Data Supplement

Airbrush
Diatomaceous Earth
Glyceryl Acrylates
Zeolites

EXPERT PANEL MEETING
MARCH 7-8, 2022

Commitment & Credibility since 1976

Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons

From: Christina L. Burnett, Senior Scientific Analyst/Writer, CIR
Priya Cherian, Senior Scientific Analyst/Writer, CIR
Jinqiu Zhu, PhD, DABT, ERT, CIR Toxicologist

Date: February 25, 2022

Subject: Comments from WVE on Kaolin and Acrylates/Octylacrylamide Copolymer as used in airbrush products, as well as clarifications on airbrush use by US CPSC

Enclosed are the comments received from the Women's Voices for the Earth (WVE), dated February 21, 2022, regarding the use of Kaolin (an ingredient included in Clays report) and Acrylates/Octylacrylamide Copolymer (an ingredient in the Acrylamide/ Acrylate Copolymers report) in cosmetic products applied via airbrush technology. (This file is named *WVEcomments-Kaolin-AcrylatesOctylacrylamideCopolymer_AirbrushDiscussion_Wave2_032022* in the pdf.)

Data reliability is crucial in health risk assessments if robust conclusions are to be drawn. Basically, frequency and concentration of use data of an ingredient under safety evaluation by the Expert Panel for Cosmetic Ingredient Safety (Panel) are sourced from the US Food and Drug Administration (FDA) Voluntary Cosmetic Registration Program (VCRP), as well as the use surveys conducted by the Personal Care Products Council (Council). Data completeness and accuracy also rely on submissions from Industry when ingredients are applied in a formula by stakeholders who market such cosmetics and have a legal responsibility for the safety of their products and ingredients.

While the product formulations submitted by WVE in their comments contain certain information on the usage of Kaolin and Acrylates/Octylacrylamide Copolymer in airbrush products, it should be pointed out that none of them provide data relevant to concentration or frequency of use, or any toxicological endpoint. In addition, please note *Acrylic Polymers* was highlighted by WVE as an ingredient in an airbrush product by the brand *Tickled Pink*; however, no further clarification was provided with regard to which discrete ingredient of the chemical group is applied in such product. In these regards, with very limited information, it is not applicable for a safety assessment to be performed or any safety conclusion to be arrived upon. In general, data included in CIR reports should clearly cite the source, while product brands as well as their corresponding web links (which present formulation information for that specific cosmetics) should not appear in the reports.

Regarding the inhalation risks resulting from airbrush device usage, the Panel discussed the concerns robustly at the December 2020, September 2021, as well as December 2021 meetings. Please note, titanium dioxide (TiO_2) is listed as an ingredient in most formulations submitted by WVE in their memo, and recent research findings suggest it can be emitted into the consumer breathing zone in nano-form during the airbrush applications. For more discussion related to safety concerns raised by in-use studies that monitored aerosol generation during airbrush applications, please refer to a section titled *Inhalation Exposure of Engineered Metal Nanoparticles (ENPs) from Aerosolized Consumer Products* in the updated CIR Inhalation Resource Document (available at https://www.cir-safety.org/sites/default/files/Inhalation.pdf).

As CIR continues efforts to clarify current federal regulations relating to the categorization and safety management of consumer products applied with airbrush technologies, enclosed herein are communications between the CIR and US Consumer Product

Safety Commission (CPSC; *CPSCresponse-CIRmemo_AirbrushDiscussion_Wave2_032022*). Combined with previous responses received from the US FDA Center for Devices and Radiological Health as well as the Office of Cosmetics and Colors (see page 16 – 19 at https://www.cir-safety.org/sites/default/files/Wave2_122021.pdf), classification of airbrush devices warrants further investigation. As indicated by US CPSC in their message, "[I]f the hazard is associated with inhaling/ingesting the cosmetic that was airbrushed, addressing that hazard would likely fall under FDA's jurisdiction. However, if the hazard involved the airbrush device itself, addressing the hazard would likely fall within CPSC's jurisdiction." The following characteristics of airbrush devices should be considered on the variations between jurisdictions over different federal agencies:

1. based on currently available data, airbrush applications are associated with prolonged duration exposure to airborne nanosized particles;
2. nano-enabled consumer airbrush products have a complex mixture that contains many elements, and airbrush applications might result in inhalation exposure to nanosized metal oxides, such as TiO_2, which is classified as a "Carcinogen Category 2 (inhalation)" by the European Commission, and not allowed to be used in applications that may lead to exposure of the end-user's lungs by inhalation.

