

## METHYL ALCOHOL

The Expert Panel for Cosmetic Ingredient Safety (Panel) published the Final Report on the Safety Assessment of Methyl Alcohol in 2001.<sup>1</sup> The Panel concluded that based on the data presented in the safety assessment, Methyl Alcohol is safe as used to denature alcohol used in cosmetic products.

Because it has been at least 15 years since the final report was published, in accordance with Cosmetic Ingredient Review (CIR) Procedures, the Panel considered whether the safety assessment should be reopened. At its December 2022 meeting, the Panel reviewed updated information regarding product types and ingredient use frequencies as reported in the US Food and Drug Administration (FDA) Voluntary Cosmetic Registration Program (VCRP) database (2022)<sup>2</sup> and maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council in 2021.<sup>3</sup> In 2022, FDA VCRP data indicated that Methyl Alcohol had 3 reported uses, while 4 uses were reported in 1998. The reported maximum use concentration for this ingredient also decreased. Because concentration of use data were not reported to the FDA at the time of the 2001 report, 1984 data were used, which indicated that the reported concentration of use was 0.1 - 5% (product categories not identified). According to the survey conducted in 2021, the maximum reported concentration of use is 0.15% in hair dyes and colors. The frequency and concentration of use is presented both cumulatively by likely duration and exposure and individually by product category in Table 1.

In October 2022, an extensive search of the world's literature was performed for studies dated 1996 forward, and a substantial amount of new data was found from two sources, a European Chemicals Agency dossier and a screening assessment dataset initial assessment profile issued by the Organisation for Economic Co-operation and Development.<sup>4,5</sup> A wide breadth of data was included; notably, a short-term and a subchronic oral toxicity study, several short-term and chronic inhalation toxicity studies, 2 Ames tests, carcinogenicity studies in mice and rats, and a guinea pig maximization test for sensitization were found, all of which were not present in the original report. Additionally, chemical properties, dermal, oral, and inhalation toxicokinetic and acute toxicity studies, multiple in vitro genotoxicity studies, an in vivo genotoxicity study (administered via the inhalation route), an in vitro developmental toxicity study in mice, a skin irritation study in rabbits, and an ocular irritation study in rabbits were also found that were supplemental to, and did not conflict with, results found in the original report. It was also noted that Methyl Alcohol is now approved as a food additive [21CFR173.250] as well as a component of adhesives, defoaming agents, paper and paperboard products that come in contact with food [21CFR175.105; 21CFR176.200; 21CFR176.210; 21CFR176.80].

The Panel stated that the newly available data was mostly additive to the original report, with studies reporting negative results, and that the number of reported uses remained relatively constant over time,. Thus, the Panel agreed that in spite of the volume of data that was available, the published literature did not reveal toxicity or other data considered significantly different to warrant re-evaluation of the safety of this ingredient in cosmetic products.

The Panel did observe that Methyl Alcohol now has a reported use in aerosol hair sprays (0.006%). However, negative inhalation toxicity data from the previous report, as well as 18-month and 24-month inhalation toxicity studies with negative results considered for this re-review, mitigated any concern. Furthermore, the Panel reasoned that the maximum reported concentration of use for Methyl Alcohol in sprays is far below the permissible exposure limit issued by the Occupational Safety and Health Administration (200 ppm).

In summary, the Panel reviewed 2022 frequency of use and 2021 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, the Panel reaffirmed the 2001 conclusion.

**Table 1. Frequency (2022; 1998) and concentration (2021; 1984) of use according to likely duration and exposure and by product category**

	# of Uses		Max Conc of Use (%)	
	Methyl Alcohol			
	2022 <sup>2</sup>	1998 <sup>1</sup>	2021 <sup>3</sup>	1984 <sup>1</sup>
<b>Totals*</b>	<b>3</b>	<b>4</b>	<b>0.005 – 0.15</b>	<b>0.1-5***</b>
<b>summarized by likely duration and exposure**</b>				
<b>Duration of Use</b>				
Leave-On	3	NR	0.005-0.006	***
Rinse-Off	NR	NR	0.15	***
Diluted for (Bath) Use	NR	4	NR	***
<b>Exposure Type</b>				
Eye Area	1	NR	NR	***
Incidental Ingestion	NR	NR	NR	***
Incidental Inhalation-Spray	1 <sup>a</sup>	NR	0.006; 0.005 <sup>b</sup>	***
Incidental Inhalation-Powder	1 <sup>a</sup>	NR	NR	***
Dermal Contact	2	4	NR	***
Deodorant (underarm)	NR	NR	NR	***
Hair - Non-Coloring	1	NR	0.005 – 0.006	***
Hair-Coloring	NR	NR	0.15	***
Nail	NR	NR	NR	***
Mucous Membrane	NR	4	NR	***
Baby Products	NR	NR	NR	***
<b>as reported by product category</b>				
<b>Eye Makeup Preparations</b>				
Eyebrow Pencil	1	4	NR	***
<b>Hair Preparations (non-coloring)</b>				
Hair Spray (aerosol fixatives)	NR	NR	0.006	***
Tonics, Dressings, and Other Hair Grooming Aids	NR	NR	0.005	***
Other Hair Preparations	1	NR	NR	***
<b>Hair Coloring Preparations</b>				
Hair Dyes and Colors (all types requiring caution statements and patch tests)	NR	NR	0.15	***
<b>Skin Care Preparations</b>				
Face and Neck (exc shave)	1	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 is derived based on product category (see Use Categorization <https://www.cir-safety.org/cir-findings>)

\*\*\*at the time of the 2001 safety assessment, concentration of use data were not reported by the FDA, and an industry survey was not conducted; 1984 FDA data were used, but without specifying use category

<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.

## REFERENCES

- Andersen FA (ed.). Final report on the safety assessment of Methyl Alcohol. *Int J Toxicol*. 2001;20 Suppl 1:57-85.
- U.S. Food and Drug Administration Center for Food Safety & Applied Nutrition (CFSAN). 2022. 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, 2022; received January 11, 2022.)
- Personal Care Products Council. 2021. Concentration of Use by FDA Product Category: Methyl Alcohol. (Unpublished data submitted by Personal Care Products Council on January 12, 2022.)
- European Chemical Agency (ECHA). REACH registration dossier: Methanol (CAS No. 67-56-1). <https://echa.europa.eu/da/registration-dossier/-/registered-dossier/15569/1/1>. Last Updated: 2022. Accessed: 10/15/2022.
- Organisation for Economic Cooperation and Development (OECD) Screening Information Dataset (SIDS). OECD SIDS Initial Assessment Report: Methanol (Methyl Alcohol; CAS No. 67-56-1). 2004. <https://hpvchemicals.oecd.org/ui/handler.axd?id=f6aca735-7365-4578-986c-5a3cd5027555>. Accessed 10/08/2022.