Wave2 Communications

Barley
Basic Yellow 57
Diatomaceous Earth
Equisetum arvense
Glyceryl Acrylates
Glycolactones
Levulinic Acid
Melaleuca alternifolia
Methicones
Polyquaternium-6
Red Algae
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Saccharide Isomerate et al.
Saccharum officinarum
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Ubiquinone
Yeast

EXPERT PANEL MEETING
September 13-14, 2021

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 8, 2021

SUBJECT: Draft Tentative Report: Safety Assessment of Barley-Derived Ingredients as Used in Cosmetics (draft prepared for the September 2021 CIR meeting)

The Personal Care Products Council respectfully submits the following comments on the draft tentative report, Safety Assessment of Barley-Derived Ingredients as Used in Cosmetics.

Key Issue

Introduction – Rather than stating: "potential toxicity from exposures to mixtures of different chemical compounds may not replicate the biological activity of the individual components", it should state that "toxicity from single components may not predict the potential toxicity of mixtures." This would provide justification as to why studies on individual components are not included in the CIR report. The way the statement is currently written links "toxicity" with "biological activity". If the statement is left in the report, "biological activity" should be changed to "toxicity".

Additional Considerations

Introduction; Toxicological Studies; Summary - It is not clear why malt ingredients are mentioned as ingredients in the Dictionary with the word "malt", e.g., Malt Extract, are not included in this report.

Introduction – It is not clear what is meant by "small portion". Please delete the word "small".

Introduction – There is no information in this report on the concentration of gluten in cosmetics. It would be better to indicate that the concentrations of the barley ingredients are low. Some information on the amount of gluten in barley should then be added to the CIR report.

Introduction – Please correct "will be used will be used"

Table 4 – Please add a footnote to this table to describe what is meant by the check mark.

Table 7, References 71 and 72 – Although these studies did not specifically say “undiluted”, they do describe the study or test material and state that the study or test material was applied. Therefore, it is misleading to state “dilution status not reported”.

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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 8, 2021

SUBJECT: Draft Report: Safety Assessment of Basic Yellow 57 as Used in Cosmetics (draft prepared for the September 2021 CIR meeting)

The Personal Care Products Council respectfully submits the following comments on the draft report, Safety Assessment of Basic Yellow 57 as Used in Cosmetics.

Key Issue

Composition/Impurities – The SCCS opinion included the analysis of 3 batches of Basic Yellow 57 that were used in the toxicity studies. It is not clear why only the analytical results for 2 batches are presented. The CIR report should also indicate that 2 of the batches analyzed were standardized with respect to color strength by the addition of sodium chloride or saccharose. The other batch was not standardized.

Additional Considerations

Dermal Penetration, Animal – "The potential for a hair setting formula containing 0.1% Basic Yellow 57 (purity not reported) to penetrate through the skin…." should be revised to clearly indicate that the dermal penetration of Basic Yellow 57 (not the formula) was studied.

Genotoxicity – Please indicate the system used for the *in vitro* micronucleus test.

Ocular Irritation, Animal – Please add the units after "0.1" in the second sentence.

Margin of Safety; Summary – Please note that the "product" was a hair dye.

Hair Dye Epidemiology – Please correct "Basic Brown 17" to "Basic Yellow 57"

Summary – Please make it clear that dermal penetration of Basic Yellow 57 was studied, not the penetration of the aqueous test material or the standard formulation. Units of mg/kg bw should be called dose rather than “concentrations”. Please correct: “in rabbit studies Basic Yellow 57” (please add “of”)..

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

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

DATE: September 8, 2021

SUBJECT: Draft Report: Safety Assessment of Diatomaceous Earth as Used in Cosmetics (draft prepared for the September 2021 CIR meeting)

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

Repeated Dose – Stating that "….Diatomaceous Earth did not exhibit adverse effects outside of increased body weight gains in one study" suggests that the increased body weight was an adverse effect. Please delete the word "adverse".

