

THE SCIENTIFIC COMMITTEE ON COSMETIC PRODUCTS AND NON-FOOD PRODUCTS
INTENDED FOR CONSUMERS

OPINION

CONCERNING

A CLARIFICATION ON THE FORMALDEHYDE AND PARA-FORMALDEHYDE
ENTRY IN DIRECTIVE 76/768/EEC ON COSMETIC PRODUCTS

Adopted by the SCCNFP during the 22nd plenary meeting
of 17 December 2002

Evaluation and opinion on : clarification on the Formaldehyde and para-Formaldehyde Entry in Directive 76/768/EEC on cosmetic products

1. Background

The EU Cosmetic Directive 76/768/EC regulates the contents of formaldehyde, para-formaldehyde and formaldehyde releasers in cosmetic products. The official EU methods should be used to check the compliance of cosmetic products with the EU Cosmetic Directive. The EU Working Party (WP) on Methods of Chemical Analysis of Cosmetic Products has identified certain formaldehyde releasers for which it may not be possible to develop analytical method with the present state of knowledge (Annex 1). In the previous opinion (SCCNFP/586/02) it is demonstrated that benzylhemiformal, sodium hydroxymethylglycinate, diazolidinyl urea and imidazolidinyl urea are decomposed in aqueous and polar solvents to release some or all of their formaldehyde content. Thus, it is not possible with present state of knowledge to develop suitable methods for the identification and quantification of these compounds, in their native forms, in cosmetic products. The decomposition products of benzylhemiformal are known compounds and their safety profile can be assessed. However, there is no information about the decomposition products of diazolidinyl urea and imidazolidinyl urea, as well as about the safety profile of the decomposition products.

One of the approaches to overcome the analytical problems may be to treat such formaldehyde donors, from the legislative point of view, as formaldehyde; and regulate these formaldehyde releasers together with formaldehyde and paraformaldehyde (entry 5, Annex VI, part 1) on the basis of total formaldehyde content in cosmetic products.

2. Request to the SCCNFP

With reference to above-mentioned background the SCCNFP was requested to answer following questions :

- Does the SCCNFP consider it possible to amend the above-mentioned entry 5 in a way so that the maximum authorised concentration could be expressed as a concentration of total formaldehyde without prejudicing the safety of cosmetic products?
- If so, can the SCCNFP propose maximum authorised concentration in cosmetic products as total formaldehyde?

3. Legislation on formaldehyde content of cosmetic products

According to Annex VI of the Cosmetic Directive 76/768/EC, the maximum authorised concentration of free formaldehyde is 0.2%. In addition, the provisions of Annex VI state that, *All finished products containing formaldehyde or substances in this Annex and which release formaldehyde must be labelled with the warning “contains formaldehyde” where the concentration of formaldehyde in the finished product exceeds 0.05%.*

The legislation is thus dependent upon the ability of analytical methods to differentiate free formaldehyde from the bound, inert form. The official EC method (1) for analysis determines the level of free formaldehyde in the presence of its donor compound.

4. Formaldehyde releasers and analytical problem

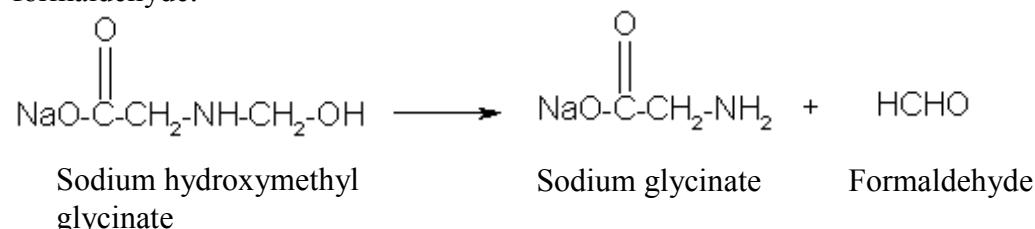
The formaldehyde releasers for the use in the cosmetic formulations to be marketed in EU are described in the Annex. The official EU methods should be used to check the compliance of cosmetic products with the EU Cosmetic Directive. The EU WP on Methods of Chemical Analysis of Cosmetic Products develops and validates methods for compliance testing. During the development of methods for the analysis of formaldehyde releasers in cosmetic products, the WP observed that imidazolidinyl urea, diazolidinyl urea, sodium hydroxymethyl glycinate and benzylhemiformal decompose very rapidly to release formaldehyde when dissolved in aqueous/polar solvents; and therefore, identification and determination of these compounds in cosmetic products may not be possible with the present state of knowledge. The details of these 4 formaldehyde releasers and problems associated with their chemical analysis in cosmetic products are described in a previous Opinion (SCCNFP/586/02).

