

Baby's Tub Is Still Toxic

Two years after public outrage about cancer-causing chemicals in baby shampoo, America's leading baby shampoo is caught in a double standard.



The Campaign for Safe Cosmetics

www.SafeCosmetics.org



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About the Campaign for Safe Cosmetics

The Campaign for Safe Cosmetics is a national coalition of nonprofit women's, environmental, public health, faith and worker safety organizations. Our goal is to protect the health of consumers and workers by securing the corporate, regulatory and legislative reforms necessary to eliminate dangerous chemicals from cosmetics and personal care products.

Core partners include the Alliance for a Healthy Tomorrow (represented by Clean Water Action and Massachusetts Breast Cancer Coalition), the Breast Cancer Fund, Commonweal, Environmental Working Group, Friends of the Earth and Women's Voices for the Earth. The Breast Cancer Fund, a national 501(c)(3) organization focused on preventing breast cancer by identifying and eliminating the environmental links to the disease, serves as the national coordinator for the Campaign for Safe Cosmetics.

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Overview

November 1, 2011—More than two years after leading health and parents' groups asked Johnson & Johnson (NYSE: JNJ) to reformulate its flagship baby shampoo to remove a cancer-causing chemical,¹ the company is still putting the formaldehyde-releasing preservative quaternium-15 into baby shampoo sold in the United States, Canada, China, Indonesia and Australia, while Johnson's Baby Shampoo formulas sold in Denmark, Finland, Japan, the Netherlands, Norway, South Africa, Sweden and the U.K. contain non-formaldehyde preservatives, according to a new analysis conducted by the Campaign for Safe Cosmetics.

This double standard for American consumers seems especially ironic given a recent Forbes survey that showed Johnson & Johnson to be the most trusted corporate brand in America.²



Between July and October of 2011, the Campaign for Safe Cosmetics purchased and reviewed labels of Johnson's Baby Shampoo sold in 13 countries to see if the products contained quaternium-15, a chemical preservative that kills bacteria by releasing formaldehyde.

Formaldehyde was recently added to the U.S. government list of known human carcinogens by the Department of Health and Human Services.³ Formaldehyde and quaternium-15 are also potent allergens that can trigger rashes and other skin inflammation problems.⁴

The analysis reveals that Johnson's Baby Shampoo sold in the United States, Australia, Canada, China and Indonesia contains quaternium-15, while Johnson's Baby Shampoo sold in Denmark, Finland, Japan, the Netherlands, Norway, South Africa, Sweden and the U.K. contain non-formaldehyde preservatives.

Leading health and environmental groups in the United States have sent letters and met with Johnson & Johnson executives several times over the past two and a half years to urge the company to reformulate its baby products to remove chemicals of concern, including quaternium-15.⁵

The dialogue began in 2009 after a report by the Campaign for Safe Cosmetics revealed that Johnson's Baby Shampoo, along with many other children's bath products, contained two carcinogens—

formaldehyde and 1,4-dioxane—that were not listed on labels.⁶

In May 2009, more than 40 organizations representing 1.7 million parents, health care providers and environmental health advocates wrote to Johnson & Johnson, detailing their concerns about the toxic chemicals found in the company’s baby products. The letter was signed by the American Nurses Association, Physicians for Social Responsibility, the National Association of Pediatric Nurse Practitioners, MomsRising and many other groups.⁷

In September 2009, the Campaign for Safe Cosmetics wrote again to Johnson & Johnson, asking the company to immediately remove the formaldehyde-releasing preservative quaternium-15 from its baby products in light of new research linking the chemical to increased rates of allergic contact dermatitis.⁸

The American Nurses Association and the Campaign for Safe Cosmetics have since met several times with Johnson & Johnson executives to discuss these concerns. In response to growing consumer demand for safer alternatives, the company launched a new “natural” version of baby shampoo that does not contain chemicals associated

with formaldehyde or 1,4-dioxane. However, the original Johnson’s Baby Shampoo, which is priced at about one-half the cost of the new “natural” shampoo, has not been reformulated in the U.S. or other markets.

In light of the new information that Johnson & Johnson is already successfully using non-formaldehyde preservatives in other baby products and in other countries, the Campaign for Safe Cosmetics and allies are urging the public to express their concerns to the company and to not buy Johnson & Johnson products until the company agrees to remove formaldehyde-releasing chemicals from all its baby products sold in all markets around the world.

