Asthma-Allergy Denmark

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Background for Requirements for Labelling of Hygiene and Tissue Products with The Blue Label

This document describes the background for the requirements set for the product categories hygiene and tissue products. This includes diapers, sanitary towels, panty liners, sanitary pads, plaster, kitchen towels, toilet paper and similar products intended to be in contact with the skin and where the purpose is to absorb and contain or enclose fluids or the like.

The Blue Label requires that no substance in direct contact to the skin may be considered sensitizing. This applies for both substances classified as sensitizing and substances where other kinds of documentation imply allergenic properties. This means that scientific articles or literature may be cause of a decision to consider a substance sensitizing. It may be done in several ways:

- More than one article reporting of cases where allergic reaction has been observed over a period of time and where the cases have clinical relevance
- Epidemics where lots of cases are reported over a short period of time to an identified substance
- Substances where dermatologists encounter several reactions towards the substance and where the number of cases are assumed to be higher than reported because the substance not is a part of the test series
- A steady number of cases where patients have positive reactions when tested (rule-of-thumb 2% of the tested patients have positive reactions towards the substance combined with clinical relevance)

The definition of whether a substance is considered sensitizing or not is not well-defined and borderline cases will appear. I such cases Asthma-Allergy Denmark will discuss the matter at hand with a network of specialists such as dermatologists from the Danish National Allergy Research Centre, University of Southern Denmark and international dermatologists with expert knowledge on the substance/case in question. The overall principle for The Blue Label is a cautious approach when assessing substances balancing between protecting patients with contact allergy and people who wishes to be cautious and at the same time knowing that some very sensitive people might still have allergic reactions from the labelled products. It is important to emphasize that even though a substance is not considered sensitizing, some people might be allergic to the particular substance and might have allergic reactions to the amounts used in the products.

The reason for having criteria for these types of products is that the products are in direct contact with the skin and because some products on the market contains substances that may be problematic when it comes to contact allergy when used often or over longer periods of time. Here a special concern would be fragrances and preservatives, but it could also be other allergens such as rosin (colophony).

The products foam washcloths, cotton and cotton pads differentiate from the other products in this product group by not being paper-based. The reason for including these products is that their function falls within the scope of the product group since they are sued for washing and cleaning the skin. Foam washcloths, cotton and cotton pads may be used as alternatives to products that are potentially more problematic with regards to allergy.

At present, The Blue Label do not set requirements as to product packaging.

Which Products Can Be Labelled?

The product group includes diapers, sanitary towels, panty liners, sanitary pads, plaster, kitchen towels, toilet paper and similar products intended for direct skin contact and where the purpose is to absorb and contain or enclose fluids or the like. This means that incontinence products, disposable change mats, tissue handkerchiefs, paper napkins, dry wipes, foam washcloths, cotton and cotton pads are also included in the criteria.

Information on Product Composition (requirement 1)

In order to be able to make an assessment of the final product, Asthma-Allergy Denmark need access to the full composition of the product as well as any process chemicals that may be present in the final product. This is because even small amount of a given substance may cause contact allergy, and this is especially true for people who are already sensitized towards the substance. The information will not be used for public declaration but solely for the purpose of assessing the product. Obtaining this information may be difficult for the producers since the suppliers regard this information confidential. Suppliers may send the information directly to Asthma-Allergy Denmark and, if necessary, a confidentiality agreement will be signed with the suppliers and sub-suppliers. Asthma-Allergy Denmark may help collect the required information, it is, however, always the responsibility of the applicant to make sure all the necessary information is provided for assessment.

Documentation requirements are the full composition of the product stating all ingoing substances by chemical name/INCI or name of raw material as well as cas-no., amount and function. Raw materials may be given by their trade names if the supplier provides the needed information directly to Asthma-Allergy Denmark. Ingoing substance is defined as: all substances in the product or raw material regardless of amount. To give a full overview of the product a composition drawing or schematics must be provided and all components must be identified on a schematic drawing or the like – preferably with reference to the composition list – and a description of where in the processes chemicals may be used and which chemicals are used where.

Non-woven, Fluff and Pulp (requirement 2)

Asthma-Allergy Denmark must know the composition of the raw material. This means that it must be stated which substances are used for the raw material (non-woven) or which species of wood the raw material consists of (fluff/pulp).

