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

SCIENTIFIC COMMITTEE ON CONSUMER PRODUCTS

SCCP

Opinion

On

Amino Acids obtained by Hydrolysis of Human Hair

Adopted by the SCCP
during the 4th plenary of 21 June 2005

TABLE OF CONTENTS

1.	BACKGROUND	3
2.	TERMS OF REFERENCE	4
3.	OPINION	4
4.	CONCLUSION	8
5.	MINORITY OPINION	8
6.	REFERENCES	8
7.	ACKNOWLEDGEMENTS	8

1. BACKGROUND

Annex II of the Cosmetic Directive 76/768/EEC (List of substances which must not form part of the composition of cosmetic products) prohibits the use of cells, tissues or products of human origin from use in cosmetic products marketed in the EU. These materials are listed under entry 416 of Annex II. Such materials were prohibited from use in cosmetic products due to the potential risk of transmission of Creutzfeldt-Jakob disease, human spongiform encephalopathy and viral diseases. This prohibition has excluded the use of materials derived from human hair in cosmetic products, such as amino acids. COLIPA, The European Cosmetic Toiletry and Perfumery Association, had requested that the entry be modified in order to allow the use of some materials derived from human hair and have produced a safety rationale to support this proposal.

The proposed modification to entry 416 was:

Cells, tissues or products of human origin. However, amino acids obtained by hydrolysis of human hair may be used provided that the following method has been used and certified by the producer:

- *Hydrolysis with HCl (> 20% throughout the whole process) for at least 6 hours at 100°C.*

In its opinion of 28 June 2000 concerning Amino Acids Obtained By Hydrolysis Of Human Hair, the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) stated:

“According to the opinion on the safety of amino acids from human hair hydrolysate used in cosmetic products for topical application, with regard to Transmissible Spongiform Encephalopathy (TSE) risk, adopted by the Scientific Steering Committee (SSC) at its meeting of 25-26 May 2000, it may be concluded that the risk resulting from the use of human hair to provide amino acids for incorporation into human hair- and skin-care products would appear to be negligible....The SCCNFP is of the opinion that amino acids obtained by hydrolysis of human hair can be considered safe as long as they are not contaminated with risk material.... the current scientific knowledge fully support the modification of entry 416 of Annex II to reflect the COLIPA proposal.... the SCCNFP does not recommend alternative conditions nor restrictions. The opinion is based on current knowledge on TSE and on the fact that amino acids can not transmit TSE.”

A proposal to amend 76/768/EEC accordingly was discussed in the Standing Committee on Cosmetics (COSCOM) meeting on 26 July 2001. On the proposed entry 416 on the use of amino acids extracted from human hair, some delegations had concern to adopt this. The proposal to amend entry 416 within the Cosmetic Directive was therefore deleted and one Member State delegation was asked to send in any information regarding the subject which then would be sent to SCCNFP for further investigations.

The issue was again discussed in the meeting of the Working Group of Member States, stakeholders and the European Commission services on Cosmetics on 31 January/1 February 2002. At that meeting again one Member State delegation had great concern to use amino acids extracted from human hair in cosmetic products based on a safety report published by the

Agence française de sécurité sanitaire des produits de santé (AFSSAPS). As the information given dealt with the possible risk of contamination with naked viruses of the family of the Papillomavirus, of the Picornavirus and of the Parvovirus, the delegation provided a dossier with all the scientific evidence.

2. TERMS OF REFERENCE

1. *Does the method to hydrolyse human hair with HCl (> 20% throughout the whole process) for at least 6 hours at 100°C guarantee the absence of a possible risk to transmit adventitious agents which could have contaminated the raw material?*
2. *Is the safety of amino acids obtained from human hair comparable to the safety of amino acids obtained from other non-human origin (e.g. chicken feathers)?*

3. OPINION

The product, the object of this evaluation is a mixture of amino acids obtained from human hair hydrolysates after hydrolysis with concentrated HCl (> 20%), 6 hours at 100°C combined with subsequent activated carbon filtration, crystallisation and drying according to a recognised process (Ref. 107). A potential equivalent product could be considered to be obtained from chicken feathers using the same industrial process. Currently, the SCCP is unaware of feathers being used to obtain amino acids or any other ingredient for cosmetics.

3.1. Chemical and Physical Specifications

Not applicable

3.2. Function and uses

For cosmetics, amino acids are generally supplied in powder form and used in skin care products as moisturisers (e.g. arginine, lysine, glycine and glutamic acid) and in hair care products to improve hair good looking and its physical properties (e.g. proline and cystine). Amino acids increasingly are being used in anti-ageing formulations. In 2004, 20 tonnes of amino acids were used by the personal care industry and the forecast by 2010 is 46 tonnes. The amino acids used in personal care products are manufactured by hydrolysing proteins. The main sources are: animal collagen, milk proteins, silk and human keratin (hair) (Ref.: 105).

3.3. Toxicological Evaluation

3.3.1. Acute toxicity

Not applicable

3.3.2 Irritation and corrosivity

Not applicable

3.3.3. Skin sensitisation

Nor applicable

3.3.4. Dermal / percutaneous absorption
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Not applicable

3.3.5. Repeated dose toxicity

Not applicable

3.3.6. Mutagenicity / Genotoxicity

Not applicable

3.3.7. Carcinogenicity

Not applicable

3.3.8. Reproductive toxicity

Not applicable

3.3.9. Toxicokinetics

Not applicable

3.3.10. Photo-induced toxicity

Not applicable

3.3.11. Human data

Not applicable

3.3.12. Special investigations

Not applicable

3.3.13. Safety evaluation (including calculation of the MoS)**CALCULATION OF THE MARGIN OF SAFETY**

Qualitative and quantitative data are lacking from the submitted dossiers and from the current scientific literature.

