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Revision 18 September 2012

Scientific Committee on Consumer Safety

SCCS

OPINION ON

Methylene glycol

The SCCS adopted this opinion at its 15th plenary meeting

of 26-27 June 2012

About the Scientific Committees
Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.
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SCCS
The Committee shall provide opinions on questions concerning all types of health and safety risks (notably chemical, biological, mechanical and other physical risks) of non-food consumer products (for example: cosmetic products and their ingredients, toys, textiles, clothing, personal care and household products such as detergents, etc.) and services (for example: tattooing, artificial sun tanning, etc.).

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This opinion has been subject to a commenting period of four weeks after its initial publication. Comments received during this time have been considered by the SCCS and discussed in the subsequent plenary meeting. Where appropriate, the text of the relevant sections of the opinion has been modified or explanations have been added. In the cases where the SCCS after consideration and discussion of the comments, has decided to maintain its initial views, the opinion (or the section concerned) has remained unchanged.
Revised opinions carry the date of revision.

TABLE OF CONTENTS

1. BACKGROUND

Methylene glycol (CAS 463-57-0; EC 207-339-5), or hydrated formaldehyde is formed upon dissolution of formaldehyde in water and exists in equilibrium with formaldehyde in aqueous solutions. While restrictions for the use of formaldehyde in cosmetic products exist in Directive 76/768/EEC, Annex III, entry 13 (concerning formaldehyde in nail hardeners) and in Annex VI, entry 5 (concerning formaldehyde and paraformaldehyde used as preservatives), methylene glycol is not explicitly included in these entries.

Ireland sent information on the use of methylene glycol in hair straightening products to the Commission. This use was considered as unsafe due to the release of formaldehyde during normal and foreseeable use conditions of such products. By RAPEX several Member States notified the presence of the same or similar products on their markets.

The Irish Authorities analysed 21 products using the testing method for the determination of free formaldehyde according to Commission Directive 90/207/EEC (5. Determination in the presence of formaldehyde donors), and determined the following formaldehyde contents:

7 products had a content < 0.04% of formaldehyde
2 products had content from 0.1% to 0.9% of formaldehyde
10 products had content from 1.6% to 2.8%
2 products had a content from 8.8% to 9.6% (those 2 product also contained the formaldehyde releasing preservative methyldibromo glutaronitrile (MDBG) not authorised for use in cosmetic products).

In Germany, formaldehyde contents of 1.7-1.8% were measured in various hair straightening products.

Information on one specific hair straightening product submitted to the European Commission stated a concentration of methylene glycol of 2% in the product. Manufacturers of hair straightening products have claimed being compliant with the cosmetics legislation, as the products do contain methylene glycol, which in their argumentation is chemically different from formaldehyde and as free formaldehyde is only present in trace amounts in the product. Moreover, it was argued that the official EU analytical method for determination of free formaldehyde would produce artificially high results, as during the analysis methylene glycol is converted to formaldehyde, and thus the measured values do not reflect the formaldehyde levels in the cosmetic product.

However, according to the Member State assessments, formaldehyde vapours are generated during normal use of such hair straightening products, as this procedure involves treatment with a hot straightening iron at temperatures of ~ 230°C. It is assumed that the application of heat converts methylene glycol to formaldehyde, which then can act as a fixative in the hair.

2. TERMS OF REFERENCE

The SCCS is asked to answer the following questions:

1. *Based on the current knowledge on the chemistry, biology and toxicology of methylene glycol, should methylene glycol be considered equivalent to formaldehyde?*

2. *If the answer to question 1 is yes, does the currently established safe level of 0.2% formaldehyde/paraformaldehyde for use as preservatives also ensure the safety of methylene glycol, when used as an ingredient in hair straightening products, taking into account the specific conditions of use of such products?*

3. *If the answer to question 1 is no, can a safe level for the use of methylene glycol in hair straightening products, taking into account the specific conditions of use of such products and the information on current use concentrations, be established?*

4. *Does the SCCS have any further scientific concern with regard to the use of methylene glycol in cosmetic products?*

