



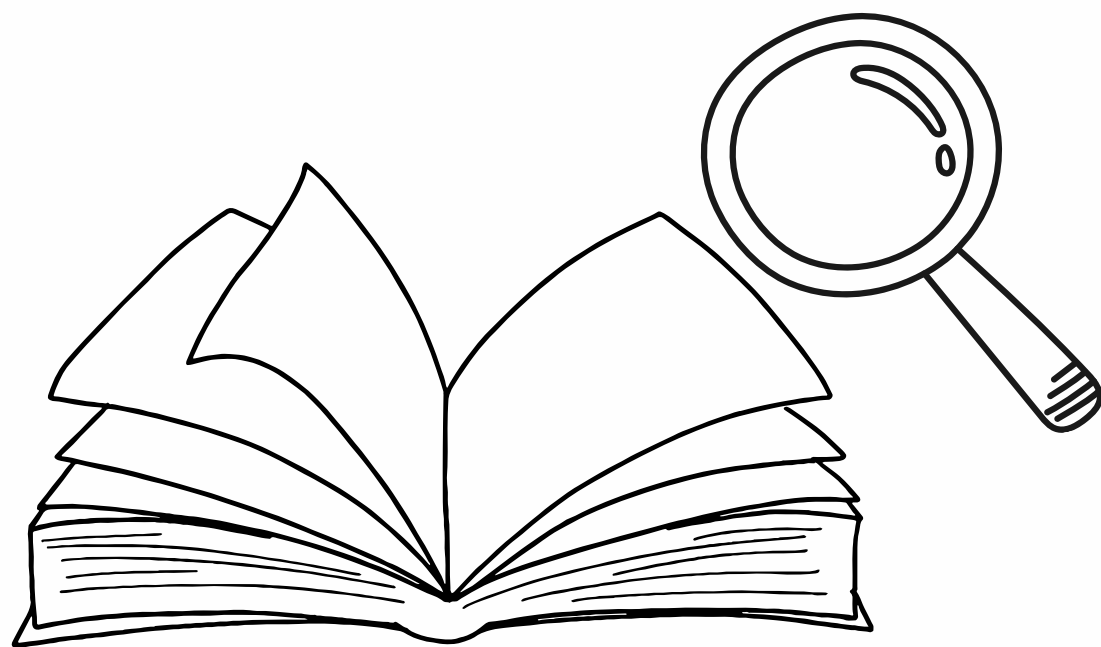
REGULATORY



NEWS



OCT/NOV 2023



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October/November 2023



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 when used up to the maximum concentrations as provided in Table 1 of Opinion SCCS/1658/23.**

Deadline for comments: 12 January 2024.

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%.** A mild to moderate eye irritation potential of the test item cannot be excluded. Hydroxypropyl p-phenylenediamine and its dihydrochloride salt is a moderate skin sensitiser based on animal data.

Deadline for comments: 8 January 2024.

Ref.: SCCS/1659/23



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SCCS Final Opinions

- **Benzyl salicylate:** based on the assessment of data provided and taking under consideration the concerns related to potential endocrine disrupting properties, the SCCS considers Benzyl Salicylate **safe when used up to the maximum concentrations as provided in Table 1 of Opinion SCCS/1656/23.**

Ref.: SCCS/1656/23

- **Fullerenes, Hydroxylated Fullerenes and hydrated forms of Hydroxylated Fullerenes (nano):** the SCCS **cannot conclude on the safety** of fullerenes and (hydrated) hydroxylated forms of fullerenes due to a number of uncertainties and data gaps in regard to physicochemical, toxicokinetic and toxicological aspects.

Ref.: SCCS/1649/23

- **Butylparaben:** the SCCS is of the opinion that the use of Butylparaben **as a preservative in cosmetic products at concentrations of up to 0.14% (expressed as acid) is safe.** In the absence of exposure data specific for children to Butylparaben in cosmetic products, potential safety concerns cannot be excluded.

Ref.: SCCS/1651/23

- **Water-soluble zinc salts:** The SCCS has calculated aggregate exposure to water-soluble zinc salts via toothpaste at the concentrations of 1% and from diet, and concluded that the use of **zinc in toothpaste is safe per se except for children under the age of 1 year** because the intake exceeds the upper limit level.

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For **children between 6 months and 1 year of age**, the SCCS recommends a **safe concentration of 0.72% for soluble zinc salts (as zinc) in toothpaste**. The inclusion of **zinc in mouthwash at 0.1% Zn is considered safe across all age groups above 6 years**.

Ref.: SCCS/1657/23

SCCS Mandates - Request for a scientific Opinion on

- **Silver**: deadline 6 months.
- **New coating for Titanium Dioxide (nano form) (Sodium Myristoyl Sarcosinate)**: deadline 9 months.
- **Hydroxyapatite (nano)**: deadline 9 months.

Microplastics restriction: The REACH restriction on intentionally added microplastics in products enters into force on 17 October 2023. This will **impact also cosmetic industries**. Some polymers are excluded from this designation.



Completion of the consultation stage on PFAS restriction proposal: On the 25th September 2023, consultation about the proposal to restrict per- and polyfluoroalkyl substances (PFAS) was closed with more than 5.600 comments from more than 4.400 organisations, companies and individuals. **The Commission, together with the EU Member States, will decide on the restriction.**

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MoCRA updates: FDA announced **Delayed Enforcement** and Publishes **Updated Structured Product Labeling (SPL) Implementation Guide** with Validation Procedures for Cosmetic Product Facility Registrations and Product Listings.



EPA Finalizes PFAS Data Reporting Rule: Under the final rule, **any person that manufactures or imports or has manufactured or imported PFAS or PFAS-containing articles in any year since January 1, 2011 will be required to electronically report information to the EPA.** The final rule will be effective on November 13, 2023. Under the final rule, companies will have one year to collect the information required to be reported, followed by a six-month period during which reports must be submitted to the EPA.



OEHHA Proposes Amendment to Proposition 65 Short-Form Warning Requirements: On October 27, 2023, the OEHHA issued a Notice of Proposed Rulemaking (NPR) to **amend Prop 65 Article 6, Clear and Reasonable Warnings with notable changes.** The deadline for public comments is December 20, 2023.

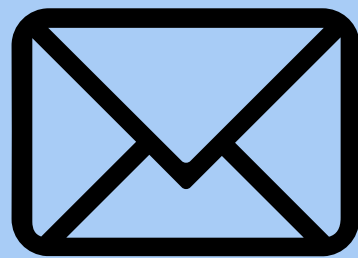


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