Genotoxicity; Summary – Please revise the following phrase as it suggests increased cell division was noted in the Diatomaceous Earth. "In studies with Syrian hamster embryo (SHE) cells, high temperature calcined and flux-calcined Diatomaceous Earth had increased cell division aberrations and cell transformations in a concentration dependent-manner;". The following would be clearer: "In studies with Syrian hamster embryo (SHE) cells treated with high temperature calcined and flux-calcined Diatomaceous Earth, concentration dependent increases in cell division aberrations and cell transformations were observed."

Dermal Irritation and Sensitization – It would be helpful to include a few more details in the text concerning the human studies such as the number of subjects in each test and information about the light exposure for the phototoxicity study.

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

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

DATE: September 8, 2021

SUBJECT: Draft Tentative Report: Safety Assessment of *Equisetum arvense*-Derived Ingredients as Used in Cosmetics (draft prepared for the September 2021 CIR meeting)

The Personal Care Products Council respectfully submits the following comments on the draft tentative report, Safety Assessment of *Equisetum arvense*-Derived Ingredients as Used in Cosmetics.

Key Issue

Introduction – Rather than stating: "potential toxicity from exposures to mixtures of different chemical compounds may not replicate the biological activity of the individual components", it should state that "toxicity from single components may not predict the potential toxicity of mixtures." This would provide justification as to why studies on individual components are not included in the CIR report. The way the statement is currently written links "toxicity" with "biological activity". If the statement is left in the report, "biological activity" should be changed to "toxicity".

Additional Considerations

Genotoxicity, In Vitro, Equisetum Arvense Extract – If the study on x-irradiated cells (reference 39) is left in the report, how it was conducted, and the results need to be clarified. Were there cells included in the study that were not also treated with Equisetum Arvense Extract? The results that would be most useful would be in unirradiated cells with and without Equisetum Arvense Extract.

Hepatotoxicity, Equisetum Arvense Extract – What concentration of Equisetum Arvense Extract was used in the study of human hepatocytes *in vitro* (reference 32)?

Summary – The induction concentrations used in the guinea pig maximization tests should also be stated in the Summary.

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

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

DATE: September 8, 2021

SUBJECT: Draft Report: Safety Assessment of Glyceryl Acrylates as Used in Cosmetics (draft prepared for the September 2021 CIR meeting)

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

Key Issue

Glyceryl Polyacrylate should be considered for addition to this report. Glyceryl Polyacrylate was originally included in the CIR glyceryl monoester report (2004) and has a safe as used conclusion. Glyceryl Polyacrylate was not included in the re-review on monoglyceryl monoesters (2020). There are 138 uses of Glyceryl Polyacrylate reported to the 2021 VCRP. If it is not added to the report, the previous review of Glyceryl Polyacrylate should be mentioned in this report.

Additional Considerations

Introduction – Please correct “gent – emollient” to “agent – emollient”

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

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

DATE: September 8, 2021

SUBJECT: Draft Report: Safety Assessment of Glycolactones as Used in Cosmetics (draft prepared for the September 2021 CIR meeting)

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

Memo – It should be made clear that "product" in the in vitro dermal irritation assay was an ingredient mixture containing 70-80% Gluconolactone, not a finished cosmetic product.

Introduction – As the Expert Panel does not evaluate ingredients for function, please revise the following: "the Expert Panel for Cosmetic Ingredient Safety (Panel) will not be evaluating these ingredients for this particular function."

Chronic Toxicity – Please also indicate that the control diet also did not contain Sodium Nitrite (as stated in the Carcinogenicity section).

Effect on Skin Barrier Function and Irritation – Please revise the following sentence: "Control applications of the base cream alone was also applied on each subject."

Summary – In the presentation of the 29-month study, please also mention the control group that was fed meat without Gluconolactone and Sodium Nitrite.

