Lead in Cosmetics
Information on Data Collection

DEPARTMENT OF ECOLOGY
State of Washington

Introduction

This document is for manufacturers who are using Option 2 under the Interim Policy on Lead in Cosmetics for one or more of their products. Its purpose is to inform and support manufacturers in their data collection efforts by providing relevant information, context, and resources. It also describes the governing law and policy, why we need the information, what we'll do with it, when and how to submit it, and how to request confidential treatment of your information.

Overview

The Toxic-Free Cosmetics Act[1] restricts nine toxic chemicals and chemical classes from use in cosmetic products in Washington. Restrictions went into effect on January 1, 2025. Lead and lead compounds are restricted when intentionally added or present at or above 1 part per million (ppm) in a cosmetic product.

Washington State Department of Ecology (Ecology, we) issued an Interim Policy on Lead in Cosmetics[2] in December 2024 to provide manufacturers who are unable to comply with the statutory lead limit an alternative method of compliance. The interim policy allows Ecology enforcement discretion for some products and requires some manufacturers to provide data to Ecology upon request. In December 2024, we also announced a rulemaking process to identify a feasible approach to regulating lead in cosmetic products, including potentially adopting a different limit on lead impurities than the statutory lead limit of 1 ppm.

To meet the requirements of Option 2 for color cosmetics and clay masks, the lead level in each batch of the product can exceed 5 ppm but must be below 10 ppm. Manufacturers must test for lead in each batch of each product for which they select Option 2. The manufacturer must submit the lead testing data and information including analytical methods to Ecology upon request.

Why we need the information

We will use the lead testing data we collect to inform the rulemaking process. We will not use this data for compliance now or in the future. In order to consider changing the statutory lead limit through rulemaking, we need data and information to demonstrate that the 1 ppm limit is not being achieved for some or all products.

We need to identify product categories or subcategories, if any, where the legal limit isn't feasible. For those, we also need to figure out an alternative lead limit or regulatory approach,

[1] Chapter 70A.560 RCW: https://ecology.wa.gov/TFCA
[2] apps.ecology.wa.gov/publications/SummaryPages/2404036.html

especially where keeping lead levels below 1 ppm isn't consistently possible. The data we're collecting will help us understand which color cosmetic and clay mask products currently don't meet the legal limit or consistently stay below 5 ppm.

What we'll do with the information

We plan to analyze the data to look for patterns in distribution and variability of lead levels by attributes including batch, product category, and test method for this subset of products. We will use this data in combination with publicly available data on lead levels in cosmetic products and market data on cosmetic products from our research to inform rule development.

When and how to submit the information

You don't need to submit anything at this time. We expect to request data from some manufacturers starting in late 2025 or the first half of 2026. You will receive an email when you are required to submit data that will specify a data submission deadline, and a deadline to request confidential treatment of your information. You will have at least 75 days from the date of the request to submit the data. We must receive all requests for confidential treatment of business information at least 60 days prior to the data submission deadline.

You must submit the data using the Lead in Cosmetics Data Collection Template provided by Ecology and fill it out completely. You can download the template from our Toxic-Free Cosmetic Act interested parties webpage.[3] We recommend you use the template now to document all the information we may ask you to submit.

If you do not submit the requested data and information by the deadline, you will no longer meet the requirements of the policy and must meet the statutory lead limit of 1 ppm to comply with the law.

What to measure and document

You can measure lead levels in finished products, or measure ingredient lead levels and calculate product lead levels. We highly recommend you test finished products rather than use ingredient testing to get accurate lead levels in the final products. A third-party laboratory must complete all testing and measure total lead. See Appendix 1 for guidance on acceptable analytical test methods for lead testing.

Note that you may assign your own identifiers to products and ingredients, such as "Product 1". As long as you maintain an internal record for the manufacturer-selected identifiers, there is no requirement to report the commercial name or identity of products or ingredients.

[3] ezview.wa.gov/site/alias__1962/38927/toxic_free_cosmetics.aspx

You must document the following for each product for which you have selected Option 2:

- The lead data type, either product or ingredient lead levels. You will use Form A in the data collection template to report measured product lead levels or Forms B1 and B2 to report measured ingredient lead levels and calculated product lead levels.
- The test methods used for sample preparation and testing lead levels. This includes the extraction method, the acid used for digestion, and the analytical method and instrument used to obtain lead levels.
- Test results, including lead level in parts per million (ppm), and quality assurance information, including the limit of quantitation and the limit of detection.
- Measured or calculated product lead level for each batch produced since January 1, 2025. At a minimum, you must submit data for each batch produced since June 1, 2025.

