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

Liquidambar spp. Balsam Extracts and Oils (Storax)

(sensitisation only)

Adopted by the SCCP during the 3rd plenary meeting
of 15 March 2005

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1. BACKGROUND

During the 18th Plenary meeting of 25 September 2001, the SCCNFP[1] adopted an opinion (SCCNFP/0392/00 final) on an initial list of perfumery materials to be included in Annex III to Directive 76/768/EEC.

Following a review of the list, the SCCNFP adopted an updated opinion (SCCNFP/0770/03) during the 26th plenary meeting of 9 December 2003. The SCCNFP asked for additional information to allow further evaluation of fragrance ingredients.

For further evaluation of fragrance ingredients the SCCNFP asked for additional information.

In June 2004, the European Flavour & Fragrance Association submitted additiona1 information on the following fragrances:

- Methylhydrocinnamic aldehyde
- Tagetes absolute, Tagetes minuta absolute and Tagetes oil
- Opoponax
- Storax

2. TERMS OF REFERENCE

- *On the basis of currently available information, the SCCP is asked to assess the risk to consumers when Liquidambar spp. Balsam Extracts and Oils (Storax) are present in cosmetic products, and if necessary, to revise the maximum concentration in fragrances used in cosmetic products considering the concentration limits or other restrictions suggested by industry.*

- *Does the SCCP recommend any further restrictions with regard to the presence of Liquidambar spp. Balsam Extracts and Oils (Storax) as ingredients of fragrances used in cosmetic products?*

[1] SCCNFP - Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumer

3. OPINION

3.1. Chemical and Physical Specifications

3.1.1. Chemical identity

3.1.1.1. Primary name and/or INCI name

This opinion concerns the following fragrance ingredients according to EU Inventory Names [(*)]:

1. *Liquidambar Orientalis* Balsam Extract (EU Inventory Name)
2. *Liquidambar Orientalis* Balsam Oil (EU Inventory Name)
3. *Liquidambar styraciflua* Balsam Extract (EU Inventory Name)
4. *Liquidambar styraciflua* Balsam Oil (EU Inventory Name)

(*) The complete EU Inventory entries are given in the Appendix.

3.1.1.2. Chemical names

1. *Liquidambar Orientalis* Balsam Extract is the extract of the exudate obtained from the trunk of *Liquidambar orientalis, Hamamelidaceae.* It consists primarily of cinnamic and benzoic acids and their esters. Its main constituents are α- and β-storesin and its cinnamic ester (33-50%), styracin (5-10%), ethyl- and phenylpropyl-cinnamate (10%), benzyl cinnamate, free cinnamic acid (5-15%), a levorotatory oil 0,4%) and traces of vanillin.

2. *Liquidambar Orientalis* Balsam Oil is the Essential oil of the exudate obtained from the trunk of *Liquidambar orientalis, Hamamelidaceae.*

3. *Liquidambar styraciflua* Balsam Extract is the extract of the exudate obtained from the trunk of *Liquidambar styraciflua, Hamamelidaceae.* It consists primarily of cinnamic and benzoic acids and their esters. Its main constituents are α- and β-storesin and its cinnamic ester (33-50%), styracin (5-10%), ethyl- and phenylpropyl-cinnamate (10%), benzyl cinnamate, free cinnamic acid (5-15%), a levorotatory oil (0,4%) and traces of vanillin.

4. *Liquidambar styraciflua* Balsam Oil is the Essential oil of the exudate obtained from the trunk of *Liquidambar styraciflua, Hamamelidaceae.*

- The above definitions include all types of extracts (Tinctures, Concretes, Resinoids, Pomades, Absolutes, Rectified extracts etc.) and all types of Essential Oils (obtained either by dry-distillation or by steam-distillation, flash pasteurization etc.).

3.1.1.3. Trade names and abbreviations

- The names Storax and Styrax are known as generic synonyms *L. orientalis* and *L. styraciflua* Extracts. Synonyms of specific extracts are e.g. Storax or Styrax Absolute, Storax or Styrax Concrete, Storax or Styrax Resinoid etc. Synonyms of the respective oils are Storax or Styrax Oil, etc.
- The names Storax Levantinisch, Storax Levant, Storax Asian, Storax Turkish and Sweet Oriental Gum are generic synonyms of the products derived from *L. orientalis* (mainly native of Asia Minor).
- The names Storax Honduras, Storax American, Swee Gum are generic synonyms of the products derived from *L. styraciflua* (native of the Atlantic coast from Connecticut to Central America).

