DEPARTMENT OF ECOLOGY
State of Washington

Addendum to Quality Assurance Project Plan: Product Testing Program, Version 1.0

Formaldehyde in Children's Products 2019

March 2020

Publication No. 20-03-107

Publication Information

This Quality Assurance Project Plan Addendum is on the Department of Ecology's website at https://fortress.wa.gov/ecy/publications/SummaryPages/2003107.html. This is an addition to an original Quality Assurance Project Plan (QAPP). It is not a correction (errata) to the original plan.

This QAPP addendum was approved to begin work in December 2019. It was finalized and approved for publication in March 2020.

Suggested citation for this addendum:
Nelson, K. 2020. Addendum to Quality Assurance Project Plan: Product Testing Program, Version 1.0 — Formaldehyde in Children's Products 2019. Publication 20-03-107. Washington State Department of Ecology, Olympia
https://fortress.wa.gov/ecy/publications/SummaryPages/2003107.html.

Data for this study will be available on the Product Testing Database (PTDB) website at http://ecyapeem/ptdbpublicreporting. Search Study: Formaldehyde in Children's Products 2019.

Activity Tracker code: Ecology's Activity Tracker code for this addendum is 19-040.

Original Quality Assurance Project Plan:
Quality Assurance Project Plan: Product Testing Program, Version 1.0.
Publication No. 16-03-113.
https://fortress.wa.gov/ecy/publications/SummaryPages/1603113.html.

Contact Information

For more information contact:

Publications Coordinator
Environmental Assessment Program
Washington State Department of Ecology
P.O. Box 47600
Olympia, WA 98504-7600
Phone: 360-407-6764

Washington State Department of Ecology – ecology.wa.gov

Headquarters, Olympia	360-407-6000
Northwest Regional Office, Bellevue	425-649-7000
Southwest Regional Office, Olympia	360-407-6300
Central Regional Office, Union Gap	509-575-2490
Eastern Regional Office, Spokane	509-329-3400

Addendum to Quality Assurance Project Plan: Product Testing Program, Version 1.0

Formaldehyde in Children's Products 2019

by Ken Nelson
Published in March 2020

Approved by:

Signature:	Date:
Tina Schaefer, Client, HWTR Program	
Signature:	Date:
Megan MacClellan, Client's Acting Supervisor, HWTR Program	
Signature:	Date:
Ken Zarker, Client's Section Manager, HWTR Program	
Signature:	Date:
Ken Nelson, Author / Project Manager, EAP	
Signature:	Date:
James Medlen, Author's Toxic Studies Unit Supervisor, EAP	
Signature:	Date:
Jessica Archer, Author's Section Manager, EAP	
Signature:	Date:
Alan Rue, Lab Director, Manchester Environmental Laboratory, EAP	
Signature:	Date:
Arati Kaza, Ecology Quality Assurance Officer	

Signatures are not available on the Internet version.
EAP: Environmental Assessment Program
HWTR: Hazardous Waste and Toxics Reductions

3.0 Background

3.1 Introduction and problem statement

Under the Children's Safe Products Act (CSPA) reporting rule [Chapter 173-334 Washington Administrative Code (WAC)], chemicals of high concern to children (CHCCs) must be reported when present in children's products offered for sale in the state of Washington. The Washington State Department of Ecology (Ecology) periodically performs analyses of children's products to assess compliance with CSPA and the reporting rule.

In 2017, Ecology assessed levels of formaldehyde, octamethylcyclotetrasiloxane (D4), methyl ethyl ketone (MEK), and styrene in children's products, in support of CSPA reporting (Sekerak, 2017). We conducted a follow-up in 2018, purchasing a subset of products matching those of original study, when available, and evaluating them for the presence of formaldehyde (Sekerak, 2018). This addendum describes the December 2019 assessment for formaldehyde in the same or similar children's products.

3.2 Study area and surroundings

3.2.3 Parameters of interest and potential sources

Selected children's products will be investigated for the presence of formaldehyde.

