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BACKGROUND AND REQUIREMENTS

TEXTILES - VERSION 1.0, DRAFT FOR HEARING

ASTHMA ALLERGY NORDIC

Asthma Allergy Nordic

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Background and Requirements for Labelling of Textiles with Asthma Allergy Nordic

This document describes the background and requirements set for textiles. In this document, each section will have a background text explaining, why the requirement is set and the reasoning behind the level of requirement. It is followed by the requirement itself and the accompanying documentation requirement; this is marked in a light blue box. A summary of the requirements can be found in Appendix 1. Please note, that all requirements relevant for the product type must be met in order to be recommended by Asthma Allergy Nordic. It is always required to fulfil the regulatory requirements of the laws governing the area of the market on which the product is sold. This will not be controlled by Asthma Allergy Nordic as part of the assessment for eligibility of the allergy label.

The reason why criteria have been made for textiles is that there is a concern about skin sensitisation of consumers due to exposure to problematic chemicals in textiles. Allergic reactions after wearing textiles have been known to occur for a long time but exactly what causes it is not well known. A limited range of dyestuffs are known or suspected to cause allergic reactions but when a person has got an allergic reaction after contact with a textile it is not easy to find the root of the problem. Instead, it is often just recommended to find another product.

The European legislation for textiles (REACH Regulation 1907/2006 EC) aims at making the products safe for both consumers and the environment. There has been an increased focus on skin sensitizing chemicals in REACH regarding textiles and leather. Substances like chromium (VI), nickel and dimethyl fumerate (DMFu) have been restricted for years and many more are in the process of being classified according to their skin sensitizing properties.

In 2019 the French and Swedish authorities proposed a new restriction on skin sensitizing chemicals in textile, leather, synthetic leather, hide and fur articles. If adopted by the European Commission, this proposal would limit the use of over 1,000 skin sensitizing chemicals (all those with a harmonised classification as well as some 'disperse' dyes considered to have skin sensitizing properties) in clothing, footwear and other articles that come in contact with the skin, such as bed linen or upholstered furniture (ECHA 2019). Initiatives like this is aims to reduce the risk of becoming allergic.
However, the levels set in this proposal might not be strict enough for persons who are already allergic to substances in textiles to avoid an allergic reaction.

Asthma Allergy Nordic aims to help consumers who are already sensitised or consumers who want to be extra careful, by making it easy to choose a product where the risk of getting an allergic reaction on the skin and respiratory system is reduced because the levels of known or suspected allergens are very low.

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

- No sensitizing preservatives
- No sensitizing dyestuffs
- No perfume
- Minimal risk of allergic reactions on the skin

The definition of allergenic substances

Asthma Allergy Nordic requires that no substance in direct contact with the skin and/or mucous membranes may be regarded as sensitizing. **Note**, that a substance is not considered to be present if the amount of the substance is below 0.1 ppm in the final product. To assess whether a substance is considered an allergen, the following is taken into consideration:

- Is the substance classified as a sensitizer according to the CLP Regulation (1272/2008/EC)?
- Is there other documentation presented to prove the potential of the substance to sensitize the skin and/or mucous membranes? This could be the case if…:
    - There may be published articles on cases where allergic reactions have been reported over a period and where the clinical relevance has been established.
    - There may be epidemics where a lot of cases are reported over a short period of time towards a specific substance.
    - There may be substances where dermatologists experience allergic reactions in consumers towards a specific substance, and it is assumed that the actual number of cases is higher due to the substances not being in the baseline test series.
    - There may be a constant number of consumers having a positive reaction when tested. This will be set in relation to the usage of the substance both in terms of amounts and groups of consumers.

These bullets will often – with the exception of a harmonised classification – have to be evaluated under more than one point to confirm the conclusion of the assessment.

The definition on whether a substance is sensitizing or not is not well defined, and grey zones may arise. In such cases, Asthma Allergy Nordic will consult data and assessments with a network of experts from the Nordic countries and international dermatologists with expertise within the field. The baseline for the label will be a cautious view of the substances with the balance between protecting consumers with contact allergy or respiratory issues and consumers who want to be extra careful. At the same time Asthma Allergy Nordic acknowledge that for a small group of people this will not be a guarantee against having an allergic reaction to a given product. It is important to emphasize that even though a substance is not considered to be an allergen, there may be a minor group that are/might be allergic towards the substance and may have an allergic reaction towards this.

Analysis: Methods and Results

There is now more focus on and specification of the documentation requirements in the criteria. This means that some requirements must be documented by testing and not just by a statement. It is important to be aware that the choice of laboratory, test method as well as detection limits will influence the outcome of the test/test results.

Asthma Allergy Nordic can be of assistance with guidance and dialogue both on choice of test and detection limits as well as on interpretation of test results and dialogue with the laboratories. Please, contact us early in the process, so that we might can be of help providing the necessary documentation. Contact information may be found on the Asthma Allergy Nordic website.

