

Documentation demands – indoor paint

Substances that can cause contact allergy or adverse reaction when in contact with the skin:

1. All substances that are present in the product will be evaluated regarding contact allergy by AllergyCertified, based on scientific literature.

Documentation demand: The AllergyCertified application recipe formula must be filled out or a similar document that contains the same information. Total composition (stating composition and impurities) for each raw material must be supplied, see appendix 1 for schematic.

2. Substances that are classified with ..., according to the CLP regulative.
 - a. H317 (R43) “May cause an allergic skin reaction”: can generally not be added unless the concentration used is under a known safe concentration for people who are already sensitized.
 - b. H334 (R42) “May cause allergy or asthma symptoms or breathing difficulties if inhaled”: can generally not be used unless the concentration is under a known safe concentration for people who do not already have asthma.
 - c. CMR can generally not be added unless the concentration used is under a known safe concentration.

Hazard Class and Category Code(s)	H-code
Carcinogenic: Carc. 1A/1B/2	H350, H351
Mutagenic: Mut. 1A/1B/2	H340, H341
Toxic for reproduction: Repr 1A/1B/2	H360, H361, H362

Documentation demand: Recipe and documents as mentioned in demand 1

3. Methylisothiazolinone (MI), Methylchloroisothiazolinone (MCI), Benzisothiazolinone (BIT) and Octylisothiazolinone (OIT) are not allowed in paint, as there are no safe levels in regard to direct skin contact and contact allergy.

Documentation demand: Recipe and documents as mentioned in demand 1

4. Formaldehyde and formaldehyde donors:
Formaldehyde donors must not be added or present in the product. Formaldehyde must not be added deliberately. As an impurity Formaldehyde can be technically unavoidable and the known no effect level on Formaldehyde is 10 ppm in regard to contact Allergy. Therefore, the level must not exceed 10 ppm in the product.

Documentation demand: Based on the information from the raw material 100 % composition with impurities from demand 1, the content of formaldehyde must be calculated by the applicant and shown to be 10 ppm or below.

5. Perfuming ingredients or substances must not be added or be a part of the product, this includes substances mentioned in the cosmetic legislation 1223/2009/EU.

Documentation demand: Recipe and documents as mentioned in demand 1

6. Residual monomers from polymer:
Some monomers are known to cause allergy and other adverse effects. Therefore, the residue of monomers in the raw materials must be stated in the application in order for AllergyCertified to evaluate the risk.

Documentation demand: Recipe and documents as mentioned in demand 1.

Airborne substances

7. An evaluation is made on every substance from the emission report for the paint regarding allergy and CMR related effects.

Documentation demand: A Chamber emissions test EN 16402, must be done. In order to comply with the demands made in this criteria, changes have to be made to the EN 16402 (be aware that no preconditioning is required!). The changes are specified in appendix 2. Test EN 16516 and ISO 16000-3-6-9-11 prior to 2018 it also allowed if the preparation and demands mentioned in appendix 2 are followed.

8. As an impurity Formaldehyde can be technically unavoidable and in regard to inhalation there is a short term known no effect level on 100 µg/m³, AllergyCertified allow formaldehyde in the following concentrations:

Measure:	Limit (µg/m ³)
24 hours	<= 100
72 hours	<= 20
28 days	<= 10

Documentation demand: Test report mentioned in demand 7. The level of formaldehyde will be shown in the Emission test.

9. Emission of VVOC, VOC and SVOC:
The definition of VVOC, VOC and SVOC is defined according to EN 16402: VVOC <C₆, VOC C₆-C₁₆ and SVOC <C₁₆-C₂₂.

Emission demands:

Measure:	Limit (µg/m ³)
24 hours	TVOC <= 10.000 Carcinogenic* <= 10
72 hours	TVOC <= 2.000 Carcinogen* <= 10

28 days	TVOC <= 200 TSVOC <= 20 Carcinogen* <= 1
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Carcinogen*: Substances that are classified with Carc 1A and 1B according to the CLP directive (H350) and does not have a Least Concentration of Interest (LCI) value. An informative list can be found in EN 16402:2017 and EN 16516. Substances that are classified with Carc 2 (H351), are evaluated within the LCI risk concept.

For some VVOC substances a LCI value is derived. In this case, it must be included in the risk assessment in demand 10. VVOC are not included in the TVOC.

For some SVOC substances a LCI value is derived. In this case it will be excluded from the TSVOC calculation and included in the risk assessment in demand 10.

Documentation demand: Test report as mentioned in demand 7. The calculation of TVOC and TSVOC are done according to clause EN 16402 clause 11.2.7. (Toluene equivalent).

10. Long term risk evaluation according to LCI-values:

The long term risk assessment using LCI values are done according to EN 16402, using the specific concentrations of the substances. The LCI values that must be used are the EU LCI values. Where there are no EU LCI values the lowest Belgian or German LCI value must be used.

The LCI assessment does only apply to a 28 day concentration measurement, as the LCI values are based on long term exposure with a 28 day measure in mind.

- a. Risk assessment of single substances with known LCI values:
 $R_i = C_i/LCI_i$, must be <1,0.
- b. Cocktail effect based on the total risk. This is based on sum of the individual risks.
 $R = \sum R_i$, must be <= 1,0
- c. VOC with no LCI value. In order to avoid unknown risk from nonassessable VOC, a limit of 10 % is permitted. This mean that the sum of the substances that does not have a LCI value or cannot be identified, must correspond to the following demands. Calculations are done based on Toluene Equivalents.

Measure:	Limit (µg/m3)
24 hours	TVOC <= 1.000
72 hours	TVOC <= 200
28 days	TVOC <= 20

Documentation demand: The concentrations for these calculations come from the test report in demand 7. The calculation of the individual risk (demand 10a), total risk (demand 10b) and TVOC of VOC with no LCI are done according to EN 16402, with the above formulas. The calculation for these demands can be done by AllergyCertified for a fee.

Links for the LCI values can be found in the background document.

