

# ReReview Summaries

Sodium Carbonate  
VA/Crotonates Copolymer

EXPERT PANEL MEETING  
March 28-29, 2024

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## **Safety Assessment of Sodium Sesquicarbonate, Sodium Bicarbonate, and Sodium Carbonate as Used in Cosmetics**

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Status: Re-Review Summary for Panel Consideration  
Release Date: March 4, 2024  
Panel Meeting Date: March 28-29, 2024

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### **History**

Original Safety Assessment – published 1987

Original Re-Review – published 2006

Most Recent Action – new data considered at the December 2023 Panel meeting; not re-opened

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The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; David E. Cohen, M.D.; Curtis D. Klaassen, Ph.D.; Allan E. Rettie, Ph.D.; David Ross, Ph.D.; Thomas J. Slaga, Ph.D.; Paul W. Snyder, D.V.M., Ph.D.; and Susan C. Tilton, Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D., and the Senior Director is Monice Fiume.

## **SODIUM SESQUICARBONATE, SODIUM CARBONATE, AND SODIUM BICARBONATE**

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report on the Safety Assessment of Sodium Sesquicarbonate, Sodium Bicarbonate, and Sodium Carbonate in 1987.<sup>1</sup> The Panel concluded that these 3 ingredients were “safe as presently used” in cosmetics. Upon re-review in March 2005, the Panel reaffirmed the original conclusion, as published in 2006.<sup>2</sup>

Because it has been at least 15 years since the prior re-review was published, in accordance with Cosmetic Ingredient Review (CIR) Procedures, the Panel again determined whether the safety assessment should be reopened. At the December 2023 meeting, the Panel considered updated (2023) information regarding product types and ingredient use frequencies as reported in the US Food and Drug Administration (FDA) Voluntary Cosmetic Registration Program (VCRP) database<sup>3</sup> and maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council.<sup>4</sup> The frequencies of use for both Sodium Bicarbonate and Sodium Carbonate have increased since the previous rereview was conducted; of note, the frequency of use of Sodium Bicarbonate increased from 66 uses in 2002 to 571 reported uses in 2023. The frequency of use of Sodium Sesquicarbonate has decreased. Additionally, the maximum reported concentrations of use of all 3 ingredients have decreased since the previous re-review. The cumulative frequency and concentration of use data are presented in Table 1.

In October 2023, an extensive search of the world’s literature was performed for studies dated 2000 forward, and new data were found.<sup>5-20</sup> European Union regulations, toxicology, genotoxicity, carcinogenicity, anti-carcinogenicity, dermal irritation, ocular irritation, and clinical studies were considered by the Panel. The Panel observed that although a considerable amount of new data were available, no findings were noted that would change the existing conclusion.

In summary, the Panel reviewed 2023 frequency and concentration of use data, in addition to any new, available, relevant safety data. Considering this information, as well as the information provided in the original safety assessment and the prior re-review document, the Panel reaffirmed the 1987 conclusion. The Panel discussed the possibility for these ingredients to be used in cosmetic products which may be incidentally inhaled. A detailed discussion and summary of the Panel’s approach to evaluating incidental inhalation exposures to ingredients in cosmetic products is available at <https://www.cir-safety.org/cir-findings>.

**Table 1. Frequency (2023/2001)<sup>2,3</sup> and concentration (2023/2004)<sup>2,4</sup> of use according to likely duration and exposure and by product category**

