Food and Chemical Toxicology 66 (2014) 36–43

Contents lists available at ScienceDirect

Food and Chemical Toxicology

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

Probabilistic assessment of exposure to nail cosmetics in French consumers

A.S. Ficheux *, T. Morisset, G. Chevillotte, C. Postic, 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 13 January 2014
Available online 19 January 2014

Keywords:
Exposure assessment
Nail cosmetics
Probabilistic method

ABSTRACT

The aim of this study was to assess probabilistic exposure to nail cosmetics in French consumers. The exposure assessment was performed with base coat, polish, top coat and remover. This work was done for adult and child consumers. Dermal, inhalation and oral routes were taken into account for varnishes. Exposure evaluation was performed for the inhalation route with polish remover.

The main route of exposure to varnishes was the ungual route. Inhalation was the secondary route of exposure, followed by dermal and oral routes. Polish contributed most to exposure, regardless of the route of exposure. For this nail product, P50 and P95 values by ungual route were respectively equal to 1.74 mg (kg bw week)$^{-1}$ and 8.55 mg (kg bw week)$^{-1}$ for women aged 18–34 years. Exposure to polish by inhalation route was equal to 0.70 mg (kg bw week)$^{-1}$ (P50) and 5.27 mg (kg bw week)$^{-1}$ (P95). P50 and P95 values by inhalation route were respectively equal to 0.08 mg (kg bw week)$^{-1}$ and 1.14 mg (kg bw week)$^{-1}$ for consumers aged 18–34 years exposed to polish remover. This work provided current exposure data for nail cosmetics, and a basis for future toxicological studies of the uptake of substances contained in nail cosmetics in order to assess systemic exposure.

1. Introduction

As defined in the second article of the European Regulation (EC) No 1223/2009, a cosmetic product corresponds to "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 odours" (EU, 2009). This Regulation, repealing the Directive No 76/768/EEC and taking effect from 11 July 2013, states that cosmetic products found on the European market have to be safe for consumer health when applied under normal or reasonably foreseeable conditions of use (EU, 2009). As mentioned in the Regulation, a safety assessment has to be done prior to placing a cosmetic product on the market. In case of cosmetic products, no pre-marketing authorization procedure is required. The safety assessment is entirely performed under the responsibility of the industry (Pauwels and Rogiers, 2010). In order to perform a safety evaluation on cosmetic products, the assessor needs to possess relevant toxicological data of all composing ingredients and accurate exposure data to assess systemic exposure (EU, 2009).

Some cosmetic consumption or exposure data are available in Europe. The European cosmetics industry (Cosmetics Europe) has published adult exposure data for shampoo, shower gel, antiperspirant, toothpaste, mouthwash, body lotion, hand cream, facial moisturiser, hair styling products, lipstick and liquid foundation. The amount of products used was obtained from the Edinburgh population in Scotland. The frequency enquiry was carried out in Denmark, France, Germany, Great Britain and Spain (Hall et al., 2007, 2011; McNamara et al., 2007). These values are currently used by the Scientific Committee on Consumer Safety (SCCS) to estimate daily exposure levels of European consumers for these cosmetic products (SCCS, 2012). Biesterbos et al. assessed the frequency and the amount of thirty-two types of personal care products used by the Dutch adult population. Tested products included general hygiene, shaving care, skin care, hair care, nail care, makeup and tanning products (Biesterbos et al., 2013). Manova et al. determined the frequency of use of face cream, make up foundation, lip care, lipstick, aftershave lotion/balm, body lotion, hand cream and sunscreen. This study was conducted among children, adolescents and adults in Switzerland (Manova et al., 2013).

Among nail cosmetics, nail polish is a lacquer applied to human finger and/or toenails to decorate the nail plate. Nail polish is available in various forms, such as base coat and top coat. Base coat can be applied to the nail before the application of polish. Base coat promotes polish adhesion and reduces staining of the natural nails.

