

# THE HAZARD COMMUNICATION OF FRAGRANCE ALLERGENS MUST BE IMPROVED<sup>†</sup>

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**Abstract:**

Contact allergy is a global health problem that could be alleviated considerably if the general public could reduce contact to sensitizers. Efficient hazard communication would be a valuable instrument to achieve this. What do current regulations concerning fragrance sensitizers in cosmetic products in Europe contribute? There are for example bans and restrictions according to the Cosmetic Regulation, there is the “26 allergens rule” that requires that the names of some allergenic fragrance ingredients are listed on the containers, there is labelling and classification of hazardous products according to Regulation 1272/2008, and there is the regulation concerning the Registration, Evaluation, Authorization and Restriction of Chemicals. Do these regulations increase consumer protection by suitable hazard communication instruments? Four main problems were identified: (1) According to the “26 allergens rule” consumers carry a very large part of the responsibility for risk reduction management. They need to be capable and motivated to recognize the names of strong allergens listed in the ingredient list and decide for themselves whether they want to run the risk or not, provided that they are aware of their responsibility. (2) Cosmetic products do not need to be classified and labelled like other consumer goods according to EC 1272/2008 if they contain hazardous substances. (3) Some pictograms for hazardous substances as for example the exclamation mark for sensitizers are not well understood by the majority of the general public. (4) Very often, the design of cosmetic containers implies health and well being, even if the respective products contain sensitizers or other hazardous substances. Against this background, the following improvements are proposed: (1) The “26 allergens rule” needs revision. (2) The exception for cosmetic products from labelling and classification should be abolished. (3) A new self-explanatory pictogram for skin sensitizers and skin irritants should become mandatory for consumer products containing allergens. (4) Packaging of products containing hazardous substances should not be allowed to be attractive and evoke feelings that the products were harmless.

Labelling of consumer products can be a very efficient tool for risk communication, however the addressees must be sufficiently trained to understand the system and know the consequences of their behavior. Transparent labelling will increase the credibility of manufacturers and can lead to a subsequent improved risk management with a benefit for all stakeholders.

**Key words:** classification and labelling; consumer protection; contact allergens; cosmetic products; fragrances; hazard communication; pictograms.

## 1. WIDESPREAD CONTACT ALLERGY

Allergy is a serious health problem worldwide. Fragrance compounds such as isoeugenol, cinnamal or Majantol play an important role as skin sensitizers, in addition to nickel, preservatives, dyes or other compounds (e.g. de Groot and Frosch 1997; Heisterberg et al. 2011; Yazar et al. 2009; 2011). Fragrances can act as sensitizers in non-sensitized persons and elicit the symptoms of skin allergy in sensitized individuals. Around one to two per cent of the German population are sensitized to the standard mix of allergenic fragrance compounds (Schnuch et al. 2002). We could gain control of contact allergy by avoiding contact to these substances. Actions have been taken (Api and Vey 2007; de Groot and Frosch 1997), but fragrance contact allergies still prevail (Schnuch et al. 2004; 2007; Thyssen et al. 2007).

Therefore, it is important to analyze whether all risk reduction measures have been taken. Do consumers know the residual risk? Is public awareness sufficient? The number of surveys which analyzed the situation of the consumers is very small. The present study analyses the status quo, describes the resulting problems on the basis of the available data and suggests possible solutions.

## 2. CRITICAL REVIEW OF LEGAL MEASURES

Several regulations concern the use of fragrance allergens in cosmetic products in the European Union. Some of them are assembled here and discussed briefly, including assessments and proposals for improvements. Tab. 1 in the online supplement shows a brief synopsis.

### (A) Bans And Restrictions

The best way to avoid sensitization is by protection from contact with sensitizing agents. Some substances are banned in cosmetic products when used as fragrance ingredients, such as trans-2-heptenal, pseudo-isomethyl ionone or verbena oil (EC 2009, Annex II). Others, like musk ketone or methyleugenol, may not be used above a certain threshold in certain products (EC 2009, Annex III). However, these lists do not comprise all sensitizing fragrances.

It will hardly be possible to ban all allergens, as time and again substances reveal to be allergens. The decision whether a substance is a contact allergen or not is not straightforward (Schnuch et al. 2011; Basketter et al. 2005). Therefore, hazard communication will always be necessary.