4.0 Project Description

This study plan describes follow-up testing for formaldehyde for the same or similar products from the study (plan): Addendum to Quality Assurance Project Plan: Product Testing Program, Version 1.0 — Formaldehyde in Children's Products 2018 (Sekerak, 2018).

4.1 Project goals

The primary goal of this study is to provide data to Ecology's enforcement officer to assess and support compliance actions under CSPA and the reporting rule. Based on the products assessed in the first follow-up study in 2018, the same or similar products from the specific manufacturers will be tested.

4.4 Tasks required

Specific tasks for this study include:

- Review the 2018 formaldehyde study to determine products to purchase for follow-up testing.
    - Research product manufacturer and/or retailer websites to identify purchasing locations and/or online purchasing.
- Purchase Paw Patrol Skye 8 oz Bubble Head with Wand Set, Teenage Mutant Turtle Action Bubble Blower, and Sesame Street Giant Bubble Wand (Universal Product Codes 093539831030, 093539014228, and 093539018059, respectively) manufactured by Little Kids, Inc.
    - Purchase one product in duplicate at the same location. The duplicate product will be used as a field replicate.
    - Purchase an alternate bubble liquid-containing product manufactured by Little Kids Inc. when original product is not available.
    - The result is a total of up to four products purchased for testing.
- Purchase Paw Patrol Bowl, Nemo Plate, Girl's Paw Patrol Bowl, and Ninja Turtle Bowl (Universal Product Codes 707226794736, 707226805883, 707226887810, and 707226756284, respectively) manufactured by Zak Designs, Inc.
    - Purchase one product in duplicate at the same location. The duplicate product will be used as a field replicate.
    - Purchase an alternate bowl/plate product manufactured by Zak Designs Inc. when original product is not available.
    - The result is a total of up to five products purchased for testing.
- Log products into the Product Testing Database (PTDB), and process product components following Product Testing Standard Operating Procedures (see Section 8.2).
    - Send samples to Manchester Environmental Laboratory (MEL) to perform the formaldehyde analysis.

    - Send a portion of the original previously-tested Paw Patrol Bowl (component ID: AM-19-1-1) to MEL for analysis.
    - Send a portion of a previously tested product (component ID: DT-11-4-2) for analysis as a cryomilling blank which was previously analyzed to be "free" of formaldehyde (<5 mg/kg).
    - In summary, send up to four purchased bubble liquid-containing products manufactured by Little Kids, Inc., up to five purchased bowl/plate products manufactured by Zak Designs, Inc., and two previously tested components to MEL for the analysis (as noted above) of formaldehyde at a reduced temperature.
- Perform a quality assurance (QA) review on analytical data and database entries.
- Transfer initial findings to client.
- Write a Data Quality Narrative.

5.0 Organization and Schedule

5.4 Proposed project schedule

Tables 1 – 4 lists key activities, due dates, and lead staff for this project.

Table 1. Schedule for completing product collection and data entry.

Task	Due Date	Lead Staff
Product collection complete	12/2019	Ken Nelson
Product data entry complete (7 days after product collection complete)	12/2019	Prajwol Tuladhar
Internal data entry QA complete	1/2020	Chrissy Wiseman

Table 2. Schedule for sending samples to the lab and lab analysis

Task	Due Date	Lead Staff
Samples sent to lab complete	1/2020	Ken Nelson
All laboratory analyses complete (30 days from receipt)	2/2020	Alan Rue

Table 3. Schedule for data and study reviews and data transfer to client.

Task	Due Date	Lead Staff
Lab data QA reviewed	2/2020	Ken Nelson
Lab data loaded into PTDB	2/2020	Ken Nelson
PTDB study QA review complete	2/2020	Ken Nelson
Preliminary Data Transfer to Client	2/2020	Ken Nelson

Table 4. Schedule for final data quality narrative.

