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BACKGROUND AND REQUIREMENTS

HYGIENE & TISSUE VER. 1.1

ASTHMA ALLERGY NORDIC

Asthma Allergy Nordic

February 2022 version 1.1

Content

Background and Requirements for Labelling of Hygiene and Tissue Products with Asthma Allergy Nordic

This document describes the background and requirements for the product categories hygiene and tissue products. 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 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 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 contain substances that may be problematic when it comes to contact allergy when used often or over longer periods of time. A special concern would be fragrances and preservatives, but it could also be other allergens such as rosin (colophony). People, who are discomforted by scent from these products may also find it relieving that fragrance is not accepted.

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

- No fragrance or lotion
- No sensitizing preservatives (e.g., MIT)
- 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. 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 the choice of test and detection limits as well as on the 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 *Retailers & Manufacturers Portal, an internal communication platform for the contract holders,* provides a list of laboratories that have indicated that they may provide the service of testing according to the requirements in these criteria. [RMP]. 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 Can Be Labelled?

The product group includes diapers, sanitary towels, panty liners, sanitary pads, plaster, kitchen rolls, 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, tampons, disposable change mats, tissue handkerchiefs, paper napkins, dry wipes, foam washcloths, cotton, cotton pads and face masks are also included in the criteria.

Some products in the product group definition differ from the main part of the products by not being paper-based (e.g. cotton pads, foam wash cloths, and face masks). The reason for including these products is that their function falls within the scope of the product group with similar functions as other products included in the product group. Foam washcloths, cotton and cotton pads may be used as alternatives to products that are potentially more problematic with regards to allergy.

Please note, that some of the requirements in the criteria are elaborated and specified further for face masks (see Appendix 3), as they contain components that differ slightly from the other products in the product group. All basic criteria are, however, the same for all products in the products group.

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 raw materials, auxiliaries, and process chemicals. A raw material 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 or component.

Documentation: Composition of the product containing information and all ingoing substances stating chemical name/INCI, cas-no., amount, and function. Raw materials 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 raw material to Asthma Allergy Nordic.

Note, that it is the obligation of the applicant to inform of all aspects, e.g., information on contaminants in raw materials, relevant for the assessment of the product.

Note, that if wood-based raw materials are used, it must be stated if conifers are used (cf. req. 2) and the requirement on colophonium must be met (cf. req. 3).

Criterion 2 – Non-woven, Viscose, Fluff and Pulp

Asthma Allergy Nordic 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 wood the raw material (fluff/pulp/viscose) consists of.

Since some process chemicals from the manufacturer of non-woven, viscose, 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 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 finish used on the fibres.

Requirement 2

It must be stated which substances the raw material consists of (non-woven) or if conifers have been used in wood-based raw materials (fluff/pulp/viscose).

It must be disclosed whether the production process involves process water, process chemicals or auxiliaries that get in contact with the raw material; and if this is the case which process chemicals are used. A description of the process should 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.

Note, that there are requirements as to the content of colophonium for wood-based raw materials (cf. req. 3C).

Criterion 3 – Specifically Excluded Substances

Some substances in these types of products 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 (auxiliary) 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 "spend" and hence not present in the raw material and subsequent not present in the final product. There are many examples of this but in common of them all are 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 classified 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 3). 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 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 excludes 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 is 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/viscose) 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.

Considerations on the requirement on colophonium can be seen in more detail in Appendix 2.

Fragrance

Fragrance, scent, and masking agents are not accepted in products with Asthma Allergy Nordic Label. This also applies to this product group. This is documented by a full composition list (as described under req. 1). Substances that are used for odour control, that is not essentially a fragrance or masking agent, is accepted. This could be substances that are absorbing or encasing the fluids inside the products.

Lotion, ointment, cream etc.

Some products within this product group have the addition of cosmetic products such as lotion, ointment, cream, or the like. Generally speaking, cosmetics should 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, occluded, and in areas where the need for the product may not always be present. 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).

Requirement 3

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. Colophonium must not be added to the product or raw materials. If wood-based raw materials are part of the product, the raw materials must have a low content of the colophonium markers: abietic acid, dehydroabietic acid and 7-oxodehydroabietic acid. The markers must not be present in the raw material in amounts exceeding 5 ppm each.
D. Fragrance, scent, or masking agents may not be part of the product or raw material.
E. Lotion, ointment, cream, or other cosmetic products may not be part of the product.

