

Assessment of formaldehyde-containing hair straighteners

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Hair straightening products are used to straighten frizzy or extremely curly hair. Products are applied to the hair, and after 30 minutes a straightening iron is used to straighten the hair permanently.

The control authorities of the German *Länder* have taken several samples of new straightening products and detected free formaldehyde at higher concentrations between 1.7 and 1.8 percent in these products.

The Federal Institute for Risk Assessment (BfR) has assessed the health risk of hair straightening products that contain formaldehyde. Formaldehyde is a strong irritant for the eyes, skin and mucous membrane. The substance has strong allergenic potential, and BfR has classified it as carcinogenic for humans. During the straightening process, formaldehyde is released and can thus be inhaled by customers and hairdressers. This can lead to respiratory, skin and eye irritation during and after treatment. BfR concludes that hair straightening products with formaldehyde concentrations of 1.7 to 1.8 percent can be harmful to the health of private as well as professional users and their customers.

In the European Union, formaldehyde is not authorised as active ingredient in hair straightening products. The control authorities of the *Länder* assume that products with a strong effect are imported directly or ordered through the Internet. Hairdressers and private persons are urgently advised to refrain from purchasing and using such hair straightening products. BfR recommends that the *Länder* initiate measures for consumer protection.

1 Subject of the assessment

In several samples of hair straighteners free formaldehyde in a concentration of 1.7-1.8% was detected by the chemical and veterinary inspection agency (CVUA) Karlsruhe.

According to the European Cosmetics Directive, formaldehyde is allowed as active ingredient in nail strengtheners in a concentration of up to 5%. As a preservative, formaldehyde is allowed up to a concentration of 0.2% in cosmetic formulations, in products for oral hygiene up to 0.1%. Cosmetics with a minimum content of 0.05% free formaldehyde have to be labelled “contains formaldehyde” due to the allergenic potential of the substance.

2 Results

In its Opinion “Toxicological Assessment of Formaldehyde” (No. 023/2006), BfR classified formaldehyde as an inhalative human carcinogen for the naso-pharyngeal cavity. According to recent epidemiologic data from a study on Chinese workers, formaldehyde also causes myeloid leukemia in humans (Zhang et al. 2010).

With regard to toxicity, data on irritation of the upper respiratory tract in humans as well as data on cell proliferation in animals served to establish a 0.1 ppm threshold for formaldehyde air concentration.

Formaldehyde is a moderate to strong sensitiser and an important contact allergen. In addition to allergic contact dermatitis, anaphylactic shock as a result of exposure to formaldehyde has been reported.

On the basis of the available data, BfR assessed formaldehyde in a concentration of 1.7-1.8% in hair straighteners as potentially harmful to human health and recommends that the competent authorities take measures to protect the consumer.

3 Rationale

3.1 Risk assessment

A literature search was carried out in the following databases: DIMDI's data base, ISI/Web of Science, Pubmed, Scopus, ScienceDirect, NTP, Litdoc, Chemici.

3.1.1 Hazard identification

Formaldehyde was detected as an ingredient in hair straighteners. The formulation is applied to the hair; after 30 minutes excess product is removed by brushing. Hair straightening is achieved by treatment with a 230 °C straightening iron. This process disrupts the keratin and formaldehyde is used to cross-link the keratins again. During this procedure, formaldehyde is released, which results in inhalative and dermal exposure via respiration and contact of the gas with skin, mucous membrane and eyes.

3.1.2 Hazard characterisation

Carcinogenicity

The "International Agency for Research on Cancer" (IARC) classified formaldehyde as human carcinogen (category 1) (IARC 2006). In a BfR Opinion of 30 March 2006, BfR assessed formaldehyde as carcinogenic for the upper respiratory tract (BfR 2006). However, in a recent study (meta-analysis of epidemiologic studies up to 2007), no additional risk for these kinds of cancer was perceived (Bosetti et al. 2008).

Recent studies support the assumption that formaldehyde induces myeloid leukemia (Zhang et al. 2010). This prompted the US National Toxicology Program Scientific Advisory Committee to recommend registration of formaldehyde as leukemogen.