3. OPINION

3.1. The chemistry of formaldehyde and methylene glycol in aqueous solutions

Formaldehyde (b.p. -21°C) is a gaseous substance at normal temperatures. It is absorbed in water up to a concentration of about 37% w/w (known as formalin). Although formaldehyde is a very polar substance expected to be well soluble in water, the actual concentration of gaseous formaldehyde achievable in water is very low. The reason is that formaldehyde is highly reactive and, in absence of other nucleophilic partners, reacts very quickly with water forming methylene glycol (methanediol) which dissolves much better in water than gaseous formaldehyde. At room temperature and neutral pH, formaldehyde in water is hydrated to more than 99.5% forming methylene glycol (shown e.g., by ^{13}C-NMR; Emeis et al., 2007). Methylene glycol is therefore considered the hydrated form of formaldehyde and serves as a reservoir of formaldehyde in water because the dehydration of methylene glycol is rapidly reversible under a variety of conditions. Formalin, technically produced by catalytic oxidation of methanol, typically contains a saturated concentration of about 37% (w/w) of formaldehyde in water when based on formaldehyde and about 59% when based on methylene glycol. The difference of the percentage is due to higher molecular weight of methylene glycol compared to formaldehyde (48 g/mol versus 30 g/mol).

Typical for geminal alcohols [1], methylene glycol is chemically unstable but is stabilized in water by hydrogen bonding of surrounding water molecules. Due to its inherent instability it cannot be isolated as a parent compound from aqueous solutions and has been isolated by trapping with a trimethylsilyl reagent in formalin solution and in the vapour phase above. The existence of free formaldehyde in the vapour phase has not been reported but cannot be excluded because of the analytical and other limitations such as formation of artefacts in these trapping experiments (Utterback et al. 1985, Little 1999). The rate of the hydration reaction of formaldehyde is very fast: The half-life of gaseous formaldehyde in contact with water is 70 milliseconds (CIR 2012, Winkelman et al. 2000, 2002). The equilibrium methylene glycol/formaldehyde is dynamic and dependent e.g., on temperature, solution density, pH, and the presence of other solutes or solvents. Any removal of formaldehyde in aqueous solution, e.g., by the common analytical method based on trapping with 2,4-dinitrophenylhydrazine (2,4-DNPH) immediately shifts the equilibrium to the release of formaldehyde from methylene glycol such that the latter is consumed. Accordingly, irrespective any high concentration of methylene glycol in aqueous solution compared to formaldehyde, the chemical equilibrium can rapidly shift towards the liberation of formaldehyde due to a high rate of dehydration when the balance is disturbed (CIR 2012, Winkelman et al. 2000, 2002; Emeis et al. 2007). Overall, although the chemical equilibrium of formaldehyde and methylene glycol in aqueous solution is almost exclusively on the side of methylene glycol, any changes of the equilibrium, the formation of methylene glycol or the release of gaseous formaldehyde occur extremely quickly. Via this dynamic equilibrium in aqueous solution, formaldehyde and methylene glycol are mutually converted and hence inherently linked with each other due to rapid formation and degradation of methylene glycol.

