DEPARTMENT OF ECOLOGY
State of Washington

Addendum to Quality Assurance Project Plan

Toxic Chemicals in Cosmetics: Phthalates and Asbestos

January 2023

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Addendum to
Quality Assurance Project Plan

Toxic Chemicals in Cosmetics

by Prajwol Tuladhar

January 2023

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

1.0 Table of Contents

Note: The numbered headings in this document correspond to the headings in the original QAPP. Only relevant sections are included here; therefore, some numbered headings may be missing.

List of Tables

2.0 Abstract

In 2022, the Washington State Legislature provided one-time funding to the Washington State Department of Ecology (Ecology) to identify and evaluate cosmetic products marketed to or used by people of color for potentially harmful chemicals or chemical classes. In July 2022, Ecology initiated the "Toxic Chemicals in Cosmetics" study to assess formaldehyde, lead, cadmium, and arsenic in cosmetic products marketed or sold to people of color.

This addendum supplements the 2022 original Quality Assurance Project Plan (QAPP) by providing details for assessing ortho-phthalates and asbestos in 60 additional cosmetic products.

This study will evaluate nail polishes, hairsprays, feminine hygiene products, and body washes for nine ortho-phthalates. Eight of these are currently on Washington State's chemicals of high concern to children (CHCC) list. In addition to these eight ortho-phthalates, dimethyl phthalate (DMP), an ingredient mostly found in hairsprays, will be assessed in all these products.

This study will also evaluate talc-containing cosmetic products, such as eyeshadows and blushes, for asbestos contamination.

This addendum includes only sections and information that differ from the original QAPP or that clarify the study for the reader.

Data from this study may be used to support future legislation.

3.0 Background

3.1 Introduction and problem statement

In 2022, the Washington State Legislature provided one-time funding to Ecology to identify and evaluate cosmetic products marketed to or used by people of color for potentially harmful chemicals or chemical classes. Pursuant to Engrossed Substitute Senate Bill 5693, Sec. 302 (56) (2022), Ecology was required to provide a technical report on the testing results to the appropriate committees of the Legislature by December 31, 2022. Ecology initiated the Toxic Chemicals in Cosmetics Study to fulfill this obligation.

Testing for the original study was completed in September 2022 with some allocated funds still available. The availability of funds made it possible for Ecology to do more testing and provide additional information to the Legislature. This addendum provides details for purchasing and evaluating 60 additional cosmetic products marketed or sold to people of color in Washington. This expanded study will assess these additional cosmetic products for asbestos and nine different ortho-phthalates not included in the first round of testing.

Asbestos and talc are found near each other in earth. Talc is a mineral that is often used as an ingredient in cosmetics to absorb moisture, to prevent caking, to make facial makeup opaque, or to improve the feel of the product (FDA 2022b). Previous cases of talc products contaminated with asbestos have been reported by the U.S. Food and Drug Administration (FDA) in their 2019 survey and various other interest groups (U.S PIRG 2018, Zaniewski 2018, and FDA 2022b).

Phthalates have been used in cosmetics as solvents, stabilizers, or plasticizers in a variety of cosmetic products such as: nail polishes, perfumes and scented products, hairsprays, and skin care products (FDA 2022a). Certain ortho-phthalates such as diethyl phthalate (DEP), di (2-ethyl hexyl) phthalate (DEHP), and dibutyl phthalate (DBP) have been found to be endocrine disruptors and harmful to human health causing them to be restricted or prohibited from use in consumer products (CSC 2022a, and ECHA 2022c).

In order to use the funds available, the testing and data validation phase of this study must be completed by June 30, 2023.

3.2.2 Summary of previous studies and existing data

This section highlights some of the previous studies and existing data for asbestos and phthalates in cosmetic products.

Asbestos

- In November 2020, the Environmental Working Group (EWG) commissioned a study of 21 cosmetic samples and found asbestos in about 14% (3 of 21) of the samples evaluated (Stoiber et al. 2020).
- In their 2019 survey of 52 products, the FDA found nine products (about 17%) that tested positive for asbestos fibers. Seven of the nine samples were detectable only after using the Transmission Electron Microscopy (TEM) method, confirming the need for use of TEM methods for detection of low-level asbestos contamination in cosmetics (FDA 2022b).
- Following up on the 2017 reports of asbestos in children's makeup sold at Claire's and Justice Stores, the U.S. Public Research Group (U.S. PIRG) tested 4 makeup products using an independent laboratory. They found asbestos in 75% (3 of 4) of the makeup products purchased at Claire's (U.S. PIRG 2018, and Zaniewski 2018).
- In 2019 and 2021, the FDA conducted two other surveys. These yielded no findings of asbestos in the cosmetic products tested (FDA 2022b).

Phthalates

- In 2018, Young et al. published results of a study that measured plasticizer content against nail polish labels. They tested 40 nail polish samples for 12 phthalates and 10 organophosphate plasticizers. Di (2-ethyl hexyl) phthalate (DEHP) was detected in approximately 98% of the samples. Eight of these samples had DEHP above a 100 ppm. Five of these did not disclose it in their ingredients, and three claimed to be phthalates free. Di n-butyl phthalate (DnBP) a plasticizer commonly used in nail polishes in the past was not listed or detected above 1 ppm in any of the samples (Young et al. 2018).
- In 2013, Guo and Kannan published results of a study that surveyed 170 personal care products for the presence of phthalates and parabens. The products were categorized into rinse-off, leave-on, and baby products. DEHP was the most detected phthalate in both rinse-off and leave-on categories. However, due to the low concentrations detected (<10 ppm), the authors attribute DEHP presence to the migration of phthalates from the packaging. Diethyl phthalate (DEP) was found at highest levels in fragrances, body washes, shampoos, and hair care products while Dibutyl phthalate (DBP) was found at highest levels in nail polish products (Guo and Kannan 2013).

- In 2011, Koniecki et al. published results of a study that surveyed 252 personal care products in the Canadian market. They concluded that fragrances and lotions, followed by deodorants, were the primary source of exposure to DEP, and nail polishes were the primary source of exposure to DnBP (Koniecki et al. 2011).
- In 2010, the FDA conducted a limited survey on 84 cosmetic products. Approximately 52% of adult use products (31 of 60) and 21% of baby products (5 of 24) were found to contain at least one phthalate. DEP and DBP were the most detected phthalates at concentrations ranging from 80 to 36,006 ppm and 123 to 62,607 ppm, respectively (Hubinger 2010).

