The requirement also includes the wipe material in wet wipes and the process chemicals used in the production process of the wipe (see requirement 4).

Documentation for this is a full formulation of the product including all ingoing substances (see definitions below). The formulation must have the following information included: trade name of the product, formulation no. (if applicable), trade name of raw material, INCI, cas-no., active amount of the substance in the final product and function of each raw material. Furthermore, 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.

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 name under which a given raw material is sold from the producer 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.

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 of groups of substances has 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 substance/amount is all the substances in a raw material or product excluding water.

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 amount of a substance may cause allergic reactions to the skin in consumers with allergic contact dermatitis 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 The Blue Label. 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, since impurities are also part of the assessment regarding the risk of allergic reactions, see more of this under req. 2. Impurities are not required to be declared on the product.

Specifically Limited or Excluded Substances (requirement 2)

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, but perfectly legal products may still contain substances classified as sensitizing, if the substances are deemed safe to use. This is because, in legal context, contact allergy is regarded as an individual problem, and as such not included in the regulatory framework. Since the aim with The Blue Label not only is to 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 The Blue Label is excluded entirely – regardless of concentration. This requirement includes all substances. The reasons are also valid for products not comprised by the Cosmetics Regulation.

This is documented by the product formulation and safety data sheets for the raw materials/substances.

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). 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 eye irritating potential exists, may be present in the final product in limited amounts. How large a fraction of classified substances that may be present is assessed on the composition of irritants in the product as well as other substances that may in- or decrease the irritancy potential, combined with the area of use of the product and the duration of use.

If the amount of irritating substances in the product is higher than may be directly accepted, a test may be performed to show, that the product is not irritating to eyes or skin. The test may be part of ECVAM's validation program (e.g. HET-CAM and RBC) or test commonly accepted (e.g. Zein), if the test has not been specifically dismissed by ECVAM, SCCS or other scientific committees or bodies. The test conclusion must be provided. If the conclusion gives rise to any questions, the entire report may be requested.

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.

Fragrance

Fragrance is not accepted in products labelled with The Blue Label, and this also applies to cosmetics. Fragrance is not allowed since it is generally problematic in relation to contact allergy. 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.

This is documented by the product formulation.

Colorants

Colorants is not accepted in products with The Blue Label. This is because colorants are not regarded as essential for the function of the product on the body.

Exempted from this is decorative cosmetics (makeup), where colorants are essential for the function of the cosmetic product, see req. 5 for requirements on makeup.

This is documented by the product formulation.

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 made by Asthma-Allergy Denmark, when it is decided that the raw material may be accepted in products with The Blue Label. 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 Denmark 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 may 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 Denmark assess the raw materials and based on this 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 or purify the raw material (fully or partly), 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. For these raw materials, documentation must be provided, that the requirements are met continuously once a year, unless the raw material is certified and found in 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

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 The Blue Label 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 described in Kemilex.

Formaldehyde is a special case. Formaldehyde 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 classified as sensitizing to skin (H317) and formaldehyde is present in the product intentionally and with a purpose. Here formaldehyde is not an impurity. But 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.

Natural Ingredients (requirement 3)

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 Denmark 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 Denmark 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.

Asthma-Allergy Denmark is currently working on a note on this issue and more details on the requirements will be presented.

Wet Wipes (requirement 4)

Lotion in the wet wipe must fulfil the requirements in this document. Besides this, the composition of the wipes material must be stated.

Wood-based Wipes

If the wipe consists of wood-based raw materials, the species of wood must be stated. If the species is all or partly conifer, the pulp must meet the requirements for colophonium (see below). Further, it must be

stated which process chemicals have been used in the production of the pulp from the wash and bleaching and forward. The reason why the process chemicals from the production of the wipe material must be stated is, that there have been cases when residues of these chemicals have been found in the final product in amounts high enough to cause allergic contact dermatitis in consumers already sensitized to these substances. This requirement applies to all chemicals used in the production including process water (e.g. preservatives) and auxiliaries (e.g. chemicals used in the yankee-cylinder).

Colophonium

Colophonium is not allowed in cosmetic products labelled with The Blue Label. This also applies for the wipe material. Colophonium is a complex mixture of substances found in resin from conifers. This means that products containing raw materials made from conifers will have small amounts of colophonium present. However, since we assess it possible to protect most consumers allergic to colophonium by setting strict requirements to the level of colophonium present in the final product, colophonium is allowed in wood-based raw materials. To ensure as low a content of colophonium in the products as possible, the content must be tested by gas chromatography or another laboratory test by measuring the markers: abietic acid, dehydroabietic acid and 7-oxodehydroabietic acid, and none of these substances may be found in the raw material in amount above 5 ppm. The test must be made on three different batches. It is always the responsibility of the applicant, that the requirements are met, and Asthma-Allergy Denmark may always ask for documentation for compliance with the requirement – including time after the award of the approval. 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) it will only be necessary with test of one batch.

The requirement must be documented by a test report showing the content of the marker substances measured by gas chromatography or corresponding laboratory test on three different batches (at the time of approval).

Products, where only wood from other species than conifers are used, are exempted to document this requirement by testing.

Synthetic Wipes

If the wipe materials consist of synthetic materials, it must be stated which fibres and which production process has been used as well as which process chemicals have been used in the production. The reason that the process chemicals from the production of the wipe material must be stated is, that there have been cases when residues of these chemicals have been found in the final product in amounts high enough to cause allergic contact dermatitis in consumers already sensitized to these substances. This requirement applies to all chemicals used in the production including chemicals in the process water (e.g. preservatives) and auxiliaries (e.g. spin finish on the fibres).

