

**OPINION OF THE SCIENTIFIC COMMITTEE ON COSMETIC PRODUCTS AND NON-FOOD  
PRODUCTS INTENDED FOR CONSUMERS**

CONCERNING

**MUSK XYLENE**

adopted by the plenary session of the SCCNFP  
of 8 December 1999

## Executive Summary

### 1. General data

- 1.1 Identity of the ingredient : Musk Xylene  
1.2 CAS n° : 81-15-2  
1.3 Use : Fragrance ingredient

### 2. Terms of reference

#### 2.1 Context of the question

The adaptation to technical progress of the Annexes to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products.

Change in Annex III, part 1, n° 12 to Council Directive 76/768/EEC to set limits for Musk Xylene in cosmetic products.

#### 2.2 Request to the SCCNFP

The SCCNFP is requested to answer the following questions :

- \* Is Musk Xylene safe for use in cosmetic products?
- \* Does the SCCNFP propose any restrictions or conditions for its use in cosmetic products?

### 3. Safety Assessment & Classification

The assessment followed the SCCNFP Notes of Guidance under scientifically based premises of consumer safety and leads to a classification 1 for the intended use.

Evaluation of acute toxicity (oral, dermal), skin and mucous membrane irritation, sub-chronic toxicity (oral, dermal), reproductive toxicity (oral), genotoxicity, percutaneous absorption have shown that the Musk Xylene can be safely used under the conditions stated in the Opinion.

### 4. Opinion

The opinion that consumer exposure to Musk Xylene should be reduced is based on the findings in long term studies in mice and the presence of the substance in human fat and its excretion in human milk.

It is estimated that exposure to Musk Xylene from cosmetic use is about 207 µg/kg/day. This equates to about 20.7 µg/kg/day theoretically absorbable.

It is not possible to identify a threshold dose from the mice chronic effects data. However, it is recommended that the absorbed dose of Musk Xylene from exposure to cosmetic products should be reduced to about 10 µg/kg/day. This restriction is based on quantitative risk assessment assuming that the calculated worst case lifetime cancer risk of about  $1 \times 10^{-4}$  should be tolerable for a non-genotoxic carcinogen.

Current exposure to Musk Xylene from cosmetic products is demonstrated by the following table:

<i>Product</i>	<i>% Musk Xylene</i>	<i>absorbed dose µg/kg/day</i>
Fine fragrance*	1.3	6.4
Eau de toilette*	0.57	7.1
Fragranced cream	0.28	6.9
Body lotion	0.028	2.7
Other		4.0
<b>Total</b>		<b>20.0 - 20.7</b>

This provides an absorbed dose of 20 or 20.7 µg/kg/day assuming that either a fine fragrance product or eau de toilette is used (\*).

A reduction in absorption of Musk Xylene from cosmetic exposure can be achieved in a number of ways and the following are given as examples:

	<i>absorbed dose (µg/kg/day)*</i>
- At present	20.0 - 20.7
- maximum of 0.1% Musk Xylene in any cosmetic product**	9.5 - 10.3
- fine fragrance 1.0%; eau de toilette 0.4%; other products 0.03%***	10.6 - 10.7

\*The first column is based on the use of fine fragrance and the second on the use of eau de toilette

\*\*This calculation is based on no increase in Musk Xylene in product containing less than 0.1%

\*\*\*This calculation is based on no increase of Musk Xylene in "other product" containing less than 0.03%

On review of the information presently available, it is the opinion of the SCCNFP that Musk Xylene can be safely used in cosmetic products, excluding oral care products, up to a maximum daily theoretically absorbed dose of about 10 µg/kg/day.

The above has been formulated only on review of the cosmetic use of Musk Xylene. For the full safety assessment of Musk Xylene, it is necessary to consider other sources of consumer exposure from non-food products e.g., laundry products.

## 5. Statement on the toxicological evaluation

The SCCNFP is the scientific advisory body to the European Commission in matters of consumer protection with respect to cosmetics and non-food products intended for consumers.

The Commission's general policy regarding research on animals supports the development of alternative methods to replace or to reduce animal testing when possible. In this context, the SCCNFP has a specific working group on alternatives to animal testing which, in co-operation with other Commission services such as ECVAM (European Centre for Validation of Alternative Methods), evaluates these methods.

The extend to which these validated methods are applicable to cosmetic products and its ingredients is a matter of the SCCNFP.

SCCNFP opinions include evaluations of experiments using laboratory animals; such tests are conducted in accordance with all legal provisions and preferably under chemical law regulations. Only in cases where no alternative method is available will such tests be evaluated and the resulting data accepted, in order to meet the fundamental requirements of the protection of consumer health.