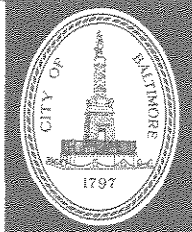


CITY OF BALTIMORE

MARTIN O'MALLEY, Mayor



HEALTH DEPARTMENT

JOSHUA M. SHARFSTEIN, M.D., Commissioner  
210 Guilford Avenue  
Baltimore, MD 21202

September 11, 2006

Andrew C. von Eschenbach, M.D.  
Acting Commissioner  
U.S. Food and Drug Administration  
5600 Fishers Lane, Rockville MD 20857-0001

Dear Dr. von Eschenbach,

I am writing to make you aware that products containing kohl – a color additive that FDA considers illegal – recently contributed to the lead poisoning of two Maryland toddlers.

I request that FDA investigate how such products entered commerce in violation of the Food, Drug, and Cosmetic Act. FDA should then take all necessary action to prevent the further sale of these products and the lead poisoning of other children.

The two toddlers came to the attention of the Maryland Department of the Environment when their blood lead levels exceeded 20 micrograms per deciliter, placing them at risk for long-term cognitive impairment. Lead poisoning at this level routinely triggers an environmental investigation. Investigators from the state agency, however, did not find a source of lead poisoning in the paint at home. Instead, they discovered that the parents of both toddlers routinely applied the same kohl-containing product around the eyes.

The product, called Hashmi Surma Special, is manufactured in Pakistan. The state tested two samples – one proved to be 39% lead by weight, and the other 45% lead by weight. Incredibly, the package label for this hazardous product encourages parents to apply the cosmetic every night around the eyes of infants so that they will not need glasses later in life.

State investigators informed me on Friday that one of the two families (neither of whom live in Baltimore City) purchased Hashmi Surma Special in my jurisdiction. I immediately sent a Health Department investigator to the store. She found several kohl-containing products for sale and removed them from the shelves. The Maryland Department of the Environment issued a health advisory to warn consumers. I issued an order under my authority as health commissioner banning the sale of all kohl-containing cosmetic products in Baltimore City.

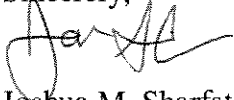
The coordinated state and city actions need to be matched by federal action to trace the origin of these products and shut down any distribution networks in the United States.

I am attaching a copy of the press release from the Maryland Department of the Environment, my order, and a copy of the recent FDA statement on these products.



Thank you for your prompt attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Joshua M. Sharfstein". The signature is fluid and cursive, with the first name "Joshua" being the most prominent part.

Joshua M. Sharfstein, M.D.  
Commissioner of Health

cc: Kendl Philbrick, Secretary, Maryland Department of the Environment



**BALTIMORE CITY HEALTH DEPARTMENT  
NOTICE AND ORDER TO REMOVE HEALTH NUISANCE**

**To: BALTIMORE CITY RETAIL ESTABLISHMENTS**

**Issuance Date: September 8, 2006**

**Compliance Date: September 11, 2006**

The Baltimore City Health Department has determined that products sold within Baltimore City pose an immediate health and safety hazard to inhabitants of the City. These products are marketed as containing a substance known as Kohl, Kajal, Al-Kahl, or Surma (hereinafter referred to as "kohl"). The Maryland Department of the Environment tested the "Hashmi Surma Special" product and found lead levels of 39% and 45%. These products are applied around the eyes, and two Maryland children have suffered lead poisoning after using the products.

The U.S. Food and Drug Administration has found that products containing kohl are a source of lead poisoning. Selling these products is illegal under federal law. Federal Food, Drug, and Cosmetic Act, 21 U.S.C.S. §§ 301, et seq. The Commissioner of Health has determined that products containing kohl are a health hazard and a nuisance pursuant to Titles 2 and 5 of the Baltimore City Health Code. Health Code §§ 2-201, et seq. and 5-101, et seq.

Therefore, by authority of the Commissioner of Health under sections 2-105(5) and 5-101 et seq. of the Baltimore City Health Code, all Baltimore City retail establishments are hereby ordered to take the following corrective action:

- 1) Immediately stop the sale and/or distribution of "Hashmi Surma Special" and any other cosmetic products containing Kohl, Kajal, Al-Kahl, or Surma within Baltimore City;**
- 2) This action must be completed by 5:00 p.m. on September 11, 2006.**

Failure to comply with this notice and order is a misdemeanor and, if convicted, violators will be subject to a fine of up to \$1,000.00 for each offense.

If any retail establishment fails to comply with this Notice and Order within the time frame allotted, in addition to initiating criminal prosecution or other legal enforcement proceedings, the Commissioner of Health may secure personnel to remove the nuisance items from the shelves of retail establishments. The person in charge of the property will be liable for the

expenses incurred by such corrective action and such expenses may act as a lien against the property until they are paid in full.

You have the right to request an administrative review of this notice and order in writing, within 10 days, setting forth in full the reason therefore.

