Communications Wave 2

Diatomaceous Earth

Hydroxyacetophenone

Phenyl-Substituted Methicones

RRSums

Trisodium Ethylenediamine Disuccinate

EXPERT PANEL MEETING
September 26-27, 2022

Personal Care Products Council
Committed to Safety, Quality & Innovation

Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review

FROM: Alexandra Kowcz, MS, MBA
Industry Liaison to the CIR Expert Panel

DATE: September 15, 2022

SUBJECT: Draft Final Report: Safety Assessment of Diatomaceous Earth as Used in Cosmetics (September 26-27, 2022 meeting draft)

The Personal Care Products Council respectfully submits the following comments on the draft final report, Safety Assessment of Diatomaceous Earth as Used in Cosmetics.

Key Issue
Discussion – Are there any data to support the following statement? "Although heavy metals may be present during mining, those should be readily avoidable/separable." Language similar to the heavy metal boilerplate for non-botanicals should be used in this report. It would be helpful if the heavy metal recommendations were for finished cosmetic products rather than ingredients. International Cooperation on Cosmetic Regulation (ICCR) recommendations for mercury and lead in finished cosmetic products should be considered.

Additional Considerations
Introduction – Please correct: "the report on these ingredients are available" ("are" should be "is")

Method of Manufacture – Please correct: "further process by heating" ("process" should be "processed")

Non-Cosmetic Use – Please correct: "insultation bricks" (should be "insulation bricks")

Short-Term, Subchronic, and Chronic; Summary – Please correct "a light increase in intra-alveolar macrophage" (it would make more sense if "light" was "slight")

Summary – Please correct "abdominal activity" (should be "abdominal cavity"); "100 healthy subjected" ("subjected" should be "subjects")

Discussion – As one of the main components of Diatomaceous Earth is silica, the word "residual" should be deleted from the following: "lack of residual silica absorption".

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Executive Director - Cosmetic Ingredient Review

FROM: Alexandra Kowcz, MS, MBA
Industry Liaison to the CIR Expert Panel

DATE: September 15, 2022

SUBJECT: Draft Final Report: Safety Assessment of Hydroxyacetophenone as Used in Cosmetics (September 26-27, 2022 meeting draft)

The Personal Care Products Council respectfully submits the following comments on the draft final report, Safety Assessment of Hydroxyacetophenone as Used in Cosmetics.

Dermal Irritation and Sensitization – Please add "Hydroxyacetophenone" after "75%" in the following sentence: "Animals were challenged with a topical application of 0.5 g of 75% in petrolatum for 24h; the test article was not sensitizing."

Summary – Please revise the following sentence as the use of "In spite of.." suggests that the results of the study were not interpreted correctly. Minor reactions in an HRIPT during induction do not indicate sensitization potential. "In spite of 1 subject presenting with 2, grade 0.5 reactions during induction, 5% Hydroxyacetophenone, in glycerin, was deemed a non-sensitizer in 104 subjects."

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Executive Director - Cosmetic Ingredient Review

FROM: Alexandra Kowcz, MS, MBA
Industry Liaison to the CIR Expert Panel

DATE: September 15, 2022

SUBJECT: Draft Report: Safety Assessment of Phenyl-Substituted Methicones as Used in Cosmetics (September 26-27, 2022 meeting draft)

The Personal Care Products Council respectfully submits the following comments on the draft report, Safety Assessment of Phenyl-Substituted Methicones as Used in Cosmetics.

Key Issue
If the safety data on Diphenylsiloxy Phenyl Trimethicone from the Australia NICNAS assessment is acceptable for the CIR report, it is not clear why the physical chemical properties information on the same notified material is not acceptable for the CIR report. The NICNAS assessment is about a cosmetic ingredient described as a clear liquid with a molecular weight <1,000 g/mol and a purity of ≥75%. Most importantly, the water solubility is listed as <0.00052 g/L at 20°C. All this information should be added to the CIR report.

Additional Considerations
Non-Cosmetic Use – If the only information on use as an indirect food additive is the CFR, it should state that the ingredients are permitted for use rather than saying "are used as adhesives".

