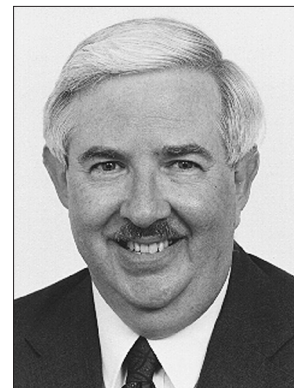


# European Cosmetic Regulatory Update<sup>a</sup>



By David Steinberg, Steinberg & Associates Inc., Plansboro, NJ

Personal care products are regulated in the European Union under the 6<sup>th</sup> Amendment to the Cosmetic Directive 76/768/EEC. Changes are made via Technical Adaptations and new Amendments. The recently passed 26<sup>th</sup> Commission Directive on Technical Adaptations has a significant impact on fragrances and ingredients found in fragrances. The proposed 7<sup>th</sup> Amendment has suggested changes that will completely change the way fragrances are sold to cosmetic companies — if they are approved in the currently suggested form.

## Current Regulations

The current regulations require products that contain fragrances to list this in the ingredient declaration as the word “parfum.” Products that contain flavors list this as “aroma.”<sup>1</sup> Further, in the Product Information Package<sup>2</sup> — also called the dossier — the company must list the name and code number of the composition and the identity of the supplier of the fragrance.<sup>2</sup> Other requirements regarding this issue contained in the dossier include specifications of the fragrance including a microbiological specification and a Material Safety Data Sheet. Additional information that may be requested includes safety data.

Fragrance and flavor compounds, unless they contain water, should be hostile to microorganisms and, hence, most suppliers simply put — “not applicable” (na) under microbiological specifications. Compounds containing water need specifications and must be checked and put on Certificates of Analysis.

## The 26<sup>th</sup> Technical Adaptation

In October of 2001, before this new change, most fragrance suppliers had little difficulty supplying their customers with the needed information to be in compliance with these regulations. However, this new adaptation will require more time and data to constitute compliance. The

changes include the prohibition of certain ingredients used by the perfumery industry in addition to level restrictions.

The ingredients listed in Table 1 are prohibited. It does not make any difference if they are used as actual components or are present in any amount as part of other components. If you currently use these, they must be replaced in all formulations sold in the EU. You will need analytical methods to check if they are present in any raw materials used to compound your fragrance.

If your fragrances do not contain any of these ingredients from any source, it will probably be sufficient to send a signed form letter to your accounts stating that your compounds do not contain any ingredients prohibited on Annex II of the Cosmetic Directive 76/768/EEC, 26<sup>th</sup> Technical Adaptation.

Methyleugenol is prohibited except for normal content in the natural essences used and provided the concentration does not exceed:

- 0.01 percent in fine fragrances
- 0.004 percent in eau de toilette
- 0.002 percent in fragrance cream
- 0.001 percent in rinse-off products
- 0.0002 percent in other leave-on products and oral hygiene products.

This presents a difficult problem for fragrance suppliers. You may not add methyleugenol to any compound. You will need to know the exact amounts present in any naturals that you compound with and then you will need to know how much of your product is used in what type of formulation. If you do find some in your products, you need to contact your customer immediately and resolve these issues.

Despite all this, a positive change has been made concerning musk xylene (CAS# 81-15-2) and musk ketone (CAS# 81-14-1). These materials are now permitted, but with the following restrictions:

Musk xylene	1.0 percent in fine fragrances
	0.4 percent in eau de toilette
	0.03 percent in other products
	prohibited in oral care products

<sup>a</sup>Adapted from an article originally published in GCI Magazine

Musk ketone	1.4 percent in fine fragrances
	0.56 percent in eau de toilette
	0.0042 percent in other products
	prohibited in oral care products

This presents the same customer problems as with methyleugenol.

### The Proposed 7<sup>th</sup> Amendment

This year, the European Parliament proposed that the Scientific Committee for Cosmetics and Non-Food Products (SCCNFP) issue guidelines for the safety assessment of products intended for children or for intimate hygiene. More important, the Parliament requested labeling of 26 fragrance allergens in the ingredient list, when present at more than 10 ppm in leave-on products or 100 ppm in rinse-off products. In the Parliament committee discussions, the proposal was to go even further, calling for a separate warning statement, "Can cause an allergic reaction," but this was voted out in the plenary session. These proposed ingredients are listed in Table 2.

The total amount in the fragrance is what is needed for the warning. It makes no difference if the chemical comes in as a natural component (i.e., it is a chemical that already exists in the un-fragranced product) or is added (i.e., it is a chemical whose sole purpose is to provide a fragrance). Further, it doesn't make a difference if the chemical is added as a component of another ingredient such as an essential oil, or is added as a pure chemical. It is the total regardless of origin.

