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**Expert opinion of the National Reference Centre on Cosmetics
on the content of toxic metals identified by chemical analyses
in counterfeits of the product Dermacol make-up cover by NIPH laboratories.**

On request of the manufacturer, Dermacol, a.s., the National Institute of Public Health (NIPH) performed chemical analyses on the toxic metals content in the original product Dermacol make-up cover and in counterfeits of this product that were recognized on the EU market. Chemical analyses identified in the counterfeits over 15 mg/kg of arsenic (As), over 200 mg/kg of lead (Pb) and significant amounts of cadmium (Cd) in different batches.

It is known that long-term exposure to As in higher doses may induce carcinogenic effects. Toxic effects on reproduction, immunity, bone construction, kidneys and/or neural system are known for Cd, while neurotoxic, cardiotoxic, angiotoxic, reprotoxic and nephrotoxic effects are significant for Pb. In case of powdered, dry products applied on skin, only very low skin permeability and systemic exposure is assumed. In case of products partially in emulsion, such as make-up, more significant skin permeation and systemic exposure should be considered, especially under conditions of repeated and long-term application. The key safety indicator for such products is thus the absence of toxic elements in raw materials and finished products.

The original product Dermacol make-up cover was marketed in the EU by the company Dermacol, a.s., after qualified safety assessment of the product for human health. The product documentation comprises the Safety Assessment Report which was elaborated according to strict rules laid down in the Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products. The Report includes safety assessment of individual raw materials (ingredients), assessment of product formulation, results of chemical, microbiological and toxicological examinations and dermatological skin compatibility tests.

The available data on ingredients and results of chemical analyses performed by NIPH on the original product Dermacol make-up cover repeatedly confirmed extremely low, toxicologically negligible contamination by toxic elements such as As, Cd, Pb or Hg. Low levels of contamination by toxic elements result from a careful selection of raw material suppliers and high responsibility of the manufacturing company Dermacol, a.s., with the aim to protect consumers health against possible adverse effects resulting from the exposure to toxic metals.

The company Dermacol, a.s., employs highly purified ingredients (pigments) for manufacturing of the Dermacol make-up cover product. The original product contains less than 0.5 mg/kg of As and Cd, less than 2 mg/kg of Pb and less than 0.001 mg/kg of Hg. Usual and still safe levels of contamination in decorative cosmetic products are considered concentrations of As < 5 mg/kg, Cd < 5 mg/kg, Pb < 20 mg/kg and Hg < 1 mg/kg. Thus the original Dermacol make-up products contain more than ten times lower levels of contamination compared to usual levels. On the opposite, the counterfeits exhibit more than hundred times higher levels of contamination.

Ingredients of mineral origin, such as pigments used in decorative cosmetic products, are harvested in different world localities using different procedures, for different purposes, in different quality and for different price. For cosmetic purposes, responsible manufacturers employ only pigments in cosmetic, food and/or pharmaceutical quality with negligible and toxicologically non-significant content of toxic metals. DERMACOL, a.s., belongs among these manufacturers.

The unacceptable quality of counterfeits regarding the content of toxic metals documents an irresponsible approach of counterfeits' manufacturer to raw materials selection and compromises the health safety of counterfeits. Under the conditions of long-term and repeated application of counterfeits on larger skin areas, adverse effects can not be excluded, especially in vulnerable, sensitive organisms.

Unfortunately, marketing of counterfeits to renowned products is quite frequent and the manufacturer of the original product has a limited number of instruments how to prohibit the distribution of counterfeits. The external appearance of counterfeits and their packaging is often perfect and does not allow the consumer to clearly identify the original from counterfeit. If the consumer does not recognize differences in user properties, such as a different shade, when compared to the original, different perfume, different consistency or covering ability, then the only instruction is to buy the products exclusively from certified sources, preferably in stores guaranteed by the manufacturer.

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