3.2.3 Parameters of interest and potential sources

In this study cosmetic products marketed to people of color will be analyzed for six forms of asbestos fibers, total asbestos, and nine ortho-phthalates. This study will test cosmetic products for eight different ortho-phthalates currently on Washington State's CHCC list. In addition to these eight phthalates, dimethyl phthalate (DMP), an ingredient mostly found in hairsprays, will also be tested in all products. The nine ortho-phthalates were chosen based on the testing lab's ability to analyze samples within the timeline of the project. The complete list of ortho-phthalates and forms of asbestos fibers to be tested in this study are listed in Tables 1 and 2.

Table. 1 Ortho-phthalates

Analyte Name	Abbreviations	CAS Registry Number
Bis(2-Ethylhexyl) phthalate	DEHP*	117-81-7
Butyl Benzyl phthalate	BBP*	85-68-7
Diethyl phthalate	DEP	84-66-2
Dihexyl phthalate	DHP	84-75-3
Diisodecyl phthalate	DIDP*	26761-40-0
Diisononyl phthalate (unbranched)	DINP*	28553-12-0
Dimethyl phthalate	DMP	131-11-3
Di-n-butyl phthalate	DnBP*	84-74-2
Di-n-octyl phthalate	DnOP*	117-84-0

CAS Chemical Abstracts Service
*These phthalates are restricted in children's products under the Children's Safe Product Act (CSPA)

Table 2 Asbestos fibers

Analyte Name	CAS Registry Number	Chemical Formula
Chrysotile	12001-29-5	$[Mg_3Si_2O_5(OH)_4]_n$
Amosite	12172-73-5	$[(Mg, Fe^{2+})_7Si_8O_{22}(OH)_2]_n$
Tremolite	77536-68-6	$[Ca_2Mg_5Si_8O_{22}(OH)_2]_n$
Crocidolite	12001-28-4	$[Na_2(Fe^{2+}_3Fe^{3+}_2)Si_8O_{22}(OH)_2]_n$
Anthophyllite	77536-67-5	$[(Mg, Fe^{2+})_7Si_8O_{22}(OH)_2]_n$
Actinolite	77536-66-4	$[Ca_2(Mg, Fe^{2+})_5Si_8O_{22}(OH)_2]_n$
Total Asbestos*	1332-21-4	

*Total asbestos content for a sample is the sum of all the fibers reported.

Asbestos

Asbestos is the name given to a group of six different fibrous silicate minerals that occur naturally in the environment. It is this fibrous silicate mineral that can be released into the atmosphere by abrasion and other processes. Asbestos minerals fall into two classes depending on silicate mineral structure: (1) serpentine asbestos and (2) amphibole asbestos. Chrysotile is the

most abundantly used form of asbestos and belongs to the serpentine class. Amosite, crocidolite, and the fibrous variety of tremolite, actinolite, and anthophyllite belong to the amphibole class. Asbestos fibers do not evaporate, dissolve, burn or undergo significant reactions with most chemicals making it the desired material of choice in building materials, friction products and heat resistant fabrics (ATSDR 2001). This study will test for all six forms of asbestos in the sample. The sum of all individual asbestos fibers provides the total asbestos content.

In cosmetics, asbestos comes mainly from talc, which is a naturally occurring mineral found near deposits of asbestos. Talc can be used in cosmetic products to absorb moisture, prevent caking, to make facial makeup opaque, or to improve the feel of the product (FDA 2022b). Talc can be found mainly in baby powders, body and shower products, lotions, feminine hygiene products, eyeshadows, foundations, lipsticks, deodorants, and face masks (CSC 2022b).

Phthalates

Phthalates or phthalate esters are chemical compounds developed in the last century to make plastics more flexible and durable. These compounds are often referred to as "plasticizers" based on their most common uses. They can enter the environment through (1) industrial waste waters, (2) by evaporation into the air from disposal sites (shorter chain phthalates), (3) directly from consumer products, (4) burning of plastic products, and (5) leaking from landfills into soil or water. People can be easily exposed to phthalates in consumer products and plastics as they are not permanently bound to the products (ATDSR 1995).

Phthalates can be used in cosmetics as solvents, stabilizers, or plasticizers. Diethyl phthalate (DEP) is reported as the most common phthalate still used in cosmetic formulations. It is used in bath preparations (oils, tablets, and salts), eye shadows, perfumes and other fragrance preparations, hair sprays, wave sets, nail polish removers, nail extenders, nail polish, bath soaps, detergents, aftershave lotions, and skin care preparations (ATSDR 1995). Dibutyl phthalate (DBP) is used as a plasticizer in products such as nail polishes to reduce cracking, and dimethyl phthalate (DMP) is used in hair sprays to avoid stiffness (FDA 2022a). Even though DEHP is not used in most cosmetic formulations, studies have shown low levels in cosmetic products leaching from the containers (Guo and Kannan 2013).

3.2.4 Regulatory criteria or standards

The following sections detail the regulations on asbestos and phthalates as used in cosmetic products.

Federal Law

The federal Food, Drug, and Cosmetics Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA) are the two main laws pertaining to cosmetics marketed in the United States. The U.S. Food and Drug Administration (FDA) prohibits cosmetics which are adulterated or misbranded under the authority of these two laws. However, cosmetic products and ingredients other than color additives do not require approval from the FDA before they go on the market. Both asbestos and ortho-phthalates are not on the list of ingredients prohibited or restricted in cosmetics by the FDA.

Asbestos is mainly a trace contaminant found in talc and it has no functional use in any cosmetic products. The only way to identify talc contaminated with asbestos is through independent testing. In 1976, the cosmetic industry voluntarily implemented a protocol to test cosmetic talc for amphibole asbestos minerals using the Cosmetic, Toiletry, and Fragrance Association (CTFA) J-41 method.

In 2018, the FDA formed an Interagency Working Group on Asbestos in Consumer Products (IWGACP) to develop a consensus document that would support the development of standardized testing methods in order to (1) improve the sensitivity and consistency of analyses, and (2) support inter-laboratory concurrence when reporting asbestos and other amphibole mineral particles in talc. In 2022, IWGACP published a white paper with their recommendations on standardized testing and reporting methods for asbestos in cosmetic products containing talc (IWGACP 2022a; 2022b).