|   | Sodium Sesquicarbonate |                   |                     |                    | Sodium Bicarbonate                |                                    |  |   | Sodium Carbonate                    |                                 |                            |  |
|---|------------------------|-------------------|---------------------|--------------------|-----------------------------------|------------------------------------|--|---|-------------------------------------|---------------------------------|----------------------------|--|
|   | # of Uses              |                   | Max Conc of Use (%) |                    | # of Uses                         |                                    | Max Conc of Use (%)                                |   | # of Uses                           |                                 | Max Conc of Use (%)        |  |
|   | 2023 <sup>3</sup>      | 2002 <sup>2</sup> | 2023 <sup>4</sup>   | 2004 <sup>2</sup>  | 2023 <sup>3</sup>                 | 2002 <sup>2</sup>                  | 2023 <sup>4</sup>                                  | 2004 <sup>2</sup>                                   | 2023 <sup>3</sup>                   | 2002 <sup>2</sup>               | 2023 <sup>4</sup>          | 2004 <sup>2</sup>  |
| <b>Totals*</b>                                      | 9                      | 24                | 0.5-69.1            | 2-90               | 571                               | 66***                              | 0.00001-67.6                                       | 0.006-95  | 76                                  | 21                              | 0.0002-48.7                | 0.000002-51  |
| <b>summarized by likely duration and exposure**</b> |                        |                   |                     |                    |                                   |                                    |  |   |                                     |                                 |                            |  |
| <b>Duration of Use</b>                              |                        |                   |                     |                    |                                   |                                    |  |   |                                     |                                 |                            |  |
| Leave-On  | 2                      | 1                 | 35                  | 35-59              | 142                               | 26                                 | 0.0003-55.1  | 0.01-56   | 22                                  | 7                               | 0.0002-0.044               | 0.000002-0.6   |
| Rinse-Off   | 1                      | 3                 | 34.9                | NR                 | 132                               | 33                                 | 0.00001-66.4                                       | 0.006-95  | 16                                  | 10                              | 0.0002-2.3                 | 0.01-32  |
| Diluted for (Bath) Use                              | 6                      | 20                | 0.5-69.1            | 2-90               | 297                               | 7                                  | 63.2-67.6  | 1-64  | 38                                  | 4                               | 0.0012-48.7                | 0.009-51   |
| <b>Exposure Type</b>                                |                        |                   |                     |                    |                                   |                                    |  |   |                                     |                                 |                            |  |
| Eye Area  | NR                     | NR                | NR                  | NR                 | NR                                | 8                                  | 0.012  | 0.04-0.2  | 4                                   | NR                              | 0.00068                    | 0.004-0.3  |
| Incidental Ingestion                                | NR                     | 1                 | NR                  | NR                 | 69                                | 13***                              | 0.35-66.4  | 0.03-95   | 6                                   | 3                               | 0.0009-2                   | 2***   |
| Incidental Inhalation-Spray                         | NR                     | 1                 | 35 <sup>a</sup>     | 35-59 <sup>a</sup> | 34 <sup>a</sup> , 18 <sup>b</sup> | 6 <sup>a</sup> , 4 <sup>b</sup>    | 0.001; 1-55.1 <sup>a</sup>                         | 0.1, 0.2-0.4 <sup>a</sup> ,<br>0.01-56 <sup>b</sup> | 1; 6 <sup>a</sup> , 11 <sup>b</sup> | 1 <sup>a</sup> , 2 <sup>b</sup> | 0.0009-0.19 <sup>b</sup>   | 0.03; 0.008 <sup>a</sup> ;<br>0.000002-0.01 <sup>b</sup> |
| Incidental Inhalation-Powder                        | NR                     | NR                | 35 <sup>a</sup>     | 35-59 <sup>a</sup> | 18b, 1 <sup>c</sup>               | 9; 6 <sup>a</sup> , 1 <sup>c</sup> | 20; 1-55.1 <sup>a</sup> ;<br>0.0003-7 <sup>c</sup> | 20, 0.01-56b, 5 <sup>c</sup>                        | 6 <sup>a</sup>                      | 1 <sup>a</sup>                  | 0.0004 <sup>c</sup>        | 0.008 <sup>a</sup>                                       |
| Dermal Contact                                      | 8                      | 23                | 0.5-69.1            | 2-90               | 495                               | 34                                 | 0.00001-67.6                                       | 0.006-64  | 69                                  | 12                              | 0.0002-48.7                | 0.002-51   |
| Deodorant (underarm)                                | NR                     | NR                | NR                  | NR                 | 80 <sup>b</sup>                   | NR                                 | 0.05-15<br>(not spray)                             | 0.01-15 <sup>b</sup>                                | NR                                  | NR                              | 0.012-0.016<br>(not spray) | 0.002 <sup>b</sup>                                       |
| Hair - Non-Coloring                                 | NR                     | NR                | NR                  | NR                 | 5                                 | 3                                  | 0.05-3.4   | 0.09-10   | NR                                  | 4                               | 0.0002-2.3                 | 0.000002-1   |
| Hair-Coloring                                       | NR                     | NR                | NR                  | NR                 | NR                                | 8                                  | 6  | 0.1-10  | 1                                   | 2                               | 1-2                        | 0.02-25  |
| Nail  | 1                      | NR                | NR                  | NR                 | 2                                 | NR                                 | 35.5   | 39  | NR                                  | NR                              | NR                         | 0.6  |
| Mucous Membrane                                     | 7                      | 23                | 0.5-69.1            | 2-90               | 393                               | 33                                 | 0.00001-67.6                                       | 0.03-95   | 52                                  | 10                              | 0.0009-48.7                | 0.009-51   |
| Baby Products                                       | NR                     | NR                | NR                  | NR                 | 1                                 | 1                                  | 0.001  | 5   | NR                                  | NR                              | 0.044                      | NR   |
| <b>as reported by product category</b>              |                        |                   |                     |                    |                                   |                                    |  |   |                                     |                                 |                            |  |
