

## 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>				
<i>Leave-On</i>	17	33	1.5 – 5.2	0.05 – 11
<i>Rinse-Off</i>	4	5	NR	2 - 9
<i>Diluted for (Bath) Use</i>	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.