

OAR 333-016-4001

Toxic Free Cosmetic Program; Effective Date

(1) OAR 333-016-4001 to 333-016-4080 implement the Toxic-Free Cosmetics Act established by the Legislature in ORS 431A.330 to 431A.349. The presence of a high priority chemical of concern in a cosmetic product does not necessarily mean that the product is harmful to human health or that there is any violation of existing safety standards or laws.

(2) These rules apply to any cosmetic product sold or offered for sale in Oregon by a manufacturer on or after January 1, 2027, that contains a high priority chemical of concern used in cosmetic products listed in OAR 333-016-4020 or an intentionally added chemical or class of chemical listed in OAR 333-016-4060.

333-016-4010 Definitions

The following definitions apply to OAR 333-016-4001 to 333-016-4080.

(1) ~~(2)~~ “Authority” means the Authority.

(2) ~~(3)~~ “Authoritative Source” means ~~a source listed in OAR 333-016-4030~~ any of the following sources, including subsequent revisions when adopted by the authoritative body, identifying high priority chemicals of concern:

- (a) United States Environmental Protection Agency’s (USEPA) Integrated Risk Information System identifying chemicals as:
 - a. being "carcinogenic to humans",
 - b. "likely to be carcinogenic to humans", or
 - c. found to have a reference dose or reference concentration based on neurotoxicity.
- (b) Monographs on the Potential Human Reproductive and Developmental Effects, published by the federal National Toxicology Program, Office of Health Assessment and Translation, identifying reproductive or developmental toxicants.
- (c) Guidance, statutes, or rules developed by the California Safe Cosmetics Program, California Department of Public Health, including the Reportable Ingredient List and the California Health and Safety Code, Division 104, Part 3, Chapter 14, Cosmetic Safety (commencing with Section 108980).

- (d) Guidance, statutes, or rules developed by the Washington Department of Ecology, including the Toxic-Free Cosmetics Act, Chapter 173-333 of Title 173 of the Washington Administrative Code.
- (e) Guidance, statutes, or rules developed by the State of New York, Department of Environmental Conservation relating to cosmetic or personal care, including New York Conservation Law §37-0117
- (f) Annex II of the European Union Cosmetics Regulation (EC) No. 1223/2009.
- (g) Center for Disease Control and Prevention, National Biomonitoring Program, *National Report on Human Exposure to Environmental Chemicals*.
- (h) European Chemicals Agency (ECHA) Chemicals Database
- (i) Any guidance developed by other federal, state, international, or nongovernmental organization with applicable expertise identifying chemicals as being potentially harmful to human health.

(3)(4) “Authority Website” means the Authority’s website for the Oregon Toxic-Free Cosmetics Program, currently at www.healthoregon.org/toxicfreecosmetics.

(4)(5) “Chemical Abstracts Service Registry Number” or “CAS Registry Number” means the number assigned for the identification of a particular chemical by the Chemical Abstracts Service (CAS), a service of the American Chemical Society that indexes and compiles abstracts of worldwide chemical literature called Chemical Abstract.

(5) “Chemical sensitizer” means a chemical that is classified as a skin or respiratory sensitizer if evidence shows it induces allergic responses in a substantial proportion of exposed people or animals.

(6) “Contaminant” means trace amounts of chemicals that are incidental to manufacturing and that serve no intended function in the product component, including but not limited to:

- (a) Unintended by-products of chemical reactions during the manufacture of the product component;
- (b) Trace impurities in feedstock; (c) Incompletely reacted chemical mixtures; and (d) Degradation product

(7)(a) “Cosmetic product” means an article 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 any article intended for use as a component of such an article.

- (b) “Cosmetic product” includes cosmetics marketed to professionals.
- (c) “Cosmetic product” does not include:
 - (A) Soap;
 - (B) Dietary supplements; or
 - (C) Food and drugs regulated by the United States Food and Drug Administration.

(8) “De minimis level” means:

- (a) For a chemical that is an intentionally added chemical, the practical quantification limit; or
- (b) For a chemical that is a contaminant, a concentration of 100 parts per million.

(9) “HPCCCP” means high priority chemicals of concern used in cosmetic products, as described in OAR 333-016-4020.

(10) “Intentionally added chemical” means a chemical in a product that serves an intended function in the product component

(11) (a) “Manufacturer” means any person that produces a cosmetic product or an importer or domestic distributor of a cosmetic product.

(b) “Manufacturer” does not mean:

- (A) A retailer that sells to consumers cosmetic products produced by a third party.
- (B) A grocery wholesaler or grocery retailer that contracts with a third party to produce cosmetic products on behalf of and under the brand of the grocery wholesaler or grocery retailer.

(c) For the purposes of this subsection, “importer” means the owner of the product.

(12) “Practical quantification limit” (PQL) means the lowest concentration of a chemical that can be reliably measured within specified limits of precision, accuracy, representativeness, completeness and comparability during routine laboratory operating conditions.

(13) “Prominently Displayed” means immediately visible and adjacent to the product image or listing on the product’s detail page and appearing in legible type that contrasts with the surrounding content. The font size shall be at least 75% of the size of the adjacent text on the product’s detail page.

(14) “Respiratory sensitizer” means a substance that will lead to hypersensitivity of the airways following inhalation of the substance.

(15) “Skin sensitizer” means a substance that will lead to an allergic response following skin contact.

(16) “Product’s Detail Page” means a dedicated page on a manufacturer’s website that provides all essential information for a single product.

(17) “These rules” means OAR 333-016-4001 to 333-016-4080.