| <b>Baby Products</b>                                |                        |                   |                     |                    |                                   |                                    |  |   |                                     |                                 |                            |  |
| Baby Lotions/Oils/Powders/Creams                    |                        |                   |                     |                    | 1                                 | 1                                  | NR   | 5   |                                     |                                 |                            |  |
| Other Baby Products                                 |                        |                   |                     |                    | NR                                | NR                                 | 0.001 (wipes,<br>leave-on)                         | NR  | NR                                  | NR                              | 0.044                      | NR   |
| <b>Bath Preparations (diluted for use)</b>          |                        |                   |                     |                    |                                   |                                    |  |   |                                     |                                 |                            |  |
| Bath Oils, Tablets, and Salts                       | 2                      | 16                | 0.5-69.1            | 2-90               | 261                               | 7                                  | 63.2-67.6  | 30-64   | 36                                  | 4                               | 13.5-48.7                  | 40-51  |
| Bubble Baths  | NR                     | 2                 | 50                  | 18                 | 15                                | NR                                 | NR   | 5-52  | 1                                   | NR                              | NR                         | 7-39   |
| Bath Capsules                                       |                        |                   |                     |                    | 1                                 | NR                                 | NR   | 49  |                                     |                                 |                            |  |
| Other Bath Preparations                             | 4                      | 2                 | NR                  | 10-35              | 20                                | NR                                 | 63.3   | 1-64  | 1                                   | NR                              | 0.0012-42.3                | 0.009-39   |
| <b>Eye Makeup Preparations</b>                      |                        |                   |                     |                    |                                   |                                    |  |   |                                     |                                 |                            |  |
| Eyebrow Pencil                                      |                        |                   |                     |                    | NR                                | NR                                 | NR   | 0.2   | NR                                  | NR                              | 0.00068                    | 0.2  |
| Eyeliners   |                        |                   |                     |                    | NR                                | 1                                  | NR   | 0.04-0.1  | 1                                   | NR                              | NR                         | NR   |
| Eye Shadow  |                        |                   |                     |                    |                                   |                                    |  |   | NR                                  | NR                              | NR                         | 0.3  |
| Eye Lotion  |                        |                   |                     |                    |                                   |                                    |  |   | NR                                  | NR                              | NR                         | 0.004  |
| Mascara   |                        |                   |                     |                    | NR                                | 6                                  | 0.012  | 0.2   | 1                                   | NR                              | NR                         | 0.2  |
| Other Eye Makeup Preparations                       |                        |                   |                     |                    | NR                                | 1                                  | NR   | NR  | 2                                   | NR                              | NR                         | NR   |
| <b>Fragrance Preparations</b>                       |                        |                   |                     |                    |                                   |                                    |  |   |                                     |                                 |                            |  |
| Cologne and Toilet water Spray                      |                        |                   |                     |                    | NR                                | NR                                 | 0.001  | NR  | 1                                   | NR                              | NR                         | 0.03   |
| Powders (dusting/talcum,<br>excl aftershave talc)   |                        |                   |                     |                    | NR                                | 9                                  | 20   | 20  |                                     |                                 |                            |  |
| Other Fragrances                                    | NR                     | 1                 | NR                  | NR                 |                                   |                                    |  |   |                                     |                                 |                            |  |
| <b>Hair Preparations (non-coloring)</b>             |                        |                   |                     |                    |                                   |                                    |  |   |                                     |                                 |                            |  |
| Hair Conditioner                                    |                        |                   |                     |                    | NR                                | NR                                 | 0.05   | 5   | NR                                  | 2                               | 0.0002                     | 0.01   |
| Hair Straighteners                                  |                        |                   |                     |                    |                                   |                                    |  |   | NR                                  | NR                              | 2.3                        | NR   |
| Permanent Waves                                     |                        |                   |                     |                    | NR                                | 3                                  | 0.8  | 10  | NR                                  | 1                               | NR                         | NR   |
| Rinses (non-coloring)                               |                        |                   |                     |                    |                                   |                                    |  |   |                                     |                                 |                            |  |
| Shampoos (non-coloring)                             |                        |                   |                     |                    | 4                                 | NR                                 | 3.4  | 0.09  | NR                                  | 1                               | 0.0053-0.41                | 0.08   |

