



CANADIAN COSMETIC, TOILETRY  
AND FRAGRANCE ASSOCIATION

ASSOCIATION CANADIENNE DES COSMÉTIQUES,  
PRODUITS DE TOILETTE ET PARFUMS

## **STATEMENT**

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### **Activist Group Allegations About Safety of Children's Bath Products False**

On Thursday, March 12, 2009, a report was released in Washington, DC, by the U.S. based "Campaign for Safe Cosmetics (CSC)" making false allegations that certain baby care products were contaminated with formaldehyde and 1,4 dioxane ("CSC Report").

The allegations refer to the presence of formaldehyde and 1,4 dioxane which they found in certain personal care products for children. The CSC alleges that 23 out of 28 the products which they selected and tested contained formaldehyde at levels ranging from 54 to 610 parts per million (ppm). The levels of 1,4 dioxane found in 32 of 48 products ranged from 0.27 to 33 ppm.

#### **Formaldehyde in personal care products**

Formaldehyde is a simple compound consisting of hydrogen, oxygen and carbon. It occurs naturally in the air we breathe and is even part of the human metabolism. Plants and animals also produce formaldehyde.

Today, formaldehyde and formaldehyde-releasing preservatives are ingredients used to help ensure the safety of products by protecting them from harmful contamination by microorganisms during storage and use. Exposure to formaldehyde through personal care products is generally extremely low. Since all cosmetics in Canada must display a list of ingredients, either formaldehyde or a formaldehyde-releasing ingredient (such as Quaternium-15, DMDM hydantoin, or diazolidinyl urea for example), must appear on the product ingredient list. The European Union lists 10 different formaldehyde releasers acceptable for use in cosmetics.

The Cosmetic Ingredient Review (CIR) Panel, an independent panel of scientific and medical experts who assess the safety of ingredients used in the U.S. cosmetic and personal care products, concluded that formaldehyde in cosmetics and personal care products is safe and should not exceed levels of 0.2% (2,000 ppm).

In Canada, formaldehyde is listed on the Cosmetic Ingredient Hotlist. The Hotlist refers to ingredients that are permitted for use with certain restrictions or cannot be used at all as ingredients in personal care products. Formaldehyde is listed as a permitted ingredient in personal care products at a maximum concentration that does not exceed 0.2% or 2,000 ppm. For oral care products the limit is 0.1% or 1,000 ppm, and for nail hardeners the limit is 5.0% or 50,000 ppm.

The FDA and the European Union have similar regulations that allow formaldehyde in cosmetic and personal care products at maximum levels of 2,000 ppm.

It is important to note that all the levels allegedly found of formaldehyde in the CSC report (54 to 610 ppm) are far below this 2,000 ppm safety threshold.

#### **1,4 dioxane in personal care products**

1,4 dioxane is a byproduct that can form in trace or miniscule amounts during the manufacturing process for ingredients that help to ensure the mildness of some personal care products including shampoo and bubble bath. It is not an ingredient that is intentionally added. Raw material manufacturers routinely take necessary steps to reduce its presence to the lowest feasible levels.



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Health Canada has included 1,4 dioxane on the Hotlist as an *ingredient* not permitted for use in cosmetics. Since 1,4 dioxane is not added as an actual ingredient in cosmetics, but rather may appear as a byproduct, Health Canada has advised that it has examined the USP (United States Pharmacopeia) limit for residual solvents permitted in drugs for guidance for an acceptable safety threshold. In the USP, the limit for 1,4 dioxane is 380 ppm. The 0.27 to 33 ppm of 1,4 dioxane quoted in the CSC study falls well below (less than 10%) of this limit -- which is set for the higher risk category of drug products versus topically applied cosmetics.

The FDA has stated that 1,4 dioxane levels found in their monitoring of personal care products “do not present a hazard to consumers.”

### **Summary**

The children’s personal care products listed in the CSC Report of March 12, 2009 are safe as they meet all requirements set by Health Canada, whose mandate is to protect the health and well-being of Canadians. This conclusion is based on comparing the levels of both formaldehyde and 1,4 dioxane stated in the CSC Report against established safety thresholds that have been set based on a sound scientific review by regulatory authorities in not only Canada, but also the European Union and the United States.

The CCTFA is the leading Canadian industry association for the personal care products sector in Canada. Its member companies are at the forefront of a \$5.4 billion (retail) industry in Canada and with more than 160 members, the CCTFA acts as the principal voice of the personal care products industry -- which includes cosmetics, cosmetic-like drugs and natural health products.

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