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Consumption of cosmetic products by the French population. Third part: Product exposure amount

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ABSTRACT

A recent study in France provided valuable data on the frequency and amount of use of cosmetic products (Ficheux et al., 2015, 2016a). The aim of the present study was to generate Product Exposure Amount data, i.e. the amounts of cosmetics applied to the skin among the French population using the raw data collected during the previous enquiry. These data are useful to derive Consumer exposure level data which are paramount for skin sensitization risk assessments.

Exposure data were generated for 69 different cosmetics, classified as products for the hair, face, buccal hygiene, hands, feet, body, shaving and depilation, sunscreens as well as products specifically intended for babies. Exposure was calculated using a probabilistic Monte Carlo method.

The main strength of this work was the break-down of data by age and sex. The results showed that some data used by the International Fragrance Association in skin sensitization risk assessments, in particular facial care products and deodorants, could be unsuitable for the protection of French consumers. For the first time, data were also generated for products intended for babies' nappy area.

These data will be useful for the implementation of the Quantitative Risk Assessment for skin sensitization among the French population.

1. Introduction

Cosmetic products are defined by the European regulation (EC) No 1223/2009 on cosmetics as substances or mixtures “intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours” (EU, 2009). A wide range of products, intended for the whole family and for various uses, e.g. daily hygiene, perfuming or making-up, meet this definition. Unfortunately, various adverse effects resulting from the application of cosmetic products on the skin may occur and may be of varying severity depending on the case, such as skin irritation reactions, phototoxicity or allergic reactions. Different compounds may be responsible for allergic reactions. Mention can be made of methylisothiazolinone, contained for example in shampoos or shower gels as preservatives or fragrance ingredients, such as geraniol or eugenol, used in numerous cosmetics (ANSM, 2010).

Cosmetics are widely consumed throughout France by the whole population: infants, children, adolescents and adults (Ficheux et al., 2015, 2016a). Therefore, dermal exposure to sensitizers concerns all of the French population to a greater or lesser extent. Individuals are not all equal regarding the risk of contact allergy development. A range of parameters have to be taken into account in the development of such allergies. This can include for example genetic variability, skin conditions and consumption patterns, i.e. frequency and quantity (Api and Vey, 2008; Api et al., 2008; Basketter and Safford, 2016). It is difficult to quantify the precise prevalence of skin sensitization caused by substances found in cosmetics among the French population, mainly because of the lack of multicentric studies in France, in comparison with the works undertaken in the rest of Europe such as those of the European Dermato-Epidemiology Network (EDEN) or the European Surveillance System of Contact Allergies (ESSCA) (Diepgen et al., 2016; Frosch et al., 2015; Rossi et al., 2010). However, contact allergies caused by the application of cosmetics are serious adverse events frequently observed in France in the context of so-called

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'cosmetovigilance'. For example, in 2010, 57% of 219 cases reported to the French National Agency for Medicines and Health Products Safety were contact allergies (ANSM, 2010). Furthermore, the Scientific Committee on Consumer Safety considers contact allergies to fragrance substances to be a major problem, which can seriously alter the lives of those affected and represent a significant cost within the European Union due to medical consultations and the possible treatments it entails (SCCS, 2012).

