# Report to The Vermont Legislature

## Lead in Cosmetics Products 2025 Report to the Legislature

In Accordance with Act 131, Section 12

**Submitted to:** House Committee on Human Services

**Senate Committee on Health and Welfare** 

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## Lead in Cosmetics Products 2025 Report to the Legislature

#### Introduction

This report is submitted by the Department of Health (Department) pursuant to Act 131 (2024).

Act 131 (2024) requires the Department to observe and evaluate Washington's experience of implementing a one part per million limit on the presence of lead in cosmetic products.

This report presents the Department's findings after reviewing Washington's publicly available materials on the implementation of the Toxic-Free Cosmetics Act and discussions with Washington Department of Ecology staff tasked with implementing the law.

#### **Findings**

In 2023, the Washington State Legislature passed the Toxic-Free Cosmetics Act.<sup>1</sup> Effective January 1, 2025, cosmetics products<sup>2</sup> must not include: (1) any lead that has been intentionally added to the product, nor (2) lead impurities over 1 ppm. The law also authorizes the Washington Department of Ecology (Ecology) to conduct rulemaking to adopt a different limit on lead impurities.

In 2024, three separate but related petitions were filed with Ecology requesting the department use its rulemaking authority to change the lead contamination limit to match the federal recommendation of 10 ppm. Ecology declined to initiate rulemaking to adopt that rule; that decision was upheld on an appeal to the governor.

After meeting with many cosmetics manufacturers, Ecology learned that a strict 1 ppm limit can be difficult, if not impossible, to achieve in some products. As a result, Ecology determined that more information was needed before a final determination can be made about a feasible level for allowed lead impurities.

Given the need for additional time to evaluate the feasible level for allowed lead impurities, Ecology made a determination not to enforce strict compliance with the 1 ppm limit on lead with respect to a cosmetic product for which the manufacturer meets the safe harbor provisions established in the interim policy<sup>3</sup> issued by the department. The interim policy provides manufacturers with alternative paths to compliance for cosmetic products that are unable to

<sup>&</sup>lt;sup>1</sup> Toxic-Free Cosmetics Act (Chapter 70A.560 RCW), <a href="https://app.leg.wa.gov/RCW/default.aspx?cite=70a.560">https://app.leg.wa.gov/RCW/default.aspx?cite=70a.560</a>.

<sup>&</sup>lt;sup>2</sup> Under Washington state law, the term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such article; except that such term shall not include soap (see Chapter 69.04.011).

<sup>&</sup>lt;sup>3</sup> The full text of the Interim Policy is provided as Appendix A in this report and also available at: <a href="https://apps.ecology.wa.gov/publications/documents/2404036.pdf">https://apps.ecology.wa.gov/publications/documents/2404036.pdf</a>.

achieve lead concentrations below 1 ppm, while still requiring manufacturers to work toward the lowest lead levels possible in products.

The options for compliance include:

- Option 1 The lead concentration is 2 ppm or below for general cosmetics<sup>4</sup> or 5 ppm or below for color cosmetics<sup>5</sup> or clay masks, and the manufacturer has notified Ecology of its decision to meet these limits for its products sold in Washington.
- Option 2 The lead concentration of a color cosmetic or clay mask is above 5 ppm and below 10 ppm, *and* the manufacturer has notified Ecology of its decision to meet these limits for its products sold in Washington *and* is monitoring lead in each batch of the product and retaining lead concentration data and information. Submission of supporting data and information, including analytical methods, is not required unless requested by Ecology. Ecology provides additional requirements for measuring or estimating lead concentrations for this option in the interim policy.

The interim policy provides different compliance options for general cosmetics, color cosmetics, and clay masks to account for the potential challenges of reducing lead concentrations in specific product categories. Color cosmetics typically include pigments that are a common source of lead impurities with concentrations that vary. The variability of lead concentrations is problematic for manufacturers because they are unable to guarantee consistently compliant levels of lead impurities in finished color cosmetic products.

Clay masks are addressed separately in the interim policy because they tend to be products that manufacturers have the most difficulty with meeting the lead limits. The clay, which is mined from the earth and contains lead impurities, can account for more than half of the product formulation, making it challenging for manufacturers to reduce the levels of lead to meet restrictions.

Manufacturers of cosmetic products sold in Washington that choose to use the interim policy must notify Ecology through an online submission form of their decision to meet the conditions of the policy and provide contact information.

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<sup>&</sup>lt;sup>4</sup> Under Ecology's Interim Policy, the term "general cosmetic" means all cosmetics excluding color cosmetics and clay masks.