On October 31, 2011, the Campaign for Safe Cosmetics, American Nurses Association, Physicians for Social Responsibility and many other health and parents' groups delivered another letter to Johnson & Johnson asking the company to immediately remove formaldehyde-releasing chemicals from all its children’s products in all markets worldwide. The letter asked for the company to make a commitment by November 15, 2011.⁹

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The Double Standard: Different Chemicals in Different Countries

For this analysis, the Campaign for Safe Cosmetics worked with allies around the world between July and October of 2011 to purchase and/or analyze labels of Johnson's Baby Shampoo.

All the products analyzed for this project were baby shampoos made by Johnson & Johnson marketed with the slogan "no more tears." Products purchased in the Netherlands and Sweden are marketed under the name Natusan.



Baby shampoo purchased in the following countries contained the formaldehyde-releasing preservative quaternium-15:

Australia
Canada
China
Indonesia
United States

Baby shampoo purchased in the following countries did not contain quaternium-15:

Japan
Netherlands*
South Africa
Sweden
United Kingdom
Johnson's Natural Baby Shampoo purchased in the U.S.

*Products sold in Denmark, Norway and Finland use the same formulation as the Johnson's baby shampoo purchased in the Netherlands.



The Problem with Quaternium-15

Quaternium-15 is a chemical preservative that kills bacteria by releasing formaldehyde. In March 2009, the Campaign for Safe Cosmetics commissioned an independent laboratory to analyze dozens of top-selling children's bath and shampoo products. As part of that analysis, the lab tested two samples of Johnson's Baby Shampoo and found formaldehyde in the products at levels of 200 and 210 parts per million.¹⁰

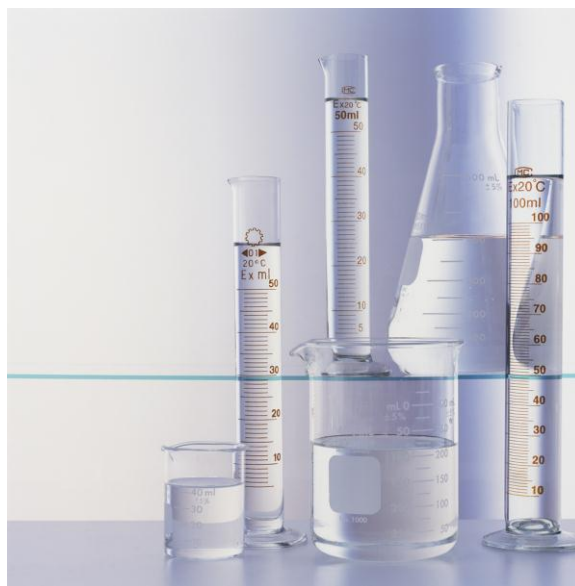
Formaldehyde is a known carcinogen. In June of 2011, after years of delay because of pressure from the chemical industry, the U.S. Department of Health and Human Services added formaldehyde to its list of known human carcinogens.¹¹ The International Agency for Research on Cancer has identified it as a known human carcinogen. Recently, the National Academy of Sciences confirmed the Environmental Protection Agency's determination that formaldehyde causes cancer in humans.¹² The National Cancer Institute, the World Health Organization and the National Toxicology Program have all identified a possible link between formaldehyde exposure and leukemia.^{13,14,15}

Formaldehyde in cosmetics is also widely understood to cause allergic skin reactions

and rashes in some people.^{16, 17, 18} Although concentrations of formaldehyde in personal care products are generally low, for people who are sensitive, everyday products can contain enough formaldehyde to trigger a reaction.^{19, 20}

Formaldehyde sensitivity may not appear at the first exposure. Rather, with each additional exposure, a person may become more likely to develop a sensitivity to formaldehyde.²¹ To help prevent developing formaldehyde allergies, contact dermatitis specialists recommend that children avoid exposure to products containing formaldehyde.²²

Quaternium-15 itself is also a sensitizing chemical that can trigger allergic reactions. According to a peer-reviewed paper in the *Journal of the Dermatology Nurses' Association*, quaternium-15 is "the most sensitizing formaldehyde-releasing preservative and has been repeatedly shown to be a strong allergen that can cause contact dermatitis." The North American Contact Dermatitis Group considers quaternium-15 to be among the most clinically significant contact allergens in children.²³



Other Formaldehyde-Releasing Preservatives

While quaternium-15 is the formaldehyde-releasing preservative used in Johnson's Baby Shampoo, a variety of other formaldehyde-releasing preservatives are found in many other personal care products, including children's products. The Campaign for Safe Cosmetics recommends avoiding all formaldehyde-releasing preservatives. These include DMDM hydantoin, 2-bromo-2-nitropropane-1,3 diol (Bronopol), imidazolidinyl urea, diazolidinyl urea and sodium hydroxymethylglycinate.²⁴



Alternatives to Quaternium-15

In order to prevent contamination and spoilage in cosmetics and body care products, it is important for products to contain preservatives. However, it is not necessary for preservatives to contain or release formaldehyde. A range of effective non-formaldehyde preservatives are available for use in cosmetics and bath products.

