

Phthalates in Baby Skin Care Products

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Background: The systemic toxicity of phthalates has been extensively reported. Although rarely sensitizing, phthalates have been implicated in promoting the development of both atopy and contact dermatitis in animal models. Dermal absorption of phthalates may contribute to overall chemical burden. Infants may be particularly susceptible to chemical exposures. Baby skin care products may be a significant source of phthalate exposure.

Objective: We measured the phthalate content of 30 skin care products intended for babies and children.

Methods: Nineteen leave-on and 11 wash-off baby skin care products were analyzed for 17 unique phthalates by an independent laboratory using standard gas chromatographic mass spectrometry.

Results: Of 30 products tested, four had phthalate levels above the reporting limit (0.1–0.5 ppm); of these, only one had levels above 1 ppm (44 ppm). There was no statistical significance of phthalate detection in leave-on versus wash-off products ($p = .578$).

Conclusion: The majority (26 of 30) of the baby skin care products analyzed did not have detectable phthalate levels. Four products had detectable phthalate levels. In baby skin care products, levels of the 17 phthalates tested are low overall, but occasional products may contain higher phthalate levels. Monitoring products to ensure safety standards are met may be warranted.

PHthalates are man-made esters of phthalic acid and are used in many industries. Their use adds flexibility, durability, and transparency to plastic (usually polyvinyl chloride). Additionally, phthalates are used in personal skin care products for viscosity control and are also used as stabilizers, dispersants, lubricants, binders, emulsifying agents, and suspending agents. Although rarely listed as ingredients, phthalates have been detected in numerous adult skin care products.^{1,2} Their presence has been attributed to contaminants, to part of the “fragrance” in the ingredient list, or to by-products of manufacturing.

In the last decade, there has been increasing public concern about environmental exposure to phthalates,^{3–5} given their association with systemic toxicity in both animal and in vitro studies.^{6–20} For example, there has been a correlation between phthalates and toxic effects on the genitourinary system from di-n-butyl phthalate (DnBP) in rats,⁷ as well as from diethyl phthalate (DEP),

mono-n-butyl phthalate (MBP), monobenzyl phthalate (MBzP), and monoisobutyl phthalate in humans.⁸ Studies have noted reproductive-system effects in rats from DnBP⁹ and bis(2-ethylhexyl) phthalate (DEHP),^{10–12} in mice offspring from DEP,¹³ and in humans from DnBP and DEHP¹⁴ as well as DEP, MBP, and MBzP.^{15,16} Cardiopulmonary-system consequences have been reported with exposure to mono-2-ethylhexyl phthalate in vitro¹⁷ and to DEHP in rats.^{18,19} DEHP has also been documented to affect the rat gastrointestinal system.^{10,20}

There are also data to support dermatologic manifestations of phthalate exposure. Contact urticaria from DEHP following exposure to polyvinyl chloride-coated cotton gloves²¹ and to a work uniform²² has been described. Although phthalates are not highly sensitizing,²³ reports of allergic contact dermatitis from phthalates have been published.^{24–33} There is evidence that DnBP promotes susceptibility to (and development of) contact dermatitis in mouse models.³⁴ Atopic dermatitis-like lesions in mice have also reportedly been exacerbated by exposure to DEHP at low concentration levels³⁵ and also by exposure in utero,³⁶ suggesting that widespread exposure to phthalates may play a role in the increasing prevalence of atopic dermatitis.

Human exposure to phthalates is extensive; in the 1999-to-2000 United States National Health and Nutrition Examination Survey, at least one phthalate urinary metabolite was detected in 99% of the 2,540 adult urine samples analyzed.³ As a result of the current public health

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concern, the Consumer Product Safety Improvement Act was passed by Congress in 2008, banning several common phthalates, DEHP, DnBP, n-butyl benzyl phthalate, diisononyl phthalate, diisodecyl phthalate, and di-n-octyl phthalate in concentrations greater than 0.1% in any children's toy or child care articles such as teethers.⁴

Additionally, it has been proposed that dermal absorption of phthalates may contribute to the overall chemical burden of exposure.^{37,38} Sathyanarayana and colleagues measured nine phthalate metabolites in the urine of 163 infants and reported a significant correlation between the application of lotions, powders, and shampoo products in the 24 hours prior to collection and increased urinary phthalate concentrations. This association was even stronger in younger infants and increased with the number of products applied.³⁹ With their developing livers and a unique ratio of surface area to volume, infants may be a particularly susceptible population with regard to dermal absorption of chemicals.^{40,41}

At the time of this study, there were no published studies evaluating baby skin care products for the presence of phthalates. This study sought to determine if phthalates are present in baby skin care products, including leave-on, wash-off, and "soaking" products (ie, products—such as bubble baths—that are intended as wash-off products but that may in practice entail longer skin exposures).

