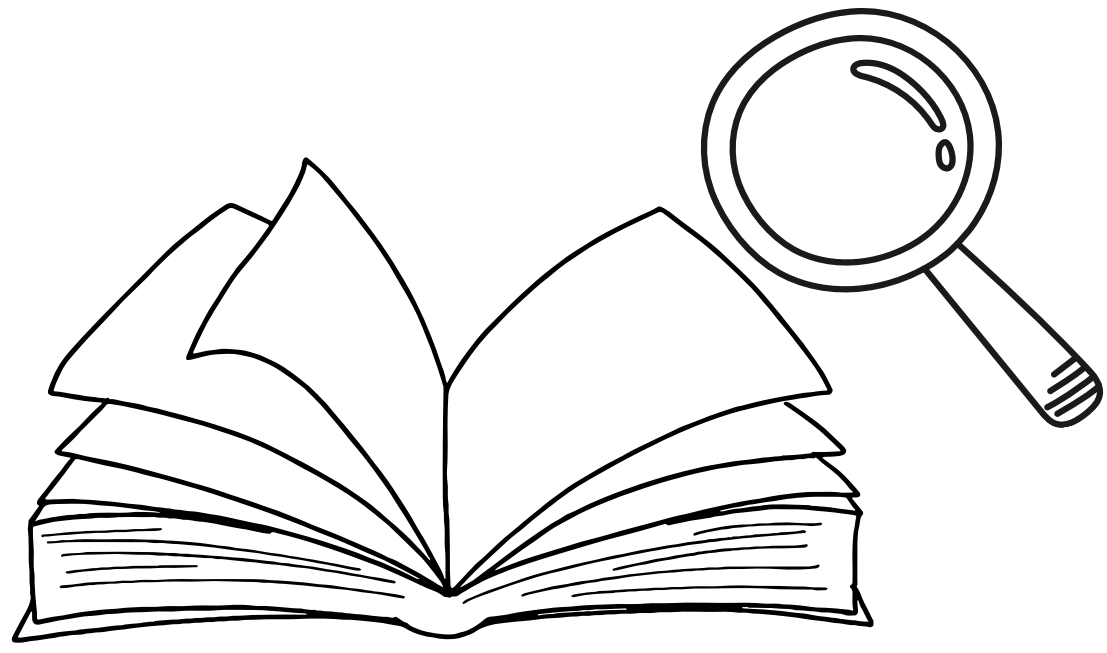
REGULATORY COSMETICS NEWS

DEC 23 - APR 24



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December 2023 -April 2024

EU

SCCS Preliminary Opinions open for comments

- **Acetylated Vetiver Oil (AVO):**

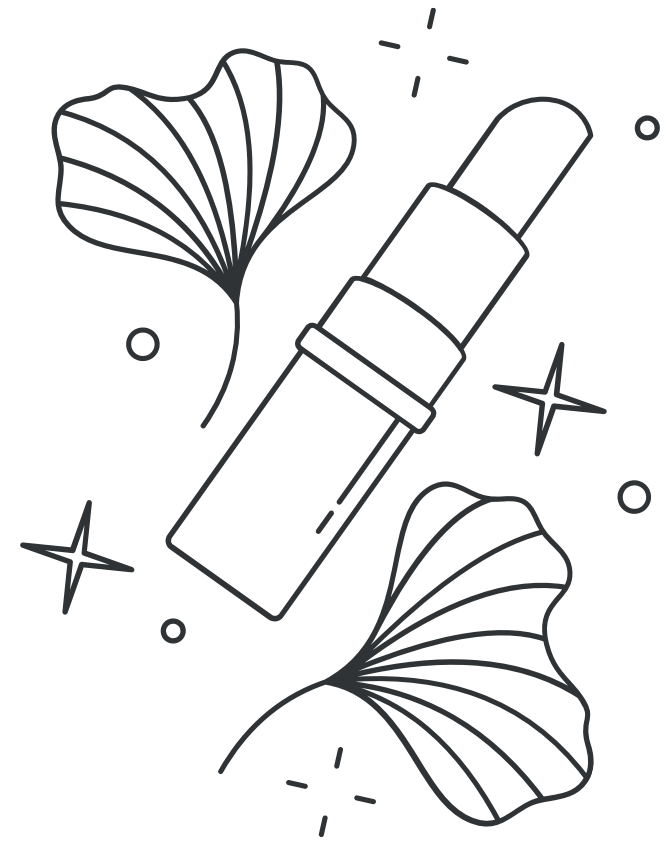
Having considered the data provided concerning inhalation toxicity and aggregate exposure, the SCCS considers Acetylated Vetiver Oil (AVO) (with 1% alpha-tocopherol) **safe** when used at the intended maximum concentrations (IMCs) of **0.9%** (w/w) in fragrance pump sprays, **0.05%** (w/w) in deodorant sprays and **0.1%** (w/w) in hairsprays and body lotion sprays. The findings of an *in vitro* study using Mucilair™ also support this conclusion.

