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Consumption and exposure assessment to cosmetic products for children under 2 years old

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ABSTRACT

Today, the use of personal care products is an integral part of daily life. Little information about children's consumption and exposure to cosmetic products is available. The aim of the study was to assess the consumption and the exposure of French babies aged 0-23 months old to seven common baby care products: shampoo, shower gel, cleansing water, cleansing milk, moisturizing cream, bottom cream and wipes. Consumption and exposure were assessed using small age intervals in order to identify any differences. Exposure was calculated using a probabilistic method. These original data will be useful for safety assessors and safety agencies in order to protect consumers.

1. Introduction

Today, the use of personal care products is an integral part of daily life and involves all types of consumers regardless of age, socio-economic or cultural lifestyles. With the exception of food, there is no other product class to which people are so repeatedly exposed throughout life. The European Regulation (EU) No 1223/2009 requires that the safety of the ingredients and therefore of the finished product is ensured prior to marketing. A specific safety assessment must be conducted for products intended for use on children under the age of three. Appropriate exposure data is part of it (EU, 2009; SCCS, 2016). Exposure to a finished cosmetic product can be determined from the ratio of the daily consumption of the product to the body weight of the population (mg of product/kg bw/day).

Cosmetic products used for children are as numerous as they are varied from common products used for adults and aimed at baby's use such as shampoo, shower gel or body cream, to talcum powder and bottom cream to protect babies' bottoms against diaper rash. Nowadays, consumption and exposure data to cosmetic products are available for adults (Biesterbos et al., 2013; Ficheux et al., 2014, 2015, 2016a, 2016b; Hall et al., 2007, 2011; Loretz et al., 2005, 2006; 2008; Manova et al., 2013; Wu et al., 2010). However, very little information about children's consumption and exposure to cosmetic products is available, especially for children under the age of three. Gomez-Berrada et al. (2017) assessed the consumption and exposure to family cosmetic products by children aged 0–3 years. Likewise, Ficheux et al. (2015, 2016b and 2016c) presented a similar study in French children aged 0–3 years. Wu et al. (2010) also assessed the frequency of use of cosmetic products by American children aged 0–5 years.

In a previous work, we studied the consumption and exposure to cosmetic products used for children from 0 to 10 years old with data pooling by age group: 3–5 months, 6–11 months, 12–23 months, 24–35 months, 36–71 months and 72–132 months (Gomez-Berrada et al., 2013). The consumption data were obtained from 48 clinical safety studies aimed to assess the cutaneous tolerance and efficacy of the products. These clinical safety studies were performed according to a specific protocol, such as the frequency of use parameter which was defined by the company. Consequently, this previous study did not fully reflect the use of the products under real-life conditions. Thus, the aim of the present study was to assess the real consumption and exposure of French babies under 2 years old to seven common baby care products.

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Consumption and exposure were assessed using small age intervals to identify any differences. Exposure was calculated using a probabilistic method.

2. Materials and methods

2.1. Tested products

Seven cosmetic products dedicated to babies were included in this study. These products were selected as they were very commonly used for babies and as they were applied on a large surface area: shampoo, shower gel, cleansing water, cleansing milk, moisturizing cream, bottom cream and wipes. Among cleansers, shampoo and shower gel were rinse-off products; cleansing water and cleansing milk were leave-on products. Creams and wipes were leave-on products. Information was summarized in Table 1.

2.2. Study design

This study took place between 2010 and 2011 in the Northwest of France in the city of Rennes and surrounding area. More than 700 families were contacted according to their demographic data, and were asked about their habits in the use of cosmetic products on their babies. The main inclusion criterion was the age of the baby which had to be less than 24 months old. According to this first criterion, 150 families were eligible for inclusion in this study. The other inclusion criteria were as follows: the baby was cared for on a full time basis by at least one of the parents (no nanny or nursery was permitted); the baby was free of any pathology and allergy; only one baby under 24 months per family and parents were habitual users of the same types of products as tested in this study. Based on these last criteria, 90 of the 150 families were included in this study.

All volunteers signed a study information form and a volunteer consent form. Cosmetic products were provided to parents who were invited to use them at home on their children in the closest possible way to their personal usage patterns. Products were split into two groups (A and B). Each group of products was tested separately over a 3-week period to avoid the use of two different product types on the same body part at the same time: shampoo and shower gel for rinse off products and cleansing water and milk for leave on products. Half of the population used group A products over the first period and the group B products of over the second period and inversely for the other half of the population. This design allowed the use of all the product types. Bottom cream was tested across the whole duration of the study because of its punctual use (Table 2). Concerning wipes, a pack was delivered to each family at the end of the two 3-week periods.

2.3. Data collection

During the study, parents were asked to record in a diary the daily usage of each product over the two 3-week periods. Daily records of the wipe's use was monitored until the end of the pack. At the end of the study, the participants returned the completed diaries and the tested products. The diaries were reviewed and checked to ensure they were filled out correctly and completely. All the cosmetic products were weighed with a precision balance with sensitivity equal to 10 mg at the beginning and at the end of the study to determine the individual total amount of product used. Each baby's body weight was also collected less than 15 days preceding the inclusion of the study according to the last medical control or recorded in the home.

Table 2
Distribution of cosmetic products according to their use.

	Group A	Group B
Tested products	Shower gel (hair and body) Cleansing water Bottom cream Moisturizing cream	Shower gel (body only) Cleansing milk Bottom cream Shampoo
Study duration	3 weeks	3 weeks

2.4. Data analysis

2.4.1. Consumption analysis

The following parameters were firstly calculated for each child and for each product used:

- Frequency of use: The frequency of use was calculated by dividing the total number of use (obtained in the diary) by the number of days of the study (j^{-1}).
- Amount per use: The amount of product per use was calculated by dividing the total amount of product consumed during the study (obtained by weighing) by the total number of use according to the diary (g/use).
- Amount per day: The amount of cosmetic product consumed per day was obtained by dividing the total amount of product used (obtained by weighing) by the total number of days of the study (g/day).

For these three parameters, the mean, standard deviation, median, 90th and 95th percentile values were then calculated for all children aged 0–23 months. Data were also pooled by age group: 0–5 months, 6–17 months and 18–23 months. A Mann-Whitney test was performed on consumption data obtained between girls and boys when at least 30 data points were available. Only p-values less than 0.05 were considered to be significant.

A discriminant analysis (DA) was used to graphically assess if the groups of children were distinct as a function of age (0–5 months, 6–17 months and 18–23 months) taking into account their consumption to all cosmetic products used. DA was performed with shampoo, shower gel (applied on body), cleansing water, moisturizing cream and bottom cream. Cleansing milk was not included in DA as its function was similar to that of cleansing water (a leave-on

Table 1
For each cosmetic product, the application site, the condition of use and the retention factor were described.

Cosmetic product	Application site	Condition of use	Retention factor
Shampoo	Hair	Rinsed off	0.01
Shower gel	Body or body and hair	Rinsed off	0.01
Cleansing water	Body, face, hands and bottom	Leave on	1
Cleansing milk	Body, face, hands and bottom	Leave on	1
Moisturizing cream	Face and body	Leave on	1
Bottom cream	Bottom	Leave on	1
Wipes	Body, face, hands and bottom	Leave on	1