OCTOBER 2024

BACKGROUND AND REQUIREMENTS

BEDDING – VERSION 1.0

ASTHMA ALLERGY NORDIC

Asthma Allergy Nordic

October 2024, version 1.0

Content

Background and Requirements for Labelling of Bedding with Asthma Allergy Nordic

This document describes the background and requirements for the product category Bedding. 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 to the product type must be met in order to be recommended by Asthma Allergy Nordic. Products must always fulfil the regulatory requirements governing the market in 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 for having criteria for these types of products is that the products can affect consumers who have skin allergy. Some products on the market can contain chemicals that cause discomfort for respiratory sensitive individuals as well. A special concern would be materials from feathers such as dust and sand, but it could also be fragrances and preservatives used in bedding products.

Chemicals and substances used in beddings must comply with national regulations. Hence, it is the responsibility of the applicant to ensure compliance with the applicable national regulation. However, the specifics of the national regulations are often not enough to prevent people with allergies from having allergic reactions to products on the market. Asthma Allergy Nordic wish to add to this aspect with these criteria.

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

With *Asthma Allergy Nordic label* on the product, you will get:

- Minimal risk of allergic skin reactions
- Focus on minimising nuisances in sensitive airways
- Minimised dust and sand from feathers
- No fragrance or sensitizing preservatives

Compliance

It is always the responsibility of the applicant that the requirements in this document are continuously met. Asthma Allergy Nordic can request documentation for compliance with the requirements at any time – including the time after the approval of the product. The approval of product only covers raw materials evaluated by Asthma Allergy Nordic. Hence, any changes in raw materials in the supply chain must be evaluated by Asthma Allergy Nordic to maintain the certification of the product.

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 or component.

To assess whether a substance is considered an allergen, the following is taken into consideration:

- Is the substance harmonised classified as a skin sensitizer according to the EU CLP Regulation [1272/2008/EC]?
- Is there other documentation presented to establish the potential of the substance to sensitize the skin and/or mucous membranes? This could be the case if…:
    - There may be published cases in which allergic reactions have been reported over a period and where the clinical relevance has been established.
    - There may be epidemics of allergic reactions towards a specific substance reported with a lot of cases over a short period of time.
    - There may be specific substances to which dermatologists experience allergic reactions in consumers, and it may be 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 percentage of consumers having a positive allergic reaction towards a specific substance when tested. However, this will be considered in relation to the usage of the substance both in terms of amounts and groups of consumers.
    - The substance is notified through the European Chemicals Agency (ECHA) with classification as a skin sensitiser by several notifiers.

The above bullets will often – except for a harmonised classification – have to be evaluated under more than one point to confirm the conclusion of the assessment.

How to establish whether a substance is sensitising or not is not well-defined and grey areas may arise. In such cases, Asthma Allergy Nordic will consult our network of experts from the Nordic countries and international dermatologists with expertise within the field. The baseline in the assessment of substances will be cautious to protect the majority of consumers with contact allergy or respiratory issues and also to help consumers who want to be extra careful. At the same time, Asthma Allergy Nordic acknowledges 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 minority that is/might be allergic to the substance and may have an allergic reaction towards this.

Analysis: Methods and Results

There is focus on 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 can be of help providing the necessary documentation. Contact information may be found on the Asthma Allergy Nordic website [AAN website].

The *Information Portal* provides a list of laboratories that have indicated that they may provide the service of testing according to the requirements in these criteria [AAN IP]. 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. The list can also be provided by direct contact to Asthma Allergy Nordic by email.

We recommend that you do not test your product until you have had the composition assessed by Asthma Allergy Nordic, as we often discover some hidden ingredients in the raw materials that may affect the outcome of the assessment.

Which Products May Be Labelled?

The product category "Bedding" in these criteria includes duvets, pillows, comforters, sleeping bags, baby sleeping bags, stroller bags, mattress pads, mattress toppers and similar products with stuffing intended for a sleeping environment.

Products not Included in the Product Group

Products that fall under other criteria from Asthma Allergy Nordic, e.g., bed linen that are included in the criteria for textiles, are not included in these criteria.

Components made of latex are not included in these criteria since allergy towards natural rubber latex are well documented and latex is known to contain substances that might promote allergic reactions. In bedding products, latex may be used in mattress pads, mattress toppers, and products not specifically mentioned, but containing latex.