Deadline for comments: 3 May 2024.
Ref.: SCCS/1663/24

- **Triphenyl phosphate:**

Based on the currently available information, it is **not possible** for the SCCS **to conclude on the safety** of Triphenyl phosphate because the genotoxicity potential cannot be excluded.

Deadline for comments: 2 June 2024.
Ref.: SCCS/1664/24



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SCCS Preliminary Opinions open for comments

- **Citral:**

The SCCS is of the opinion that Citral can be considered **safe** in relation to the induction of sensitisation at the concentrations proposed for use in cosmetic products.

Whilst the proposed **QRA2** methodology is an improvement to QRA1 methodology, the SCCS recommendation is specific for the sensitisation potential of Citral at the proposed use concentrations. **More case studies are needed** to further confirm the applicability of this approach to other fragrances and other cosmetic ingredients. Until then, the SCCS will consider the suitability (for a population not already sensitised) of this methodology for other fragrances and other cosmetic ingredients on a case-by-case basis.

Deadline for comments: 2 June 2024.
Ref.: SCCS/1666/24

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SCCS Opinions being finalized

- **Titanium dioxide (TiO2):**

(1) In light of the EFSA Opinion on genotoxicity concerns for E171, does the SCCS consider Titanium dioxide safe in oral cosmetic products?

Having considered all the information (including that evaluated by EFSA, 2021), the SCCS considers that the available **evidence is not sufficient to exclude the genotoxicity potential of almost all of the types of TiO2 grades used in oral cosmetic products**. The only exception are two nano grades (RM09 and RM11) for which the provided genotoxicity data indicate no genotoxicity concern. More information is, however, needed on the potential uptake and cellular effects of the nano grades in the oral mucosa to consider them safe for use in oral-care products.

(2) In light of the EFSA Opinion, does the SCCS consider that previous Opinions issued by the SCCS on inhalation and dermal exposure to Titanium dioxide need to be revised?

The **conclusions** drawn in previous SCCS Opinions **remain unchanged** for the TiO2 grades and the coatings evaluated in those Opinions.

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SCCS Opinions being finalized

(3) In the event that the estimated exposure to Titanium dioxide from cosmetic products is found to be of concern, SCCS is asked to recommend safe concentration limits for each category of products and types of use.

Since the genotoxicity hazard of almost all of the grades of titanium dioxide could not be excluded (with the exception of RM09 and RM11), the **SCCS cannot recommend any safe limits** for the materials when used in cosmetic products that could lead to oral or inhalation exposure, other than those already indicated in the previous SCCS Opinions (SCCS/1516/13, SCCS/1580/16 and SCCS/1617/20).

(**4) In light of the potential removal of the E 171 purity specification from the food additives Regulation, the SCCS is requested to review and indicate the respective specifications for Titanium dioxide when used in cosmetics.**

In view of the concerns on the potential genotoxicity of the TiO2 grades considered in this Scientific Advice, the SCCS is of the opinion that the **Applicants should draw up a proposal for specifications of the different TiO2 grades** used in those cosmetic products that could lead to oral and inhalation exposure. The SCCS will be able to assist the Commission in reviewing the proposal.

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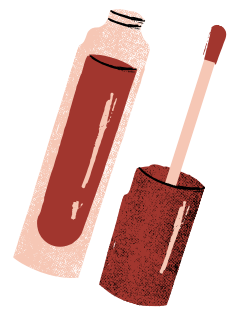
(5) Does the SCCS have any further scientific concerns regarding the use of Titanium dioxide in cosmetic products?

