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Contact: Rachel Weintraub (202) 387-6121

Expert Panel Finds that Formaldehyde and Methylene Glycol are Potentially Hazardous in Hair Care Products when a Vapor Forms During Use

Consumers and Hair Care Professionals should be Cautious when Using or Applying “Keratin-Based” Hair Smoothing Products

Washington DC— On March 4, 2011, the Cosmetic Ingredient Review (CIR) Expert Panel reviewed the cosmetic ingredient formaldehyde and methylene glycol due to numerous reports of consumer reactions as a result of the application of “keratin-based” hair smoothing products.¹

Numerous press reports and reports submitted to the FDA over the last year and a half documented that 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.”² While manufacturers of the product have claimed that there is no formaldehyde in the product, testing by a variety of organizations of select products has shown levels of formaldehyde of up to 10%.³

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

¹ Health Canada tested select hair smoothing products. These include: Brazilian Keratin Treatment by Marcia Teixeira, Advanced Brazilian Keratin Treatment by Marcia Teixeira, Chocolate Extreme De-Frizzing Treatment by Marcia Teixeira, Keratin Complex Smoothing Therapy by Coppola, Global Keratin Taming System Strawberry by Global Keratin, Global Keratin Taming System with Juvexin Strawberry Resistant by Global Keratin, Global Keratin Taming System with Juvexin Strawberry Light Wave by Global Keratin, Pro-Collagen RX Keratin Treatment, I-Straight Keratin (Advanced Keratin Treatment) by IBS Beauty; and Brazilian Thermal Reconstruction by Cadiveu. These products were found to have formaldehyde limits above the 0.2% limit. Available on the web at: http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2010/2010_222-eng.php Health Canada warned about Brazilian Blowout Solution in a separate earlier release: http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2010/2010_167-eng.php.

² *Brazilian Blowout ingredients investigated*, February 16, 2011, Eye Witness News, WTHR, Cat Andersen, Available on the web at <http://www.wthr.com/story/1400882/brazilian-blowout-ingredients-investigated?clienttype=printable>.

³ Health Canada has conducted testing of numerous hair smoothing products, see footnote 1 above. In addition, Oregon OSHA, A Division of the Oregon Department of Consumer and Business Services and CROET at Oregon Health & Sciences University conducted a study of “Keratin-Based” Hair Smoothing Products and the Presence of Formaldehyde. Available on the web at http://www.orosha.org/pdf/Final_Hair_Smoothing_Report.pdf.

the Council but the review process is independent from the Council and the cosmetics industry. Senior staff from FDA and CFA participate as liaison members. The CIR expert panel is composed of 9 scientific experts representing the fields of dermatology, toxicology, chemistry and pharmacology.

The panel's conclusion clarified that while a product may not list formaldehyde in its ingredient list, it could still contain levels of formaldehyde. This is due to the fact that formaldehyde and methylene glycol "exist in an equilibrium in aqueous cosmetic formulations whenever either one is present." In hair smoothing products, formaldehyde and/or methylene glycol is applied to the hair; the hair is dried; and then heated with an iron. This process may produce formaldehyde gas.

"The CIR Panel review clarifies how formaldehyde can be formed from heating up a "keratin based" hair smoothing product and how consumers and stylists can be at risk from formaldehyde exposure during the application of this product," stated Rachel Weintraub, Director of Product Safety and Senior Counsel with Consumer Federation of America and Consumer Liaison to the CIR Panel. "We urge consumers and stylists to stop using this product until manufacturers can verify that these products do not emit dangerous levels of formaldehyde."

The Panel noted that formaldehyde is a dermal sensitizer; that nasopharyngeal cancers are produced by formaldehyde gas; and that epidemiology studies have suggested an association between exposure to formaldehyde and leukemia.

While the CIR review is not final, the Panel tentatively concluded that formaldehyde and/or methylene glycol are safe in cosmetic products when formulated to ensure use at the minimal effective concentration as a preservative, but in no case should formaldehyde equivalents exceed 0.2%. Further, CIR found that it cannot be concluded that formaldehyde and/or methylene glycol is safe in cosmetic products intended to be aerosolized or in which formaldehyde gas (vapor) will be produced under conditions of use.

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 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.

Consumer Federation of America * 1620 Eye St, NW, Suite 200 * Washington, DC 20006 * (202) 387-6121 * www.consumerfed.org