#### (B) “26 Allergens Rule”

According to the so-called “26 allergens rule” (EC 2003) 26 supposedly allergenic fragrance compounds must be specified on the containers of cosmetic products if they are present above certain mass percentages in the product (Klaschka 2010). This mandatory labelling procedure was also taken over for washing and cleansing products (EC 2006a), whereas no such labelling is required for other product categories. This compulsory labelling is meant to help end-users to identify cosmetic products which contain any of these 26 presumptive allergens above a certain concentration. These 26 fragrances are widely used in cosmetic products: three market studies conducted in Germany showed that up to 83 per cent of the deodorants contain at least one of the “26 allergens”, and up to 30 per cent of all products contain strong allergens above the threshold for labelling (0.001 per cent in the product) (Klaschka 2012a). Many customers are not aware that the risk reduction measure of some fragrance allergens is not more than the naming of the substances on the label (Noiesen et al. 2007). Some of the names of the “26 allergens” are very long and difficult to remember, and do not invite customers to become familiar with the “26 allergens rule”. A big effort and a great deal of knowledge are required by the customers (Klaschka 2010). Even informed patients with allergic contact dermatitis did not rely on the labels and the listed fragrances only (Noiesen et al. 2007). The “26 allergens rule” has many drawbacks. A revision of this list by the European Commion’s Scientific Committee on Consumers’ is in progress. The author suggests the following improvements (see also Klaschka 2010):

- (1) General criteria for sensitizers applicable to all ingredients would be preferable to a list of compounds for the following reasons: The list does not comprise all fragrance allergens used in cosmetic products (Nardelli et al 2011; van Oosten et al. 2009). The allergenic potentials of these

26 fragrance compounds were evaluated by various expert groups (compilation see Klaschka 2010), with the result that it comprises strong, medium and weak allergens, which are treated equally in the “26 allergens rule” despite their strongly differing sensitization potencies (Schnuch et al 2007). It became evident that substances belonging to the list of the “26 allergens” were replaced by other strong allergens which were not on the list (Rastogi and Johansen 2008; Tanaka et al. 2004). Furthermore, various sensitizing fragrance ingredients are used and the preferences vary greatly over the years, so that a static list will not be able to cover the actual situation on the market (Nardelli et al. 2011; Rastogi et al. 2003).

(2) For most substances it is not possible to determine a “safe” level (Buckley 2007). Therefore, the threshold concentrations for labelling should be abolished or at least reduced for strong sensitizers.

(3) Maximum concentrations in the products should be specified depending on the sensitization potentials and the use patterns (see also Jansson and Lodén 2001).

According to the “26 allergens rule” products need not be safer than before the compulsory labelling, unless consumers exert their power and would no longer buy products where these fragrances are labelled, which is apparently not the case in the German market of deodorants (Klaschka 2012a). The allergens listed on the containers do not seem to be of great help, even for allergic patients (Lysdal and Johansen 2009; Noiesen 2007). As long as the “26 allergens rule” is not improved, end-users should be supported, as it is not easy to detect the allergens named on the products package. For example, if the use of smart media becomes more popular in future, a user friendly method could be a smart media application, so-called “app” in a smart phone. Such an “app” could recognize the names of allergens on the label and indicate graphically whether the product contains strong, medium or weak allergens. This support could also be offered on the shelves of retail stores.

### (C) Classification And Labelling

Labelling of consumer products can be a very efficient tool for risk communication. However, cosmetic products are exempt from the requirement of labelling and classification according to European Regulation on Classification, Labelling and Packaging (CLP) (EC 2008). The CLP Regulation is the implementation of the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (UN GHS) ([www.unece.org](http://www.unece.org)). If cosmetic products were not hazardous, the exception would not be needed. The author applied criteria for classification and labelling to 33 formulas of various cosmetic product groups. Only one product would not have to be labelled as hazardous mixture. The majority of the products analyzed would have to be labelled due to potential negative effects to the eye or to the skin. The signal word WARNING would have to be on the labels of 64 per cent, DANGER would have to be on 33 per cent of the products (Klaschka 2012b). The user has the right to know about potential risks, like for any other consumer product containing hazardous chemicals. Therefore, the exception for cosmetic products should be repealed to improve the end-users' safety.