Washington State Law

The Safer Products for Washington Act (SPWA; RCW 70A.350) identifies phthalates as a priority chemical class. Ecology has identified "fragrances" in personal care products as a priority product and proposes restrictions on intentionally added ortho-phthalates used as solvents or fixatives for fragrance ingredients in personal care and beauty products (Ecology 2022).

Under the Children's Safe Products Reporting rule (WAC 173-334) manufacturers must report the use of 12 specific ortho-phthalates in the CHCC list in children's products including children's cosmetics. Children's Safe Product Act (CSPA) of Washington (RCW 70A.430.020) restricts six out of 12 phthalates at 0.1% individually or in combination in children's cosmetics.

European Union (EU) and Canada

EU allows the use of talc in cosmetic products but prohibits talc in both powdery and non-powdery cosmetic products intended to be used for children under 3 years of age (ECHA 2022b). In Canada, talc is allowed for use in cosmetics and products in powder form intended for infants. However, when used in products intended for infants, they must have a warning label. (Government of Canada 2019)

DEHP is prohibited as a cosmetic ingredient in Canada (Government of Canada 2019). Under the EU Prohibited Substances: Annex II, Regulation 1223/2009/EC on Cosmetic Products, as amended by Regulation (EU) 2021/1902, OJ L 387 of 3 November 2021, there are currently 16 different ortho-phthalates that are prohibited in all cosmetic products (ECHA 2022a).

4.0 Project Description

This study plan describes Ecology's efforts to increase testing on cosmetic products marketed to or used by people of color. This addendum includes testing of cosmetic products for chemicals of concern not included in the original QAPP (Tuladhar, 2022). A detailed explanation on the outreach and the research used for determining each of the priority product type for this study is available in the Appendix.

4.2 Project objectives

The following objectives will be carried out to meet the study goals:

- Extend testing for additional cosmetic products and product types marketed to or used by people of color.
- Purchase and test 20 eyeshadows and blushes for asbestos contamination.
- Purchase and test 20 nail polish products for ortho-phthalates.
- Purchase and test 20 other cosmetic products for ortho-phthalates. The priority products for this category may include a combination of fragrance-free hair care products, as well as unscented or fragrance-free female hygiene products and body washes.
- Ecology will purchase all products from retail stores like the ones identified during the outreach efforts mentioned in the original QAPP (Tuladhar, 2022). For equivalent items that are available and meet the criteria, Ecology will prioritize the product that is least expensive.

4.4 Tasks required

This study will include the following tasks:

- Work with Manchester Environmental Laboratory (MEL) to secure an accredited contract laboratory for the analysis of asbestos.
- Scope the availability of priority products online and in retail stores to strategize purchasing events.
- Conduct purchasing events either online or in retail stores to acquire 60 unique cosmetic products.
- Record purchase and product information along with product photos in Ecology's Product Testing Database (PTDB).
- Process product components from cosmetics products into samples for laboratory analysis.
- Submit up to 40 product samples to MEL for ortho-phthalates analysis.
- Submit up to 20 product samples to a contract lab for asbestos analysis.
- Submit lab data packages to MEL's data validation team for data validation.
- Enter final validated lab data into the PTDB.
- Conduct quality assurance (QA) review on analytical data and database entries.
- Analyze findings and document methods, data quality assessment, and results.
- As needed, consult with subject matter experts (SMEs) regarding data interpretation and quality assurance of asbestos testing results. The SMEs could include analysts and data validators from contract labs as well as any other persons internal or external experienced in assessing asbestos data.
- On or before May/June 2023, provide the Hazardous Waste and Toxics Reduction (HWTR) Program with drafted content on study methods, data quality assessment, and results to be included in a second report to the Legislature.
- Make lab data and product information from the study available to the public on Ecology's PTDB website when the report is published.

5.0 Organization and Schedule

5.1 Key individuals and their responsibilities

Table 3 shows the responsibilities of those who will be involved in the study.

Table 3. Organization of project staff and responsibilities

Staff[1]	Title	Responsibilities
Iris Deng ChemAction Unit P2RA, HWTR Phone: 360-480-6555	Client	Clarifies scope of the project. Provides internal review of the QAPP and approves the final QAPP.
Prajwol Tuladhar Product Testing Unit SCS, EAP Phone: 360-407-6745	Project Manager	Writes the QAPP. Coordinates with client and laboratory, Oversees purchase of products, data entry. Conducts QA review of these entries. Oversees field sampling and transportation of samples to the lab. Conducts QA review of data, analyzes and interprets data, and enters data into PTDB. Drafts the report sections on study methods, data quality assessment, and results to be included in the joint report provided to the legislature.
Jenna Rushing Product Testing Unit SCS, EAP Phone: 360-407-6492	Sample Prep Lead	Leads purchasing, entering purchases and products into PTDB, chain of custody, transport of samples to/from laboratory, and assists with conducting QA review of data entry.
Sara Sekerak Product Testing Unit SCS, EAP Phone: 360-480-9501	Unit Supervisor for Project Manager	Reviews the project scope and budget. Provides internal review of the QAPP, tracks progress, approves the budget, and approves the final QAPP
Jessica Archer SCS, EAP Phone: 360-890-2721	Section Manager for Project Manager	Reviews the project scope and budget, approves peer reviewer of draft QAPP, and approves the final QAPP
Nathan Lubliner ChemAction Unit P2RA, HWTR Phone: 360-688-6703	Unit Supervisor for Client	Coordinates client project scope. Reviews and approves the final QAPP
Richelle Perez P2RA, HWTR Phone: 360-742-6794	Section Manager for Client	Reviews the project scope and budget and approves the final QAPP.
Christina Frans MEL Phone: 360-995-2473	MEL QA Coordinator	Reviews QAPP, coordinates contracts with external laboratories, writes SOW and conducts/coordinates data validation on asbestos analysis.
John Weakland MEL Phone: 360-480-7515	Data Validation Chemist	Reviews QAPP and conducts data validation for phthalates analysis.
Alan Rue MEL Phone: 360-871-8801	Director	Reviews and approves the final QAPP.
Arati Kaza Phone: 360-407-6964	QA Officer, Ecology	Reviews and approves the draft QAPP and the final QAPP.