Makeup (requirement 5)

Decorative cosmetics (makeup) are exempted requirement 2 regarding colorants, since the use of colorants serve an essential purpose for the product function on the body in these product types.

Which substances should be considered?

During the task of making criteria for makeup, Asthma-Allergy Denmark has reviewed literature and have had a dialogue with Danish and international experts in the field. 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.

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.

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*."

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*". 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 colorant 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 should the limit be set at?

In the work of setting limits for the three metals, it has been considered, that the aim for the allergy-label The Blue Label 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 product, which means that consumers cannot make informed choices not the be exposed to these substances.

When setting the limits, it must be assessed what the consumers are actually exposed to – called the *bio-available amount* (or content). Knowledge on, what is bio-availability, 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 the substances, that are allergens. In this context it means looking at the total

content of the metals is the precautionary approach and most sensible solution when protecting the consumers with allergy.

On top of this, Asthma-Allergy Denmark 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. They point out that the test methods for seat-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 seat-soluble metal content in cosmetic products. Asthma-Allergy Denmark feels, that the requirement based on the total-content of the metals, is the only right choice, when it comes to protecting the consumers.

As to the limit value, it is not possible to set requirements, where all allergic people avoids discomforts, but literature shows that a limit of 1 ppm total-content for each of the metal is a sensible limit. Asthma-Allergy Denmark has been in dialogue with leading Danish 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.

May any products meet the requirements?

Asthma-Allergy Denmark 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 popular brands and brand 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. These levels are very widespread, but it also shows that some products contains 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.

Summary and requirement level

On basis on the background described above and the knowledge collected during this work, Asthma-Allergy Denmark has decided that the requirement at 1 ppm total-content per metal (Ni, Co, Cr) is the right limit for the allergy-label The Blue Label, 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 color variants that shall be approved. The test must be made on 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, that will confirm the level of metals in the products. It is always the responsibility of the applicant, that the requirements are met, and Asthma-Allergy Denmark may always ask for documentation for compliance with the requirement – including time after the award of the approval. 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) it will only be necessary with test of one batch.

Alternatively, it is possible to test all pigments (colors and color-effect substances) used in the products, meaning that there must be test results for all metal and all pigments. In addition, there must be provided a calculation showing compliance for each final product with the limits for metals. Finally, one test of a finished product must be provided for substantiation of the calculated results. This final step is required to ensure that there is no systematic error when calculating the metal content in the final products on the basis of tests made on the raw materials.

Same requirements regarding number of tests and continuous documentation applies to pigments as to the final products (see above). This means, that the content of metals in the pigments must be made on three different batches and that the requirement may show compliance at any time, see section above.

Hand Disinfectants and Degreasing Products (requirement 6)

Hand disinfectants and degreasing products contain high amounts of substances that makes the skin dry. To counteract this effect and thus minimise skin irritation it is required, that there in the product is added substances to counteract this effect. It must be clearly stated from the product formulation which substances are added to give skin conditioning effect. An example of this could be glycerine added to a hand disinfectant as skin conditioner/humectant.

Note, only products not regulated by the Biocide Regulation (528/2012/EC) may be labelled with The Blue Label.

This is documented by the product formulation.

Spray (requirement 7)

Spray products may cause increased irritation of the respiratory tract and may cause discomfort for consumers with asthma or consumers with a sensitive respiratory system. Therefore, it is important that products that are dispensed by aerosols or by pump has a particle size that prevents the product from reach the deeper parts of the lungs.

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 pump dispenser, and therefore Asthma-Allergy Denmark allows spray products as long as 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.

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.

Products dispensed by aerosols or pump will to an extent be inhalable and hence would be able to cause discomfort for consumers with sensitive respiratory system. Despite requirements to both the product composition and the particle size of the dispensed product, some consumers might experience discomfort by using spray products. Since the choice of packaging and dispensing system is an active choice for the consumers, such products may be deselected by sensitive consumers, who do not want this exposure of their respiratory system.

Generally speaking, pump sprays generate larger particles than aerosolized 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 Denmark. Asthma-Allergy Denmark may at any time ask for documentation that the requirement is fulfilled and may at all times make external controls to see if the requirement is met.

Aerosolized products may be accepted, if the aerodynamic diameter of the particles is larger than 10 µm.

Documentation for this must be a laboratory test conducted at 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 95% of the particles of the product according to the test.

Note, only products that will be dispensed by pump/aerosols to form airborne particles is included in this requirement. Products that by pump or spray dispenses as e.g. lotion, cream, foam or mousse, is not included, but will be accepted without further documentation.

Artwork/label (requirement 8)

The use of Asthma-Allergy Denmark's logo, The Blue Label, is subject to the requirements of the Logo manual. Artwork/label must be presented so correct usage may be verified.

Besides this, a full and unambiguous declaration of all ingoing substance (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 colorants may *not* be used, but the specific colorants must be found on the relevant product.

The requirement is set to ensure, that the consumers always may see precisely what is in the product and should a case of irritation or an allergic reaction to the skin occur towards a substance in the product, this may help increase the chance of identifying the substance, when the precise declaration is present. Asthma-Allergy Denmark 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 on making an informed choice at the time of purchase.
2. It provides the consumer the possibility of identifying substances towards which they have an allergic reaction to the skin, should such a situation arise.

With regards to point 1, then 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 Denmark 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 may not have doubts as to which declaration is relevant for the actual product.

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

Areas of Interest Not Included in the Criteria

Packaging could potentially be of interest but is not currently regarded as part of the product. The consumer contact with the packaging will in most cases be short-term and limited compared to the use of the actual product. Should problems with the packaging arise this may be included in a revision of the criteria.

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