To date, skin sensitization risk assessments may be based on a "Quantitative Risk Assessment" (QRA) approach. Briefly, QRA consists in comparing a dose of an allergen considered to be safe for the consumer, i.e. an Acceptable Exposure Level (AEL), with the consumer exposure per unit of body surface area, i.e. the Consumer Exposure Level (CEL), both expressed in mg/cm^2/day. The AEL/CEL ratio must be greater than one to support the safe use of the skin sensitizer. The most relevant period for the risk assessment is considered by some authors to be of one day (Api et al., 2008; IPCS, 2012). As a consequence, current studies are working on the development of aggregated exposure models to sensitizers on particular skin sites over a 24-h period (Nijkamp et al., 2015; Safford et al., 2015). It should be noted, however, that this period represents a pragmatic approach, as no formal evidence exist to define the adequate time for skin sensitization (IPCS, 2012). Cosmetic consumption, i.e. frequency of use and quantity per use, as well as the anthropometric characteristics are the three fundamental factors for defining the CEL. The Research Institute for Fragrance Materials (RIFM) and the International Fragrance Association (IFRA) adopted the QRA approach for primary prevention of dermal sensitization to sensitizing chemicals in consumer products (Api and Vey, 2008; IFRA and RIFM, 2015). This approach was adopted in May 2006 with the advent of the 40th Amendment of IFRA (IFRA and RIFM, 2015). Regularly updated and now in its 48th version, this methodology is currently being used to determine global fragrance industry product management practices and to set standards, e.g. limitations on incorporation for the fragrance industry to protect consumers against skin sensitization (IFRA and RIFM, 2015). Knowledge of the Product exposure amount (PEA) per type of cosmetic, i.e. the amount of product applied on the skin is paramount to derive CEL and to set IFRA standards. To date, PEA data compiled by IFRA are based on the selection of data from different sources (Api et al., 2006). For example, data on the consumption of hydroalcoholic products were calculated using measured distributions of amounts, frequencies of use and surface areas (Api et al., 2006). Data for the other products were derived from studies conducted by the Colipa (now Cosmetics Europe), the CTFA (now Personal Care Products Council), the SCCNFP (now SCCS), the EC (European Commission), the HERA (Human and Environmental Risk Assessment) programme, the FMA (now International Fragrance Association North America) and the RIFM (Api et al., 2006). Data relating to human parameters, e.g. the reference surface area per product, were taken from different sources (Bremmer et al., 2006; Collins and Dawes, 1987; Ferrario et al., 2000; USEPA, 1997). The different PEAs per product type were then determined using consumption and anthropometric data from all the different sources with a hierarchical approach according to their respective robustness (Api et al., 2006). However, the PEA may considerably vary depending on the case. First, the frequency of use and the quantity per application of a product may vary from one individual to another in different populations across the world. Second, the body surface area may also lead to variations in exposure as it is dependent on body size and body weight (USEPA, 2011). Finally, given the evolution of anthropometric parameters during growth, it is important to know whether there are differences in exposure between adults and young children.

A recent national survey in France provided valuable information on the consumption of cosmetic products (Ficheux et al., 2015, 2016a). The aim of the present work, which constitutes the third part of this French national study, is to generate PEA data among the general French population for different products according to sex and age following the method proposed by IFRA and RIFM. This work is intended to check whether IFRA's data are applicable in France, but also to generate data for products that have not yet been studied by IFRA and RIFM. These new data will enable safety assessors to more effectively protect consumers against skin sensitization.

2. Materials and methods

2.1. Data collection

An enquiry was conducted among individuals mainly from Brest, but also from Paris, Nancy and Toulouse to ensure a representative sample across France. The participants were asked to fill in a questionnaire regarding their cosmetic usage patterns, i.e. in relation to the products they usually consume. Parents of young children/babies were also asked to fill in this questionnaire regarding the way they used products on them. The products studied were purchased in French supermarkets and provided for use by the volunteers. The volunteers were asked to use the cosmetic products in the closest possible way to their habits at home, according to the galenic form of the product, e.g. by putting the corresponding amount per use in their hand for creams or lotions, by spraying it in the air in the case of aerosol, or by application on cotton pads in the case of make-up removers. In the case of cosmetics that could be used on different parts of the body, the volunteers were asked to specify the body part(s) corresponding to the amount applied. The amount of each cosmetic used was determined by differential weighing before and after use. Additional information on age, place of residence, socio-professional category, body weight and height was collected at the end of the questionnaire (For more details See Ficheux et al., 2016a). Data were collected for adult men and women, girls from 4 to 14 years and babies from birth to 3 years.

2.2. Skin Surface Area calculation

Several formulas exist for determining the Skin Surface Area (SSA). Many of these relate height to body weight (USEPA, 2011). The Gehan and George formula was determined by the United States Environment Protection Agency (USEPA) to be the best choice for estimating total SSA because it is based on a large number of direct measurements (Gehan and Georges, 1970; USEPA, 2011). The Gehan and George formula relates height to body weight in the following way:

$$SSA = 0.02350 * H^{0.42246} * W^{0.51456}$$

where

SSA is the Skin Surface Area (cm^2),
H is the Height (cm),
W is the Weight (kg).

This formula was used to calculate the SSA for all the respondents who participated in the study and their children (see Tables 1 and 2).

2.3. Product Exposure Amount calculation per use

The Consumer Exposure Level was calculated per type of