

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion: Vitamin A CAS n. 68-26-8 / 11103-57-4/ 116-31-4 (Retinol, Retinyl Acetate, Retinyl Palmitate; Retinyl Linoleate and Retinal)

1. Background

Vitamin A (CAS n. 68-26-8 / 11103-57-4/ 116-31-4) constitutes a group of lipid-soluble compounds including retinol, retinyl palmitate, retinyl acetate, retinyl linoleate and retinal. Vitamin A is a lipophilic-soluble vitamin and as such a micronutrient essential for most of mammalian species.

The risk characterisation for generical use of Vitamin A for all age groups is based on the tolerable upper intake levels (UL) derived from earlier opinions from the Scientific Committee of Food (SCF)¹ and European Food Safety Authority (EFSA)². In 2002, the SCF considered that the upper level of 3000 µg RE/day is appropriate for all women of child-bearing age but also for men and for infants and children after correction for differences in metabolic rate. In 2008, EFSA considered that a maximum intake of 1500 µg RE/day would serve as a guidance level (GL) for individuals at greater risk of osteoporosis and bone fracture (particularly post-menopausal women).

In January 2012, the Commission received some documents from German authorities requesting a safety assessment of Vitamin A in cosmetics products. According to the Member State, the use of retinol and its esters in cosmetics should be restricted in view of increasing number of products containing Vitamin A, increasing concentrations and/or greater penetration (e.g. as a result of packaging in liposomes) and the fact that the UL is already exceeded by some parts of the population.

In February 2012, a safety dossier was submitted by Cosmetics Europe³ to support the continuous use of Vitamin A in cosmetic product. It relates to the use of retinol, retinyl palmitate and retinyl acetate as cosmetic ingredients at maximum use concentrations of 0.05% (retinol equivalents) in body lotions, 0.3% (retinol equivalents) in hand and face creams as well as in other leave-on or rinse-off products.

In July 2013, The Commission received the Norwegian risk assessment of the use of vitamin A (retinol and retinyl esters) in cosmetic products.

The Commission asked the opinion of the European Medicine Agency (EMA) to exclude the possibility that, at maximum use concentrations of 0.05% (retinol equivalents) in body lotions, 0.3% (retinol equivalents) in hand and face creams as well as in other leave-on or rinse-off products, Vitamin A could be considered a medicinal product instead of a cosmetic product. EMA replied that "*locally applied products containing Vitamin A at the maximum concentrations of 0.05% (retinol equivalents) in body lotions, 0.3% (retinol equivalents) in hand*

and face creams as well as in other leave-on or rinse-off products, are not considered to be medicinal products by virtue of their function."

2. Terms of reference

- (1) *On the basis of data provided does the Scientific Committee on Consumer Safety (SCCS) consider Vitamin A (retinol, retinyl palmitate, retinyl acetate, retinyl linoleate and retinal) safe when used as cosmetic ingredient:*
- a) *in body lotions up to the maximum concentration of 0.05 % of retinol equivalent?*
- b) *in hand/face cream, leave-on (other than body lotions) and rinse-off products up to the concentration of 0.3 % of retinol equivalent ?*

If no, what concentration limits in the above mentioned categories of cosmetic products does the SCCS consider Vitamin A to be safe?

- (2) *The SCCS is asked, when making the assessment, to take into account the specific age and sex groups who might be particularly susceptible to the effects of Vitamin A, such as the use of lip products for fertile age and postmenopausal women.*
- (3) *Does the SCCS have any further scientific concerns with regard to the use of Vitamin A (retinol, retinyl palmitate, retinyl acetate, retinyl linoleate and retinal) in cosmetic products ?*

3. Deadline:

4. Supporting documents

1. Data used as a basis for an analysis carried out by the Federal Institute for Risk Assessment (*Bundesinstitut für Risiko-bewertung - BfR*)- German Authority
2. Dossier on Vitamin A(Retinol, Retinyl Acetate and Retinyl Palmitate) in cosmetic products –Cosmetics Europe - October 2011
3. Opinion of the Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics of the Norwegian Scientific Committee for Food Safety – August 2012
4. CHMP scientific opinion to DG Internal Market, Industry, Entrepreneurship and SME's, Unit for Health Technology and Cosmetics I/4, on the question whether Vitamin A containing topical products fall under the definition of a pharmaceutical product.

Annex

Submission summary

- 1- http://ec.europa.eu/food/fs/sc/scf/out145_en.pdf
- 2- <http://www.efsa.europa.eu/en/ndatopics/docs/ndatolerableuil.pdf>
- 3- Cosmetics Europe- European Cosmetics Toiletry and Perfumery Association