Studies have indicated that oral mucosal cells are prone to the uptake of nanoparticles (including TiO2 nanoparticles), as they may penetrate the mucous layer and may be internalised by the epithelial cells. Considering that some oral products containing TiO2 nanoparticles, such as toothpastes and mouthwashes, will be used every day and potentially more than once a day, **further investigations are needed to exclude the risk to the consumer from long-term repeated exposures of the oral mucosa to TiO2 nanoparticles.**

The SCCS also recommends that safety assessment of the pigmentary TiO2 grades used in cosmetics should take account of the fact that some of them contain a sizeable proportion of the particles in the nano size scale – some over 50% (in terms of particle number, median constituent particle size).

Ref.: SCCS/1661/23

SCCS Final Opinions



- **Hexyl Salicylate:**

Based on the assessment of data provided and taking into consideration the concerns related to potential endocrine disrupting properties, the SCCS considers Hexyl Salicylate **safe when used up to the maximum concentrations as provided in Table 1 of Opinion SCCS/1658/23.**

Ref.: SCCS/1658/23

- **Hydroxypropyl p-phenylenediamine and its dihydrochloride salt (A165):**

In light of the data provided, the SCCS considers that hydroxypropyl p-phenylenediamine and its dihydrochloride salt are **safe when used in oxidative hair colouring products up to a maximum on-head concentration of 2%.**

Ref.: SCCS/1659/23

- **Silver Zinc Zeolite:**

The SCCS considers that Silver Zinc Zeolite (CAS No. 130328-20-0) incorporating a maximum silver content of 2.5% is **safe in spray deodorant and powder foundation when used at the proposed concentration of 1%.**

Ref.: SCCS/1650/23

- **Methylparaben:**

On the basis of the safety assessment considering all available data and the concerns related to endocrine activity, the SCCS is of the opinion that the use of Methylparaben as a preservative in cosmetic products at **concentrations of up to 0.4% (expressed as acid) is safe**.

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SCCS Final Opinions

It is also **safe when used up to 0.4% in a mixture of esters** for which the **total concentration of all esters does not exceed 0.8% (as acid)**, as indicated in entry 12 of Annex V to the Cosmetics Regulation.

Ref.: SCCS/1652/23

- **Benzophenone-4:**

The SCCS is of the opinion that benzophenone-4 is **safe when used as UV filter up to a maximum concentration of 5%** in sunscreen, face and hand cream, all leave-on and rinse-off products (total dermal aggregate), lipstick, sunscreen propellant spray and pump spray, when used separately or in combination (based on deterministic aggregated exposure).
Any additional use of benzophenone-4, such as protectant for stabilising cosmetic formulations when exposed to light, should remain within the concentration mentioned above (i.e. 5%), including the use as UV-filter.

Ref.: SCCS/1660/23

- **Aluminium compounds in cosmetic products:**

The SCCS considers that aluminium compounds are **safe when used**:
- in **non-sprayable product categories at the maximum levels indicated in Tables 1 and 2** of Opinion SCCS/1662/23.
- in **sprayable products, at the maximum levels for the total formulation** (i.e. including propellant) indicated **in Table 1**, provided that the percentage of particles/droplets with a diameter of less than 10 µm does not exceed 20% of the total aerosolised particles/droplets.

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Since the Applicant's data submission indicated that aluminium is not used in sunscreen aerosol sprays, this Opinion does not cover sunscreen aerosol sprays.
- the SCCS considers that aluminium in talc is not bioavailable. Therefore, **talc with aluminium-content of up to 2% may be used in cosmetic products**.

Ref.: SCCS/1662/23

SCCS Mandates - Request for a scientific Opinion on

- **HC Red 18 (B124 or FPK 245):** deadline 7 months.
- **HC Yellow 16 (B123):** deadline 7 months.
- **Children's exposure to Butylparaben from cosmetic products:** deadline 8 months.
- **Biphenyl-2-ol and Sodium 2-biphenylolate:** deadline 6 months.
- **Ethylhexyl Methoxycinnamate (EHMC):** deadline 9 months.
- **Ethyl Tafluprostamide' (DDDE), Methylamido-Dihydro-Noralfaprostal (MDN) and Isopropyl Cloprostenate (IPCP):** deadline 12 months.
- **Children's exposure to Salicylic Acid from cosmetic products:** deadline 8 months.

