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An Assessment of Children's Safe Product Act Data

Addendum to Quality Assurance Project Plan: Product Testing Program Version 1

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Addendum

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This addendum is an addition to an original Quality Assurance Project Plan. It is not a correction (errata) to the original plan.

Data for this study will be available on Product Testing Database (PTDB) website at https://fortress.wa.gov/ecy/ptdbpublicreporting/Default.aspx. Search Study: CSPA Assessment.

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EAP: Environmental Assessment Program
HWTR: Hazardous Waste and Toxics Reduction Program

2.0 Abstract

For 5 years manufacturers of children's products have been reporting the presence of selected chemicals in their products to the Washington State Department of Ecology (Ecology) Children's Safe Product Act (CSPA) Manufacturer Reporting Database. This database has compiled tens of thousands of chemical-product records. An analysis of these data characterized, ranked, and prioritized the chemicals reported in children's products (Smith et al., 2016). That analysis considered the product, potential exposure routes, and chemical toxicity. The chemical prioritization that emerged from the reported data analysis is used to focus this study of specific chemicals in specific products. Ecology will test for four organic chemicals identified as high priority by the reported data analysis: formaldehyde, styrene and methyl ethyl ketone (MEK), and octamethylcyclotetrasiloxane (D4). The results of this study will provide data to further assess chemicals in products.

3.0 Background

The CSPA (Chapter 70.240 Revised Code of Washington (RCW)) sets limits on cadmium, lead, and phthalates in children's products. CSPA required Ecology to establish a list of chemicals of high concern to children (CHCC) and a manufacturer reporting process in rule (Chapter 173-334 Washington Administrative Code (WAC)) Manufacturers of children's products are required to report if their products contain any of the 66 CHCCs or chemical groups identified in the rule. To make the process more efficient, Ecology developed a database which manufacturers use to submit annual reports.

When one or more of the 66 CHCCs exist in a children's product, the manufacturer submits a report in the database by the product's specific *Brick*, a common term used in manufacturing, Bricks are composed of products that share the same categorical attributes, serve a common purpose, or are of similar form or material. A Brick is the most specific level in a hierarchical scheme that includes, from top-down, *Segment*, *Family*, *Class,* and *Brick*.

For each reporting, the *chemical* present in a product *component* is reported by *concentration* range (i.e., <100, 100-500, 500-1,000, 1,000-5,000, 5,000-10,000 and > 10,000 ppm), and the chemical *function* is designated from a list that includes pigments, preservatives, solvents, as well as no function and contaminant. The product is assigned to one of two intended *age* ranges for the children using the product: either less than 3 years of age or 3 to 12 years of age. An example of manufacturer reported data is displayed in Table 1.

Table 1 Example: Manufacturer Reported Data.

Chemical	Component	Concentration	Chemical Function	Product Family	Product Class	Product Description	Target Age	Date Submitted
Formaldehyde	Synthetic Polymers (synthetic rubber, plastics, foams etc.)	Equal to or greater than 1,000 but less than 5,000 ppm	No function - Contaminant	Toys/Games	Fancy Dress Costumes/ Accessories	Fancy Dress Costumes/ Accessories Variety Packs	3 to 12	4/1/2014
Methyl ethyl ketone	Surface coatings (paints, plating, waterproofing etc.)	Equal to or greater than 10,000 ppm	Protective coating	Baby Welfare	Baby Furniture/ Transportation/ Safety	Baby High Chair	Under 3	2/6/2013

The Brick is displayed in the database as “Product Description”

Manufacturers began reporting into the CSPA Manufacturer Reporting Database in August 2012, and by September 2016, nearly 44,000 reports were recorded. Detailed analysis of the extensive amount of data collected offers an opportunity to augment the current scientific understanding of chemicals in children’s products.

In 2015, an analysis of the manufacturer reported data was completed using a toxicological approach. The toxicological analysis was summarized in a recently published journal article, *A Toxicological Framework for the Prioritization of Children’s Safe Product Act Data* (Smith et al., 2016). The term “toxicological framework” will be used throughout this QAPP to refer to this analysis of the manufacturer reported data.

This toxicological framework interpreted the reported data based on potential route of exposure and mechanism of toxicity that resulted in the identification of high priority chemicals and children’s products potentially containing these high priority chemicals.

