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BACKGROUND AND REQUIREMENTS

PAINT & VARNISH – VERSION 1.0

ASTHMA ALLERGY NORDIC

Asthma Allergy Nordic

March 2023, version 1.0

Content

Background and Requirements for Labelling of Paints & Varnishes with Asthma Allergy Nordic

This document describes the background and requirements set for allergy labelling of Paints & Varnishes with the Asthma Allergy Nordic label. In this document, each section will have a background text explaining, why the requirement is set and the reasoning. This is followed by the requirement itself and the accompanying documentation requirement. All requirements and documentation are highlighted in the format of 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. 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 why criteria have been developed for paints and varnishes is to put focus on the sensitizing properties of paints and varnishes and their constituents. Paints and varnishes have been the source of an outbreak-like rise in cases with sensitization towards the preservative methylisothiazolinone (MI). This has also given focus to the fact, that this biocide may cause airborne allergic contact dermatitis. Besides the issue with the use of potent allergenic biocides, paints and varnishes also may contain volatile substances that may cause discomfort for people with sensitive airways.

Paints and varnishes on the European market are regulated under several different legislations namely the so-called EU Paints Directive (2004/42/CE), the EU Biocide Regulation (BPR) (528/2012/EC), the EU Classification, Labelling, and Packaging Regulation (CLP) (1272/2008/EC), and the EU Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (REACH) (1907/2006/EC). The EU Paints Directive regulates the total content of volatile organic compounds (VOCs) in the products, it also requires the VOC content to be displayed on the product label. The BPR regulates which biocides may be used as preservatives in the products. The CLP focuses on product hazard labelling and packaging, and criteria for hazard classification. Finally, the REACH Regulation focuses on the overall safety of human health and environment, however the specifics of the REACH Regulation are often not enough to prevent people with allergies from having allergic reactions to products on the market. Corresponding legislation may be found on other markets around the world. Even though there are a lot of regulations for paints and varnishes none of them have special focus on allergies, or asthma. Asthma Allergy Nordic wish to add this aspect to paints and varnishes 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 asthma, 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 paints and varnishes you get:

- No fragrance
- No sensitizing preservatives (e.g., MI)
- Minimal risk of allergic reactions on the skin
- Low content of volatile organic compounds (VOCs)

The Definition of Allergenic Substances

Asthma Allergy Nordic requires that no substance present in the final product 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 (0.00001%) in the final product. To assess whether a substance is considered sensitising, the following is taken into consideration:

- Does the substance have a harmonised classification as a sensitizer according to the EU CLP Regulation (1272/2008/EC)?
- Is there other documentation presented to prove the potential risk of the substance to sensitize the skin and/or mucous membranes? This could be the case if:
    - There are published articles on cases where allergic reactions have been reported over a period and where the clinical relevance has been established.
    - There are epidemics where a lot of cases are reported over a short period of time towards a specific substance.
    - There are 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 is a constant number of consumers having a positive reaction when tested. This must be assessed in relation to use of the substance both in terms of frequency and levels, and to exposed groups of consumers.

With the exception of a harmonised classification the above points will often 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 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 minor group that are/might be allergic towards 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 on 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* 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. 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 formulation 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 following products are comprised by these criteria as paints and varnishes [2004/42/CE]:

a) 'matt coatings for interior walls and ceilings'
b) 'glossy coatings for interior walls and ceilings'
c) 'interior trim and cladding paints for wood, metal or plastic'
d) 'interior trim varnishes and woodstains'
e) 'minimal build woodstains'
f) 'primers'
g) 'binding primers'
h) 'one-pack performance coatings'
i) 'two-pack performance coatings'
j) 'multicoloured coatings'
k) 'decorative effect coatings'

Similar products not specifically mentioned above but chemically identical and with similar purpose may also be included in the product group. However, this will be based on a case-by-case assessment.

Products not Included in the Product Group

Paints and varnishes that are provided in spray delivery systems (spray can/spray paint) are not included in the product group as the dispersion of the products into fine particles will increase the risk of causing problems to the airways – and especially so for people with asthma and sensitive airways. This means that an evaluation of the product applied by spray delivery systems is not a part of the assessment for the allergy label.