3.1.1.4. CAS / EINECS number

L. orientalis products	CAS	:	94891-27-7 (replacing 91845-54-4)
	EINECS	:	305-627-6
L. styraciflua products	CAS	:	8046-19-3 (replacing 8046-19-3 and 8024-01-9)
	EINECS	:	232-458-4

3.1.1.5. Structural formula

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3.1.1.6. Empirical formula

/

3.1.2. Physical form

/

3.1.3. Molecular weight

/

3.1.4. Purity, composition and substance codes

/

3.1.5. Impurities / accompanying contaminants

/

3.1.6. Solubility

/

3.1.7. Partition coefficient (Log P_{ow})

/

3.1.8. Additional physical and chemical specifications

Organoleptic properties	:	/
Melting point	:	/
Boiling point	:	/
Flash point	:	/
Vapour pressure	:	/
Density	:	/
Viscosity	:	/
pKa	:	/
Refractive index	:	/

3.2. Function and uses

Storax preparations are widely used fragrance ingredients of many fragrance compounds used in perfumery. Based on the positive results of maximization tests by industry, the IFRA standard recommends:

"Crude gums of American and Asian styrax should not be used as fragrance ingredient. Only extracts or distillates (resinoids, absolutes and oils), prepared from exudations of Liquidambar styraciflua L. var. macrophylla or Liquidambar orientalis Mill., can be used and should not exceed a level of 0.6 % in consumer products. This is equivalent to 3 % in a fragrance compound used at 20% in the consumer product.

This recommendation is made in order to promote good manufacturing practice (GMP) for the use of styrax derivatives as fragrance ingredients. It is based on a wide variety of RIFM test data with gums, resinoids, absolutes and oils of American and Asian styrax (private communication to IFRA)."

In the updated EU Inventory, Section II: Perfume and Aromatic Raw Materials (doc. SCCNFP/0389/00), the above restriction (previously flagged with one asterisk) is summarized as follows:

"The final concentration of Styrax extracts or distillates (resinoids, absolutes, oils) from exudates shall not exceed 0.6 % in the finished product."

3.3. Toxicological Evaluation

3.3.1. Acute toxicity

/

3.3.2 Irritation and corrosivity

/

3.3.3. Skin sensitisation

Human Maximization Studies

Human predictive (induction) studies were performed during 1972-1980 by the Kligman maximization test (ref. 52) on different Storax products. According to the summarized reports provided in combination with the respective compiled data worked out by RIFM (ref. 51), the test substance was applied as 8% solution in petrolatum or in diethyl phthalate (ref. 30-35) or in diethyl phthalate/petrolatum (ref. 36, 39, 40, 42, 43). Application was under occlusion to the same site on the volar forearms or backs of all subjects for five alternate-day 48-hour periods. Patch test sites were pretreated for 24-48 hours with 2.5% aqueous sodium lauryl sulfate (SLS) under occlusion. Following a 10-14-days rest period, a challenge patch at the same concentration was applied to a fresh site for 48 hours under occlusion. The challenge sites were pretreated for 30-60 min with 2.5%, 5% or 10% aqueous SLS under occlusion. Reactions to challenge were read at patch removal and 24 hours thereafter. The results are summarized in the following table.

Material tested	Number of volunteers	Results	Ref.
Storax Asian, distilled	25 male	3/25 reactions	13
Storax Asian, distilled (2nd test)	25 male	no reactions (0/25)	14
Storax Asian gum	25 male	6/25 reactions	12
Storax Asiatic crude	28 male	5/28 reactions	28
Storax Asiatic crude (2nd test)	35 male	no reactions (0/35)	30
Storax Asiatic crude (3rd test)	8 male and 17 female	4/25 reactions	39
Storax Asiatic, purified	11 male and 14 female	2/25 reactions	38
Storax Asiatic purified (2nd test)	30 male	no reactions (0/30)	31
Storax Asiatic purified (3rd test)	6 male and 21 female	no reactions (0/27)	36
Storax Asiatic Purified	12 male and 13 female	20/25 reactions	21
Storax Asiatic	22 male	no reactions (0/22) 4 irritant reactions	23
Storax Asiatic clarified	14 male and 11 female	12/25 reactions	19
Storax Turkish	26 male and female	4/26 reactions	11
Storax Turkish	25 male and female	no reactions (0/25)	45
Storax Turkish crude	35 male volunteers	no reactions (0/35)	34
Storax Turkish	25 male and female	no reactions (0/25) 1 irritant reaction	33
Storax Honduras crude	33 male	no reactions (0/33)	35
Storax Honduras	24 male and female	no reactions (0/24)	44
Storax Honduras clarified	12 ma1e and 13 female	3/25 reactions	20