Fragrance allergens that would have to be identified on cosmetics labels in the EU under certain conditions, as proposed by Parliament in the 7<sup>th</sup> Amendment are listed in Table 2.

### Latest News

The SCCNFP met and adopted their recommendations on September 25,

2001. They proposed that the following perfumery materials be allowed under these stated restrictions and conditions:

Name	CAS#
<i>Abies alba</i> oil from cones	8021-27-0
<i>Abies alba</i> oil from needles	8021-27-0
<i>Abies sachalinensis</i> oil fir balsam	8021-28-1
fir needle oil	8021-29-2
fir needle oil, Canadian	8021-28-1
pine needle, dwarf, oil	8000-26-8
pine needle oil	8021-29-2
pine scotch oil	8023-99-2
<i>Pinus nigra</i> oil	90082-74-9
turpentine gum	9005-90-7
turpentine oil	8006-64-2
turpentine oil, rectified	8006-64-2
turpentine, steam distilled	8006-64-2

**Restrictions and conditions:** Essential oils and isolates derived from the Pinacea family, including *Pinus* and *Abies* genera, should be used only when the level of peroxides is kept to the lowest practicable level, for instance by adding antioxidants at the time of production. Such products should have a peroxide value of less than 10 millimoles peroxide per liter.

Name	CAS#
acetyl hexamethyl indan	15323-35-0

**Restrictions and conditions:** For applications on areas of skin exposed to sun, excluding bath preparations, soaps and other rinse off products, limit use to 2 percent in the finished cosmetic product

Name	CAS#
allyl butyrate	2051-78-7
allyl cinnamate	1866-31-5
allyl cyclohexaneacetate	4728-82-9
allyl cyclohexanepropionate	2705-87-5
allyl heptanoate	142-19-8
allyl hexanoate	123-68-2
allyl isovalerate	2835-39-4
allyl octanoate	4230-97-1
allyl phenoxyacetate	7493-74-5
allyl phenylacetate	1797-74-6
allyl 3,5,5-trimethylhexanoate	71500-37-3

**Restrictions and conditions:** Use only when the level of free allyl alcohol in the ester is less than 0.1 percent.

Name	CAS#
allyl heptene carbonate	73157-43-4

in

Table 1. Prohibited ingredients

Name	CAS#
alanroot oil ( <i>Inula helenium</i> )	97676-35-2
benzyl cyanide	140-29-4
cyclamen alcohol	4756-19-8
diethyl maleate	141-05-9
dihydrocoumarine	119-84-6
2,4-dihydroxy-3-methylbenzaldehyde	6248-20-0
3,7-dimethyl-2-octen-1-ol (6,7-dihydrogeraniol)	40607-48-5
4,6-dimethyl-8-tert-butylcoumarin	17874-34-9
dimethyl citraconate	617-54-9
7,11-dimethyl-4,6,10-dodecantrien-3-one	26651-96-7
6,10-dimethyl-3,5,9-undecatrien-2-one	141-10-6
diphenylamine	122-39-4
ethyl acrylate	140-88-5
fig leaf absolute ( <i>Ficus carica</i> )	68916-52-9
<i>trans</i> -2-heptenal	18829-55-5
<i>trans</i> -2-hexenal diethyl acetal	67746-30-9
<i>trans</i> -2-hexenal dimethyl acetal	18318-83-7
hydroabietyl alcohol	13393-93-6
6-isopropyl-2-decahydronaphthenol	34131-99-2
7-methoxycoumarin	531-59-9
4-(4-methoxyphenyl)-3-butene-2-one	943-88-4
1-(4-methoxyphenyl)-1-penten-3-one	104-27-8
methyl <i>trans</i> -2-butenolate	623-43-8
7-methylcoumarin	2445-83-2
5-methyl-2,3-hexanedione	13706-86-0
2-pentylidenecyclohexanone	25677-40-1
3,6,10-trimethyl-3,5,9-undecatrien-2-one	1117-41-5
verbena oil ( <i>Lippia citriodora</i> Kunth.)	8024-12-2

**Ingredients prohibited previous to 26<sup>th</sup> Technical Adaptation**

allyl isothiocyanate	57-06-07
chenopodium oil	8006-99-3
hydroquinone monoethyl ether	622-62-8
4-methoxyphenol	150-76-5
p- <i>tert</i> -butylphenol	98-54-4
4-phenyl-3-buten-2-one	122-57-6
musk ambrette	83-66-9
moskene	
musk tibetene	

**Restrictions and conditions:** Should not be used such that the level in the finished cosmetic products exceeds 0.002 percent. This material should not be used in combination with any other 2-alkynoic acid esters (e.g. methylheptene carbonate).

