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Safety evaluation of traces of nickel and chrome in cosmetics: The case of Dead Sea mud

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ABSTRACT

Background: Metal impurities such as nickel and chrome are present in natural ingredients-containing cosmetic products. These traces are unavoidable due to the ubiquitous nature of these elements. Dead Sea mud is a popular natural ingredient of cosmetic products in which nickel and chrome residues are likely to occur.
Objective: To analyze the potential systemic and local toxicity of Dead Sea mud taking into consideration Dead Sea muds' natural content of nickel and chrome.
Methods: The following endpoints were evaluated: (Regulation No. 1223/20, 21/12/2009) systemic and (SCCS's Notes of Guidance) local toxicity of topical application of Dead Sea mud; health reports during the last five years of commercial marketing of Dead Sea mud.
Results and conclusions: Following exposure to Dead Sea mud, MoS (margin of safety) calculations for nickel and chrome indicate no toxicological concern for systemic toxicity. Skin sensitization is also not to be expected by exposure of normal healthy skin to Dead Sea mud. Topical application, however, is not recommended for already nickel-or chrome-sensitized persons. As risk assessment of impurities present in cosmetics may be a difficult exercise, the case of Dead Sea mud is taken here as an example of a natural material that may contain traces of unavoidable metals.

1. Introduction

According to the European Cosmetic Regulation 1223/2009/EC, the responsibility for safety and legal compliance of cosmetics is with the “Responsible Person” (RP) (Regulation No. 1223/20, 21/12/2009). The latter can be a natural or legal person, established in the EU, but is in most cases the manufacturer or importer. The RP must take care that the cosmetic product under consideration is safe for human health when used under normal or foreseeable conditions of use (Regulation No. 1223/20, 21/12/2009). This is done through safety assessment, performed by a qualified safety assessor, and being an integral part of the product information file (PIF) of that particular product.

Impurities or traces present in the composing ingredients and raw materials need to be stated in the PIF, along with their characterization and concentration. They are, however, not considered as ingredients and must not be labeled on the product. In the Notes of Guidance of the Scientific Committee on Consumer Safety (SCCS), it is further clarified that the RP must ensure that neither other impurities nor increases in the identified impurities are present in the representative commercial material (SCCS's Notes of Guidance). This can be realized by monitoring all different batches. In case impurities come from their presence in a natural substance, it still needs to be demonstrated that the cosmetic product, containing these impurities, does not pose a threat to the health of the consumer. In any case, it must be shown that the quantities of the impurities are as low as possible and technically unavoidable (Regulation No. 1223/20, 21/12/2009).

As risk assessment of impurities present in cosmetics may be a difficult exercise, the case of Dead Sea mud is taken here as an

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example of a natural material that may contain, because of its natural origin, traces of metals such as nickel and chrome. It further needs to be considered that due to human industrial activities and environmental pollution, these concentrations could potentially increase over time.

Since ancient times, Dead Sea mineral mud has been used as well for health reasons (atopic or psoriatic skin, rheumatic patients) as for beauty purposes (Halevy and Sukenik, 1998; Hodak et al., 2003; Moses et al., 2006). The mineral-rich mud is harvested from lakes' banks and is topically applied either as warm relaxing mudpacks at local resorts or marketed worldwide after industrial processing, mixing and filtering (Halevy and Sukenik, 1998; Hodak et al., 2003; Moses et al., 2006; Ma'or et al., 2006; Abdel-Fattah and Pingitore, 2009). One to 4 packs are used per week, usually for a limited time period. In skin care cosmetics, it may be present as a natural humectant, but it also has protective effects against UV-B induced stress (Ma'or et al., 1996; Ma'or, 2008; Portugal-Cohen et al., 2009). Mineral mud has also been reported to display some anti-microbial properties (Ma'or et al., 2006).

This paper provides the risk assessment (systemic and topical toxicity), of Dead Sea mud with respect to its nickel and chrome content and concludes with some practical recommendations.