Furthermore, components made of wool with direct exposure to skin are not included in these criteria since wool is known to be itchy and can irritate the skin which especially is unpleasant on sensitive and eczema skin. Even though this is not caused by an allergic reaction it is still something that Asthma Allergy Nordic acknowledge as problematic for the target group. The itching is entirely a mechanic reaction caused by a large diameter of the wool fibres and not because wool fibres contain substances that irritate skin.

Asthma Allergy Nordic is aware, that it is possible to use wool that has a smaller diameter of the fibres, or that has a polymer coating, and therefore is less irritating. However, it is difficult to graduate how itchy fibres can be before they irritate skin, and furthermore people have different, subjective preference for what they like. Because of this, wool is not included in the criteria except where no exposure to consumers can be expected.

Criterion 1 – Product Composition

To be able to assess the final product, Asthma Allergy Nordic needs 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 a 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 assessing the product. Obtaining this information may be difficult for the producers since the suppliers regard this information as confidential. Suppliers may send the information directly to Asthma Allergy Nordic and, if necessary, a confidentiality agreement will be signed with the suppliers and sub-suppliers. Asthma Allergy Nordic may help collect the required information; however, it is always the responsibility of the applicant to make sure all the necessary information is provided for the assessment and that this information is the correct information relating to the product application.

Requirement 1

The full composition of the product must be disclosed including all components (fabrics, threads, zippers, buttons, hangtags, foam, fillings etc.). All raw materials and process chemicals used for each single component (auxiliaries, dyes, pigments, tackifiers, finishing agents etc.) must also be disclosed. Each component/raw material must be stated with all ingoing substances* (Trade name, CAS-no., amount, and function).

*Ingoing substances or raw materials are defined as all substances or raw materials in the product/component stated down to 0.1 ppm.

***Documentation*:** Composition of the product containing information and all ingoing substances, raw materials, and components stating trade name, chemical name, CAS-no., amount, and function. Components may be stated with trade names only, provided the composition is disclosed by the supplier. It is the responsibility of the applicant that the suppliers provide the necessary information on the requested component and/or raw material to Asthma Allergy Nordic.

Trade name is the name under which the product/components/raw materials are sold to the consumers. The trade name can often be found in the invoice from the manufacturing company, or on the packaging on the product.

Chemical name is the identification of the substances according to IUPAC nomenclature. IUPAC is an abbreviation for International Union of Pure and Applied Chemistry, and it has a standardized nomenclature for naming chemical substances.

CAS-no. is an abbreviation for *Chemical Abstract Service* number and is a way of identifying substances. CAS-no. should be a unique identifier for a substance, but this is not always the case. Some substances or groups of substances have multiple CAS-no. and some CAS-no. covers multiple substances. In many cases, CAS-no. does help identifying substances and must therefore be stated on the formulation to avoid misinterpretations.

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. Note, a substance is not considered to be present if the amount of the substance is below 0.1 ppm in the final product or component.

Raw material is defined as a single substance or a mixture of several ingoing substances. It can either be solutions or materials such as fibres. Multiple raw materials together will form the basis of a component.

Component is the final fabric, thread, button, zipper, hangtag, etc. ready to use in production. The final consumer product is created from multiple components.

Auxiliaries, solvents, tackifiers, and finishing agents are considered as ingoing substances since they may vary from raw material to raw material and hence is unique to the individual raw material.

Impurities are not considered as an ingoing substance *per se* 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 of substances and their inherent risk of allergic reactions, see more of this under req. 2 A and B.

Process chemicals are substances or mixtures used in the production process, but not part of the components of the final product as such. Process chemicals are in contact with the components or the final product and may therefore leave traces of substances behind on the final product. Since process chemicals have been known to cause allergic reactions from residuals alone, it is important to include these in the assessment of the product, and hence, process chemicals must be disclosed along with the other information needed for the assessment.

