Asthma-Allergy Denmark

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The Blue Label Criteria for Cosmetic Products

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. 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.

With *The Blue Label* on cosmetics you get:

- No fragrance
- No colorants (makeup exempted)
- Full declaration on the product (including makeup)

Which Products May Be Labelled?

Products comprised by these criteria are cosmetic products as defined in the Cosmetics Regulation (1223/2009/EC) and similar products intended to use on animals, wet wipes and some types of medical equipment (non-invasive equipment), which are in composition and use comparable with cosmetics.

Requirement 1 – Information on Product Composition

The full composition of the product must be provided. The full formulation must state the trade names 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.

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

Ingoing substance *defined as all substances present in the product in the form of active substances and auxiliaries, solvents and the like, but not contaminants and impurities in the raw materials. There is no lower limit as to where a substance is regarded as ingoing.*

Auxiliaries *and solvents are regarded as* ***ingoing substances****.*

***Impurities** is 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. Impurities are not subject to declaration, cf. req. 8.*

Documentation: Full formulation stating the information mentioned in the requirement. Safety datasheet and technical datasheet for the raw materials must be provided upon request. Datasheet must always be provided for raw materials for which there are requirement of purification according to Kemilex.

Requirement 2 – Specifically excluded or limited substances

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 amount where the finished product causes irritation to the skin, eyes or respiratory tract.
D. Fragrance may not be part of the product or raw materials.
E. Colorants may to be part of the product or raw materials.
    a. *Exemption*: colorants 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 – Natural Ingredients

Raw materials of natural origin may be used in products labelled with The Blue Label. The raw materials are assessed and based on the assessment the raw materials are placed in categories and the use may be limited. Asthma-Allergy Denmark is currently working on a note handling this issue in detail and requirements to the raw materials will be presented.

Requirement 4 – Wet Wipes

Lotion in the wet wipes must meet the requirements in this document. Besides this, the wipe material must be stated, and the wipe must meet the requirement below. Process chemicals and auxiliaries in contact with the wipe material and that may be found in the final product must also meet the requirement in this document.

A. Wood-based Wipes
   It must be stated, which species of wood have been used for the wipe, as well as the process chemicals used in the production of the wipe, from washing and bleaching. All chemicals in contact with the final wipe must be stated including preservatives and auxiliaries (e.g. yankee-cylinder chemicals).
   If wood fibres from conifers are used, it must be documented that the amount of colophonium in the wipe is below 5 ppm for each of the marker substances: abietic acid, dehydroabietic acid and 7-oxodehydroabietic acid.
B. Synthetic Wipes
   It must be stated, which fibres are used for the wipe and it must be stated, which process chemicals are used in the production of the wipe. All chemicals in contact with the wipe must be stated including chemicals used in process water (e.g. preservatives) and auxiliaries (e.g. spin finish on the fibres).

Documentation: Full formulation cf. req. 1. In addition, a description of the production of the wipe must be provided and it must contain information about the wipe material (fibres/wood species) and which chemicals are used. It must be clearly stated, where in the process each chemical is used. For wood-based wipes made from conifers, a test report must be provided showing the amount of the colophonium markers measured by gas chromatography or another relevant laboratory test and where the detection limit is appropriate compared to the requirement. The requirement must be documented continuously (see background document for definition).

Requirement 5 – Makeup

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 color-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. ***Alternatively***, a laboratory test may establish the level of metals in each pigment raw material (colorants and color-effect substances) and on basis of this the amount of metals may be calculated in the final product. To eliminate systematic errors, such calculation must be supported by test of one final product.

Requirement 6 – Hand Disinfectants and Degreasing Products

The product 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.

Requirement 7 – Spray

Spray products must have an aerodynamic diameter larger than 10 µm.

Note, the requirement only applies for product, that are dispensed in a mist – not products that is dispensed as lotion, cream, foam, mousse or the like.

Documentation: Documentation must only be provided if the product is using aerosols. 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 95% of the dispersed particles. Documentation is not required for products using pump sprays; the requirement must, however, still be fulfilled at all times for all products.

Requirement 8 – Artwork/label

Artwork/label must be approved. Asthma-Allergy Denmark's allergy label, The Blue Label, must be designed in accordance with the guidelines in the logo manual.

There must be a full and unambiguous declaration containing all ingoing substances on the primary packaging of the products (see background document for dispensation option). By unambiguous declaration is meant that the symbol "±" may not be used in the declaration, but the specific colorants for the specific product must be stated.

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

Documentation: Artwork/label.