The complex toxicological framework assigned scores to the attributes of each product reported in the CSPA manufacturer reporting database. Attribute scores were further aggregated and factored out into three main framework components; (1) exposure score, (2) toxicity score, and (3) the total priority index. The Appendix shows the toxicological framework chemicals sorted by total priority index (Table 3 from Smith et al., 2016).

3.1.3 Chemicals of concern

Individual children’s products will be investigated for the presence of the one or more of the prioritized chemicals: formaldehyde, styrene and MEK, and D4.

4.0 Study Description

This study is an addendum to the Product Testing (PT) Program, Version 1.0 Quality Assurance Project Plan (QAPP) (Sekerak, 2016a) that serves as the universal project plan guidance for all Product Testing Program studies. Children’s products will be selected and tested for chemicals that ranked as high priority from the toxicological framework.

The toxicological framework identified formaldehyde, styrene and MEK with high total priority indices. Several phthalates, parabens and metals identified with high total priority indices by the toxicological framework will not be included in this study, because they have been evaluated in several recent studies (Mathieu and Sekerak, 2015; Sekerak, 2016b; and Stone, 2014a,b).

The toxicological framework identified D4 with one of the highest exposure risks, but a lower overall total priority index. Ecology will include D4 in this study because of its high exposure score and because it is a listed persistent, bioaccumulative and toxic (PBT) chemical, and it is prioritized high on other prioritization methods such as ExpoCast and ToxPi[1]. D4 is also currently on United States Environmental Protection Agency's (EPA) Toxic Substance and Control Act (TSCA) work plan for further assessment and managing[2].

4.1 Study goals

This study aims to assess the data reported into the CSPA Manufacturers Reporting Database for the chemicals prioritized from the toxicological framework[3]. Four chemicals will be tested in children's products: formaldehyde, MEK, styrene, and D4.

The data from this study will serve to:

- Further efforts in characterizing toxic chemicals in children's products.
- Identify where data pools or gaps may exist as a result of the design of the CSPA Manufacturer Reporting Database or due to manufacturer reporting tendencies.
- Provide data for the further development (or refinement) of the Toxicological Prioritization Framework.
- Provide data to Ecology's enforcement officers to assess compliance with CSPA as necessary.

4.6 Tasks required

In addition to the tasks stated in the PT Program, Version 1.0 QAPP, additional tasks for selecting products for testing will include:

- A review of the CSPA Manufacturer Reporting Database data.
- Literature review and internet research of the use and application of formaldehyde, MEK, styrene, and D4 products and product manufacturing processes.

[1] ExpoCast: Exposure forecasting tool developed by the EPA; and ToxPi: Toxicological Prioritization Index.
[2] The EPA restricts their investigations to environmental analyses of D4 in waste water discharge, sediment, water and biota.
[3] Manufacturer reported data of a CHCC in a children's product does not necessarily mean that the product is harmful to human health or that there is any violation of existing safety standards or laws. The reported information will help fill a data gap that exists for both consumers and agencies.

5.0 Organization and Schedule

5.4 Project Schedule

Table 2. Schedule for Completing Product Collection and Laboratory Work, Data Reviews, Data Entry into Product Testing Database (PTDB), and Reports.

Product Collection, Processing, and Laboratory Work	Due date	Lead staff
Product collection completion	9/2016	Sara Sekerak
Product logging in completion	10/2016	Chrissy Wiseman
Internal data QA completion	11/2016	Chrissy Wiseman
Laboratory analyses completion	12/2016	
Data		
Lab data QA reviewed	1/15/2017	Sara Sekerak
Lab data loaded into PTDB	1/31/2017	Sara Sekerak
Lab data to enforcement officer	1/31/2017	Sara Sekerak
PTDB data QA review completion	1/15/2017	Chrissy Wiseman
Final Report		
Author lead / Support staff	Sara Sekerak / Chrissy Wiseman	
Schedule		
Draft due to supervisor	2/15/2017	
Draft due to client/peer reviewer	3/1//2017	
Final (all reviews done) due to publications coordinator	3/28/2017	
Final report posted to the web	4/31/2017	

5.6 Budget and Funding

Table 3 Project Budget and Funding.