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. The list is not exhaustive and other laboratories may also be able to provide the service, but we encourage you to contact us prior to analysis, if other laboratories are used.

Which Products May Be Labelled?

The product group includes textiles for clothing where prolonged skin contact can be expected, including bed linen.

In this context clothing is products like e.g.:
Shirts
T-shirts
Trousers
Baby clothes
Kids wear
Bed linen

Products not Included in the Product Group

Curtains
Carpets
Rugs
Fabric for furniture
Footwear

Textiles with stuffing aimed for sleeping (e.g., sleeping bags, baby sleeping bags) are included in the criteria for Bedding.

Criterion 1 – Information on 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 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 etc.). We must know all process chemicals used for each single component (auxiliaries, dyes, pigments, tackifiers, finishing agents etc.). Each chemical must be stated with all ingoing substances (cf. definition below), CAS-no., amount, and function.

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

Documentation: Composition of the product containing information and all ingoing substances stating chemical name, CAS-no., amount, and function. It is the responsibility of the applicant that the suppliers provide the necessary information on the raw material to Asthma Allergy Nordic.

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 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.

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 as long as it is not present in the final

product in amounts above the Lower Limit of Interest (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 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. There are many examples of this common to them all is the assessment that the substance will no longer be present in the final product. These assessments must be either directly calculated or supported by a test.

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 requirement 2). This is documented by providing a full composition list and – upon request – 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 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. 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

The use of fragrance/perfume is normally not a big problem in this product group. However, it can be used to mask any unwanted smell from production chemicals and the use of perfume is not allowed in this product group.

Requirement 2

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

Ingoing substance is defined as all substances in the product/raw material stated down to 0.1 ppm in the final product.

Documentation: Same as requirement 1.

Criterion 3 – Colourants/pigments

A special case relates to the use of colour. Colourants are normally not regarded as essential for the function of a product. Therefore, colourants are normally not accepted in products with Asthma Allergy Nordic.

For textiles colourants are considered necessary and are therefore allowed but must meet the same requirements as other chemicals. The requirements stated in this document apply to process chemicals in all components of the textile including small items such as sewing thread and hang tags.

Requirement 3

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

Ingoing substance is defined as all substances in the product/raw material stated down to 0.1 ppm in the final product.

Documentation: Same as requirement 1 and 2.

Criterion 4 – Fibres

Allergy to textile fibres is not common and only few incidents are reported. When textile allergy is suspected and consumers state that they have allergy for a specific fibre it is normally not the fibre itself but rather substances used for dyeing, printing or finishing. Because of this most of the criteria are related to the chemicals used in wet processing.

Viscose and other cellulose 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 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.

Wool

Traditionally, 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.

Because of this it is not allowed to use wool in products with the Asthma Allergy Nordic Label.

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.

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 people also have different, subjective preference for what they like. Because of this wool is not included in the criteria.

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.

Leather

Strictly speaking leather is not a textile. Textiles are often defined as various fibre-based materials normally made of yarns. Leather is not made of fibres 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.

Since leather production is so different from textile production, leather is not included in these criteria.

Latex

Components made of latex are not included in these criteria. Latex is mostly used in elastic waistbands in e.g., underwear but it is possible to use alternatives.

The reason for not including latex is that it contains substances that might promote allergic reactions.

Requirement 4

Viscose, and other cellulose-based fibres must state the origin of the fibres. If the fibres are from conifers/softwood, the content of colophonium must be low.

See requirements in appendix 2.

If polyester is used it must be disclosed which process chemicals or auxiliaries that get into contact with the fiber. A description of the process must be submitted identifying where the process chemicals are used.

Documentation: A description of the process as well as a list of the substances the raw material 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 5 – Natural ingredients

Natural ingredients have been used to colour textiles for thousands of years but since it became cheaper to produce manmade dyestuffs natural ingredients were not used in normal textile production. 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 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 rec. 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 textile is manufactured.

Often – but not always – the textile 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. Chemical fails are more often found in trim/accessories compared to the main fabrics.

Components of metal can contain small amounts nickel, cobalt, and chromium, and buttons of softwood could potentially contain colophonium.

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 low, see appendix 2 for requirement and documentation.

Components of metal must meet the testing requirements described in appendix 3.

Materials made of textile fibres must fulfil criteria 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 substance database from Asthma Allergy Nordic.

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. Artwork/label must be presented so correct usage can be verified.

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

Requirement 8

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

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

Documentation: Artwork/label.

References

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.