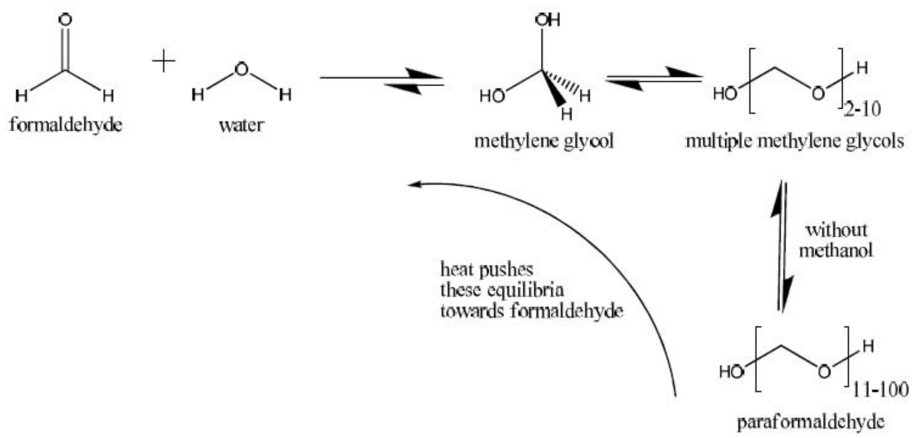
Other (but slower) reactions of formaldehyde competing with hydration in aqueous solutions are the formation of oligomers and polymers of formaldehyde and methylene glycol such as trioxan and paraformaldehyde, in the first step probably by nucleophilic attack of methylenglycol to formaldehyde and subsequently split-off of water. It could be shown by use of NMR methods (which do not disturb the chemical equilibria), that monomeric formaldehyde and methylene glycol are the only observable species at formaldehyde/methylene glycol concentrations below about 0.5 weight% at room temperature and neutral pH. Oligomers of formaldehyde are preferentially formed at low

[1] Bearing two hydroxyl groups at the same carbon atom

concentrations of formaldehyde whereas polymerisation of formaldehyde and the formation of paraformaldehyde predominate in concentrated solutions of formaldehyde. Equilibria between monomeric formaldehyde and oligomers attain within minutes whereas the formation and depolymerisation of paraformaldehyde takes hours to days (Emeis et al., 2007). Compared to the very rapid attainment and shifts of the equilibrium between formaldehyde and methylene glycol, both the formation of oligomers and polymers of formaldehyde are characterized by much lower kinetic constants of forward and backward reactions and hence slower release of formaldehyde/methylene glycol from their oligomers and polymers (Emeis et al. 2007, Winkelman 2000, 2002). Thus, the rapid, reversible formaldehyde/methylene glycol equilibrium can be distinguished from the slow, reversible release of formaldehyde resulting from paraformaldehyde and other so-called formaldehyde releaser preservatives (e.g. diazolidinyl urea). In technical preparations of formalin, methanol is typically present as an inhibitor of the polymerization reaction.

The chemistry and equlibria of formaldehyde, methylene glycol, oligomers and polymers of formaldehyde in aqueous solutions have been recently reviewed in more detail by the CIR Expert Panel. The following scheme illustrating the different reactions and equilibria is taken from CIR (2012).

Scheme 1 – Equilibria in aqueous formaldehyde solutions such as formalin



In conclusion, formaldehyde and methylene glycol are different molecules from a scientific chemical point of view and can be distinguished e.g., by spectroscopic methods. However, due to the close interrelationship of formaldehyde and methylene glycol in aqueous solution and their rapid mutual conversion in a dynamic equilibrium, both molecules are considered to constitute "free formaldehyde" because they are immediately available for any chemical reactions typical for formaldehyde in aqueous solutions including any biological system that contains water. Hence, from a practical point of view, it is justified to consider any aqueous mixture of gaseous formaldehyde and methylene glycol as containing "formaldehyde equivalents", preferably expressed as formaldehyde concentration. The term "formaldehyde equivalents" adequately describes the fact that methylene glycol is continuously converted to gaseous formaldehyde in aqueous solution, and vice versa, at any equilibrium, which can be easily shifted by heating, drying, and any other conditions that increase or decrease the amount of gaseous formaldehyde. Therefore, the SCCS, in line with the position of other bodies and panels (American Chemical Council 2010, CIR 2012, OSHA 2010), considers methylene glycol as a formaldehyde equivalent.

3.2. Inhalation of formaldehyde as a relevant exposure route of toxicity

The concentration of endogenous formaldehyde [2] in human blood is about 2–3 mg/L; similar concentrations were determined in monkeys and rats. Exposure to formaldehyde by inhalation has not been found to alter these concentrations. More than 90% of inhaled formaldehyde is absorbed in the upper respiratory tract (IARC 2006). The transport form of formaldehyde in blood and tissues is methylene glycol attaining the dynamic equilibrium with formaldehyde formation described above. According to IARC (2012), further investigation of this equilibrium in living biological systems is warranted. Human exhaled air contains formaldehyde in concentrations in the order of 0.001–0.01 mg/m^3, with an average value of about 0.005 mg/m^3 (WHO 2010).