**Table 1. Frequency (2023/2001)<sup>2,3</sup> and concentration (2023/2004)<sup>2,4</sup> of use according to likely duration and exposure and by product category**

|   | Sodium Sesquicarbonate |                   |                     |                   | Sodium Bicarbonate |                   |                         |                   | Sodium Carbonate  |                   |                            |                   |
|---|------------------------|-------------------|---------------------|-------------------|--------------------|-------------------|-------------------------|-------------------|-------------------|-------------------|----------------------------|-------------------|
|   | # of Uses              |                   | Max Conc of Use (%) |                   | # of Uses          |                   | Max Conc of Use (%)     |                   | # of Uses         |                   | Max Conc of Use (%)        |                   |
|   | 2023 <sup>3</sup>      | 2002 <sup>2</sup> | 2023 <sup>4</sup>   | 2004 <sup>2</sup> | 2023 <sup>3</sup>  | 2002 <sup>2</sup> | 2023 <sup>4</sup>       | 2004 <sup>2</sup> | 2023 <sup>3</sup> | 2002 <sup>2</sup> | 2023 <sup>4</sup>          | 2004 <sup>2</sup> |
| Tonics, Dressings, and Other Hair Grooming Aids |                        |                   |                     |                   |                    |                   |                         |                   | NR                | NR                | NR                         | 0.000002-0.01     |
| Wave Sets                                       |                        |                   |                     |                   |                    |                   |                         |                   |                   |                   |                            | 1                 |
| Other Hair Preparations                         |                        |                   |                     |                   | 1                  | NR                | NR                      | NR                |                   |                   |                            |                   |
| <b>Hair Coloring Preparations</b>               |                        |                   |                     |                   |                    |                   |                         |                   |                   |                   |                            |                   |
| Hair Dyes and Colors                            |                        |                   |                     |                   | NR                 | 8                 | 6                       | NR                | NR                | 2                 | 1                          | 0.1-0.6           |
| Hair Rinses (coloring)                          |                        |                   |                     |                   |                    |                   |                         |                   | NR                | NR                | NR                         | 0.02              |
| Hair Color Sprays (aerosol)                     |                        |                   |                     |                   |                    |                   |                         |                   |                   |                   |                            |                   |
| Hair Bleaches                                   |                        |                   |                     |                   | NR                 | NR                | NR                      | 0.1-10            | 1                 | NR                | NR                         | 25                |
| Other Hair Coloring Preparation                 |                        |                   |                     |                   |                    |                   |                         |                   | NR                | NR                | 2                          | 1                 |
| <b>Makeup Preparations</b>                      |                        |                   |                     |                   |                    |                   |                         |                   |                   |                   |                            |                   |
| Blushers (all types)                            |                        |                   |                     |                   |                    |                   |                         |                   | NR                | NR                | NR                         | 0.03              |
| Foundations                                     |                        |                   |                     |                   | NR                 | NR                | NR                      | 0.09              | NR                | 1                 | NR                         | 0.3               |
| Lipstick  |                        |                   |                     |                   | NR                 | NR                | NR                      | 0.03-1            | NR                | 3                 | NR                         | NR                |
| Other Makeup Preparations                       |                        |                   |                     |                   | 1                  | NR                | NR                      | NR                |                   |                   |                            |                   |
| <b>Manicuring Preparations (Nail)</b>           |                        |                   |                     |                   |                    |                   |                         |                   |                   |                   |                            |                   |
| Other Manicuring Preparations                   | 1                      | NR                | NR                  | NR                | 2                  | NR                | 35.5                    | 39                | NR                | NR                | NR                         | 0.6               |
| <b>Oral Hygiene Products</b>                    |                        |                   |                     |                   |                    |                   |                         |                   |                   |                   |                            |                   |
| Dentifrices                                     |                        |                   |                     |                   | 42                 | 10                | 0.35-66.4               | 3-95              | 2                 | NR                | 0.65-2                     | 2                 |
| Mouthwashes and Breath Fresheners               |                        |                   |                     |                   | 9                  | 2                 | NR                      | 0.1               | 1                 | NR                | 0.0009                     | NR                |
| Other Oral Hygiene Products                     |                        |                   |                     |                   | 18                 | 1                 | NR                      | 0.5               | 2                 | NR                | NR                         | 22 <sup>d</sup>   |