Criterion 1 – Information on Product Composition

To assess the allergenic potential of the constituents of the product, Asthma Allergy Nordic require the full composition of the product. The reason for this is that even very small amounts of a given substance may cause an allergic reaction of the skin. This will often mean that Asthma Allergy Nordic will have to have information on the composition of raw materials sent directly from suppliers and sub-suppliers. To assist with this process, Asthma Allergy Nordic must receive a help form, which is available on the *Retailers & Manufacturers Portal*, or the information must be provided in any other way similar to the help form. [RMP]. The help form can also be provided by direct contact to Asthma Allergy Nordic by email.

Requirement 1

The full composition of the product must be provided. The full composition must include the trade name of the product and (if applicable) formulation number or ID, trade name of raw materials, name of supplier, chemical name, cas-no., active amount of the substances in the finished product as well as function of each raw material.

Documentation: Full formulation of the product including all ingoing substances (see definitions below). The formulation must contain information on all aspects as described in the requirement. Safety data sheets for the raw materials must be provided upon request.

Trade name is the name under which the product is sold to the consumers.

Formulation number is used by some manufacturers to identify a specific product in the production. Information on formulation number is not mandatory and should only be provided if the applicant believes it will ease identification and communication in the application process.

Name of raw material is the trade name under which a given raw material is sold from the supplier of the raw material. It must be provided since some raw materials need additional information of full composition and hence it is important to know which raw material is used in the product formulation. Our certification requires traceability down the supply chain, and the trade names are an integral part of this.

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 belonging to a group of substances have multiple cas-no.'s and some cas-no.'s cover multiple substances. In many cases, the cas-no. does help in identifying substances and must therefore be stated on the formulation to avoid misinterpretations.

Active amount is the amount of the substances in a raw material or product excluding water. It may be referred to as active concentration or active content as well.

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**, that the Lower Limit of Interest (LLoI) is defined as 0.1 ppm, and a substance is considered not to be present if it is not present above 0.1 ppm in the final product.

Auxiliaries and solvents 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.

Criterion 2 – Specifically Limited or Excluded Substances

Some substances used in paints and varnishes may be problematic with regards to contact allergy or sensitive airways. These substances need to be limited or excluded entirely.

Substances Classified Sensitizing to Skin and/or Respiratory System, H317/H334

The aim of Asthma Allergy Nordic is not only to prevent induction of contact allergy but also minimise the risk to consumers already sensitized from getting allergic reactions when using paint and varnish. The use of these substances in products labelled with Asthma Allergy Nordic is excluded entirely – regardless of concentration (***note***, the defined lower limit of interest in 'The definition of allergenic substances'). This requirement includes all substances with a harmonised classification as skin sensitizer (H317) and/or respiratory sensitizers (H334).

Substances Where Alternative Evidence of Allergenic Potential Exists

Some substances are considered sensitizing by dermatologists even though the substances are not classified as such. These substances are considered the same way as substances with a harmonised classification (see above). Another way to qualify under this definition, could be, if the substance has several notifiers suggesting classification as sensitizing according to the ECHA Inventory. [ECHA Inventory]. The reason for this is that the process for classification of substances is long and the knowledge of the effects of the substances may be generally accepted long before the change of classification. Also see 'The definition of allergenic substances' in the beginning of the document.

Fragrance

Fragrance allergy is of rising concern and correlates with exposure to fragrance substances. A general limitation in exposure may therefore help limit the risk of developing fragrance allergy, and people with hypersensitivity may feel the requirement helps them too. Fragrances are not commonly known to be used in paints; however, some types of paints may use essential oils for various reasons, and it is important to emphasize, that essential oils often contain fragrances and largely will be considered fragrances themselves.

Fragrance must not be part of the product or raw material. That means that the product should always comply to the EU Cosmetic Regulation's requirement for using the claim "perfume free" or "fragrance free". Masking substances will in most cases be considered as a fragrance and will hence not be accepted in the product.