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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 7, 2021

SUBJECT: Draft Final Report: Safety Assessment of Levulinic Acid and Sodium Levulinate as Used in Cosmetics (draft prepared for the September 2021 CIR meeting)

The Personal Care Products Council respectfully submits the following comments on the draft final report, Safety Assessment of Levulinic Acid and Sodium Levulinate as Used in Cosmetics.

Non-Cosmetic Use – It would be helpful to state that the FDA Inactive Ingredient List is for approved drug products.

Sensitization, Human Levulinic Acid – Please identify "the test substance", was it Levulinic Acid or a mixture containing Levulinic Acid?

Summary – When describing the short-term oral study in guinea pigs, please also state the maximum volume tested (5 ml).

Discussion – Usually the outer most layer of the epidermis is called "stratum corneum" rather than "corneum stratum" as stated in the Discussion.

Reference 17 – It is not clear where "Last updated 2016" comes from as there have been more recent adaptations to the EU cosmetic regulations.

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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 7, 2021

SUBJECT: Draft Final Report: Safety Assessment of *Melaleuca alternifolia* (Tea Tree)-Derived Ingredients as Used in Cosmetics (draft prepared for the September 2021 CIR meeting)

The Personal Care Products Council respectfully submits the following comments on the draft final report, Safety Assessment of *Melaleuca alternifolia* (Tea Tree)-Derived Ingredients as Used in Cosmetics.

Key Issue

Introduction – Rather than stating: "potential toxicity from exposures to mixtures of different chemical compounds may not replicate the biological activity of the individual components", it should state that "toxicity from single components may not predict the potential toxicity of mixtures." This would provide justification as to why studies on individual components are not included in the CIR report. The way the statement is currently written links "toxicity" with "biological activity". If the statement is left in the report, "biological activity" should be changed to "toxicity".

Additional Considerations

Composition/Impurities, Melaleuca Alternifolia (Tea Tree) Leaf Extract – Please correct "EU Directive" to "EU Cosmetics Regulation" as the "Directive" no longer exists (occurs twice in this section).

Composition/Impurities, Tea Tree Oil – Please revise: "must less than 20 mmol" (add the word "be")

Cosmetic Use – As there are multiple ingredients in this report, please correct "this ingredient in cosmetics" to "these ingredients in cosmetics".

Acute; Short-Term; Summary – Wherever reference 85 is described, please make it clear that a nano-emulsion containing tea tree oil was studied. The term nano-tea tree oil is misleading. The other components in the emulsion may impact penetration and toxicity.

Immunologic Effects – The study with UVB exposure with tea tree oil should be presented in the phototoxicity section.

Retrospective and Multicenter Studies – Please revise: “reactions in skin care products” to “reactions to skin care products”

Summary – Please correct: “estimated rates pf oral”; Please correct “fragrance makers” to “fragrance markers”

Discussion – Indicating that tea tree oil is not an INCI name suggests the INCI materials Melaleuca Alternifolia (Tea Tree) Leaf Oil and Melaleuca Alternifolia (Tea Tree) Flower/Leaf/Stem Oil are different than tea tree oil. This is not correct; it is just a different name.

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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 7, 2021

SUBJECT: Draft Revised Final Report: Amended Safety Assessment of Dimethicone, Methicone, and Substituted-Methicone Polymers as Used in Cosmetics (draft prepared for the September 2021 CIR meeting)

The Personal Care Products Council respectfully submits the following comments on the draft revised final report, Amended Safety Assessment of Dimethicone, Methicone, and Substituted-Methicone Polymers as Used in Cosmetics.

Introduction – Please revise: "Please note that most of the toxicology studies described in these documents were summaries,…" as "all" of the studies mentioned in the ECHA dossier, and the ECETOC and AICIS assessments are summaries.

Cosmetic Use – Please revise: "via aerosolized airbrush devices" as the airbrush devices produce aerosols, they are not aerosolized.

Ocular Irritation – The description of reference 34 indicates that mice were also included in this study, but no results are given for mice. What happened to the mice?

Summary – In which product categories did the maximum use concentrations increase?