Criterion 2 – Specifically Excluded Substances

Some substances in textiles may be problematic regarding contact allergy. Per definition, these are not allowed in products with Asthma Allergy Nordic, but for contaminants, it is possible to make a specific assessment where exposure and amounts are taken into consideration. Allergenic substances may be used somewhere in the supply chain or as a production chemical if it is not present in the individual components of the final consumer product in amounts above the non-present limit of 0.1 ppm. An example could be a preservative in a raw material used as a process chemical, but it is diluted until it is non-present in the process water and hence non-present in the final product. Another example could be a substance that initiates a reaction in a production, which leaves the original substance “spent” and hence not present in the raw material and subsequently not present in the final product.

Substances Classified as Sensitizing to the Skin, H317

Substances with a harmonized classification as sensitizing to the skin (H317) may not be part of products recommended by Asthma Allergy Nordic. This includes all ingoing substances (see the introduction to criterion 2). This is documented by providing a full composition list and – upon request – safety data sheets for the substances/raw materials used.

Substances Where Alternative 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 are considered in the same way as substances with a harmonized classification (see above). Another way for a substance to qualify under this definition, would be 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 takes time and the knowledge of the effects of the substances may be generally accepted a long time before the harmonization of classification. Also see the definition of allergenic substances in the beginning of the document.

Perfume/Fragrance

Perfume/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. Therefore, fragrance may not be part of the product or raw material. Perfumes/fragrances are not commonly known to be used in bedding; however, it can be used to mask any unwanted smell from production chemicals. It is very important to emphasize this point, and also point out that essential oils will often be considered fragrances themselves as they normally contain high amounts of fragrance substances. Essential oils will therefore be assessed under this requirement along with traditional synthetic fragrances.

It is a challenge to all that there is no generally accepted definition of perfume/fragrance. The intention of this requirement is, that the manufacturer must actively address this issue, and that the product must not contain any substances that are considered as fragrances. This will also mean that the fragrances mentioned in the SCCS opinion SCCS/1459/11, but not exclusively, are not allowed in the final product (SCCS, 2011).

Requirement 2

A. Substances classified as sensitizing to the skin (H317) may not be part of the product, raw material, or component.
B. Substances where evidence of sensitizing potential exist without the substances being classified may not be part of the product, raw material, or component.
C. Fragrance, scent, or masking agents may not be used in the making of the bedding or raw material.

Ingoing substances or raw materials are defined as all substances or raw materials in the product/component stated down to 0.1 ppm.

Documentation: Same as requirement 1.

Criterion 3 – Fillings and Fibres

All relevant fillings in all products are included in the scope of the criteria. The fillings must be fully disclosed in the composition list of the raw materials used as described under req. 1.

Feathers and Downs

The type and origin of the feathers and down must be stated as part of the full composition under req. 1. Feathers and downs can contain foreign organic and inorganic materials, which can be a nuisance for people with asthma or sensitive airways. To ensure that the fillings contain a minimum of foreign organic and inorganic materials, Asthma Allergy Nordic requires that the filling has been tested with the standards EN 1162 for *oxygen number* and EN 1164 for *turbidity* [EN 1162], [EN 1164]. *Oxygen number* is a test that shows the content of foreign organic material, which can be small particles from the duck or goose. *Turbidity* shows the content of inorganic materials such as dust and sand.

Furthermore, the feathers and downs can be treated with chemicals. If this is the case, it must be stated in the composition which chemicals are used (cf. req. 1). These chemicals/substances will be assessed as ingoing substances in the final product.

Wool

Wool is known to be itchy and can irritate the skin which especially is unpleasant on sensitive and eczema skin. This is not caused by an allergic reaction but a mechanic reaction. Therefore, Asthma Allergy Nordic accepts wool as filling in bedding and textiles where no exposure to consumers can be expected. Any treatment and natural impurities of the wool must comply with requirement 1 and 2.

To ensure that the filling contain the minimum of foreign organic and inorganic materials, Asthma Allergy Nordic requires that the wool filling purity is equal to the purity of feathers and downs. This

evaluation will be based on a case-by-case assessment. Moreover, the content of lanolin and wool alcohols, which are known allergens, will be evaluated.

Any additives and process chemicals used in the manufacture of the wool filling must comply with req. 1 and 2.

Synthetic Fillings and Fibres

The polymer of which the synthetic fibres are made is considered a component of its own, and full composition of this must be provided under req. 1.

Synthetic fillings may be treated with chemicals during the production process. If this is the case, it must be stated in the composition which chemicals are used (cf. req. 1). These chemicals/substances will be assessed as ingoing substances in the final product.

