



**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**

***Commiphora Erythrea Glabrescens* Gum Extract and Oil  
(Opopanax)**

**(sensitisation only)**

Adopted by the SCCP during the 3<sup>rd</sup> plenary meeting  
of 15 March 2005

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Opinion on *Commiphora Erythrea Glabrescens* Gum Extract and Oil (Opoponax)

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## 1. BACKGROUND

During the 18<sup>th</sup> Plenary meeting of 25 September 2001, the SCCNFP<sup>1</sup> 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 26<sup>th</sup> 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 additional 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 Opoponax is 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 Opoponax as an ingredient of fragrances used in cosmetic products?*

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<sup>1</sup> SCCNFP - Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumer

Opinion on *Commiphora Erythrea Glabrescens* Gum Extract and Oil (Opoponax)**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. *Commiphora erythrea Glabrescens* Gum Extract (EU Inventory Name)
2. *Commiphora erythrea Glabrescens* Gum Oil (EU Inventory Name)

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

**3.1.1.2. Chemical names**

1. *Commiphora erythrea Glabrescens* Gum Extract is the extract obtained by solvent extraction or steam distillation from the gum exudate of the barks of *Commiphora erythrea var. glabrescens, Burseraceae*.

This definition includes all types of extracts, including Tinctures, Concretes, Resinoids, Pomades, Absolutes, Rectified extracts etc.

2. *Commiphora erythrea Glabrescens* Gum Oil is the essential oil distilled from the gum exudate of the barks of *Commiphora erythrea var. glabrescens, Burseraceae*.

This definition includes 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**

1. The names Opoponax, Bisabol-myrrh and Sweet myrrh are known as generic synonyms *C. erythrea Glabrescens* Gum Extracts. Synonyms of specific extracts are e.g. Opoponax Absolute, Bisabol-myrrh Concrete, Sweet myrrh Resinoid etc.

Opopanax (gum) [CAS 9000-78-6, EINECS 232-558-8] is also another older synonym of Opoponax, in which the term in brackets is necessary for distinction from Opopanax (resin), which is a synonym of *Opopanax chironium* Resin [CAS 93384-32-8, EINECS 297-241-9]

2. The names Opoponax Oil, Bisabol-myrrh Oil and Sweet myrrh Oil are known as generic synonyms *C. erythrea Glabrescens* Gum Oils. Synonyms of specific products are e.g. Opoponax co-distilled with a solvent, Bisabol-myrrh oil boiling water distilled *ex* gum, Sweet myrrh oil steam distilled *ex* gum, Opoponax oil *ex* alcohol 39 °C resinoid, Opoponax oil *ex* benzene resinoid, Opoponax oil *ex* methanol resinoid etc.

**3.1.1.4. CAS / EINECS number**

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CAS : 93686-00-1 (replacing 9000-78-6)  
EINECS : 297-649-7 (replacing 232-558-8)

3.1.1.5. Structural formula
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3.1.1.6. Empirical formula
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3.1.2. Physical form
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3.1.3. Molecular weight
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3.1.4. Purity, composition and substance codes
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3.1.5. Impurities / accompanying contaminants
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3.1.6. Solubility
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3.1.7. Partition coefficient (Log P <sub>ow</sub> )
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3.1.8. Additional physical and chemical specifications
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Organoleptic properties	:	/
Melting point	:	/
Boiling point	:	/
Flash point	:	/
Vapour pressure	:	/
Density	:	/
Viscosity	:	/
pKa	:	/
Refractive index	:	/

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### 3.2. Function and uses

Opoponax 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:

“Opoponax preparations, obtained from opoponax gums (the exudation from the bark of *Commiphora erythraea* var. *glabrescens* Engler) by solvent extraction or steam distillation, should not be used such that the level in consumer products exceeds 0.6%. This is equivalent to 3% in a fragrance compound used at 20% in the consumer product.

This recommendation is based on test results of RIFM with samples of resinoids, concretes, absolutes and oil of opoponax. Earlier samples showed limited sensitisation reactions when tested at 8% whereas tests on a larger number of more recent samples showed no sensitisation at 8% (private communication to IFRA).”

