



Retrospective exposure data for baby and children care products: An analysis of 48 clinical studies



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ABSTRACT

To conduct a reliable safety assessment, accurate exposure information for cosmetic products and ingredients is needed. The aim of the present retrospective study was to determine the amount per application and the daily exposure for some of the most commonly used baby cosmetic products. Consumption data from 48 clinical studies performed on 1481 babies and children (from 0 to 10 years old) were reviewed and used to conduct a probabilistic evaluation of dermal exposure. Six categories of products were reviewed: rinseoff products for hair and body; rinse-off products for the whole body; leave-on products for face and body; cleansers for face and body; diaper dermatitis treatment products; shampoos. Subjects were provided with products and recorded detailed daily usage information over a 1–4-week period, depending on the study. Products were weighed at the start and upon completion of each study in order to determine the total amount of product used.

The mean, median, standard deviation and 95th percentile were calculated for daily consumption and exposure, for several age groups from 0 to 10 years old. This study provides current baby cosmetic exposure information for commonly used products which will be useful for risk assessment purposes.

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1. Introduction

Risk assessment usually includes four steps (Samet, 2004): hazard identification, which consists in studying how a substance may be toxic; hazard characterization, which consists in characterizing toxic doses; exposure assessment, which consists in assessing the amount of the substance to which consumers are exposed; risk characterization. This last step consists, roughly, in a comparison between non toxic doses characterized by dose-response and exposure doses from exposure assessment. A risk can be assessed if, and only if, hazard and exposure have been characterized. The present study deals with the third step, exposure assessment, for baby cosmetic products.

A specific assessment for products intended for use on children under the age of three is required by European regulation 1223/2009 (EU, 2009), and a specific exposure assessment is a part of it. However, available exposure data on children's cosmetic products are few. Those products are as numerous as they are varied: talcum powder to protect babies' bottoms against diaper humidity, creams for seborrheic dermatitis, lotions, etc. But also common products used by adults, aimed at baby use: shampoos, shower gels, body creams, etc.

Nowadays, some data on adult cosmetic product consumption are available (Hall et al., 2011; Loretz et al., 2005, 2006, 2008) and are from large population samples. Yet there exists very little information about children's consumption. Rijksinstituut voor Volksgezondheid en Milieu (RIVM) has published some data on child-specific cosmetic products, in its cosmetics fact sheet (Bremmer et al., 2006) but it only covers consumption, and does not take into account the children's age. In literature, data for widely used cosmetic products, designed for children, can be found, but age groups are quite large: a single age group from 0 to 5 years old for example in Wu's paper (Wu et al., 2010).

Except for the RIVM cosmetics fact sheet and this work by Wu, there are no available data on the consumption of children and baby care products. The purpose of this study is to provide relevant data on baby care product consumption and exposure, for specific

Abbreviations: CSEFH, Child Specific Exposure Factors Handbook; RIVM, Rijksinstituut voor Volksgezondheid en Milieu; SCCS, Scientific Committee on Consumer Safety; USEPA, United States Environmental Protection Agency.

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Table 1
Characteristics of the study population. All the values are from the Child Specific Exposure Factor Handbook (EPA, 2008a, 2008b), except the bottom's surface area, missing in CSEFH, and found in the RIVM cosmetics fact sheet (Bremmer et al., 2006).

Age group	Age (months)	N	Body weight			Total body surface area (cm ²)			Relative body surface area (percent of total)			
			Mean	P05	P95	Mean	P05	P95	Head	Trunk	Bottom	Hands
2	3 to <6	66	7.4	5.7	9.1	3800	3300	4400	18.2	35.7	6.0	5.3
3	6 to <12	205	9.2	7.1	11.3	4500	3800	5100	18.2	35.7	6.0	5.3
4	12 to <24	407	11.4	8.9	14	5300	4500	6100	16.5	35.5	5.9	5.7
5	24 to <36	293	13.8	10.9	17.1	6100	5200	7000	14.2	38.5	6.4	5.3
6	36 to <72	379	18.6	13.5	26.2	7600	6100	9500	13.7	31.7	5.3	5.9
7	72 to <132	131	31.8	19.7	52.5	10,800	8100	14,800	12.6	34.7	5.8	5

Table 2
Details of products used and exposed surface for each category of products. For shampoos, it is considered that products are applied by parents. Thus, and contrary to the SCCS's guidance (SCCS, 2011), hands are not considered as an exposed surface.

