



Exposure assessment of family cosmetic products dedicated to babies, children and adults



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ABSTRACT

Very few consumption and exposure data is available for family cosmetic products. The aim of the present study was to assess the consumption and the exposure to family cosmetic products used by babies, children and adults. 10 categories of products were studied: shampoo, shower gel, solid soap, cleansing lotion, emollient foam, emollient bath, cream, milk, balm and lip balm.

Consumption data were obtained from 2994 participants (789 babies aged 0–3 years, 837 children aged 4–12 years and 1368 adults aged more than 18 years) included in 87 clinical safety studies. Exposure was performed using a probabilistic method.

The implementation of consumption and exposure assessment by age has strengthened this work, as consumption and mainly exposure differences were shown. In fact, babies were always the most exposed to family products, followed by children and adults. These original data will be useful for safety assessors and safety agencies in order to protect consumers.

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1. Introduction

As defined by 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 [...] 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). As mentioned in the Regulation, a safety assessment has to be done prior to placing a cosmetic product on the European market (EU, 2009). In order to perform this safety evaluation, the assessor needs relevant toxicological data on all composing ingredients as well as accurate exposure data for the finished product. Exposure (mg/kg bw/day) can be determined by dividing the daily consumption of a finished product by the body weight of the studied population. Current and relevant consumption and body weight data for each type of cosmetic products and consumers are essential for a correct exposure assessment.

Some consumption and exposure data to cosmetic products are

available. Most of them were collected on adults (Hall et al., 2007, 2011; Loretz et al., 2005, 2006, 2008). Furthermore Dey et al. (2016), Fichoux et al. (2016a) and Gomez-Berrada et al. (2013) assessed the exposure to cosmetic products intended for babies and children. Other studies provide consumption and/or exposure data for cosmetic products intended for adults and also for cosmetic products intended for children (Fichoux et al., 2015, 2016b; 2016c; Garcia-Hidalgo et al., 2017; Manova et al., 2013; Wu et al., 2010). These studies showed that many types of cosmetic products such as shower gel, shampoo, body lotion, sunscreen... were used independently of age and sex. Taking into account this information, it would be pertinent to investigate the consumption of a common cosmetic product among babies, children and adults in order to assess the corresponding exposure.

Although family cosmetic products are widely marketed, no definition is available for this type of cosmetics either in the European regulation or in the literature. For the purpose of the present paper, family products were defined as cosmetics intended for all subjects regardless of age or sex. The population included adults, children and a potential at risk sub population named as children under 3 years old in the Regulation (EC) No 1223/2009 (and defined here as “babies”). Currently, no consumption and exposure data is available for family products.

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The aim of the present study was to assess the consumption and the exposure of babies, children and adults to 10 categories of family products. Exposure was performed using a probabilistic method.

2. Material and methods

2.1. Products studied

All the studied cosmetic products were family products, i.e. there were intended for babies, children and adults. 10 types of family products were studied: shampoo, shower gel, solid soap, cleansing lotion, emollient foam, emollient bath, cream, milk, balm and lip balm. Cleansing lotion, emollient foam, cream, milk, balm and lip balm were leave-on products; shampoo, shower gel, solid soap and emollient bath were rinse-off products. 8 different shampoos were included in the family product type named as shampoo. In the same way, 11 shower gels were included in the family product type named as shower gel (See Table 1 for the other cosmetics). Most of products were intended to be applied on the face and/or the body. The shower gel could also be applied on hair for babies. The shampoo was applied on hair and the lip balm was used on lips. Information was summarized in Table 1.

2.2. Consumption data

2.2.1. Origin of data

Consumption data were obtained from clinical safety studies conducted in order to assess the cutaneous tolerance and efficacy of the products. These studies were commissioned by a French

cosmetic manufacturer and implemented by different contract research organizations. 87 clinical safety studies were performed between 2002 and 2016 in different countries. Most of the studies were conducted in Europe: 28 were carried out in France, 21 in Macedonia, 14 in Spain, 7 in Germany, 7 in Poland and 2 in Portugal. Some studies were conducted outside Europe: 3 took place in Mauritius, 3 in South Africa and 2 in Brazil (Table 2).

2.2.2. Participants

Participants were selected according to the criteria of each clinical safety study (age, sex, type of skin...). The subjects were healthy babies, children and adults (males and females) with different type of skin (normal, dry, very dry, sensitive, non-sensitive, possibly with atopic dermatitis) and with different Fitzpatrick phototypes (I to V).

2.2.3. Study design

Clinical studies were carried out over a 2–4 week-periods, depending on the protocol. One family care product was provided to each participant. The tested product had to replace the usual one. For young children, the cosmetic product was applied by their parents. The tested product had to be used under normal conditions or under specific conditions defined by the sponsor. In fact, the frequency of use was mostly imposed by the protocol. In this case, the frequencies were defined as follows: 1 or 2 time(s) per day for a shower gel, 1 or 2 time(s) per day for a cream, 3–4 times per week for a shampoo, 3 times per day or more for a lip balm... and were close to real life conditions of use.

All the studies were carried out under dermatological, ophthalmological and/or paediatric control.

Table 1

Family product types investigated. For each type of product, the number of tested cosmetic products, the application site, the condition of use and the retention factor were described.

Family product types	Number of cosmetic products per product type	Application site	Condition of use	Retention factor
Shampoo	8	Hair	Rinsed off	0.01
Shower gel	11	Face/body	Rinsed off	0.01
		Face/body/hair (babies)		
Solid soap	3	Face/body	Rinsed off	0.01
Cleansing lotion	3	Face/body	Leave on	1
		Face/body/bottom (babies)		
Emollient foam	1	Face/body	Leave on	1
Emollient bath	6	Face/body	Rinsed off	0.01
Cream	9	Face/body	Leave on	1
Milk	6	Face/body	Leave on	1
Balm	10	Face/body	Leave on	1
Lip balm	7	Lips	Leave on	1

Example: 8 different shampoos were included in the shampoo family product type. Shampoo was applied on hair. The retention factor was equal to 0.01.

Table 2

Number of studies performed by country and by tested product.

	Number of studies	Number of studies per product type									
		Shampoo	Shower gel	Solid soap	Cleansing lotion	Emollient foam	Emollient bath	Cream	Milk	Balm	Lip balm
France	28	7	6			1	4	4	1	4	1
Macedonia	21	2	5	1		1	1	1	3	6	1
Spain	14	1	1	1	4		1	1	2		3
Germany	7	2					1	2		2	
Poland	7			1				1	2	1	2
Mauritius	3	2	1								
South Africa	3		1				1		1		
Brazil	2							1		1	
Portugal	2			1				1			
Total	87	14	14	4	4	2	8	11	9	14	7

Example: 28 studies were conducted in France. Among them, 7 were performed on shampoo, 6 on shower gel, 4 on emollient bath, 4 on cream, 4 on balm, 1 on emollient foam, 1 on milk and 1 on lip balm.

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