

## **Parents can use baby care products with confidence: Latest US activist group claims are baseless**

The Australian cosmetic and personal care products industry places the highest regard on the safety and environmental performance of its products.

Our industry's products are regulated for public health and safety by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the Federal Health Department.

These government bodies independently assess the safety of ingredients in cosmetics and other personal care products, like baby care products.

Our industry fully supports the strong, independent and expert regulatory system in operation in Australia. The protection of public health is the centrepiece of Australia's regulations.

Both NICNAS and the Federal Health Department have a watching brief to assess any new studies, reports or activist group allegations. This includes recent unfounded allegations being made in the US media by the political activist group Campaign for Safe Cosmetics.

The Australian industry immediately alerted NICNAS to these latest allegations and the US industry has responded with a detailed scientific assessment that shows these allegations are baseless.

The two chemicals mentioned in the allegations – formaldehyde and 1,4-dioxane – have both been subject to comprehensive safety assessment by NICNAS in the agency's Priority Existing Chemical Review program ([www.nicnas.gov.au](http://www.nicnas.gov.au)).

Commenting specifically on the US claims, the US Personal Care Products Council concludes:

"The levels of the two chemicals the group reportedly found are considered to be "trace" or extremely low, are well below established regulatory limits or safety thresholds, and are not a cause for health concern.

When present, these chemicals would likely be found at very low levels precisely because companies have gone to great lengths in the formulation and manufacturing processes to ensure that the products are safe and gentle for children and also protected from harmful bacterial growth."

*(A copy of the full US industry statement is attached).*

This politically motivated US anti-cosmetic campaign raises no concerns for the health and safety of Australian consumers.

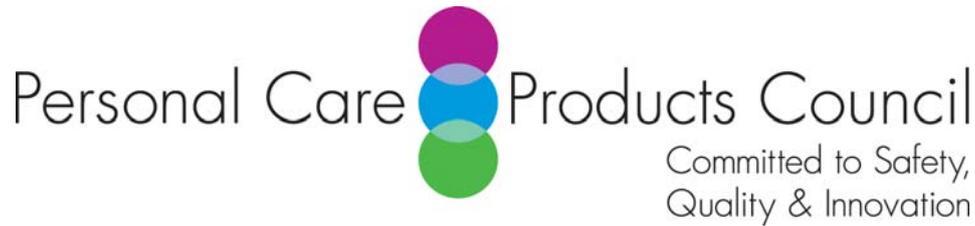
Baby care products are specially formulated for both mildness and safety.

Parents can continue to use baby care products with confidence and in the knowledge that they are safe when used in accordance with the directions on the product label.

Media contact – Craig Brock, 0422 363 646

20 March 2009

- ends -



**FOR IMMEDIATE RELEASE**

**March 11, 2009**

**Contact: Kathleen Dezio, 202/454-0302 or Lisa Powers, 202/466-0489**

**ACTIVIST GROUP ALLEGATIONS ABOUT BABY CARE PRODUCTS FALSE;  
PRODUCTS MEET ESTABLISHED SAFETY STANDARDS**

**WASHINGTON, DC--**Allegations made today that commonly used baby products are somehow contaminated with harmful levels of carcinogenic chemicals are patently false and a shameful and cynical attempt by an activist group to incite and prey upon parental worries and concerns in order to push a political, legislative and legal agenda.

The allegations about the presence of 1,4 dioxane and formaldehyde in personal care products were made in a report to be released March 12, 2009, by the Campaign for Safe Cosmetics (CSC). The levels of the two chemicals the group reportedly found are considered to be "trace" or extremely low, are well below established regulatory limits or safety thresholds, and are not a cause for health concern. When present, these chemicals would likely be found at very low levels precisely because companies have gone to great lengths in the formulation and manufacturing processes to ensure that the products are safe and gentle for children and also protected from harmful bacterial growth.

