



**March 9, 2011**

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**STATEMENT BY JOHN BAILEY, CHIEF SCIENTIST  
PERSONAL CARE PRODUCTS COUNCIL  
ON  
COSMETIC INGREDIENT REVIEW (CIR) EXPERT PANEL PRELIMINARY  
FINDINGS ON SAFETY OF TWO INGREDIENTS USED IN PROFESSIONAL HAIR  
SMOOTHING PRODUCTS**

***BACKGROUND:** On March 4, 2011, the Cosmetic Ingredient Review (CIR) Expert Panel, an independent, non-profit body of scientific and medical experts that assesses the safety of ingredients used in cosmetics in the U.S., reached a tentative conclusion on the safety of formaldehyde and methylene glycol as they are used in cosmetics and in “professional use only” hair straightening and smoothing products.*

*The Panel reaffirmed its 2005 conclusion that formaldehyde/methylene glycol are safe in cosmetic products when formulated to ensure use at the minimal effective concentration and reiterated that amounts used in formulations should not exceed 0.2 percent measured as free formaldehyde.*

*However, the panel said it could not conclude” that formaldehyde/methylene glycol is safe in cosmetic products intended to be aerosolized or in which formaldehyde/methylene glycol vapor or gas will be produced under conditions of use.”*

*When hair smoothing products that contain these ingredients are heated, they can release low levels of formaldehyde gas. Formaldehyde and methylene glycol are sensitizing agents, and consumers or salon workers may experience allergic reactions if they become sensitized. Various studies also have indicated a link to cancer in humans when inhaled chronically over a long period of time.*

*The Panel did not evaluate any potential mitigating effects of ventilation in salons in which the treatments are given.*

*The Panel did not reach a conclusion on the safety of nail builder products. In order to do so, the CIR has requested additional information from nail manufacturers, which they have agreed to provide. The industry is not aware of any studies alleging adverse effects from the use of these ingredients in nail builder products. FDA’s policy on the safe use of formaldehyde in nail hardeners may be found at: <http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074952.htm>.*

**(MORE)**

## **ADD ONE/ CIR PRELIMINARY FINDINGS ON TWO INGREDIENTS IN PROFESSIONAL HAIR SMOOTHING PRODUCTS**

*For tentative CIR safety assessments, interested persons are given 60 days to comment, provide information, and/or request an oral hearing before the CIR Expert Panel. Information may be submitted without identifying the source or the trade name of the cosmetic product containing the ingredient. All unpublished data submitted to CIR will be discussed in open meetings, posted on the CIR Web site, and are available at the CIR office for review. Data on this tentative review should be submitted as soon as possible but no later than May 20, 2011. The next CIR Expert Panel meeting will be held June 27-28, 2011.*

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### **STATEMENT:**

“The Personal Care Products Council (PCPC) joined FDA and consumer groups several months ago in requesting that CIR review the safety of formaldehyde/methylene glycol as they are used in professional hair straightening and smoothing products, and we support these tentative findings of the CIR Expert Panel. Until the review is completed and regulatory authorities have had the opportunity to assess it and come to their own conclusions, we urge consumers to exercise caution in using these products.

“Safe and proper use depends largely on the ventilation in the salon and the application procedure. For this reason, we strongly advise consumers and beauticians not to use professional hair straightening products in the home. Consumers who do visit a salon to receive hair-smoothing treatments by a trained salon worker should be certain that the salon is properly ventilated and that the products and application process meet the safety guidelines set by the U.S. Occupational Safety and Health Administration (OSHA), which is responsible for regulating workplace safety. OSHA has established limits for safe levels of inhalation exposure to formaldehyde gas.

“We urge FDA to work expeditiously with OSHA and appropriate state and local organizations to objectively determine if salon hair smoothing products emit levels of formaldehyde gas that are unsafe for consumers or salon workers under their intended conditions of use and taking into consideration salon ventilation practices. We recommend FDA take prompt and appropriate action to make sure these products have been fully tested and substantiated for safety under their conditions of use.

“Consumers should report any adverse reactions from use of these products to FDA. For more information on this important consumer health issue, visit the FDA website at:  
<http://www.fda.gov/Cosmetics/ProductandIngredientSafety/ProductInformation/ucm228898.htm>.”

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For more information on cosmetic and personal care products, please visit [www.CosmeticsInfo.org](http://www.CosmeticsInfo.org).”

Based in Washington, D.C., the Personal Care Products Council is the leading national trade association representing the global cosmetic and personal care products industry. Founded in 1894, the Council's more than 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the U.S. As the makers of a diverse range of products millions of consumers rely on everyday, from sunscreens, toothpaste and shampoo to moisturizer, lipstick and fragrance, personal care products companies are global leaders committed to product safety, quality and innovation.