

ICMAD

Independent Cosmetic
Manufacturers And Distributors

August 20, 2019

Ms. Meredith Williams
Acting Director
Department of Toxic Substances Control
11001 I Street
Sacramento, CA 95814-2828

Dear Ms. Williams:

Thank you for the agency's excellent work in protecting the citizens of California and taking the time to consider these remarks. I am a native of California myself and understand the need to protect our environment.

I am writing comments on behalf of over 250 small businesses in California that would be adversely affected by limiting residual trace amounts of 1-4 dioxane in cosmetics and personal care products to a level below 10ppm. With the technology available today, it is possible to manage a maximum of 10 ppm with careful formulation and increasing the cost of some raw materials. Some brands have already been able to achieve that goal but for others, especially small businesses, there remains some difficulty in reaching it.

If it is proven necessary to mandate the maximum trace amount to below 10 ppm, it is important to note that there must be development of technology to achieve that. This takes time and significant investment. There is no proof or justification that setting the level below 10ppm would result in any improvement to the environment yet it would place a crippling burden on many small companies. It would require reformulation of a significant number of products that would be very costly due to several issues including; obsolescence of existing products, necessary new product testing, and re-labeling.

For small companies with limited product distribution, the amount of 1-4 dioxane delivered to the environment is negligible with a limit of 10ppm. In addition, it is not currently technically feasible for a meaningful part of the industry, especially small and medium sized companies, to reach a level below 10 ppm. Further, it is unreasonable to assume that a safety standard should be established merely because the substance is detectable at a lower level.

Setting a limit in finished products in the parts per billion range as proposed would not increase the safety profile for finished personal care and cosmetic products beyond the 10ppm level accepted by major governments. Major governments have been aware of and tracking this question for decades. After thorough review by numerous international experts, 10 ppm has been established as the limit in finished cosmetic products for the US, Canada and EU. In addition, FDA has set a limit on 1,4-dioxane at 10 ppm as safe for cosmetic & personal care products, and ingestible products (such as dietary supplements) by approving the food additives glycerides and polyglycerides in dietary supplements. 21 CFR 172.736.

Therefore, we are requesting the agency to set the limit of residual 1-4 dioxane in cosmetics and personal care products to less than or equal 10ppm as following international convention.

Independent Cosmetic Manufacturers & Distributors, Inc.

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Thank you for taking the time to consider our comments.

Sincerely

A handwritten signature in black ink, appearing to read 'Kenneth D. Marenus', with a stylized, flowing script.

Kenneth D. Marenus Ph.D.

President

ICMAD, the Independent Cosmetic Manufacturers and Distributors, has been the voice of independent cosmetic companies around the world since 1974. Offering innovative business tools, timely publications, educational programs, networking opportunities, and key advocacy support, ICMAD provides invaluable guidance and support for all facets of the independent cosmetic industry. We can be found at www.ICMAD.org