It is a challenge to all that there is no generally accepted definition of perfume/fragrance. In the EU Cosmetics Regulation (1223/2009/EC), there is a need to actively consider if fragrance is present, if one wishes to use the claim "fragrance free", since a working group under the European Commission has made a technical document on cosmetic claims, addressing this claim, and they state that, "*The claim 'free from perfume' should not be used when a product contains an ingredient which exerts a perfuming function in the product, regardless of its other possible functions in the product.*" In light of this, a manufacturer must know if a fragrance substance is present, even if it is not used for fragrance purposes, and should such a substance be present, then the claim "Fragrance free" cannot be applied to the product. The intention of this requirement is, that the manufacturer must actively address this issue, and that the product should always comply to the Cosmetic Regulation's requirement for using the claim "perfume free" or "fragrance free". This also means that fragrances mentioned in the SCCS opinion SCCS/1459/11 are not allowed in the final product. [SCCS/1459/11].

Residual monomers

Polymers may contain residual monomers. Some monomers are considered sensitizers even if the polymer itself is not considered as such, and therefore the presence of these monomers is unwanted. In some cases, like monomers in polymers, it may be hard to avoid unwanted residuals for some reason, and therefore those impurities/residuals have been tolerated as present in the product but limited in

some way based on either a risk of the allergenic potential or technical available solutions. In this case, it is the assessment of Asthma Allergy Nordic that monomers in polymers pose less of a risk for causing allergic reactions in consumers as they are often covalently bound in the polymer. There are several clinical cases of people who have had allergic reactions to monomers but always from un-cured polymers and freely available monomers. This is not the case in polymers used in paints. Therefore, residual monomers are accepted in small amounts. The tolerated level on sensitizing monomers is based on the experience from the Danish and Norwegian national labels and the limit from the Nordic Ecolabel.

To minimise the content of sensitising monomers in allergy labelled paint and varnish, polymer raw materials must not contain more than 100 ppm of monomers that are considered sensitizing.

The requirement must be documented by the manufacturer of the polymer by means of specification or statement.

Requirement 2

A. Substances classified sensitizing with H317 and/or H334 may not be part of the product or raw materials.
B. Substances, where alternative evidence of sensitizing potential to the skin exists, may not be part of the product or raw materials.
C. The product must be able to claim "*Fragrance Free"* according to the Cosmetics Regulation.
D. The polymer raw material must not contain more than 100 ppm of monomers that are considered sensitizing.

Documentation: Full formulation cf. req. 1. 2D: this information shall be provided from the supplier of the polymer as part of the assessment of the polymer raw material.

Criterion 3 – Emission of Volatile Substances

After application, paints and varnishes dry/cure and during this time, fumes dissipate from the painted surface into the air. The diffusion of gasses into the air (emissions) is a process that lasts for a long time. It begins at the time of application and is usually followed by a gradual decrease over time, finally reaching a baseline after some weeks. The emissions are various volatile compounds, both organic and inorganic which influences the indoor air quality (IAQ). There is mounting evidence that volatile compounds affect the individuals who apply the product and the people living in the painted rooms after application of the product by increasing their risk of asthma and contact allergy. Since Asthma Allergy Nordic aims to protect people with sensitive airways, it is reasonable to set acceptable levels for volatile substances in allergy labelled paints and varnishes as low as possible, even at the early stages of use such as application and curing.

This criterion aims to limit the emissions of volatile organic compounds (VOCs), including formaldehyde, as well as ammonia, over time by requiring testing.

The test result will also be evaluated with regards to the individually identified VOCs. Should any of them also be sensitizing substances, it must be shown that the amount of these, present in the product is below the lower limit of interest on 0.1 ppm.

The amount of volatile substances emitted from the product must not exceed the following values:

Measure point / Limit value (µg/m^3)	24 hours	3 days	28 days
TVOC*	300	300	10
SVOC*	30	30	10
Formaldehyde	20	10	10
Ammonia	140	-	-

* Toluene-equivalents

The requirement must be documented by at test performed by an accredited laboratory according to the standard EN16516 or EN16402 with the following specifications and modifications:

- The emission test(s) shall be made on the paint's ready-to-use state. This means that if tinting is provided, there must be a test on at least one tinted variant. The number of tests required will be decided in dialogue with Asthma Allergy Nordic, to ensure, that a representative selection is tested. As a minimum, the tinted variant with the highest expected emissions must be tested, and the reason for choice of variant must be clearly stated.
- TVOC and individual VVOCs/VOCs/SVOCs must be measured for all time points; after 24 hours, 3 days, and 28 days. Individual VVOCs/VOCs/SVOCs must be stated in the test report given as toluene-equivalents.
- No preconditioning of samples shall be part of the test, i.e., paint samples shall be applied to the substrate and then moved directly into the test chamber.
- A loading factor 1 m^2/m^3 must be used for both short and long exposure, corresponding to a loading factor for walls.
- The application amount shall be based on EN16516 (technical data sheet), but minimum 150 g/m^2 as specified by EN16402.

Limit Values and Timepoints

The timepoints for measuring emissions are based on the following reasoning:

From a technical point of view, it is hard to make precise, reproducible results earlier than 24 hours (± 3 hours). [Klinke 2021], [Neuhaus 2021]. After 24 hours the paint is not fully cured, and the measure point will be somewhat representative for simulating the painting situation. [Klinke 2021]. The 3 days measure point will simulate the newly cured paint and possibly the situation where a consumer will take a painted room into use. The measure point of 28 days is to ensure a sufficient decrease in emissions from the product and a satisfactory low level when fully cured.

The limit values are based on the following reasoning…:

TVOC and SVOC

Since VOC's are not an easily limited group of substances, it has not been possible to regard single substance properties like odor or occupational exposure limits in this part of the requirement. It based on more general considerations of indoor air quality.

General guidelines for TVOC have been proposed by several sources over the last decades, but most notably are the TVOC thresholds proposed by researchers such as Seifert and Mølhave more than three decades ago. [Seifert 1990], [Mølhave 1986]. Of interest here, is the "*no necessary action level"* for indoor air quality for TVOC, which was proposed to be located somewhere in the 200-300 µg/m^3 range. Levels above were suggested to call for more specific actions such as increased ventilation or even more drastic measures such as removal or reduction of the TVOC sources if the levels increase up towards 3,000 µg/m^3 or even beyond. These data have been debated in the literature; however, the findings are still related to what is used today in various building schemes.

BREEAM's guideline value at 300 µg/m^3 is based on CEN/TR 16798-2:2019 Annex B, section B.4 *Example on how to define low and very low polluting buildings*, where TVOC 300 µg/m^3 is the limit value specified for "very low polluted buildings". The term "low polluted" is defined as any building material that emits less than 300 µg/m^3 after 28 days in a test chamber according to EN16516. The intention is to create an expected baseline for a building space that never exceeds 300 µg/m^3. Here the standard's assumption is based on sampling at 28 days (and beyond).

The composition of TVOC from building materials reflects the legislation at any given date, as the regulations that govern chemicals in use, evolves over time. Several more recent initiatives have been made to establish guideline levels, mostly targeted towards environmental building schemes. Several building schemes have introduced TVOC guidelines in their proposals such as BREEAM (300 µg/m^3), LEED (500 µg/m^3), and WELL (500 µg/m^3), as well as values found in e.g., Hong Kong building guidelines (600 µg/m^3 for Good and 200 µg/m^3 for Excellent IAQ). [LEED 2022], [WELL 2020], [Hong Kong 2019].

Although more research is needed to map out the correlation between exposure to VOC's and asthma and allergy, there are strong indications that such a correlation exists. [Berkley 2022]. The levels used in BREEAM and mentioned by Mølhave are considered low and in level with good indoor air quality. These therefore make out the base requirement set by Asthma Allergy Nordic.

None of the mentioned sources state levels of this kind regarding SVOC's. To ensure a satisfactory low level of SVOC's the limit to a tenth of the TVOC requirement for the early measure points, and the same level for the last measure as it is considered very low altogether.

Formaldehyde

Formaldehyde is a very volatile organic compound (VVOC), and it is classified as a skin sensitizer. Formaldehyde may, as such, not be intentionally added to the product formulation; however, formaldehyde is known to be formed from other substances and may therefore be untraceable from the product formulation and still be present and measurable in the VOC-test. However, since the formaldehyde may be formed after the initial 24 hours, formaldehyde must be measured at all measure points and reported as part of the VOC-test report.

