

AllergyCertified labelling of Cosmetic Products



January 2018



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What is AllergyCertified Cosmetics

The EU Cosmetics Regulation 1223/2009 defines the group of cosmetics products – these are for example creams, lotions, make-up, shampoos and conditioners. On top of that we certify wet wipes, medical devices group 1 and 2 and animal care products within this product group.

AllergyCertified cosmetic products are products where you find the absolutely lowest risk possible of developing skin allergy. All ingredients and raw materials have been through an allergy risk assessment before certification.

This means that if you already have an allergy towards a specific ingredient, you should be able to use an AllergyCertified cosmetic product, since the product has been assessed in order for the user not to get an allergic reaction. Since Contact Dermatitis is concentration depended only concentrations known **not** to sensitize are allowed. This means, that AllergyCertified products will make it possible to prevent the user from developing skin allergy.

Cosmetic products come into direct skin contact. Some you leave on your skin (leave-on products like a face cream or body lotion) and others you rinse off (rinse-off products such as shampoos and conditioners). There are stricter requirements for a leave-on product than for a rinse-off product to be AllergyCertified. This because the skin contact time is longer for leave-on.

What does it mean when a product has been AllergyCertified

There are strict requirements on chemicals:

- No perfumes – this include all perfumes, also if the perfume is used as a preservative
- No classified endocrine disrupting chemicals
- No classified carcinogenic chemicals

Strict requirements on raw materials

- AllergyCertified investigates all impurities in order to make sure they are not allergenic

Strict requirements on tests made in laboratory

- AllergyCertified requires tests on specific product groups such as mascaras, paint and when specific raw materials are used.



Why choose AllergyCertified

The AllergyCertified logo is designed in order for consumers to be able to decode the meaning of the logo within few seconds no matter where in the world they live. This make AllergyCertified a good tool for marketing purposes.

- The AllergyCertified label is an easy way to communicate care for consumers skin.
- AllergyCertified will be able to guide product developers when it is necessary to substitute one ingredient with another.
- AllergyCertified offers a wide range of articles about ingredients in order to improve knowledge for brand owners and consumers
- AllergyCertified offer to educate everyone working with cosmetic products when it comes to ingredients and allergy.

Costs

In order to be as transparent as possible AllergyCertified has set a fixed price for certification of cosmetic products. This means that we invoice three hours work for each cosmetic product. Hourly rate is 162 euros. There is a turnover based fee for all certified products. The fee is 0,4 percent of the yearly turnover. This fee is paid twice a year – in January and July. There is a maximum payment for the fee of 54.000,00 euros per year. For further information and more details contact ceo Lene Stiil at lene@allergycertified.com. She will be able to send you an agreement with all the details.

Requirements and tests

AllergyCertified has strict requirements regarding chemicals allowed in the certified products.

Chemicals not allowed

Chemicals classified with following H-sentences are **not** allowed in AllergyCertified products.

Sensitizing and skin effects:

- H310 Fatal in contact with skin
- H311 Toxic in contact with skin
- H312 Harmful in contact with skin
- H314 Causes severe skin burns and eye damage
- H317 May cause an allergic skin reaction (there are a few H317 we can allow in low concentrations such as for example Tocopherol, which we allow in 0,5 percent)



Cancer

- H350 May cause cancer
- H351 Suspected of causing cancer

Reproduction

- H360 May damage fertility or the unborn child
- H361 Suspected of damaging fertility or the unborn child

Perfumes

Perfume and essential oils are not allowed in certified products. This is regardless the ingredients function and thus includes perfumes with a multifunctional function such as Benzyl alcohol which can be used as both perfume and preservative.

Preservatives

Following ingredients can not be used as a preservative in a certified product.

- Formaldehyde
- Formaldehyde donors:
 - Benzylhemiformal
 - 2-bromo-2-nitropropane-1,3-diol
 - 5-bromo-5-nitro-1,3-dioxane
 - Diazolidinyl urea
 - DMDM hydantoin
 - Imidazolidinyl urea
 - Methenamine
 - Paraformaldehyd
 - Sodium hydroxymethylglycinate
 - Quaternium-15
- Methylisothiazolinone (MI/MIT)
- Methylchlorisothiazolinone (MCI)
- Kathon (MI/MCI)

Plants

Plants from the Compositae or Asteraceae family are only allowed if they are purified from the allergenic sesquiterpene lactone. Documentation for this by either MSDS (Material Safety Data Sheets) or TDS (Technical Data Sheets) or a test is required.

