Food and Chemical Toxicology xxx (2014) xxx–xxx

Contents lists available at ScienceDirect

Food and Chemical Toxicology

journal homepage: www.elsevier.com/locate/foodchemtox

Exposure method development for risk assessment to cosmetic products using a standard composition

G. Chevillotte, A.S. Ficheux *, T. Morisset, A.C. Roudot

Laboratoire d'Evaluation du Risque Chimique pour le Consommateur (LERCCo), Université Européenne de Bretagne – Université de Bretagne Occidentale (UEB-UBO), UFR Sciences et Techniques, 6 Av. Victor Le Gorgeu, CS93837, 29238 Brest Cedex 3, France

ARTICLE INFO

Article history:
Received 15 November 2013
Accepted 6 March 2014
Available online xxxx

Keywords:
Cosmetic products
Composition
Risk
Exposure
Nail polish

ABSTRACT

In a risk assessment of cosmetic products, it is necessary to know both qualitative and quantitative compositions. Currently, European Regulation No. 1223/2009 requires the industries to provide ingredient lists for finished cosmetic products but not their concentrations. Ingredient concentrations are available in few bibliographic references but in an incomplete and approximate way.

In this study, we propose a method to qualitatively and quantitatively estimate the composition of a cosmetic product. This method has the advantages of being applicable to all cosmetic products and supplying concentration data for all ingredients. The results obtained seem quite fair compared to literature data. Applied to nail polish as an example, this method can be used to assess exposure per ingredient according to the Monte Carlo probabilistic method. It should be promising to assess the consumer risk to cosmetic product compositions.

1. Introduction

Chemical risk assessment is defined as a process to calculate or estimate the probability of an adverse health effect which occurs after humans are exposed to a substance. This process consists of three important steps: (i) hazard assessment (identification and characterization), (ii) exposure assessment (global or systemic) and (iii) risk characterization (EU, 2000a,b; OECD, 2003).

A cosmetic product is currently defined as "any substance or mixture 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 odors" (EU, 2009).

This definition includes many products and substances whose risk assessment for consumers should be conducted to ensure they are safe. Cosmetics were recently subjected to the European Regulation No 1223/2009 (EU, 2009) governing the Cosmetic Products Directive (EU, 1976). The process of cosmetic products marketing described in these regulation texts is different from other sectors (food and drugs). Indeed, given the lack of a pre-marketing authorization procedure, a cosmetic must be considered as "safe" for the consumer before being placed on the market. The responsibility for the "risk assessment", conveniently called "safety evaluation" in the case of cosmetics, is entirely under the responsibility of the person (legal or natural) that markets the product (EU, 2009; Pauwels and Rogiers, 2010). According to these regulatory texts, the safe character of the cosmetic product shall be ensured when it is consumed under normal or reasonably foreseeable conditions of use (EU, 2009). These reasonably foreseeable conditions are defined as the usual way that consumers are expected to use these products. Thus, it is necessary to have a sufficiently large and accurate exposure database, that contains data such as how frequently consumers use the products and how much is applied per application, to estimate the real exposure in the population.

Some data on exposure to different cosmetic products are available. Loretz et al. (2005, 2006, 2008) have assessed the exposure of American women to hygiene products (shower gel, shampoo, antiperspirant, etc.), health care (hair spray, moisturizer, etc.), makeup (lipstick, mascara, etc.) and perfumes. Other studies conducted in Europe by Hall et al. (2007, 2011) and McNamara et al. (2007) assessed exposure to the same product types with toothpaste and mouthwash in addition.

All studies were carried out in the context of a global exposure assessment to cosmetic products. But in the present state of things, risk assessment by assessors who do not have access to confidential company data on ingredient concentration is difficult. A risk

* Corresponding author. Tel.: +33 2 98 01 79 60.
E-mail address: anne-sophie.ficheux@univ-brest.fr (A.S. Ficheux).

http://dx.doi.org/10.1016/j.fct.2014.03.010
0278-6915/

assessment can be performed exclusively per ingredient and for this purpose, it is necessary to know both the product amounts applied by the consumer and the concentrations of ingredients in the formulation. However, the current legislation does not oblige industries to supply the concentrations of ingredients present in the finished cosmetic product. Industry is only required to establish, in decreasing order of concentrations, the list of ingredients with concentrations by weight greater than 1% in the final product (EU, 2009). In the current literature, there are few quantitative data on the composition of cosmetic products. When information is available, it is approximate and limited (RIVM, 2006; Andre and Baran, 2009). Therefore, risk assessors often overestimate exposure by using conservative assumptions, such as assuming that concentrations of ingredients in a product are greater than they are in reality in order to be conservative or protective of the consumer.

The aim of this study is to propose a simple and rapid method to estimate ingredient concentrations in the final composition of a cosmetic product. This method allows, from a virtual composition of a cosmetic product, to estimate a quantitative profile of ingredients commonly found in a set of brands of a product. A more accurate exposure assessment can thus be achieved for ingredients in cosmetic product. This method was applied to an exposure assessment of a nail polish in the French population. Conducted according to the probabilistic Monte Carlo method, the probability exposure in the population was calculated considering the existing variability as well as the estimated uncertainties (US-EPA, 2001; van der Voet and Slob, 2007).

2. Methods

2.1. Estimation of cosmetic product compositions

The method involves three major steps (Fig. 1): (i) elaboration of the list of ingredients commonly present in a cosmetic product of interest and establishment of families; (ii) determination of concentrations by weight of ingredients and families in the final cosmetic product and (iii) concentration adjustments under distribution form. Two refinement steps, located between step 2 and step 3, may also be needed to implement the general method. Their use is governed by different conditions that will be described in Section 2.1.3.

