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Parabens in Children's Products

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Parabens in Children's Products

by

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Abstract

The Washington State Department of Ecology's [Waste 2 Resources \(W2R\)](#) and [Hazardous Waste and Toxics Reduction \(HWTR\)](#) programs conducted a study to evaluate the presence of five parabens in children's products. Parabens are most commonly used as preservatives. The study was conducted to evaluate compliance with Washington's [Children's Safe Product Act \(CSPA\)](#) and to determine possible presence of parabens in children's products. It was funded by a grant from the Washington State Attorney General's Office.

Children's products were tested for five parabens (methyl paraben, ethyl paraben, n-propyl paraben and two butyl paraben esters, n-butyl and iso-butyl). A wide range of product types were tested, and parabens were found in appreciable levels in many products to which children are exposed primarily either by mouth or applied to their skin. Seasonal products such as Halloween makeup contained both the highest levels and the greatest incidence of detection. Parabens were found in 78 percent of the Halloween product components tested.

Test results show that a wide range of paraben products can be tested using existing methodologies and that parabens were routinely detected at less than the 1 ppm level validating the practical quantitation limit (PQL) of 30 ppm in Ecology's Reporting Guidance.¹ The lower detection limits obtained suggest a lower PQL in the Reporting Guidance may be appropriate.

Ecology initiated compliance correspondence for 38 paraben results. Methyl paraben was the most common subject of compliance assurance (16 results), followed by propyl paraben (13). All manufacturers were found to be in compliance as the company's annual aggregate gross sales were sufficiently low that reporting was not yet required due to the phased in schedule in the CSPA reporting rule².

¹ Children's Safe Product Act-Reporting Rule-WAC 173-334, Reporting Guidance-Practical Quantitation Limits (PQLs), available at: http://www.ecy.wa.gov/programs/swfa/cspa/pdf/cspaguide_pql.pdf, accessed 12/2013.

² Specifically, WAC 173-334-110

Background

Parabens

Parabens are a class of chemicals added to consumer products primarily as a preservative. Parabens are the most widely used preservatives in cosmetics. Traditionally, more than one paraben is used in each product and parabens are often used in combination with other preservatives (USFDA³, 2012). Cosmetics that may contain parabens include makeup, moisturizers, hair care products, and shaving products, among others. Most major brands of deodorants and antiperspirants do not currently contain parabens. (USFDA, 2012)

All parabens are esters of para-hydroxybenzoic acid (CAS 99-96-7). The four major esters evaluated in this study in cosmetics and personal care products are:

- Methyl paraben (CAS 99-76-3)
- Ethyl paraben (CAS 120-47-8)
- n-Propyl paraben (CAS 94-13-3)
- Butyl paraben (two isomers):
 - n-Butyl paraben (CAS 94-26-8)
 - iso-Butyl paraben (CAS 4247-02-3)

Numerous studies have indicated humans are exposed to large amounts of parabens. Using a small sample of U.S. adults, Ye et al., (2006) reported methyl and n-propyl paraben in 99% and 96% of urine specimens, respectively. Paraben values ranged from 43.9 µg/L for the methyl ester to 0.5 µg/L for the butyl ester at the low end. Calafat et al., (2010) reported similar values using the National Health and Nutrition Examination Survey (NHANES) 2005-2006 sample data. Females had three times higher levels of methyl paraben and seven times higher levels of n-propyl paraben than males. Similar results have been reported in the European Union. Frederiksen et al., (2011) reported that the main four groups of parabens were detected in 80% or more of the urine specimens from a small sample of Danish males.

Concerns have been raised about the potential estrogenic effects of parabens. Although parabens have been shown to be weak estrogenic compounds compared with other synthetic estrogens, the high levels of parabens to which humans are exposed may compensate for their weak estrogenic activity (DOH⁴, 2012). In addition, parabens have demonstrated adverse effects on sperm production and testosterone levels following oral exposure (DOH, 2012).

The European Union (EU) identified four of the parabens on Washington's Chemicals of High Concern to Children (CHCC) list as Category 1 potential endocrine disruptors, i.e., chemicals that have shown 'Evidence of endocrine disruption activity' (Stone and Delistraty, 2010). The EU determination was prior to the implementation of the REACH (Registration, Evaluation,

³ United States Food and Drug Administration

⁴ Washington State Department of Health

Authorisation of Chemicals) regulations and is currently being re-evaluated. As reviews of each chemical are completed, any found to be of sufficient concern will be added to the substances of very high concern (SVHC) list. Recent evidence, however, suggests a link between parabens and breast cancer. (Barr, 2012) The EU information and an extensive review of the literature were sufficient to place parabens on Washington's CHCC list.