"Contrary to their attempt to position this report as something new and scientifically noteworthy, there is nothing revelatory or scientifically objective in it," said Dr. John Bailey, chief scientist for the Personal Care Products Council. "The U.S. Food & Drug Administration (FDA), the Cosmetic Ingredient Review (CIR), an independent panel of scientific and medical experts who assess the safety of ingredients used in U.S. cosmetic and personal care products, and other authoritative bodies throughout the world have long been aware of the potential presence of 1,4 dioxane and formaldehyde in personal care products and found them to be safe when present at low levels."

The report is one of many the group has issued in the last several years attacking different preservatives and other chemicals used in personal care products and cosmetics, misrepresenting the science behind the products and their safety, and grossly distorting the facts about how the products are regulated in the U.S. and around the world. Although it is customary for authors of studies to include a detailed explanation of their methodology, such a discussion was absent from the CSC report. This is particularly important for formaldehyde because the process for accurately determining and measuring its presence is a highly complex procedure that must be correctly performed.

**(MORE)**

## **BABY PRODUCTS/ADD ONE**

### **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 mildness of some personal care products such as shampoo and bubble bath. The presence of 1,4 dioxane can be controlled and minimized, and raw material manufacturers routinely take necessary steps to reduce its presence to the lowest feasible levels. The extremely low levels of 1,4 dioxane reported by CSC likely reflect efforts by manufacturers to control the levels of this contaminant through proper selection of raw materials and quality control of finished products.

FDA has monitored 1,4 dioxane in cosmetic and personal care products since the 1970s by assessing products and raw materials using sophisticated analytical methods. The levels at which any substance would be considered harmful in a cosmetic or personal care product depends on the conditions of use and exposure. FDA has stated that the 1,4 dioxane levels found in their monitoring of personal care products and cosmetics "do not present a hazard to consumers."

FDA's statement about 1,4 dioxane in personal care products may be found at:  
<http://www.cfsan.fda.gov/~dms/cosdiox.html>.

### **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, and it is released as a byproduct of certain vegetables, such as Brussels sprouts and cabbage, when they are cooked.

Historically, formaldehyde was first used as a biological preservative more than a century ago. Today, formaldehyde-releasing preservatives are ingredients that help to ensure the safety of products by protecting them from harmful contamination by microorganisms during storage and during continued use by consumers. These preservatives have the ability to replace used-up formaldehyde by releasing it in very small amounts over time as needed. The use of formaldehyde-releasing preservatives ensures that the actual level of free formaldehyde in the product remains very low but sufficient enough to prevent or eliminate bacterial growth. Exposures to formaldehyde through personal care products are generally extremely low.

The CIR Expert Panel concluded that formaldehyde in cosmetics and personal care products is safe and should not exceed 0.2 percent (2,000 ppm) when measured as free formaldehyde.

Likewise, the European Union's Cosmetic Directive allows use of formaldehyde in cosmetic and personal care products at a maximum concentration of 0.2 percent or 2,000 ppm (free formaldehyde). The EU Cosmetics Directive may be found at:  
[http://ec.europa.eu/enterprise/cosmetics/html/consolidated\\_dir.htm](http://ec.europa.eu/enterprise/cosmetics/html/consolidated_dir.htm)

(MORE)

## **BABY PRODUCTS/ADD TWO**

The FDA regulation for formaldehyde may be found at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=173.340&SearchTerm=formaldehyde>

All of the levels allegedly found in the report are far below this 0.2 percent (or 2,000 ppm) safety threshold.

### **FDA Regulatory Authority**

Under the Food, Drug, and Cosmetic Act (FD&C), companies must substantiate the safety of all ingredients and products *before* they are marketed. The Act requires that labeling be truthful and not misleading. The laws give FDA broad legal authority to regulate cosmetic and personal care products and provides severe penalties for the manufacturers of products that do not meet these standards, including fines, seizures, bans and prosecution.

“Cosmetic and personal care product companies take their commitment to safety and their responsibilities under the law very seriously and work hard to earn and keep the trust of consumers and their families,” Bailey said. “Parents should be given complete and accurate information about their products based on sound science rather than on incomplete and alarmist reports.”

For more information on cosmetic and personal care products and their ingredients, 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 \$250 billion 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.