Viscose and Other Cellulose-based Fibres

Asthma Allergy Nordic must know the composition of the raw material. This also means that it must be stated what kind of cellulose the raw fibres consist of. If the raw material is a conifer/softwood the amount of colophonium must be limited, and the requirement in Appendix 2 must be fulfilled.

Since some process chemicals from the manufacturing of viscose may be found in the finished raw material and/or component, it must be stated which chemicals are used in the production of the raw material/component. 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.

Polyester

It is well-known that some people have allergic reactions to polyester products, however, allergic reactions to the polyester fibres are not reported. Instead, the reactions are most likely caused by certain dyestuffs used when dyeing polyester. Some of these dyes – normally belonging to a group called disperse dyes – are known to cause allergic reactions (Carlsson et al., 2022), (lisi et al., 2014) (Malinauskiene et al., 2013). Polyester fibres are accepted if they fulfil the general requirements in criteria 1 and 2.

PUR

Polyurethan foam is based on isocyanates and polyols which are substances classified as sensitising. However, manufacturing of the foam ensures contents of such allergic substances are very low, and allergy cases towards PUR foams are infrequent.

If the final foam product is post processed, the used process chemicals must be disclosed.

Requirement 3

Fillings of feathers and downs must meet the following requirements for *oxygen number* and *turbidity*:

A. The *oxygen number* must be < 4.8 mg/100g

B. *Turbidity* must be > 1,000 mm

Purity of wool fillings must be equal to the purity of feathers and downs.

Viscose, and other cellulose-based fibres must state the origin of the fibres.

If wood-based fibres are used, the raw material/component/product must have a low content of colophonium markers; abietic acid, dehydroabietic acid and 7-oxodehydroabietic acid. The markers must not be present in the raw material/product in amounts exceeding 5 ppm each.

See requirements in Appendix 2.

If synthetic fillings and/or fibres are used it must be disclosed which process chemicals or auxiliaries that get into contact with the filling/fibre. A description of the process must be submitted identifying where the process chemicals are used.

Composition of the chemicals used during the process must be sent if the fillings are treated.

Documentation: For feathers and downs: Composition of the chemicals used during the process must be sent if the fillings are treated. Test report for EN 1162 (oxygen number) and EN 1164 (turbidity) must be provided. A description of the process, as well as a list of the substances the raw material/components consists of, together with a list of the process chemicals used in the production of the raw material, with chemical name/INCI, CAS-no. and amount.

Criterion 4 – Colourants

Colourants in textiles and beddings are generally known to be the cause of allergic skin reactions. Different dyes are used for different fibres. Disperse dyes used for dyeing synthetic fabrics such as polyester are known as the most frequent skin sensitisers in textiles allergic contact dermatitis [Hernández Fernández 2024].

Colourants, dyes, and printing inks can be used for products under this product group. Inks, dyes, and colourants used in the products are regarded as ingoing substances/mixtures and must fulfil the requirements set in criteria 1 and 2.

It must be clearly stated exactly where the colourants, dyes, and inks are used on the product with a schematic drawing, product sample, or picture.

Requirement 4

Colourants (dyes and pigments) and auxiliary chemicals in each single component of the bedding must be stated with all ingoing substances*, CAS-no., amount, and function.

**Ingoing substances or raw materials are defined as all substances or raw materials in the product/component stated down to 0.1 ppm.*

Documentation: Same as requirement 1 and 2. Print must be clearly marked on a schematic drawing of the product. Alternatively, a product sample or picture may be provided.

Criterion 5 – Natural Ingredients

Natural ingredients have been used to colour textiles for thousands of years, including textiles used in bedding. Natural ingredients may originate from plants, algae, or animals (e.g., snails) and can amongst others be found in form of extracts (e.g., from dried flowers, crushed bark, or fruit peels).

An increasing interest has developed in the potential use of natural plants as raw material to produce natural dyes for dyeing textiles used in bedding products due to concerns of both the external environmental and human health. The use of natural ingredients can be expected to rise (Baliarsingh et al., 2013).

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. 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. 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.

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.

The approval of natural ingredients relies on the accessible information. Approval is done by individual assessment of these substances, and a deficiency in information can hinder the endorsement of a natural ingredient.