Carlsson, J, Åström, T, Östman, C, Nilsson, U. Disperse azo dyes, arylamines and halogenated dinitrobenzene compounds in synthetic garments on the Swedish market. *Contact Dermatitis*. 2022; 87(4): 315- 324. doi:10.1111/cod.14163

(ECHA, 2019). European Chemicals Agency (ECHA). Registry of restriction intentions until outcome. Restriction on the placing on the market of textile, leather, hide and fur articles containing skin sensitising substances. Accessed June 9, 2023. https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e182446136

Gallo. M, Naviglio. D, Ferrara. L (2014). NASUNIN, AN ANTIOXIDANT ANTHOCYANIN FROM EGGPLANT PEELS, AS NATURAL DYE TO AVOID FOOD ALLERGIES AND INTOLERANCES. European Scientific Journal March 2014 edition vol.10, No.9 ISSN: 1857 – 7881 (Print) e - ISSN 1857- 7431

Lidén C, Andersson N, White IR. Preservatives in non-cosmetic products: Increasing human exposure requires action for protection of health. Contact Dermatitis. 2022 Nov;87(5):389-405. doi: 10.1111/cod.14181. Epub 2022 Jul 18. PMID: 35794071; PMCID: PMC9796024.

Lisi, P., L. Stingeni, A. Cristaudo, C. Foti, P. Pigatto, M. Gola, D. Schena, M. Corazza, and L. Bianchi. 2014. "Clinical and epidemiological features of textile contact dermatitis: an Italian multicentre study." Contact Dermatitis 70 (6):344-50. doi: 10.1111/cod.12179

Malinauskiene, L., Bruze, M., Ryberg, K., Zimerson, E. and Isaksson, M. (2013), Contact allergy from disperse dyes in textiles–a review. Contact Dermatitis, 68: 65-75. https://doi.org/10.1111/cod.12001

Verschoor, A.H., van Leeuwen, H.J. & Verschoor, L. Are there consumer hazards from fumigant residues?. *Zbl Arbeitsmed* **62**, 44–45 (2012). https://doi.org/10.1007/BF03345043

Appendix 1 – Criteria in summery

Requirement 1

The full composition of the product must be disclosed including all components (fabrics, threads, zippers, buttons, hangtags etc.). We must know all process chemicals used for each single component (auxiliaries, dyes, pigments, tackifiers, finishing agents etc.). Each chemical must be stated with all ingoing substances (cf. definition below), CAS-no., amount, and function.

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

Documentation: Composition of the product containing information and all ingoing substances stating chemical name, CAS-no., amount, and function. It is the responsibility of the applicant that the suppliers provide the necessary information on the raw material to Asthma Allergy Nordic.

Requirement 2

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

Ingoing substance is defined as all substances in the product/raw material stated down to 0.1 ppm in the final product.

Documentation: Same as requirement 1.

Requirement 3

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

Ingoing substance is defined as all substances in the product/raw material stated down to 0.1 ppm in the final product.

Documentation: Same as requirement 1 and 2.

Requirement 4

Viscose, and other cellulose-based fibres, must state the origin of the fibres. If the fibres are from conifers/softwood, the content of colophonium must be low.

See requirements in appendix 2.

If polyester is used it must be disclosed which process chemicals or auxiliaries that get into contact with the fiber. A description of the process must be submitted identifying where the process chemicals are used.

Documentation: A description of the process as well as a list of the substances the raw material 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 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 rec. 1.

Requirement 6

Components of wood must state origin. If the origin is confiers/softwood, the content of colophonium must be low, see appendix 2 for requirement and documentation.

Components of metal must meet the testing requirements described in appendix 3.

Materials made of textile fibres must fulfil criteria 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 substance database from Asthma Allergy Nordic.

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.

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 material 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 or raw materials, cf. req. 2.

Since it has previously been decided that wood-based raw material and components are accepted within the scope of the allergy label, it has resulted in setting requirements to these instead of excluding them. 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 and should be documented continuously.

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, you may find a list of laboratories that have indicated they can provide the test on the Information Portal

Appendix 3 - Metal

- Trim can consist of metal. Since requirement 3A and 3B 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, which has a harmonised classification as a skin sensitizer (H317). As such, nickel may not be part of the nose clip (or any other component). In relation to a requirement this means that nickel must not migrate from the metal component. This must be documented through a migration test.

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

Trim Consisting Fully or Partially of Metal

As mentioned above it is required for metal trim consisting of metal (fully or partially) that nickel is not migrating from the component. This is done to ensure that individuals with nickel allergy still may use textiles with the allergy label that contain trim of this kind.

Asthma Allergy Nordic requires it can be shown in a laboratory test that no nickel is migrating from component. This means that when a migration test is performed, the result of nickel must be below the detection limit of 0.1 µg/cm^2/week or below the general lower limit of interest of 0.1 ppm (0.1 mg/kg or 0.1 µg/g) depending on the test (see below).

The test must be performed by an accredited laboratory and/or an accredited test metho.

Test/test conditions for nickel migration

Usually, a migration test is performed for 7 days in a sweat matrix. If this test is performed, the result must meet the requirement of 0.1 µg/cm^2/week.

The migration test must be performed according to methods for determining nickel migration from metals as accepted by the EU Commission and published on their website [REACH Restrictions]. A list of the accepted methods can be found here: EU List of Methods. [European Commission]. The test chosen must be appropriate to measure down to the limit requirement or lower.