The US Agency for Toxic Substances and Disease Registry (ATSDR) has summarized a lot of different sources for recorded measured levels of formaldehyde both indoor and outdoor. [ATSDR 1999]. Mean indoor values for unpolluted homes are found at levels of 0.1 ppm or lower. While the outdoor atmospheric concentration varies a great deal depending on location, a long-term background concentration is mentioned to be 0.2 ppb. This value is, however, far below the levels measured in city environments, where the average atmospheric concentration for all measured sites was found to be 5.3 ppb.

[ATSDR 1999] mentions the odour detection threshold (ODT) for formaldehyde to be 0.5-1 ppm in air, even though some sources have stated an even lower limit (as low as 0.05 ppm).

The OEL for formaldehyde recommended by the EU Commission is:

OEL $STEL_{15\ min}$ = 0.6 ppm (or 0.74 mg/m^3); OEL TWA = 0.3 ppm (or 0.37 mg/m^3).

The OEL for formaldehyde in Sweden and Norway (suggested January 2021) is the same as the EU Commission recommendations above. [ECHA 2019], [Arbeidstilsynet 2021].

The OEL for formaldehyde in Denmark is: OEL $STEL_{Ceiling}$ = 0.3 ppm (or 0.4 mg/m^3); OEL TWA = 0.3 ppm (or 0.4 mg/m^3).

OEL STEL = Occupational Exposure Limit – Short Time Exposure Limit (15 min.)
OEL TWA = Occupational Exposure Limit – Time Weighted Average (8 h)

Using a safety factor with the OEL as done for the limit set for ammonia (see below) gives a limit of 5 µg/m^3 (corresponding to 0.005 mg/m^3), taking into account the way results are presented at very low concentrations according to both EN16516 and EN16402.

Comparing this value with the measured indoor levels from ATSDR 1999 we end up on practically the same magnitude.

Considering that formaldehyde will in certified paints will be from untraceable sources and not intentionally added, it must be expected to vary from batch to batch and from test to test. With this in mind, it will not be feasible to set the limit on the lowest possible level, since this will not take into consideration the variations that will inevitable be present in reality.

When looking at the current national criteria for paint and varnish in Denmark and Norway, the requirement is set at 20 µg/m^3 at the 24-hour measure point and 10 µg/m^3 at the following measure points. Since all these values are very small, they can all be considered to be in the same order of magnitude, and a low level of formaldehyde can be set based on the experience obtained from certifying paints under the current national labels; the certification also show that the strict limit is possible for paints already on the market today.

This low level should ensure a minimal risk of allergic reactions from formaldehyde emission from the paint or varnish and represent the "*normal level*" for indoor air quality, while still make allowance for variations in levels caused by the nature of the presence of the formaldehyde. The limit is also well below the odour detection threshold.

Ammonia

Ammonia can be present in paints and varnishes either as a directly added constituent or as a secondary constituent that is formed by chemical reactions in the product or through the degradation of other constituents. Since ammonia is a gas at room temperature it is highly volatile and will be emitted both during painting and the early curing phases.

Airborne volatiles, like ammonia, can provoke 2 types of sensations in the nose: the first one being sensations of smell, mediated by the olfactory nerve, and the second one being sensations of irritancy (typically: burning, tingling, or prickling), mediated primarily by the trigeminal nerve. [Smeets et al 2007].

Ammonia has a very distinct, unpleasant, pungent smell and as it is corrosive to skin it will, in gaseous form, also be irritating to the airways when inhaled.

The presence of ammonia in allergy labelled paint is a problem for sensitive individuals because of the irritancy and odour of the substance. Asthma Allergy Nordic wish to lower the risk of discomfort caused by ammonia. A limit of ammonia that aims to be below that of irritancy and of smell in allergy labelled paint is therefore established.

The odour detection threshold (ODT) for ammonia is debateable as different sources state different limits. [Smeet et al 2007] states the ODT to be 2.62 ppm (1.9 mg/m^3), while [ATSDR 2017] states the ODT to be 5 ppm (3.5 mg/m^3). Other sources mention the ODT to be up to 50 ppm. Conservatively a limit below 2 mg/m^3 is to be preferred.