For some steps (steps 1 and 2), a theoretical example is shown in tabular form in order to improve the reader's understanding (Tables 1 and 2, respectively).

2.1.1. Step 1: List of ingredients and creation of families

The aim of this step is to obtain a virtual composition of a cosmetic product of interest and to define ingredient families. The virtual composition is, as its name suggests, not a real composition. It represents an average composition of a set of marketed compositions of a particular product. The virtual composition is necessary for certain steps of the method, such as the verification of the correspondence between the qualitative (obtained from the labels of marketed product) and quantitative (obtained from patents) data or for pooling the data of some compounds (refinement step).

List of ingredients: The ingredients indicated on labels of several brands are listed. A number according to each ingredient position on each label is assigned. Indeed, in accordance with Article 19 of Regulation No 1223/2009 currently in effect, industrial firms have an obligation to supply the list of ingredients on the label in descending order of weight (EU, 2009).

A mean of the listed positions for all brands is carried out and the ingredients are classified in descending order of their position: ingredients with low average position are present in large concentrations in the cosmetic product, and *vice versa*. After assigning the new position of each ingredient in the composition of the cosmetic product (attribute position), a virtual composition is obtained. A same brand may propose two products with slightly different ingredient compositions. In this case, the compositions are combined into one, and a mean of the position numbers of the same ingredients is calculated.

Family creation: Cosmetic products contain ingredients that possess one or several functions. For example in nail polish, ingredient can be an organic solvent, plasticizer, forming agent, UV absorber, etc. The main function of each ingredient is researched in the literature and is referred to in this method as the "ingredient family" or "family" (solvents, plasticizers, dyes, etc.). The same family may combine several main functions. This choice can be motivated by different factors: the similarity of functions (e.g. "density control agent" and "pH regulator" in the family of "agents of physicochemical properties control"), families already established in literature, etc.

2.1.2. Step 2: Elaboration of a quantitative composition

The aim of this step is to establish a quantitative composition of the cosmetic product. Publications and patents have been sought on web in this objective. Patents have the advantage of providing examples of compositions for which the concentration of ingredients is often expressed as a weight fraction (or weight value) compared to a final composition of the product equal to 100 (w/w).

The weight values obtained for each ingredient are listed. Ingredients and their weight fraction are assigned to their respective families. For each composition, all ingredient concentrations of a same family are added in order to obtain a weight value per family.

At this stage of the method, a virtual qualitative composition of the cosmetic product and quantitative data for ingredients and for their respective families are obtained.

In theory and in the best case, (i) the ingredients presented in the virtual product are found in most compositions of marketed brands, (ii) each ingredient has a specific position (i.e. ingredients do not share the same position), (iii) the number of weight values per ingredient is high and the mean of these weight values corresponds to the assigned ingredient position (i.e. the highest ingredient weight value corresponds to the lowest position in the virtual product). In this case, and if the user considers that there is enough data per ingredient, the refining steps are not necessary. Otherwise (i.e. if there are few common ingredients between brands, overlapping positions per ingredient and/or few quantitative data), it is possible to group ingredients into subgroups to merge their data or delete some ingredients.

Refining steps can be used to obtain a simplest qualitative and quantitative composition and to keep only the ingredients most commonly found in the cosmetic product of interest.

2.1.3. Refinement 1: Fusion of ingredient data

This step is submitted to conditions in a defined order of importance. The decision tree provides guidance on the feasibility of this step (Fig. 2).

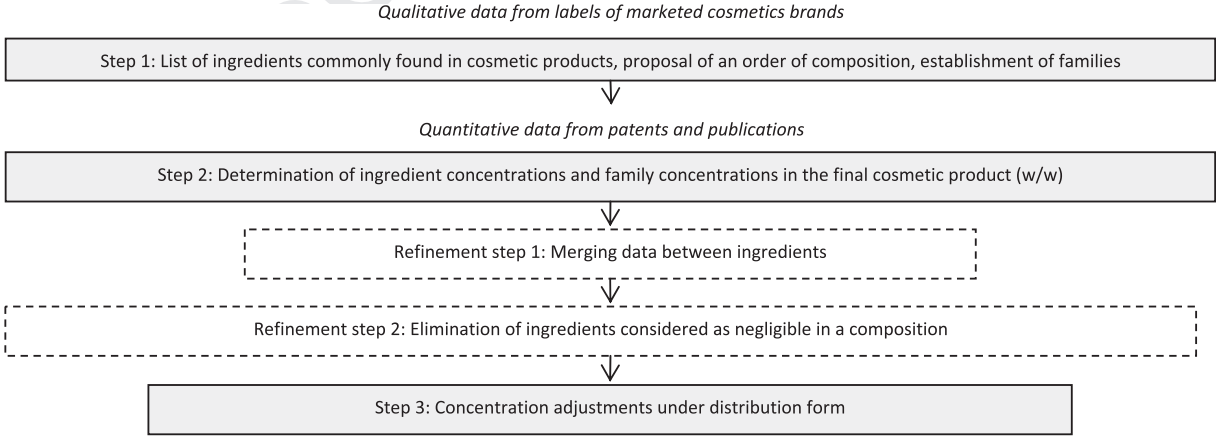

Fig. 1. Overview of the general estimation method for cosmetic product composition.

Please cite this article in press as: Chevillotte, G., et al. Exposure method development for risk assessment to cosmetic products using a standard composition. Food Chem. Toxicol. (2014), http://dx.doi.org/10.1016/j.fct.2014.03.010