[1]All staff except the clients are from EAP.
EAP: Environmental Assessment Program
HWTR: Hazardous Waste and Toxics Reduction Program
MEL: Manchester Environmental Laboratory
PTDB: Product Testing Database
SCS: Statewide Coordination section
QAPP: Quality Assurance Project Plan
P2RA: Pollution Prevention and Regulatory Assistance
SOW: Statement of Work

5.4 Proposed project schedule

Tables 4 – 7 list key activities, estimated due dates, and lead staff for this study.

Table 4. Schedule for completing product collection and data entry

Task	Due date	Lead staff
Product Purchase complete	Dec 2022	Jenna Rushing
Product Data Entry complete	Dec 2022	Jenna Rushing
Product Data Entry QA	Dec 2022	Prajwol Tuladhar

Table 5. Schedule for sending samples to the lab and lab analysis

Task	Due date	Lead staff
Samples sent to MEL complete	Dec 2022	Jenna Rushing
Samples sent to the contract lab	Dec/Jan 2022	Jenna Rushing
All lab analyses complete (asbestos)	Mar 2023	External lab
All lab analyses complete (phthalates)	Mar 2023	MEL

Table 6. Schedule for data and study reviews and data transfer to client

Task	Due date	Lead staff
Lab data validation (asbestos)*	Apr/May 2023	Christina Frans/ Contract*
Lab data validation (phthalates)	Apr/May 2023	John Weakland
Lab data QA reviewed	May/June 2023	Prajwol Tuladhar
Lab data loaded into internal PTDB	May/June 2023	Prajwol Tuladhar
PTDB Study QA review complete	May/June 2023	Prajwol Tuladhar
Preliminary data transfer to client	May/June 2023	Prajwol Tuladhar
Study data published in the external PTDB	With published report	Prajwol Tuladhar

*Validation of asbestos data may be contracted out to an external validator
QA: Quality Assurance
PTDB: Product testing Database

Table 7. Schedule for final report

Task	Due date	Lead staff
Draft sections due to supervisor/peer reviewer	May 2023	Prajwol Tuladhar
Draft sections due to HWTR	May/June 2023	Prajwol Tuladhar
Final report	June 2023	HWTR

5.5 Budget and funding

Total estimated cost for the study is projected to be $47,200 which includes the cost of product collection, laboratory budget, and data validation. Table 8 presents a breakdown of the estimated study budget. Table 9 presents laboratory budget costs for phthalates analysis, estimated to be $21,160. Table 10 presents laboratory budget costs for asbestos analysis, estimated to be $14,560. Funding for this study is provided by a cosmetics proviso in the state appropriations budget, which expires after June 30, 2023.

Table 8. Total study budget

Item	Cost ($)
Product Collection* (up to 60 products)	2,880
Laboratory MEL (see Table 7 for details)	21,160
Contract Laboratory (see Table 8 for details)	14,560
MEL Contract Fee^	4,368
MEL Data Validation Fee (phthalates)	4,232
Study Total	47,200

*Some products may be purchased in replicate of up to four to provide a sufficient amount of sample for lab analysis and/or field sample duplicates.
^MEL contract fee is 30% of the cost of an external contract and includes the cost of level 4 data validation.

Table 9. Study budget for lab analysis of ortho-phthalates

Lab Analysis	Number of Lab Samples for Analysis	Lab QC Samples*	Total Number of Samples	Cost Per Sample ($)	Lab Subtotal ($)
Ortho-phthalates^	40	6	46	460	21,160

*Quality control (QC) samples in this table are those not provided free of charge (matrix spike, matrix spike duplicates and sample duplicate).
^Each sample will be tested for all nine ortho-phthalates mentioned in this study.

Table 10. Study budget for lab analysis of asbestos

Lab Analysis	Total Number of Samples^	Cost Per Sample ($)	Lab Subtotal ($)
Asbestos# (PLM)	20	99	1,980
Asbestos# (TEM)	20	441	8,820
XRD Screening*	20	188	3,760
Lab Analysis Total	20	728	14,560

PLM – Polarized Light Microscopy
TEM – Transmission Election Microscopy
XRD – X-Ray Diffraction
^ The total number of samples sent to the lab for asbestos analysis will be 20. Each of the 20 samples will be separated for XRD, TEM, and PLM analysis. QC samples for asbestos are included in the cost.
# Asbestos analysis using both methods (PLM and TEM) will assess and report each sample for all six forms of asbestos. The reported concentrations can be added to obtain total asbestos content of a sample. Only the final concentrations obtained from the TEM method will be reported in the database for each sample.
*XRD screening will assess the presence or absence of serpentine and amphibole minerals in the product samples. It can also be used to identify minerals other than talc in the samples. The lab will use XRD specifications in the EPA 600/R-93/116 method and the current U.S. Pharmacopeia (USP) monograph.

6.0 Quality Objectives

6.2 Measurement quality objectives

6.2.1 Targets for precision, bias, and sensitivity

Tables 11, 12, and 13 show MQOs for analysis of ortho-phthalates and asbestos expressed in terms of acceptable precision, bias, and sensitivity. Table 11 shows MQOs for analysis of ortho-phthalates. Tables 12 and 13 show MQOs for analysis of asbestos using the PLM and TEM methods, respectively. The XRD screening method will require the use of verification standards and instrument calibration in accordance with the SOP of the laboratory doing the analysis.

Table 11. Measurement quality objectives for analysis of ortho-phthalates

Analyte	LCS (recovery)	Matrix Spike (recovery)	Sample and LCS Duplicates (RPD)	Matrix Spike Duplicates (RPD)	Target Reporting Limit Ω
Ortho-phthalates*	50-150%	50-150%	≤ 40%	≤ 40%	25 – 50 ppm

LCS = laboratory control sample
RPD = relative percent difference
ppm = parts per million
Ω Individual lab reporting limits may vary based upon specific matrix type
*Ortho-phthalates refer to all nine ortho-phthalates being tested in this study

Table 12. Measurement quality objectives for analysis of asbestos using the PLM method

Measurement Performance Activity	Measurement Performance Criteria
Intra analyst QC	R* Value <1
Inter analyst QC	R Value <1
Analysis of a certified reference slide#	Correctly identify optical properties of all forms of asbestos fibers in the reference slide. Visual estimate versus point count percentages within ± 50% of the asbestos content in a certified slide
Equipment blanks, Preparation blanks	Asbestos < Target Reporting Limit
Target Reporting Limit	0.1%Ω

QC – Quality control
*Here the R value is (a-b) / ((a + b) / 2) where, “a” is the result from the analyst being checked or 1st result, and “b” is the result from another analyst for the same sample or the 2nd result.
A set of certified reference materials containing varying concentrations of each of the six regulated asbestos types are used for reference slide QC checks. Each analyst selects one of the references slides for PLM point count analysis each week.
Ω the % unit here represents an area percent that is calculated by counting identified asbestos and non- asbestos material over 1000 points.