It would seem that the US CPSC has confirmed that airbrush devices alone (i.e., not including what chemicals/ingredients are applied with the devices) are within its purview. However, these ingredients as used in cosmetics (including as used in airbrush devices), are yet within the jurisdiction of the US FDA, and thus the purview of this Panel. As stated in the updated Inhalation Resource Document, the "available data, however, are insufficient to determine median particle sizes (and distributions) resulting from airbrush device use." (This is merely one example, as the use of these devices is also insufficient for other relevant inhalation exposure/toxicity parameters and endpoints.) Thus, unless manufacturers provide relevant inhalation safety data, specific to the cosmetic ingredients used and the specific airbrush device used, all future assessments comprising airbrush use will result in insufficient data conclusions.

Accordingly, would the Panel consider making a broad statement that the use of airbrush devices for the application of cosmetic ingredients is presumed a "use not supported," until relevant and specific data are made available to obviate such insufficiencies?

WOMEN'S VOICES FOR THE EARTH

February 21, 2022

To the CIR:

I am writing to provide you with information on two ingredients currently under review that are commonly found in airbrush cosmetics.

Specifically, **Kaolin** (in the Clays Safety Assessment) and

Acrylates Octylacrylamide Copolymer (in the Acrylamide/Acrylate Copolymers Safety Assessment).

Recently the CIR has had lengthy conversations about the potential hazards of airbrush cosmetics and concluded that the safety of certain ingredients (Methicones) could not be determined when used in airbrush cosmetics. I have appreciated the attention and detail of these conversations – which are incredibly important to public health given the potential health impacts to users of airbrush cosmetics.

I was surprised, therefore, to find that there was no mention of airbrush cosmetics in the draft safety assessments of Clays and Acrylamide/Acrylate Copolymers. I have previously submitted comments to the CIR containing information on ingredients lists for numerous airbrush cosmetic products (aware that this information is rarely available from the VCRP). In fact, in my comments submitted in January 2021, I specifically highlighted that both kaolin and Acrylates Octylacrylamide Copolymer were present in airbrush cosmetics – as these were ingredients I knew were priorities to be reviewed in the following year.

I am now resubmitting the following information on ingredients in airbrush cosmetic products. I have specifically included here only those products I have identified which contain kaolin and/or Acrylates Octylacrylamide Copolymer.

I recommend that a discussion (and assessment) of the use of these ingredients in airbrush cosmetics be included in these two safety assessments.

I also recommend that the CIR develop a procedure to identify when cosmetic ingredients under review are present in airbrush cosmetics, given the potential safety concerns that have been identified. While I understand that the VCRP is of limited use in identifying ingredients in airbrush cosmetics, there should be a more comprehensive way of obtaining this important information than relying on comments from Women's Voices for the Earth. I was able to obtain this ingredient information quite easily from the internet. I believe the CIR should be able to easily confirm this ingredient information from the manufacturers themselves. There are relatively few manufacturers of airbrush cosmetics, and a relatively small palette of ingredients used in these products. Developing and maintaining a list of

PO Box 8743, Missoula, MT 59807 406.543.3747 www.womensvoices.org womensvoices@womensvoices.org

ingredients used in airbrush cosmetics would be of great use to the CIR to improve future safety assessments.

Thank you for your consideration of these comments.

Alexandra Scranton
Director of Science and Research

Examples of Airbrush Cosmetics containing Kaolin and Acrylates Octylacrylamide Copolymer:

Brand: Aeroblend

AEROBLEND Airbrush Ingredients

WATER/AQUA, PROPYLENE GLYCOL, GLYCERIN, TALC , PERSEA GRATISSIMA (AVOCADO) OIL, SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL, POLYURETHANE-34, KAOLIN, CETYL HYDROXYETHYLCELLULOSE, TETRASODIUM EDTA, BHT, TRIETHANOLAMINE, LAVANDULA OFFICINALIS (LAVENDER) OIL, CAMELLIA SINENSIS (WHITE TEA) EXTRACT, PHENOXYETHANOL, CAPRYLYL GLYCOL, POTASSIUM SORBATE, HEXYLENE GLYCOL.
MAY CONTAIN: TITANIUM DIOXIDE 13463-67-7, IRON OXIDES 1309-37-1, 20344-49-4, 1309-37-1, SILICA 7631-86-9, ULTRAMARINE BLUE, ULTRAMARINE PINK, ALUMINA, MICA

https://aeroblend.com/blogs/how-to/what-are-the-ingredients-used-in-aeroblend-airbrush-makeup