<sup>&</sup>lt;sup>5</sup> Under Ecology's Interim Policy, the term "color cosmetic" means a cosmetic that contains pigments or colorants intended to beautify, promote attractiveness, or alter the appearance by adding color to skin, hair, eyelashes, or nails.

To date, Ecology has received the following notifications<sup>6</sup> from 211 manufacturers:

	General Cosmetics	Color Cosmetics or Clay Masks
Interim Policy Option 1	197	111
• $\leq 2$ ppm for general cosmetics		
• $\leq$ 5 ppm for color cosmetics or		
clay masks		
Interim Policy Option 2	N/A	69
• $\geq$ 5 ppm but $\leq$ 10 ppm for color		
cosmetics or clay masks		
Not Using the Interim Policy	12	10
Must comply with 1 ppm limit		
Do Not Produce, Import, or	2	21
Distribute		

For general cosmetics, most manufacturers (197 out of 211 manufacturers) are choosing to use interim policy option 1. For color cosmetics or clay masks, about half of the manufacturers (111 out of 211 manufacturers) are choosing to use interim policy option 1 and about a third of the manufacturers (69 out of 211 manufacturers) are choosing to use interim policy option 2. For general cosmetics, color cosmetics, and clay masks, only a small number of manufacturers are choosing not to use the interim policy (12 manufacturers and 10 manufacturers respectively).

The interim policy took effect January 1, 2025. It will remain in effect until either a rule is adopted, the policy is repealed, or December 31, 2026, whichever occurs first. Ecology may extend the policy if it determines the policy is still needed after December 31, 2026.

In December 2024, Ecology also started a rulemaking<sup>7</sup> under the authority of the Toxic-Free Cosmetics Act to identify a feasible approach to regulating lead in cosmetic products, including potentially adopting a different limit on lead impurities than the statutory limit of 1 part per million (ppm). Ecology will work with interested parties to better understand compliance challenges with the statutory limit and determine the lowest feasible limit that manufacturers can achieve that is also protective of people and the environment. Ecology is projecting that the rule development phase will continue through Summer 2026.

Washington's experience to date indicates that a statutory lead limit of 1 part per million can be difficult, if not impossible, to achieve in some cosmetics products. However, it appears that it is possible to achieve lead limits below the federal recommendation of 10 ppm for general cosmetics, color cosmetics, and clay masks. Specifically, based on notifications received from manufacturers, it appears that it is possible for manufacturers to achieve lead limits below 2 ppm for general cosmetics and below 5 ppm for color cosmetics and clay masks.

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<sup>&</sup>lt;sup>6</sup> Notifications received by Ecology are available at: <a href="https://www.ezview.wa.gov/site/alias\_1962/38927/toxic\_free\_cosmetics.aspx">https://www.ezview.wa.gov/site/alias\_1962/38927/toxic\_free\_cosmetics.aspx</a> (see "Lead-in-Cosmetics Rulemaking" section and "Interim Policy Form responses." Responses received by Ecology as of March 7, 2025 are used in this report.

<sup>&</sup>lt;sup>7</sup> Chapter 173-339 WAC – Cosmetic Products Restrictions (Lead in Cosmetics), <a href="https://ecology.wa.gov/regulations-permits/laws-rules-rulemaking/rulemaking/wac-173-339-lead-in-cosmetics#101">https://ecology.wa.gov/regulations-permits/laws-rules-rulemaking/rulemaking/wac-173-339-lead-in-cosmetics#101</a>.



## Policy Statement: Interim Policy on Lead in Cosmetics

Program Name: Hazardous Waste and Toxics Reduction

Date Issued: December 19, 2024

Date(s) of Minor Revisions and Clarifications: January 15, 2025

Date(s) of Substantive Updates: Not applicable at this time

References: Toxic-Free Cosmetics Act (Chapter 70A.560 RCW)

### **Purpose**

To provide cosmetic manufacturers with alternative paths to compliance for products that are unable to achieve lead concentrations below 1 part per million (ppm), while still requiring manufacturers to work toward the lowest lead levels possible in products.

## **Background**

In 2023, the Washington State Legislature passed the <u>Toxic-Free Cosmetics Act</u>.¹ This law restricts the sale of cosmetic products containing certain chemicals, including lead and lead compounds. Makeup, shampoo, shaving cream, deodorant, and other personal care products are all covered by the new law. Effective January 1, 2025, these products must not include: (1) any lead that has been intentionally added to the product, nor (2) lead impurities over 1 ppm. The law also authorizes the Department of Ecology (Ecology) to conduct rulemaking to adopt a different limit on lead impurities.