| <b>Personal Cleanliness Products</b>            |                        |                   |                     |                   |                    |                   |                         |                   |                   |                   |                            |                   |
| Bath Soaps and Detergents                       | NR                     | 2                 | NR                  | NR                | 20                 | 2                 | 0.00001-43.5            | 25-54             | 3                 | 1                 | 0.0074-0.4                 | 3-32              |
| Deodorants (underarm)                           |                        |                   |                     |                   | 80                 | NR                | 0.05-15<br>(not spray)  | 0.01-15           | NR                | NR                | 0.012-0.016<br>(not spray) | 0.002             |
| Douches   |                        |                   |                     |                   | NR                 | 2                 | NR                      | NR                |                   |                   |                            |                   |
| Feminine Deodorants                             |                        |                   |                     |                   | 2                  | 2                 | 1                       | NR                |                   |                   |                            |                   |
| Other Personal Cleanliness Products             | 1                      | 1                 | 34.9<br>(rinse-off) | NR                | 5                  | 3                 | 1                       | 0.07-56           | 6                 | 2                 | NR                         | NR                |
| <b>Shaving Preparations</b>                     |                        |                   |                     |                   |                    |                   |                         |                   |                   |                   |                            |                   |
| Preshave Lotions (all types)                    |                        |                   |                     |                   | 1                  | NR                | NR                      | NR                |                   |                   |                            |                   |
| Shaving Cream                                   |                        |                   |                     |                   | 1                  | NR                | NR                      | 0.006             | NR                | NR                | 0.0051                     | NR                |
| Other Shaving Preparations                      |                        |                   |                     |                   | 1                  | 1                 | 1.3                     | NR                | NR                | NR                | 0.0053                     | NR                |
| <b>Skin Care Preparations</b>                   |                        |                   |                     |                   |                    |                   |                         |                   |                   |                   |                            |                   |
| Cleansing                                       |                        |                   |                     |                   | 29                 | NR                | 0.01-43.5               | 0.04-26           | 1                 | 1                 | 0.003-0.93                 | 0.02-0.2          |
| Face and Neck (exc shave)                       |                        |                   |                     |                   | 11                 | NR                | NR                      | 0.01-7            | 4                 | NR                | NR                         | 0.008             |
| Body and Hand (exc shave)                       |                        |                   |                     |                   | 5                  | NR                | 0.0003-7<br>(not spray) | 10                | 2                 | 1                 | 0.0004<br>(not spray)      | NR                |
| Foot Powders and Sprays                         | NR                     | NR                | 35                  | 35-59             | NR                 | 4                 | 55.1                    | 25-56             |                   |                   |                            |                   |
| Moisturizing                                    |                        |                   |                     |                   | 20                 | NR                | 11.8<br>(not spray)     | 0.4               | 7                 | 2                 | 0.0002<br>(not spray)      | NR                |
| Night (Spray)                                   |                        |                   |                     |                   |                    |                   |                         |                   | 1                 | NR                | NR                         | NR                |
| Paste Masks (mud packs)                         |                        |                   |                     |                   | 2                  | 1                 | 0.02-4                  | 61                |                   |                   |                            |                   |
| Skin Fresheners                                 |                        |                   |                     |                   | 4                  | 2                 | NR                      | NR                | 2                 | NR                | 0.019                      | NR                |
| Other Skin Care Preparations                    | 1                      | NR                | NR                  | NR                | 14                 | 4                 | 0.005-30.8              | 2-5 <sup>d</sup>  | 1                 | NR                | NR                         | NR                |
| <b>Suntan Preparations</b>                      |                        |                   |                     |                   |                    |                   |                         |                   |                   |                   |                            |                   |
| Suntan Gels, Creams, and Liquids                |                        |                   |                     |                   | NR                 | NR                | NR                      | 0.2               |                   |                   |                            |                   |
| Other Suntan Preparations                       |                        |                   |                     |                   | 1                  | NR                | NR                      | NR                |                   |                   |                            |                   |