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

Documentation: *Point A, B, D and E*: Same as requirement 1. *Point C*: The amount of colophonium markers in the raw material/batch must be documented by gas chromatography or equivalent laboratory test (three batches must be tested). The detection limit for the applied test must be below the required limit. This must be documented continuously.

Criterion 4 – Colourants

Colourants are not accepted in tissue products such as toilet paper, kitchen rolls and paper handkerchiefs as they do not have an essential function in these products.

In hygiene products, colourants may have a practical function. For example, print on the exterior may inform the user about the size of the product and it may help differentiating between back and front. Therefore, colourants are only allowed on the exterior of hygiene products. Colourants (and hence printing inks) are regarded as ingoing substances and must fulfil all requirements in the criteria. Colourants are accepted in wetness indicators as well.

Requirement 4

Colourants are not accepted on tissue products.

In hygiene products, colourants are accepted on the exterior of the product and in wetness indicators. Colourants/printing inks must meet the requirements for ingoing substances (requirement 3).

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

Criterion 5 – Control of Artwork

The use of Asthma Allergy Nordic is subject to the rules laid out in Asthma Allergy Nordic's logo manual. Artwork/label/packaging must be provided for control of the use of logo. In addition, control of claims connected to the label will be done.

Requirement 5

Artwork/label/packaging must be submitted digitally for approval. The use of the logo must conform to the rules set by Asthma Allergy Nordic.

Documentation: Artwork/label/packaging.

Criterion 6 – Packaging

Substances from packaging, based on wood-based materials, may migrate from the packaging onto the product. At present, Asthma Allergy Nordic has knowledge that this could be the case for colophonium, migrating from wood-based packaging that is in direct contact with the use-surface of the product. An example of this is panty liners, where some products are found set directly into a cardboard box. In this situation, migration of colophonium onto the surface of the product may take place resulting in an elevated exposure of colophonium to the consumer's skin in amounts that could be relevant for those allergic to colophonium. At present, Asthma Allergy Nordic is not aware of similar problems with other kinds of packaging.

Since Asthma Allergy Nordic consider this issue of relevance for the assessment of the products, the amount of colophonium in the wood-based packaging will be limited in line with other wood-based raw materials. Products for which there is not direct contact with the packaging, this documentation is not needed.

Requirement 6

Wood-based packaging in direct contact with the product must contain a limited amount of colophonium. This means that req. 3C also applies for packaging components.

Documentation: See req. 3C.

References

AAN website: https://www.asthmaallergynordic.com/

Colophonium Note, Asthma-Allergy Denmark, December 2016. (Appendix 2).

Logo Manual, Asthma Allergy Nordic

RMP: http://www.rm-portal.eu/

Appendix 1 – Criteria in Summary

Requirement 1

The full composition of the product must be disclosed including all raw materials, auxiliaries and process chemicals. A raw material 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: Composition of the product containing information and all ingoing substances stating chemical name/INCI, cas-no., amount and function. Raw materials 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 raw material to Asthma Allergy Nordic.

Requirement 2

It must be stated which substances the raw material consists of (non-woven) or if conifers have been used in wood-based raw materials (fluff/pulp/viscose).

It must be disclosed whether the production process involves process water, process chemicals or auxiliaries that get in contact with the raw material; and if this is the case which process chemicals are used. A description of the process should 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 3

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. Colophonium must not be added to the product or raw materials. If wood-based raw materials are part of the product, the raw materials must have a low content of the colophonium markers: abietic acid, dehydroabietic acid and 7-oxodehydroabietic acid. The markers must not be present in the raw material in amounts exceeding 5 ppm each.
D. Fragrance, scent, or masking agents may not be part of the product or raw material.
E. Lotion, ointment, cream, or other cosmetic products may not be part of the product.

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

Documentation: *Point A, B, D and E*: Same as requirement 1. *Point C*: The amount of colophonium markers in the raw material/batch must be documented by gas chromatography or equivalent laboratory test (three batches must be tested). The detection limit for the applied test must be below the required limit. This must be documented continuously.

