

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

# SCIENTIFIC COMMITTEE ON CONSUMER PRODUCTS

# **SCCP**

# Opinion on

Peru Balsam

Adopted by the SCCP during the 7<sup>th</sup> plenary meeting of 28 March 2006

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#### 1. BACKGROUND

The SCCNFP<sup>1</sup> adopted at its 26<sup>th</sup> plenary meeting the 9 of December 2003, an update opinion (SCCNFP/0771/03) to the opinion (SCCNFP/0320/00) "An Initial List of Perfumery Materials which must not Form Part of Fragrances Compounds used in Cosmetic Products".

The opinion was based on IFRA<sup>2</sup> determination for:

"Peru balsam (Myroxylon pereirae Klotzsch) CAS n° 8007-00-9 Peru balsam (the exudation from Myroxylon pereirae (Royle) Klotzsch) should not be used as a fragrance ingredient.

The recommendation is based on a wide variety of test results on the sensitizing potential of Peru balsam. (D.L. Opdyke (1974), Fd. Cosmet. Toxicol. 12, 951 and 953 and private communication to IFRA)".

On this basis, the Commission adopted the 20 June 2005 the Directive 2005/42/EC, which *inter alia* ban the following substance:

"1136. Peru balsam (INCI name: Myroxylon pereirae; CAS No 8007-00-9), when used as a fragrance"

A substance with the same name and CAS number is also part of the opinion (SCCNFP/0392/00) "An Initial List of Perfumery Materials which must not Form Part of Fragrances Compounds used in Cosmetic Products except Subject to the Restrictions and Conditions laid down". In this opinion under entry 7 it is mentioned:

"Balsam oil, Peru (Myroxylon pereirae Klotzsch) CAS n°: 8007-00-9; Balsam absolute, Peru CAS n°: 8007-00-9; Balsam anhydrol, Peru CAS n°: 8007-00-9:

Extracts and distillates of Peru balsam (the exudation from Myroxylon pereirae (Royle) Klotzsch) should not be used such that the total level exceeds 0.4% in cosmetic products. Based on a wide variety of test results on the sensitising potential of Peru balsam and its derivatives."

EFFA<sup>3</sup> has drawn the Commission's attention to a possible confusion among the different existing forms of Peru Balsam. Industry agrees with the Commissions Directive to the ban of <u>crude</u> Peru Balsam, but refers to the opinion SCCNFP/0392/00 for Peru Balsam <u>extracts</u> and <u>distillates</u> and proposes to regulate these entries under the restricted materials in Annex III of the Cosmetic Directive.

According to EFFA - only one CAS number (8007-00-9) exists for the given different forms of Peru Balsam, its distillates, and extracts.

### 2. TERMS OF REFERENCE

<sup>&</sup>lt;sup>1</sup> Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers

<sup>&</sup>lt;sup>2</sup> The International Fragrance Association

<sup>&</sup>lt;sup>3</sup> European Flavour & Fragrance Association

- 1. Does the SCCP confirm that the ban proposed in the opinion SCCNFP/0771/03 and set out in the directive 2005/42/EC is restricted to the crude Peru Balsam only?
- 2. Does the SCCP confirm that the use for the consumers of Peru Balsam <u>extracts and distillates</u> are safe under the restrictions as proposed in the SCCNFP/0392/00?

#### 3. CONCLUSION

## Answer to question 1

The sentence "Peru Balsam (Myroxylon pereirae Klotzsch) CAS n° 8007-00-9: Peru balsam (the exudation from Myroxylon pereirae (Royle) Klotzsch) should not be used as a fragrance ingredient" in opinion n° SCCNFP/0771/03 of 9 December 2003 relates to the crude exudates only.

## Answer to question 2

Opinion SCCNFP/0392/00 of 25 September 2001 clearly proposes that Peru Balsam extracts and distillates may be used as fragrance ingredients of cosmetic products up to a maximum concentration of 0.4 % in the finished cosmetic product.

#### 4. REFERENCES

- Opinion of the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers concerning an initial list of perfumery materials which must not form part of fragrance compounds used in cosmetic products, adopted by the SCCNFP during the 12<sup>th</sup> plenary meeting of 3 May 2000. Doc n° SCCNFP/0320/00
- Opinion of the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers concerning an initial list of perfumery materials which must not form part of cosmetic products except subject to the restrictions and conditions laid down, adopted by the SCCNFP during the 18<sup>th</sup> plenary meeting of 25 September 2001. Doc. n° SCCNFP/0392/00
- Opinion of the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers concerning an update of the initial list of perfumery materials which must not form part of fragrance compounds used in cosmetic products, adopted by the SCCNFP during the 26<sup>th</sup> plenary meeting of 9 December 2003. Doc n° SCCNFP/0771/03

# 5. ACKNOWLEDGEMENTS

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