The CSPA Reporting Rule was finalized in June of 2011 (Ecology, 2011) and implements the reporting requirements under the CSPA. Companies making children's products must report on 66 chemicals or classes of chemicals if found in children's products (Ecology, 2009). The CHCC list includes chemicals that have primarily either been found in children's products or have been documented to be present in human tissues. Four parabens and their parent compound p-hydroxybenzoic acid are included in this list. Certain children's products containing these compounds were reported to Ecology. Reporting requirements began with the largest manufacturers making products intended for mouth or skin contact or any product that is mouthable for children three years and under. Other manufacturers report using a phased-in schedule included in the rule.

Children's cosmetic and personal care products were purchased in numerous sampling events. Samples suspected to contain parabens were sent to a contract laboratory for analysis. Components were screened using an XRF⁵ analyzer for metals of interest and those samples containing high levels of metals were submitted for analysis.

Sampling Process Design (Experimental Design)

Product labels, product databases from government and non-governmental organizations (NGO) sources, internet searches, etc. were used to identify products potentially containing parabens. Children's cosmetic and personal care products were purchased from local stores and internet retailers for testing. Special emphasis was placed on products designed to be applied to the skin or ingested.

The products were separated into three components; packaging, containers, and product. For example, a container of children's lip gloss was separated into packaging, product (lip gloss itself), and container (the device used to store or apply the product). Depending on its construction, the container was further separated into different components as identified in the CSPA rule. Packaging is not covered by CSPA but it was retained for potential analysis under a separate study as four toxic metals (cadmium, hexavalent chromium, lead, and mercury) are restricted by Washington's toxics in packaging legislation (WSL⁶, 1991).

Sixty-eight components were sent to the laboratory for paraben analysis. Laboratory analyses were conducted by high performance liquid chromatography-mass spectroscopy (HPLC/MS) (parabens). More information on method used and Quality Assurance/Quality Control requirements may be found in the Quality Assurance Project Plan (QAPP) for this sampling event (Ecology, 2012a).

⁵ X-ray fluorescence

⁶ Washington State Legislature

Metals

The QAPP for this sampling event included the analysis of product components for a suite of ten metals. As these metals were also the subject of other QAPPs for analysis of children’s products for phthalates (Ecology, 2012b) and formaldehyde and volatile organic compounds (Ecology, 2012c), metals analyses for children’s products and will be published in a single report.

Data Quality

One baby lotion sample (RA003) was submitted as an unannounced check on the quality of the data provided. There was excellent agreement between the paraben results for the two samples (Table 1).

Table 1: Results of unannounced duplicate sample

Sample	Methyl	Ethyl	Propyl	Butyl	Isobutyl
RA003-c01	560.0	0.0	600.0	180.0	0.0
RA003-d01	470.0	0.0	520.0	160.0	0.0

Variability for these results ranged between 5.6 to 9.6%, well within the acceptable ranges identified in the QAPP. All data results were found to be within the quality assurance and quality control parameters established within the QAPP (Ecology, 2011a.)

Paraben Results

Forty-three individual products (Table 2) were analyzed for five parabens. From these 43 products, 68 individual samples were sent to the laboratory for analysis as some products were separated into multiple individual components. For example, the Monster Value Makeup Set (Figure 1) was separated into sixteen different components. Each color of makeup, separate vials and individual crayons were treated as potentially unique samples. To simplify analysis and to obtain sufficient sample, products were sometimes combined into composite samples. Individual samples of the white cream makeup and glitter were collected and were submitted along with the two composites from the makeup and crayons for analysis. Multiple samples were collected from another eleven products and results from each component will be presented separately.

Table 2: Products Tested for Parabens

Category	Description	Category	Description
Baby accessories	Baby changing wipes	Halloween	"How to" DVD Makeup Kit
Baby accessories	Baby Lotion	Halloween	Face Painting Kit
Baby accessories	Baby Lotion	Halloween	Family Value Makeup kit
Baby accessories	Baby Lotion	Halloween	Halloween Makeup variety pack
Baby accessories	Baby Lotion	Halloween	Monster High Makeup kit
Baby accessories	Baby Lotion	Halloween	Monster Value Makeup Set
Baby accessories	Baby Lotion	Halloween	White face powder

Category	Description	Category	Description
Baby accessories	Baby wipes	Lip balm	Butterscotch lip balm
Baby accessories	Blue teething ring	Lip balm	Princess keychain and chapsticks
Baby accessories	Petroleum Jelly	Lip balm	Princess keychain and chapsticks
Baby accessories	Petroleum Jelly	Lip balm	Princess lip balm & keychain in tube
Baby accessories	Supreme unscented wipes	Lip balm	Princess lip balm & keychain in tube
Baby accessories	Toddler wipes	Lip balm	Ring pop chapstick
Baby accessories	Travel baby wipes	Lip balm	Strawberry lip balm
Bath accessories	Bath and body collection	Lip gloss	12 roll-on lip glosses
Bath accessories	Color Bath Dropz	Lip gloss	4 lip glosses with zipper pouch
Cosmetics	Face paint transfer sheets & crayon	Lip gloss	Lip gloss set
Cosmetics	Glitter face makeup	Lip gloss	Lip gloss set
Cosmetics	Make up pack	Lip gloss	Lip gloss set
Cosmetics	Princess lip gloss/nail polish	Lip gloss	Tangled Flavored Lip Gloss 4 pack
Footwear	White Tennis Shoes and bib	Toy	Green slimy toy
Fragrances	Perfume and Body Wash		