In 2024, three separate but related petitions were filed with Ecology requesting the department use its rulemaking authority to change the lead contamination limit to match the federal recommendation of 10 ppm. Ecology declined to initiate rulemaking to adopt that rule; that decision was upheld on an appeal to the governor.

#### Situation

After meeting with many cosmetics manufacturers, Ecology learned that a strict 1 ppm limit can be difficult, if not impossible, to achieve in some products. The federal Food and Drug Administration (FDA) recommends cosmetic products and ingredients not exceed 10 ppm of lead impurities.

Lead is a naturally occurring metal that can be found in raw ingredients such as minerals and clay that are sometimes used in cosmetics. Ingredients used for pigments are a common source of lead impurities, but manufacturers have a limited number of

<sup>&</sup>lt;sup>1</sup> Chapter 70A.560 RCW (https://app.leg.wa.gov/RCW/default.aspx?cite=70a.560)

FDA-approved pigments available to them. Concentrations of lead in these ingredients varies, which in turn affects lead concentrations in finished cosmetic products.

The variability of lead concentrations is problematic for manufacturers, because they are unable to guarantee consistently compliant levels of impurities across products. Although manufacturers report the majority of their products comply with the 1 ppm standard, they cannot guarantee every package of every product they produce does so.

Product testing data from Germany and the United Kingdom show that 90 percent of cosmetic products can achieve lead concentrations of 2 ppm for general cosmetics (such as lotion or cleansers) and 5 ppm for color cosmetics (such as blush or eye shadow). While there may be some variability in lead concentrations by geographic location, the data support the technical feasibility of lower concentrations. To protect human health and the environment, Washington's goal is to reduce lead in cosmetic products to the lowest level possible.

#### **Interim Actions**

More information is needed before Ecology can make a final determination about a feasible level for allowed lead impurities. Ecology also acknowledges the approaching January 1, 2025, compliance deadline. Our agency has committed to take the following interim actions by January 1, 2025:

#### 1. Implement an interim policy.

This interim policy provides manufacturers with alternative paths to compliance for cosmetic products that are unable to achieve lead concentrations below 1 ppm, while still requiring manufacturers to work toward the lowest lead levels possible in products.

#### 2. Open rulemaking on lead impurities in cosmetics in 2025.

This <u>rulemaking</u><sup>2</sup> will be an open public process that will allow us to continue working with interested parties. To protect human health and the environment, Washington's goal is to reduce lead in cosmetic products to the lowest level possible.

While the department begins the lengthy process to better understand compliance challenges, these interim actions will provide regulatory flexibility and assurance to industry. This will allow companies to continue to manufacture, distribute, and sell products in Washington while taking steps to reduce lead impurities in products.

This interim policy is effective while Ecology gathers information for rulemaking about approaches to handling lead impurities in cosmetic products sold in Washington.

<sup>&</sup>lt;sup>2</sup> https://ecology.wa.gov/regulations-permits/laws-rules-rulemaking/rulemaking/wac-173-339-lead-in-cosmetics

### **Interim Policy**

As an exercise of enforcement discretion, Ecology will not enforce strict compliance with the 1 ppm limit on lead with respect to a cosmetic product for which the manufacturer has met the safe harbor provisions stated below.

The intent of this policy is to:

- Align enforcement with currently achievable limits to maintain product availability.
- Obtain product monitoring data from manufacturers to:
  - 1) Better understand the feasibility of a 1 ppm lead limit, and
  - Inform considerations for a feasible approach to regulating lead in cosmetics, including potentially changing the lead impurity limit to a new level between 1 and 10 ppm.

# Interim safe harbor provisions for cosmetics exceeding 1 ppm lead impurity limit

Ecology will use its enforcement discretion for some cosmetic products with lead impurities exceeding 1 ppm.

While this policy remains in effect, Ecology will not enforce compliance with the 1 ppm limit on lead in cosmetic products under the following circumstances:

#### **Option 1**

The lead concentration is 2 ppm or below for general cosmetics or 5 ppm or below for color cosmetics or clay masks, *and* the manufacturer has notified Ecology of its decision<sup>3</sup> to meet these limits for its products sold in Washington.

#### **Option 2**

The lead concentration of a color cosmetic or clay mask is above 5 ppm and below 10 ppm, *and* the manufacturer has notified Ecology of its decision<sup>3</sup> to meet these limits for its products sold in Washington *and* is monitoring lead in each batch of the product and retaining lead concentration data and information. Submission of supporting data and information, including analytical methods, is not required unless requested by Ecology.

