



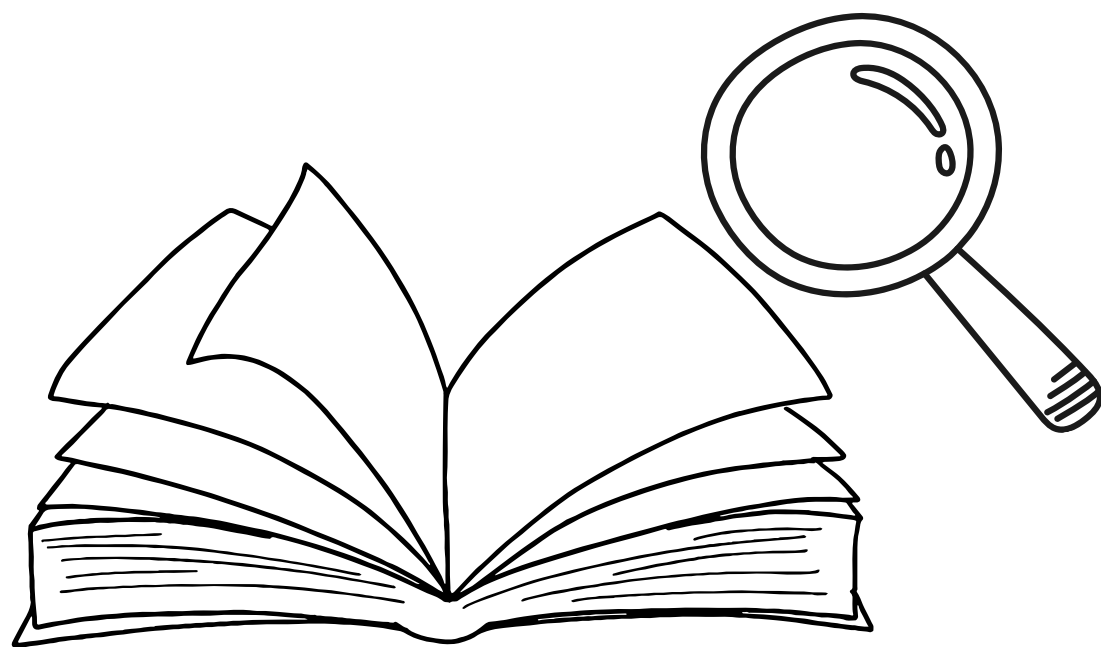
# REGULATORY COSMETICS



# NEWS



MAY 24 - SEP 24



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# May 2024 -September 2024



## SCCS Preliminary Opinions open for comments

- **HC Yellow No. 16:**

In the light of the data provided, SCCS considers that the use of HC Yellow No. 16 (B123) as an ingredient at **1%** in oxidative hair dye formulations and at **1.5%** in non-oxidative hair dye formulations is safe, considering the specifications of the new commercial batches as described in the submission II file.

Deadline for comments: 27 September 2024.

Ref.: SCCS/1670/24

- **Biphenyl-2-ol and Sodium 2-biphenylolate:**

In light of the data provided, the SCCS considers o-Phenylphenol safe when used as preservative up to a maximum concentration of **0.2%** in rinse-off and **0.15%** in leave-on cosmetic products.

O-Phenylphenol and Sodium o-Phenylphenate, when used together, should not exceed the maximum concentration **0.15%** in leave-on cosmetic products.

O-Phenylphenol and Sodium o-Phenylphenate, when used together, should not exceed the maximum concentration **0.2%** in rinse-off cosmetic products.

Deadline for comments: 27 September 2024.

Ref.: SCCS/1669/24

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## SCCS Preliminary Opinions open for comments

- **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 for children < 3 years old when used up to the maximum concentrations of **0.1%** for shower gel, hand soap, shampoo, hair conditioner, body lotion, face cream, hand cream, lipstick/lip balm, fragrance products and **0.001%** for toothpaste.

Salicylic Acid may be present in the products as an impurity or resulting from the breakdown of hexyl salicylate. Salicylic Acid is classified as a skin sensitiser Category 1 and it is not permitted in cosmetic products used by children under the age of 3 years.

The amount of toothpaste ingested by children below 3 years old considered in this opinion for the calculation of the Margin of Safety (MoS) has been adapted based on available data and now is much higher than the one used in previous opinions on Salicylates in cosmetic products used by children (eg. Methyl salicylates, SCCS/1654/23). This may raise concerns about their safety, in particular where the MoS is close to 100.

Deadline for comments: 23 September 2024.

