Commission of the European Communities

Environment and Quality of Life

REPORTS
OF THE SCIENTIFIC COMMITTEE ON COSMETOLOGY
(First series)

Report
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LEGAL NOTICE

SUMMARY

This publication contains the first series of reports by the Scientific Committee on Cosmetology on:

- the use of chloroform in toothpaste
- the use of boric acid in cosmetic products
- the use of 1,1,1-trichloroethane (methylchloroform) in cosmetic products
- the presence of safrol as an impurity in cosmetic products.

CONTENTS

INTRODUCTION

The Scientific Committee on Cosmetology was set up by Commission Decision 78/45/EEC of 19 December 1977 (OJ N° L 13 of 17 January 1978, p. 24) in order to provide the Commission with informed opinions on any scientific and technical problems arising in connection with cosmetic products, and in particular on the substances used in their manufacture, on their composition and on the conditions for their use.

The members of the Committee are independent scientists highly qualified in the fields of medicine, toxicology, biology, chemistry or other similar disciplines.

The Committee is serviced by the Environment and Consumer Protection Service.

This volume contains a collection of the Committee's first reports setting out the opinion it delivered on the dates given in the headings.

Members of the Scientific Committee on Cosmetology

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(1) Resigned on 5 January 1979
(2) Elected Chairman on 19 September 1978
(3) Elected Vice-Chairman on 19 September 1978
(4) Resigned on 30 March 1979
(5) Appointed on 17 May 1979
(6) Appointed on 4 September 1979

REPORT OF THE SCIENTIFIC COMMITTEE ON COSMETOLOGY ON THE USE OF CHLOROFORM IN TOOTHPASTE

(opinion expressed 16 January 1979)

THE COMMITTEE'S MANDATE

To give its opinion on the question of whether the use of chloroform in toothpaste - in a maximum concentration of 4 % - is admissable from the health point of view.

CONCLUSION

The committee recommends that the use of chloroform in toothpastes should be discontinued.

BACKGROUND

1. Article 5 of Council Directive 76/768/EEC on approximation of the laws of the Member States relating to cosmetic products obliges the Member States to permit the marketing of toothpaste containing chloroform in a maximum concentration of 4 % until 27 July 1979. After that date the use of chloroform in making toothpaste will be:

   - permanently authorized;
   - permanently banned, or
   - permitted for a further three years.

2. Under Article 12 of the above-mentioned Directive, which empowers Member States to prohibit provisionally the marketing in their territory of a cosmetic product if they note, on the basis of a statement of detailed grounds, that this product, although complying with the requirements of the Directive, represents a hazard to health. Several Member States have prohibited the marketing of cosmetic products, including toothpastes, containing chloroform because of the known toxic effects of chloroform.

3. Consequently, the committee was called on to say whether the use of chloroform in toothpaste in a maximum concentration of 4 % is acceptable from the health point of view.

DISCUSSION

1. The experiments carried out by the National Cancer Institute in the USA indicate that, in rats and mice, chloroform fed in high doses showed an increased incidence of malignant tumours.

   In both male and female mice, the target organ was the liver whereas in male rats there was significant increase in the incidence of renal epithelial tumours.

   The Committee concluded this was suggestive of carcinogenic potential.

   However, other long-term experiments with rats, mice and dogs showed only renal tumours in ICI mice.

   Further, chloroform is without mutagenic effect on yeasts even after enzymatic activation.

   To date, there is no epidemiological data to suggest that chloroform is a carcinogen in man.

   Because of these findings the Committee was unable to take an unanimous view with respect to the potential carcinogenicity of this compound to man.

2. From the toxicity studies carried out in several animal species, it is possible that the margin of safety between the level causing hepatotoxicity in animals and the possible daily human intake, especially by children, is relatively small.

3. Because of the potential carcinogenicity and the known toxicity of this compound, the Committee recommends that the use of chloroform in toothpaste be discontinued.

REPORT BY THE SCIENTIFIC COMMITTEE ON COSMETOLOGY ON THE USE OF BORIC ACID IN COSMETIC PRODUCTS

(opinion expressed 22 May 1979

THE COMMITTEE'S MANDATE

To give its opinion on the question of whether the restrictions and conditions provided for by Council Directive 76/768/EEC on the use of boric acid in cosmetic products are adequate from the public health point of view.

CONCLUSION

The committee is of the opinion that:

- for talcums the conditions of use and the instructions which must be carried on the packaging should be supplemented by the phrase "not to be used on damaged skins";

- for products for oral hygiene the restrictions and conditions provided for by the afore-mentioned Directive are adequate;

- for other products the warning "not to be used on damaged skins" must be carried on the packaging.

BACKGROUND

1. Article 4 of Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products obliges the Member States to prohibit the marketing of cosmetic products containing substances listed in the first part of Annex III beyond the limits and outside the conditions laid down in this Directive.