Task	Due Date	Lead Staff
Draft due to supervisor/peer/client reviewer	3/2020	Ken Nelson
Final Data Quality Narrative due to client	5/2020	Ken Nelson

5.5 Budget and funding

The estimated study budget is displayed in Tables 5 and 6.

Table 5. Study budget for purchasing products.

Products	Number of Products	Product Duplicates	Average $ per Product	Subtotal
Products manufactured by Little Kids, Inc. and Zak Designs, Inc.	7	2*	$15	$ 135

Table 6. Study budget for lab analysis

Lab Analysis	Number of Samples	QC Samples	$ per Sample	Subtotal
Cryomilling	5	2**	$115	$805
Formaldehyde	11	7^	$345	$6,210

* Field duplicates for each of the two matrix types.
** Client-provided previously tested products, two total.
^ Includes duplicate, matrix spike, matrix spike duplicate for the two product matrices. Also includes a rinsate blank from the cryomilling.

6.0 Quality Objectives

6.2 Measurement quality objectives

6.2.1 Targets for precision, bias, and sensitivity

All measurement quality objectives (MQOs) and quality assurance (QA) targets are outlined in the original Product Testing Program QAPP, Version 1.0 and restated in Table 7. MEL's modified procedure uses a surrogate and the MQO for surrogate standards is updated to reflect this modification.

Table 7. Measurement quality objectives

Analyte	Rinsate and Method Blanks	LCS (recovery)	Matrix Spikes (recovery)	Sample and LCS Duplicates (RPD)	Matrix Spike Duplicates (RPD)	Surrogate Standards (recovery)	Target Reporting Limit (ppm) Ω
Formaldehyde	<LLOQ	50 - 150%	50 - 150%	≤ 40%	≤ 40%	50 - 200%	5.0

LLOQ = lower limit of quantitation
LCS = laboratory control sample
RPD = relative percent difference
ppm = parts per million

ΩIndividual lab reporting limits may vary based upon specific matrix type

7.0 Study Design

7.5 Possible challenges and contingencies

7.5.1 Logistical problems

Product selection of children's products will remain consistent with the strategy used in the 2018 study. Products that may have been available during the 2018 study may or may not be available in the marketplace during the purchasing event. This plan presents a strategy for collecting alternate products (retail stores or online purchasing) to mitigate limited product availability, as outlined in section 4.4 Tasks Required.

8.0 Field Procedures

8.2 Measurement and sampling procedures

The following product testing standard operating procedures will be followed:

- PTP001 Consumer Product Sample Collection and Processing, Version 2.0 (Wiseman, 2018), with these additional procedures:
    - Samples should be processed the day before the courier transports the samples to MEL.
- PTP002 Product Testing Database Standard Operating Procedure For Data Entry and Data Entry Quality Assurance, Version 2.0 (Wiseman, 2019).

8.3 Containers, preservation methods, holding times

Liquid samples will be sent to the laboratory in their original sealed container. Solids will be reduced in size in pre-cleaned glass jars provided by MEL. Solid samples will be processed the day before the courier transports the samples to MEL and will be sent to the lab at a reduced temperature.

9.0 Laboratory Procedures

9.1 Lab procedures table

The formaldehyde testing will be performed at Manchester Environmental Laboratory (MEL). The laboratory methods and requested reporting limits are presented in Table 8. MEL developed a method for the extraction and analysis of formaldehyde in consumer products based on Environmental Protection Agency (EPA) 8315A. The performance-based modifications to the preparation technique (EPA 8315A-PREP) include a reduction in sample size and extraction fluids, as well as the addition of surrogates to monitor extraction efficiency. Analysis will be performed by gas chromatography-mass spectrometry (GC-MS; EPA 8270E-SIM) as an alternative to high performance liquid chromatography-ultraviolet/visible detection (HPLC-UV/Vis).

Table 8. Table of laboratory methods, instrumentation and reporting limits.