Material tested	Number of volunteers	Results	Ref.
Storax Honduras clarified (2nd test)	25 male and female	no reactions (0/25)	40
Storax Honduras	3 male and 22 female	no reactions (0/25)	32
Storax Honduras	12 male and 13 female	2/25 reactions	27
Storax Honduras crude	23 male	1/23 reactions 3 irritant reactions	16
Storax gurn South American	25 male	no reactions (0/25)	11
Storax Absolute Resin	27 male	5/27 reactions	24
Storax Anhydrol	21 male	no reactions (0/21)	15
Storax Honduras crude (2nd test)	8 male and 17 female	no reactions (0/25)	43
Storax	6 male and 19 female	no reactions (0/25)	26
Storax	11 male and 14 female	no reactions (0/25)	25
Storax Oil	8 male and 17 female	no reactions (0/25)	22
Storax Oil extra	29 male	no reactions (0/29)	41
Storax Oil American	16 male and 9 female	1/25 reactions	17
Storax Oil American (2nd test)	16 male and 9 female	2/25 reactions	18
Storax Pyrogenee	29 male and female	9/29 reactions	29
Storax Pyrogenee (2nd test)	12 male and 13 female	no reactions (0/25)	42
Storaxoide (Storax gums processed with methyl phthalate at 90°C after neutralisation of the acids)	8 male and 21 female	no reactions (0/29)	31

Human Patch Tests on eczema and dermatitis patients, or sensitized to Peru balsam etc.

Study 1

Materia1 tested : Styrax
Concentration : 2% in petrolatum
Subjects : 49 male and 36 female dermatitis patients allergic to Peru balsam

Patch Test
The test substance was applied to the back and reactions read at 24 and 72 hours (no more details are given).

Results
20/85 reactions

Ref.: 1

Study 2

Materia1 tested : Styrax ba1sam
Concentration : 2% in petrolatum, and 1% and 10% in alcohol
Subjects : eczema patients who had previously exhibited a positive reaction to Peru balsam

Test

Closed patch tests. Patches consisted of a piece of 1 cm^2 lint with a 2 cm^2 cellophane disc placed on the lint and then covered with a 4 cm^2 plaster. Patches were applied to the back, the forearm and the inside of the upper arm for 24 to 48-hours. Reactions were read 30-minutes after patch removal.

Results
16/28 reactions at 2% (14/16 of these subjects a1so cross-reacted to benzoin)
5/13 reactions at 1 % (all 5 of these subjects a1so cross-reacted to benzoin)
1/10 reactions at 10% (this subject a1so cross- reacted to benzoin).

Patch tests with Styrax in vaseline produced positive reactions more frequently than test with Styrax in alcohol, probably because of a better absorption from vaseline than from alcohol, or because of lower solubility of common antigens to alcohol. Cross-sensitization from balsam of Peru to Styrax is so common that patients sensitive to balsam of Peru are exposed to a risk of dermatits from perfumes containing Styrax. Primary sensitivity to styrax was ascertained during the study. As storesinol has been reported to contain abietic acid, it may be mentioned that positive reactions to colophony were found in two patients with positive and two with negative reactions to Styrax. All other cases tested with Styrax showed negative reactions to colophony.

Ref.: 2

Study 3

Materia1 tested	:	Styrax balsam
Concentration	:	2% in petrolatum and 1% and 10% in a1coho1
Subjects	:	eczema patients exhibiting positive reaction to coniferyl benzoate

Patch Test
A 48-hour closed Patch test using a Lysaplast Special patch. Reactions read 10-20 minutes after patch removal and again 72 or 96 hours after patch removal. Reactions read again after 7 -8 days in 50% of the patients.