Figure 1: Example of product for testing

Products were separated into five larger groups; baby and bath accessories, cosmetics and fragrances, lip balms and glosses, Halloween products (primarily makeup), and miscellaneous (Table 3).

Table 3: Breakdown of products into categories

Category	Nr.	%
Baby and bath accessories	16	37.2
Cosmetics & Fragrances	5	11.6
Lip balm & gloss	13	30.2
Halloween (makeup)	7	16.3
Misc. (toy & shoes)	2	4.7

Complete paraben analyses are provided in Appendix 1.

Emphasis was placed upon products likely to be placed into the mouth or applied to the skin, which accounts for the larger number of samples of baby and bath accessories, and lip balms and glosses. In addition, sampling occurred prior to Halloween in 2012 and Halloween products were collected and analyzed. In general terms, high levels of methyl and propyl paraben were found in several samples.

Methyl and propyl paraben are the most commonly found parabens in the product components tested (Table 4) followed by butyl, ethyl, and propyl, respectively. Methyl and propyl paraben were found in 69.7 and 60.3% of the 68 product components tested and were the only parabens found at concentrations exceeding 1,000 ppm. Ethyl, butyl, and isobutyl paraben were found in substantially fewer product components and at lower levels.

Table 4: Breakdown of parabens found in product components

Chemical	NR %	< 1	%	1 to < 100	%	100 to < 1,000	%	1,000 or >	%
Methyl paraben	30.9	9	13.2	16	23.5	16	23.5	6	8.8
Ethyl paraben	83.8	2	2.9	7	10.3	2	2.9	0	0.0
Propyl paraben	39.7	10	14.7	4	5.9	23	33.8	4	5.9
Butyl paraben	77.9	2	2.9	10	14.7	3	4.4	0	0.0
Iso-butyl paraben	88.2	1	1.5	6	8.8	1	1.5	0	0.0

To better clarify which type of products contained the highest levels of parabens, the sampling results were separated into the four largest categories, i.e., baby and bath accessories (Figure 2), cosmetics and fragrances (Figure 3), lip balm and gloss (Figure 4), and Halloween products (Figure 5). For the remaining two samples, no parabens were detected in a green slimy toy. One sample, labeled white tennis shoes, however, contained detectable levels of all five parabens (Table 5) for a total paraben concentration of 1,980 ppm. As it is unlikely that tennis shoes contain parabens, there is concern that this sample was mislabeled. The issue has been extensively researched and no alternative sample name has been identified. These sample results should be assumed to be an error and not representative of paraben concentration in shoes.

Table 5: Paraben results for analysis of white tennis shoes

Product ID	Methyl	Ethyl	Propyl	Butyl	Isobutyl
JN000-c01	950.0	290.0	160.0	400.0	180.0

Figure 2 shows paraben concentrations in baby and bath accessories. Two products, TG001 and WM037 contained high levels of methyl and propyl parabens. The baby lotion (TG001) contained methyl and propyl parabens at 1,800 and 740 ppm, respectively. WM037 is a watermelon-flavored lip smackers bath and body collection. Component WM037-c02, the body wash found in the collection, contained methyl and propyl parabens at 1,800 and 320 ppm, respectively. WM037-c01 is lotion from the same collection and contained methyl and propyl parabens at 940 and 370 ppm, respectively. TG001 and WM007-c01, both baby lotions, and TG004-c01, baby wipes, also contained high levels of methyl and propyl parabens.