Brand: Photo Finish

Photo Finish Airbrush Foundation

Ingredients

Purified Water, Propylene Glycol, Acrylates Octylacrylamide Copolymer, Glycerin, Triethanolamine, Magnesium, Aluminum Silicate, Phenoxyethanol, Sodium Benzoate, Titanium Dioxide, Iron Oxides, Kaolin Clay. May Contain: Xanthan Gum, Silica, Butylene Glycol, Lecithin, Mica, Cetearyl Alcohol, Polysorbate 60

https://advancedskincarestore.com/makeup/airbrush-makeup/airbrush-foundation/

Brand: Tickled Pink

Waterproof Makeup Sealant

Ingredients: Aqua, Denatured Ethanol, Acrylic Polymers, Phenoxyethanol, Dimethlaminoethanol(DMAE Bitartrate), Tetrasodium EDTA

https://www.tickledpinkairbrush.com/water-proof-sealant/

Water-based Airbrush Foundation

Ingredients: Aqua (Purified Water), Glycerine, Silica, Coco-Glucasides/Coconut Alcohol, Cetyl Esters, Potassium Cetyl Phosphate, Kaolin, Cetyl Alcohol, PEG-40 Apricot Oil, Alchemilla Vulgaris (Lady's Mantle) Extract, Silybum Marianum Fruit (Milk Thistle) Extract, Ginko Biloba Leaf (Gingko) Extract, Equisetum, Arvense Leaf (Horsetail) Extract, Hypericum Perforatum (St. Johns Wart) Extract, Helianthus Annus (Sunflower) Seed Oil, Caprylyl Glycol, Natural Fragrance, Magnesium Aluminum Silicate, Carboxymethylcellulose, Citric Acit, Disodium EDTA. Setting Spray Ingredients: Aqua (Purified Water), Acrylates Copolymer, Propylene Glycol, Soya Protein Phthalate, Polysorbate-20, Natrual Fragrance, Disodium EDTA.

https://www.tickledpinkairbrush.com/products/waterbased-foundations.html#description

Brand: Rock Candy

NOFILTER 4K Foundation:

Matte Finish: Water, Glycerin, Hydrolyzed Rice Protein, Propanediol, Hydrolyzed Jojoba Esters, Palmitoyl Tripeptide-5, Benzyl Alcohol, Microcrystalline Cellulose, Acrylates/Octylcrylamide Copolymer, Prunus Amygdalus Dulcis (Sweet Almond) Seed Extract, Jojoba Esters, Tetrasodium Glutamate Diacetate, Tromethamine, Salicylic Acid, Xanthan Gum, Cellulose Gum, Avena Sativa (Oat) Bran Extract, Sorbic Acid, Sodium Benzoate, Potassium Sorbate, Camellia Sinensis Callus Extract, Panax Ginseng Callus Culture Extract, Phyllostachys Pubescens Meristem Cell Lysate , Titanium Dioxide (CI 77891), Iron Oxides (CI 77492), Iron Oxides (CI 77491), Iron Oxides (CI 77499).

Satin Finish: Water, Propanediol, Glycerin, Hydrolyzed Rice Protein, Brassica Napus Seed Oil, Hydrolyzed Jojoba Esters, Glyceryl Citrate/Lactate/Lineolate/Oleoate, Palmitoyl Tripeptide-5, Acrylates/Octylcrylamide Copolymer, Benzyl Alcohol, Mica, Glyceryl Caprylate, Polyglyceryl-3 Caprate, Polyglyceryl-4 Cocoate, Prunus Amygdalus Dulcis (Sweet Almond) Seed Extract, Jojoba Esters, Tromethamine, Tetrasodium Glutamate Diacetate, Salicylic Acid, Microcrystalline Cellulose, Avena Sativa (Oat) Bran Extract, Sorbic Acid, Sodium Benzoate, Potassium Sorbate, Cellulose Gum, Xanthan Gum, Camellia Sinensis Callus Extract, Panax Ginseng Callus Culture Extract, Phyllostachys Pubescens Meristem Cell Lysate, Titanium Dioxide (CI 77891), Iron Oxides (CI 77492), Iron Oxides (CI 77491), Iron Oxides (CI 77499).