Exposure to ammonia may cause irritation of the airways, and this is especially true for people with sensitive airways. [Sherson 2022]. Therefore, a limit to minimise the risk of discomforts from ammonia both when applying paint and during curing is advisable. To establish this limit, the limits for occupational exposure have been considered. The occupational exposure limits (OEL) are:

OEL for Europe: OEL STEL = 50 ppm (or 36 mg/m^3); OEL TWA = 20 ppm (or 14 mg/m^3).

The limit value is set using the occupational exposure limit and a safety factor of 100. This should ensure a minimal risk of irritant effect from ammonia emission, and gives a limit of 140 µg/m^3 (corresponding to 0.14 mg/m^3). Since this value is lower than the conservative limit set for irritancy due to odour, it is considered to be sufficient to address both the problem of smell and irritation of the airways.

The product must be tested for ammonia according to standard EN15615 or NIOSH 6016:1996 or equivalent. The requirement must be documented by a test performed by an accredited laboratory. The test must use the following modifications/specifications:

- The emission test(s) shall be made on the paints ready-to-use state. This means that if tinting is provided, there must be a test on a tinted variant. The tinted variant must be the tint with the highest content of ammonia and the choice of variant must be clearly stated.

- Ammonia must be measured 24 hours after application, using the same sampling as for formaldehyde and TVOC if this is feasible.
- The test sample shall not be pre-conditioned before the test is performed.

In case a method, other than the ones mentioned above, is chosen the justification must be stated clearly. Asthma Allergy Nordic may reject other methods used if they are not deemed sufficient to document the requirement.

The modifications to the test methods are based on the following reasoning:

Since ammonia is highly volatile, it is assumed that the emission of ammonia will be the highest at the time of application and during early curing stages. It is assumed that the emission from later curing stages will be significantly lower than in the early stages. It will therefore suffice to measure ammonia at an early measure point. Furthermore, the first measure point requirement is set at a level that minimises discomforts, so further measure points will not add to this issue.

Requirement 3

The emission of volatile organic compounds (including very volatile and semi volatile compounds) must not exceed the following limits:

Measure point / Limit value (µg/m³)	24 hours	3 days	28 days
TVOC*	300	300	10
SVOC*	30	30	10
Formaldehyde	20	10	10
Ammonia	140	-	-

Documentation: Test performed by an accredited laboratory and a report according to the requirements in EN16516/EN16402. The test must state all specifications and modifications given above.

Criterion 4 – Preservatives

Preservatives pose a special problem in paints. On one hand preservatives are needed in water-based paints and varnishes, on the other hand, preservatives are of special concern regarding their allergenic potential, and some have recently caused an outbreak of sensitisation. Thirdly, the variety of preservatives available to preserve these products on the European market are restricted by the EU Biocide Regulation. These issues combined makes preservation of paints and varnishes very challenging.

Another emerging issue of concern is that of airborne allergic contact dermatitis, with cases of people getting an allergic skin reaction to a substance that they have not been in physical contact with, but only seen exposure to through the air.

All these serious concerns have caused special attention to preservatives in general.

Asthma Allergy Nordic has decided that sensitizing substances are not accepted in products recommended by Asthma Allergy Nordic, and that applies to preservatives as well. **Note**, that the lower limit of interest applies here, which means that sensitizing preservatives may be used down the supply chain, if the total amount in the finished product is below 0.1 ppm.

Sensitizing substances includes respiratory sensitizers as described under req. 2A.

Requirement 4

The product must not contain preservatives that are considered as sensitizing to either skin or respiratory system (H317 and/or H334) in amounts above the lower limit of interest (0.1 ppm).

Documentation: Formulation of the product and all ingoing components (cf. req. 1).

Criterion 5 – 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 within the area of interest of Asthma Allergy Nordic must also be approved. Artwork changes that concern areas not related to the label, and our organization, do not require prior approval. However, Asthma Allergy Nordic must always be supplied with the current artwork to ensure traceability when communicating and controlling certified products.