Ref.: SCCS/1668/24

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## SCCS Opinions being finalized

- **New coating for titanium dioxide (nano form):**

**(1) In light of the data provided, does the SCCS consider safe the use of Titanium Dioxide (nano) coated with a combination of w/w 6% Aluminium Hydroxide, 14% Sodium Myristoyl Sarcosinate and 10% Dimethicone, for use as UV filter in dermally applied cosmetic products?**

Considering all the provided information, the SCCS is of the view that there are a number of uncertainties and data gaps that do not allow a conclusion on the safety of titanium dioxide (nano) coated with a combination of w/w 6% aluminium hydroxide, 14% sodium myristoyl sarcosinate and 10% dimethicone (Eclipse 70) - either on the basis of a similarity to the TiO<sub>2</sub> nanomaterials previously assessed by the SCCS, or on the basis of the additional information provided in the current submission.

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## SCCS Opinions being finalized

**(2) Does the SCCS have any further scientific concerns regarding the use of Titanium Dioxide (nano) coated with the above-mentioned materials when used as UV-filter in dermally applied cosmetic products?**

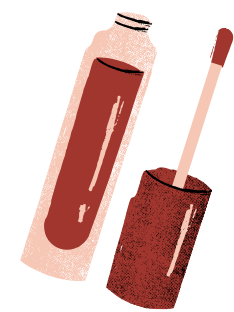
The provided information has not demonstrated a similarity of the titanium dioxide with the above-mentioned composite coating (Eclipse 70) to other TiO<sub>2</sub> nanomaterials assessed in the previous SCCS Opinion (SCCS/1516/13 - Revision of 22 April 2014) in terms of physicochemical characteristics, stability of the coating, and the lack of dermal absorption of the nanoparticles. If these aspects cannot be addressed, additional data on physicochemical, toxicological and exposure aspects specifically relating to the nanomaterial under evaluation (Eclipse 70) will be needed to conclude on the safety of its use in cosmetic products.

Ref.: SCCS/1667/24

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## SCCS Final Opinions



- **Silver:**

In light of the data provided and taking under consideration the classification as toxic for reproduction Cat. 2, the SCCS considers micron-sized particulate Silver **not safe at concentrations up to 0.2 % in rinse-off and 0.3 % in leave-on cosmetic products** when used alone or in combination.

However, the use of micron-sized particulate Silver in eye shadow and oral exposure products (lip balm, toothpaste and mouthwash) at concentrations mentioned in Section 3.5 is considered safe, either used alone or in combination.

Ref.: SCCS/1665/24

- **Citral:**

The SCCS has noted that the QRA2 methodology has indicated that Citral can be considered **safe in relation to the induction of sensitisation at the concentrations proposed for use in cosmetic products**. However, the SCCS has identified some aspects of the QRA2 methodology that still need clarification and therefore, some refinement is needed before a firm conclusion on the safety of Citral could be drawn.

Whereas the SCCS considers that the proposed **QRA2 methodology** is an improvement to QRA1 methodology, **more case studies are needed** to further confirm the applicability of this approach to fragrances and other cosmetic ingredients. Until then, the SCCS will consider the suitability (for a population not already sensitised) of this methodology for fragrances and other cosmetic ingredients on a case-by-case basis.

Ref.: SCCS/1666/24

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## SCCS Final Opinions

- **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.

Ref.: SCCS/1664/24

## SCCS Mandates - Request for a scientific Opinion on

- **Hexyl Salicylate:** deadline 9 months.

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## **FDA Proposes Increase in Color Certification Fees:**

The U.S. Food and Drug Administration (FDA) is **extending the comment period** on May 28, 2024, for the proposed rule entitled Color Additive Certification; Increase in Fees for Certification Services that appeared in the Federal Register on November 2, 2022. On April 26, 2024, the FDA reopened the comment period for 30 days to provide for comment on supporting information added to the administrative record. The FDA received a request for a 90-day extension of the comment period. The agency is extending the comment period by 30 days, until June 27, 2024. The FDA believes that a 30-day extension is reasonable and allows adequate time for interested parties to review the supporting information added to the administrative record and to develop and submit additional comments to the proposed rule.

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## **Deadline for Registration and Listing of Cosmetic Product Facilities and Products: What Does the Deadline Mean to You, and How is FDA Helping You Comply?:**

On June 13th, 2024 the FDA reminds industry of the resources available to help firms comply with the new registration and listing requirements established by the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) by July 1, 2024, consistent with FDA's Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing.

FDA established a dedicated **Registration & Listing of Cosmetic Product Facilities and Products Web page** that consolidates links to all resources.



## **FDA Announces Registration and Listing Updates: The Release of New Discontinuation/Relisting Features in Cosmetics Direct:**

On July 29th, 2024 the FDA announced the availability of two new features in Cosmetics Direct, the electronic submission portal for the new registration and listing of cosmetic product facilities and products requirements established by the Modernization of Cosmetics Regulation Act of 2022 (MoCRA).

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