https://rockcandybeauty.com/products/nofilter-4k

Brand: Luminess

Airbrush Eraser Concealer

Purified Water (Aqua), Glycerin, Potassium Olivoyl PCA, Stearic Acid, Triethanolamine, Phenoxyethanol, Butylene Glycol, PEG-100 Stearate, Glyceryl Stearate, Potassium Sorbate, Propylene Glycol, Iodopropynyl Butylcarbamate, Diazolidinyl Urea, Azadirachta Indica (Neem) Extract, Lecithin, Kaolin, Acrylates Octylacrylamine Copolymer, Magnesium Aluminum Silicate, Xanthan Gum, Disodium EDTA, Tocopheryl Acetate, Ascorbyl Palmitate | May Contain (+/-): Titanium Dioxide (CI 77891), Iron Oxides (CI 77492, 77491, 77499)

https://www.luminesscosmetics.com/airbrush-eraser-concealer/LMER00-GEN.html

Airbrush Moisturizing Primer

Purified Water (Aqua), Glycerin, Potassium Olivoyl PCA, Stearic Acid, Phenoxyethanol, Triethanolamine, Glyceryl Stearate, PEG-100 Stearate, Tocopheryl Acetate, Ascorbyl Palmitate, Butylene Glycol, Potassium Sorbate, Disodium EDTA, Lecithin, Kaolin, O-Cymen-5-OL, Prolylene Glycol, Azadirachta Indica (Neem) Extract, Acrylates Octylacrylamide Copolymer, Magnesium Aluminum Silicate, Diazolidinyl Urea, Iodopropynyl Butylcarbamate, 1,3-Propanediol

https://www.luminesscosmetics.com/airbrush-moisturizing/LMMR00-GEN-1.html

Silk 4-in-1 Enhanced Airbrush Foundation

Purified Water (Aqua), Glycerin, Potassium Olivoyl PCA, Stearic Acid, Hydrolyzed Silk, Butylene Glycol, Acrylates Octylacrylamide Copolymer, Lecithin, Triethanolamine, Calcium Carbonate, Propylene Glycol, Azadirachta (Neem) Extract, Silk Protein, Kaolin, Tocopheryl Acetate, Glyceryl Stearate, PEG-100 Stearate, Magnesium Aluminum Silicate, Phenoxyethanol, Potassium Sorbate, Iodopropynyl Butylcarbamate, Diazolidinyl Urea, Chlorphenesin, Xanthan Gum, Disodium EDTA | May Contain (+/-): Titanium Dioxide (CI 77891), Iron Oxides (CI 77491, 77492, 77499)

https://www.luminesscosmetics.com/silk-4-in-1-enhanced-airbrush-foundation/LMSE-GEN.html

Brand: Joyus

Serum Infused Airbrush Foundation (Mocha)

Ingredients: L-ascorbic acid, calendula extract, kaolin, jojoba extract, kelp extract

https://www.joyus.com/sales/serum-infused-foundation-mocha

Brand: Ben Nye

Ben Nye ProColor Foundation Airbrush Makeup

Ingredients: Aqua (Water), Acrylates Copolymer, Peg-12, Talc, Propylene Glycol, Kaolin, Potassium Sorbate, Cyclomethicone, Trisodium Hedta, Phenoxyethanol +/- (May Contain): Ci No. 77891, 77491, 77492, 77499, 77007, 42090, 77289, 77288, 77742, 19140, 15850, 73360 (Titanium Dioxide, Iron Oxides, Ultramarines, Blue 1, Chromium Hydroxide, Green, Chromium Oxide Green, Manganese Violet, Yellow 5, Red 6, Red 7, Red 30)

https://camerareadycosmetics.com/products/ben-nye-procolor-foundation-airbrush-makeup

Jurisdiction for airbrush devices to apply cosmetics

From: Center, Information <Info@cpsc.gov>
Sent: Tuesday, January 25, 2022 6:27 PM
To: Bart Heldreth
Subject: Jurisdiction for airbrush devices to apply cosmetics

Dr. Heldreth,

My apologies for the delay of this reply. The response below was provided after a review by our General Counsel's Office and our Hazard Analysis Division.

