

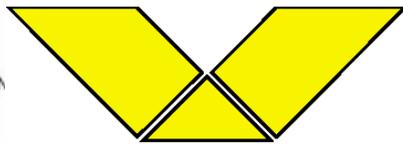


---

COSMETICS EUROPE:  
N° 15: PETROLATUM

JULY 2004

---



Date: 5 July 2004  
Contact: Florian Schellauf  
Tel: +32 – 2 – 227 66 21  
E-mail: fschellauf@colipa.be

## **JOINT COLIPA/EFW RECOMMENDATION**

### **SAFETY OF PETROLATUM AS RAW MATERIAL FOR THE COSMETIC INDUSTRY**

#### Background

For the purpose of their carcinogenicity classification in the Dangerous Substances Directive (67/548/EEC) all petroleum substances were allocated to a number of distinct groups according to their refinery processing history.

These groups include 'Highly Refined Base Oils', 'Paraffin and Hydrocarbon Waxes' and 'Petrolatum'. 'Highly Refined Base Oils' and 'Paraffin and Hydrocarbon Waxes' are classified as not carcinogenic, whereas 'Petrolatum' is classified as carcinogenic, category 2, unless base oil from which it derives is not carcinogenic (Nota N).

Nota N: The classification as a carcinogen need not apply if the full refining history is known and it can be demonstrated that the substance from which it was produced is not a carcinogen.

Because of their similarity in chemical composition petrolatum refined by hydrogenation or clay treatment (white (yellow) soft paraffin as defined in the European Pharmacopoeia) as well as unrefined Petrolatum are included in the same Petrolatum group.

As a consequence Nota N not only applies to unrefined petrolatum but also to the pharmaceutical quality products, although their safety for human health is warranted by the purity criteria in the monographs in the European Pharmacopoeia.

Compliance to Nota N is demonstrated by the fact that the products from which petrolatum is produced are not carcinogens because they contain less than 3% DMSO-extract according to test method IP 346. This is the legal requirement for these materials for non-carcinogenicity. A copy of test method IP 346 is available from Colipa upon request.

## Use of Petrolatum in the cosmetics industry

According to the Cosmetics Directive (7<sup>th</sup> amendment) category 2 carcinogens are not allowed for use in cosmetic products. Over and above the compliance to the European Pharmacopoeia suppliers of Petrolatum will have to give absolute assurance that their product is not a carcinogen according to the Dangerous Substance Directive.

There are two possibilities to achieve this objective:

- The supplier will guarantee that the full refining history of the raw materials for the production of Petrolatum is known. It is suggested that the supplier includes a statement thereof in the Certificate of Analyses as follows:

*It is hereby guaranteed that the product is produced from substances that are not carcinogens according to the Dangerous Substances Directive and of which the full refining history is known.*

Compliance to the European Pharmacopoeia may be included in the Certificate of Analysis.

- If the product has been manufactured of components from substances from the two non-carcinogenic groups ('Highly Refined Base Oils' and 'Paraffin and Hydrocarbon Waxes') the supplier may apply for a new INCI-name for its trade name material as a mixture, instead of the single ingredient Petrolatum. However, it is important to note that INCI-names can only be assigned or changed by the International Nomenclature Committee, and, that if a trade material receives an INCI-name as a mixture, the INCI-name Petrolatum cannot be stated as an ingredient in the declaration of the cosmetic product.

COSMETICS EUROPE IS THE EUROPEAN TRADE  
ASSOCIATION REPRESENTING THE INTEREST OF THE  
COSMETICS, TOILETRY AND PERFUMERY INDUSTRY

COSMETICS EUROPE – THE PERSONAL CARE ASSOCIATION  
AVENUE HERRMANN-DEBROUX 40, 1160 BRUSSELS  
T. +32 2 227 66 10, F. +32 2 227 66 27  
[WWW.COSMETICSEUROPE.EU](http://WWW.COSMETICSEUROPE.EU)