### Comment

The following confusing statement is included in the submission (ref. 29)

OPOPONAX (*Commiphora erythraea* var. *glabrescens* Engler) used in perfumery includes the following natural materials:

1. Opoponax (*Commiphora erythraea* var. *glabrescens* Engler) RIFM # 341, CAS # 9000-78-6
2. Opoponax absolute (*Commiphora erythraea* var. *glabrescens* Engler) RIFM # 1097, CAS # 9000-78-6

Data from other forms of Opoponax extract are included in this submission for information only.

According to known terminology (section 3.1.1.3.), the term Opoponax alone includes Opoponax Absolute. The submitted data include maximization tests for 9 extracts and 11 oils.

### 3.3. Toxicological Evaluation

#### 3.3.1. Acute toxicity

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#### 3.3.2 Irritation and corrosivity

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#### 3.3.3. Skin sensitisation

Opinion on *Commiphora Erythrea Glabrescens* Gum Extract and Oil (Opopanax)**Human Maximization Studies**

Human predictive (induction) studies were performed during 1972-1980 by the Kligman maximization test (ref. 28) on different Opopanax products (9 extracts and 11 oils). According to the summarized reports provided in combination with the respective compiled data worked out by RIFM (ref. 29), the test substance was applied as 8% solution in petrolatum (a few exceptions are indicated in the table). 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.

According to the results of these tests, summarized in the table, five of the tested samples (2 extracts and 3 oils) gave some positive results indicating that Opopanax products may have a mild sensitizing potential depending on the origin and the quality of the product. In the introductory report (ref. 29) it is stated that the earlier studies with positive results were most likely due to the utilization of samples that contained undefined impurities. The more recent studies yielding negative results used better-defined materials. However, in the same report it is also stated that the source of the samples with positive results is unknown, and may have been obtained from *Pastinaca opopanax L.* (Fam: *Umbelliferaceae*) instead of from genuine opopanax gums from *Commiphora erythraea* var. *glabrescens* Engler (Fam: *Burseraceae*). Taking also into consideration that the most recent studies mentioned above were carried out in 1979-1980, these two partially contradicting statements cannot be evaluated.

<b>Sample tested</b>	<b>Subjects</b>	<b>Results</b>	<b>Ref.</b>
Opopanax absolute, sample 74-8-277	11 male and 14 female volunteers	no reactions (0/25)	9 (1975)
Opopanax absolute, sample 78-8-RBD-BA**	31 male volunteers	no reactions (0/31)	19 (1978)
Opopanax concrete, sample 78-8-RBD-BC**	33 male volunteers	no reactions (0/33)	20 (1978)
Opopanax resinoid, retest of sample 73-8-66-D	9 male and 16 female volunteers	1/25 reactions (1/25)	21 (1979)
Opopanax resinoid, sample 73-8-66-D	15 male and 10 female volunteers	1/25 reactions (1/25)	8 (1974)
Opopanax resinoid <i>ex</i> alcohol 39 °C, sample JK-8-2	8 male and 17 female volunteers	no reactions (0/25)	11 (1976)
Opopanax resinoid <i>ex</i> benzene, sample JK-8-1	9 male and 16 female volunteers	no reactions (0/25)	10 (1976)
Opopanax resinoid <i>ex</i> methanol, sample JK-8-5	25 male volunteers	no reactions (0/25)	15 (1976)
Opopanax tincture, sample 72-10-260*	25 male volunteers	no reactions (0/25)	6 (1973)