The Lead in Cosmetics Data Collection Template, linked below, provides instructions and more details on what to submit.

Confidential business information

Washington State law (RCW 43.21A.160[4]) defines what information Ecology may consider for confidential treatment. To request confidential treatment, follow the process described in Appendix 2 and use the Lead in Cosmetics Request for Confidential Treatment of Information Form[5] posted on the Toxic-Free Cosmetics Act interested parties webpage.

We must receive all requests for confidential treatment of business information at least 60 days prior to the data submission deadline. Requesting confidential treatment doesn't change the deadline to submit the lead data. We must receive all lead data by the data submission deadline provided in the email notification.

Templates and technical support

Review the following documents for additional guidance:

- Lead in Cosmetics Data Collection Template[6]
- Lead in Cosmetics Data Collection Example[7]

For questions and technical support, email us at ToxicFreeCosmetics@ecy.wa.gov.

[4] https://app.leg.wa.gov/RCW/default.aspx?cite=43.21A.160
[5] ezview.wa.gov/Portals/_1962/Documents/Cosmetics/LeadInCosmeticsRequestforConfidentialTreatmentForm_05.01.2025.docx
[6] ezview.wa.gov/Portals/_1962/Documents/Cosmetics/LeadinCosmeticsDataCollectionTemplate_05.01.2025.xlsx
[7] ezview.wa.gov/Portals/_1962/Documents/Cosmetics/LeadinCosmeticsDataCollectionExamples_05.01.2025.xlsx

Appendix 1:
Lead in cosmetics test methods guidance

Ecology's Interim Policy on Lead in Cosmetics requires that manufacturers who choose Option 2 must monitor lead in each batch of each product for which they selected Option 2. You must retain all lead concentration data and other information. This appendix provides guidance on how you should collect lead testing data and should be used with the Lead in Cosmetics Data Collection Template, available on the Toxic-Free Cosmetics Act interested parties webpage[8].

This guidance is solely for data collection purposes under the interim policy. You may not use the test methods guidance for compliance purposes. It does not prescribe or imply approval of any test method(s) for demonstrating compliance with the Toxic-Free Cosmetics Act, now or in the future.

Minimum testing requirements

A third-party laboratory (lab) must conduct lead testing under Ecology's interim policy. A lab that is part of any entity in the supply chain, also known as an in-house lab, is not a third-party lab. For example, we do not consider a testing unit within the ingredient supplier's organization a third-party lab. Manufacturers should work with their contracted third-party lab to obtain testing information. You are welcome to share the Lead in Cosmetics Data Collection Template with your lab and invite them to attend our information session with Q&A.

You must determine lead levels by measuring total lead, rather than leachate or bioavailable levels. The test methods should demonstrate that the analysis of total lead is appropriate for the sample matrix. We may ask for test results from every batch of every product for which you selected policy Option 2.

Template instructions: Forms A and B

To acknowledge the complexity of different testing arrangements, we developed this template for manufacturers who may test final products only, test ingredients only, or use a combination—product testing for some products and ingredient testing and calculating lead levels for other products. We highly recommend you test finished products rather than use ingredient testing to get accurate lead levels in the final products.

To fill out testing information in the worksheet tab entitled, "4-Form A Product Testing," we require you to use the same testing procedures for all the batches of a given product. You can use different labs, methods, or procedures for different products.

To fill out testing information in the worksheet tab entitled "5-Form B1 Ingredient Testing," we require you to use the same test methods for different lots of a single ingredient. You can use different labs, methods, or procedures for different ingredients. If you obtain your ingredient lead results from different labs or procedures, please specify the method for each ingredient in the associated row of the worksheet.

[8] www.ezview.wa.gov/site/alias__1962/38927/toxic_free_cosmetics.aspx

Template instructions: test method information

In the Lead in Cosmetics Data Collection Template, we collect information about test methods, including the extraction method, the acids used for digestion, the analytical method, and the instrument used for analysis from the third-party laboratory conducting the test.

We ask what methods you used for extraction and analysis. Fill out this information under the **Extraction Method** column and **Analytical Method** column:

- If the laboratory follows a standardized method, you can cite the method name and reference number such as EPA 3050B, EPA6020, or ISO 17294-2.
- If the laboratory uses a modified method, you must provide us with the standardized test method they have modified, the laboratory's description of the key modifications to the standardized test method, and their rationale for each modification.
- If the laboratory uses a proprietary method, you must provide us with the laboratory's detailed description of the methodology. If the proprietary method is available to the public, you can provide a link instead of a text description. If you provide a text description, please make sure it includes:
    - Digestion conditions.
    - Instrument conditions.
    - Quality assurance (QA) and quality control (QC) criteria, including method blanks, initial calibration verification (ICV), continuing calibration verification (CCV), calibration standards, duplicate relative percent difference (RPD), etc.