If we may be of any assistance in the future, please do not hesitate to contact us again.

Respectfully,

Michael June

-----Original Message----------

Hi Michael,

Dan V. asked that I respond to you. This inquiry pertains to airbrush devices that apply cosmetics. According to the email from the Cosmetic Ingredient Review (CIR), FDA CDRH and FDA Cosmetics have already indicated that they don't consider the airbrush to be a medical device or a cosmetic such that it would be subject to their jurisdiction. This appears to be in line with previous jurisdictional determinations in which we have found that, pursuant to input from FDA, that a hair styling brush and a mechanical eye lash curler were neither medical devices nor cosmetics. Because the airbrush device is neither a medical device nor a cosmetic, it is not excluded from the definition of "consumer product" by section 3(a)(1)(H) of the CPSA.

CIR is asking whether we are aware of "publicly available consumer uses and practices data related to the use of airbrush devices to apply cosmetics," as well as "frequency of use and product type/route of exposure data, specific to sprays and powders, to assess the potential for incidental respiratory exposure." I am not aware that we have such data, but those questions are probably more

appropriately addressed to EXHR and perhaps Compliance.

We checked and we do not have any injury/exposure data related to incidents with air brushes and cosmetics. We are not aware of any voluntary standards related to the use of airbrushes for cosmetics.

If the hazard is associated with inhaling/ingesting the cosmetic that was airbrushed, addressing that hazard would likely fall under FDA's jurisdiction. However, if the hazard involved the airbrush device itself, addressing the hazard would likely fall within CPSC's jurisdiction.

-----Original Message----------
From: info@cpsc.gov <info@cpsc.gov>
Sent: Monday, December 6, 2021 9:48 AM
To: Center, Information <Info@cpsc.gov>
Subject: Form submission from: Send a Message to CPSC's Information Center

Submitted on 12/06/2021 - 09:47
Submitted by user: Anonymous

Submitted values are:
Name: Dr. Bart A Heldreth
Organization / Affiliation:: Cosmetic Ingredient Review Daytime Phone:: 2025407045 E-mail address:: heldrethb@cir-safety.org Your Message::
Subject: Airbrush Use with Cosmetics

Dear Ms. Boyle,

The Cosmetic Ingredient Review (CIR) was established in 1976 by the industry trade association (then the Cosmetic, Toiletry, and Fragrance Association; now the Personal Care Products Council (Council)), with the support of the US Food and Drug Administration and the Consumer Federation of America. The solitary purpose of CIR is to assess the safety of individual ingredients as used in cosmetics. Although funded by the Council, CIR, the Expert Panel for Cosmetic Ingredient Safety (Panel), and the review process are independent from the Council and the cosmetics industry (much like members of an FDA special advisory committee). CIR and the Panel operate under a set of procedures. If interested, you may learn more about the Expert Panel for Cosmetic Ingredient Safety here (https://linkprotect.cudasvc.com/url?a=https%3a%2f%2fingredientsafetyexpertpanel.org%2f&c=E,1,Lyf4mcG4YE_3JhCWU0djZsWFNXunTWdXka8vx-_1utPmdhIUMx-dvk4y9j87-RV5xq_SLlq-Yohdb27kW0O_sxjo2D8oiE-iBLq8SeRrBUFcWjNODwOC&typo=1).

Recent deliberations of the Panel have obviated the need to better understand the use of airbrush devices. Traditionally, CIR and the Panel have closely examined the use of pump and propellant sprays with regard to cosmetic product delivery. However, the use of airbrush devices to apply cosmetics has not been fully explored. As we try to construct a picture towards an actionable understanding of airbrushes devices, a number of puzzling pieces are missing from that picture, and we are hoping you would be willing to help.

Firstly, would you be willing to explain the US regulatory environment as it applies for the use of airbrush devices to apply cosmetics? Further to that end, are such devices, and their use, exclusively under the regulatory authority of any particular center? (FDA CDRH and FDA Cosmetics have already

said the devices are not under their purview.)

Secondly, are you aware of publicly available consumer uses and practices data related to the use of airbrush devices to apply cosmetics? Such use and practice data have previously been of great benefit to the Panel in assessing the risks associated with pump and propellant sprays. For airbrush device use, however, we have found no such data. Any additional data (e.g., particle sizes and volumes) or sources of such, related to respirable risks and safeties for airbrush device use, could also be of immeasurable assistance.