Methods

Thirty skin care products intended for infants and children were purchased from an independent infant-focused retail store. In regard to selection methodology, an attempt was made to obtain at least one product from each manufacturer available, and an adequate representation of diverse product types was intended. These included 19 leave-on products and 11 wash-off products from a variety of manufacturers. Each product was categorized as body wash, baby bath, moisturizer, sunscreen, or diaper cream (Table 1). The products were shipped in their original containers to an independent laboratory (Analytical Sciences, Petaluma, CA), where phthalate analysis was performed. For each product, 0.5 to 1.0 g of the sample was carefully weighed to the nearest tenth of a milligram (ie, ± 0.0001 g) in a 40 mL vial. Exactly 10 mL of clean hexane was added to each sample vial, which was then sealed with a polytetrafluoroethylene-lined cap. The vials were mixed with a vortex mixer and placed (sealed) into a sonication bath for 30 minutes. After extraction by sonication, the vials were allowed to stand for at least 2 hours, at which point a portion of the hexane solvent

extract was removed and placed into a sealed autosampler vial for analysis by gas chromatographic mass spectroscopy (GC/MS). In some cases, a dilution was used in the initial analysis owing to the overall hydrocarbon content expected in the original sample, and the reported detection limit (RDL) increased by the dilution factor.

The GC/MS instrument was optimized and calibrated for 17 specific phthalate compounds prior to the analysis of the extracted skin care products (Table 2). The phthalate compounds in the analyzed products were identified and quantitated by the GC/MS software. Results were reported in units of parts per million (ppm) or milligrams per kilogram of phthalate present in the analyzed product.

Results

Phthalates were detected in 4 of the 30 products tested (Table 3). Two products were leave-on products and two

Table 1. Baby Skin Care Products Tested

<i>Product No.</i>	<i>Product Type</i>	<i>Application</i>
1	Baby bath	Wash-off
2	Body wash	Wash-off
3	Moisturizer	Leave-on
4	Diaper cream	Leave-on
5	Sunscreen	Leave-on
6	Moisturizer	Leave-on
7	Moisturizer	Leave-on
8	Moisturizer	Leave-on
9	Moisturizer	Leave-on
10	Body wash	Wash-off
11	Moisturizer	Leave-on
12	Body wash	Wash-off
13	Body wash	Wash-off
14	Sunscreen	Leave-on
15	Diaper cream	Leave-on
16	Diaper cream	Leave-on
17	Sunscreen	Leave-on
18	Sunscreen	Leave-on
19	Moisturizer	Leave-on
20	Baby bath	Wash-off
21	Body wash	Wash-off
22	Body wash	Wash-off
23	Body wash	Wash-off
24	Diaper cream	Leave-on
25	Moisturizer	Leave-on
26	Moisturizer	Leave-on
27	Sunscreen	Leave-on
28	Body wash	Wash-off
29	Baby bath	Wash-off
30	Moisturizer	Leave-on

Table 2. Tested Phthalates

Bis(2-n-butoxyethyl) phthalate	Diethyl phthalate
Bis(2-ethoxyethyl) phthalate	Dihexyl phthalate
Bis(2-ethylhexyl) phthalate	Diisobutyl phthalate
Bis(2-methoxyethyl) phthalate	Diisodecyl phthalate
Bis(4-methyl-2-pentyl) phthalate	Diisononyl phthalate
Butyl benzyl phthalate	Dinonyl phthalate
Diamyl phthalate	Dimethyl phthalate
Di-n-butyl phthalate	Di-n-octyl phthalate
Dicyclohexyl phthalate	

were wash-off products. Product #21 (a body wash) contained 0.14 ppm of DnBP (RDL, 0.1 ppm), whereas product #20 (a baby bath) contained 0.34 ppm of DEHP (RDL, 0.1 ppm). Product #5 (a sunscreen) contained 44.0 ppm of DEP (RDL, 1.0 ppm), and product #26 (a moisturizer) contained 0.29 ppm of DEP (RDL, 0.2 ppm) (see Table 3). There was no statistical significance between the wash-off and leave-on product groups in terms of phthalate detection ($p = .578$). The remaining products tested did not have phthalates detected above the RDL.