### (D) "Small Quantity Exception"

According to the CLP Regulation, only certain hazard-statements need to be written on the labels of containers smaller than 125 mL (so called "small quantity exception"). Skin irritation and eye irritation do not need to be indicated. As many cosmetic products contain skin and eye irritants, the small quantity exception should be amended in the interest of the consumers: It is important to note here, that it is not always easy to discriminate whether dermatitis is the symptom of an irritation or an allergy (Bruze et al. 2005, de Groot and Frosch 1997). Consumers of cosmetic products of all sizes should also obtain clear explanations for a safe use, i.e. the precautionary statements (Klaschka 2012b).

## (E) Pictograms

Clearly understandable icons such as the ones used for classification and labelling are better suited as risk communication instrument than listing the names of certain chemical substances on product labels. Substances and products (except e.g. cosmetic products or pharmaceuticals, according to Art. 1 (5)) EC 2008) containing contact allergens above 1 per cent have to be labelled according to the CLP Regulation with H 317 'May cause an allergic reaction', the pictogram GHS07 (exclamation mark) and the signal word "WARNING". Labelling fulfils its purpose only if the pictograms are understood correctly by the majority of the general public. However, laymen often misinterpret symbols: The recent study by the European Agency "Communication on the safe use of chemicals" revealed that some pictograms of the CLP regulation are not well understood. The GHS07 (exclamation mark) "is familiar to 59 per cent, but understood by only 11 per cent." (ECHA 2011; ECHA 2012). One main conclusion of this study is that "misunderstandings are clearly evident." The results depend e.g. on the individual education of the interviewees, and also on the nation of origin (ECHA 2012). For example, in many countries (Germany, France or Italy) where the traffic sign for general caution is very similar to the GHS07 pictogram, it must be assumed that more people will unconsciously be familiar with the exclamation mark, even if they do not know the special meaning of GHS07 on a product containing hazardous chemicals. Another study which lucidly showed the discrepancy between intention of experts and interpretation by end-users was conducted as a mental model approach with South African farmers who were asked about the significance of pesticide labels (Morgan et al. 2001; Rother 2008). The exclamation mark was not among the labels used in the interviews, but its predecessor, the St. Andrew's cross, the FAO sign for 'Harmful'. 35.7 per cent of the respondents did not know this sign and 31.3 per cent gave a wrong interpretation ("for emergency, first aid kit, shows hospital, don't use, do not enter where this sign is shown"). It is important to promote the understanding of existing hazard labels, but it would be even more efficient if their designs were self-explanatory. The author suggests to use a better understandable, more pictorial icon for sensitizers. This could help consumers and persons at

the workplace to take the necessary safety measures. The newly designed pictogram presented here (Fig. 1) is much clearer than a simple exclamation mark. As long as cosmetic products are exempt from classification and labelling in the EU, and as long as allergens are not prohibited in consumer products, this pictogram could warn consumers of potential allergenic ingredients in consumer products. The author suggests that this new pictogram is called GHS17 as subgroup of GHS07. It should be applied to substances and products classified as H317 'May cause an allergic skin reaction.' and on products that bear the statement: EUH208 'Contains (name of sensitizing substance). May produce an allergic reaction.' (according to EC 2008,). Skin irritation can be a reversible effect, but it can also be the manifestation of a developing sensitization and subsequent allergic reactions. Therefore, it would be in agreement with the precautionary principle to use the new pictogram GHS17 also for substances and products labelled as H315 'Causes skin irritation.' It is important to differentiate between leave-on cosmetic products, such as hand cream or decorative cosmetics, which lead to higher exposure of the human body, and rinse-off products, such as shampoo or shaving cream, which are discharged mainly into the waste water. Therefore, the thresholds for labelling with GHS17 should be lower for leave-on products than for rinse-off products.