2. Materials and methods

2.1. Composition of Dead Sea mud

Dead Sea mud is a natural suspension consisting of a water and solid phase. The latter is mainly composed of various clay minerals: illite-semectite, kaolinite, illite, calcite, quartz and small concentrations of chlorite, palygorskite, dolomite and halite (Ma'or et al., 1996; Kafri et al., 2002). Some metal traces are present, including nickel (Ni) and chromium (Cr). Both are metals, present in Annex II of the Cosmetic Regulation 1223/2009 (Regulation No. 1223/20, 21/12/2009), and thus not allowed as ingredients in cosmetic products. It is, however, not surprising to detect traces of these in mineral mud as it is known that Ni naturally occurs in soils and volcanic dust (Sunderman, 1988). Likewise Cr is an element found in rocks, soils, volcanic dust and gasses, animals and plants (Hamilton and Wetterhahn, 1988), predominantly as Cr^{3+}. Cr^{3+} is also an essential element in man that plays a role in glucose metabolism (Hamilton and Wetterhahn, 1988; ICH Guideline, 2015). Cr^{6+} is in particular produced by industrial processes and its potential increase, if detected in the Dead Sea mud, could give an indication of ongoing pollution (Hamilton and Wetterhahn, 1988; ICH Guideline, 2015).

2.2. Analysis data available on mud and stream sediment

Over the last 10 years some analyses on mud and stream sediments have been carried out. As a part of the results were already published, the sampling procedure and analytical methods used could be retrieved (Ma'or et al., 2006; Abdel-Fattah and Pingitore, 2009).

Mud samples from mining points around the Dead Sea Lake were collected. Stream sediment sample sites were selected according to the drainage pattern. The sample density was about 1 sample per 1 km^2. Around 1 kg samples were taken and dried, split and sieved to a final size of <0.15 mm and this fraction was analyzed for major and trace elements by inductively coupled plasma mass spectrometry (ICP-MS), used in kinetic energy discrimination mode (KED). The Dead Sea mineral mud (dry weight 77.5% weight to weight (w/w)) was analyzed by inductive coupled plasma atomic emission spectrometry (ICP-AES) and ICP-MS as described earlier (Kafri et al., 2002). The samples were decomposed by sintering with sodium peroxide, followed by dissolution in nitric acid.

3. Results

3.1. Nickel and chromium content in crude and commercial Dead Sea mud

Collected samples, commercially available mud bags and interstitial water from both preparations were analyzed for their Cr- and Ni-contents. Their levels are shown in Table 1.

Table 1
Ni-and Cr-concentrations in crude and commercial Dead Sea mud.

Heavy metals	Crude mud Israel (Ma'or et al., 2006) n = 3	Crude mud Jordan (Abdel-Fattah and Pingitore, 2009) n = 4	Commercial mud pack Israel (*) n = 1	Commercial mud pack Jordan (Abdel-Fattah and Pingitore, 2009) n = 3	Interstitial water of crude mud Israel/Jordan (Abdel-Fattah and Pingitore, 2009)	Interstitial water of commercial mud pack Israel/Jordan (Abdel-Fattah and Pingitore, 2009)
Ni	0.0040	0.0023	0.0017	0.0014	0.0000028	0.000008
Cr	0.0075	0.0038	0.0032	0.0025	<0.000001	<0.000001

Dead Sea crude mud, dried to 77.5%, w/w, commercial mud packs samples and interstitial water of crude and commercial mud samples were analyzed. The results are expressed as % (w/w); n = number of repetitions.

Precision of measurements' determination is about ±10%.

(*) inspection sample by French Inspection in 2014.

The Ni-content varies in crude and commercialized mud between 0.0023% (w/w) to 0.0040% (w/w), and 0.0014% (w/w) to 0.0017% (w/w), respectively. In interstitial water, obtained by centrifugation, the Ni-content is less than 0.000008% (w/w).

The Cr-content of mud varies in crude and commercialized samples between 0.0075% (w/w) and 0.0038% (w/w), and 0.0032% and 0.0025%, respectively. Cr-concentration in interstitial water is less than 0.000001%.

3.2. Nickel and chromium content in stream sediments

More than 400 samples of stream sediments were collected in a survey from different spots at the Dead Sea area (Gil and Halicz, 1992). Stream sediments from 400 different points in the area of the city of Jerusalem were also sampled (Wolfson et al., 1992). Chemical analysis of stream sediment samples was performed using conventional methods as described earlier (Kafri et al., 2002). The results for Ni-and Cr-concentrations are presented in Table 2.

Table 2 shows that the mean Ni-concentration at the Dead Sea area and in stream sediments at Jerusalem is 0.0051% (w/w) and 0.0062% (w/w), respectively. The mean Cr-concentration is 0.0096% (w/w) and 0.0103% (w/w), respectively.

3.3. Exposure to nickel

3.3.1. Evaluation of the systemic toxicity following topical application of Dead Sea mud

The systemic toxicity was determined according to the margin of safety (MoS) principle as explained in the SCCS Notes of