Table 13. Measurement quality objectives for analysis of asbestos using the TEM method

Measurement Performance Activity	Measurement Performance Criteria
Intra analyst QC	Within 2 times the Poisson Standard deviation^
Inter Analyst QC	Within 2 times the Poisson Standard deviation^
Verified analysis	Within 1.5 times the Poisson Standard deviation^
Analysis of certified reference slide*	Identification of asbestos fiber types in the reference slide
Preparation blanks	Asbestos < Target Reporting Limit
Target Reporting Limit Ω	0.1 ppm

QC – Quality control
ppm = parts per million by weight
*The analyst will be given one reference slide to verify
Ω Individual lab reporting limits may vary based upon specific matrix type
^ The upper and lower limit for the intra/inter analyst QC and the verified QC analysis results are A ± (2 x $\sqrt{A}$) and A ± (1.5 x $\sqrt{A}$) respectively, where A is the original analysis count.

7.0 Study Design

7.1 Study boundaries

Ecology will purchase up to 60 distinct products and send up to 20 samples to a contract laboratory and 40 samples to MEL for analysis.

- Purchase and test 10 eyeshadows and 10 blushes, with talc as a listed ingredient for asbestos contamination.
- Purchase and test 20 nail products for phthalates. The nail products can include items such as clear topcoats, base coats, or topcoats with glitter finishes.
- Purchase and test 20 additional product samples from the following categories for phthalates: (1) hair care products that are fragrance-free, (2) unscented or fragrance-free feminine hygiene products, and (3) unscented or fragrance-free body washes.

Manufacturers are not required to disclose phthalates as an ingredient if used in "fragrances." Ecology will target fragrance-free hair care products, to test for the use of phthalates not associated with fragrance ingredients. Ecology will purchase hair care products that do not have "fragrance" or "parfum" listed in the ingredients label.

Feminine hygiene products and body washes that are marketed as unscented or fragrance-free will be selected regardless of the presence or absence of "fragrance" and "parfum" in the ingredients list.

Ecology will purchase multiples of each product to ensure enough sample is provided for all testing parameters. Ecology will ensure that the multiples of a product purchased represent the same item by confirming, at a minimum, that the same tint or color is described in the package.

7.2.2 Field parameters and laboratory analytes to be measured

The analytes to be analyzed in product component samples for this study are listed in Table. 1 and Table. 2 (See Section 3.2.3). The product component samples containing the analytes may be composed of complex matrices that are solids, semi-solids, liquids, or cream based.

7.5 Possible challenges and contingencies

Some products purchased may not have enough weight necessary for analysis. Sample may also be lost while processing the products. Ecology will purchase multiples of the same product (see Section 7.5.2) to fulfill the weight requirements for analysis. The cost of buying multiples is factored into the budget (see Table 6).

7.5.1 Logistical problems

Limitations in receiving products through online purchases may occur due to unforeseen product unavailability and/or shipping delays after purchase. Some product purchases may need to be cancelled if the products are on back-order and not be received within the proposed timeframe. Products may be reordered through a different online retailer or purchased at a retail store if it can be achieved within the purchase timeline mentioned in this QAPP (see Table 2).

7.5.2 Practical constraints

Eyeshadow palettes with multiple colors will be consolidated into one composite sample to be tested for asbestos. If found positive the whole product will be identified as containing asbestos but the true color that attributes to the presence of asbestos will be unknown.

Similarly for composite samples made from multiples of the same products to garner enough weight, all products that make up the composite sample will be considered contaminated with asbestos. However, Ecology will ensure that the multiples of a product purchased represent the same item by confirming at minimum, the same tint or color described in the package.

7.5.3 Schedule limitations

Complications in the laboratory digestion and extraction processes due to complex product matrices, may cause a need for reanalysis of a sample. However, time constraints may limit the possibilities for reanalyzing a sample. In such cases, results may be accepted with qualifications.

Contracting process for asbestos testing may take longer than anticipated which could delay sending of samples to the lab mentioned in the proposed project schedule (See Table 3). The project manager will verify with the lab on how long it can be delayed while achieving results in accordance with the proposed schedule.

8.0 Field Procedures

8.3 Containers, preservation methods, holding times

Sample containers, minimum quantity, storage, preservation, and holding times for sample matrices are shown in Table 14. Hand-reduced lab samples will be stored in certified clean wide-mouth glass jars received from the lab. Solids and powders will be hand-reduced and transferred to pre-cleaned glass jars provided by MEL or the contract lab. Products such as eyeshadow palettes that have multiple colors will be consolidated into one composite sample.

Liquid and semi-liquid (homogeneous cream-based) samples will be sent to the laboratory in their original sealed container. Multiple bottles of the same product may be used as one sample for liquid samples that do not have enough weight. Such samples will be individually labeled with both the MEL sample ID and the product testing sample ID and consolidated into one sample bag. The sample bag will also be labeled with MEL sample ID and product testing sample ID.

Table 14. Sample containers, preservation, and holding times.

Parameter	Matrix/ Source Code	Minimum Quantity Required	Container	Preservative	Holding Time
Asbestos	CP/ PC	5.0 grams	4 to 8 oz. glass jar	Ambient temperature	30 days after the contract lab submits the final report
Phthalates	CP/PC	2.5 grams	4 to 8 oz. glass jar	Ambient temperature	1 year

CP: Consumer Products
PC: Personal Care Products

9.0 Laboratory Procedures

MEL will perform the analysis of nine ortho-phthalates using the EPA 8270E method.