ADME – If the study (reference 12) only looked for silicon, please revise the following sentence: "Tissue, feces, and urine were examined for test article presence." – as it is not known if it was the test article or silicon, or a silicon-containing metabolite of the test article that was present.

Acute – In the paragraph on inhalation exposure, it says: "At higher volumes of dispensation…." The paragraph only talks about concentrations. Were different size chambers used? Or should "volumes" be "concentrations"?

Subchronic, old report summary – Please revise: "per 8.4% body surface area of the test article" ("of the test article should be moved before "per 8.4% body surface".

DART, Diphenylsiloxy Phenyl Trimethicone – Please correct: "mean ration" to "mean ratio"

Genotoxicity – As only one cell line (V79 cells) was used, please delete the "s" from cell lines (occurs twice in this paragraph).

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FROM: Alexandra Kowcz, MS, MBA
Industry Liaison to the CIR Expert Panel

DATE: September 15, 2022

SUBJECT: Re-Review Summaries (September 2022 meeting draft)

The Personal Care Products Council respectfully submits the following comments on the re-review summaries prepared for the September 2022 CIR meeting.

General Comments

When new information on ingredients being re-reviewed has been identified, it would be helpful if a few details of the information found e.g., type of studies found, was included in the re-review summary. Specific examples are provided below.

N,N-Bis(2-Hydroxyethyl)-p-Phenylenediamine
In the re-review summary, it would be helpful to mention the 2006 SCCS opinion on N,N-Bis(2-Hydroxyethyl)-p-Phenylenediamine and note that most of the new data were summarized in this opinion.

PEG-11 and PEG-15 Stearyl Ethers
Rather than just saying new data were found, it would be helpful to be more specific and say that a single study concerning dermal penetration enhancement potential of PEG-15 Stearyl Ether was found.

Amyl and Isoamyl Acetates
Rather than just listing the RIFM reviews of Amyl Acetate and Isoamyl Acetate in the reference section, these references should be mentioned in the re-review summary.

Additional Comments

Polyacrylamide
It is not correct to state that acrylamide is "a possible carcinogen in animal tests." Acrylamide is a carcinogen in animal tests. Perhaps the 1994 IARC monograph on acrylamide should be added as a reference. IARC concluded that there is sufficient evidence of carcinogenicity in animals and that acrylamide is probably carcinogenic to humans (Group 2A).

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DATE: September 15, 2022

SUBJECT: Draft Report: Safety Assessment of Trisodium Ethylenediamine Disuccinate and Tetrasodium Iminodisuccinate as Used in Cosmetics (September 26-27, 2022 meeting draft)

The Personal Care Products Council respectfully submits the following comments on the draft report, Safety Assessment of Trisodium Ethylenediamine Disuccinate and Tetrasodium Iminodisuccinate as Used in Cosmetics.

Method of Manufacture – Wikipedia has an article on Tetrasodium Iminodisuccinate that includes a method of manufacture. Although Wikipedia is not an appropriate reference for CIR reports, the method of manufacture is cited to a patent (US 6107518, Torsten Groth, Winfried Joentgen, Paul Wagner, Frank Dobert, Eckhard Wenderoth, Thomas Roick, "Preparation and use of iminodisuccinic acid salts", issued 2000-08-22, assigned to Bayer AG), and a product information sheet (https://aniq.org.mx/pqta/pdf/BAYPURE%20DS%2010040%20(HT).pdf) that can be cited in a CIR report.

Developmental and Reproductive Toxicity – In the text, for the first study, please state that both males and females were treated, and the duration of treatment.

Summary – Please revise the following sentences: "In an oral toxicokinetic assay, [^{14}C] labeled Trisodium Ethylenediamine Disuccinate performed in Crl:(WI)BR rats.…" "However, in a different 14-d oral toxicity assay performed in Wistar rats given up to Trisodium Ethylenediamine Disuccinate,…" (what was the maximum dose?)

Summary – Since only radioactivity was measured in the toxicokinetic studies, please revise "test substance was detected" to "radioactivity was detected" (unless they confirmed that the radioactivity was still associated with the test substance when it was found in the analyzed tissues).