Discussion – As this report is about use in cosmetics, in the paragraph about use in products applied with an airbrush, please change "consumer products" to "cosmetics".

Conclusion – Please revise "with airbrush use" to "with airbrush application"

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

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

DATE: September 7, 2021

SUBJECT: Draft Final Report: Safety Assessment of Polyquaternium-6 as Used in Cosmetics (draft prepared for the September 2021 CIR meeting)

The Personal Care Products Council respectfully submits the following comments on the draft final report, Safety Assessment of Polyquaternium-6 as Used in Cosmetics.

Summary – The Summary should state only once that Polyquaternium-6 is made by polymerizing DADMAC. It should then indicate the MW and monomer levels of the ingredient reported by the two suppliers.

Discussion – As there is only one ingredient in this report, "these ingredients" should be corrected to "this ingredient".

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

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

DATE: September 7, 2021

SUBJECT: Draft Final Report: Safety Assessment of Red Algae-Derived Ingredients as Used in Cosmetics (draft prepared for the September 2021 CIR meeting)

The Personal Care Products Council respectfully submits the following comments on the draft final report, Safety Assessment of Red Algae-Derived Ingredients as Used in Cosmetics.

Algae Identification – Please check the status of Pyrrhophyta, it is likely a phylum rather than a family.

Composition/Impurities, Palmaria Palmata Extract – The report that *Digenea simplex* may produce kainic acid should be stated in the subsection on *Digenea simplex*. A specific literature search on kainic acid and *Digenea simplex* is likely to result in additional papers on this topic that could be added to the CIR report.

Composition/Impurities, Porphyra Umbilicalis Extract – The units for antimony and the substance that follow are not stated. If the units are all ppm, the units should be stated at the start of the list of metals for which the analysis was completed.

Dermal Irritation and Sensitization; Summary – In the paragraph on the human sensitization studies, please indicate which studies are on the ingredients and which are on formulations containing the stated ingredient.

Summary – Please revise: "100% dry extract Asparagopsis Armata Extract" to "undiluted dry Asparagopsis Armata Extract".

Discussion – It should be made clear that the GRAS designation is for food use.

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

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

DATE: September 8, 2021

SUBJECT: Draft Report: Safety Assessment of *Rosa damascena*-Derived Ingredients as Used in Cosmetics (draft prepared for the September 2021 CIR meeting)

The Personal Care Products Council respectfully submits the following comments on the draft report, Safety Assessment of *Rosa damascena*-Derived Ingredients as Used in Cosmetics.

Key Issue

Introduction – Rather than stating: "potential toxicity from exposures to mixtures of different chemical compounds may not replicate the biological activity of the individual components", it should state that "toxicity from single components may not predict the potential toxicity of mixtures." This would provide justification as to why studies on individual components are not included in the CIR report. The way the statement is currently written links "toxicity" with "biological activity". If the statement is left in the report, "biological activity" should be changed to "toxicity".

Additional Considerations

Introduction – It should be made clear that the materials listed as not being cosmetic ingredients is based on the VCRP and not being named in the Dictionary.

Cosmetic Use – The EU cosmetic regulation labeling requirements for the fragrance allergens (Annex III) (benzyl alcohol, eugenol, geraniol, citronellol, limonene, linalool) should be added to the Cosmetic Use section.

Short-term and Subchronic – In the dog study, when it states: "no further changes or adverse effects were observed", it is not clear what endpoints were examined.

Short-term and Subchronic – In the description of the 90-day study in mice it states: "No significant differences were observed in body and weights…", perhaps the word "organ" needs to be added before the word "weights".

In Vitro Cell Transformation – The following does not make sense: “Doses of 0, 1, 2, 3, 4, 5, or 10 µl of a *Rosa damascena* flower oil were induced in triplicate”. Perhaps the word “induced” should be “introduced”?

Hematological and Clinical Effects – As there are no specific hematological or clinical effects caused by these ingredients, it is not clear why the studies need to be in a special section. These studies should be presented in the duration appropriate toxicity sections.