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US

FDA Announces the Availability of Additional Submission Tools for Cosmetic Product Facility Registration and Cosmetic Product Listing:

On January 8th 2024 the U.S. Food and Drug Administration (FDA) announced the availability of **SPL Xforms**, a Structured Product Labeling (SPL) authoring tool for cosmetic product facility registration and cosmetic product listing mandated by the Modernization of Cosmetics Regulation Act of 2022 (MoCRA).
The FDA also announced the availability of **Form FDA 5066 and Form FDA 5067** as an additional submission tool for providing cosmetic product facility registration and cosmetic product listing information to FDA. These paper forms are available at Registration & Listing of Cosmetic Product Facilities and Products.

The California Safe Cosmetic Program (CSCP) has updated the reporting guidance for fragrance allergens added in the **December 2023 Reportable Ingredients List update** on March 29th, 2024.

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News on Chemicals

New update to Candidate List of Substances of Very High Concern (SVHCs)

On 23rd January 2024, the ECHA (European Chemicals Agency) released the new Candidate List of SVHCs. With the addition of five new substances, the current list of SVHCs now contains 240 substances.

Dibutyl phthalate entry update on the SVHCs list of REACH

On 23rd January 2024, the ECHA (European Chemicals Agency) updated the existing Candidate List of SVHCs for dibutyl phthalate entry. Its endocrine disrupting properties for the environment are included.

Exemption for cadmium and lead in plastic profiles

On the 10th January 2024, the European Commission published Commission Delegated Directive (EU) 2024/232 which amends Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium and lead in plastic profiles in electrical and electronic windows and doors containing recovered rigid polyvinyl chloride.

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Mercury deal to completely phase out in the EU

On the 21st February 2021, the Council and European Parliament reached a provisional political agreement on the Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury as regards dental amalgam and other mercury-added products subject to manufacturing, import and export restrictions.

Nickel standards update under REACH

On 20th December 2023, the European Commission published a Commission communications related to entry 27 (nickel) of Annex XVII to REACH which lists the titles and references of European standards under this entry.

Publication of REF-10 project report on consumer products

On 13 December 2023, the European Chemical Agency (ECHA) published the REF-10 project report on the integrated chemical compliance of products.

European Council and Parliament strike deal on CLP Regulation

On 22 December 2023, The Council and the European Parliament reached a provisional agreement which proposes a regulation about chemical substances, to better protect of human health and the environment.

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The European Commission welcomes provisional agreement for more sustainable, repairable and circular products.

The Commission welcomes the provisional agreement reached on December 4th, 2023 between the European Parliament and the Council on the **Ecodesign for Sustainable Products Regulation.** It will help make **sustainable products the new norm in the EU**, by making them last longer, use energy and resources more efficiently, easier to repair and recycle, contain fewer substances of concern and include more recycled content.

The new Ecodesign requirements will go beyond energy efficiency and aim to boost circularity, covering, among others:

- product **durability, reusability, upgradability, and repairability**
- presence of **chemical substances** that inhibit reuse and recycling of materials
- **energy and resource efficiency**
- **recycled content**
- **carbon and environmental footprints**
- available product information, by implementing a **Digital Product Passport (DPP).**