Activity/Parameter	Number of Samples	QC Samples*	Cost \ per Sample	Subtotal	
Product Collection	300	---	$20	$6,000	---
				Product Collection Total:	$6,000
Manchester Environmental Laboratory (MEL) Testing					
Cryomilling	30	--	$100	$3,000	---
Formaldehyde	60	12	$300	$21,600	---
MEK	60	12	$100	$7,200	
Styrene	60	12	$100	$7,200	---
Contract Laboratory Testing (ALS-Kelso)					
D4	60	12	$410^	$29,520	---
				Laboratory Total:	$62,616
				Project Total:	**$74,520**

*QC samples in this table include those that are not provided free of charge (matrix spikes, duplicates, and cryomill rinseates).

^D4 price include 25% Manchester Environmental Laboratory (MEL) contract fee.

6.0 Data Quality

All measurement quality objectives (MQOs) and quality assurance (QA) targets are clearly outlined in the original PT Program QAPP, Version 1.0.

7.0 Sample Process Design (Experimental Design)

7.1 Study Design

Product Collection

Products will be selected based upon data reported in the database and through literature reviews and internet research. The database does not contain the Universal Product Code (UPC) information that uniquely identifies trade items thus no specific manufacturer products will be targeted.

Component Isolation

When applicable, the database will be used to select samples based on manufacturer reporting of product components or component material containing or potentially containing any of the four target chemicals.

For example: From within the product Segment- *Toys/games*, Brick- *Spinning Tops/Yo-Yos*, the manufactured component reported to contain *styrene* was reported as *Synthetic Polymers (e.g., synthetic rubber, plastic, foams)*. This means that for the analysis of styrene the yo-yo's plastic housing would be targeted for sampling rather than the non-polymer yo-yo string.

8.0 Sample Procedures

8.2 Sampling and measurement SOPs

Product collection, cataloging, and preparation will follow the PT Program SOPs:

- PTP001 Sample Collection and Processing (Wiseman et al., 2016a)
- PTP002 Data Entry and Database (Wiseman et al., 2016b)

Additional study specific procedures are outline below.

Sample Processing

Special precautions will be taken by staff purchasing, preparing, and performing laboratory analyses to not introduce target chemical contamination to the products, components, and samples. Staff need to avoid wearing any personal products that contain target chemicals. Staff

personal care and daily hygiene routines may need to be altered during product purchasing, processing and analysis processes.

Target chemicals (formaldehyde, MEK, styrene and D4) are often prevalent in personal care, make-up and hygiene products such as nail polish, moisturizer, facial powder, and hair products such as frizz control and conditioners. Use of products that contain these ingredients should be avoided by staff during this study. The target chemical may be listed instead by a synonym, generic class name, or trade name than the target chemical name, for example:

- Octamethylcyclotetrasiloxane (D4), a cyclic dimethyl polysiloxane compound, may be listed cyclotetrasiloxane, 2,2,4,4,6,6,8,8-octamethyl-, or cyclopentasiloxane, octamethyl-, or generically as cyclomethicone. It may also co-exist in products listing several other cyclomethicone ingredients and other ingredients with the suffix –siloxane (e.g., cyclopentasiloxane or D5).
- Formaldehyde may be listed as formalin, methaldehyde, methylene oxide, or oxymethylene. Methylene glycol should also be considered a source of formaldehyde.
- Styrene may be listed as vinylbenzene, ethenylbenzene, cinnamene, phenyletheylene, or styrole.
- Methyl ethyl ketone may be listed as butanone, 2-butanone, or ethyl methyl ketone.

Care should be taken to avoid contaminating styrene product samples with outer packaging materials made of polystyrene. Any product component packaged with−or that was in direct contact with−polystyrene that becomes a laboratory sample will be documented accordingly.

Any unanticipated potential contamination source that arises will be addressed and documented.

Sample Size

Components not requiring cryomilling, will be reduced in size to 5 mm x 5 mm pieces. Samples will contain no less than 2.5 grams in weight for the analysis of any one analyte: formaldehyde, MEK, styrene, or D4. Five grams will be sufficient volume for samples to be analyzed by MEL for the suite: formaldehyde, MEK, and styrene.

An initial sample size of 8 grams will be required if a sample requires cryomilling and analysis of all analytes: formaldehyde, MEK, styrene, and D4. MEL will split the cryomilled sample and provide no less than 2.5 grams to the contract laboratory.

Samples not needing cryomilling that require analysis of D4 and any other analyte will be split between two jars, in the required aliquots, by HQ staff.