#### (F) REACH

The European chemicals regulation REACH (Registration, Evaluation, and Authorization of Chemicals) (EC 2006b) introduced a registration and authorization procedure for chemicals. It is to be expected that this will lead to more data for the effects on human health and the environment. However, waiving conditions are applicable to many fragrances which could lead to a much smaller improvement of their data situation than for other substance groups. Only some of these alleviations are listed below: Substances produced below one ton per year in the European Union need not be registered and a chemical safety report is not required if the registered tonnage stays below ten tons per year (EC 2006b). Most fragrance substances are produced in small tonnages. Substances are exempt from the obligation to register if they occur in nature and are not chemically modified,

unless they are classified and labelled according to the CLP Regulation (EC 2006b). Many fragrances occur in nature, and especially for natural ingredients the data basis is often not sufficient for classification and labelling. A chemical safety report for the mixture is not required if it contains a hazardous substance below the thresholds for classification, which is  $< 1$  per cent for a sensitizing substance (EC 2006b). For cosmetic products this threshold is rather high, considering the high sensitizing potency of some compounds (e.g. 0.0063 per cent of isoeugenol in deodorants, Bruze et al. 2005). The registration process according to REACH is now well advanced. The author suggests that it would be a good moment to analyze to what extent waiving affects fragrance allergens.

#### (G) Design Of Containers

The design of most cosmetic containers implies health and well being even if the respective products contain sensitizers (Klaschka 2012b). In a market study for German deodorants recommended for sensitive skin 88 per cent listed at least one of the “26 allergens” on their labels and 15 per cent at least one of the strong allergens. The words “sensitive” or “soft” on the packages must be considered as misleading in these cases (Klaschka 2012a). These descriptions and pictures on the containers evoke emotions that tend to impede a proper risk perception. This was also described in the ECHA study (ECHA 2012). As long as there are no hazard statements and pictograms that contradict the graphic innocent message of the package design, it must be assumed that consumers trust the perfect safety of the products. According to the CLP Regulation it is forbidden to mislead consumers (Article 34 (2) in EC 2008, Klaschka 2012b). As soon as the exception for cosmetic products would be abolished in the CLP Regulation, either the design of the containers or even better the formulas of many cosmetic products would have to be adjusted.

### 3. SHARED RESPONSIBILITY

In principle, everybody who deals with hazardous substances in some way carries part of the responsibility for hazard communication and for the safe use: for example regulators on various

levels, scientists, medical practitioners, instructors, production managers, workers, consumer associations, private end-users and so on. For a more focussed picture of the complex process of hazard communication strategies it is useful to concentrate on the responsibilities taken over by the three main parties which are manufacturers, authorities and consumers.

● Manufacturers are the party who is equipped with the most profound knowledge about their products. It is now generally accepted, that they should carry the biggest share like in the approach used in REACH, following basically the “polluter pays principle”, where the manufacturers carry the responsibility for the safety of their products. The reversal of the burden of proof is one fundamental idea in REACH (Federal Environment Agency 2012). Now the manufacturers of chemicals need to prove that their products are safe for the users and the environment, a task that had to be fulfilled by the authorities before. This includes also the responsibility of producers to take over voluntary actions and make products safer beyond the legal requirements.

The situation is quite different in the case of the “26 allergen rule” (as illustrated in Fig. 2 in the online supplement): Manufacturers must specify the “26 allergens” on the label of their products. Authorities should control the implementation of the labelling at least by spot checks, which is not easy, as for example around 20,000 new or modified cosmetic products enter the German market every year (Butschke and Dross 2010). Consumers carry the biggest share (Klaschka 2010; 2012a,b): They should read the labels, know which names belong to the “26 allergens” and decide whether they want to buy and use a certain product containing potential allergens. Consumers need to know a lot, they should be able to make a kind of risk assessment for their private use and decide whether they want to run the risk or not. On top of that most consumers are not aware that they carry this responsibility and assume that cosmetic products were free of hazardous substances. Regulations which load the major responsibility for risk management on consumers and not on authorities and manufacturers are not effective, especially in this rather complicated matter which would ask for special training of the consumers. The labelling of the “26 allergens” is a hazard communication instrument, but it does not communicate the unavoidable

“residual” hazard after all feasible hazard control measures have been taken. It rather charges the general public with the tasks of risk assessment, risk control and risk management, even if their risk perception is minute or even inexistent.

