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Commentary

Opinion of the Scientific Committee on Consumer Safety (SCCS) – Final version of the Opinion on Vitamin A (retinol, retinyl acetate and retinyl palmitate) in cosmetic products

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Abstract

The SCCS has estimated that exposure to Vitamin A (retinol, retinyl palmitate, and retinyl acetate) and *via* body lotion at the maximum concentration of 0.05% and *via* hand cream, face cream and other leave-on or rinse-off products at the maximum concentration of 0.3% per se is safe.

The exposure from all cosmetic products may lead to a daily systemic dose of 4855 IU for an adult. The teratogenic potential of Vitamin A was considered and effects on liver and local effects in the skin are the most critical toxicological endpoints. To take into account more susceptible population groups such as women suffering osteoporosis or children above 6 years old who may also be exposed to Vitamin A *via* cosmetic products, the SCCS has used the value of 1500 μg RE/day (5000 IU) for the safety assessment of Vitamin A in cosmetic products. Vitamin A and esters are not used for children in the EU. However, based on a theoretical scenario, exposure to Vitamin A *via* these products has been assessed in this opinion for children above 1 year. Based on information received, Vitamin A and esters are not used in sunscreen products in the EU and therefore this exposure was not assessed.

Opinion to be cited as: SCCS (Scientific Committee on Consumer Safety), Opinion on Vitamin A (Retinol, Retinyl Acetate, Retinyl Palmitate), SCCS/1576/16, 20 April 2016, final version of 6 October 2016.

Conclusion of the Opinion

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 general 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) and European Food Safety Authority (EFSA). In 2002, the SCF considered that the upper level of 3000 μg RE (retinol equivalents)/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 (5000 IU) 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 (BfR, 2012). 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.

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In February 2012, a safety dossier was submitted by Cosmetics Europe 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% RE in body lotions, 0.3% RE 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% RE in body lotions, 0.3% RE 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."

The SCCS has considered that the teratogenic potential of Vitamin A, and effects on liver and local effects in the skin are the most critical toxicological endpoints. For assessing the systemic toxicity of Vitamin A after cosmetic exposure, the SCCS has relied on the Tolerable Upper Intake Level (UL) for preformed Vitamin A.

To take into account more susceptible population groups such as women suffering osteoporosis or children above 6 years old who may also be exposed to Vitamin A via cosmetic products, the SCCS has used the value of 1500 μg RE/day (5000 IU) for the safety assessment of Vitamin A in cosmetic products. This value is appropriate for women of childbearing age and also for middle age and elderly women who may suffer decreasing bone density as well as men and children above 6 years.

The SCCS has estimated that exposure to Vitamin A (retinol, retinyl palmitate, and retinyl acetate) *via* body lotion at the maximum concentration of 0.05% may lead to a daily systemic dose of 1003 IU for an adult. This exposure would constitute up to 20% of the Upper Limit (UL) of 5000 IU/day of Vitamin A. Therefore, the SCCS considers that the use of Vitamin A in body lotions per se is safe.

The SCCS has also estimated that exposure to Vitamin A (retinol, retinyl palmitate, and retinyl acetate):

- *via* hand cream at the maximum concentration of 0.3% may lead to daily systemic dose of 1661 IU for an adult. This exposure could constitute up to 33% of the UL of 5000 IU/day of Vitamin A. Therefore, the SCCS considers that the use of Vitamin A in hand cream products per se is safe.
- *via* face cream at the maximum concentration of 0.3% may lead to daily systemic dose of 1185 IU for an adult. This exposure could constitute up to 24% of the UL of 5000 IU/day of Vitamin A. Therefore, the SCCS considers that the use of Vitamin A in face cream products per se is safe.
- *via* rinse-off products at the maximum concentration of 0.3% may lead to a daily systemic dose of 408 IU for an adult. This exposure could constitute up to 8.8% of the UL of 5000 IU/day of Vitamin A. Therefore, the SCCS considers that the use of Vitamin A in rinse-off products per se is safe.

The SCCS has finally estimated that aggregated exposure to Vitamin A (retinol, retinyl palmitate, and retinyl acetate) from all cosmetic products (including lip products) may lead to a daily systemic dose of 4855 IU for an adult. This exposure could constitute up to 97% of the UL of 5000 IU/day of Vitamin A. Excluding lip products, the daily systemic dose is estimated at 4256 IU for an adult, which constitutes up to 85% of the UL of 5000 IU/day of Vitamin A. It is of note that these estimates are based on a worst-case scenario assuming that all the cosmetic products used (hand and face cream, body lotion, rinse-off products, products for the lips) contain Vitamin A at the maximum concentrations.

Based on information provided by the cosmetic industry, Vitamin A and esters are not used for children in the EU. However, based on a theoretical scenario, exposure to Vitamin A *via* these products has been assessed in this opinion for children above 1 year. Exposure to Vitamin A for children below 1 year has not been assessed in this Opinion.

The SCCS has used the value of 800 μg RE/day (2700 IU) for the safety assessment of Vitamin A in cosmetic products for children aged 1–3 years. Application of Vitamin A containing baby skin care products such as body lotions and creams were also considered by SCCS relevant for 1- and 3-years old children. The SCCS has estimated that exposure to Vitamin A (retinol, retinyl palmitate, and retinyl acetate) *via* all cosmetic products may lead to a daily systemic dose of 1064 IU for a child of 15 kg. This exposure could constitute up to 39% of the UL of 2700 IU/day of Vitamin A. Based on these estimates, the SCCS considers that the use of Vitamin A in the respective cosmetic products at the maximum notified concentration per se is safe for children above 1 year old.

It is of note that these estimates are based on a worst-case scenario assuming that all the cosmetic products used (hand and face cream, body lotion, rinse-off products) contain Vitamin A at the maximum concentrations.

Based on information provided by the applicants, Vitamin A and esters are not used in sunscreen products in the EU. Therefore exposure to Vitamin A *via* these products has not been assessed in this Opinion.

Retinyl linoleate and retinal may also be used in cosmetic products. However, since no specific data were provided by the applicant, these two Vitamin A derivatives have not been assessed in this Opinion.

Exposure to Vitamin A may also occur from sources other than cosmetic products. The most important source of Vitamin A in the population is diet, followed by food supplements and cosmetics. This assessment has not taken into account people taking dietary supplement containing Vitamin A.

On the basis of data from 12 dietary surveys in nine EU countries, Vitamin A intake was assessed and average intake ranged between 409 and 651 μg RE/day in children aged 1 to <3 years; between 607 and 889 μg RE/day in children aged 3 to <10 years; between 597 and 1078 μg RE/day in children aged 10 to <18 years; and between 816 and 1498 μg RE/day in adults. Therefore exposure to Vitamin A *via* food may already be very close to the UL and any additional source of exposure, including cosmetic products, may exceed this UL. It is however not up to the SCCS to advise which portion of the UL should be dedicated to the different sources of exposure. For example, when assessing exposure to chemicals *via* toys or drinking water, usually 10% or 20% of the reference value is considered. In the case of Vitamin A, these portions would be equivalent to 150 or 300 μg RE/day, which means that at the maximum-notified concentrations, the use of hand and face cream products, rinse-off products, body lotion and cosmetic products for lips may lead to exceeding this value.

Transparency document

Transparency document related to this article can be found online at http://dx.doi.org/10.1016/j.yrtph.2016.11.017

Reference

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_199.pdf.