As the Campaign for Safe Cosmetics analysis shows, Johnson & Johnson is using various

preservatives in different markets, including many non-formaldehyde preservatives that appear to work just as well as quaternium-15. The scores and concerns in the table below are based on the data sets currently available in the Environmental Working Group's Skin Deep cosmetics database. In order to understand the full breadth of concerns, the government needs to conduct a full toxicological review of these chemicals.

Formaldehyde is a known carcinogen. In June of 2011, after years of delay because of pressure from the chemical industry, the U.S. Department of Health and Human Services added formaldehyde to its list of known human carcinogens.

**The following preservatives were found in
Johnson's Baby Shampoos purchased in 13 countries:**

Preservative	Countries in Which Preservative Is Used	Formaldehyde Releaser?	EWG's Skin Deep Cosmetics Database Score ²⁵ (scale of 0-10; 10 = highest hazard)	Concerns ²⁶
Quaternium-15	Australia Canada China Indonesia United States	Yes	Quaternium-15: 6 Formaldehyde: 10	<p>Quaternium-15: <i>Moderate Concerns:</i> Allergies and immunotoxicity, Organ system toxicity (non-reproductive); formaldehyde-releasing preservative</p> <p>Formaldehyde: <i>High Concerns:</i> Cancer; Organ system toxicity (non-reproductive); Occupational hazards</p> <p><i>Moderate Concerns:</i> Allergies & immunotoxicity; Irritation (skin, eyes, or lungs); Biochemical or cellular level changes</p>
Benzyl Alcohol (aka phenylcarbinol)	Australia China Indonesia	No	6	<p><i>High Concern:</i> Occupational Hazard</p> <p><i>Moderate Concerns:</i> Neurotoxicity, Organ system toxicity (non-reproductive)</p>

Methylchloroisothiazolinone	Japan	No	6	<i>Moderate Concern:</i> Allergies & immunotoxicity
Methylisothiazolinone	Japan	No	6	<i>Moderate Concern:</i> Allergies & immunotoxicity <i>Low Concern:</i> May be neurotoxic
Potassium Sorbate	Denmark Finland Netherlands Norway Sweden	No	3	<i>Moderate Concerns:</i> Organ system toxicity; Allergies & immunotoxicity
Sodium Benzoate	Denmark Finland Netherlands Norway South Africa Sweden United Kingdom Also in Johnson's Natural Baby Shampoo purchased in the U.S.	No	1	<i>Moderate Concern:</i> Limited evidence of sense organ toxicity

In countries around the world, including Japan, South Africa and the Netherlands, whether required by law or not, Johnson & Johnson has moved away from formaldehyde releasers, while the company continues to use these problematic preservatives in the U.S., Canada, China and other markets. . .there's no reason it can't make this shift globally.

Regulatory Standards and Reformulation

In the United States there are no restrictions on the levels of formaldehyde allowed in any body care products, no requirement to test products made with formaldehyde-releasing preservatives for possible formaldehyde contamination, and no obligation to include formaldehyde on the ingredient label when it occurs as a contaminant. Sweden and Japan have banned formaldehyde in cosmetics and toiletries.²⁷

In countries around the world, including Japan, South Africa and the Netherlands, whether required by law or not, Johnson & Johnson has moved away from formaldehyde releasers, while the company

continues to use these problematic preservatives in the U.S., Canada, China and other markets. It is clear that the company is responding to regulatory as well as market pressure and there's no reason it can't make this shift globally.



Concerns About 1,4-Dioxane Contamination

In the 2009 report, “No More Toxic Tub,” the Campaign for Safe Cosmetics also reported finding 1,4-dioxane in several products made by Johnson & Johnson, including Johnson’s Baby Shampoo, Johnson’s Oatmeal Baby Wash, Johnson’s Moisture Care Baby Wash and Aveeno Baby Soothing Relief Creamy Wash.²⁸

1,4-dioxane is widely recognized as a carcinogen in animal studies. The federal Consumer Product Safety Commission reports that “the presence of 1,4-dioxane, even as a trace contaminant, is cause for concern.”²⁹

1,4-dioxane occurs as a byproduct of the chemical process of ethoxylation, during

which various chemicals are processed with ethylene oxide to make them more soluble and, in the case of personal care products, to make them gentler on people’s skin.