Whereas formaldehyde is a known skin irritant and skin sensitizer, inhalation of formaldehyde is also considered a relevant exposure route of toxicity. Inhalation exposure to high concentrations of formaldehyde can induce squamous cell carcinoma of the nasal cavity in rats and nasopharyngeal cancer in humans. Long-term exposure to 7.5 mg/m^3 formaldehyde and above caused squamous cell carcinoma of the nasal cavity of rats with a non-linear, biphasic concentration–response relationship having the break point at or above 2.5 mg/m^3. In humans, no excess nasopharyngeal cancer has been observed at mean exposure levels at or below 1.25 mg/m^3 and with peak exposures below 5 mg/m^3 (reviewed by WHO 2010). IARC (2006) has evaluated formaldehyde as a known human carcinogen (Group 1) confirmed by IARC in a recent evaluation in 2009 (IARC 2012). Formaldehyde exposure is also causally associated with human leukaemia[3].

Formaldehyde is an irritant of the eyes and the respiratory tract. A WHO working group (2010) has re-assessed and confirmed an earlier derived Indoor Air Guideline Level. The rationale is summarized in the following.

"Increases in eye blink frequency and conjunctival redness appear at a concentration of 0.6 mg/m^3 which is considered the NOAEL. There is no indication of accumulation of effects over time with prolonged exposure.
The perception of odour may result in some individuals reporting subjective sensory irritation, and individuals may perceive formaldehyde at concentrations below 0.1 mg/m^3. However, this is not considered to be an adverse health effect. The NOAEL of 0.6 mg/m^3 for the eye blink response is adjusted using an assessment factor of 5 derived from the standard deviation of nasal pungency (sensory irritation) thresholds, leading to a value of 0.12 mg/m^3, which has been rounded down to 0.1 mg/m^3 (0.08 ppm). Neither increased sensitivity nor sensitization is considered plausible at such indoor concentrations in adults and children. This value is thus considered valid for short-term (30-minute) duration, and this threshold should not be exceeded at any 30-minute interval during a day. Thus, a short-term (30-minute) guideline value of 0.1 mg/m^3 (0.08 ppm) is recommended as preventing sensory irritation in the general population.
There is sufficient evidence that formaldehyde causes nasal cancer in animals and nasopharyngeal cancer in humans with a non-linear, biphasic concentration–response relationship. …" The WHO Working Group defined that different approaches, a threshold approach and a biologically motivated approach, have yielded similar results, with values of approximately 0.2 mg/m^3 and finally concluded: *"These values are above the guideline value for short-term effects of 0.1 mg/m^3. Thus use of the short-term (30-minute) guideline value of 0.1 mg/m^3 will also prevent long-term health effects, including cancer."* (WHO, 2010)

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[2] Formed in normal one-carbon biosynthetic pathways.

[3] The Working Group of IARC (2012) was not in full agreement on the evaluation of formaldehyde causing leukaemias in humans, with a small majority viewing the evidence as sufficient of carcinogenicity and the minority viewing the evidence as limited.

3.3. Inhalation exposure by release of formaldehyde in hair straightners

According to the Cosmetics Directive 76/768/EEC, formaldehyde is restricted for use in cosmetics as a preservative at concentrations ≤0.2% (w/w) and the limit for products of oral hygiene is ≤0.1%. Products containing >0.05% formaldehyde must be labelled "contains formaldehyde". The limit of 0.2% in cosmetics primarily applies to skin and aims at avoiding skin irritation and sensitization. This limit should also be suited for the intended release of aerosolized formaldehyde from cosmetic products such as hair straighteners.