Provided that the pictograms are designed so that most consumers understand their message correctly, classification and labelling could be seen in a middle position, where all three parties carry more or less an even share of the responsibility. However, as long as misinterpretations are common, regulators and manufacturers would have to work on a better instruction of the general public about the CLP regulation. Consumers need to be motivated and encouraged to use the information given on the labels. In this context, it must be conveyed to consumers that products bearing a hazard icon do not necessarily lead to a health problem. Consumers need to learn also about the difference between hazard (intrinsic property of a substance) and risk (dependent on exposure). Hazardous chemicals cannot be avoided completely, but the proper handling can keep the risk low. Exposure reduction strategies are crucial. Safety behavior can prevent much suffering and also helps to save costs for the healthcare system.

#### **4. INCREASED TRANSPARENCY AND TRUST BENEFITS ALL STAKEHOLDERS**

The main purpose of these regulations should be the protection of the health of the consumers. The actual regulations could be regarded as ransom for producers who have legally done their share by printing the names of sensitizers or labels on the containers. As manufacturers affirm the safety of fragrances (e.g. Cadby et al. 2002), it should be in their interest to learn from the experiences made and improve products further. A transparent hazard communication strategy builds trust between manufacturers and end-users. It increases the credibility also in other areas of producer - consumer relationships. Therefore, an effective hazard communication has many winners, not only the consumers, but also the manufacturers and other stakeholders.

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Fig. 1: Proposal for an easily understandable warning signal for consumer products containing potential allergens, called GHS17, in comparison with the current pictogram GHS07. The new pictogram in the left column would symbolize in a self-explanatory way the hazard of skin irritation and allergic skin reaction. The exclamation mark is not able to do this.

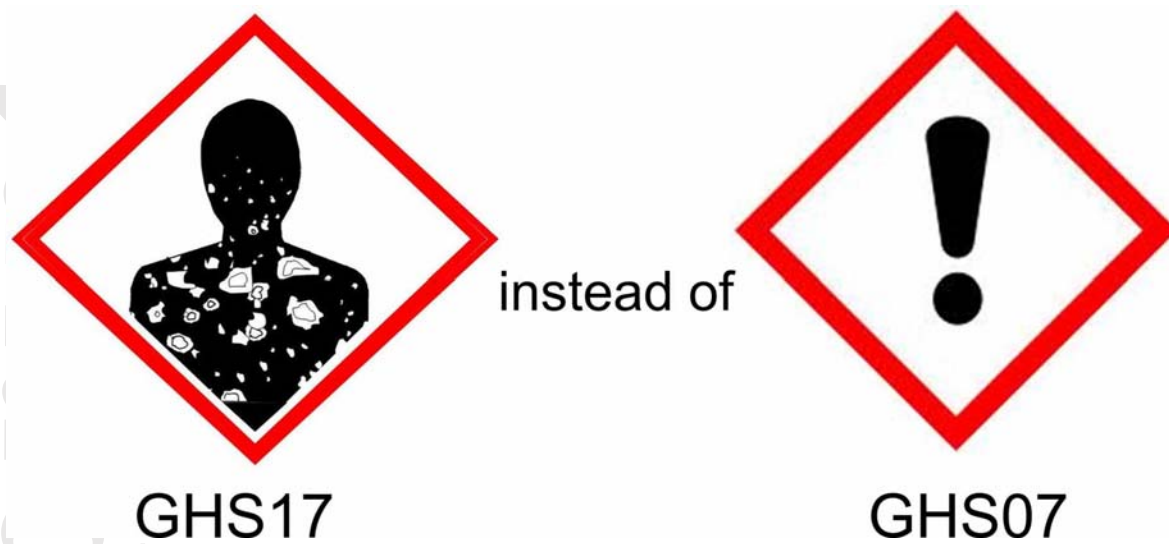
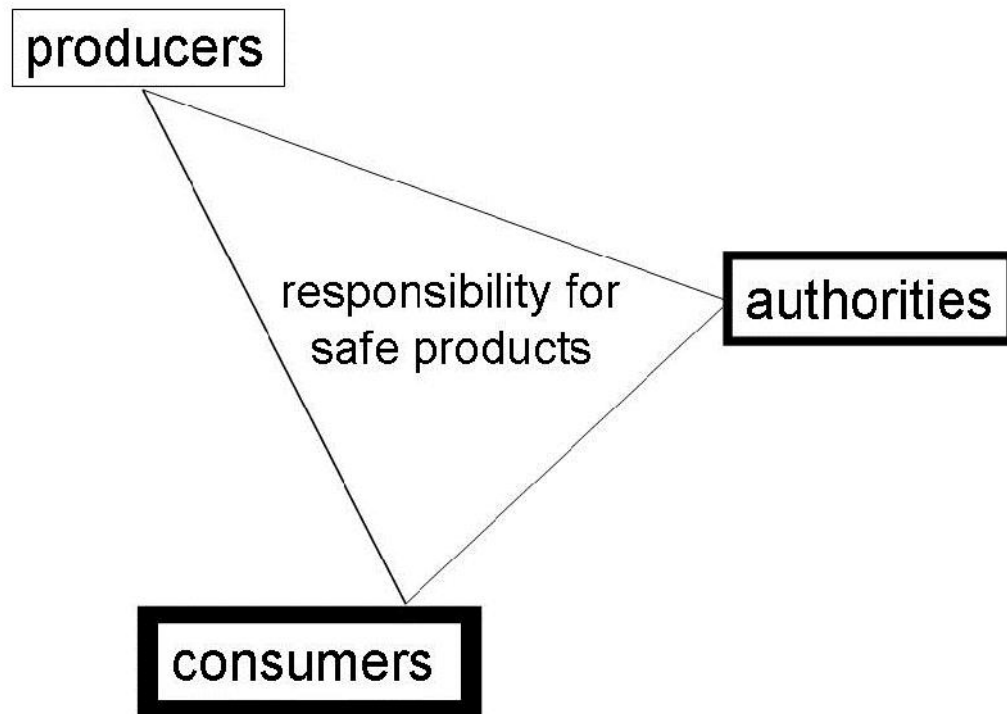