Dermal Irritation and Sensitization; Summary; Table 7 – The Episkin assay of the mixture of the flower oil and flower water in pentylene glycol examined gene expression for activated genes associated with irritation and activated genes associated with sensitization. This study was negative for both dermal irritation and sensitization. Depending on the section/table where this study is presented, it is described as an irritation or a sensitization study. It needs to be described as both an irritation and sensitization study consistently in all sections of the report.

Dermal Irritation and Sensitization – Please make it clear which HRIPT had 100 subjects and which HRIPT had 107 subjects.

Summary – The fragrance allergen components found in *Rosa damascena* should be mentioned in the Summary.

Table 6 – Were histopathologic examinations completed in the dog study?

Table 7 – In the description of the Episkin study, it should be made clear that they also looked at sensitization biomarker genes. It suggests this in the Results column, but not in the Procedure column.

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

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

DATE: September 7, 2021

SUBJECT: Draft Final Report: Safety Assessment of Anhydrogalactose, Anhydroglucitol, Anhydroxylitol, Arabinose, Psicose, Saccharide Hydrolysate, and Saccharide Isomerate as Used in Cosmetics (draft prepared for the September 2021 CIR meeting)

The Personal Care Products Council respectfully submits the following comments on the draft final report, Safety Assessment of Anhydrogalactose, Anhydroglucitol, Anhydroxylitol, Arabinose, Psicose, Saccharide Hydrolysate, and Saccharide Isomerate as Used in Cosmetics.

Dermal Penetration, Saccharide Isomerate; Summary – As the activity of Saccharide Isomerate is not discussed in the report, please delete the word "active" when describing this ingredient.

ADME, Animal, Oral, Psicose – In reference 35, did they really confirm that the material that entered the bloodstream was Psicose, or were they just measuring radioactivity from [^{14}C]Psicose?

Ocular Irritation – It should be noted that OECD test guideline 405 states that the preferred species is the rabbit.

Summary – Please revise: "groups of least 10 rats" (add the word "at")

Summary – The description of the subcutaneous carcinogenicity study in the Summary states that tumors were not observed in mice. Then it states that the tumors in rats and mice were at sites remote from the injection site. This is not consistent with what is in the Carcinogenicity section. Please revise the sentence to make it clear that tumors remote from the injection site were only observed in rats.

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

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

DATE: September 8, 2021

SUBJECT: Draft Tentative Report: Safety Assessment of *Saccharum officinarum* (Sugarcane)-Derived Ingredients as Used in Cosmetics (draft prepared for the September 2021 CIR meeting)

The Personal Care Products Council respectfully submits the following comments on the draft tentative report, Safety Assessment of *Saccharum officinarum* (Sugarcane)-Derived Ingredients as Used in Cosmetics.

Key Issues

Introduction – Rather than stating: "potential toxicity from exposures to mixtures of different chemical compounds may not replicate the biological activity of the individual components", it should state that "toxicity from single components may not predict the potential toxicity of mixtures." This would provide justification as to why studies on individual components are not included in the CIR report. The way the statement is currently written links "toxicity" with "biological activity". If the statement is left in the report, "biological activity" should be changed to "toxicity".

Draft Discussion – Please delete "elevated levels of" when describing heavy metals and pesticide residues. Although the report describes heavy metal analysis, it is not clear if the reported levels are "elevated". There is no study of pesticide residues in the report.

Additional Considerations

Method of Manufacture – As one method came from a cosmetic ingredient manufacturer, it is misleading to state that "it is unknown if they apply to cosmetic ingredient manufacturing".

Cosmetic Use – Please revise: "used hair sprays" (add the word "in")

Acute – Are the doses "50, 20 or 2000 mg/kg" correct? Usually, doses are presented in ascending order. Perhaps the middle dose is supposed to be 200? Did they complete

microscopic examinations of the organs in this study (they are often not done in single dose studies)? The following sentence does not make sense. "No gross histopathological alterations were found at necropsy." Gross examinations are done by eye, while histopathologic examinations are done with a microscope, so if they completed both types of examinations, it should state "No gross or histopathological alterations". The organs examined should be stated.