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

0278-6915/$ - see front matter © 2014 Elsevier Ltd. All rights reserved.
http://dx.doi.org/10.1016/j.fct.2014.01.022

Top coat can be used after applying nail polish. It forms a hardened barrier for the nail to prevent chipping. Nail polish is composed of up to 70% organic solvents (such as ethyl acetate, butyl acetate or ethyl alcohol), cellulose nitrate (10%), plasticizer (such as acetyl tributyl citrate, phthalates), synthetic resin (alkyd, sulfonamide or acrylic resins) and coloring (organic or inorganic pigments). Base coat consists of more than 10% synthetic resin. Top coat contains more cellulose nitrate and plasticizer but less synthetic resin (RIVM, 2006; Andre and Baran, 2009). The consumer is exposed to nail polish, base coat and top coat by the dermal route, but also by inhalation by breathing in the solvents contained in products. Upon application of varnishes, solvents evaporate inducing the drying of products. The film formed becomes tough, stable and waterproof. The oral route can be a relevant means of exposure for consumers practicing onychophagia (i.e. nail biting).

Nail varnishes can be removed with polish remover. Polish remover dissolves nitrocellulose and removes lipids from the nail plate. This product is composed of a mixture of more than 95% solvents (such as acetone, ethyl acetate, butyl acetate and water), with small amounts of oil added to counteract the drying effect of the solvents. Nail polish remover may also contain perfume, coloring, preservatives, vitamins or UV absorbers (RIVM, 2006; Andre and Baran, 2009). Consequently, the consumer is mainly exposed to this cosmetic by inhalation by breathing in organic solvents.

Nail cosmetic consumption data are very limited in Europe. Biesterbos et al. demonstrated that 51% and 47.7% of Dutch women use nail polish and nail polish remover. The mean amount used per application was estimated at 0.3 g and 2.0 mL, respectively (Biesterbos et al., 2013). Currently, no exposure assessment to nail cosmetics has been made in Europe. Therefore, the safety of consumers cannot be guaranteed.

The aim of this study was to assess the exposure in French consumers to cosmetics on finger nails including base coat, polish, top coat and nail polish remover using the Monte Carlo probabilistic method. This evaluation was performed for adult and child consumers. Dermal, inhalation and oral routes were taken into account for base coat, polish and top coat. Exposure was assessed by inhalation for nail polish remover.

2. Materials and methods

2.1. French enquiry

A web questionnaire survey was conducted in March 2013 by a national survey company. This enquiry enabled us to collect information on usage patterns of base coat, polish and top coat on finger nails, i.e. percentage of users, frequency of use, wearing time and number of coats applied. The frequency of use was investigated for each season of the year. The percentage of users and frequency of use were also obtained for polish remover. Participants were asked about their bodyweight and if they practiced onychophagia in the presence of nail cosmetics. The enquiry was made among adult French women aged 18–85 years. Mothers were questioned on practices concerning their children to determine the percentage of users and the frequency of application. Complementary data were obtained for children aged 0–17 years.

Adult women were selected to form a nationally representative panel. Selections were realized using quota by age, socio-professional category, size of household, geographical area and degree of urbanization.

2.2. Experimental data

2.2.1. Volunteers

Volunteers were recruited by different communication sources (press articles, public notices, flyers etc.) in the Brest area in Western France. Study subjects entered a room specially arranged for cosmetic tests. Participants were asked to read and sign a consent form informing of the terms and conditions of the test. If children under 18 years wanted to participate, they had to be accompanied by a parent. Subjects were not remunerated for their participation in the study.

Volunteers filled in a questionnaire to obtain information on products habitually used (base coat, polish, top coat and/or polish remover) and to collect personal data: age, place of residence, socio-professional category, body weight and height.

Products habitually used by the volunteer were offered: base coat, different colored or colorless polishes, top coat and nail polish remover. All test products were commercialized and purchased on French markets. Volunteers were instructed to adhere to their personal habits of product use. During the test, setting and drying time of base coat, polish and top coat used were measured and the number of coats applied was noted. The time of use of nail polish remover was also measured. The quantity of each nail cosmetic used was determined by differential weighing before and after use, always in the absence of the volunteer. All subjects were invited to repeat the experiment in order to assess the intra-individual variability regarding the amount of nail cosmetic applied per use. All tests were performed on different days. Photography of the hands of participant was taken and was analysed with the software Image J to estimate the surface and the width of finger nails. Nail wall area, which is the area of skin around the nail, was estimated by multiplying the perimeter of the nail bed by 1 mm (i.e. arbitrary value defined by RIVM – Netherlands National Institute for Public Health and the Environment) (RIVM, 2006).

