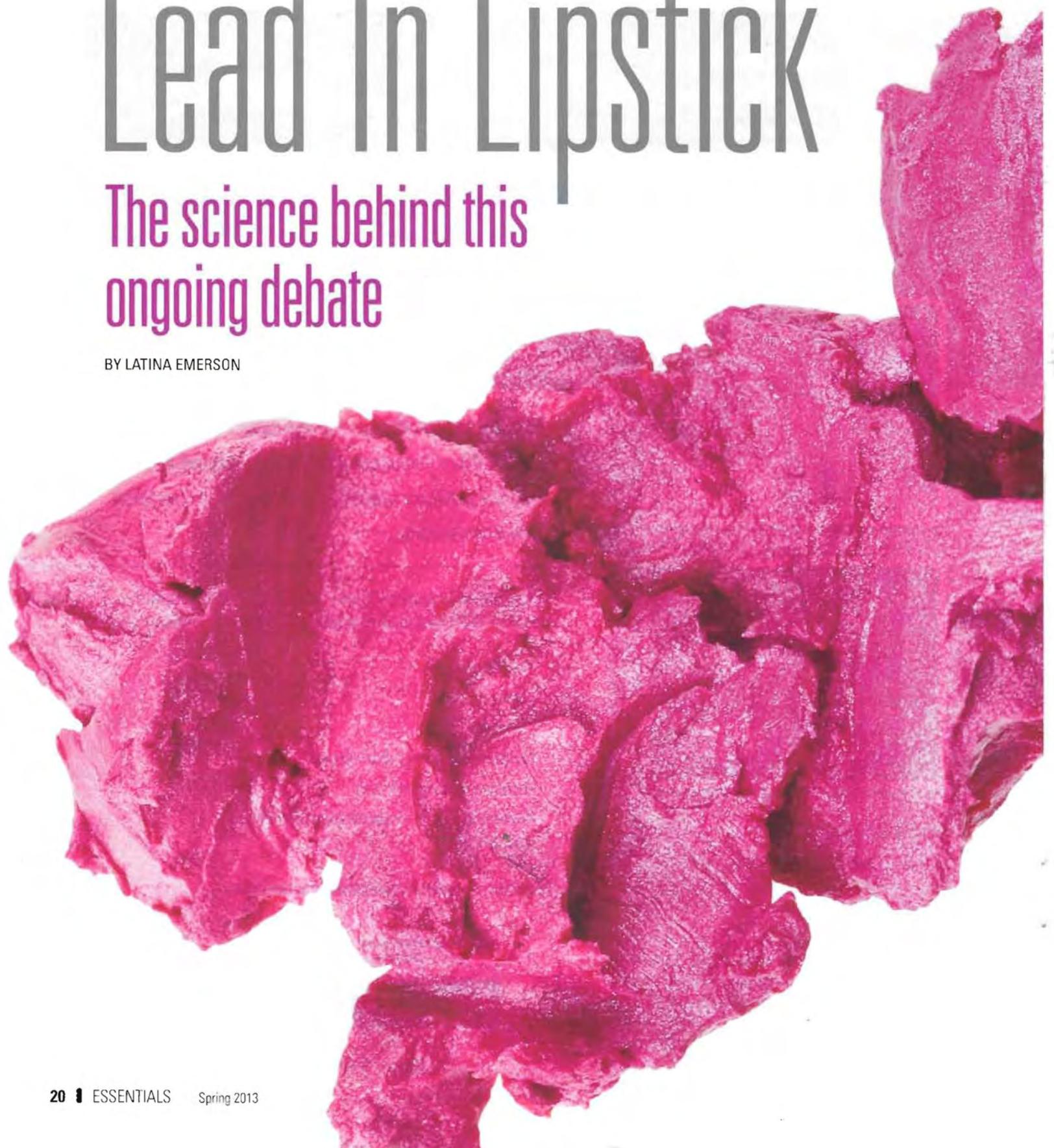


GET THE FACTS

# Lead In Lipstick

The science behind this ongoing debate

BY LATINA EMERSON





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—Tamara Ward, spokeswoman,  
U.S. Food and Drug Administration

FOR YEARS, THERE has been a longstanding debate about the safety of a common beauty item: lipstick. Trace amounts of lead are common in lipsticks, but should consumers kiss their favorite shades goodbye for fear of the health risks?

#### **Safe and Sound**

While studies have reported on traces of lead in lipsticks since the 1990s, the U.S. Food and Drug Administration has unequivocally stated that lead levels in lipstick do not pose safety concerns when lipstick is used as intended.

“Lipstick, as a product intended for topical use with limited absorption, is ingested only in very small quantities,” said FDA spokeswoman Tamara Ward in an emailed response. “We do not consider the lead levels we found in the lipsticks to be a safety concern. The lead levels we found are within the limits recommended by other public health authorities for lead in cosmetics, including lipstick.”

In 2009, FDA scientists retested 20 lipsticks analyzed in 2007 by the Campaign for Safe Cosmetics, using a new highly sensitive method for finding total lead content. The FDA study found lead levels ranging from 0.09 to 3.06 parts per million (ppm), with an average value of 1.07 ppm—all within the range expected from lipsticks formulated with permitted color additives and other ingredients that had been prepared under safe manufacturing conditions.

To further the investigation, the FDA conducted an expanded survey of approximately 400 lipsticks available on the U.S. market in the spring of 2010, covering a variety of shades, prices and manufacturers. The selection of lipsticks was based on the parent company's market share, and the FDA also included some from niche markets to evaluate lipsticks with unusual characteristics. Frontier Global Sciences Inc., a private laboratory based in Seattle, performed the analysis. The FDA required the lab to show continued reliability of the results using specific quality control procedures, Ward said.