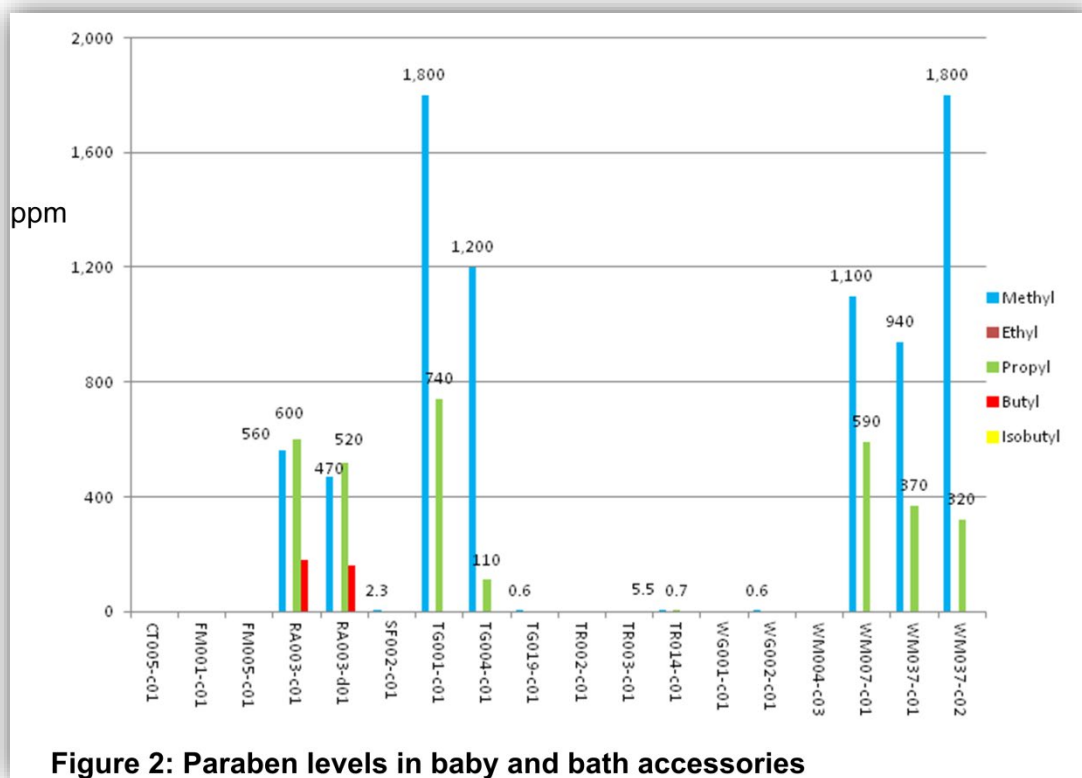
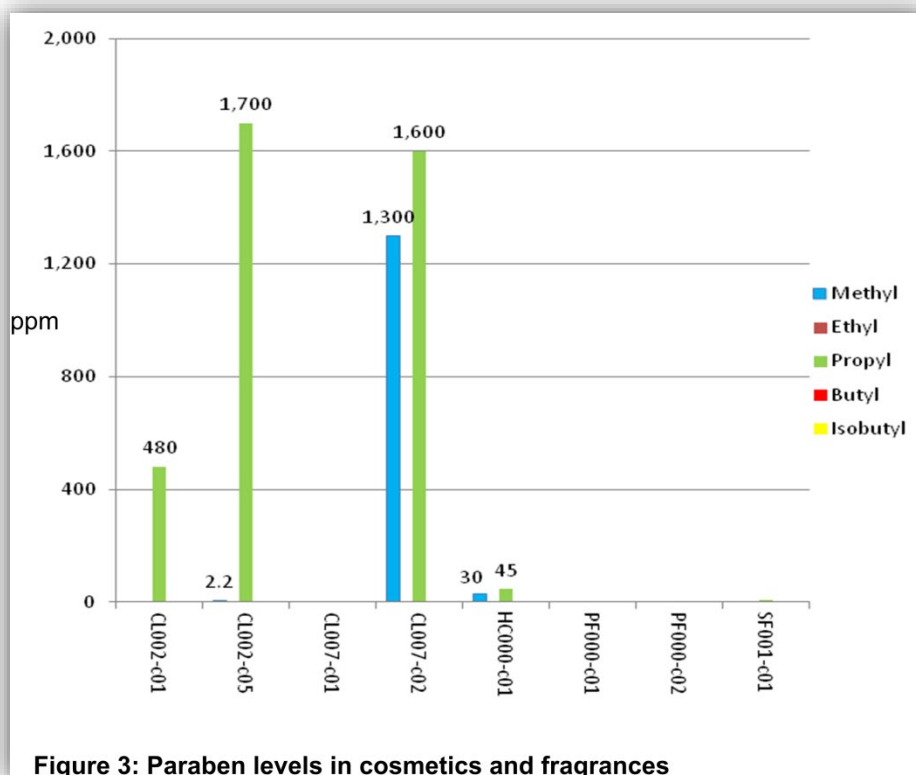


Figure 2: Paraben levels in baby and bath accessories

High levels of propyl parabens were found in two of the five cosmetics and fragrances tested (Figure 3). Product CL002, a Princess lip gloss and nail polish, was separated into two components CL002-b01,⁷ purple lip gloss and CL002-b05, a composite of pink and blue lip glosses. CL002-b01 and CL002-b05 contained propyl parabens at 480 and 1,700 ppm, respectively. CL007-c02, a composite of eye shadow from a make-up kit, contained methyl and propyl parabens at 1,300 and 1,600 ppm, respectively. None of the other sample components contained appreciable concentrations of parabens.