5. Regulation of formaldehyde releasers (entries 27, 46, 51, 55, Annex VI, part 1) together with formaldehyde and paraformaldehyde (entry 5, Annex VI, part 1)

The maximum authorised concentrations of imidazolidinyl urea, diazolidinyl urea, sodium hydroxymethyl glycinate and benzylhemiformal in cosmetic products are based on the risk assessments of these compounds.

5.1 Sodium hydroxymethyl glycinate

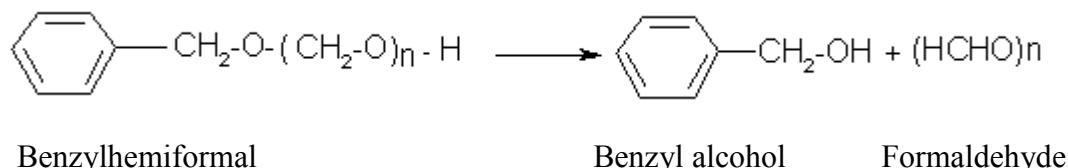
Sodium hydroxymethyl glycinate in aqueous solution decomposes to sodium glycinate and formaldehyde:



Glycine is an essential amino acid, and does not appear to be harmful. So, the regulation of sodium hydroxymethyl glycinate as total formaldehyde should not give any additional safety problem to consumers, as long as the maximum authorised concentration of this compound is maintained.

5.2 Benzylhemiformal

Benzylhemiformal in aqueous solution is decomposed to benzyl alcohol and formaldehyde:



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Benzyl alcohol is regulated according to Annex VI, part 1 of the Cosmetic Directive as maximum authorised concentration 1%, and as a solvent for perfumes according to Annex III of the Directive. So, the regulation of benzylhemiformal as total formaldehyde should not raise any additional safety problem to consumers, as long as the maximum authorised concentrations of this compound in rinse-off cosmetic products is maintained. The formaldehyde content ($n = 1.5$) of the benzylhemiformal should also be maintained, as the risk assessment was performed only on this compound.

5.3 Imidazolidinyl urea and diazolidinyl urea

Imidazolidinyl urea and diazolidinyl urea in aqueous solutions decompose to formaldehyde and some unidentified products. The release of formaldehyde from imidazolidinyl urea is dependent on temperature, pH and storage period of the solution. The decomposition products of these compounds have not yet been characterised. However, it is considered that the toxic profile of the decomposition products has been elucidated together with their respective parent compounds. It appears that both of these formaldehyde releasers are a mixture of isomers.

6. Opinion

The amendment of entry 5 in Annex VI of the Cosmetic Directive to include formaldehyde releasers is not suitable, as the maximum authorised concentration of each of these preservatives is based on risk assessments of individual compounds.

In the absence of analytical methods to check the compliance of cosmetic products with respect to the content of the four preservatives, consumer safety may be ascertained by adequately assessing the presence of formaldehyde in the cosmetic products; the total content of formaldehyde in the finished cosmetic product must not exceed 0.2%

7. References

1. SCCNFP/586/02 Final. Determination of certain formaldehyde releaser in cosmetic products.

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Annex

Status of methods for analysis of formaldehyde and formaldehyde releasers permitted for the use in cosmetic formulations according to the Directive 76/768/EC.

Substance	Entry n° Annex VI, part 1	Method of Chemical Analysis
Formaldehyde and Paraformaldehyde	5	Available
Benzylhemiformal	55	Not possible
2-Bromo-2-nitropropane-1,3-diol	21	Proposed
5-Bromo-5-nitro-1,3-dioxane	20	Proposed
Diazolidinyl urea	46	Difficulties, further research needed
Imidazolidinyl urea	27	Difficulties, further research needed
Quaternium-15	31	Proposed
DMDM Hydantoin	33	Proposed
Sodium hydroxymethyl glycinate	51	Not possible
Methenamine	30	Proposed