Requirement 4

Colourants are not accepted on tissue products.

In hygiene products, colourants are accepted on the exterior of the product. Colourants/printing inks must meet the requirements for ingoing substances (requirement 3).

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

Requirement 5

Artwork/label/packaging must be submitted digitally for approval. The use of the logo must conform to the rules set by Asthma Allergy Nordic.

Documentation: Artwork/label/packaging.

Requirement 6

Wood-based packaging in direct contact with the product must contain a limited amount of colophonium. This means that req. 3C also applies for packaging components.

Documentation: See req. 3C.

Appendix 2 – Considerations on Colophonium in Detail

The purpose of this note is to be able to set adequate and relevant requirements to colophonium in paper-based products that are labelled with Asthma Allergy Nordic.

Colophonium is a resin consisting of a mixture of substances found in conifers. [Downs & Sansom, 1999], [VfA, 2016]. According to literature, resin is used in a broad variety of applications and colophonium is a sensitizer and as such unwanted in products that are labelled with Asthma Allergy Nordic.

Several literature sources mention that colophonium can be found in adhesives, paints and varnishes, cosmetics, paper products, hygiene products, cutting oil etc. Of the products mentioned, the following are of interest for Asthma Allergy Nordic:

- Cosmetics
- Paints and varnishes
- Adhesives
- Plaster (patches)
- Hygiene products (incl. diapers)
- Tissue products
- Paper products

The areas of interest regarding these product categories can be divided into three: products based on paper, products that are or contains adhesives, and cosmetics.

As colophonium resin originates from conifers such as pine, larch and spruce, other species of wood is of minor concern (this could be birch, asp, or more exotic wood species) and these may be disregarded.

Articles

A report from CIR (the US Cosmetic Ingredient Review) shows that there has been an increase in the use of colophonium-containing ingredients in cosmetics. The report also shows that the ingredients themselves are not sensitising, but patients with colophonium allergy may show allergic reactions to contents of colophonium as low as 10 ppm. [CIR, 2015]. Furthermore, the report mentions that the use of these colophonium-containing ingredients has increased significantly during the last decade – both in terms of the types of products containing them and in terms of amount used in the products.

There are some studies that have looked at colophonium in consumer products. [Karlberg & Magnusson, 1995] have published an article about the findings of colophonium in diapers. The article also mentions older studies, where colophonium in newspapers and surgical paper clothes have caused allergic reactions. In the study, six diapers have been tested for colophonium markers (abietic acid, dehydroabietic acid and 7-oxodehydroabietic acid). Colophonium was found in all diapers, but in very different amounts. The study

concludes that the amounts of colophonium found in the diapers (20-200 ppm) might be enough to cause an allergic reaction in individuals already sensitized. This was based on previous studies on colophonium contact allergy induced by handling paper, which may contain colophonium components in the range of 50-300 ppm.

An article from [Saino et al, 1996] refers to a study of colophonium in mascaras. Although colophonium in mascaras is not accepted in Asthma Allergy Nordic, the study may help with respect to levels found in consumer products. The article mentions that the levels of colophonium found in the products (0.25-0.7% ~ 2,500-7,000 ppm) would probably cause an allergic reaction in individuals already sensitized to colophonium.

An article from [Kanerva et al, 2001] describes a study of colophonium in sanitary pads. The levels of colophonium found in the products range from <0.004% (40 ppm) up to 0.056% (560 ppm), where the amounts might cause an allergic reaction in individuals already sensitized to colophonium.

Input from producers

As the sensitizing potential of colophonium is undisputable, it is not acceptable to intentionally add colophonium to a product. However, often producers do not add the colophonium; it is present as a part of the raw materials (e.g., wood fibres or resin).

Communication with producers of adhesives has shown that the presence of colophonium in adhesives is complex. Colophonium as a natural material is not used in the production of the kinds of adhesives that are in question here (as an intermediate or component of a product). The substances that are used are chemically modified. The substances used in tissue and hygiene products are not the Methyl Esters, which may compose a risk due to sensitization. In hotmelt adhesives Pentaerythriol Esters may be used and these may contain small residual amounts of resin. The risk of an allergic reaction to these small amounts of colophonium is considered negligible if the adhesive is not used in direct and/or prolonged skin contact as is the case when used in tissue and hygiene products. Communication with a producer of paint and varnish has shown, that they do not (knowingly) add colophonium or resin to their products. Should colophonium be present it would be residual in raw materials and the producers are not aware of this presence.