The contract lab will use X-Ray Diffraction (XRD) analysis to screen for the presence or absence of serpentine and amphibole minerals in product samples. This analysis can also provide additional information on other minerals in the analyzed samples. The contract lab will follow XRD specifications in EPA 600/R-93/116 and the current U.S. Pharmacopeia (USP) monograph (USP 2011).

The contract lab will also perform asbestos analysis on all samples using the EPA 600/R-93/116 method for Polarized Light Microscopy (PLM) and Transmission Electron Microscopy (TEM). This method will incorporate both PLM and TEM methods to determine the presence of all six forms of asbestos fibers greater than 0.5 µm. The PLM method can be limited by the visibility of asbestos in the matrix tested. Therefore, TEM and XRD methods will be used in conjunction with the PLM method to obtain a complete characterization of each sample. Only the quantitative results of the TEM method will be used to report asbestos concentrations.

XRD Screening

The laboratory analyst should determine if any sample preparation (gravimetric reduction) is required and document any such sample preparation steps taken before the XRD analysis. For qualitative analysis by XRD methods, samples should be initially scanned over limited diagnostic peak regions for the serpentine and amphibole minerals. All samples that exhibit diffraction peaks in the diagnostic regions for asbestiform minerals should be submitted to a full qualitative XRD scan, and their diffraction patterns should be compared with standard reference powder diffraction patterns to verify initial peak assignments and to identify possible matrix interferences. More details on the testing method, standard peak regions, and interferences can be obtained from EPA 600/R-93/116 and the USP talc monograph. The IWGACP advises that analysis by TEM, in addition to PLM, should be used regardless of the XRD result with talc-containing cosmetics (IWGACP 2022b).

PLM Analysis of Asbestos

The criteria set in the EPA method for positive identification of asbestos using PLM requires the determination of following optical properties: (1) morphology, (2) birefringence, (3) color and if present pleochroism, (4) extinction characteristics, (5) refractive indices (±0.005), and (6) sign of elongation. Asbestos cannot be reported in any quantity, including trace, until its optical properties have been measured and recorded. When non-asbestos fibers are observed the contract lab will verify that all optical properties that distinguishes the fiber from asbestos are measured and recorded on the bench sheet. Area % quantitation will be done by using the point counting method as described in the EPA 600/R-93/116 method.

For each sample to be point counted, mounts are made by dispersing the sample in a suitable fluid. Each mount may have up to 200 grid points that can be superimposed over a field of view. A reticule is placed on the eyepiece of the microscope that superimposes a grid of points over the field of view. Empty and non-empty points are examined for each mount until 1000 points have been observed, some of which would be identified as asbestos and the rest as non-asbestos material. A simple calculation gives the percentage of asbestos; For example, 10 points identified with having asbestos fibers in 1000 points observed would give a result of 1.0 % asbestos fibers (MEI 2020).

TEM Analysis of Asbestos

For TEM analysis, fibrous asbestos structures are classified based on morphology, diffraction pattern, and elemental composition, which must be properly recorded and supported by the applicable Selected Area Electron Diffraction (SAED) pattern photographs and Energy Dispersive X-Ray Analysis (EDXA) spectra. A minimum of two grids per sample will be prepared and analyzed, with a total of 35 grid openings analyzed for each sample. Each identified structure is converted into a mass weight, using the dimensions from the TEM to determine the quantitative weight percent of asbestos in the sample. This can be done using either the ISO 22262-2 method or as specified by the laboratory.

9.1 Lab procedures table

The lab methods and requested target reporting limits are presented in Table 15.

Table 15. Laboratory measurement methods.

Analyte	Sample Matrix/ Source Code	Samples*	Expected Range of Results	Target Reporting Limit^	Sample Prep Method	Analytical (Instrumental) Method
Asbestos (PLM)	CP/PC	20	Unknown	0.1%	Gravimetric Prep+	EPA 600/R-93/116
Asbestos (TEM)	CP/PC	20	Unknown	0.1 ppm	Gravimetric Prep	EPA 600/R-93/116
Ortho-phthalates	CP/PC	40	Unknown	25-50 ppm	EPA 3580A	EPA 8270E

^Individual reporting limits may vary based upon specific analyte and matrix type
*Each of the 20 samples sent to the lab for asbestos testing will be divided and analyzed using the PLM and, TEM analysis techniques separately.
+Gravimetric Prep includes the gravimetry procedures described in section 2.3 of method EPA 600/R-93/116 which includes thermal ashing and acid dissolution
CP: Consumer Products
PC: Personal Care Products
ppm: parts per million

The asbestos target reporting limit of 0.1 ppm and 0.1% is based on the optimization and performance sensitivity of the TEM and PLM methods, respectively.

The target reporting limit of 25-50 ppm for phthalates reflects the current capabilities of MEL and is based on the optimization and performance of their method. For ortho-phthalates undetected laboratory results will be reported as non-detect and qualified as "U" at the method reporting limit. Analyte concentrations in samples that are less than five times the detected analyte concentrations in the method blank will be qualified as non-detect due to method blank contamination.

9.2 Sample preparation methods

Solid, semi-solid and powdered products will be processed into lab samples for analysis using procedures from the Product Testing SOP PTP001. Ecology employees will process samples to be tested for asbestos in the fume hood as an added safety measure.

Liquid and semi-liquid (cream based homogenous) samples will be sent to the laboratory in their original sealed container. The laboratory analyst will identify liquid samples in original containers that do not have a seal or a seal that may have been compromised during shipment. The project manager will ensure this requirement in the Chain of Custody (COC) form.

Samples in a pressurized aerosol containers will need to be sprayed directly onto the extraction solvent. To determine the weight of the sample being analyzed the analyst must pre-weigh the container with the extraction solvent before spraying in the sample.

9.4 Labs accredited for methods

MEL is accredited by the Washington State's Lab Accreditation Unit (WA-LAU) for phthalates analysis using EPA 8270E.

Asbestos analysis will be conducted by a lab accredited by WA-LAU for asbestos analysis using EPA 600/R-93/116.

10.0 Quality Control Procedures

10.1 Table of field and laboratory quality control

Phthalates

Laboratory quality control (QC) tests for analysis of phthalates will consist of the method blanks, laboratory control samples, laboratory control sample duplicates, sample duplicates, matrix spikes, and matrix spike duplicates. See Table 16.

Table 16. Quality control samples, types, and frequency for analysis of phthalates.