Asthma Allergy Nordic would ideally prefer that all ingoing substances are declared on the product, however, experience shows that due to confidentiality in the supply chain, this is not possible. In addition, the list of contents may prove to be too long to provide the consumers with actual help and may also result in the erroneous assumption that allergy labelled products are “worse” than other products that do not have a similar list of contents. To still address the problem of preservatives being a focus point for paints, Asthma Allergy Nordic requires all preservatives used to preserve the final product to be mentioned on the product label. This is also an important information for people, who are allergic to preservatives, not commonly regarded as sensitizing, and for dermatologists when trying to identify possible allergens when determining allergies in patients. The information must be presented on the product label with the following wording or equivalent: “*The product is preserved with [chemical name or INCI of preservative].*”. We wish to avoid the use of the term ‘deliberately added’ since preservatives in raw materials are equally ‘deliberately added’. To avoid this discussion, we prefer to use the phrase suggested, however, similar phrases may be used.

To underline that the assessment was carried out based on the expected usage of the product, and that it does not include prolonged skin contact, the product shall include the following or equivalent consumer information on the product label:

"It is recommended to wear gloves, long sleeves, goggles, and other suitable protective equipment/gear. Keep ventilation rates elevated during work and throughout the first 72 h. Wash off any spill on the skin."

Other wordings may be used such as "*Avoid contact with the skin by using gloves and long sleeves. Ventilate thoroughly during and in the course of the first 72 h after using the paint*" or wording to the same effect.

Please note, that "or equivalent wording" also applies, so that when any safety phrases stemming from the CLP Regulation give equivalent information, this will fulfill the requirement, e.g., P280, "Wear protective gloves/protective clothing/eye protection/face protection", and/or P264, "Wash… thoroughly after handling", and/or P304, "If inhaled…".

Requirement 5

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.

All biocides used for preservation of the product must be declared on the product in the following way – or equivalent: "*The product is preserved with [chemical name or INCI of preservative].*"

The following use instruction – or equivalent wording must be found on the product label:
"It is recommended to wear gloves, long sleeves, goggles, and other suitable protective equipment/gear. Keep ventilation rates elevated during work and throughout the first 72 h. Wash off any spill on the skin."

Documentation: Artwork/label.

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Appendix 1 – Criteria in Summery

Requirement 1

The full composition of the product must be provided. The full composition must include the trade name of the product and (if applicable) formulation number or ID, trade name of raw materials, name of supplier, chemical name, cas-no., active amount of the substances in the finished product as well as function of each raw material.

Documentation: Full formulation of the product including all ingoing substances (see definitions below). The formulation must contain information on all aspects as described in the requirement. Safety data sheets for the raw materials must be provided upon request.

Requirement 2

A. Substances classified sensitizing with H317 and/or H334 may not be part of the product or raw materials.
B. Substances, where alternative evidence of sensitizing potential to the skin exists, may not be part of the product or raw materials.
C. The product must be able to claim "*Fragrance Free"* according to the Cosmetics Regulation.
D. The polymer raw material must not contain more than 100 ppm of monomers that are considered sensitizing.

Documentation: Full formulation cf. req. 1. 2D: this information shall be provided from the supplier of the polymer as part of the assessment of the polymer raw material.

Requirement 3

The emission of volatile organic compounds (including very volatile and semi volatile compounds) must not exceed the following limits:

Measure point / Limit value (µg/m³)	24 hours	3 days	28 days
TVOC*	300	300	10
SVOC*	30	30	10
Formaldehyde	20	10	10
Ammonia	140	-	-

Documentation: Test performed by an accredited laboratory and a report according to the requirements in EN16516/EN16402. The test must state all specifications and modifications given above.

Requirement 4

The product must not contain preservatives that are considered as sensitizing to either skin or respiratory system (H317 and/or H334) in amounts above the lower limit of interest (0.1 ppm).

Documentation: Formulation of the product and all ingoing components (cf. req. 1).

Requirement 5

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.

All biocides used for preservation of the product must be declared on the product in the following way – or equivalent: "*The product is preserved with [chemical name or INCI of preservative].*"

The following use instruction – or equivalent wording must be found on the product label:
"It is recommended to wear gloves, long sleeves, goggles, and other suitable protective equipment/gear. Keep ventilation rates elevated during work and throughout the first 72 h. Wash off any spill on the skin."

Documentation: Artwork/label.