A handwritten signature in black ink, appearing to read "Josh M. Sharfstein", written over a horizontal line.

**Joshua M. Sharfstein, M.D.**  
**COMMISSIONER OF HEALTH**



# News Release

MARYLAND DEPARTMENT OF THE ENVIRONMENT

1800 Washington Boulevard • Baltimore, Maryland 21230 • [www.mde.state.md.us](http://www.mde.state.md.us)

Robert L. Ehrlich, Jr.  
Governor

Kendl P. Philbrick  
Secretary

## FOR IMMEDIATE RELEASE

**Media Contacts:**  
**Julie Oberg**  
**(410) 537-3003**

**Robert Ballinger**  
**(410) 537-3012**

## MARYLAND DEPARTMENT OF THE ENVIRONMENT AND THE BALTIMORE CITY HEALTH DEPARTMENT PARTNER TO HELP CHILDREN

BALTIMORE, MD (September 8, 2006) –The Maryland Department of the Environment (MDE) in partnership with the Baltimore City Health Department calls on the public to stop using the cosmetic black powdered substance called Surma (kohl). This material may contain very high levels of lead. Surma (Kohl) cosmetics may often be applied to the eyes of children. It is also used as a teething powder for infants.

The Maryland Department of the Environment plans to notify all Maryland local health departments about the concern of Surma (Kohl) and its effects on children. MDE performs environmental investigations for children with elevated blood lead levels. In some of the investigations no typical source of lead is discovered and tenants are asked questions about the possible use of non-traditional remedies. There is evidence that some of these remedies contain hazardous levels of lead, particularly Surma. In recent investigations, inspectors determined that Surma was used on children with elevated blood lead levels. The parents were advised to stop using Surma. The Maryland Department of the Environment has referred this issue to the Office of the Attorney General's Consumer Protection Division

“Lead is one of the most significant and widespread environmental hazards for children in Maryland but exposure is preventable,” states Jonas Jacobson Deputy Secretary Maryland Department of the Environment. “Although there continues to be a steady decline in childhood lead exposure in Maryland, the goal of protecting children from lead poisoning in Maryland by 2010 will only be accomplished with the cooperation of local health departments and the public.”

The reduction of children with lead poisoning has occurred both statewide and in areas of highest risk such as Baltimore City. Non-standard sources of lead, such as Surma, some candies from Mexico, and some metal trinkets for children, take on an increasing role in the lead poisoning problem as lead paint sources are reduced and eliminated.

“The Baltimore City Health Department is pleased to be working with MDE to ensure that we are protecting children from lead hazards,” explains Dr. Joshua M. Sharfstein Commissioner “Parents need to be vigilant about how young children can come in contact with lead and the products that could contain lead.”

The Baltimore City Health Commissioner is issuing an order barring the sale of Kohl containing cosmetic products in the city. MDE obtained two containers of Surma - one was purchased in a specialty market in Baltimore City. The material was sent to a private laboratory for testing. The results showed that the two samples contained nearly 750 times the national limit for lead (39 percent and 45 percent lead by weight). As a comparison, lead-based paint is defined in the Maryland lead regulations as having 0.5 percent lead by weight. The current national standard for paint limits any lead to 0.06 percent by weight.

Children are at the greatest risk from birth to age six while their neurological systems are being developed. Exposure to lead can cause long-term neurological damage that may be associated with learning and behavioral problems and with decreased intelligence.

Additional information is available from MDE:

[www.mde.state.md.us/Programs/LandPrograms/LeadCoordination/index.asp](http://www.mde.state.md.us/Programs/LandPrograms/LeadCoordination/index.asp) and the U.S. Environmental Protection Agency [www.epa.gov/lead/](http://www.epa.gov/lead/)

# # #



# U.S. Food and Drug Administration



## CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

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CFSAN/Office of Cosmetics and Colors

October 24, 2003

## Kohl, Kajal, Al-Kahl, or Surma: By Any Name, a Source of Lead Poisoning

Many people are aware of some of the most common and best known sources of lead poisoning, such as lead paint and fumes from leaded gasoline. But many may be unaware of the risk of lead poisoning from an easily avoidable source: the traditional eye cosmetic known variously as kohl, kajal, al-kahl, or surma.

The following information is intended to answer questions people may ask about kohl and its dangers:

### What is kohl made of?

Kohl may contain a variety of materials. Although it is commonly thought to consist of antimony compounds, samples tested often contain significant amounts of lead. Lead sometimes accounts for more than half the weight of a sample of kohl, usually in the form of lead sulfide.<sup>1, 4, 5, 6, 7</sup>

### Is kohl directly linked to increased levels of lead in children?

Yes. A number of studies have shown that children exposed to kohl have increased levels of lead in their blood.<sup>2, 3, 6, 8</sup> This exposure puts them at increased risk for the serious consequences of lead poisoning.