High formaldehyde concentrations detected in hair straightening cosmetic products (in some cases far above the limit of 0.2%) and complaints about irritating effects during use of hair straighteners have raised concerns about formaldehyde release and inhalation exposure of hair dressers and their customers by formaldehyde aerosolized at high temperatures (dry-blowing and treatment with a hot straightening iron at temperatures of ~230^{o}C). As far as known, investigations in European Member States have been to date restricted to determinations of formaldehyde in hair straightening cosmetic products and calculations of possible concentrations of formaldehyde in the breathing zone of exposed persons.

A worse case calculation of inhalation exposure was performed by a monitoring authority in southern Germany (cited by BfR 2010). Using 1.7% free formaldehyde in an application amount of the hair straightening cosmetic product of 60-90 g and a proportion of only 10% formaldehyde released during treatment into the air of a small hair dresser's shop (air volume 24 m³) without active ventilation would result in an amount of 100-150 mg formaldehyde in the air corresponding to a concentration of 4.17-6.25 mg/m³ formaldehyde or **3.3 to 5 ppm**. The formaldehyde concentration would be even higher in the breathing zone of the hair dresser and its client. Assuming these conditions**, 0.2% formaldehyde** as a limit in the hair straightener would result in about **0.4 to 0.6 ppm** formaldehyde in the air of the hair dresser's shop as a worse case.

According to a recent WHO report (2010), indoor air levels of formaldehyde on the average are less than 0.05 mg/m³ in homes and about half that in public buildings, although concentrations above 0.2 mg/m³ may be encountered in new or renovated buildings, in new furnishings and at hot and humid times of the year. The most important way to control the formaldehyde concentration is the air exchange rate and the use of low-emitting materials and products.

Use of hair straightening cosmetic products containing formaldehyde predominantly appears to take place in salons but use in homes is not excluded. In the U.S., several studies on formaldehyde concentrations in the air of hair salons were conducted during the use of hair straighteners. Six of these studies have been summarized by the CIR Expert Panel (Table 1, CIR 2012). The studies were conducted by various institutions using different sampling and analytical determination methods. Other factors, including differences in air exchange rates, room dimensions, application techniques also play a role. In some studies, personal samples were taken, whereas air samples in a distance of up to some meters from the persons exposed were taken in other studies. Therefore, direct comparisons of the studies are not possible.

Background samples of formaldehyde taken in two studies ranged from 0.0068 to 0.032 ppm. Concentrations of formaldehyde resulting from hair straightening cosmetic products applied ranged from 0.041 to 2.69 ppm during sampling/exposure periods ranging from 6 minutes to nearly 2 1/2 hours (Table 1). The comparison of the determined formaldehyde concentrations with guideline limits revealed that most of the formaldehyde concentrations exceeded the 30 min guideline value of the WHO (relevant for consumers), the majority also exceeded the ACGIH ceiling value (relevant for workers) and some concentrations even exceeded the US NAC AEGL-1[4] (see Table 1). However, only in the ChemRisk study, the concentrations of formaldehyde in the hair straightening cosmetic products were reported.

In the ChemRisk study (Pierce at al. 2011; summarized in CIR 2012, Table 1), air samples were collected at a salon during four consecutive keratin hair smoothing treatments performed by a licensed cosmetologist (stylist) on 4 separate human hair wigs mounted on mannequin heads over a 6-hour period. The salon's ventilation system was a forced air system. Four different hair-smoothing products were used, in random order, during a 1-day study. In a second approach, each of the four products was used 4 times over a 6-hour period during one day. Bulk samples from each of the hair straightening cosmetic products were collected to identify and quantify formaldehyde and other chemical components such as propylene glycol and decamethyl cyclopentasiloxane that may degrade to formaldehyde under excessive heat. Background air samples were collected in the stylist's breathing zone immediately before each treatment. Treatment-duration samples and task-duration samples (blow-drying, flat-ironing) were collected in the stylist's and mannequin's breathing zones, in areas representing the breathing zones of potential bystanders, and in the salon's reception area.