We require you to report information in the **Acid(s) Used for Digestion** column to understand whether the sample preparation is designed to test total digestion. We also require you to report on the analytical instrument used in the **Analytical Instrument** column because we need it to evaluate data quality. You can work with your third-party lab to obtain the required information.

Acceptable test methods

Ecology's interim policy doesn't prescribe the method(s) to test for lead in cosmetics. However, to ensure that we have reliable quality data to support rulemaking, we accept testing data using the following standard methods. We may accept other modified or proprietary methods, based on review of the required information concerning methods as specified in the previous section. The acceptable methods are listed below, in order of preference from highest to lowest.

- EPA 3052 for extraction[9] plus EPA 6020B for instrument analysis;[10] alternatively, EPA 6010D for instrument analysis.
- FDA-validated method published in Survey of Cosmetics for Arsenic, Cadmium, Chromium, Cobalt, Lead, Mercury, and Nickel Content,[11] in the Journal of Cosmetic Science.

[9] https://www.epa.gov/sites/default/files/2015-12/documents/3052.pdf
[10] https://www.epa.gov/sites/default/files/2015-12/documents/6020b.pdf
[11] https://pubmed.ncbi.nlm.nih.gov/25043485/

- FDA EAM 4.7 Inductively Coupled Plasma-Mass Spectrometric Determination of Arsenic, Cadmium, Chromium, Lead, Mercury, and Other Elements in Food Using Microwave Assisted Digestion.[12]
- ISO 21392:2021 Cosmetics — Analytical methods — Measurement of traces of heavy metals in cosmetic finished products using Inductively Coupled Plasma Mass Spectrometry (ICP-MS) technique.[13]
- USP 233 Evaluation of Elemental Impurities.[14]

[12] https://www.fda.gov/media/87509/download
[13] https://www.iso.org/standard/70854.html
[14] https://www.usp.org/sites/default/files/usp/document/our-work/chemical-medicines/key-issues/233_ElementalImpuritiesProcedures.pdf

Appendix 2:
Toxic-Free Cosmetics Act confidential business information (CBI) process

Purpose of this document

This document describes how you can apply for limited protection of confidential business information, if desired. It includes additional details on how we will handle information granted confidentiality protection by Ecology's director under RCW43.21A.160, which we call certified confidential business information or certified CBI.

Background

Ecology regulates toxic chemicals in consumer products. To make decisions, we often work with manufacturers to learn more about toxic chemicals in products and potential safer alternatives. We understand you may be reluctant to share information about proprietary formulations with us due to concerns that the information will be made public and could become available to your competitors. Because of this, Ecology has a process to hold specific information confidential, if you demonstrate the need.

A broad group of interested parties often reviews our work. We also include our work in reports to the Legislature and can use it as the basis of rulemaking. Ecology's public materials and reports will need to include sufficiently detailed information to explain and give confidence in Ecology's findings.

Therefore, in order to hold information confidential, you must show that the product details are legitimately unique to your company or are worthy of protection due to real potential for competitive harm to you from disclosure to competitors.

Confidential treatment of manufacturer information under RCW 43.21A.160

Requesting confidential treatment

If you plan to provide data that may qualify for confidential treatment under RCW 43.21A.160, you may submit a request as described in this document.

Do not submit the information you believe meets the standard for confidential treatment until we deliver a decision. We must receive all requests for confidential treatment of business information at least 60 days prior to the data submission deadline.

Your request must offer convincing evidence that one or both of the criterion in RCW 43.21A.160 for confidential treatment are met. These criteria include:

- Information that "relate[s] to the processes of production unique to the owner or operator thereof," and
- Information that "may affect adversely the competitive position of such owner or operator if released to the public or to a competitor."

Following this request, Ecology staff will determine whether to recommend that the director grant confidential treatment, subject to any exceptions needed to meet Ecology's public transparency needs. Contact us if you have questions about your request.

Ecology contractor access to certified confidential business information

In some cases, Ecology will need to provide your information to a contractor.

To inform rulemaking, Ecology may need manufacturers to provide:

- A list of products containing specific chemicals.
- Product ingredients.
- A description of the amount and the function of specific chemicals in the product.