⁷ Note: The laboratory results attribute all analytical results from CL002-b01 and -b05 to CL002-c01 and -c05. As no sample was created with the 'c' or component identifier, it is assumed there was an error in the sample chain of custody and that CL002-bXX samples were the actual sample submitted for analysis. This report corrects for the assumed error.

Three lip balms and lip gloss products contained appreciable levels of propyl and methyl parabens (Figure 4). Product CL001, a Tangled Flavored Lip Gloss 4-pack, contained levels of propyl parabens ranging from 310 to 460 ppm in purple lip gloss (CL001-c01), bubble gum lip gloss (CL001-c02) and red lip gloss (CL001-c07). Product SK018, a make your own lip gloss kit, contained methyl and propyl parabens in chapstick base (SK018-c02) at 120 and 520 ppm and coloring or flavoring (SK018-c03) at 790 and 1,300 ppm, respectively. Product TG011, a lip balm, contained the only appreciable level of propyl parabens at 250 ppm. Small amounts of parabens were found in other products.

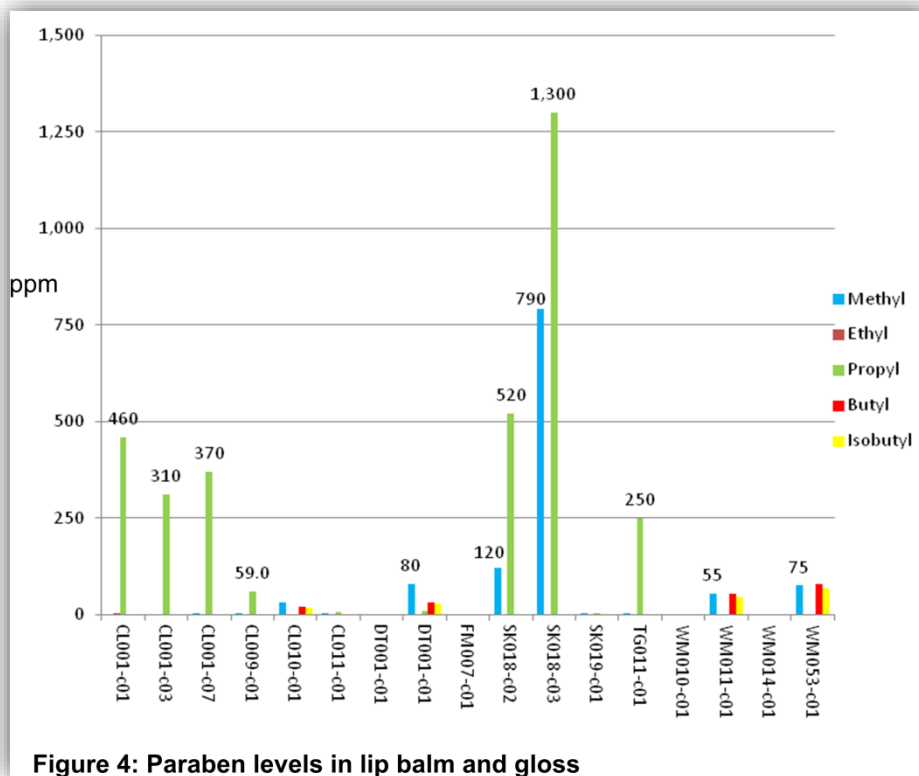


Figure 4: Paraben levels in lip balm and gloss

Parabens were found consistently across many of the Halloween products purchased and included the single highest levels of parabens found in any product component (Figure 5). Product SH001, white face powder, contained methyl, ethyl, and propyl parabens at 1,700, 190 and 2,500 ppm, respectively, for a total paraben concentration of 4,390 ppm. Of the seven products and 23 Halloween product components tested, parabens were found in all products and a majority of the product components above 100 ppm. Only five of the 23 product components (22%) did not contain appreciable levels of parabens.