Analyte	Matrix	Expected Range of Results	Target Reporting Limit	Preparation Method	Analysis Method	Analysis Instrument
Formaldehyde	Solids	<5 – 5,000 mg/kg	5 mg/kg	EPA 8315A-PREP	EPA 8270E-SIM	GC-MS SIM
Formaldehyde	Liquids	<5 – 1,000 mg/kg	5 mg/kg	EPA 8315A-PREP	EPA 8270E-SIM	GC-MS SIM

9.3 Special method requirements

MEL will perform the cryomilling on all solid samples prior to preparation and analysis following their cryomill standard operating procedure.

A cryomill grinding blank will be performed using a sample previously analyzed to be "free" of formaldehyde (<5 mg/kg). This sample will be sent to MEL along with the study samples.

10.0 Quality Control Procedures

10.1 Table of field and laboratory quality control

Laboratory quality control tests will consist of the method blanks, laboratory control samples, laboratory control sample duplicates, sample duplicates, matrix spike, matrix spike duplicates, and, for solids, the rinsate and grinding blanks (Table 9).

Table 9. Quality control

Analyte	Matrix	Field Replicate	LCS/ LCSD[Ω]	Method Blank[Ω]	Sample Duplicate	Matrix Spike/ MSD	Rinsate Blank	Grinding Blank
Formaldehyde	Solids	1/batch	1/batch	1/batch	1/batch	1/batch	1/batch	1/batch
Formaldehyde	Liquids	1/batch	1/batch	1/batch	1/batch	1/batch	n/a	n/a

LCS = laboratory control sample
LCSD = laboratory control sample duplicate
MSD = matrix spike duplicate
Batch = 20 samples or fewer
[Ω]The LCS/LCSD and method blank can be part of a single extraction batch or split into separate batches for liquids and solids.

11.0 Data Management Procedures

11.1 Data recording and reporting requirements

Product login will follow the Product Testing Program Standard Operating Procedure:

- PTP002 Product Testing Database Standard Operating Procedure For Data Entry and Data Entry Quality Assurance, Version 2.0 (Wiseman, 2019).

12.0 Audits and Reports

12.4 Responsibility for reports

The project manager will provide a reviewed and approved data set to the client after the product testing database data entry QA review and the laboratory data review.

The project manager will be responsible for writing a Data Quality Narrative discussing the data quality and usability of the data to the Client.

15.0 References

Sekerak, S. 2016a. Quality Assurance Project Plan: Product Testing Program, Version 1.0. Washington State Department of Ecology, Olympia, WA. Publication No. 16-03-113. https://fortress.wa.gov/ecy/publications/SummaryPages/1603113.html.

Sekerak S. 2016b. Addendum to Quality Assurance Project Plan: Product Testing Program, Version 1.0. — An Assessment of Children's Safe Products Act Data. Washington State Department of Ecology, Olympia, WA. Publication No. 16-03-121. https://fortress.wa.gov/ecy/publications/SummaryPages/1603121.html.

Sekerak S. 2017. Formaldehyde, D4, MEK, and Styrene in Children's Products. Washington State Department of Ecology, Olympia, WA. Publication No. 17-03-020. https://fortress.wa.gov/ecy/publications/SummaryPages/1703020.html

Sekerak S. 2018. Addendum to Quality Assurance Project Plan: Product Testing Program, Version 1.0 — Formaldehyde in Children's Products 2018. Washington State Department of Ecology, Olympia, WA. Publication No. 18-03-110. https://fortress.wa.gov/ecy/publications/SummaryPages/1803110.html.

Wiseman, C. 2018. Standard Operating Procedure for Consumer Product Sample Collection and Processing, Version 2.0. Document No. PTP001. Washington State Department of Ecology, Olympia. Publication 18-04-018. https://fortress.wa.gov/ecy/publications/SummaryPages/1804018.html

Wiseman, C. 2019. Product Testing Database Standard Operating Procedure for Data Entry and Data Entry Quality Assurance, Version 2.0. Document No. PTP002. Washington State Department of Ecology, Olympia. Publication No. 19-04-015. https://fortress.wa.gov/ecy/publications/SummaryPages/1904015.html.