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EFSA NEWS

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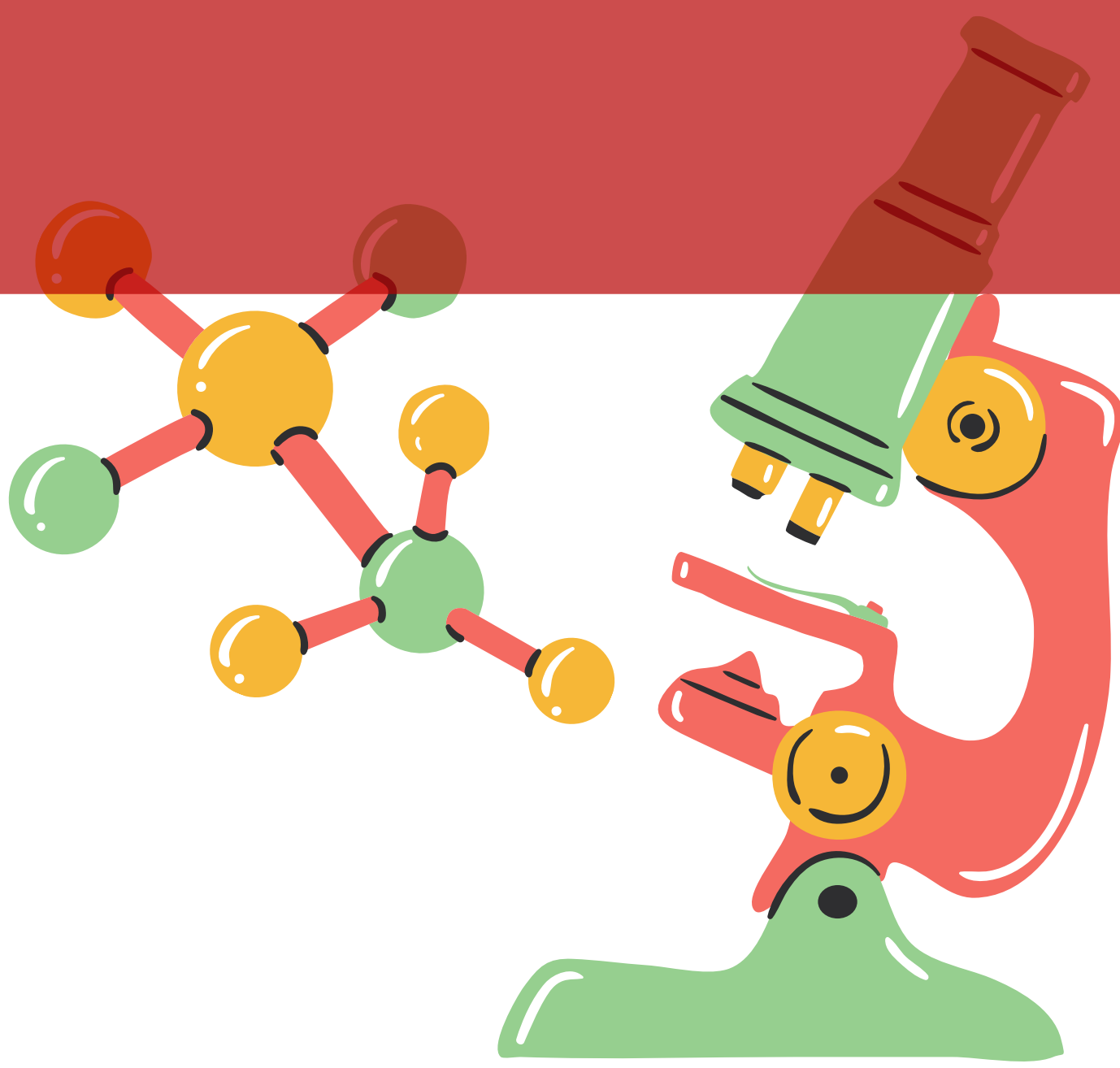

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EFSA Scientific Opinion Updates

- **Scientific opinion on the tolerable upper intake level for manganese** (https://doi.org/10.2903/j.efsa.2023.8413)

- **Safety evaluation of synthesized DNA oligonucleotides as a food additive** (https://doi.org/10.2903/j.efsa.2023.8452)

- **Re-evaluation of erythritol (E 968) as a food additive** (https://doi.org/10.2903/j.efsa.2023.8430)

- **Safety of HelixComplex snail mucus (HSM) as a novel food pursuant to Regulation (EU) 2015/2283** (https://doi.org/10.2903/j.efsa.2024.8492)

- **Scientific and technical assistance to the evaluation of the safety of calcidiol monohydrate as a novel food** (https://doi.org/10.2903/j.efsa.2024.8520)

- **Chemical monitoring reporting guidance: 2024 data collection** (https://doi.org/10.2903/sp.efsa.2024.EN-8596)

- **Follow-up of the re-evaluation of quillaia extract (E 999) as a food additive and safety of the proposed extension of uses** (https://doi.org/10.2903/j.efsa.2024.8563)

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