Requirement 5

Raw materials of natural origin may be used in products with the Asthma Allergy Nordic Label. The raw materials must fulfil criteria 1 and 2 both for active substance, and any known or unknown impurities.

Documentation: Full formulation of all known substances in the natural ingredient must be stated as part of req. 1.

Criterion 6 – Trim/Accessories

Trim/accessories can be sewing thread, buttons, zippers, elastic bands, hang tags with print etc. Such items can be made of textile, metal, plastic, wood etc. and can be dyed/printed/coated and are normally used when the final bedding product is manufactured. Components of metal can contain nickel, cobalt, and chromium, and wood-based components may contain colophonium.

Often – but not always – the bedding manufacturer has a reasonable knowledge about which chemicals that can be found in the main fabric(s), but trim/accessories are often purchased separately from specialized suppliers, and it can be difficult to get information about what kind of chemicals that is in these components.

Allergies towards small amounts of nickel, cobalt and chromium are well documented. Therefore, the content of these sensitizing metals in the metal alloy must fulfil the non-presence limit described in the introduction for all other components, raw materials, and substances. The assessment has been that the requirement may possibly be hard to meet, but there are currently other products with same functionality on the market.

Allergies towards small amounts of colophonium is likewise well documented, and therefore components of wood-based materials must show a low content of colophonium. Information on the requirement and documentation required can be found in Appendix 2.

Trim consisting entirely of plastic has no special requirement and must be documented the same way as every other polymer component.

Trim of leather is not included in these criteria as leather – strictly speaking, is not a textile, but is a natural material made by tanning hides from animals. The processes behind producing and dyeing leather are different from normal textile manufacturing. This also includes the chemicals used including chromium used for tanning of leather which is known as a skin sensitizer. Therefore, since leather production is significantly different from textile production, leather is not included in these criteria.

All trim/accessories including coatings, dyes, auxiliary chemicals, pigments etc. must meet the same requirements as the rest of the product.

Requirement 6

Components of wood must state origin. If the origin is conifers/softwood, the content of colophonium must be below 5 ppm for each colophonium markers: abietic acid, dehydroabietic acid and 7-oxodehydroabietic acid. See Appendix 2 for further information on requirement and documentation.

Components of metal must fulfil criteria 1 and 2. See Appendix 3 for requirements and documentation.

Component made of textile fibres must fulfil criterion 4.

Documentation: All components must meet criteria 1, 2, 3 and 4.

Criterion 7 – Substances Used During Transportation and Storage

Chemical substances can be used during transportation or storage of textile products, both semi-finished products and end products. Usually, this will be biocidal substances, but other functions are also possible.

Biocidal substances can be used during storage and/or transportation to avoid mould which especially is a problem under hot and humid conditions. This is normally done by fumigation which effectively spread the biocidal substances in shipping containers.

It is normally the shipping agency that decides if fumigation is needed and what kind of substance, they want to use to protect the goods from mould. Because of this, we will not be able to assess the biocide used under transportation or storage under the application process. However, the use of allergenic substances is not allowed. The documentation for this is a statement from the applicant, of non-use of allergenic biocidal substances during storage and/or transportation.

Requirement 7

Substances used during transportation and/or storage may not be classified as sensitizing to the skin, H317, or assessed by Asthma Allergy Nordic to have allergenic risk. The assessment can be found in the Asthma Allergy Nordic Customer Database [AAN DB].

Documentation: A statement of non-use from the applicant.

Criterion 8 – 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.

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

Requirement 8

Artwork/label must be approved. The Asthma Allergy Nordic label must be designed in accordance with the guidelines in the Logo Manual [AAN Logo Manual].

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

Documentation: Artwork/label.

References

[AAN DB]: astma-allergi-webcustomer.onteamshare.com/Identity/Account/Login

[AAN IP]: asthmaallergynordic.org/infoportal/

[AAN Logo Manual]: asthmaallergynordic.org/infoportal/general-information/graphic-guidelines/

[AAN Web]: asthmaallergynordic.org/

[1272/2008/EC]: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures

[Baliarsingh et al., 2013]. Baliarsingh, Jyotsnarani Jena, Trupti Das, Nalin B. Das. (2013). Role of cationic and anionic surfactants in textile dyeing with natural dyes extracted from waste plant materials and their potential antimicrobial properties. Industrial Crops and Products, Volume 50, October 2013, Pages 618-624.