### What are the effects of lead poisoning?

The risks associated with exposure to lead are especially serious for children, who are particularly susceptible to absorbing lead from the environment. Among the effects associated with high levels of exposure are anemia, kidney problems, and neurological damage that may include seizures, coma and death. Even at relatively low levels, chronic exposure to lead may lead to learning and behavior problems (see Dangers of Lead Still Linger," *FDA Consumer*, January-February 1998).

### How are children exposed to kohl?

In some cultures, it is common for parents to apply kohl to the eyes of infants and children. Infants of mothers who use kohl sometimes have elevated levels of lead in their blood.<sup>6, 8, 9</sup> Also, some people traditionally paint a newborn's umbilical stump with kohl, supposedly for medicinal reasons.<sup>2, 3</sup>

Unlike some sources of exposure to lead, this one is easily avoidable by not using kohl on your children or yourself, and keeping it out of your home.

## **If someone in my family has been exposed to kohl, what should I do?**

Stop all use of kohl immediately and be especially careful to protect children from further exposure. Place unused kohl in a sealable container or plastic bag and contact your local sanitation or waste department regarding appropriate methods for disposal. Thoroughly wash hands and any other body parts that may have come in contact with kohl. Wash exposed household surfaces with soap and hot water. Ask a health care provider to test children as well as pregnant or nursing women for lead poisoning if they have used kohl.

## **Is kohl legal in the U.S.?**

No. Kohl is a color additive as that term is defined in the Federal Food, Drug and Cosmetic Act (FD&C Act), and there is no regulation permitting its use in a cosmetic or in any other FDA-regulated product. Color additives that are not permitted by regulation are considered unsafe under the law. (For more information on color additives and the law, see the FD&C Act, sections 201(t) and 721.)

FDA has an Import Alert in effect for cosmetics containing kohl, not only because it is an unsafe color additive, but also because of labeling violations. For example, some samples have been labeled with the false statement, "FDA Approved." Such products are subject to detention and refusal of admission at U.S. ports of entry.

NOTE: Some manufacturers may label eye cosmetics with the term "kohl" simply to indicate the shade, not because the product actually contains kohl. If the product is properly labeled, consumers can check the ingredient declaration to determine whether it contains only color additives that are approved for cosmetic use in the area of the eye. If no color additives are declared, it would be wise to stay on the safe side and assume that the product is, in fact, kohl.

## **Where does kohl come from?**

Popular in much of the world since ancient times, particularly in parts of Africa, the Middle East, Iran, Pakistan, and India, kohl now sometimes appears in Europe and North America, especially in some Middle Eastern and Asian specialty markets. Despite its illegal status in the U.S., it may be imported surreptitiously, for example, in personal luggage. It also has been advertised for mail order on some Web sites.

## **Where can I learn more about lead poisoning?**

The following are some useful resources:

FDA:

"Dangers of Lead Still Linger," FDA Consumer, January-February 1998

"Los Peligros del Plomo"

Centers for Disease Control and Prevention:

Childhood Lead Poisoning Prevention Program

Environmental Protection Agency:

Traditional remedies reported to contain lead

References:

1. al-Hazzaa SA, Krahn PM. "Kohl: a hazardous eyeliner." *International Ophthalmology*, 1995;19(2):83-8.
2. Alkhwajah AM, Alkohl use in Saudi Arabia. "Extent of use and possible lead toxicity." *Tropical Geographical Medicine*? 1992 Oct; 44 (4):373-7.
3. Al-Saleh I, Nester M. DeVol E, Shinwari N, Al-Shahria S. "Determinants of blood lead levels in Saudi Arabian schoolgirls." *International Journal of Environmental Health*, 1999 Apr-Jun; 5(2):107-14.
4. Hardy AD, Vaishnav R, Al-Kharusi SS, Sutherland HH, Worthing MA. "Composition of eye cosmetics (kohls) used in Oman." *Journal of Ethnopharmacology*, 1998 Apr; 60 (3):223-34.
5. Lekouch N, Sedki A, Nejmeddine A, Gamon S. "Lead and traditional Moroccan pharmacopoeia." *Science of the Total Environment*, 2001 Dec. 3; 280(1-3):39-43.
6. Nir A, Tamir A, Nelnik N, Iancu TC. "Is eye cosmetic a source of lead poisoning?" *Israel Journal of Medical Science*. 1992 Jul; 28(7):417-21.
7. Parry C, Eaton J. "Kohl: a lead-hazardous eye makeup from the Third World to the First World." *Environmental Health Perspectives*, 1991 Aug; 94:121-3.
8. Rahbar MH, White F, Agboatwalla M, Hozhbari S, and Luby S. "Factors associated with elevated blood lead concentrations in children in Karachi, Pakistan." *Bulletin of the World Health Organization* 2002, 80 (10):769-775.
9. Shaltout A, Yaish SA, Fernando N. "Lead encephalopathy in infants in Kuwait. A study of 20 infants with particular reference to clinical presentation and source of lead poisoning." *Annals of Tropical Paediatrics*, 1981 Dec; 1(4):209-15.

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Cosmetics

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