Subchronic and Chronic – In the last sentence of the description of the chronic rat study, please delete "other toxicity" as this implies that lowered serum cholesterol was a toxic effect.

Carcinogenicity – Please correct "malignant of benign neoplasms" to "malignant or benign neoplasms". As rates of spontaneous lesions vary by the strain of mice used, please revise "reported for this species" to "reported for this strain".

Summary – Please correct: "used 211 formulations" (add the word "in"). The Summary should not include more details than previously stated in the text. The text does not state that the test substance was fed to monkeys "wrapped in banana" (this is stated in Table 3).

Table 3 – For each study in this table, please identify the organs that were examined microscopically.

Reference 26 – Where does "Last Updated: 2016" come from? There have been several adaptations to the EU cosmetic regulations since 2016.

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Executive Director - Cosmetic Ingredient Review

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

DATE: September 7, 2021

SUBJECT: Draft Final Report: Amended Safety Assessment of Silicates as Used in Cosmetics (draft prepared for the September 2021 CIR meeting)

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

Abstract – It would be helpful to also state that the synthetic ingredients are amorphous silica.

Cosmetic Use – "aerosolized airbrush devices" does not make sense – this should be revised to make it clear that the airbrush devices aerosolize the cosmetic product.

Cytotoxicity, old report summary – Please include the concentration of Aluminum Silicate that was used in the *in vitro* assay.

Occupational and Environmental Exposure – Please revise the following (delete data): "Available regulatory information data on silica is provided below."

Summary – Please state the occupational limit values in the Summary.

Conclusion – Please revise "airbrush use" to "airbrush application"

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

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

DATE: September 8, 2021

SUBJECT: Draft Tentative Report: Safety Assessment of Ubiquinone Ingredients as Used in Cosmetics (draft prepared for the September 2021 CIR meeting)

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

ADME, Human, Oral, Ubiquinol – If the observed events were not clinically significant, please delete the word "adverse" (reference 46).

Short-Term, Subchronic and Chronic – Please add the word "in" to "were found animals dosed…"

Developmental and Reproductive Toxicity Studies – Please state the gestation days the animals were treated (references 2 and 3 rabbit and rat studies).

Miscellaneous Biological Effects – What dose of Ubiquinone was used in the 16-week longitudinal study (reference 60)?

Sensitization, Animal, Ubiquinone – As there was only one positive control, please delete the "s" from "controls". Please correct "DCNB" to "DNCB"

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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 8, 2021

SUBJECT: Draft Report: Safety Assessment of Yeast-Derived Ingredients as Used in Cosmetics (draft prepared for the September 2021 CIR meeting)

The Personal Care Products Council respectfully submits the following comments on the draft report, Safety Assessment of Yeast-Derived Ingredients as Used in Cosmetics.

Introduction – It would also be helpful to note that the FCC definition of dried yeast includes the species *Saccharomyces cerevisiae*, *Saccharomyces fragilis* and *Torula utilis*.

Definition – As this report focuses on *Saccharomyces cerevisiae*, it would be helpful to include some information about this species in the Definition section.

Composition and Impurities, Yeast – Yeast does not actually "contain" ash. It contains minerals that do not degrade when the yeast is burned. The 8% value represents the acceptance criteria for the ash left when a specific test is completed. Please revise the following sentence to accurately represent this acceptance criteria. "In addition, dried yeast may not contain more than 8% ash."

Acute, Inhalation – In the description of the inhalation study (reference 22), please describe the endpoints examined.

Summary - Since not all ingredients in the group have all the listed functions - please revise "Other functions of this ingredient group…" to "Other functions of ingredients in this group..."

Summary – Please add "%" after 0.36