Since some process chemicals from the manufacture of non-woven, fluff and pulp may be found in the finished raw material and/or product, it must be stated which chemicals are used in the production of the raw material. These chemicals/substances will be assessed as ingoing substances in the final product, if the assessment concludes that the substance may be present in the final product (cf. requirement 3).

Specifically, it must be stated whether or not process water that comes in contact with the raw material is used , and, if this is the case, which chemicals are added to the process water – including biocides added to the process water or spin finished used on the fibres.

Documentation requirements are a description of the production process together with list of the substances the raw material consists of as well as the process chemicals used in the production of the raw material with chemical name/INCI, cas-no. and amount. If wood-based fibres are used, the species of wood must be stated and the requirements on colophonium must be met (cf. requirement 3).

Specifically excluded substances (requirement 3)

Some substances in these types of products may be problematic in regards to contact allergy. Per definition these are not allowed in products with The Blue Label, but for contaminants it is possible to make a specific assessment where exposure and amounts are taken into consideration. An example could be a component in a raw material, which contains a preservative that is considered an allergen. The function of the preservative is solely to preserve the component of the raw material until it is used in the production of said raw material, and the preservative will therefore no longer be present in the final product. In this case the preservative is regarded as not present in the final product even though it has been used at some point in the production process. Also, in the case of an allergenic substance in a auxiliary chemical used in the production, but it would be assessed that this substance would not be found in the final product, the process chemical may be accepted regardless of the content of an allergen in the production process.

Substances classified sensitizing to skin, H317

Substances classified sensitized to skin (H317) may not be part of products certified by Asthma-Allergy Denmark. This includes all ingoing substances (see introduction to requirement 3). This is documented by providing a full composition list and safety data sheets for the substances/raw materials used.

Substances where alternate evidence of contact allergenic potential exists

Some substances are considered by dermatologists to be sensitizing to skin despite the lack of a harmonized classification as such. These substances will be evaluated in the same way as classified substances (see above).

Colophonium

Colophonium is a complex mixture of substances found in softwood (conifers such as pine, spruce and larch). Colophonium is allergenic and may therefore not be added to the product or raw materials.

Since a requirement that fully exclude the use of softwood probably would result in a dramatic decrease of paper products able to be certified; and since we expect the requirements to protect most colophonium allergic patients with our limitation of colophonium, wood from conifers are allowed in certified products. Colophonium as an unavoidable part of wood-based raw materials is accepted if the amount of colophonium is kept to a minimum. This means that products containing wood from conifers must document the content of colophonium by gas chromatography, or equivalent laboratory test, measuring the colophonium markers: abietic acid, dehydroabietic acid and 7-oxodehydroabietic acid. None of these substances may be found in the raw material (fluff/pulp) in amounts exceeding 5 ppm. The test must be made on three different batches and should be documented continuously. Products based entirely on other species of wood do not need to document this requirement. If more than one wood-based raw materials are components in the final product, each raw material must meet the requirement.

Fragrance

Fragrance is not accepted in products with The Blue Label. This also applies to this product group. This is documented by a full composition list (as described under requirement 1).

Lotion, ointment, cream etc.

Some products within this product group have the addition of cosmetic product such as lotion ointment, cream or the like. Generally speaking, should cosmetics only be used when necessary. A cosmetic product in e.g. diapers or nursing pads provides exposure to that cosmetic product 24 hours a day and in areas where the need for the product may not always be present. The products on the market today are so efficient that they do not feel wet against the skin. Because of this, cosmetic products are not accepted as part of the product. This is documented by a full composition list (as described under requirement 1).

Colourants (requirement 4)

Print is not accepted in hygiene and tissue products as they do not have an essential function in products.

In diapers, print may have a practical function in products. For example, print on the exterior may tell the user which size the diaper is and it helps differentiate between back and front. Therefore, print is only

allowed on the exterior of diapers. Printing ink is regarded as an ingoing substance and must fulfil the requirements in the criteria.

Prints necessary for production process are allowed if they are minimized and the arguments are valid.

This is documented by the full composition list and safety data sheets for the substances/raw materials used. Print must be clearly marked on the schematic drawing of the product. Alternatively, send a product sample or a picture of the product.

Control of Artwork (requirement 5)

The use of The Blue Label is subject to the rules laid out in Asthma-Allergy Denmark's logo manual. Artwork/label/packaging must be provided for control of the use of logo. In addition, control of claims regarding contact allergy will be done.

Ares 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's 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.

References

Colophonium Note, Asthma-Allergy Denmark, December 2016

Logo Manual, Asthma-Allergy Denmark