#### Additional requirements for option 2

Manufacturers may measure or estimate lead concentrations by testing raw ingredients, testing final products, or tracking lead concentrations in raw ingredients as reported by the certificates of analysis. If using certificates of analysis, the measured lead concentration must be reported. Any testing must be completed by a third-party laboratory. This policy does not specify or require specific analytical methods. Lead levels must be verified by measuring total lead (for example, using digestion), rather than

<sup>&</sup>lt;sup>3</sup> The word "decision" replaces the word "plan" in the original version of the policy. Submission of a written plan is not required.

leachate or bioavailable levels. The detection limit must be lower than the restriction level to provide reliable testing results.<sup>4</sup>

Manufacturers that are small businesses should demonstrate a good faith effort to monitor lead in products. Small businesses may rely on theoretical calculations from estimations in raw ingredients, composite testing, or exclude ingredients from their estimations if information is not available, so long as they have demonstrated a good faith effort to obtain data and information.

#### Additional requirements for all options

All manufacturers who use the safe harbor conditions described in this policy must notify Ecology of their decision<sup>5</sup> to meet the conditions of this policy and provide contact information. This notice must be provided through Ecology's online submission form<sup>6</sup> unless otherwise approved by Ecology staff.

#### **Definitions of key terms**

"Color cosmetic" means a cosmetic that contains pigments or colorants intended to beautify, promote attractiveness, or alter the appearance by adding color to skin, hair, eyelashes, or nails.

"Cosmetic"<sup>7</sup> means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such article; except that such term shall not include soap.

"General cosmetic" means all cosmetics excluding color cosmetics and clay masks.

"Manufacturer" means any person, firm, association, partnership, corporation, governmental entity, organization, or joint venture that produces a product or is an importer or domestic distributor of a product sold or offered for sale in or into the state.

"Small business" means a business employing less than fifty people.

#### Confidential business information

Trade secrets may be eligible for protection from disclosure. On request and approval by Ecology, testing data and other sensitive information can be designated "confidential business information." Businesses wishing to obtain protection for such information must contact Ecology staff before submitting documentation to Ecology.

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<sup>&</sup>lt;sup>4</sup> These two sentences with additional guidance on lead testing were added in this revised policy.

<sup>&</sup>lt;sup>5</sup> The word "decision" replaces the word "plan" in the original version of the policy. Submission of a written plan is not required.

<sup>6</sup> https://forms.office.com/g/8aNzPabq83

<sup>&</sup>lt;sup>7</sup> RCW <u>69.04.011</u> (https://app.leg.wa.gov/RCW/default.aspx?cite=69.04.011)

<sup>8</sup> RCW <u>70A.350.010</u> (https://app.leg.wa.gov/RCW/default.aspx?cite=70A.350.010)

<sup>9</sup> RCW 70A.500.020 (https://app.leg.wa.gov/RCW/default.aspx?cite=70A.500.020)

#### Policy use and compliance

Distributors, retailers, and other sellers not covered by this policy may rely on it for compliance purposes. Cosmetic products purchased or received from manufacturers that notify Ecology of their intent to come within the conditions of this policy are considered compliant during the effective term of the policy.

#### Policy effective dates

This policy takes effect January 1, 2025. It will remain in effect until either a rule is adopted, the policy is repealed, or December 31, 2026, whichever occurs first. Ecology may extend the policy if it determines the policy is still needed after December 31, 2026.

## **Scope of Interim Policy**

#### What does the interim policy cover?

The policy covers all cosmetic products as defined in RCW 70A.560.010. <sup>10</sup> This is the same definition as RCW 69.04.011<sup>11</sup> and as used by the FDA.

#### Who can use the interim policy?

Manufacturers of cosmetic products sold or manufactured in Washington.

#### Is my business required to follow the interim policy?

No. Manufacturers may elect to follow this policy but are not required to do so. Manufacturers who do not follow this policy must comply with the 1 ppm limit on lead in their cosmetic products.

#### Contact

Shari Franjevic, Toxic-Free Cosmetics Act Lead

Email: <u>ToxicFreeCosmetics@ecy.wa.gov</u>

Telephone: (360) 407-6700

Webpage: Toxic-Free Cosmetics Act<sup>12</sup>

## **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 <a href="http://hwtpubs@ecy.wa.gov">hwtrpubs@ecy.wa.gov</a>. For Washington Relay Service or TTY call 711 or 877-833-6341. Visit <a href="mailto:Ecology's website">Ecology's website</a><sup>13</sup> for more information.

<sup>10</sup> https://app.leg.wa.gov/RCW/default.aspx?cite=70A.560.010

<sup>11</sup> https://app.leg.wa.gov/RCW/default.aspx?cite=69.04.011

<sup>12</sup> https://ecology.wa.gov/TFCA

<sup>13</sup> https://ecology.wa.gov/accessibility