Results
18/28 reactions. The reactions to Styrax and balsam of Tolu observed in patients sensitised by balsam of Peru might conceivably be due to a common content of cinnamic acid or ester. An analysis of the present results seems to tell against this, as positive reactions to cinnamic acid occur independently of reactions to coniferyl benzoate, while positive reactions to the latter appear to be a prerequisite for positive reactions to Styrax and balsam of Peru.

Ref.: 3

Study 4

Materia1 tested	:	Styrax
Concentration	:	0.05% in a perfumed base cream.
Subjects	:	48 Japanese male and female volunteers (10% of which were eczema-prone or allergic persons).

Patch Test

The test material was applied to the inside of the upper arm and to the flexer aspect of the fore arm. A 1cm^2 lint patch was put with the test substance and covered with a cellophane 4cm^2. It was affixed to the skin by means of adhesive tape 9cm^2. The results were read after 24 hours, 30 minutes after removal.

Results
No reactions (0/48)

Ref.: 4

Study 5

Materia1 tested : Styrax
Concentration : 0.05-0.5% in 99% ethanol or in a base cream (composition given).
Subjects : 48 dermatitis patients

Patch Test
The test material was applied to a 1 cm^2 lint patch covered with a 2 cm^2 cellophane and applied to the back, the flexer aspect of the forearm and the inside of the upper arm with 4cm^2 adhesive tape. Reactions were read after 24-48 hours, 30 minutes after patch removal.

Results
No reactions (0/48)

Ref.: 49

Study 6

Materia1 tested : Styrax Oil (oil of styrax crude rectified)
Concentration : no dose reported
Subjects : a 62-year oId female with contact dermatitis from an eye cream was tested with the individual ingredients of the eye cream

Patch Test
The liquid fragrance components of the eye cream (including styrax oil) were applied “as is” to the back using the “Aluminium Patch Test” (A1-test). Reactions were read after 48 hours and again after 5 days.

Results
A positive reaction to styrax was observed at the 48-hour reading but not at the 5-day reading.

Ref.: 7

Study 7

Materia1 tested : Storax
Concentration : 2% (vehicle not reported)

Subjects : 21 male voIunteers with suspected occupational dermatitis from working at a particleboard manufacturing plant

Test
A 48-hour closed Patch test using a Lysaplast Special patch. Reactions read 10-20 minutes after patch removal and again 72 or 96 hours after patch removal. Reactions read again after 7 -8 days in 50% of the patients.

Results
No reactions (0/21)

Ref.: 48

Study 8

Materia1 tested : Styrax gum
Concentration : 2% in diethyl phthalate
Subjects : 8 male and 13 female dermatitis patients allergic to perfumes and sweet-smelling constituents

Patch Test
Reactions read at 48 hours.

Results
No reactions (0/21)

Ref.: 10

Study 9

Materia1 tested : Styrax resinoid
Concentration : no dose reported
Subjects : dermatitis patients
Patch Test : /
Results : Positive reactions were observed in 2.9% of the patients.

Ref.: 5

Study 10

Materia1 tested : Styrax
Concentration : 2% in petrolatum
Subjects : a 67-year old female with irritation and redness of her oral mucosa from her toothpaste
Patch Test : /
Results : patient reacted to styrax

Ref.: 47

Study 11

Materia1 tested	:	Styrax resinoid
Concentration	:	5% (no vehicle reported)
Subjects	:	355 eczema and dermatitis patients; 49 control patients
Patch Test	:	Patch tests were conducted from 1978- 1986 with cosmetic ingredients.
Results	:	8/355 positive reactions in eczema and dermatitis patients no reactions in control patients (0/49)

Ref.: 6

Study 12

Materia1 tested	:	Styrax
Concentration	:	no dose reported
Subjects	:	4 bakers who reacted to cinnamon and other spices
Patch Test	:	/
Results	:	patients did not react to styrax

Ref.: 8

Study 13

Materia1 tested	:	Styrax
Concentration	:	2% in petrolatum
Subjects	:	130 consecutive eczema patients
Patch Test	:	/
Results	:	7/130 reactions

Ref.: 50

Study 14

Materia1 tested	:	Styrax
Concentration	:	no dose reported
Subjects	:	22 male and 78 female dermatitis patients with leg ulcers
Patch Test	:	/
Results	:	no reactions (0/100)