Figure 1

Fig. 2



## online supplement

Tab. 1: Regulations for allergenic fragrances in cosmetic products in Europe. Compilation of the present situation and proposals for improvements as discussed in the text.

| status quo                                                                                                        | details                                                                            | potential solutions                                                                                                                                                                                                                                                                              |
|-------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (A) Products may contain strong allergens.                                                                        | Certain allergens are banned, others restricted (EC 2009).                         | The ideal risk reduction would be a general ban of allergens.                                                                                                                                                                                                                                    |
| (B) 26 allergenic fragrances must be listed on the product containers.                                            | „26 allergen rule“ (EC 2003)                                                       | General criteria applicable to all substances are preferable to a list of compounds. The threshold concentrations for labelling should be abolished. Consumers should be able to detect the ingredients named on the products container by user friendly methods, e.g. by apps for smart phones. |
| (C) Labelling and classification of cosmetic products is not required.                                            | General exception laid down in the CLP Regulation in the European Union (EC 2008). | Exception for cosmetic products should be repealed.                                                                                                                                                                                                                                              |
| (D) Only certain H-statements and no P-statements need to be written on the labels of containers smaller than 125 | “small quantity exception” (EC 2008).                                              | The small quantity exception should be amended and for example skin irritation (category 2) and eye irritation (category 2)                                                                                                                                                                      |

|                                                                                                                                                         |                                                                                 |                                                                                                                                                                                                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| mL.                                                                                                                                                     |                                                                                 | should also be written on cosmetic products in containers smaller than 125 mL.                                                                                                                                    |
| (E) Symbols (St. Andrew's cross (Hazardous substance directive) and exclamation mark (CLP Regulation) are not well understood by the general public.    | (ECHA 2011, ECHA 2012)                                                          | The new pictogram proposed here (Fig. 1) should be obligatory for substances and products classified as H315 'Causes skin irritation' or H317 'May cause an allergic skin reaction' or with the statement EUH208. |
| (F) Waiving is assumed to affect fragrances more than other substances.                                                                                 | REACH (EC 2006b)                                                                | The consequences of waiving should be analyzed quantitatively for allergens.                                                                                                                                      |
| (G) The design of cosmetic containers tend to imply health and well being, even if the respective products contain strong sensitizers (Klaschka 2012b). | According to the CLP Regulation it is forbidden to mislead consumers (EC 2008). | It should not be allowed that containers of cosmetic products deceive consumers. Product designs that evoke positive feelings do not match with hazardous ingredients.                                            |