Parameter	Sample Duplicates	LCS/LCSD	Method Blanks	Matrix Spikes/MSD
Ortho- phthalates	1/batch	1/batch	1/batch	1/batch

LCS = lab control sample
LCSD = lab control sample duplicate
MSD = matrix spike duplicate
Batch = 20 samples or fewer

Asbestos

Laboratory QC tests for analysis of asbestos includes inter-analyst and intra-analyst checks to verify analytical accuracy, precision, and bias. Standard reference materials (SRMs) will be used to assess the analyst's ability to accurately identify different asbestos fibers.

Method blanks (Refractive index oil blanks) for PLM will be used to address contamination concerns. For method blanks, a sample of isotropic non-asbestos material such as fiberglass (SRM 1866a or approved equivalent) is mounted in a drop of refractive index liquid on a clean slide. Preparation tools including forceps and dissecting needle are rubbed in the drop of liquid and a clean cover slip must be placed on the drop.

The entire area under the cover slip is scanned by PLM to detect asbestos fiber contamination. If asbestos fibers are detected, the test must be repeated using a clean slide and cleaned preparation tools. If asbestos fibers are still found, the analyst should investigate whether the source of the contamination is the refractive index liquid or other supplies and replace as needed. The method blank must be non-detect by PLM prior to proceeding with associated sample analyses.

In addition to this blank, a preparation blank of a known material not containing asbestos (like ground quartz combined with calcium carbonate) will be subjected to the same preparation methods (gravimetric prep) as regular samples. This blank will be analyzed with both TEM and PLM methods to check for contamination. Documentation for Instrument calibration and alignment will be completed in accordance with the lab's SOP and provided with the data package for validation if necessary.

Tables 17 and 18 display the lab QC samples required for asbestos analysis. The lab QC samples have associated MQOs (section 6.2) that will be used to evaluate the quality and usability of the sample results.

Table 17. Quality control samples, types, and frequency for asbestos testing using PLM.

Data Quality Indicator (DQI)	Measurement Performance Activity	Measurement Frequency
Analytical Precision	Intra analyst QC	1/20 samples
Analytical Accuracy/Bias	Inter Analyst QC	1/10 samples
Analyst accuracy/bias	Analysis of certified reference slide	1/week
Overall accuracy/Bias (contamination)	Method blanks (refractive index blanks)	1/day
Overall accuracy/Bias (contamination)	Preparation blank	1/batch[+]
Instrument Bias/Precision	Instrument Calibration	According to Laboratory SOP

[+]Batch = 20 samples or fewer

Table 18. Quality control samples, types, and frequency for asbestos testing using TEM.

Data Quality Indicator (DQI)	Measurement Performance Activity	Measurement Frequency
Analytical Precision	Intra analyst QC	1/20 samples
Analytical Accuracy/Bias	Inter Analyst QC	1/10 samples
Verified analysis^	Same TEM grid openings analyzed by a different analyst.	1/20 samples
Analyst accuracy/bias*	Certified SRM reference or high count verified reference sample	1/annually
Overall accuracy/Bias (contamination)	Preparation blank	1/batch[+]
Instrument Bias/Precision	Instrument Calibration	According to Laboratory SOP

* A certified reference for the TEM method is analyzed by the analyst annually. The documentation of this analysis log can be requested with the data package to verify it has been completed and meets the criteria.
^A verified TEM analysis by duplicate counting will be conducted on a positive sample if it is available. In the case of no detections a random sample may be selected.
[+]Batch = 20 samples or fewer

11.0 Data Management Procedures

11.2 Laboratory data package requirements

After completing the lab analysis, the analytical lab will deliver a Level 4 data package in an electronic format to the project manager and MEL's data validation team. The analytical lab will submit lab data in a PDF format file with all required specific content, along with data in EDD format (.csv or .xlsx files). The data package must include all raw data and QA/QC documentation that would be needed to perform a review of the results.

The documentation for phthalates analysis will include bench sheets, calibration reports, chromatograms, and spectra for all calibration standards and samples.

The documentation for asbestos analysis should include all bench sheets, instrument calibration reports, spectra for all calibration standards and samples, along with TEM and PLM images and spectra collected during analysis.

For PLM, the QA/QC documents should also include verification of microscope alignment checks (daily) verifying Kohler illumination and checking cross hair alignment using a material that reliably has extinction parallel to the polarizer, reference sample analysis, and refractive index liquid checks (semi-annual) including laboratory temperature monitoring records.

For XRD, the data package should include raw data such as annotated diffraction patterns and QC documentation such as results of alignment and intensity checks and also results of reference sample analysis.

For TEM, the data package should include EDXA spectra and SAED (selected area electron diffraction) data in addition to instrument calibration records and microscope alignment records which provide information on the stability of the camera constant for SAED and detector resolution of the EDXA.

Case narratives will be included to discuss any problems encountered with the analyses, corrective action taken, changes to the requested analytical method, and a glossary for data flags and qualifiers. All sample results and QC data will be included in these case narratives.

13.0 Data Verification and Data Validation

13.3 Validation requirements, if necessary

MEL's data validation team will conduct a Stage 4 data validation on the complete set of ortho-phthalates data. Asbestos data may be validated by MEL's data validation team or a contract laboratory. The following documents may be used as references for validating the asbestos data:

- United States Environmental Protection Agency (USEPA). 2016b. TEM validation process guidelines for asbestos data review, Office of Superfund Remediation and Technology Innovation (OSRTI), Washington DC, OLEM Directive: 9200.2-180.
- USEPA. 2016a. PLM validation process guidelines for asbestos data review, Office of Superfund Remediation and Technology Innovation (OSRTI), Washington DC OLEM Directive: 9200.2-179.

If considered necessary, the project manager may consult an expert certified in conducting asbestos surveys from within the agency or an external agency, during the data verification process to ensure the data quality meets all the requirements.

14.0 Data Quality (Usability) Assessment

After MEL's data validation team completes the data validation process, the project manager will determine data usability and accomplishment of the study objectives. The project manager will examine data from all field and lab procedures to ensure that the data (1) were collected using proper procedures, (2) fall into the expected range of results, and (3) meet reporting limits as described in Sections 8 and 9. The project manager will also determine if the data satisfies the MQOs and QC procedures described in Sections 6 and 10.