Discussion

Diethyl phthalate was found in two products. It was found in highest concentration (44 ppm) in a sunscreen (product #5), and we believe it was a component of the “fragrance” listed on the label. In a recent analysis of phthalates in Canadian adult and baby skin care products performed in 2007, DEP was detected in fragrances at levels of up to 25,000 ppm. In the same study, tested adult body lotions contained DEP levels of greater than 5,500 ppm. One tested diaper cream contained more than 2,500 ppm of DEP, and one baby lotion contained 571 ppm.² Other phthalates found in our study include DEHP and DnBP. Of the 98 baby skin care products tested by Koniecki and colleagues, only one (a baby lotion) contained detectable amounts of DEHP (15 ppm). Two baby shampoos in the same study contained low levels of DnBP, with a

maximum level of 1.8 ppm.² The DnBP and DEHP found at low levels in our tested products likely were impurities and were not added intentionally.²

In our study, the RDL varied by substance, depending on the hydrocarbon content; thus, the RDL influenced the phthalate detection threshold. For example, if the RDL of product #26 (a moisturizer) was the same as that of product #5 (a sunscreen)—for example, 1.0 ppm instead of 0.2 ppm—the concentration of DEP would have been reported as undetectable. Although this may have “protected” hydrocarbon-dense products from phthalate detection by GC/MS, the RDLs in general are in a similar range (Table 4).

Additionally, this pilot study was intended to make broad observations rather than specific implications, and this is simply a limitation of this laboratory technique for measuring phthalates. Polyvinyl chloride (PVC) plastics, which use phthalates as plasticizers, can leach various phthalates directly into the products they contain.^{42,43} We were unable to locate any products cased in PVC, and all labeled containers of the products tested were considered phthalate free. It was cost prohibitive to test all infant products available at this retailer; thus, there may have been selection bias in product choice. However, an effort was made to obtain a diverse representation of products and manufacturers.

Another limitation is that only one container of each product was sent to the laboratory for analysis. Phthalate content may have varied among product batches; thus, we may have tested a particularly low- or high-phthalate product with respect to the true average phthalate content of the standard product. Manufacturing processes continue to evolve, and we could have tested an older and less contemporary product not representative of current product content. Additionally, all sunscreen products were not expired at the time of testing. Although analysis sought 17 specific phthalates (see Table 2), it is possible that novel phthalates not included among these 17 phthalates are being used in manufacturing and were therefore not detected in this study.

Table 3. Results for Products with Detectable Phthalates

Product No.	Product Type	Phthalate Detected	Detected Phthalate Concentration (ppm)	RDL (ppm)
5	Sunscreen	Diethyl phthalate	44.0	1.0
20	Baby bath	Bis(2-ethylhexyl) phthalate	0.34	0.1
21	Body wash	Di-n-butyl phthalate	0.14	0.1
26	Moisturizer	Diethyl phthalate	0.29	0.2

ppm = parts per million; RDL = reported detection limit.

Table 4. Examples of Reported Detection Limits for Diethyl Phthalate

<i>Product No.</i>	<i>Product Type</i>	<i>RDL (ppm)</i>
1	Baby bath	0.10
2	Body wash	0.20
3	Moisturizer	0.20
4	Diaper cream	0.20
5	Sunscreen	1.00
6	Moisturizer	1.00
7	Moisturizer	0.50
8	Moisturizer	0.20
9	Moisturizer	0.20
10	Body wash	0.10
11	Moisturizer	0.20
12	Body wash	0.10
13	Body wash	0.10
14	Sunscreen	1.00
15	Diaper cream	1.00
16	Diaper cream	1.00
17	Sunscreen	1.00
18	Sunscreen	1.00
19	Moisturizer	0.20
20	Baby bath	0.10
21	Body wash	0.10
22	Body wash	0.10
23	Body wash	0.10
24	Diaper cream	1.00
25	Moisturizer	0.50
26	Moisturizer	0.20
27	Sunscreen	1.0
28	Body wash	0.10
29	Baby bath	0.10
30	Moisturizer	0.20

ppm = parts per million; RDL = reported detection limit.

In 2002, a study performed an independent phthalate analysis of 72 adult personal care products and found that 72% (52 of 72) of products tested contained detectable levels of phthalates in concentrations ranging from trace to 3%.⁴⁴ A follow-up study in 2008 noted a decreased or undetectable level of phthalates in 9 of 12 products retested.⁴⁵ A 2007 analysis found detectable levels of phthalates in 44% (112 of 252) of products tested.² We found detectable levels of phthalates in 13% (4 of 30) of our tested baby skin care products. Our study confirms that, overall, low or undetectable amounts of phthalates are present in baby skin care products although occasional products have higher levels. Also, there seems to be a trend of decreasing phthalate content in skin care products, given these data (our study, performed in 2009, is the most contemporary).

However, given the occasional baby skin care product with a higher phthalate level, it may be prudent to periodically monitor such products for phthalates. Perhaps manufacturing guidelines with regard to phthalates should be considered, along with eventual global standards for individual phthalates. There is certainly a need for continued research and investigation to help determine if there is a clear cause and effect between specific phthalates and human toxicity.

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