2.2.2. Evaporation kinetics: determination of the breathable fraction

Base coat, polish and top coat were each rapidly spread in a Petri dish (diameter of 36 mm) placed on a precision balance to determine the loss of weight (which corresponds to the evaporation of solvents). Nail polish remover was applied on a cotton pad. The tested quantities were chosen in order to be the most representative of real conditions. Evaporation rates were determined by weighing the cosmetic product at regular intervals. Experiments were conducted for 30 min for base coat, polish and top coat; and for 15 min for polish remover. Then, the percentage of evaporation was calculated and was used to define the breathable fraction (BF_T). For each product, the experiments were performed at least in triplicate.

2.3. Probabilistic exposure assessment

Each parameter was described by a distribution. Probabilistic exposure assessment was performed using Monte Carlo random simulations with @Risk 6 software (Palisade Corp.) running on Excel. This method, in which the parameters are described by a distribution, is the most practical and common probabilistic exposure assessment. The probabilistic exposure assessment was used to integrate inter-individual variability and parameter uncertainty (US EPA, 2001). From a practical point of view, in a probabilistic exposure assessment, one or more parameters in the exposure equation are defined as a probability distribution rather than a single value. Similarly, the output of a probabilistic exposure assessment is a range or probability exposure distribution.

In this study, for each parameter, the values were adjusted to theoretical distributions with the chi-squared goodness of fit test using the @Risk software. Exposure distributions were assessed by 10,000 iterations according to recommendations of the US EPA (US EPA, 2001). Median and P95 values of Weekly Exposure Dose (WED) distribution were provided for each exposure route and each age class (0–12, 13–17, 18–34 and 35–85 years). The life-long exposure was calculated for each exposure route by summing the exposure of each age class weighted by the duration of exposure.

2.3.1. Base coat, polish and top coat

Exposure was assessed for the dermal route on nails or on nail walls (i.e. skin around the nail) (Eq. (1)), inhalation route (Eq. (2)) and oral route (Eq. (3)). Oral exposure was assessed only for consumers who practiced onychophagia.

$$\mathrm{WED}_d = \sum_{n=1}^{2}\left[\left(\frac{F \times Q \times (1-\mathrm{BF_T}) \times (A/(\mathrm{NA}+\mathrm{NWA}))}{\mathrm{BW}}\right) \times \%C_n\right] \quad (1)$$

WED_d: Weekly Exposure Dose for dermal exposure route (mg (kg bw week)$^{-1}$); F: frequency of use (use/week); Q: quantity of product applied on nail per coat (mg/use); A: surface area of nail or nail wall (cm^2); NA: Nail area (cm^2); NWA: nail wall area (cm^2); $\mathrm{BF_T}$: breathable fraction calculated for a time of application equal to 10 min for base and top coat and 30 min for nail polish (unitless); BW: body weight (kg bw) and $\%C_n$: percentage of consumers applying n coats of nail varnish (unitless). n was equal to 1 or 2, because consumers apply varnishes in 1 or 2 coats (Table 2).

$$\mathrm{WED}_i = \sum_{n=1}^{2}\left[\left(\frac{F \times Q \times \mathrm{BF_T} \times \mathrm{IR} \times T}{V \times \mathrm{BW}}\right) \times \%C_n\right] \quad (2)$$

WED_i: Weekly Exposure Dose for inhalation exposure route (mg (kg bw week)$^{-1}$); F: frequency of use (use/week); Q: quantity of product applied on nail per coat (mg/use); $\mathrm{BF_T}$: breathable fraction in function of T (i.e. evaporated fraction) (unitless); IR: inhalation rate (m^3/day) (US EPA, 2011); T: setting and drying time per coat (day); V: volume of the breathable air (i.e. 1 m^3, RIVM, 2006); BW: body weight (kg bw) and $\%C_n$: percentage of consumers applying n coats of nail varnish (unitless). n was equal to 1 or 2, because consumers apply varnishes in 1 or 2 coats (Table 2).

$$\mathrm{WED}_o = \sum_{n=1}^{2}\left[\left(\frac{F \times Q \times (1-\mathrm{BF_T}) \times D \times \left(\frac{\mathrm{NG}\times\mathrm{NW}}{\mathrm{NA}}\right)}{\mathrm{BW}}\right) \times \%C_n\right] \quad (3)$$