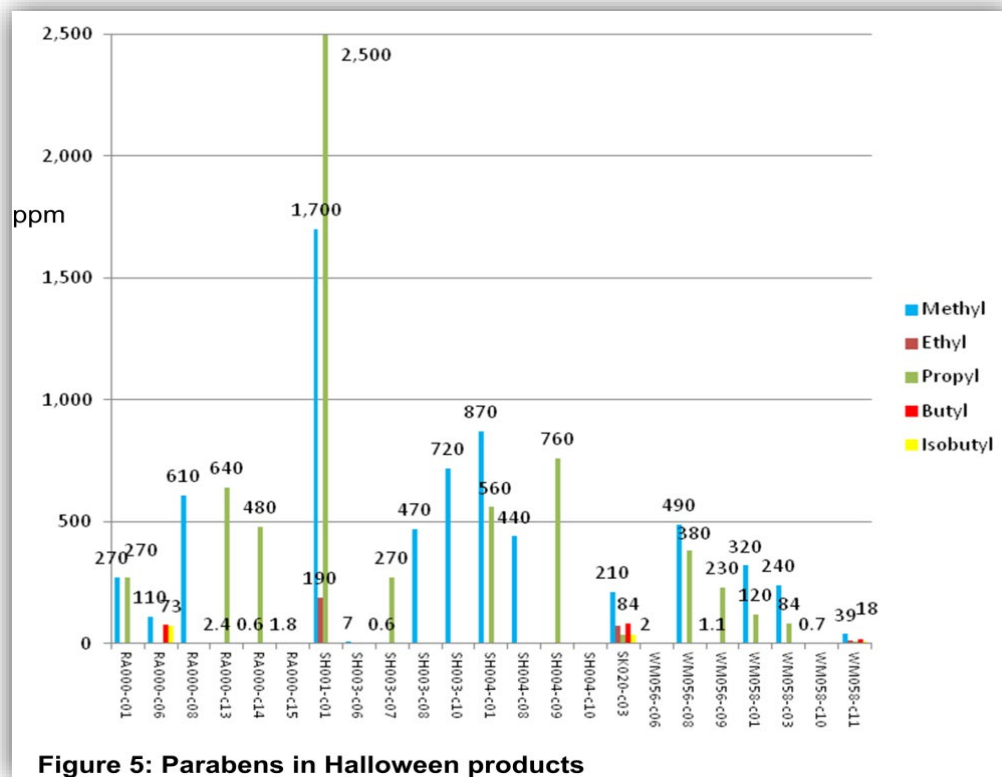


Figure 5: Parabens in Halloween products

Sampling results are available (Appendix 2).

Compliance

Analytical results were compared with product data reported to Ecology as required by the CSPA. In response to results from this and other studies funded by Attorney General’s office, Ecology initiated compliance correspondence with manufacturers regarding possible failure to report CHCCs as required by the CSPA. Ecology identified 73 results and sent 30 letters to manufacturers containing one or more analytical result that indicated a need to evaluate compliance with the CSPA.

Ecology initiated compliance correspondence for 38 paraben results. Methyl paraben was the most common subject of compliance assurance (16 results), followed by propyl paraben (13). All

manufacturers were found to be in compliance as the company's annual aggregate gross sales were sufficiently low that reporting was not yet required due to the phased in schedule in the CSPA reporting rule⁸.

Conclusions and Recommendations

Based on the results discussed above, the following conclusions can be reached:

- Parabens were found in appreciable levels in many products either mouthed by children or applied to their skin.
- Halloween makeup contained both the highest levels and the greatest incidence of detection. Parabens were found in 78% of the product components tested. These results suggest that seasonal products might warrant further scrutiny in the future.
- A wide range of product types can be analyzed for parabens.
- Parabens can be detected at less than 1 ppm levels in most products.