If Ecology determines that we must share your information with a contractor, we will notify you at the time we make that determination. You may require Ecology's contractor(s) to execute a nondisclosure agreement with you before Ecology shares your certified CBI with the contractor.

Alternatively, you may authorize Ecology to provide certified CBI to its contractor(s) subject to an agreement between Ecology and each contractor requiring that the contractor keeps the certified CBI confidential. Key terms of the nondisclosure agreements that Ecology would require with its contractor(s) are described below.

Requirements for providing documents

To facilitate confidential handling of your certified CBI, you must provide documents with the specific confidential information highlighted, but readable. This facilitates the redaction of only the confidential information. If Ecology believes you have highlighted information that exceeds Ecology's grant of confidential treatment under RCW 43.21A.160, we will return the documents to you. We will request changes to the highlighting to afford a reasonable degree of transparency to the public.

Legal challenges

In the event of legal action to challenge Ecology's determinations, the court may require us to make certified CBI part of the record for review. Should this occur, Ecology will seek a protective order from the court, asking that the court protect the certified CBI against access by the general public.

Contractor confidentiality agreement key terms

If you decide to allow Ecology to execute its own nondisclosure agreement with contractors (rather than having the contractor sign a nondisclosure agreement with you), then Ecology would require its contractor(s) to sign a confidentiality agreement with Ecology that would include the following key terms:

- Use the certified CBI only for the purposes of the contract.
- Do not disclose certified CBI to third parties.
- Store certified CBI separately and securely.

- When providing deliverables or making comments to Ecology that reference certified CBI, mark the cover sheet and each page of the document conspicuously with the words "CONFIDENTIAL UNDER RCW 43.21A.160—DO NOT DISCLOSE." Mark any information in the document that has been granted confidentiality protection with brackets and the word "CONFIDENTIAL." This will facilitate redaction by Ecology if it becomes necessary to produce a public version of the document.
- Destroy written records after the conclusion of the contract work.

Submission process

1. Manufacturer/supplier submits a request to Kimberly Grieves (contact details below) for confidential treatment of information.
    a. A template, with suggested content, is available on the Toxic-Free Cosmetics Act interested parties webpage.[15]
    b. Ecology's Consumer Products Regulatory Unit will work with our Public Disclosure Coordinator to process the request for confidential treatment of information and forward it to the director's office for approval.
2. Ecology notifies manufacturer/supplier on decision to grant confidentiality protection.
3. Manufacturer/supplier provides documents necessary to Ecology with confidential details highlighted consistent with the scope of Ecology's grant of confidentiality protection.

Ecology process to handle certified CBI

1. Ecology labels and inventories all documents covered by confidentiality protection.
2. Ecology keeps these certified CBI documents in a secure filing cabinet or a secure electronic file location with limited access by only staff who have been granted access.
3. Ecology obtains relevant nondisclosure agreements from the contractor. You may negotiate your own nondisclosure agreement with Ecology's contractor.
4. Ecology provides certified CBI, as needed, to the authorized parties during the course of the project work.
5. At the close of the project, if Ecology has supplied certified CBI to any authorized parties, Ecology obtains letters confirming that all parties with nondisclosure agreements have deleted and destroyed manufacturer/supplier certified CBI.

For additional information, contact Ecology

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ConsumerProductReg@ecy.wa.gov

Elizabeth Rios, Public Disclosure Coordinator
564-669-4644
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[15] www.ezview.wa.gov/site/alias__1962/38927/toxic_free_cosmetics.aspx

Publication information

This document is available on the Department of Ecology's website at: https://apps.ecology.wa.gov/publications/SummaryPages/2504029.html.

Contact information

Washington State Department of Ecology
Hazardous Waste and Toxics Reduction Program
P.O. Box 47600
Olympia, WA 98504-7600

Phone: 360-407-6700

Website: Washington State Department of Ecology[16]

ADA accessibility

The Department of Ecology is committed to providing people with disabilities access to information and services by meeting or exceeding the requirements of the Americans with Disabilities Act (ADA), Sections 504 and 508 of the Rehabilitation Act, and Washington State Policy #188.

To request an ADA accommodation, contact Ecology by phone at 360-407-6700 or email at hwtrpubs@ecy.wa.gov. For Washington Relay Service or TTY call 711 or 877-833-6341. Visit Ecology's accessibility webpage[17] for more information.

Language services

For information in your preferred language at no cost to you, call Ecology at 360-407-6700, email ToxicFreeCosmetics@ecy.wa.gov, or visit ecology.wa.gov/Language-services.

[16] www.ecology.wa.gov/contact
[17] ecology.wa.gov/accessibility