Thirdly, CIR commonly obtains frequency of use and product type/route of exposure data, specific to things like sprays and powders, to assess the potential for incidental respiratory exposure. The best source for such information has historically been the FDA Voluntary Cosmetic Registration Program (VCRP). Such data/information is unavailable from the VCRP, for airbrush use. Are you aware of any data sources pertaining specifically to airbrush use?

Thank you for taking the time to read this. If you have any questions, please do not hesitate to contact me.

Truly,
Bart

Dr. Bart Heldreth
Executive Director
Cosmetic Ingredient Review
1620 L Street, NW, Suite 1200
Washington, DC 20036-4702
heldrethb@cir-safety.org

Recipient: Information Center

Commitment & Credibility since 1976

Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Christina L. Burnett, Senior Scientific Writer/Analyst
Date: February 25, 2022
Subject: Safety Assessment of Diatomaceous Earth as Used in Cosmetics – Wave 2

Supplemental comments were received from the International Diatomite Producers Association (IDPA), and are attached herein (*IDPAComments_DiatomaceousEarth_Wave2_032022*). The comments that were received further address the clarification of the type of Diatomaceous Earth used in cosmetics.

1620 L St NW, Suite 1200, Washington, DC 20036
(Main) 202-331-0651 (Fax) 202-331-0088
(email) cirinfo@cir-safety.org (website) www.cir-safety.org

December 16, 2021

Carol Eisenmann, Ph.D.
Senior Toxicologist
Personal Care Products Council
1620 L Street, Suite 1200
Washington DC 20036

Re: IDPA Comments on the Draft Safety Assessment of Diatomaceous Earth as Used in Cosmetics and Other Matters

Submitted via E-Mail: eisenmannc@personalcarecouncil.org

Dear Dr. Eisenmann:

The International Diatomite Producers Association (IDPA) is a trade association representing major manufacturers of diatomaceous earth products worldwide. Founded in 1987, IDPA is committed to the safe use of diatomaceous earth products and to advancing research and maintaining a dialogue with industry, regulatory agencies and the scientific community in support of the safety of our employees and the communities we serve.

The Cosmetic Ingredient Review (CIR) Expert Panel for Cosmetic Ingredient Safety (Expert Panel) held a virtual two-day meeting on September 13 & 14, 2021, during which they considered a draft safety assessment of diatomaceous earth (DE) as used in cosmetics (https://www.cir-safety.org/sites/default/files/Diatomaceous%20Earth.pdf) (Draft Report). IDPA previously had submitted written comments to the CIR, dated June 29, 2021 (IDPA June 29, 2021 Comments), which addressed the draft Scientific Literature Review (SLR) on DE prepared by CIR staff (https://cir-safety.org/sites/default/files/Diatomaceous%20Earth.pdf). IDPA representatives subsequently offered some oral comments at the September 13 meeting sessions consistent with, and expanding upon, those earlier written comments on the draft SLR. IDPA subsequently submitted written comments to the CIR through you as an industry liaison representative of the Personal Care Products Council (PCPC) to the CIR, dated November 9, 2021 (IDPA November 9, 2021 Comments).

IDPA is pleased to submit the following supplemental comments to CIR, again through you as the PCPC industry liaison representative, on the additional information requested by the Expert Panel. IDPA respectfully requests that a copy of these comments be shared with members of the Expert Panel, other liaison representatives, and CIR staff, as appropriate, so that all may better understand the suggested approach of IDPA on CIR's consideration of DE as used in cosmetics. A courtesy copy of these comments simultaneously has been provided to Dr. Bart Heldreth, Executive Director of the CIR, for his information.

[Expert Panel Question] 1. Clarification of the type of Diatomaceous Earth used in cosmetics (i.e., natural, calcined, and/or flux-calcined)

By e-mail dated November 22, 2021, you shared with me a letter dated November 19, 2021, from Seppic, a company that develops, manufactures, and markets unique ingredients for cosmetic, nutraceutical, pharmaceutical, veterinary, and industrial products (Attachment 1). I subsequently shared the letter with IDPA member companies. At least one IDPA member company made inquiries and determined that, though it does not actively market flux-calcined DE, through a subsidiary it has sold flux-calcined DE, as well as natural DE, to at least one cosmetic manufacturer.

IPDA hopes this corrected information is responsive to the CIR Expert Panel's request for additional information.