⁸ Specifically, WAC 173-334-110

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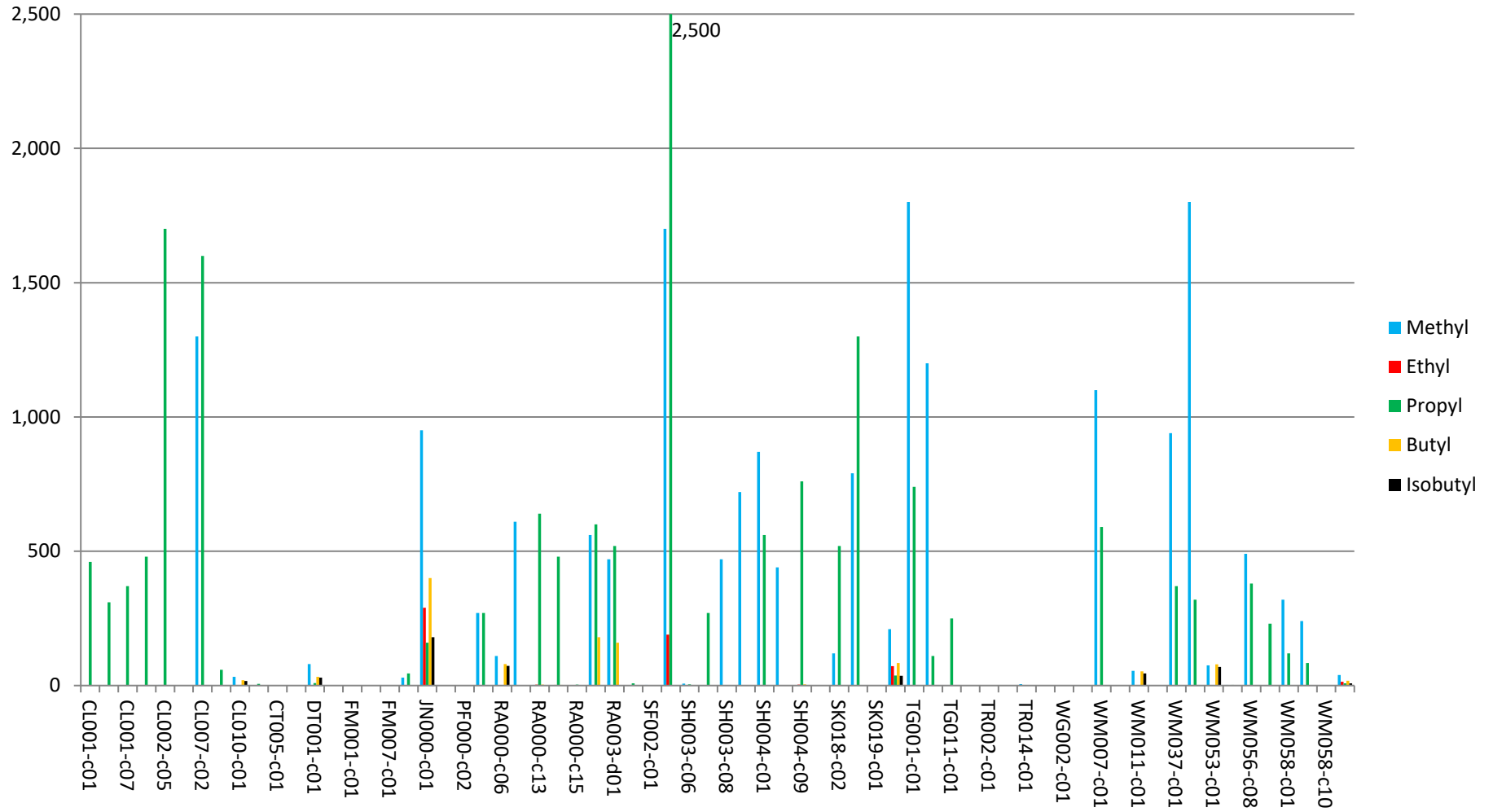
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Appendix 1: Results of paraben analyses for all product components tested



Appendix 2: Data from analysis of products for parabens

Product	Baby & Bath	Methyl	Ethyl	Propyl	Butyl	Isobutyl
Diapers	CT005-c01	0.0	0.0	0.0	0.0	0.0
Blue teething ring	FM001-c01	0.0	0.0	0.0	0.0	0.0
Baby wipes	FM005-c01	0.0	0.0	0.0	0.0	0.0
Baby Lotion	RA003-c01	560.0	0.0	600.0	180.0	0.0
Baby Lotion	RA003-d01	470.0	0.0	520.0	160.0	0.0
Unscented wipes	SF002-c01	2.3	0.0	0.0	0.0	0.0
Baby lotion	TG001-c01	1,800.0	0.0	740.0	0.0	0.0
Baby changing wipes	TG004-c01	1,200.0	0.0	110.0	0.0	0.0
Petroleum jelly	TG019-c01	0.6	0.0	0.0	0.0	0.0
Toddler wipes	TR002-c01	0.0	0.0	0.0	0.0	0.0
Baby lotion	TR003-c01	0.0	0.0	0.0	0.0	0.0
Travel baby wipes	TR014-c01	5.5	0.0	0.7	0.0	0.0
Baby Lotion	WG001-c01	0.0	0.0	0.0	0.0	0.0
Baby Lotion	WG002-c01	0.6	0.0	0.0	0.0	0.0
Color Bath Drops	WM004-c03	0.0	0.0	0.0	0.0	0.0
Baby lotion	WM007-c01	1,100.0	0.0	590.0	0.0	0.0
Lotion	WM037-c01	940.0	0.0	370.0	0.0	0.0
Body wash	WM037-c02	1,800.0	0.0	320.0	0.0	0.0

Product	Cosmetics & Fragrances	Methyl	Ethyl	Propyl	Butyl	Isobutyl
Princess purple lip gloss	CL002-b01	0.0	0.0	480.0	0.0	0.0
Princess lip gloss/nail polish	CL002-b05	2.2	1.9	1,700.0	0.0	0.0
Make up pack – pink lip gloss	CL007-c01	0.0	0.0	0.0	0.0	0.0
Make up pack – eyeshadow composite	CL007-c02	1,300.0	0.0	1,600.0	0.0	0.0
Glitter face makeup	HC000-c01	30.0	0.0	45.0	0.0	0.0

Product	Cosmetics & Fragrances	Methyl	Ethyl	Propyl	Butyl	Isobutyl
Body Wash	PF000-c01	0.0	0.0	0.0	0.0	0.0
Perfume	PF000-c02	0.0	0.0	0.0	0.0	0.0
Face paint transfer sheets and crayon	SF001-c01	0.0	0.0	8.0	0.0	0.0

