



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment
C7 - Risk assessment

SCIENTIFIC COMMITTEE ON CONSUMER PRODUCTS

SCCP

Clarification of

**the SCCNFP Opinion on the Update of Entry n° 39 of Annex VI
to Directive 76/768/EEC on Cosmetic Products:**

**Mixture of 5-Chloro-2-Methyl-Isothiazolin-3(2H)-one and 2-
Methylisothiazolin-3(2H)-one**

COLIPA n° P56

Adopted by the SCCP
during the 2nd plenary meeting of 7 December 2004

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1. BACKGROUND

The Scientific Committee on Cosmetics and Non Food Products has been consulted and has expressed its views on the Update of Entry n° 39 of Annex VI to Directive 76/768/EEC on Cosmetic Products: mixture of 5-Chloro-2-Methyl-Isothiazolin-3(2H)-one and 2-Methylisothiazolin-3(2H)-one.

In response to these opinions, the Commission is currently in the process of regulating the Update of Entry n° 39 in Annex VI of Directive 76/768/EEC.

Meanwhile the Commission feels the need to clarify the opinion of the Scientific Committee on the following point.

"Taking into consideration that the active ingredients and their ratio remain unchanged and that the concentration of the stabiliser system in the finished cosmetic products is negligible, the SCCNFP is of the opinion that the replacement of magnesium chloride and magnesium nitrate by copper sulphate or any other authorised cosmetic ingredient as a stabiliser system in the mixture of 5-Chloro-2-methyl-isothiazolin-3(2H)-one and 2-Methylisothiazolin-3(2H)-one does not alter the toxicological profile of this mixture."

Since in Directive 76/768/EEC (Cosmetics Directive) the concept of "authorisation" is not explicitly mentioned, the notion of "authorised cosmetic ingredient" was interpreted by the Commission at the meeting of the Working Group on Cosmetics as any ingredient which in the light of the Cosmetics Directive is allowed or not prohibited and may be used in cosmetic products.

2. TERMS OF REFERENCE

The SCCP is requested to answer the following questions:

- * *Clarify if the expression "authorised" was used according to the above mentioned interpretation. And if it is not the case, which ingredients such expression refers to.*

3. OPINION

3.1. Technical aspects on the stabilizing agents

(The reference numbers below refer to the references of the respective SCCNFP opinion)

The analytical request of the industry (introductory report of submission IX: *ref.* 3) includes the following statement:

“A survey of the patent literature reveals that several such stabilizers have been suggested (5-19). Many of these, such as hydrogen peroxide (5), bronopol (8), iron (11), cupric ion and an oxidant (14), formaldehyde and formaldehyde donors (16), alkyl hydantoins (17) some halogenated organics (methyl-dibromo glutaronitrile) (18) and surfactants (19) have, in their own

right been assessed for safety in use as cosmetic ingredients. Several are well known and tested preservatives (bronopol, alkyl hydantoin, methylidibromo glutaronitrile, formaldehyde and formaldehyde donors) and are already listed in Annex VI of the EC Cosmetics Directive (76/768/EEC). Some have been assessed for safety in use in cosmetic applications and have been regulated for various other functions on Annex III (e.g. hydrogen peroxide) or Annex IV (e.g. some iron and copper salts). There are several others which are “not specifically regulated in the annexes of the Cosmetic Directive and may be used under the overriding safety requirements of articles 2 and 7a.”

However, according to the patents included in the dossier (*ref. 5-19*), these “not specifically regulated” stabilizers mentioned above are a very large number of chemicals, mostly preservatives (see frame below), which have to be added in concentrations 5-50 times higher than the concentration of the MCI/MI mixture itself.

Hydrogen peroxide or perborates, perchlorates etc. (*ref. 5*) or organic epoxides and hydroperoxides, such as ethylene or propylene oxides/homologs, epoxybutane isomers, *N,N*-dimethyl 9,10-epoxystearamide and homologues, α - or β -pinene oxides, *N*-methyl-*N*-2,3-epoxy propyl acetamide, *N,N*-di(2,3-epoxypropyl) 2,3-epoxybutanoate etc. (*ref. 6*);

Formaldehyde or formaldehyde releasing agents such as 2-hydroxymethyl-2-nitro-1,3-propanediol and orthoesters of formic, acetic, benzoic and other acids (*ref. 9, 16*);

“Activated Halogen” compounds such as trichloro-isocyanuric acid, Iodobromosuccinimide, *N*-halohydantoin, 3-isothiazolones, halo-triazinetriols, *N*-halosuccinimides, *p*-toluenesulfonyl halides, α -chlorocinnamaldehyde, dimethyl-sulfamoyl chloride, bromo- β -nitrostyrene, 2,2-dibromo-3-nitropropionamide, 2,2-dibromonitrilopropionamide, 1,2-dibromo-2,4-dicyanobutane, etc.) (*ref. 8, 18*);

Hydroquinone, quinone, quinhydrone and homologues, plus magnesium permanganate, methoxyphenol, tert-butylcatechol etc. (*ref. 10*);

Dialkyl- or dicycloalkyl carbodiimides (e.g. dicyclohexyl carbodiimide) (*ref. 7*);

Maleic or toluic hydrazides, semicarbazides (*ref. 17*).

Therefore, the above industry’s request refers to permission for deviation from the rules of article 4 of the Directive 76/768/EEC and for using all these preservatives according only to the general safety requirements of articles 2 and 7a (in combination with the provision for other specific purposes –or “other functions”- in Articles 4.1[f] and 5[c]). As a consequence, the final (marketed) cosmetic products could contain preservatives not listed in Annex VI (or Annex III) of the Directive 76/768/EEC on cosmetic products.

In this context, the expression “authorised cosmetic ingredients” refers to preservatives listed in Annex VI of the Directive. It covers also colouring agents, which are listed in Annex IV, UV filters, which are listed in Annex VII, substances, which are listed in Annex III, and in addition substances which are not colouring agents, preservatives or UV filters and which are not listed in Annexes II or III of Cosmetics Directive. Thus, the interpretation of the above expression at the meeting of the Working Group on Cosmetics should be supplemented as follows.

4. CONCLUSION

In response to the questions asked, the SCCP is of the opinion that the expression “authorised cosmetic ingredient” should be interpreted as “any ingredient which, in the light of the Cosmetics Directive, is allowed or not prohibited and may be used in cosmetic products, provided that any substance belonging to the classes of ingredients listed in the Annexes III-VII of the Directive may be used only if it is included in the respective annex.”

5. MINORITY OPINION

Not applicable

6. REFERENCES

Not applicable

7. ACKNOWLEDGEMENTS

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