NR – not reported

\*Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure types may not equal the sum of total uses.

\*\*likely duration and exposure are derived based on product category (see Use Categorization <https://www.cir-safety.org/cir-findings>)

\*\*\* frequency and concentration of use of a denture cleaner were reported in 2002/2004; because this is not currently a product category, these data were omitted from the table

<sup>a</sup> Not specified whether a spray or a powder, but it is possible the use can be as a spray or a powder, therefore the information is captured in both categories.

<sup>b</sup> It is possible these products are sprays, but it is not specified whether the reported uses are sprays.

<sup>c</sup> It is possible these products are powders, but it is not specified whether the reported uses are powders.

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## Safety Assessment of VA/Crotonates Copolymer as Used in Cosmetics

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Status: Re-Review Summary for Panel Consideration  
Release Date: March 4, 2024  
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### History

Original Safety Assessment – published 1983

Original Re-Review – published 2006

Most Recent Action – new data considered at the December 2023 Panel meeting; not re-opened

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The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; David E. Cohen, M.D.; Curtis D. Klaassen, Ph.D.; Allan E. Rettie, Ph.D.; David Ross, Ph.D.; Thomas J. Slaga, Ph.D.; Paul W. Snyder, D.V.M., Ph.D.; and Susan C. Tilton, Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D., and the Senior Director is Monice Fiume. This summary was prepared by Preethi Raj, M.Sc., Senior Scientific Analyst/Writer, CIR.

## VA/CROTONATES COPOLYMER

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report on the Safety Assessment of VA/Crotonates Copolymer in 1983; at the time of the original review, this ingredient was named Vinyl Acetate/Crotonic Acid Copolymer.<sup>1</sup> The Panel concluded that VA/Crotonates Copolymer is safe as a cosmetic ingredient under the present practices of product and concentration use, as described in the safety assessment. Upon re-review in September 2002, the Panel reaffirmed the original conclusion, as published in 2006.<sup>2</sup>

Because it has been at least 15 years since the prior re-review was published, in accordance with Cosmetic Ingredient Review (CIR) Procedures, the Panel again determined whether the safety assessment should be reopened. At the December 2023 meeting, the Panel considered updated 2023 information regarding product types and ingredient use frequencies as reported in the US Food and Drug Administration (FDA) Voluntary Cosmetic Registration Program (VCRP) database<sup>3</sup> and maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council.<sup>4</sup> Overall, the reported frequency of use and concentration of use decreased for VA/Crotonates Copolymer and no new use categories were reported. In 2002, 38 uses were reported, while 21 uses were reported in 2023; the maximum reported concentration of use in 2002 was at 11% in hair sprays, compared to 5.2% in a pump hair spray in 2023. The cumulative frequency and concentration of use data are presented in Table 1.

In October 2023, an extensive search of the world's literature was performed for studies dated 2000 forward, and no relevant new data were found. However, the Panel noted that occupational studies presented in the previous review confirmed a lack of long-term effects in workers exposed to 5 to 10 ppm vinyl acetate, with intermittent exposures near 50 ppm and acute exposures up to 300 ppm.

In summary, the Panel reviewed 2023 frequency and concentration of use data and noted the lack of any new, available, relevant safety data. Considering this information, as well as the information provided in the original safety assessment and the prior re-review document, the Panel reaffirmed the 1983 conclusion. The Panel discussed that this ingredient is used in pump hair spray formulations, which may be incidentally inhaled. A detailed discussion and summary of the Panel's approach to evaluating incidental inhalation exposures to ingredients in cosmetic products is available at <https://www.cir-safety.org/cir-findings>.

**Table 1. Frequency and concentration of use (2023/2002) of VA/Crotonates Copolymer according to likely duration and exposure and by product category**