Product	Lip balm & gloss	Methyl	Ethyl	Propyl	Butyl	Isobutyl
Flavored Lip Gloss 4 pack – purple	CL001-c01	0.0	0.5	460.0	0.0	0.0
Flavored Lip Gloss 4 pack – bubble gum	CL001-c03	0.0	0.0	310.0	0.0	0.0
Flavored Lip Gloss 4 pack–lip gloss blue container	CL001-c07	0.5	0.0	370.0	0.0	0.0
Lip gloss set	CL009-c01	0.7	0.0	59.0	0.0	0.0
Lip gloss set	CL010-c01	32.0	0.0	0.0	20.0	17.0
Lip gloss set	CL011-c01	1.2	0.0	6.2	0.0	0.0
Butterscotch sundae lip balm	DT001-c01	0.0	0.0	0.0	0.0	0.0
Butterscotch sundae lip balm	DT001-c01	80.0	0.0	9.2	32.0	30.0
Lip balm	FM007-c01	0.0	0.0	0.0	0.0	0.0
Make your own lip balm – chapstick base	SK018-c02	120.0	0.0	520.0	0.0	0.0
Make your own lip balm – color/flavoring	SK018-c03	790.0	0.0	1,300.0	0.0	0.0
12 roll-on lip glosses – composite	SK019-c01	0.9	0.0	0.6	0.0	0.0
Strawberry lip balm	TG011-c01	0.5	0.0	250.0	0.0	0.0
Keychain and chapsticks	WM010-c01	0.0	0.0	0.0	0.0	0.0
Ring pop chapstick	WM011-c01	55.0	0.0	0.0	53.0	45.0
Flavored gloss and chapstick	WM014-c01	0.0	0.0	0.0	0.0	0.0
4 Lip glosses with zipper pouch	WM053-c01	75.0	0.0	0.0	79.0	69.0

Product	Halloween Makeup	Methyl	Ethyl	Propyl	Butyl	Isobutyl
Halloween Makeup variety pack–blood	RA000-c01	270.0	0.0	270.0	0.0	0.0
Halloween Makeup variety pack–white	RA000-c06	110.0	0.0	0.0	80.0	73.0

Product	Halloween Makeup	Methyl	Ethyl	Propyl	Butyl	Isobutyl
Halloween Makeup variety pack–glitter	RA000-c08	610.0	0.0	0.0	0.0	0.0
Halloween Makeup variety pack–green/black	RA000-c13	2.4	3.0	640.0	3.2	0.0
Halloween Makeup variety pack–red & white	RA000-c14	0.6	2.1	480.0	2.2	0.0
Halloween Makeup variety pack–crayons	RA000-c15	1.8	0.0	3.7	0.0	0.0
White face powder	SH001-c01	1,700.0	190.0	2,500.0	0.0	0.0
Face Painting Kit – crayon composite	SH003-c06	7.0	0.0	4.0	0.0	0.0
Face Painting Kit – makeup composite	SH003-c07	0.6	0.6	270.0	0.8	0.0
Face Painting Kit – white cream makeup	SH003-c08	470.0	0.0	0.0	0.0	0.0
Face Painting Kit – hair color	SH003-c10	720.0	0.0	0.0	0.0	0.0
Family Value Makeup kit – white cream	SH004-c01	870.0	0.0	560.0	0.0	0.0
Family Value Makeup kit – glitter	SH004-c08	440.0	0.0	0.0	0.0	0.0
Family Value Makeup kit –composite	SH004-c09	0.0	3.0	760.0	3.9	0.0
Family Value Makeup kit – crayon composite	SH004-c10	0.0	0.0	1.7	0.0	0.0
Monster High Makeup kit –composite	SK020-c03	210.0	72.0	37.0	84.0	36.0
'How to' DVD Makeup Kit–crayon composite	WM056-c06	2.0	0.0	2.5	0.0	0.0
"How to" DVD Makeup Kit – white cream	WM056-c08	490.0	0.0	380.0	0.0	0.0
"How to" DVD Makeup Kit – makeup composite	WM056-c09	1.1	1.1	230.0	0.9	0.0
Monster Value Makeup Set – white cream	WM058-c01	320.0	0.0	120.0	0.0	0.0
Value Makeup Set – glitter	WM058-c03	240.0	0.0	84.0	0.0	0.0
Monster Value Makeup Set – crayon composite	WM058-c10	0.7	0.0	0.0	0.0	0.0
Monster Value Makeup Set – makeup composite	WM058-c11	39.0	14.0	8.3	18.0	7.7

Product	Misc.	Methyl	Ethyl	Propyl	Butyl	Isobutyl
White Tennis Shoes and bib ⁹	JN000-c01	950.0	290.0	160.0	400.0	180.0
Green slimy stuff	DT014-c01	0.0	0.0	0.0	0.0	0.0

⁹ Ecology has determined these sampling results are not for this product due to a sampling error. See the discussion for more details.