Table 1: Formaldehyde levels determined in the air during use of hair smoothing products (table taken from CIR 2012)

Test	Form Levels (ppm)	Exposure Time (min)	Samples ≥ Guidelines		
			US NAC AEGL-1[a] 0.9ppm ≥ 10 min	ACGIH TLV®-Ceiling[b] 0.3 ppm	WHO 30 min Guideline[c] 0.08 ppm
Oregon OSHA	0.074-1.88	6-48	Yes (4)	Yes (9)	Yes (All ≥30 min)
Exponent 1	0.170-0.269	95-141	No	No	Yes (All)
Exponent 2	0.041-0.76	17-43	No	Yes (9)	Yes (6 ≥30 min)
Tennessee OSHA	0.3-1.07	15	Yes (1)	Yes (5)	Yes[d]
PKSC 1	0.761-1.71	15	Yes	Yes (All)	Yes[e]
PKSC 2	0.189-0.395	86-117	No	Yes	Yes[f]
ChemRisk	0.11-1.17	56-82	Yes (4)	Yes (8)	Yes[g]

[a]National Advisory Committee Interim Acute Exposure Guideline Level-1 (concentration above which the general population could experience notable discomfort, irritation, or other effects)
[b]American Conference of Government Industrial Hygienists Threshold Limit Value Ceiling (concentration that should not be exceeded during any part of the working day)
[c]World Health Organization Guideline for Indoor Air Quality
[d]Calculated levels exceed by up to 4 fold
[e]Calculated levels exceed by 12-21 fold
[f]Calculated levels exceed by up to 5 fold
[g]Calculated levels exceed by up to 15 fold

The mean aqueous formaldehyde concentrations in the hair-straightening products were below the limit of detection (LOD <5 ppb w/w) in one product and 3%, 8.3% and 11.5% (w/w) in the others. Low concentrations of propylene glycol and decamethyl cyclopentasiloxane in the range of 0.3-0.4% were also found (Table 2). The ChemRisk data in Table 1 represent formaldehyde concentrations from personal samples after complete treatments with each of the four hair-smoothing products during exposure times of 1 to 1 ½ hours[5]. Samples taken during tasks such as blow-drying yielded higher mean airborne concentrations of formaldehyde ranging from 0.08 to 2.35 ppm and during flat-ironing 0.11 to 3.47 ppm for the stylist and the mannequin, respectively (Table 3). During flat-ironing, concentrations of 0.08 to 1.11 and 0.08 to 1.05 ppm were found for the stylist and the mannequin, respectively. Using all four products in one working day resulted in an estimated 8-hr time-weighted average of 0.29 ppm for the stylist.

[4] U.S. National Academy of Science, Acute Exposure Guideline Levels derived for chemical accidents. Level 1 is the lowest of three effect levels.

[5] The formaldehyde concentrations in the last line of Table 1 do not include the formaldehyde concentrations determined during use of the hair straightener La Brasiliana and must read 0.03 – 1.17 ppm

Table 2: Formaldehyde releasing potential in hair-straightening cosmetic products investigated (data from Pierce et al. 2011)

Product	**Mean concentration determined (mg/mL)**		
	Formaldehyde	**Decamethyl cyclopentasiloxane**	**Propylene glycol**
La Brasiliana	< 0.0005	< 0.005	3.8
Coppola	29.9	3.8	n.d.
Global Keratin	82.8	2.5	n.d.
Brazilian Blowout	115.1	< 0.005	n.d.

n.d., not detected (LOD not reported)

Table 3: Task-based airborne formaldehyde concentrations (ppm) associated with the blow-dry and flat-iron tasks (Pierce et al 2011)