Name	CAS#
amylcyclopentenone	25564-22-1

**Restrictions and conditions:** Should not be used such that the level in the finished cosmetic products exceeds 0.1 percent.

Name	CAS#
angelica root oil	8015-64-3
bergamot oil	8007-75-8
grapefruit oil, expressed	8016-20-4
lemon oil	8008-56-8
lemon oil, cold pressed,	8008-56-8
California type lemon oil,	8008-56-8
cold pressed, desert type	
lime oil, cold pressed,	8008-26-2
Mexican	
lime oil, expressed	8008-26-2
lime oil, expressed	8008-26-2
rectified	
orange peel oil, bitter	68916-04-1
rue oil	8014-29-7

**Restrictions and conditions:** May be used in cosmetic products, provided that the total concentration of furocoumarin-like substances in the finished products does not exceed 1 ppm.

Name	CAS#
balsam oil, Peru	8007-00-9
balsam absolute, Peru	8007-00-9
balsa, anhydrol, Peru	8007-00-9

**Restrictions and conditions:** Extracts and distillates of Peru balsam should not be used such that the total level exceeds 0.4 percent in cosmetic products.

Name	CAS#
p- <i>tert</i> -butyldihydrocinnamaldehyde	18127-01-0

**Restrictions and conditions:** Should not be used such that the total level in the finished cosmetic product exceeds 0.6 percent.

Name	CAS#
cinnamal	104-55-2
cinnamic aldehyde-methyl anthranilate	94386-48-8

**Table 2. The European Parliament's proposed list of fragrance allergens**

amyl cinnamal
benzyl alcohol
cinnamyl alcohol
citral
eugenol
hydroxycitronellal
isoeugenol
amylcinnamyl alcohol
benzyl salicylate
cinnamal
courmarin
geraniol
hydroxymethylpentylcyclohexane carboxyaldehyde
anisyl alcohol
benzyl cinnamate
farnesol
2-(4- <i>tert</i> -butylbenzyl) propionaldehyde
linalool
benzyl benzoate
citronellol
hexyl cinnamaldehyde
d-limonene
methyl octynate
4-(2,6,6 trimethyl-2-cyclohexen-1yl)-3-methyl-3 buten-2-one
extract of <i>Evernia prunasti</i> (oakmoss) and <i>Evernia furfuracea</i>
extract of <i>Evernia furfuracea</i>

**Restrictions and conditions:** The concentration of cinnamic aldehyde in the finished product should not exceed 0.1 percent.

Name	CAS#
cassia oil	8007-80-5
cinnamon bark oil	8015-91-6

**Restrictions and conditions:** The concentration of cinnamic aldehyde in the finished product should not exceed 0.1 percent.

Name	CAS#
cinnamyl alcohol	104-54-1

**Restrictions and conditions:** Should not be used such that the level in finished cosmetic products exceeds 0.8%

Name	CAS#
cumin oil	8014-13-9

**Restrictions and conditions:** For applications on areas of skin exposed to sun, excluding bath preparations,

soaps and other rinse-off products, limit cumin oil to 0.4 percent in the finished cosmetic product.

Name	CAS#
<i>cis</i> - $\alpha$ -damascone	23726-94-5
<i>trans</i> - $\beta$ -damascone	23726-91-2
isodamascone	39872-57-6
1-(2,6,6-trimethylcyclohexa-1,3-dienyl)-2-buten-1-one	23698-85-7
1-(2,6,6-trimethylcyclohexen-1-yl)-2-buten-1-one	57378-68-4
1-(2,6,6-trimethyl-1-cyclohexen-1-yl)-2-buten-1-one	23726-92-3
1-(2,6,6-trimethyl-2-cyclohexen-1-yl)-2-buten-1-one	43052-87-5

**Restrictions and conditions:** Should not be used as fragrance ingredients such that the total level in finished cosmetic products exceeds 0.02 percent, individually or in combination.

Name	CAS#
<i>trans</i> -hexen-2-al	6728-26-3

**Restrictions and conditions:** Should not be used such that the level in finished cosmetic products exceeds 0.002 percent.

Name	CAS#
hydroxycitronellal	107-75-5

**Restrictions and conditions:** Should not be used such that the level in finished cosmetic products exceeds 1.0 percent.

Name	CAS#
isoeugenol	97-54-1

**Restrictions and conditions:** Should not be used such that the level in finished cosmetic products exceeds 0.02 percent.