Communication with a producer of fluff and pulp has shown, that species of wood used varies a lot from producer and product. A producer has provided test results of resin acids in pulp batches that range from 0.2-0.3 ppm, but also states, that the amounts may vary up to 5 ppm. The wood used for the pulps tested are fir and spruce and it is not stated which resin acids are tested. Another producer has tested wood pulp for colophonium markers and found the level in the raw pulp to be below 100 ppm. The amounts in the mixed pulps used for the actual products are below 10 ppm.

Input from patients

Asthma Allergy Nordic has asked patients with colophonium allergy, where their daily challenges are and what products they react to. Most patients respond that plaster is a major problem for them, but most do not know, whether it is the paper or the adhesive, that causes the allergic reaction. Patients also mention toilet paper, sanitary products, and paper napkins as causes of allergic reactions.

Reflections

Colophonium is a complex issue, since it is not a well-defined substance, but a mixture of many substances and their sensitizing potential varies a lot within the mixture. It is possible to choose relevant marker substances that represent the amount of colophonium in a product or material.

The articles regarding colophonium are all of older date (except [CIR, 2015]) and both consumer goods and raw materials may have changed over time. Communication with suppliers and producers indicate that this is the case.

The articles suggest that colophonium levels as low as 20 ppm may cause allergic reactions in individuals already sensitized. Though the report from CIR suggests allergic reactions might occur as low as 10 ppm.

Input from producers tells us, that the colophonium levels in paper products can be made to be below 10 ppm.

Inputs from patients with colophonium allergy tell us that most daily challenges come from plaster and substances with known high content of colophonium like resin used when playing handball – although some has had problems with both sanitary pads and toilet paper. Experiences from patients also tell us that it may be very hard to find the cause of the allergic reactions in the consumer products.

Conclusion

The content of colophonium in consumer products could and should be addressed by Asthma Allergy Nordic and the requirements should be made to give protection to most patients with colophonium allergy. Even though it has not been possible to set a validated level of colophonium to which patients elicit allergic reactions, both articles and patients experience suggest that level below 10 ppm in the raw material should provide some level of protection.

Since cosmetic products are not naturally based on ingredients originating from wood, the presence of colophonium is not acceptable in these products labelled with Asthma Allergy Nordic. Further, it is expected that the market will not be critically limited by an exclusion of colophonium-containing ingredients in cosmetics. Another point of interest is that the colophonium in these ingredients is not considered an ingoing substance in the cosmetic product and therefore colophonium will not be found on the product INCI-list.

On the other hand, colophonium in paper-based products are, to a large extent, unavoidable. Therefore, strict requirement should be set to limit the colophonium in these products. The level of colophonium cannot be explicitly determined, but levels of colophonium markers can be tested and limited and thus limiting the expected amount of colophonium in the products.

The articles mentioned and a report from the Danish EPA [Nilsson et al, 2009] suggest that the following markers can be used as measurement for the content of colophonium: abietic acid, dehydroabietic acid, 15-hydroperoxydehydroabietic acid and 7-oxodehydroabietic acid. [Nilsson et al, 2009] mentions that 15-hydroperoxydehydroabietic acid is too unstable to be a suitable marker in tests. This leaves three substances as markers for colophonium in the raw materials. It is important to include at least one oxidation product from the acids, because the oxidation products are more sensitizing than the acids. Furthermore, it is expected that the acids are rapidly oxidized and to measure only the acid could give a picture of a lower colophonium content than what is really present in the raw material.

Cosmetics

Colophonium and colophonium-containing ingredients will not be accepted in products labelled with Asthma Allergy Nordic.

Adhesives

Colophonium directly added as an ingredient in adhesives will not be accepted in products labelled with Asthma Allergy Nordic. Colophonium-containing ingredients will be evaluated individually and in the context, they will be used.

Colophonium-containing ingredients will not be accepted in adhesives used in plaster, where the adhesives are in direct skin contact for a potentially prolonged time.