|   | # of Uses          |                    | Max Conc of Use (%)             |                              |
|---|--------------------|--------------------|---------------------------------|------------------------------|
|   | 2023 <sup>3</sup>  | 2002 <sup>2</sup>  | 2023 <sup>4</sup>               | 2002 <sup>2</sup>            |
| <b>Totals*</b>  | <b>21</b>          | <b>38</b>          | <b>1.5 – 5.2</b>                | <b>0.05 - 11</b>             |
| <b>summarized by likely duration and exposure**</b>                           |                    |                    |                                 |                              |
| <b>Duration of Use</b>  |                    |                    |                                 |                              |
| Leave-On  | 17                 | 33                 | 1.5 – 5.2                       | 0.05 – 11                    |
| Rinse-Off   | 4                  | 5                  | NR                              | 2 - 9                        |
| Diluted for (Bath) Use  | NR                 | NR                 | NR                              | 9                            |
| <b>Exposure Type</b>  |                    |                    |                                 |                              |
| Eye Area  | NR                 | 5                  | NR                              | 9                            |
| Incidental Ingestion  | NR                 | NR                 | NR                              | NR                           |
| Incidental Inhalation-Spray   | 3; 13 <sup>a</sup> | 9; 10 <sup>a</sup> | 3 – 5.2; 1.5 – 3.8 <sup>a</sup> | 2 -11; 0.05 – 4 <sup>a</sup> |
| Incidental Inhalation-Powder  | NR                 | NR                 | NR                              | NR                           |
| Dermal Contact  | NR                 | NR                 | NR                              | 2 – 9                        |
| Deodorant (underarm)  | NR                 | NR                 | NR                              | NR                           |
| Hair - Non-Coloring   | 21                 | 33                 | 1.5 – 5.2                       | 0.05 - 11                    |
| Hair-Coloring   | NR                 | NR                 | NR                              | 5                            |
| Nail  | NR                 | NR                 | NR                              | NR                           |
| Mucous Membrane   | NR                 | NR                 | NR                              | 9                            |
| Baby Products   | NR                 | NR                 | NR                              | NR                           |
| <b>as reported by product category</b>  |                    |                    |                                 |                              |
| <b>Bath Preparations (diluted for use)</b>                                    |                    |                    |                                 |                              |
| Bath Capsules   | NR                 | NR                 | NR                              | 9                            |
| <b>Eye Makeup Preparations</b>  |                    |                    |                                 |                              |
| Eye Makeup Remover  | NR                 | NR                 | NR                              | 9                            |
| Mascara   | NR                 | 5                  | NR                              | NR                           |
| <b>Hair Preparations (non-coloring)</b>                                       |                    |                    |                                 |                              |
| Hair Conditioner  | 4                  | 1                  | NR                              | NR                           |
| Hair Spray (aerosol fixatives)  | 3                  | 9                  | pump spray: 3 – 5.2             | 2 - 11                       |
| Hair Straighteners  | NR                 | 1                  | NR                              | NR                           |
| Tonics, Dressings, and Other Hair Grooming Aids                               | 13                 | 10                 | 1.5 – 3.8                       | 0.05 - 4                     |
| Wave Sets   | NR                 | 3                  | NR                              | 2                            |
| Other Hair Preparations   | 1                  | 9                  | NR                              | 2 – 3                        |
| <b>Hair Coloring Preparations</b>   |                    |                    |                                 |                              |
| Hair Dyes and Colors (all types requiring caution statements and patch tests) | NR                 | NR                 | NR                              | 5                            |
| <b>Skin Care Preparations</b>   |                    |                    |                                 |                              |
| Moisturizing  | NR                 | NR                 | NR                              | 2                            |

NR – not reported

\*Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure types may not equal the sum of total uses.

\*\*likely duration and exposure are derived based on product category (see Use Categorization <https://www.cir-safety.org/cir-findings>)<sup>a</sup> It is possible these products are sprays, but it is not specified whether the reported uses are sprays.

## REFERENCES

1. Elder RL (ed.). Final Report on the Safety Assessment of Vinyl Acetate/Crotonic Acid Copolymer. *J Am Coll Toxicol.* 1983;2(5):125-140.
2. Andersen FA (ed). Annual review of cosmetic ingredient safety assessments-2004/2005. Vinyl Acetate/Crotonic Acid Copolymer. *Int J Toxicol.* 2006;25(Suppl 2):87-89.
3. U.S. Food and Drug Administration Center for Food Safety & Applied Nutrition (CFSAN). 2023. Voluntary Cosmetic Registration Program - Frequency of Use of Cosmetic Ingredients (VCRP). Obtained under the Freedom of Information Act from CFSAN; requested as "Frequency of Use Data" January 4, 2023; received February 2, 2023.
4. Personal Care Products Council. 2023. Concentration of Use by FDA Product Category: VA/Crotonates Copolymer. Unpublished data submitted by the Personal Care Products Council on February 24, 2023.