Category of products	Concerned products	Exposed surface
Rinse-off for hair and body	Gels Oils Foams	Hair and body
Rinse-off products for the whole body	Gels Foams Cream	Hair, body and face
Leave-on products for face and body	Creams Lotions Balms	Face and body
Cleansers	Cleansing waters Cleansing lotions	Whole body
Diaper dermatitis treatment products	Cream Oil spray Paste	Bottom
Shampoos	Shampoo	Hair

products, such as diaper dermatitis treatment products, but also for standard products designed for children, such as shampoos or cleansers. Consumption and exposure were assessed using small age intervals, to identify any consumption or exposure differences between babies and older children, which cannot be determined with other available studies, using as large and vague age groups as “children”.

Table 4
Probabilistic consumption and exposures data for each age group for leave-on products.

Age group		Amount per use (g)	Frequency of use (use/d)	Amount per day (g/d)	Exposure per bw unit (mg/kg bw/d)	Exposure per surface area unit (mg/cm ² /d)
2	Mean	4.50	1.16	5.21	731.99	1.51
	Median	3.33	1.10	3.67	508.13	1.05
	SD	4.05	0.39	5.22	751.82	1.53
	P95	11.90	1.88	14.60	2052.08	4.21
3	Mean	5.52	1.55	8.48	956.91	2.13
	Median	4.12	1.37	5.62	624.53	1.41
	SD	4.95	0.81	9.69	1110.96	2.49
	P95	14.46	3.09	25.33	2921.09	6.38
4	Mean	5.23	1.58	8.24	744.43	1.72
	Median	4.03	1.49	6.01	537.31	1.25
	SD	4.33	0.55	7.69	708.97	1.64
	P95	13.22	2.60	22.04	2012.19	4.64
5	Mean	5.60	1.55	8.73	645.77	1.56
	Median	4.56	1.40	6.41	468.80	1.14
	SD	4.00	0.75	8.04	607.46	1.46
	P95	13.08	2.97	23.17	1736.44	4.21
6	Mean	5.00	1.70	8.46	457.65	1.20
	Median	3.83	1.58	6.08	323.03	0.86
	SD	4.19	0.65	8.17	458.31	1.19
	P95	12.72	2.91	23.29	1281.60	3.33
7	Mean	6.58	1.80	11.82	386.76	1.18
	Median	5.33	1.56	8.39	260.48	0.82
	SD	4.81	1.02	11.98	419.31	1.25
	P95	15.51	3.72	32.71	1110.07	3.30

SD: standard deviation; P95: 95th percentile.

Table 3
Bootstrap homogeneity test between age groups: groups are statistically homogen (level of confidence 95%) if $0.025 < P < 0.975$.

Joint age groups		P				
		2–3	3–4	4–5	5–6	6–7
Leave-on products	Amount/use	0.91	0.25	0.86	0.09	1
	Absolute exposure	1	0.31	0.34	0.5	1
	Per unit bw exposure	0.96	0.01	0.03	0	0
Rinse-off products (hair and body)	Amount/use	0.87	0.36	0.72	0.14	0.84
	Absolute exposure	0.93	0.78	0.53	0.87	0.91
	Per unit bw exposure	0.56	0.07	0	0	0
Rinse-off products (whole body)	Amount/use	0.72	0.92	0.49	0.01	0.3
	Absolute exposure	0.54	0.97	0.1	0.018	0.06
	Per unit bw exposure	0.113	0.321	0	0	0
Cleansers	Amount/use	0.34	0.48	0.98	0.95	No data
	Absolute exposure	0.21	0.98	0.92	0.55	No data
	Per unit bw exposure	0.04	0.47	0.11	0	No data
Diaper dermatitis treatment products	Amount/use	0.21	0.17	0.23	No data	no data
	Absolute exposure	0.99	0.99	0	No data	No data
	Per unit bw exposure	0.91	0.98	0	No data	No data
Shampoos	Amount/use	No data	0.77	0.9	0.98	No data
	Absolute exposure	No data	0.83	0.73	0.99	No data
	Per unit bw exposure	No data	0.46	0.2	0.43	No data

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