Common ingredients that are likely to be contaminated with 1,4-dioxane include sodium laureth sulfate, cetareth-20, PEG-100 stearate, polyethylene and other chemicals beginning with “PEG-“ or ending with the suffix “eth.”³⁰

All of the versions of Johnson’s Baby Shampoo analyzed in the 13 countries contained ethoxylated chemicals that are likely to be contaminated with 1,4-dioxane except for the *Johnson’s Naturals* baby shampoo for sale in the U.S.

The Need for Reform

The widespread presence of contaminants in children's bath products further illustrates the need to strengthen federal oversight and regulation of the cosmetic industry.

1. **Products we put on our bodies, and especially products marketed for babies and children, should not contain chemicals that pose potential health risks.** Yet, in the United States, it is perfectly legal for personal care products to contain carcinogens and other toxic chemicals that are linked to harmful health effects.

The United States lags behind many other parts of the world in safety standards for personal care products. The European Union has banned more than 1,100 chemicals from cosmetics because they are known or highly suspected of causing cancer, genetic mutation or reproductive harm. In contrast, the United States bans or restricts only 11 chemicals from cosmetics.³¹

According to the U.S. Food and Drug Administration, "FDA's legal authority over cosmetics is different from other products regulated by the agency Cosmetic products and ingredients are not subject to FDA premarket approval authority, with the exception of color additives."³²

2. **Consumers have a right to know what is in the products they buy, yet loopholes in labeling laws exempt companies from disclosing all the ingredients in personal care products.** Companies are not required to list contaminants in the ingredients, and none of the products analyzed for this report included 1,4-dioxane or formaldehyde on the label. Companies are also not required to list the ingredients in "fragrance," which can include hundreds of additional chemicals in a single product. It is almost impossible for the average shopper to know whether a product contains hazardous chemicals without doing his or her own extensive research or sending products to a lab for analysis.
3. **Special protections are needed for the most vulnerable: babies and children.** Yet there are currently no requirements for cosmetics companies to conduct safety assessments of the chemicals they use, or to understand the unique risks to developing children. The fact that so many of the baby products we analyzed in 2009 and in 2011 are likely to contain known carcinogens demonstrates the need for mandatory safety assessment of cosmetics ingredients before they end up in consumer products. Babies and children are more vulnerable to chemical exposure than adults. The next generation deserves the healthiest possible foundation from which to start their lives.

Giving the Beauty Industry a Makeover

1. **We need to tell Johnson & Johnson that this double standard is unacceptable and we know it can do better.** Every baby—regardless of where she or he lives—should be protected from unnecessary exposure to carcinogens. Join the Campaign for Safe Cosmetics and ask that Johnson & Johnson immediately remove formaldehyde-releasing preservatives from all of its baby products sold in all countries, and replace them with ingredients that are safe for short-term and long-term use. Learn more and take action at www.safecosmetics.org.

2. **Vote with your dollar: Until Johnson & Johnson commits to making safer baby products for all babies, purchase products from companies making safer alternatives.** Search the Environmental Working Group's Skin Deep cosmetic database at www.cosmeticsdatabase.com to find safer products and learn about harmful ingredients in personal care products.

3. **Please help us spread the word!** We need your help in calling on all consumers and hospitals to stop buying Johnson's Baby Shampoo until the company removes formaldehyde-releasing chemicals from all its baby products sold all



around the world. Ask your friends, family and colleagues to help demand safer personal care products. Please share this report and our action alert via Facebook, Twitter and email. You can also direct friends and family to our online report at www.safecosmetics.org/tubstilltoxic.

4. **Contact your U.S. Representative and urge him or her to support the Safe Cosmetics Act of 2011,** federal legislation that would give the FDA the authority and resources it needs to strengthen federal oversight and regulation of the cosmetics industry to ensure cosmetic safety. Take action at www.safecosmetics.org/sca.

5. **Contact your governor, federal and state legislators and candidates** running for public office and ask them to support more effective regulations of chemicals, including those in personal care products.

6. **Write a letter to the editor of your local paper or post a blog** about this report and the lack of FDA oversight of the personal care products industry. Visit www.safecosmetics.org for more information (check out the FAQs about the Campaign, and our Get Involved section).

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