In addition to verifying that the QC meets all specifications for the asbestos data, the project manager will verify any positive identification made using the PLM technique. The project manager will consult with the data validator to verify that all optical properties of the asbestos fibers identified by the lab match with standards established in literature. The optical characteristics of the different asbestos fibers are available in EPA 600/R-93/116 method, and in Appendix C of "USEPA PLM validation process guidelines for asbestos data review" document.

The project manager will also check the bench sheet data to verify that the following have been recorded: (1) magnification, (2) reticule size/type, (3) number of slide mounts prepared, (4) number of empty and/or non-empty points counted, and (5) observance of fibers in a field of view but not directly under a point. This information will be used to verify that 1000 points have been counted for each sample and that related information has been documented as applicable (USEPA 2016a).

For TEM analysis data the project manager will ensure all instrument calibration documents, relevant TEM images, SAED images and EDXA spectra are available. The project manager will verify that at minimum two grids are prepared and analyzed with 35 grid openings observed per sample.

For ortho-phthalates, undetected laboratory results will be reported as non-detect and qualified as "U" at the method reporting limit. Analyte concentrations in samples that are less than five times the detected analyte concentrations in the method blank will be qualified as non-detect due to method blank contamination.

If all other specifications are met, the data quality is usable to meet study objectives. If the MQOs have not all been met, the project manager will examine the data to determine whether they are still usable and whether the data quantity and quality are sufficient to meet project objectives. The project manager will determine appropriate corrective actions for data that do not meet the criteria; this may include samples re-sampled, re-analyzed, rejected, or used with appropriate qualification. The project manager will analyze the data and determine how the results will be summarized and documented in the final report.

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16.0 Appendix. Product Selection for Phase 2 Cosmetics Testing

This guideline is provided by Ecology's Hazardous Waste and Toxics Reduction (HWTR) Program.

Total number of products: 60

- 20 products for asbestos testing (blush, eye shadow)
- 40 products for ortho-phthalates testing (nail products, hair sprays, feminine cleansers, body wash)

Product sourcing

- Prioritize purchasing all products at Walmart, Target, or equivalent stores.
- We define an equivalent store as any large stores that have physical locations and do not specialize in one type of merchandise.
- These stores frequently offer groceries, clothes, and home goods in addition to cosmetics.
- These stores are typically chains.
- We do not require items to be bought from specific locations. Prior research indicates that if an individual Walmart or Target store in WA carries a specific product, it is likely also available through the online storefront (and vice versa).
- However, since online storefronts may also carry items from third-party sellers, we would suggest that the purchaser confirm they are buying products offered by the store and not a third party.

Asbestos testing in talc-based cosmetics

Requesting 20 products be purchased in two categories: eye shadow and blush.

Research question: Is there asbestos contamination in inexpensive eye shadows and blushes?

Rationale for question:

- Cost is a clear consideration for individuals when purchasing cosmetics.
- Asbestos is a naturally occurring mineral that can contaminate mineral talc. It is carcinogenic when inhaled. (FDA 2022a).
- Certain powder cosmetics (including eye shadow and blush) contain greater than 50% talc. (Source: CA cosmetics database, https://cscpsearch.cdph.ca.gov/).
- Cosmetic usage studies in California (Harley et al. 2016; Collins et al. 2021; Dodson et al. 2021) indicate makeup, including eye makeup and blush, are used more frequently by Latina women.

Product purchasing considerations

- Purchase 10 eye shadow and 10 blush products. Prioritize products that cost $15 or less.
- Purchase only powder/pressed powder/brush-on eye shadows and blushes. Do not purchase liquid or cream products.
- Confirm the product lists talc as an ingredient.

- Single-color blush or eye shadow are typically found in 0.1 oz amounts. It is okay to combine multiple colors from the same palette into one sample. Do not combine various products into one sample.

Ortho-phthalates testing in cosmetics

Requesting 40 products be purchased in four categories: nail products, hair sprays, feminine cleansers, and body wash.

Research question: What is the amount of ortho-phthalates in inexpensive nail products?

Rationale for question:

- Cost is a clear consideration for individuals when purchasing cosmetics.
- Phthalates have been largely used in nail polishes as plasticizers to reduce cracking by making the nails less brittle (FDA 2022b).
- Non-government organizations in WA state expressed concern about phthalates used in cosmetics.
- Product purchasing considerations:
- Purchase 20 liquid-based nail polish products, including base coat and topcoat products. Prioritize products under $15 dollars.

Research question: Are there ortho-phthalates in unscented or fragrance-free cosmetic products?

Rationale for question:

- Some women avoid products with fragrances to avoid ortho-phthalates. Products that are marketed as unscented may have added fragrances that could contain ortho-phthalates.
- We also heard that some groups were concerned about ortho-phthalates that might be used in cosmetics applied to sensitive areas (like feminine hygiene products) or used for non-fragrance purposes (which are not covered by Ecology's draft regulation).
- Ortho-phthalates function as plasticizers or film-forming agents. They can be used in hair sprays to help avoid stiffness by allowing them to form a flexible film on the hair (FDA 2022b). Ortho-phthalates were also found in cleansing products.
- Phthalates may also appear in cosmetics as contaminants. Research show that the contamination may migrate from plastic packaging into the cosmetic products (Farooqi et al., 2019). Manufacturers have self-reported phthalates contaminations in personal care products to WA children's product High Priority Chemicals Data System (HPCDS).
- We are particularly concerned about ortho-phthalates in feminine hygiene products because these chemicals may pass more easily into the body when they are used on or near genitals (Branch et al., 2015).
- Cost is a clear consideration for individuals when purchasing cosmetics.

Product purchasing considerations

- Purchase 20 liquid-based products including hair sprays, feminine cleansers, and body washes. Purchase 10 hair sprays or as many as possible that are fragrance-free. Avoid hair spray products that list "fragrance," "parfum" or similar on the ingredients list. Purchase liquid-based unscented or fragrance-free feminine cleansers and body wash.
- Feminine cleansers are hygiene products that are marketed as "feminine wash," "feminine cleansing wash," "vaginal cleanser," "cleansing wash," and "hygiene wash." Check the product package for "unscented" or "fragrance-free."

- Body washes are cleansing products that could be marketed as body cleanser, body wash, shower gel. Etc.
- Prioritize lower-cost products.

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