IDPA looks forward to continuing the dialogue on the safety of DE as used in cosmetics initiated by the draft SLR, the Draft Report, IDPA's comments and the Expert Panel's deliberations. Please do not hesitate to contact me with regard to suggestions you may have as to how IDPA and its member companies can best continue this exchange of views, information and data on the relevant science.

Respectfully submitted,

Mark G. Ellis
Executive Director
International Diatomite Producers Association
1200 18th Street, NW, Suite 1150
Washington, DC 20036
(202) 457-0200
(202) 457-0287 (Fax)
(703) 927-7665 (Cell)
markellis@ima-na.org

IDPA Member Companies:

Chemviron, a Kuraray company
Dicalite Management Group, Inc.
EP Minerals, LLC, a U.S. Silica company
Imerys Performance Minerals
Showa Chemical Industry Company, Ltd.

Attachment: IDPA Attachment 1

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

Commitment & Credibility since 1976

Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Regina Tucker, Scientific Writer/Analyst, CIR
Date: February 25, 2022
Subject: Safety Assessment on Glyceryl Acrylates as Used in Cosmetics – Wave 2

Enclosed is updated information on the test concentration used in the irritation and sensitization studies on Glyceryl Acrylate/Acrylic Acid Copolymer, that were previously provided by the Council. (These studies were included in the original March Panel document, and identified as *data2_GlycerylAcrylates_032022*.)

The original data implied that the ingredient tested was undiluted Glyceryl Acrylate/Acrylic Acid Copolymer; however, the test article was actually 1.3-2% Glyceryl Acrylate/Acrylic Acid Copolymer in a water and glycerin solution. This update affects the ocular and mucous membrane studies on pdf page 22 of the report, and the animal irritation study and one sensitization study (second study under Human, Sensitization, reference 7) in Table 5 (pdf page 27).

This memo that specifies the actual concentration tested is attached (*data_GlycerylAcrylates_Wave2_032022*).

1620 L St NW, Suite 1200, Washington, DC 20036
(Main) 202-331-0651 (Fax) 202-331-0088
(Email) cirinfo@cir-safety.org (Website) www.cir-safety.org

Personal Care Products Council
Committed to Safety, Quality & Innovation

Memorandum

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

FROM: Carol Eisenmann, Ph.D.
Personal Care Products Council

DATE: February 14, 2022

SUBJECT: Glyceryl Acrylate/Acrylic Acid Copolymer: Clarification Test Concentrations

The company providing the summary information for Glyceryl Acrylate/Acrylic Acid Copolymer associated with memo 6 (submitted January 14, 2022, found beginning on p. 113 of the March 2022 Glyceryl Acrylates Panel book) has provided clarification on the concentration tested. For the irritation and sensitization tests in this summary, the Glyceryl Acrylate/Acrylic Acid Copolymer is at a concentration of 1.3-2% in a water and glycerin solution.

Commitment & Credibility since 1976

Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Christina L. Burnett, Senior Scientific Analyst/Writer, CIR
Date: February 25, 2022
Subject: Amended Safety Assessment of Zeolites as Used in Cosmetics

As stated in the transmittal memo included with the original (February 11) mailing of the Zeolites report, at the December 2021 Panel meeting, an industry representative indicated that Zeolite is used at higher concentrations in self-heating masks than what was specified in the report, but official documentation had not been received. Subsequently, a letter addressing the loading/use of molecular sieve Zeolites in self-heating creams and lotions was submitted, and is attached (*data_Zeolites_Wave2_032022*).

UnivarSolutions

2/08/2022

Carol Eisenmann, Ph.D
Personal Care Products Council
1620 L Street, Suite 1200
Washington DC 20036
202-454-0344

Subject: The Loading/Use of Molecular Sieve Zeolites in Self-Heating Creams and Lotions.

We are an ingredient distributor and innovator that sells synthetic zeolites, namely GRACE SYLOSIV A3, for use in self heating creams and lotions. To be functional as a self-heating/warming ingredient, we are aware that our customers using the SYLOSIV A3 load as high as a 30% loading in anhydrous formulations.

We hope this clarifies your request for more information on the use of synthetic zeolites in self heating applications for lotions and creams used in cosmetics.

Sincerely,

Bob Woods
Sr. Product Line Manager UNIVAR SOLUTIONS
262-893-9648
Univarsolutions.com