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[EN 1164]: EN 1164 – Feather and down - Test methods - Determination of the turbidity of an aqueous extract (1998)

[ECHA Inventory]: https://echa.europa.eu/en/information-on-chemicals/cl-inventory-database

[Hernández Fernández, 2024]. Hernández Fernández CP, Borrego L,Giménez Arnau AM, et al. Sensitization to textile dyes inSpain: Epidemiological situation (2019–2022). ContactDermatitis. 2024;90(5):486-494. doi:10.1111/cod.14513494 HERN ´ANDEZ FERN ´ANDEZ ET AL .

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[SCCS, 2011]. SCCS, Opinion on Fragrance Allergens in Cosmetic Products, 13-14 December 2011 SCCS (Scientific Committee on Consumer Safety), opinion on fragrance allergens in cosmetic products, 13-14 December 2011 (SCCS/1459/11).

Appendix 1 – Criteria in Summary

Requirement 1

The full composition of the product must be disclosed including all components (fabrics, threads, zippers, buttons, hangtags, foam, fillings etc.). All raw materials and process chemicals used for each single component (auxiliaries, dyes, pigments, tackifiers, finishing agents etc.) must also be disclosed. Each component/raw material must be stated with all ingoing substances* (Trade name, CAS-no., amount, and function).

*Ingoing substances or raw materials are defined as all substances or raw materials in the product/component stated down to 0.1 ppm.

***Documentation*:** Composition of the product containing information and all ingoing substances, raw materials, and components stating trade name, chemical name, CAS-no., amount, and function. Components may be stated with trade names only, provided the composition is disclosed by the supplier. It is the responsibility of the applicant that the suppliers provide the necessary information on the requested component and/or raw material to Asthma Allergy Nordic.

Requirement 2

D. Substances classified as sensitizing to the skin (H317) may not be part of the product, raw material, or component.
E. Substances where evidence of sensitizing potential exist without the substances being classified may not be part of the product, raw material, or component.
F. Fragrance, scent, or masking agents may not be used in the making of the textiles or raw material.

Ingoing substances or raw materials are defined as all substances or raw materials in the product/component stated down to 0.1 ppm.

Documentation: Same as requirement 1.

Requirement 3

Fillings of feathers and downs must meet the following requirements for *oxygen number* and *turbidity*:

A. The *oxygen number* must be < 4.8 mg/100g

B. *Turbidity* must be > 1,000 mm

Purity of wool fillings must be equal to the purity of feathers and downs.

Viscose, and other cellulose-based fibres must state the origin of the fibres.

If wood-based fibres are used, the raw material/component/product must have a low content of colophonium markers; abietic acid, dehydroabietic acid and 7-oxodehydroabietic acid. The markers must not be present in the raw material/product in amounts exceeding 5 ppm each.

See requirements in Appendix 2.

If synthetic fillings and/or fibres are used it must be disclosed which process chemicals or auxiliaries that get into contact with the filling/fibre. A description of the process must be submitted identifying where the process chemicals are used.

Composition of the chemicals used during the process must be sent if the fillings are treated.

Documentation: For feathers and downs: Composition of the chemicals used during the process must be sent if the fillings are treated. Test report for EN 1162 (oxygen number) and EN 1164 (turbidity) must be provided. A description of the process, as well as a list of the substances the raw material/components consists of, together with a list of the process chemicals used in the production of the raw material, with chemical name/INCI, CAS-no. and amount.

Requirement 4

Colourants (dyes and pigments) and auxiliary chemicals in each single component of the bedding must be stated with all ingoing substances*, CAS-no., amount, and function.

**Ingoing substances or raw materials are defined as all substances or raw materials in the product/component stated down to 0.1 ppm.*

Documentation: Same as requirement 1 and 2. Print must be clearly marked on a schematic drawing of the product. Alternatively, a product sample or picture may be provided.

Requirement 5

Raw materials of natural origin may be used in products with the Asthma Allergy Nordic Label. The raw materials must fulfil criteria 1 and 2 both for active substance, and any known or unknown impurities.

