Expert Panel Finds that Formaldehyde and Methylene Glycol are Unsafe as Used in Hair Smoothing Products—CFA Applauds Decision

Consumers and Hair Care Professionals should Stop Using and Applying “Keratin-Based” Hair Smoothing Products Containing Formaldehyde and Methylene Glycol

Washington DC—The Cosmetic Ingredient Review (CIR) Expert Panel, at its 120th meeting in Washington DC, reached a final conclusion about the safety of the cosmetic ingredient formaldehyde and methylene glycol. The CIR Panel concluded that as currently used in hair smoothing products, formaldehyde and methylene glycol are unsafe, after reviewing the scientific data, hearing from “Keratin-Based” hair smoothing manufacturers, consumer and stylist complaints, and data from other governmental entities. Some consumers and stylists applying and undergoing application of the hair smoothing treatment experienced health impacts including “eye irritation, breathing problems, headaches, rashes and fainting.”

“Consumer Federation of America applauds the conclusion of the CIR Panel, which determined based upon an extensive review, that the current use of formaldehyde and methylene glycol in hair straightening products is unsafe,” said Rachel Weintraub, Director of Product Safety and Senior Counsel with Consumer Federation of America and Consumer Liaison to the CIR Panel. “This conclusion will protect consumers and stylists from unsafe formaldehyde exposure.”

The panel’s formal conclusion, regarding hair smoothing products states that “formaldehyde and methylene glycol are unsafe in the present practices of use and concentration in hair smoothing products.” CIR will also include in the discussion an explanation that hair smoothers potentially could be used safely depending on concentration of formaldehyde and methylene glycol in such products, the quantity of the product used, the temperature applied, and the ventilation provided at the point of use, but in the present practices of use in hair smoothers (i.e. concentrations in the 10% range, temperatures of 450 degrees Fahrenheit, quantity of material used, inadequacy of ventilation), these ingredients are unsafe.

The CIR was established in 1976 by the industry trade association (then the Cosmetic, Toiletry, and Fragrance Association, now the Personal Care Products Council (PCPC)), with the support of the U.S. Food and Drug Administration and the Consumer Federation of America. CIR is funded by the Council but the review process is independent from the Council and the cosmetics

industry. Senior staff from FDA, CFA, and PCPC participate as non-voting liaison members. The CIR expert panel is composed of 9 scientific experts representing the fields of dermatology, toxicology, chemistry and pharmacology.

The Food and Drug Administration, on August 22, 2011 sent a warning letter to one of the manufacturers of a keratin based hair smoothing product advising them that their product was adulterated because it contains a poisonous or deleterious material that might render it injurious to users under conditions of use and misbranded due to the inclusion of a label indicating that the product was “formaldehyde free.”

In addition, the U.S. Department of Labor's Occupational Safety and Health Administration recently issued a revised hazard alert to hair salon owners and workers about potential formaldehyde exposure from working with certain hair smoothing and straightening products.

Canada has worked to stop the sale of hair smoothing products and has warned consumers about the risks associated with these types of products. After receiving reports of adverse health impacts from consumers, Health Canada tested a number of hair smoothing products and found formaldehyde levels in excess of the 0.2% limit.

If consumers or stylists have experienced health effects while applying a “keratin based” hair smoothing products, please contact the FDA by:

1) Reporting to the nearest FDA district office. Phone numbers for their complaint coordinators are posted on FDA’s Web page, "Consumer Complaint Coordinators" and in the Blue Pages of the phone book, generally under United States Government/Health and Human Services.

2) Reporting online to FDA's MedWatch adverse event reporting system. You also may call Medwatch at 1-800-332-1088 to request a reporting form by mail.

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*Consumer Federation of America is a nonprofit association of nearly 300 consumer groups that was founded in 1968 to advance the consumer interest through research, advocacy, and education.*

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2 The Food and Drug Administration letter can be found on the web at: [http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm270809.htm](http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm270809.htm)