Irritation, sensitisation, anaphylaxis

Formaldehyde is a strong irritant for the eyes, skin and mucous membrane (Eikmann et al. 2006). Moreover, studies in animals and humans substantiated a moderate to strong allergenic potential for the substance. The frequency of allergic reactions is about 2-3% in Europe (Schnuch et al. 1997; Jong et al. 2007). Once sensitisation has occurred, the threshold for elicitation may vary widely (Fransway 1991). Formaldehyde-sensitive persons can tolerate products containing less than 30 ppm (0.003%) free formaldehyde (Jordan et al. 1979). In the USA and Europe, a maximum permissible value of 0.2% in cosmetic formulations is in effect, with the obligation to declare formaldehyde contents of more than 0.05%.

In general, formaldehyde can induce two kinds of immune reactions:

1. Allergic contact dermatitis (type IV, T-cell-mediated, delayed);
2. Contact urticaria (type I, IgE-mediated immediate-type hypersensitivity reaction).

In this context, there are several case studies on the occurrence of anaphylactic reactions on exposure to formaldehyde after dental treatment, partly with life-threatening symptoms (Candura et al. 1991; Ebner und Kraft 1991; Wantke et al. 1995; Braun et al 2000; Haikel et al 2000; Nabeshima 2004; Kijima et al. 2007).

3.1.3 Exposure assessment

The CVUA Karlsruhe estimated that the intended use of the hair straightening product results in a concentration of 5 ppm formaldehyde, at an assumed air volume of a 24 m³ room. In its report on the assessment of the carcinogenicity of formaldehyde, BfR assessed formaldehyde as a genotoxic carcinogen by inhalation for the naso-pharyngeal cavity (Schulte et al. 2006). Primarily, formaldehyde affects the areas of first contact, e.g. epithelia of the naso-pharynx and the skin. The effect is dependent on local concentration, but not on dose; formaldehyde is highly reactive and rapidly metabolised locally (IARC 1995).

For the effect of formaldehyde, BfR deduced a “safe level” of 0.1 ppm in air. This value was calculated on the basis of three different approaches (Toxicological Assessment of Formaldehyde, BfR 2006). 1) Human studies (0.1 ppm); in accordance with the WHO (2002), sensory irritation was used here as surrogate for a lack of data on cytotoxicity; 2) animal studies (cytotoxic effect at 2 ppm; 1 ppm does not elicit an irritation of the nasal mucous membrane; calculation of a “safe level” for humans by applying a safety factor on the “no adverse effect level” NOAEL in rats and 3) a mathematical model which analysed key data (toxicokinetics, genotoxic events, cell proliferation) (Connolly et al. 2003).

The maximum workplace concentration (MAK) for formaldehyde was defined as 0.3 ppm (DFG 2000).

With a formaldehyde concentration of 5 ppm as calculated by the CVUA, both the safe level of 0.1 ppm and the MAK of 0.3 ppm are clearly exceeded.

3.1.4 Risk characterisation

As active ingredient, formaldehyde is allowed in nail strengtheners at a concentration of up to 5%. As a preservative, formaldehyde is allowed up to a concentration of 0.2% in cosmetics (European Cosmetics Directive 2009). IARC classified formaldehyde as carcinogenic for the naso-pharyngeal tract (IARC 2006); BfR assessed formaldehyde in a BfR Opinion of 30 March 2006 as carcinogenic for the upper respiratory tract (BfR 2006). Recent data suggest that formaldehyde induces myeloid leukemia in humans (Zhang et al. 2010). Therefore IARC classified formaldehyde as leukemogenic (Baan et al. 2009). Additionally, formaldehyde has strong allergenic potential and elicits allergic reactions including anaphylactic shock.

The use of the assessed hair straightening product, judged by exposure and hazard potential, poses a health risk because the substance is carcinogenic, has strong sensitisation potential and elicits allergies including anaphylactic reactions.

3.2 Other aspects

Not applicable

3.3 Discussion

While the carcinogenicity of formaldehyde with respect to its potential to induce nasopharyngeal cancer is under discussion again, recent data are showing a correlation between myeloid leukemia and exposure to formaldehyde. The sensitisation potential of the substance is confirmed by recent studies. Moreover, there is a growing number of case reports on the

elicitation of allergic reaction and anaphylactic shock by formaldehyde. This constitutes a serious health risk.

3.4 Risk management options, recommended measures

Formaldehyde in a concentration of 1.7-1.8% in hair straighteners is, due to its carcinogenicity and sensitisation potential, detrimental to health and poses a serious risk. The German federal states are recommended to initiate measures for the protection of the consumers. Additionally, a RAPEX notification should be released. BfR is planning a press release.

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