		Stylist				Mannequin			
Treatment[A]	Task	Number of Samples	Sample Duration (min)	Mean Concentration (ppm)	Range (ppm)	Number of Samples	Sample Duration (min)	Mean Concentration (ppm)	Range (ppm)
Coppola	Blow-dry	2	15	0.19	0.18–0.19	2	15	0.21	0.2–0.22
	Flat-iron	2	15	0.11	0.09–0.13	2	15	0.10	0.09–0.11
Brazilian Blowout	Blow-dry	2	10	2.35	2.29–2.41	2	10	3.47	3.36–3.59
	Flat-iron	2	13	1.11	0.96–1.26	2	13	1.05	1.05–1.05
Global Keratin	Blow-dry	2	8	1.62	1.48–1.76	2	8	1.68	1.58–1.78
	Flat-iron	2	16	0.53	0.52–0.55	2	16	0.52	0.51–0.53
La Brasiliana	Blow-dry	2	6	0.08[B]	< 0.05–0.14	2	6	0.11	0.09–0.14
	Flat-iron	2	15	0.08	0.08–0.09	2	15	0.08	0.08–0.09

[A]Listed in the order treatments were performed.
[B]Used 1/2 LOD when calculating the average concentration.

The concentrations of formaldehyde in the air samples collected during the treatments were related to the concentrations measured in the bulk samples following a non-linear, biphasic relationship having the break point at a content of 3% formaldehyde in the hair straightener. A steep increase of formaldehyde air concentrations released from the products containing 8.3 or 11.5% formaldehyde was observed. The data indicates release of excessive aerosolized formaldehyde from the latter products.

Under the conditions of the ChemRisk study, using a hair straightener containing 0.2% formaldehyde as a limit, it can be expected that formaldehyde release into the air would result by extrapolation in a concentration of 0.05-0.1 ppm during tasks such as blow-drying or during complete treatment. However, an average background concentration of up to 0.04 ppm in indoor areas should be taken into account as a minimum. Exceeding of a limit of 0.08 ppm (0.1 mg/m³) in the air of a smaller shop with less efficient ventilation cannot be excluded when using a hair straightener containing 0.2% formaldehyde.

4. CONCLUSION

1. Based on the current knowledge on the chemistry, biology and toxicology of methylene glycol, should methylene glycol be considered equivalent to formaldehyde?

Although formaldehyde and methylene glycol are different molecules from a scientific chemical point of view, there is a close interrelationship of formaldehyde and methylene glycol in aqueous solution and a rapid mutual conversion in a dynamic equilibrium. Therefore, from a practical point of view, it is justified to consider the aqueous mixture of gaseous formaldehyde and methylene glycol as “free formaldehyde” and the quantities as "formaldehyde equivalents" (preferably expressed as formaldehyde concentration) in aqueous solutions. The term "formaldehyde equivalents" adequately describes the fact that methylene glycol is continuously converted to gaseous formaldehyde in aqueous solution, and vice versa, at any equilibrium, which can be easily shifted by heating, drying, and any other conditions that increase or decrease the amount of gaseous formaldehyde.

Therefore, the SCCS, in line with the position of other bodies and panels (American Chemical Council 2010, CIR 2012, OSHA 2010, considers methylene glycol as a formaldehyde equivalent.

2. *If the answer to question 1 is yes, does the currently established safe level of 0.2% formaldehyde/paraformaldehyde for use as preservatives also ensure the safety of methylene glycol, when used as an ingredient in hair straightening products, taking into account the specific conditions of use of such products?*

Methylene glycol produces gaseous formaldehyde under the intended conditions of use in hair straightening products due to the application of heat by straightening irons and/or blow drying.

When methylene glycol/formaldehyde is used in hair straightening products at a concentration of 0.2% formaldehyde equivalent, the amount of gaseous formaldehyde released may exceed 0.1 mg/m^3 (0.08 ppm), which is the WHO indoor air quality guideline for short term exposure.
Therefore the use of methylene glycol/formaldehyde at 0.2% formaldehyde equivalent is not considered safe in hair straighteners.

3. *If the answer to question 1 is no, can a safe level for the use of methylene glycol in hair straightening products, taking into account the specific conditions of use of such products and the information on current use concentrations, be established?*

Not applicable.

4. *Does the SCCS have any further scientific concern with regard to the use of methylene glycol in cosmetic products?*

Not applicable

5. MINORITY OPINION

Not applicable

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