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Sample tested	Subjects	Results	Ref.
Opoponax oil, sample 80-8- Test 1	28 male volunteers	no reactions (0/28)	24 (1980)
Opoponax oil, sample 80-8-Test 2	33 male volunteers	no reactions (0/33)	25 (1980)
Opoponax oil, sample 72-8-204	25 male volunteers	2/25 reactions (2/25)	5 (1972)
Opoponax oil, sample 73-8-67R(2)	18 male and 7 female volunteers	4/25 reactions (4/25)	7 (1974)
Opoponax co-distilled with a solvent, sample 79-8-5948	9 male and 16 female volunteers	no reactions (0/25)	22 (1979)
Opoponax oil boiling water distilled, ex gum, sample JK-8-7	29 male volunteers	no reactions (0/29)	17 (1976)
Opoponax oil steam distilled ex gum, sample JK-8-3	7 male and 18 female volunteers	no reactions (0/25)	12 (1976)
Opoponax oil ex alcohol 39 °C resinoid, retest of sample JK-8-4	29 male volunteers	no reactions (0/29)	14 (1976)
Opoponax oil ex alcohol 39 °C resinoid, sample JK-8-4	11 male and 14 female volunteers	1/25 reactions (1/25)	13 (1976)
Opoponax oil ex benzene resinoid, sample JK-8-8	28 male volunteers	no reactions (0/28)	18 (1976)
Opoponax oil ex methanol resinoid, sample JK-8-6	26 male volunteers	no reactions (0/26)	16 (1976)

\* Induction and challenge with 10% test material in petrolatum.  
 \*\* Induction and challenge with 8% test material in diethyl phthalate.

**Human Patch Tests on dermatitis patients, patients sensitized to Peru balsam etc.****Study 1**

Material tested : *Commiphora Erythrea Glabrescens* Gum Extract  
 Sample : Opoponax  
 Subjects : 118 dermatitis patients  
 Concentration : 0.05 - 0.5% in a base cream or in 99% ethanol.

**Test**

A 24-48 hour closed patch test. Reactions read 30 minutes after patch removal.

**Results**

Erythema was observed in 1 patient and slight erythema was observed in 2 patients

Ref.: 27

**Study 2**

Material tested : *Commiphora Erythrea Glabrescens* Gum Extract

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Sample : Opopanax resin  
 Subjects : 11 eczema patients who had previously exhibited a positive reaction to Peru balsam  
 Concentration : 10% in alcohol

## 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

6/11 reactions

Ref.: 1

**Study 3**

Material tested : *Commiphora Erythrea Glabrescens* Gum Extract  
 Sample : Opopanax resinoid  
 Subjects : dermatitis patients  
 Concentration : no dose reported

## Test

Patch test

## Results

Reactions were observed in 3.5% of the patients (no further details reported)

Ref.: 4

**Study 4**

Material tested : *Commiphora Erythrea Glabrescens* Gum Extract  
 Sample : Opopanax gum  
 Subjects : A 22-year old male who reacted to tincture of benzoin was tested with 18 other gums and resins  
 Concentration : no dose reported

## Test

Closed patch test. Reactions read at 48 and 72 hours.

## Results

Patient did not react to opopanax

Ref.: 26

**Study 5**

Material tested : *Commiphora Erythrea Glabrescens* Gum Oil

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Sample : Opopanax oil  
Subjects : 65 dermatitis patients  
Concentration : 5% in petrolatum

Test  
Closed patch test.

Results  
2/65 reactions

Ref.: 2, 3

**3.3.4. Dermal / percutaneous absorption**

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**3.3.5. Repeated dose toxicity**

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**3.3.6. Mutagenicity / Genotoxicity**

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**3.3.7. Carcinogenicity**

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**3.3.8. Reproductive toxicity**

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**3.3.9. Toxicokinetics**

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**3.3.10. Photo-induced toxicity**

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**3.3.11. Human data**

See elsewhere in the opinion

**3.3.12. Special investigations**

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Opinion on *Commiphora Erythrea Glabrescens* Gum Extract and Oil (Opoponax)**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. Furthermore, there is some ambiguity about the types and the identity of available materials named Opoponax which are incorporated into cosmetic products.

The submitted data indicate that Opoponax products may be mild sensitizers depending on their source or quality (no more data available). Furthermore, they extensively give positive reactions on dermatitis patients and in patients previously sensitized to Peru balsam (and probably to other known sensitizers of related nature).

**4. CONCLUSION**

The term opoponax is used to describe a variety of derivatives/extracts of non-defined compositions obtained from *Commiphora Erythrea Glabrescens*.

The provided data do indicate that *Commiphora Erythrea Glabrescens* has an allergenic potential.

However, the quality of the submitted data is poor. Nevertheless, 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.