Ref.: 9

3.3.**4.** Dermal / percutaneous absorption

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3.3.**5.** Repeated dose toxicity

/

3.3.6. Mutagenicity / Genotoxicity

/

3.3.7. Carcinogenicity

/

3.3.8. Reproductive toxicity

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3.3.9. Toxicokinetics

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3.3.10. Photo-induced toxicity

/

3.3.11. Human data

See elsewhere in the opinion

3.3.12. Special investigations

/

3.3.13. Safety evaluation (including calculation of the MoS)

CALCULATION OF THE MARGIN OF SAFETY

Not applicable

3.3.14. Discussion

The exposure data provided in section 3.2 above is not considered conclusive and current exposure data specific to Europe are totally missing.

The submitted data indicate that Storax extracts/oils are mild to moderate sensitizers and they extensively give positive reactions on dermatitis or eczema patients or patients previously sensitized to Peru balsam, coniferyl benzoate (and probably to other known sensitizers of a related nature).

4. CONCLUSION

The provided data do indicate that Storax extracts/oils have allergenic potential, though the quality of the submitted data is poor.

However, under the conditions of its anticipated use as a fragrance ingredient (maximum 0.6 % in the finished cosmetic product), the risk of sensitisation is low.

Nevertheless, Storax extracts/oils may contain one or more fragrance chemicals, which have been identified as contact allergens and for which information should be provided to consumers about the known presence in cosmetic products (Opinion of the SCCNFP concerning fragrance allergy in consumers, doc n° SCCNPF/0017/98).

5. MINORITY OPINION

Not applicable

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7. ACKNOWLEDGEMENTS

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APPENDIX

Entries of the EU Inventory, 1st update (2000)

Common Name:	**LIQUIDAMBAR ORIENTALIS BALSAM EXTRACT**
EINECS No.:	305-627-6
CAS RN:	94891-27-7
Chem. Name:	"Storax; Styrax; Levant Oil; Asiatic Oil". Extract of the exudate obtained from the trunk of *Liquidambar orientalis, Hamamelidaceae.* It consists primarily of cinnamic and benzoic acids and their esters. Its main constituents are α- and β-storesin and its cinnamic ester (33-50%), styracin (5-10%), ethyl- and phenylpropyl-cinnamate (10%), benzyl cinnamate, free cinnamic acid (5-15%), a levorotatory oil 0,4%) and traces of vanillin.
Restrictions:	The final concentration of Styrax extracts or distillates (resinoids, absolutes, oils) from exudates shall not exceed 0.6 % in the finished product.

Common Name:	**LIQUIDAMBAR ORIENTALIS BALSAM OIL**
EINECS No.:	305-627-6
CAS RN:	94891-27-7
Chem. Name:	"Styrax Oil". Essential oil of the exudate obtained from the trunk of *Liquidambar orientalis, Hamamelidaceae.*
Restrictions:	The final concentration of Styrax extracts or distillates (resinoids, absolutes, oils) from exudates shall not exceed 0.6 % in the finished product.

Common Name:	**LIQUIDAMBAR STYRACIFLUA BALSAM EXTRACT**
EINECS No.:	232-458-4
CAS RN:	8046-19-3
Chem. Name:	"Styrax; Storax; Sweet Gum". Extract of the gum exudate obtained from the trunk of *Liquidambar styraciflua, Hamamelidaceae*. It consists primarily of cinnamic and benzoic acids and their esters. Its main constituents are α- and β-storesin and its cinnamic ester (33-50%), styracin (5-10%), ethyl- and phenylpropyl-cinnamate (10%), benzyl cinnamate, free cinnamic acid (5-15%), a levorotatory oil 0,4%) and traces of vanillin.
Restrictions:	The final concentration of Styrax extracts or distillates (resinoids, absolutes, oils) from exudates shall not exceed 0.6 % in the finished product.

Common Name:	**LIQUIDAMBAR STYRACIFLUA BALSAM OIL**
EINECS No.:	232-458-4
CAS RN:	8046-19-3
Chem. Name:	"Styrax Oil". Essential oil of the gum exudate obtained from the trunk of *Liquidambar styraciflua, Hamamelidaceae*.
Restrictions:	The final concentration of Styrax extracts or distillates (resinoids, absolutes, oils) from exudates shall not exceed 0.6 % in the finished product.