Paper-based products

Colophonium intentionally added to paper-based products will not be accepted in products labelled with Asthma Allergy Nordic.

Colophonium-based ingredients will be accepted, but requirements as to the content of colophonium in the raw material will be set.

In the criteria for tissue and hygiene products the limit for colophonium in the final product is set at 5 ppm for each of the marker substances measured with gas chromatography or another test method providing the same level of accuracy. The documentation is a test result made on three different batches showing that the requirements are met for all batches. In the background document, it will be stated that it will be

the responsibility of the applicant to ensure that these limits are held continuously. Asthma Allergy Nordic may perform controls of the compliance by asking for renewed test results once a year.

References for Appendix 2

Downs & Sansom, 1999: *Colophony allergy: a review*, Anthony M. R. Downs & Jane E. Sansom, Contact Dermatitis, 1999.

VfA, 2016: http://www.videncenterforallergi.dk/kliniske-retningslinjer/patientinformation/patientinformation-kolofonium/

CIR, 2015: *Safety Assessment of Monoglyceryl Monoesters as used in Cosmetics*, Final Report, 2015.

Bråred Christensson et al, 2006: *Hydroperoxides for specific antigens in contact allergy*, Johanna Bråred Christensson, Mihály Matura, Carina Bäcktorp, Anna Börje, J. Lars G. Nilsson & Ann-Therese Karlberg, Contact Dermatitis, 2006.

Karlberg & Gäfvert, 1996: *Isolated colophony allergens as screening substances for contact allergy*, Ann-Therese Karlberg & Elisabeth Gäfvert, Contact Dermatitis, 1996.

Salim & Shaw, 2001: *Recommendation to include ester gum resin when patch testing patients with leg ulcers*, A. Salim & S. Shaw, Contact Dermatitis, 2001

Cockayne et al, 2001: *Occupational contact dermatitis from colophonium in a dental technician*, Sarah E. Cockayne, Ruth Murphy & David J. Gawkrodger, Contact Dermatitis, 2001.

Kanerva et al, 2001: *Colophonium in sanitary pads*, Lasse Kanerva, Helena Rintala, Kerstin Henriks-Eckerman & Kerstin Engström, Contact Dermatitis, 2001.

Karlberg & Magnusson, 1995: *Rosin components identified in diapers*, Ann-Therese Karlberg & Kerstin Magnusson, Contact Dermatitis, 1995.

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Nilsson et al, 2009: *Udvikling og validering af en metode til analyse af kolofonium i kosmetiske produkter*, Ulrika Nilsson, Ann-Therese Karlberg & Pia Lassen, Miljøstyrelsen Miljøprojekt nr., 1271, 2009

Personal communication with producer of paints and varnishes. 29.04.2016.

Personal communication with producer of adhesives. 09.05.2016.

Personal communication with producer of fluff and pulp. 12.05.2016 and 10.06.2016.

Appendix 3 – Specification of Requirements for Face Masks

Face masks are a special sub-group under this criteria document. Since face masks differ slightly from the rest of the product group with regards to components and function, these differences have been addressed in this appendix. Face masks come in many forms and depending on the intended use they can be made from different materials. Face masks for the European market may also be regulated by different legislations according to their purpose.

Regulatory Framework (Europe)

Medical face masks or surgical face masks are products falling within the scope of the EU Regulation 2017/745/EC (MDR).

Some products, such as filtering face-piece respirators (also called protective face masks or respirators), are considered as personal protective equipment (PPE) and hence fall under the scope of the EU Regulation 2016/425/EC (PPER).

A face covering is another type of mask, for which the EU regulatory framework has not established specific legal requirements. Therefore, the EU General Product Safety Directive (GPSD) 2001/95/EC would apply. In addition, some Member States, standardisation bodies or other entities may provide guidance on the specifications and use of these face covers. [EU Commission 2020].

Special Components in Face Masks

All face mask components must meet all requirements in the criteria document. However, since some components are different from the average component in traditional hygiene and tissue products, it may be difficult to translate specific requirements in terms of the special components.