Name	CAS#
d-limonene	5989-27-5
l-limonene	5989-54-8
dl-limonene	138-86-3

**Restrictions and conditions:** Limonene and natural products containing substantial amounts of it, should only be used when the level of peroxides is kept to the lowest practicable level, for instance by adding antioxidants at the time of production. Such products should have a peroxide value of less than 20 millimoles peroxide per liter.

Name	CAS#
p-mentha-1,8-dien-7-al	2111-75-3

**Restrictions and conditions:** Should not be used such that the level in finished cosmetic products exceeds 0.1 percent.

Name	CAS#
menthadiene-7-methyl formate	68683-20-5

**Restrictions and conditions:** Should not be used such that the level in finished cosmetic products exceeds 0.1 percent.

---

<i>Name</i>	<i>CAS#</i>
methoxy dicyclopentadiene	86803-90-9
carboxaldehyde	

**Restrictions and conditions:** Should not be used such that the level in finished cosmetic products exceeds 0.5 percent.

<i>Name</i>	<i>CAS#</i>
methyl N-methylanthranilate	85-91-6

**Restrictions and conditions:** For applications on areas of skin exposed to sun, excluding bath preparations, soaps and other wash-off products, limit to 10 percent in the finished cosmetic product.

<i>Name</i>	<i>CAS#</i>
3-methyl-2(3)-nonenitrile	53153-66-5

**Restrictions and conditions:** Should not be used such that the level in finished cosmetic products exceeds 0.2%.

<i>Name</i>	<i>CAS#</i>
methyl octine carbonate	111-80-8
methyl heptine carbonate	111-12-6

**Restrictions and conditions:** MOC should not be used such that the level in finished cosmetic products exceeds 0.002 percent. MHC, when used alone in the finished cosmetic product, should not exceed 0.01 percent. When

present in combination, the combined level in the finished product should not exceed 0.01 percent, of which MHC should not be more than 0.002 percent.

<i>Name</i>	<i>CAS#</i>
oakmoss absolute	9000-50-4
oakmoss resinoid	9000-50-4
treemoss absolute	68648-41-9
treemoss concrete	68648-41-9
treemoss resinoid	68648-41-9

**Restrictions and conditions:** Should not be used such that the level in finished cosmetic products exceeds 0.1 percent. The maximum concentration of oakmoss and treemoss in combination in the finished cosmetic product should not exceed 0.1 percent.

<i>Name</i>	<i>CAS#</i>
1-octen-yl acetate	2442-10-6

**Restrictions and conditions:** Should not be used such that the level in finished cosmetic products exceeds 0.3 percent.

<i>Name</i>	<i>CAS#</i>
3-propylenephthalide	17369-59-4

**Restrictions and conditions:** Should not be used such that the level in finished cosmetic products exceeds 0.01 percent.

Name	CAS#
2,4,6-trimethyl-3-cyclohexene-1-methanol	68527-77-5

**Restrictions and conditions:** Should not be used such that the level in finished cosmetic products exceeds 0.5 percent.

Name	CAS#
verbena absolute	8024-12-2

**Restrictions and conditions:** Verbena absolute obtained from *Lippia citriodora* Kunth. should not be used such that the level in finished cosmetic products exceeds 0.2%.

## Conclusion

The changes from the 26<sup>th</sup> Technical Adaptation to the Cosmetic Directive have been approved and go into effect no later than October 2003. Suppliers of perfumery ingredients will need to establish specifications to be sure that they do not contain prohibited ingredients. Suppliers of fragrances will need to update their raw material specifications and finished goods specs. They also will have to notify their customers concerning the use of methyeugenol, musk ketone and musk xylene and resolve the levels to ensure

compliance. If the fragrance supplier is not affected and all their compounds meet the requirements, a form letter should be developed and sent to all accounts marketing in the EU.

The 7<sup>th</sup> Amendment is a long way from approval. For a detailed review of this process see *Cosmetics & Toiletries*, Vol.116 (No.11) November 2001 pages 26-34. It is doubtful that the fragrance labeling issues will disappear. The SCCNFP recommendations are more likely to be adopted. Suppliers should try to be ahead of the curve and start to see how these recommendations will affect their compounds. Cosmetic companies who use oils like bergamot, lemon, lime, etc. will also need to begin anticipating the impact of these changes. The procedure for approval of the SCCNFP position will require a new Technical Adaptation. This will still give everyone 24 months after approval.

Address correspondence to David Steinberg, Steinberg & Associates Inc., 16 Mershon Lane, Plainsboro, NJ.

## References

1. D.C. Steinberg, Aguide to European Cosmetic Regulations, ICMAD (Palatine, IL 1998) page 66.
2. Dir. 76/768/EEC Article 7a, 1 (a). ■