Colorants

Metals in colorants, some colorants can contain nickel or other allergenic metals. For these ingredients we need documentation that the NOAEL level (no-observed-adverse-effect-level) of the metal in the product is safe for consumers who have already been sensitized to the nickel (the metal).



Acrylates, some specific acrylates such as Methacrylate are not allowed. If the acrylate is an impurity in another chemical, AllergyCertified can only allow it if there is a NOAEL value and the impurity is below this value.

Raw materials and impurities

AllergyCertified need full information about all raw materials used in the certified products, and requires TDS and MSDS in order to see all ingredients used in the raw materials and possible impurities to make sure they are not allergenic.

Criteria for raw materials can be found on AllergyCertified website:

<http://allergycertified.com/business/about-allergycertified/criteria/allergycertified-criteria-raw-materials/>

Laboratory test

AllergyCertified will demand a laboratory test if a product contain nickel (for example a mascara) or if a product contain a raw material that can develop perfume or other allergenic impurities in the production process such as for example C12-15 Alkyl Benzoate

How to apply

It is always a good idea to call AllergyCertified's toxicologist in order to have a first talk. Her name is Ewa Daniél and her number is +45 2721 3760.

In order for AllergyCertified to assess and approve your product we need full insight into the recipe of the cosmetic product and the documents to support the raw materials.

Application template

This starts an application, and gives us the information on company, billing information and product information.

<http://allergycertified.com/wp-content/uploads/2014/10/Application-name-and-adress.docx>

The application template can be found here: <http://allergycertified.com/business/services/how-to-certify/>



Recipe

AllergyCertified need the recipe with:

- Company name
- Product name
- Recipe number
- Raw materials tradenames
- INCI names (and from which raw material they came)
- CAS number
- Concentration of the INCI substances (the concentration of the total recipe must give 100%)

On our website <http://allergycertified.com/business/services/how-to-certify/> you can find the recipe template. We have filled out an example which you can see below.

| | | | | | |
|--|--------------------------|-------------------------|-------------------------------|----------------------------|--------------|
| Company Name | Company XXX | | English product tradename | The lovely shampoo example | |
| Date | 25-04-2018 | | Local product tradename | | |
| Identical with earlier certified recipe If yes, name of certified product | <input type="checkbox"/> | | Recipe no. | XX-aaa-11-2 example | |
| # | INCI | Trade Name | CAS no. | Concentration (sum = 100%) | Function |
| 1 | Aqua | Own water supply | 7732-18-5 | 85,00% | Solvent |
| 2 | Sodium Laureth Sulfate | Laureth Sulfate XXX AAA | 3088-31-1 / 9004-82-4 / 68891 | 5,60% | Cleansing |
| 3 | Aqua | | 7732-18-5 | 8,40% | Solvent |
| 4 | Sodium Benzoate | Preservative name XXX | 532-32-1 | 0,50% | Preservative |
| 5 | Phenoxyethanol | | 122-99-6 | 0,30% | Preservative |
| 6 | Dehydroacetic Acid | | 520-45-6 | 0,20% | Preservative |

In the example a raw material “Laureth Sulfate XXX AAA” is used. As this raw material contains 2 INCI names, both must be stated in the recipe, Sodium Laureth Sulfate and Aqua. In this example the raw material is added in 14 %, where 40 % is Sodium Laureth Sulfate and 60 % Aqua, this means that the concentration in the recipe is 5,6 % Sodium Laureth Sulfate and 8,4 % Aqua. The same is done for the Preservative, which has another composition. For all INCI names a CAS number is added in order for us to identify the substance with a number.

When we receive this information, we will go through all INCI names and look at the toxicological information on all substances.

AllergyCertifieds assessment is based on an assessment of CMR (Carcinogen Mutagen Reproduction), contact allergy and irritation information, based on scientific information.



Further documentation

The assessment of the product cannot rely on the recipe alone, the raw materials have to be documented in order for AllergyCertified to assure there are no problematic chemicals added or unwanted impurities that can cause health problems.

The documentation demand is also described in our raw materials criteria, where specific purity demands or test demands can also be found here:

<http://allergycertified.com/business/about-allergycertified/criteria/allergycertified-criteria-raw-materials/>

Therefore we need a datasheet explaining the following

- Chemicals developed in the process of making the raw material such as perfumes, Formaldehyde.
- Level of impurities for example: Metals, Sesquiterpene, Terpene, Anthraquinone & Formaldehyde.

In some cases additional information will be required, and AllergyCertified will ask for this information.

Certification

When AllergyCertified has all the recipe and documentation information needed, the product can be approved for certification. We will Assign an approval number and send a certification document back to the responsible company. This is the proof that the product has been certified .