Introduction

According to current European legislation, cosmetic products intended for use on children under 3 years old should undergo a specific assessment than is required for products directed at other consumer groups. Indeed the safety assessment of cosmetic products intended for children under 3 years old must take into account:

- The fact that, proportionally to their weight, the body surface of children of 0-3 years old is more important than that of adults and that functional maturity of the metabolic systems may not be stabilized before 2 years old,
- Certain specific conditions of exposure, especially at the level of the seat area, which is highly exposed,
- The different types of products, especially not-rinsed products that can be applied several times a day with no limit.

However, to conduct reliable safety assessment, accurate exposure information for cosmetic products and ingredients is needed. Essential information includes both the amount of cosmetic product applied and the frequency of use. The aim of this study was to determine the amount per application for each of the most commonly used baby cosmetic products with the minimum disturbance to subject’s daily habits.

Materials and Methods

Study design and population

This study was carried out on two different places (Spot PF and Spot PC) and performed on 181 babies (cf table 1) between 2010 and 2011. Studies designs were as follow:

Spot PF: Subjects were supplied with all the products and in order to have the minimum disturbance to subject’s daily habits, no specific direction of use was provided. They were asked to record for each product the detailed daily usage information over a 3 weeks period.

Spot PC: Products were shared in two groups and tested during two periods of 3 weeks to avoid the same destination of two rinsed off products and permit the use of all the products. No specific direction of use was provided. They were asked to record for each product the detailed daily usage information over the two 3 weeks periods.

Test products

The study included 6 products: one face and body leave-on (cream), two cleansers without rinsing (cleansing water, cleansing body lotion), two rinsed-off products (cleanser, shampoo) and one diaper rash.

Data collection and statistical analysis

Spot PF: 10 samples of each product were weighted at the start to have a mean start weight and all products were weighted at the completion of the study in order to determine the total amount of product used. Spot PC: all the samples were weighed at the start and completion of the study in order to determine the individual total amount of product used.

A structured data collection sheet was created to collect information on subjects. They returned the test products and the completed diaries. The diaries were reviewed and checked to ensure they were filled out accurately and completely. The respondent’s data were then entered and linked to the weight data files.

Statistical analysis was performed on the mean weight per application which was calculated for each subject and for each product. Data homogeneity was controlled for each spot in a third time in order to extract aberrant data and in a second time, the two spots were compiled. Mean, standard deviation and 90th percentile, for each product were calculated for each spot and for the compiled file. Spots were also compared (Student’s test) in order to give rise differences between spots.

Table 1

<table>
<thead>
<tr>
<th>Population</th>
<th>Spot PC</th>
<th>Spot PF</th>
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</thead>
<tbody>
<tr>
<td>Male</td>
<td>81</td>
<td>100</td>
</tr>
<tr>
<td>Female</td>
<td>40</td>
<td>50</td>
</tr>
</tbody>
</table>

Age (months)

Mean +/- SEM: 11.0 +/- 7.3, 10.3 +/- 6.6

Mini: 15 days, 10 days

Max: 23, 24

Weight (kg)

Mean +/- SEM: 8.50 +/- 2.59, 8.55 +/- 2.53

Mini: 2.6, 3.7

Max: 14, 15

Conclusion

To assess exposure to chemicals in personal care products, one must know the ingredients of products and the relevant exposure scenarios, including both the use frequency and the amount of product used each time. Furthermore, to assess the potential health risks for the population, probabilistic models are often used, requiring distributions of product use across the population to generate a distribution of exposure. However there is great variability in product use between individuals; as illustrated by the difference between Spot PC and Spot PF. The most important aspect of exposure assessment is not to underestimate the exposure of the population to the product of interest. In summary, this study provides recent information on use patterns for a large number of commonly used personal care products dedicated to babies, thus updating the current knowledge on usage of personal care products. These data in real everyday life conditions are additional to the retrospective exposure data for baby care products.

Bibliography


Keywords: daily, cosmetic exposure, safety