Cryomilling

Samples may need to be cryomilled to obtain a homogenous sample aliquot for analysis. MEL will provide consultation to the project manager for specific products or matrices that may necessitate cryomilling to obtain an appropriate sample for the extraction preparation step. MEL will perform all cryomilling.

8.3 Containers, preservation methods, holding times

MEL will provide all glass jars for formaldehyde, MEK and styrene samples. Contract samples for the analysis of D4 will be submitted in glass jars provided by the contract lab.

9.0 Measurement Methods

9.2 Lab procedures table

Laboratory methods and desired reporting limits will follow those presented in Table 4d in the original PT Program QAPP.

The contract laboratory, ALS-Kelso, will perform the D4 analysis by the SOP: Octamethylcyclotetrasiloxane (D4) in Sediment and Biosolids by GC/MS (ALS, 2014). The reporting limit will be 1 ppm.

9.4 Special method requirements

If samples warrant cryomilling, the MEL will perform this pre-treatment process prior to all analyses, including samples sent to the contract laboratory for the analysis of D4.

11.0 Data Management Procedures

11.2 Lab data package requirements

The final contract data package is to include raw data (Tier IV deliverables) and results in an electronic data deliverable (EDD) format that meets the requirements outlined in the PT Program QAPP and Table 4 above. The EDD format is needed for loading results to Product Testing database (PTDB).

15.0 References

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Wiseman, C. and K. Inch, 2016b. Product Testing Standard Operating Procedure: Data Entry and Database. Internal document No. PT002.

16.0 Appendix

This appendix shows the toxicological framework chemicals sorted by total priority index. (Table 3 from Smith et al., 2016).

Table 3. Exposure scores and total priority indices for the CSPA chemicals considered in this framework. Chemicals are sorted based on total priority index. The three chemicals with the highest exposure scores are in bold. Standard deviations (SD) represent the variability in scores or indices within each chemical or chemical group.

Chemicals	Number of Reports	Exposure Score ± SD	Total Priority Index ± SD
Formaldehyde	**533**	**14.2 ± 3.3**	**297.8 ± 69.1**
Dibutyl phthalate	778	12.3 ± 1.7	294.7 ± 40.1
Styrene	**2251**	**13.6 ± 2.7**	**231.2 ± 45.1**
Butyl benzyl phthalate (BBP)	610	12.5 ± 1.7	225.2 ± 30.2
Di-2-ethylhexyl phthalate	909	10.6 ± 1.7	223.2 ± 34.6
Diisodecyl phthalate (DIDP)	235	11.6 ± 2.1	127.9 ± 22.8
Di-n-Hexyl phthalate	178	10.2 ± 1.1	112.0 ± 11.7
Butyl paraben	83	12.0 ± 0.94	108.0 ± 8.4
Methyl ethyl ketone	2378	10.2 ± 1.9	91.5 ± 17.1
Cobalt and cobalt compounds	6927	8.5 ± 1.5	84.5 ± 14.7
Ethylene glycol monoethyl ester	31	10.3 ± 2.4	82.1 ± 18.9
Diethyl phthalate	380	8.0 ± 0.84	80.0 ± 8.4
Ethylene glycol	6042	9.8 ± 1.9	78.5 ± 14.8
Ethyl paraben	97	12.0 ± 1.1	35.9 ± 3.2
Antimony and Antimony compounds	3378	10.3 ± 1.4	31.0 ± 4.3
Diisononyl phthalate (DINP)	357	10.3 ± 2.1	30.8 ± 6.2
Di-n-octyl phthalate (DnOP)	279	9.6 ± 0.9	19.3 ± 1.8
Octamethylcyclotetrasiloxane	**2123**	**13.9 ± 1.6**	**13.9 ± 1.6**
Methyl paraben	251	10.2 ± 1.2	0
Molybdenum and molybdenum compounds	1617	5.8 ± 0.80	0
Phthalic anhydride	137	7.6 ± 1.3	0
Propyl paraben	207	11.8 ± 0.95	0
Chemical Groups			
Phthalates	3863	10.8 ± 2.2	172.5 ± 102.9
Parabens	638	11.2 ± 1.4	19.5 ± 36.7
Ethylene Glycols	6073	9.8 ± 1.9	78.5 ± 14.9