The expanded survey found the average lead concentration in the 400 lipsticks tested was 1.11 ppm, close to the average of 1.07 ppm obtained in the initial survey. "The results ranged from the detection limit of 0.026 ppm to the highest value of 7.19 ppm, Ward said."

#### WHAT IS LEAD?

Lead is a naturally occurring element found in small amounts in the earth's crust. It can be found in all parts of the environment, from the air, soil, water and even inside our homes. Much of human exposure comes from activities such as burning fossil fuels, mining and manufacturing.

In the past, lead and lead compounds have been used in a variety of products, including paint, ceramics, pipes and plumbing materials, solders, gasoline, batteries and ammunition. Federal and state regulatory standards have helped to minimize or eliminate the amount of lead in air, drinking water, soil, consumer products, food and occupational settings, according to the U.S. Environmental Protection Agency's website.

Because of the presence of lead in the earth, lead may occur naturally in small levels in many products, including cosmetics, according to [www.cosmeticsinfo.org](http://www.cosmeticsinfo.org).

#### How Much Lead is Too Much?

While the FDA has not yet set an upper limit for lead in cosmetics, it has developed specifications for lead in color additives used in cosmetics: no more than 20 ppm, well above the highest value of lead in lipsticks from the 2010 survey. The FDA's approval of color additives is based on safety evaluations that consider the color additives' intended uses and estimated consumer exposure resulting from those uses, according to Ward. FDA-approved

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Personal Care Products Council

color additives are listed in Title 21 of the U.S. Code of Federal Regulations (CFR).

"In addition, the color additives listed under regulations in 21 CFR Parts 74 and 82 are required to be batch-certified by the FDA, which includes testing each batch for lead before they may be used in cosmetics," Ward said.

The FDA has also established maximum limits for lead levels in a number of foods, according to Dr. Halyna Breslawec, chief scientist for the Personal Care Products Council. The lead limit for bottled water is 0.005 ppm, and a person consuming an average amount of bottled water would ingest approximately 10 micrograms (ug) of lead based on two liters per person per day. The lead limit for candy is 0.1 ppm, and a person consuming 6.4 grams of candy containing 0.1 ppm of lead would result in about a 0.64 ug exposure to lead.

How does this compare to the amount of lead in lipstick? It's not easy to tell, Breslawec said.

"It is very difficult to compare these levels with the trace levels found in lipstick, because the potential amounts ingested are so different," she explained. "Likewise, it is not scientifically valid to equate the risk to consumers presented by lead levels in products intended for ingestion with that associated with lead levels in lipsticks, a product intended for topical use and ingested in incidental, much smaller amounts," Breslawec said.

However, some comparisons can be made. If lipstick containing 7ppm—the maximum amount of lead reported by the FDA—was ingested, the exposure would be 0.024 to 0.17 ug per person per day. Based on the most recent FDA survey, the average amount of lead found in lipstick is around 1 ppm per day. At that rate, a person using lipstick would be exposed to 266 times less lead than a person consuming a representative amount of candy, according to Breslawec.

## Lead in the Environment

Some argue that it's possible to make lipstick without lead, but lead is found naturally in the environment and may therefore be present at trace levels, Breslawec said.

"Lead is not deliberately added to lipstick; it is present in lipstick as an unavoidable contaminant of ingredients that are added for a reason, such as to impart color," Breslawec said. "The available tests for lead in lipstick are pretty sensitive and can detect very low levels [such as the parts per million that have been detected]. There may very well be lipsticks with extremely low levels of lead that are below the limits of detection. Non-pigment ingredients [such as lanolin or water] may also contribute minute amounts of lead to lipstick. The important point is that these tests measure total amounts of lead in lipstick, regardless of their source, and that the low levels measured do not present a safety concern."

Breslawec added that companies are responsible for substantiating the safety of their products and making sure the lipsticks they manufacture do not contain unsafe levels of lead.

## What's Next?

In the future, the FDA and others are considering taking additional steps to further address the concern of lead in lipstick.

"Although we do not believe that the lead content found in our recent lipstick analyses poses a safety concern, we are evaluating whether there may be a need to recommend an upper limit for lead in lipstick in order to further protect the health and welfare of consumers," Ward said.

In fact, the Personal Care Products Council proactively submitted a citizen's petition to the FDA in June 2010, requesting the FDA to establish an upper limit for lead in cosmetics, Breslawec said.

"The amount proposed, 10 ppm, is based on a level that is internationally accepted. In fact, the FDA agreed to that level as part of international harmonization efforts with cosmetic regulators from Canada, Europe and Japan. The petition is under review by the FDA," she said.

Still, Breslawec said that more precautions should be taken to address the public health aspect of lead poisoning in general, rather than focusing on lead in lipstick.

## RUMOR MILL

Over the years, some urban legends about lead and lipstick have circulated on the Internet. A forwarded email rumor in 2003 claimed that major brands of lipstick contained "cancer-causing" lead and consumers could test for it by putting lipstick on their hand and scratching the surface of the lipstick with a 14-karat to 24-karat gold ring. If the lipstick color changed to black, the lipstick contained lead.

However, despite repeated claims on numerous Internet sites, the gold ring test is a hoax.

"Lead poisoning is a serious issue, and to associate it with trace amounts of lead in lipstick trivializes real concerns about lead and the public health," Breslawec said. "The average amount of lead the average woman would be exposed to when using lipstick is 1,000 times less than the amount she would get from eating, breathing and drinking water that meets [Environmental Protection Agency] drinking water standards. The public should be aware that there are real risks from lead exposure, but that those risks need to be put into perspective. For example, trace amounts of lead in lipstick are 100,000 times lower than lead levels in lead-containing paint." 