3.3.14. Discussion

1. The concerns are naked viruses and the avian influenza virus. Data on the presence of naked viruses of the family of Papillomaviruses (which cause human warts and may promote tumours), Picornaviruses (enteric viruses and viruses causing respiratory illness) and Parvoviruses (only the B19 human parvovirus was found from 1980 to cause several human diseases including: fifth disease, polyarthropathies, transient aplastic anemia, erythroblastosis fetalis, erythrocyte aplasia and glow and socks disease) as contaminants of human hair are not provided with the submitted documentation and are not available in the current scientific literature.

Data on the presence of avian influenza virus on European or imported chicken feathers are not provided with the submitted documentation and are not available in the current scientific literature.

2. Human hair is obtained from hairdressing salons by cutting, in which there is no contamination with living tissue.

3. Human hair is not a specified risk material according to the relevant EU legislative texts and when obtained by cutting cannot be considered to be a specified risk material nor living tissue.

4. Although the avian influenza A virus does not usually infect humans, several instances of human infections and outbreaks of avian influenza have been reported since 1997 (Ref. 106). These cases of avian influenza infection in humans are thought to have resulted from contact with infected poultry or by respiratory secretions or faeces from contaminated surfaces or environment. It is not considered to be a food borne but a contact disease. To date, human infections with the avian influenza virus have not resulted in human-to-human transmission.

5. The influenza A virus only infects birds. Wild birds are the natural host for all subtypes of the influenza A virus. Typically, wild birds do not develop disease when they are infected with it. However, farmed poultry, such as turkeys and chickens, do become very sick and die from

avian influenza. The Influenza A virus may be detected in many different animals, including ducks, chickens, pigs, whales, horses, and seals.

Certain subtypes of the influenza A virus are specific to certain species. Birds host to all subtypes of influenza A. However, other species may carry only certain subtypes of the Influenza A virus.

Outbreaks of symptomatic avian influenza A infection (H5N1) in poultry are reported in several Asian countries, including Thailand, Vietnam, and Cambodia. Reports of sporadically occurring symptomatic human cases of influenza A (H5N1) continued through January 2005. Thailand reported five human cases of influenza H5N1 (with four deaths) in September and October 2004, but no additional cases to date. Thirteen human cases of influenza A (H5N1) infection (with 12 deaths) have been reported by Vietnam since mid-December 2004; WHO has reported that 10 of these cases (with 9 deaths) have been confirmed.

As of February 4, 2005, the cumulative number of confirmed human cases of influenza A (H5N1) reported in Asia since January 28, 2004, is 55 cases (with 42 deaths), according to WHO. The avian influenza A (H5N1) epizootic in Asia poses an important public health threat. The Center of Disease Control (CDC) in USA and the World Health Organisation (WHO) are continuously monitoring the situation (Ref. 106).

6. If viruses were present in the amino acids mixtures to be used in cosmetics, the only exposure routes for infection would be scalp/skin wounds, eyes and inhalation.

7. If feathers have been washed, dried at 60°C and sterilised by dry steam at 150°C the risk of any remaining infective avian influenza virus is nil. Also, the avian influenza virus and its subtypes are destroyed in 5 min at 60°C or in 1 min at 100°C (Ref. 100).

8. According the AFFSA (Agence Francaise de Sécurité Sanitaire des Aliments) – Ploufragan (France) note of 25 Nov 2004, the method to hydrolyse human hair or feathers with HCl >20% at 6 h at 100 °C excludes the presence of naked viruses and avian viruses (Ref. 100).

9. Also AFFSA reported in 2002 that the risk of any transmission of avian viruses to humans is nil or negligible without close contact with significant amounts of avian excretions and the transmission by any contact with avian feathers is considered nil or negligible for visitors to parks and ornithology reserves visitors and the transmission by any contact with avian feather was not addressed at all.

10. Papillomavirus, Picornaviruses and Parvoviruses: Parvoviruses are amongst the most resistant viruses. However in the absence of data to the contrary, it is considered that they too would also be inactivated by the referenced process.

11. It is generally assumed that the conditions that effectively destroy prions (Opinion of the SCCNFP on amino acids obtained by hydrolysis of human hair, adopted on 28 June 2000, doc. n° SCCNFP/0281/00), are sufficient to inactivate viruses and bacteria.

12. The only potential risk of hair being contaminated by Papillomavirus, Picornavirus or Parvovirus is when hair is cut from a person infected by one of these viruses and there is contamination of the cut hair by living tissue.

4. CONCLUSION

It is concluded that the resulting risk, based on current scientific data, of the use in cosmetic products for topical application of amino acids obtained by hydrolysis of human hair or chicken feathers under the conditions described under point 3, is negligible.

5. MINORITY OPINION

Not applicable

6. REFERENCES

100. Grippe aviaire: sécurité des articles de literie et des articles textiles. Note de l'Agence Française de Sécurité Sanitaire des Aliments. 22 Novembre 2004.
101. Le risque de transmission à l'homme des virus influenza aviaires. Rapport de l'Agence Française de Sécurité Sanitaire des Aliments. 10 Juillet Novembre 2002 (conclusion in page 76-77).
102. Opinion "Human hair hydrolisates and its possible liability to transmit the Creutzfeldt-Jakob disease and human spongiform encephalopathies", SCCNFP 200X)
105. Frost and Sullivan Market Engineering. European Markets for Active Ingredients in Personal Care. 11-1-2004)
106. Avian influenza: current situation. (http://www.who.int/csr/disease/avian_influenza/en/ and <http://www.cdc.gov/flu/avian/gen-info/>).
107. BF Goodrich Diamalt GmbH

7. ACKNOWLEDGEMENTS

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