Documentation: Full formulation of all known substances in the natural ingredient must be stated as part of req. 1.

Requirement 6

Components of wood must state origin. If the origin is conifers/softwood, the content of colophonium must be below 5 ppm for each colophonium markers: abietic acid, dehydroabietic acid and 7-oxodehydroabietic acid. See Appendix 2 for further information on requirement and documentation.

Components of metal must fulfil criteria 1 and 2. See Appendix 3 for requirements and documentation.

Component made of textile fibres must fulfil criterion 4.

Documentation: All components must meet criteria 1, 2, 3 and 4.

Requirement 7

Substances used during transportation and/or storage may not be classified as sensitizing to the skin, H317, or assessed by Asthma Allergy Nordic to have allergenic risk. The assessment can be found in the Asthma Allergy Nordic Customer Database [AAN DB].

Documentation: A statement of non-use from the applicant.

Requirement 8

Artwork/label must be approved. The Asthma Allergy Nordic label must be designed in accordance with the guidelines in the Logo Manual [AAN Logo Manual].

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

Documentation: Artwork/label.

Appendix 2 – Colophonium

Colophonium is a complex mixture of substances found in softwood (conifers such as pine, spruce, and larch) and as such relevant when assessing wood-based raw materials and components. In these criteria it would be relevant when looking at viscose stemming from softwood fibres and trims/accessories made from wood, e.g., wooden buttons.

Colophonium is allergenic and may therefore not be present in the product, components, or raw materials, cf. req. 2.

Wood-based raw material and components are accepted within the scope of the allergy label as long as they meet the set requirements. The content of colophonium must therefore be minimised and the fibre/component must document a low content based on selected colophonium markers.

This means that fibres based on softwood and components made from softwood 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 fibre/component in amounts exceeding 5 ppm. The test must be made on three different batches/samples/components.

Fibres/components based entirely on other species of wood (non-conifers) do not need to document this requirement. If more than one wood-based fibre and/or components are present in the final product, each of the ingoing parts must meet the requirement. The requirement must be documented continuously since there may be variations in the content of colophonium due to e.g., change in seasons, soil etc.

Requirement

The source of the wood used for fibres/component must be stated. If the source is a conifer/softwood, point A below must be documented.

A. The fibre/component must have a low content of the colophonium markers: abietic acid, dehydroabietic acid and 7-oxodehydroabietic acid. The marker substances must not be present in the fibre/component in amounts exceeding 5 ppm for each substance.

Documentation: The amount of colophonium markers in the fibre/component/batch must be documented by gas chromatography or equivalent laboratory test (three samples/batches must be tested). The detection limit for the applied test must be below the required limit. The requirement must be documented continuously.

Note, a list of laboratories that have indicated they can provide the necessary test can be found on the Information Portal [AAN IP]

Appendix 3 – Metals

Trim and accessories can consist of metal. Since requirement 2A and 2B excludes substances that are classified or otherwise considered sensitizing, it can be hard to translate into actual requirements and documentation for metal components. Metal alloys often contain some levels of nickel, cobalt and chromium (Ni, Co and Cr), which are classified or considered as skin sensitizers (H317).

Allergies towards small amounts of nickel, cobalt and chromium are well documented. Therefore, the content of these sensitizing metals in the metal alloy must fulfil the non-presence limit described in the introduction for all other components, raw materials, and substances. The assessment has been that the requirement may possibly be hard to meet, but there are currently other products with same functionality on the market.

A laboratory analysis is performed on the metal component without any coating. Measurements are to be taken on the total content of each metal (Ni, Co, Cr). 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.

Asthma-Allergy Denmark will be pleased to support you with guidance and communications concerning testing methods and sampling as well as dialogue with the laboratories if this is needed.

Requirement

The content of nickel, cobalt and chromium must be documented by testing the metal component

A. The fibre/component must have a low content of Ni, Co and Cr. The three mentioned metal substances must not be present in the metal component in concentrations exceeding 0.1 ppm each metal substance.

Documentation: The amount of Ni, Co, Cr must be documented by laboratory test (three samples/batches must be tested). The detection limit for the applied test must be below the required limit. The requirement must be documented continuously.

Note, a list of laboratories that have indicated they can provide the necessary test can be found on the Information Portal [AAN IP]