The typical components of a face mask are:

- Non-woven tissue of synthetic polymers and/or cotton
- Adhesives
- A nose clip of either plastic or metal
- Earloops/tie strings of synthetic polymers with or without rubber materials.

Handling the synthetic polymers (including adhesives) and cotton components in face masks are no different from the components otherwise included in the product group definition. However, two components in face masks differs:

- The nose clip 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.
  Nose clips consisting entirely of plastic has no special requirement and must be documented the same way as every other polymer component in the face mask.
- The earloops/tie strings may contain rubber materials. If this is the case, there is a risk of them containing allergenic accelerators known as rubber chemicals. This covers both individual substances such as mercaptobenzothiazole (MBT) and mixtures of substances such as mercapto mix and thiuram mix. These accelerators are not accepted in products to be used in allergy labelled face masks and information on what accelerators are used for the rubber synthesis must be documented in order to exclude the use of unwanted substances and mixtures.

Nose Clips Consisting Fully or Partially of Metal

As mentioned above it is required for nose clips 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 face masks with the allergy label that contains a metal nose bar.

Asthma Allergy Nordic requires that, it can be shown in a laboratory test, that no nickel is migrating from the nose bar. 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 method.

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.

However, since the recommended time for using face masks is much shorter than one week, a test with a short time span may be acceptable. For this purpose, metal nose clips used for face masks, an analysis of 12 hours in a sweat matrix can be performed instead. The reduced time frame is accepted as neither consumers nor healthcare professionals use the same face mask over many hours but will change it regularly. A 12-hour test is therefore considered to cover a worst-case scenario for use. If this test is performed, the result must meet the requirement of 0.1 ppm.

The migration test must be performed according to methods for determining nickel migration from metals as accepted by the EU Commission and publish 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.

Note, nose clips that are fully (100%) encased in plastic is exempted from the testing requirement. There must be no access to the metal in any areas of the nose clip, e.g., at the ends, for this exemption to be valid.

Requirement

The amount of nickel migrating from the metal nose clip must be lower than the detection limit defined as 0.1 µg/cm^2/week; or 0.1 mg/kg (0.1 ppm) measured over 12 hours.

Documentation: A migration test performed according to methods for determining nickel migration from metals as accepted by the EU Commission performed by an accredited laboratory and/or accredited test method.

Efficacy of Face Masks

Unlike other products included in these criteria the efficacy of face masks is vital for the product and for the protection of the sensitive individuals using the face masks. Unlike the other products, the efficacy of face masks is measurable and subject to objective criteria, while other products are more subjective in the concept of efficacy.

To make sure the allergy labelled face masks provide the expected protection for the sensitive individuals in the target group, Asthma Allergy Nordic has decided to set requirements to the efficacy.

Efficacy of single-use face masks

Face masks for single use must meet the requirements of CE-marking of medical face masks class II, or IIR.

This must be assessed by an independent consultant and the report must be provided as part of the assessment done by Asthma Allergy Nordic.

Note, that products marked with a CE-label class II or IIR do not need to document this requirement any further.

Efficacy of re-usable face masks

Face mask for multiple uses (re-useable) must meet the requirements of CE-marking of medical face masks class I, II, or IIR. The face mask must also have this efficacy after 10 washes of the product.

This is to ensure that users of the face mask still have the expected protection after the product has been washed several times.

This must be assessed by an independent consultant and the report must be provided as part of the evaluation done by Asthma Allergy Nordic. The assessment from the consultant must be valid for both the product as new, and after 10 washes according to the recommendations on the product. The wash must be performed according to DS3000:2021 section 5.4. The efficiency tests done as part of the assessment must be performed according to EN 14683:2019.

References

[EU Commission 2020]: Guidance on regulatory requirements for medical face masks, 2020

[ECHA Restrictions]: https://ec.europa.eu/growth/sectors/chemicals/reach/restrictions_en

[European Commission]: https://ec.europa.eu/docsroom/documents/45591

Protective Face Mask Testing & Certification | SGS

Explainer: Testing the Efficacy of Protective Face Masks (a-star.edu.sg)

Face Mask Regulations and Standards in the EU: An Overview (compliancegate.com)

[EN14683:2019]: Medical face masks – Requirements and test methods

[DS3000:2021]: Washable reusable community face covering – Requirements and test methods