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January 20, 2014

Dr G N Singh
Drugs Controller General, India
FDA Bhawan, Kotla Road,
New Delhi 110002

Subject: Presence of Heavy Metals in Cosmetics in India

Dear Dr Singh,

Toxic heavy metals in cosmetics are a growing concern across the world for several years. Heavy metals such as lead, mercury, cadmium, chromium and nickel have reportedly been found in unsafe levels in various cosmetic products. In India, on the other hand, use of cosmetics is rapidly increasing among all sections of society, particularly among young population.

Centre for Science and Environment (CSE), took a note of potential public health concern and tested over 70 cosmetic products (32 fairness creams, 30 lipsticks, 8 lip-balms and 3 anti-ageing creams) for presence of heavy metals. The tested products included commonly available Indian and International brands along with a few herbal products.

The results were startling. Presence of mercury is prohibited in cosmetics as per the Indian Drugs and Cosmetics Act and Rules, however 44 percent of the 32 fairness creams were found with mercury. Presence of mercury in these fairness creams is unlawful.

Chromium was found in 50 percent and nickel in 43 percent of the 30 lipsticks that were tested. While some chromium and nickel compounds are allowed as ingredients, there are no limits set for both in final products under Indian regulations, making their presence unregulated.

To check the safety of the products, we compared the levels of heavy metals in cosmetics with their respective Acceptable Daily Intakes (ADIs). Mercury found in fairness creams could contribute up to 71 per cent of the ADI, depending upon the product and the amount of the fairness cream used. This is a very high level of exposure to mercury from just one source of exposure. In case of chromium, for a heavy user, 13 out of 30 lipsticks would cross the ADI for chromium. Lipstick with highest level of chromium would expose a heavy user to over 15 times the safety limit.

Mercury is a neurotoxin. Inorganic mercury that is present in fairness creams can damage kidneys and may cause rashes, skin discolouration and scarring. It can also cause anxiety, depression, psychosis and peripheral neuropathy. Hexavalent chromium (CrVI), one of the forms in which chromium is present, is known to cause cancer in humans.

CSE shared the results with the companies and sought clarifications. Seven out of 14 companies responded. None disputed CSE's findings. However, most took refuge in the concept of 'trace' presence. Their defense is that the heavy metal found is small in quantity and it is unavoidable because it is part of the ingredients. They also claimed that their product is safe for long term use. CSE's study shows that it is certainly avoidable as mercury is not found in more than half of fairness creams and 40% of lipsticks do not have chromium or nickel. On the other hand the levels at which CSE found chromium in some products is exposing the consumers to well above the ADI of chromium.

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After assessing the existing regulations on cosmetics and the ground reality on monitoring, we strongly believe that there is a need for reforms on how cosmetics are regulated and the way these regulations are implemented.

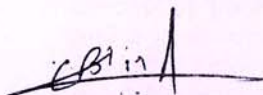
Specifically, we bring to your attention the following points and request your sincere attention in addressing this need for public safety through consumer products:

- **Standards for finished products:** There should be standards for toxins and heavy metals in finished cosmetics products. As of today BIS standards for heavy metals are applicable to synthetic and natural organic colourants. Colourants may form one small part of the cosmetics, e.g. up to 10% in lipsticks. With standards for finished products in place, all raw materials would be taken care of and the onus of safe product would in true sense be with the company which brings the product to the market (as specified in the Drugs and Cosmetics Act, 1940). This would also address the issue of maximum limit for trace presence if at all it is allowed for a particular heavy metal.
- **Independent assessment system to approve products:** A robust system should be in place to ensure that products are approved before they enter the market. The current system depends only on the information provided by the companies and has no independent assessment before approving the product.
- **Strengthening of existing implementation framework to check compliance with law:** Illegal presence of mercury in 44% of the fairness creams suggests that the existing monitoring mechanism is not effective. It needs to be strengthened and implemented well, wherein samples are picked up and tested for heavy metals and toxins to see if they are compliant with Indian law.
- **A public disclosure and warning system:** A system needs to be in place that makes the consumer aware about the types and levels of heavy metals and toxins present in all cosmetic products. It could be on the lines of a database that is open to public. The health impact of heavy metals and toxins along with advisory notes could also be a part of such information. There should also be a 'safety alert' system that timely warns the consumer about potential hazardous presence of heavy metals in a particular brand/batch. Such message could be broadcasted in mass media to prevent further usage such products/batch.

With younger generation beginning to use high amounts of cosmetics, the long-term cumulative impact of heavy metals on human health is likely to be more than ever before. Companies on the other hand are leaving no chance to exploit the regulatory loopholes and ineffective implementation. In this regard, we request you to take a note of our study and the suggested recommendations.

I look forward to your response on this matter.

Yours cordially,



Chandra Bhushan
Deputy Director General

Enclosed:

Study on Heavy Metals in Cosmetics, Pollution Monitoring Laboratory, CSE
Down to Earth Story: Beauty and the Beast