

April 6, 2012

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Via E-Mail: coshita@oehha.ca.gov

Cynthia Oshita
Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, CA 95812

Re: Comments on Notice of Intent to List Diethanolamine ("DEA") and Cocamide DEA

Dear Ms. Oshita:

I am writing on behalf of the Personal Care Products Council (the "Council") in response to the Notice of Intent to List the chemicals Diethanolamine ("DEA") and coconut acid diethanolamine ("Cocamide DEA") published by the Office of Environmental Health Hazard Assessment ("OEHHA") on January 20, 2012 (the "Notice").¹ These proposed listings are of great concern to the Council's members, who supply a diverse range of personal care products that millions of Californians rely on every day, including cosmetics, shampoos, and soaps. Many of these contain unavoidable trace levels of DEA but are entirely safe for use by our customers.

I. INTRODUCTION

The proposed listings are based on a table published by the International Agency for Research on Cancer ("IARC"), showing Cocamide DEA and DEA as "2B" possible carcinogens. The table identified Volume 101 of the IARC monographs as the source for this classification. However, IARC has not yet published volume 101.

In February, the Council requested that OEHHA hold the public comment period open until 30 days after IARC finalizes and publishes the monographs. OEHHA was unwilling to agree to an open-ended extension. The Council understood this position and appreciated OEHHA's agreement to extend the comment period to April 6, 2012.

¹ OEHHA, Notice of Intent to List Chemicals by the Labor Code Mechanism: 4 Chemicals, available on the OEHHA website, at http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/intent_to_list/noil012012.html (visited April 4, 2012).

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Accordingly, we submit our comments today based upon the available information, but with the request set forth below.

II. DISCUSSION

A. Information in the Monograph is Needed to Assure that the Proper Chemical is Listed.

Because OEHHA's Notice is based on the Labor Code provision of Proposition 65, the notice limits the opportunity for comments to "whether IARC has identified the specific chemical or substance as a known or potential human or animal carcinogen." The Council believes that the IARC monograph may contain information relevant to this inquiry.

For example, the monograph should reveal whether and to what extent IARC relied on evidence or conclusions described in the technical reports published by the National Toxicology Program ("NTP") addressing DEA (1999) and Cocamide DEA (2001) or on NTP's conclusions about those data. As you may recall, NTP's technical report on Cocamide DEA, for example, revealed that the compound it evaluated contained 18.2 percent "free DEA" as a contaminant. Other DEA condensates that NTP tested – each of which contained lower percentages of free DEA – did not present "clear evidence" of carcinogenicity. Thus, NTP concluded that there was a "strong association" between the tumors observed in the Cocamide DEA and the free DEA in the condensate.²

If IARC agrees with NTP that free DEA is the agent involved in tumor formation, it is DEA, not Cocamide DEA, that is the substance for which there is "sufficient evidence" of carcinogenicity in animals. Unless IARC has reviewed different data or has reached vastly different conclusions than NTP about those data, separately listing Cocamide DEA makes no sense.³ At most, the listing should be qualified to reflect the actual compound that was tested by NTP: Cocamide DEA compounds containing at least 18.2% free DEA as a contaminant. This is in line with OEHHA's prior qualified listings of retinol and carbon black, and its recent Labor Code listing of titanium dioxide.

² NTP, Toxicology and Carcinogenesis Studies of Coconut Oil Acid Diethanolamine Condensate (2001), at p. 51, available at http://ntp.niehs.nih.gov/ntp/htdocs/LT_rpts/tr479.pdf (visited April 5, 2012.)

³ This is the standard established for Labor Code listings under *AFL-CIO v. Deukmejian* (1989) 212 Cal. App. 3d 425, 437.

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B. Listing Without Benefit of the Monograph Will Undermine the Statutory “Grace Period” for Determining Whether Products are Exempt from the Warning Requirement.

The contents of the IARC monograph are also important both to the Council’s members and to the public in other ways that are consistent with OEHHA’s interpretation of its authority and obligations under the Labor Code provision of Proposition 65. In particular, IARC’s conclusions concerning DEA are likely to affect the calculation of the “no significant risk level” (“NSRL”) under Proposition 65 and its implementing regulations. Cal. Health & Saf. Code § 25249.10(c); Cal. Code Regs., tit. 27 § 25703(b).

This is not a theoretical issue. In the discussions leading to this monograph, IARC was presented with certain mechanistic data that could significantly affect the risk assessment for DEA. No conclusion was reached during the public meetings, and IARC’s conclusions regarding these data will presumably be set forth in the final monograph.

Specifically, this work identifies choline deficiency as the mechanism of action behind tumors observed in the B6C3F1 mouse – a highly susceptible species and strain – in the NTP study of DEA. Because humans are much less sensitive, IARC’s conclusions regarding these data could have substantial impact on determining the appropriate warning threshold. Proposition 65 regulations dictate that the model for quantitative risk assessment should be based on “evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for listing the chemical.” Cal. Code Regs., tit. 27 § 25703(a). Because this issue was important enough to be raised and discussed by IARC, but the conclusions will be known only when the monograph is published, businesses affected by a listing will not be in a position to determine the NSRL and to develop a compliance, reformulation or warning program until the monograph is available and can be reviewed.

While this issue may not bear directly on the decision on whether to list these chemicals, the timing of a listing decision could significantly affect our members’ ability to respond. As you know, Proposition 65 allows businesses twelve months from the date a chemical is listed to determine whether their products are required to carry warnings. Cal. Health & Saf. Code § 25249.10(b). During this period, businesses must determine the appropriate 10^{-5} risk level and then determine whether their products meet that level.

For companies that manufacture hundreds or thousands of products, this process is time-consuming. Moreover, given the realities of distribution systems, labeling or reformulation decisions must be made months ahead of the date that products are actually offered for sale. Thus, lag time between listing and the availability of information needed for their assessment has a substantial impact on our members. Until they know the details of IARC’s analysis, they will be unable to determine how that evidence affects their products.

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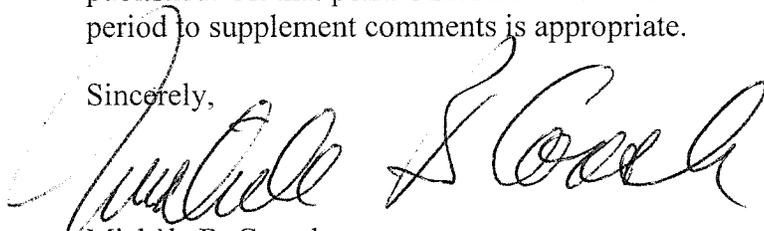
III. Conclusion

This proposed listing presents an unusual set of circumstances. First, the record indicates that the monograph will contain information that could have significant consequences to the scope and nature of the listing. Second, the need for this information is significant. Without it, our members will be unable to evaluate their own compliance with Proposition 65 and respond accordingly.

Because of the practical realities facing companies that manufacture and distribute personal care products, effectively shortening the compliance period by even one month will create a significant hardship. By contrast, waiting less than two months until the monograph is published will not create undue burdens on OEHHA or the public. In fact, doing so would avoid unnecessary post-listing amendments and could avoid unnecessary warnings for products that do not actually pose a significant risk.

For all of these reasons, the Council believes that OEHHA, our members, and the public would be best served if OEHHA would defer a listing decision until the monograph is published. At that point OEHHA can determine whether, based on its contents, a brief period to supplement comments is appropriate.

Sincerely,



Michèle B. Corash

cc: Carol Monahan-Cummings, Esq.
Director George Alexeeff