

# The Campaign for Safe Cosmetics

[www.SafeCosmetics.org](http://www.SafeCosmetics.org)



Steering Committee	January 11, 2010
Alliance for a Healthy Tomorrow	Linda Katz, M.D., M.P.H., Director Office of Cosmetics and Colors U. S. Food and Drug Administration Center for Food Safety and Applied Nutrition Harvey W. Wiley Federal Building 5100 Paint Branch Parkway College Park, MD 20740-3835
Breast Cancer Fund	
Commonweal	Dear Dr. Katz,
Environmental Working Group	We were pleased to see that in November 2009, the Office of Cosmetics and Colors (OCC) posted online the test results, including brand names, of the lipsticks purchased by the OCC in 2007 and found to contain lead. In light of the OCC's analysis, we remain very concerned about the health risks of lead-containing lipstick, a product used by millions of women of childbearing age who are unaware that they may be exposing themselves to lead each time they apply lipstick.
Friends of The Earth	
Massachusetts Clean Water Fund	Many experts agree that there is no safe blood level of lead for children and pregnant women. Lead is a proven neurotoxin that can cause learning, language and behavioral problems such as lowered IQ, reduced school performance and increased aggression.
Massachusetts Breast Cancer Coalition	The U.S. Centers for Disease Control and Prevention states that "no safe blood lead level has been identified," and the agency recommends avoiding the use of lead-containing cosmetics on children. However, any mother of a young girl will tell you, it's impossible to keep her daughter away from her lipstick. Pregnant women are also particularly vulnerable to lead exposure, because lead easily crosses the placenta and enters the fetal brain where it can interfere with normal development.
Women's Voices for the Earth	Lead builds up in the body over time and exposures to lead-containing lipstick applied several times a day, every day, can add up to harm. While we understand that lipstick is unlikely to be the largest source of lead exposure in a woman's daily life, it is a completely unnecessary additional exposure. Therefore, in the interest of public health, we urge the Office of Cosmetics and Colors to take action to reduce the amount of lead in lipstick.
	We believe that the Office of Cosmetics and Colors shares our goal of ensuring that cosmetics sold in America are as safe as they can possibly be. However, we are concerned about statements on the OCC's web page entitled, "Lipstick and Lead: Questions and Answers." <a href="http://www.fda.gov/Cosmetics/ProductandIngredientSafety/ProductInformation/ucm137224.htm">http://www.fda.gov/Cosmetics/ProductandIngredientSafety/ProductInformation/ucm137224.htm</a>
	We have the following questions and concerns:
	1. This web page states: "Is there a safety concern about the lead found by FDA in lipsticks? No. FDA has assessed the potential for harm to consumers from use of lipstick containing lead at the levels found in its testing."

FDA has not, to our knowledge, conducted a formal safety assessment of lead in lipstick, nor has the agency publicly released any data or analysis to explain the agency's position that there is no safety concern about lead in lipstick. Upon what assessment or reasoning did FDA base its opinion that lead in lipstick is safe?

2. This web page states: "Lipstick, as a product intended for topical use, is only ingested incidentally and in very small quantities."

We have searched the literature and have found no scientific studies that examine the amount of lipstick ingested into the body with the routine use of lipstick. Upon what research did FDA base its statement that lipstick is ingested only in very small quantities?

3. FDA notes on this web page that "the lead levels that it found are lower than limits recommended by other public health authorities for lead in cosmetics, including lipstick." FDA cites Health Canada's Draft Guidance on Heavy Metal Impurities in Cosmetics and a ruling based on California's Proposition 65 law.

Our concerns about this statement are as follows:

- a. The Health Canada guidance is in draft form and should not be used as a standard by the U.S. FDA since it is not aimed at reducing lead in cosmetics to the lowest levels possible.
  - b. The California Proposition 65 law is intended to provide warnings about carcinogens, reproductive toxicants and mutagens, but it does not consider the science on neurotoxicity. Since the concerns about low-level lead exposures are based on the neurotoxic effects, which is not considered in Prop. 65 rulings, the rulings cannot be used to determine a reliable "safe harbor" level for lead in cosmetics.
4. The Campaign for Safe Cosmetics has repeatedly stated that the lead found in lipstick far exceeds the FDA's recommended limit of lead in candy of 0.1 ppm. FDA states that this comparison is unfair and "not scientifically valid."

The statement is a mischaracterization of our position; the Campaign for Safe Cosmetics is making a comparison between lipstick and candy based on FDA's own logic for the candy limit. FDA recommends a maximum allowable lead level of 0.1 ppm in candy not because that level is considered safe, but because FDA determined that level to be the lowest lead level candy manufacturers can feasibly achieve. Using that logic, FDA should set a maximum allowable level of lead in cosmetics, based on the lowest lead levels that cosmetic manufacturers can feasibly achieve.

As the OCC's recent analysis of lead in lipstick demonstrates, lipsticks currently on the market contain a wide range of lead levels. The most lead-contaminated brand in the OCC's study, Cover Girl Incrediful Lip Color (by Proctor & Gamble), had a lead level of 3.06 ppm – more than 30 times higher than the least contaminated brand (at .09 ppm), and more than 10 times higher than the average lead level (.28 ppm) found in the 10 least contaminated brands.

We are also concerned to see that the top 10 most lead-contaminated lipsticks are made by three manufacturers: Proctor & Gamble (Cover Girl brand), Revlon and L'Oreal (L'Oreal, Maybelline and Body Shop brands). These are also among the most popular lipsticks on the market.

Clearly, these lipstick manufacturers can do a better job of making their products as lead free as possible, and FDA can help make that happen.

We urge FDA to take action to protect consumers from unnecessary lead exposures from lipstick, as requested in a letter dated Nov. 19, 2007 and signed by U.S. Senators John Kerry, Dianne Feinstein and Barbara Boxer. The letter urges FDA to “issue guidance to industry, recommending a maximum level of lead in lipstick and other cosmetic products, set to correspond with the lowest detectable levels found in laboratory tests.”

[http://www.safecosmetics.org/downloads/Kerry-Boxer-Feinstein\\_letter-to-FDA-lipstick.pdf](http://www.safecosmetics.org/downloads/Kerry-Boxer-Feinstein_letter-to-FDA-lipstick.pdf)

We also respectfully request that the Office of Cosmetics and Colors re-review the web page entitled “Lipstick and Lead: Questions and Answers” in light of our concerns.

Again, we thank the OCC for posting the results of your study on lead in lipstick and the brand names tested and we look forward to working with this office to ensure the safety of cosmetics and personal care products for the American consumer.

Sincerely,

Janet Nudelman  
Director of Program and Policy  
Breast Cancer Fund

Lisa Archer  
National Coordinator  
Campaign for Safe Cosmetics  
Breast Cancer Fund

CC: Dr. Margaret Hamburg  
Commissioner  
U.S. Food and Drug Administration

Dr. Joshua Sharfstein  
Principal Deputy Commissioner  
U.S. Food and Drug Administration