**5. MINORITY OPINION**

Not applicable

**6. REFERENCES**

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## 7. ACKNOWLEDGEMENTS

Members of the working group are acknowledged for their valuable contribution to this opinion. The members of the working group are:

Dr. C. Chambers	Prof. J.-P. Marty
Prof. R. Dubakiene	Dr. S.C. Rastogi
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## APPENDIX

**Entries in the original edition of EU Inventory (1996)**

232-558-8	9000-78-6	Opopanax (gum). * Extractives and their physically modified derivatives. It is a product which may contain resin acids and their esters, terpenes, and oxidation or polymerization products of these terpenes. ( <i>Commiphora</i> , <i>Burseraceae</i> ).
297-241-9	93384-32-8	Opopanax (resin) * Extractives and their physically modified derivatives. It is a product which may contain resin acids and their esters, terpenes, and oxidation or polymerization products of these terpenes. ( <i>Opopanax</i> , <i>Umbelliferae</i> ).

**Entries in EU Inventory, 1st update (2000)**

Common Name :	<b>COMMIPHORA ERYTHREA GLABRESCENS GUM EXTRACT</b>
EINECS No. :	297-649-7
CAS RN :	93686-00-1
Chem. Name :	“Opopanax”. Extract obtained by solvent extraction or steam distillation from the gum exudate of the barks of <i>Commiphora erythrea var. glabrescens</i> , <i>Burseraceae</i> .
Restrictions :	Only the rectified product obtained from crude Opopanax by solvent extraction or steam distillation may be used at a maximum level of 0.6% in the finished cosmetic products.
Common Name :	<b>COMMIPHORA ERYTHREA GLABRESCENS GUM OIL</b>
EINECS No. :	297-649-7
CAS RN :	93686-00-1
Chem. Name :	“Opopanax Oil”. Essential oil distilled from the gum exudate of the barks of <i>Commiphora erythrea var. glabrescens</i> , <i>Burseraceae</i> .

Common Name :	<b>OPOPANAX CHIRONIUM RESIN EXTRACT</b>
EINECS No. :	297-241-9
CAS RN :	93384-32-8
Chem. Name :	“Opopanax; Opopanax Gum Extract”. Extract of the resin obtained from the plant, <i>Opopanax chironium</i> , <i>Umbelliferae</i> . It is a product which may contain resin acids and their esters, terpenes, and oxidation or polymerization products of these terpenes.
Restrictions :	Only the rectified product obtained from crude Opopanax by solvent extraction or steam distillation may be used at a maximum level of 0.6% in the finished cosmetic products.
Common Name :	<b>OPOPANAX CHIRONIUM RESIN STEAM-DISTILLED OIL</b>
EINECS No. :	297-241-9
CAS RN :	93384-32-8
Chem. Name :	Steam-distilled oil of the resin obtained from the plant, <i>Opopanax chironium</i> , <i>Umbelliferae</i> .
Restrictions :	Only the rectified product obtained from crude Opopanax by solvent extraction or steam distillation may be used at a maximum level of 0.6% in the finished cosmetic products.

- The term “Extract” is used for all types of extracts, including **Tinctures, Concretes, Resinoids, Pomades, Absolutes, Rectified extracts etc.**, which are retained only in a few

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special cases (e.g. when other types should not be used according to IFRA recommendations or because they are banned by Annex II to the Cosmetic Directive).

- The term “**Oil**” is used for all types of **Essential Oils**, obtained either by dry-distillation or by steam-distillation, flash pasteurization etc. The same term is used also for the fixed oils, since their nature is declared in the Chemical Names’ field, while the terms “fixed” or “glyceridic” are not used any more in common nomenclature.
- The term “**Oil Expressed**” is used for the essential oils obtained by mechanical processes, mainly for the cold-pressed essential oils obtained from the epicarps of citrus fruits.
- The term “**Gum**” is used for all types of plant exsudates, including either natural raw materials, such as balsams, gums, gumresins, natural oleoresins, gum oleoresins, or their derivatives, such as resins. However, the terms “**Balsam**” and “**Resin**” are retained when they are included in the INCI name of the same material in Section I.