2. As regards boric acid, these limits and conditions are:

Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
Talos	5%	Not to be used in products for children under three years old	Not to be used for babies
Products for oral hygiene	0.5%		
Other products	3%		

3. Under Article 12 of the same Directive, which enables Member States prohibit provisionally the marketing of a cosmetic product in its territory or subject it to special conditions, if it notes, on the basis of a substantiated justification, that this product, although complying with the requirements of the Directive, represents a hazard to health, a Member State has prohibited the manufacture and importing of all cosmetic products containing boric acid and meant to be used for children and required that cosmetic products intended for other persons bear a warning to the effect that they must not be used for babies. These measures were inspired by the high toxicity of boric acid and the risk of poisoning by absorption, particularly through cuts or lesions of the skin (265 cases of poisoning have been reported, worldwide).

4. Accordingly, the committee was asked to give an opinion of the question of whether the restrictions and conditions provided for by Council Directive 76/768/EEC were sufficient to safeguard public health.

DISCUSSION

5. Clinical experience shows that boric acid represents a toxic hazard, especially if it is applied to damaged skin.

In the case of poisoning ingestion or absorption through the skin, the clinical signs consist mainly of gastro-intestinal disorders, skin irritation and effects on the central nervous system.

6. Tests on rats and rabbits have shown that when the skin is damaged, the quantity of boric acid absorbed depends on the nature of vehicle and on the size of the surface treated.

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Recent tests on rabbits in Denmark show that with a specific ointment of water in oil the level of urinary excretion, after application to the skin, is affected neither by skin abrasion nor by the application of an occlusive dressing. (Jens SCHOU - mai 1979).

7. The Committee considers that a pharmacokinetic study of boric acid, is the only way to obtain valid information on absorption through the skin, its distribution and excretion.

8. In babies, high permeability of the skin, large areas of exposure and wetting by urine are factors increasing percutaneous absorption.

9. Moreover, cosmetic products are intended for healthy skins and the concentrations used are too close to therapeutic doses. (1)

10. Consequently, the Committee recommends, as a minimum measure, that:

(a) for talcs (maximum concentration 5 %), the warning that must be printed on the label should be supplemented by the phrase "not to be used on damaged skins";

(b) for products for oral hygiene (maximum concentration 0,5 %), the restrictions and conditions in Directive 76/768/EEC should not be amended;

(c) for other products (maximum concentration 3 %), the warning "not to be used on damaged skins" (2) should be printed on the label.

11. However, the Committee would be prepared to review this decision if new information on the pharmacokinetics of boric acid and clinical experience with the babies (in particular blood levels), were brought to its attention for assessment.

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(1) Some members were of the opinion that boric acid had no therapeutic effects.

(2) One of the members considers that this warning was not justified for oily creams (water in oil) containing a maximum of 3 % boric acid.

REPORT BY THE SCIENTIFIC COMMITTEE ON COSMETOLOGY CONCERNING THE USE OF 1,1,1-TRICHLOROETHANE (METHYLCHLOROFORM) IN COSMETIC PRODUCTS

(opinion expressed 25 September 1979)

Terms of reference of the Committee

To give its opinion on the use of 1,1,1-trichloroethane in cosmetic products under the conditions laid down by Directive 76/768/EEC.

Conclusion

The Committee is of the opinion that the use of 1,1,1-trichloroethane in cosmetic products, under the conditions laid down by Directive 76/768/EEC, can be allowed provisionally for a period of 3 years.

Background

1. In accordance with Article 5 of Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products, as amended by Directive 79/661/EEC, the Member States are to permit - until 31 December 1980 - the marketing of cosmetic products containing 1,1,1-trichloroethane (methylchloroform) subject to the following restrictions and conditions:
   (a) field of application and/or use: solvent for aerosol dispensers;
   (b) maximum authorized concentration in the finished cosmetic product: 35 %. When mixed with dichloromethane, total concentration must not exceed 35 %;
   (c) conditions of use and warnings which must be printed on the label: do not spray on naked flame or any incandescent material.

2. On expiry of this time-limit, the substance shall be:
   - either definitively permitted, or
   - definitively prohibited (Annex II), or
   - retained for a further period of three years in Annex IV, or
   - deleted from all Annexes to the above mentioned Directive.

3. Accordingly, the Committee has been asked to give an opinion on the use of 1,1,1-trichloroethane (methylchloroform) in cosmetic products under the conditions laid down by Directive 76/768/EEC.

DISCUSSION

4. - 1,1,1-trichloroethane contains stabilizers intended to inhibit any oxidation or decomposition by light and corrosion inhibitors. These substances may present a risk of toxicity and it is essential to know the degree of purity of the trichloroethane used in cosmetics, with details of the chemical nature, concentration and toxicity of the stabilizer(s).

5. - It must be borne in mind that 1,1,1-trichloroethane must be used in concentrations of up to 35 % in aerosols. The Committee has considered the relative safety of this substance for man in comparison to the most widely used propellant gases.

- Acute inhalation studies indicate that 1,1,1-trichloroethane is more toxic than many halogen compounds used in aerosols (cardiotoxicity in primated).

- Concentrations inducing loss of coordination and anaesthesia in man can be obtained by use in a confined and poorly ventilated space. This phenomenon is, however, reversible.

6. - Long-term tests involving forcible feeding of rodents have given no indication of carcinogenicity but the short life span of the animals treated does not allow useful conclusions to be drawn from this research.

- No positive response has been observed in teratogenic research on rats and mice by inhalation.

- Long-term tests by inhalation on mice have shown that this substance is less toxic than chloroform (hepatic injury).

- 99 % of the product injected intraperitoneally in rats is eliminated unchanged by exhalation and no accumulation in the tissues is observed.

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7. - The Committee is of the opinion that the provisional authorization of 1,1,1-trichloroethane should be extended for three years. In the meantime it wishes to obtain information on:

(1) the stabilizers used, their concentration and toxicity;
(2) the level of exposure in bathrooms and hairdressing saloons;
(3) the relative toxicity of 1,1,1-trichloroethane compared to commonly used freons, in particular as regards acute and subacute toxicity by inhalation;
(4) any epidemiological data that may be available.

If no such information exists, it will require studies carried out on:

(1) the 90-day toxicity of pure 1,1,1-trichloroethane on rats;
(2) the long-term toxicity by inhalation on animals (carcinogenicity).

REPORT BY THE SCIENTIFIC COMMITTEE ON COSMETOLOGY CONCERNING THE PRESENCE OF SAFROL AS AN IMPURITY IN COSMETIC PRODUCTS

(opinion expressed 2 September 1980)

THE COMMITTEE'S TERMS OF REFERENCE

To give its opinion on whether, from the public-health point of view, a safrol content not exceeding 100 ppm is acceptable as a contaminant in a finished cosmetic product.

CONCLUSION

It is the Committee's opinion that a safrol content not exceeding 100 ppm is acceptable as a contaminant in a finished cosmetic product.

BACKGROUND

1. Article 5 of Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products provides that, until 27 July 1979, Member States shall permit the marketing of cosmetic products containing safrol in a concentration not exceeding 100 ppm. On expiry of that time limit this substance shall:

   - either be definitively permitted
   - or definitively prohibited,
   - or retained for a further period of three years.

2. Article 12 of the above mentioned directive allows a Member State provisionally to prohibit the marketing of a cosmetic product in its territory, or to make it subject to special conditions, "if it notes, on the basis of a substantiated justification, that, although complying with the requirements of the directive, the product represents a hazard to health". In implementation of that Article, one Member State has restricted the use of safrol by prohibiting the direct incorporation of the substance in cosmetic products on the grounds that, when administered orally to rats and mice, safrol has proved to be carcinogenic.

3. Nevertheless, safrol is a natural contaminant in certain essential oils used in the preparation of cosmetic products.

4. Accordingly, the Committee is requested to deliver an opinion on whether, from the point of view of public-health protection, a safrol content not exceeding 100 ppm can be accepted as a contaminant in a finished cosmetic product.

DISCUSSION

5. Studies carried out in the USA on the chronic toxicity of safrol added to the feed of rodents have shown that safrol is slightly hepatocarcinogenic in the rat and that the liver damage varies according to the sex, age and diet of the animal.

6. The results of the mutagenicity tests are not conclusive.

7. Safrol is not electrophilic. It interferes with the microsomial enzymes of the liver, and in some species is capable of stimulating its own metabolism.

8. Among the metabolites of safrol demonstrated in rodents' urine 1'-hydroxysafrol proved more carcinogenic than safrol. The other metabolism rpoducts are 1,2 dihydroxy-4 allyl benzene, safrol epoxide and diols formed along the epoxide route.

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9. Recent research carried out to compare the absorption, metabolism and excretion of safrol in the rat and in man have shown an apparent absence of the carcinogenic 1'-hydroxysafrol and its isomer 3'-hydroxysafrol as metabolites in man. It has not, however, been determined whether this absence is due to a difference of metabolism or whether it depends on the dose administered.

10. The Committee has decided that a maximum content of 100 ppm of safrol is acceptable as a technological residue in the finished cosmetic product in view of:

a) the apparent absence of the carcinogenic metabolite, 1'-hydroxysafrol, in man;

b) the absence of any significant carcinogenic effect at a safrol concentration not exceeding 100 ppm during chronic toxicity tests by oral route on the rat;

c) the fact that the safrol doses absorbed by man through the use of cosmetics are low and are in no case comparable with those used in metabolic studies on animals (see para. 9).

11. Nevertheless, the Committee reserves the right to review its decision in the light of any new information concerning the possible investigation in man of a metabolic route observed in rodents, namely the formation of carcinogenic epoxides.

12. Nevertheless, the Committee recommends that the presence of safrol be avoided in toothpase specifically intended for children.