333-016-4020

High Priority Chemicals of Concern Used in Cosmetic Products (~~HPCs~~ ~~CCPs~~)*

(1) The following chemicals are designated as high priority chemicals of concern used in cosmetic products:

- (a) ~~Allyl isothiocyanate~~ ~~(57-06-7)~~
- (b) ~~Basic blue 9~~ ~~(61-73-4)~~
- (c) Benzene (71-43-2)
- (d) Acetaldehyde (75-07-0)
- (e) ~~Trichloroacetic acid~~ ~~(76-03-9)~~
- (f) ~~2-chloroacetamide~~ ~~(79-07-2)~~
- (g) ~~Lily aldehyde~~ ~~(80-54-6)~~
- (h) Anthraquinone (84-65-1)
- (i) Propyl paraben (94-13-3)
- (j) Butyl paraben (94-26-8)
- (k) ~~Methyl paraben~~ ~~(99-76-3)~~
- (l) 4-Hydroxybenzoic acid (99-96-7)
- (m) Styrene (100-42-5)

- (n) ~~Boric acid (10043-35-3)~~
- (o) Acrylonitrile (107-13-1)
- (p) Vinyl acetate (108-05-4)
- (q) ~~Cyclohexylamine (108-91-8)~~
- (r) Triphenyl phosphate (TPP) (115-86-6)
- (s) ~~Ethyl paraben (120-47-8)~~
- (t) 1,4-dioxane (123-91-1)
- (u) Tricresyl phosphate (1330-78-5)
- (v) Estragole (140-67-0)
- (w) ~~Basic green 1 (633-03-4)~~
- (x) C.I. disperse blue 1 (2475-45-8)
- (y) Trisodium nitrilotriacetate (5064-31-3)
- (z) 2-Ethyl-hexyl-4- methoxycinnamate (5466-77-3)
- (aa) ~~Sodium perborate monohydrate (10332-33-9)~~
- (bb) ~~Octamethylcyclotetrasiloxane (D4) (556-67-2)~~
- (cc) ~~Decamethylcyclopentasiloxane (D5) (541-02-6)~~
- (dd) ~~Dodecamethylcyclohexasiloxane (D6) (540-97-6)~~
- (ee) ~~Musk xylene (81-15-2)~~

(1) This list of HPCCCPs shall be posted to the Authority's Website and shall include information regarding the known health impacts associated with exposure to the chemical or class of chemicals. The Authority shall update the list of HPCsCCPs on the Authority's Website no later than one year after the date on which the list of HPCsCCPs has been modified in rule in accordance with OAR 333-016-4030.

*Inclusion of a chemical under this rule (OAR 333016-4020) is contingent on OHA determining a practical quantification limit for the chemical

OAR 333-016-4025 Manufacturer Disclosure of HPCs/CCPs: Practical Quantification Limits

(1) The practical quantification limit for a HPCs/CCPs that is a contaminant is 100 parts per million.

(2) The practical quantification limits for intentionally added chemicals are the limits established in Exhibit A, incorporated by reference.

Exhibit A:

Chemical	CASRN	Practical Quantification Limit (PQL) in parts per million (ppm)	Method
(a) Allyl isothiocyanate	57-06-7		
(b) Basic blue 9	61-73-4		
(c) Benzene	71-43-2	1.0	Total Extraction/EPA 8260
(d) Acetaldehyde	75-07-0	1.0	Total Extraction/EPA 8315
(e) Trichloroacetic acid	76-03-9		
(f) 2-chloroacetamide	79-07-2		
(g) Lily aldehyde	80-54-6		
(h) Anthraquinone	84-65-1	100.0	
(i) Propyl paraben	94-13-3	5.0	Total Extraction/EPA 8321
(j) Butyl paraben	94-26-8	5.0	Total Extraction/EPA 8321
(k) Methyl paraben	99-76-3	5.0	Total Extraction/EPA 8321
(l) 4-Hydroxybenzoic acid	99-96-7	5.0	Total Extraction/EPA 8321 Total Extraction/HPLC [†]
(m) Styrene	100-42-5	1.0	Total Extraction/EPA 8321 8260

Chemical	CASRN	Practical Quantification Limit (PQL) in parts per million (ppm)	Chemical
(n) Boric acid	10043-35-3		
(o) Acrylonitrile	107-13-1	1.0	Total Extraction/EPA 8260
(p) Vinyl acetate	108-05-4	5.0	
(q) Cyclohexylamine	108-91-8		
(r) Triphenyl phosphate (TPP)	115-86-6	10.0	Total Extraction/EPA 8270
(s) Ethyl paraben	120-47-8	5.0	Total Extraction/EPA 8321
(t) 1,4-dioxane	123-91-1	20.0	Total Extraction/EPA 8260
(u) Tricresyl phosphate	1330-78-5	50.0	Total Extraction/GC-MSi
(v) Estragole	140-67-0	10.0	Total Extraction/GC-MSi
(w) Basic green 1	633-03-4		
(x) C.I. disperse blue 1	2475-45-8	15.0	
(y) Trisodium nitrilotriacetate	5064-31-3	100	
(z) 2-Ethyl-hexyl-4- methoxycinnamate	5466-77-3	5.0	Total Extraction/HPLC
(aa) Sodium perborate monohydrate	10332-33-9		Method
(bb) Octamethylcyclotetrasiloxane (D4)	556-67-2	10.0	
(cc) Decamethylcyclopentasiloxane (D5)	541-02-6	5.0	
(dd) Dodecamethylcyclohexasiloxane (D6)	540-97-6	5.0	
(ee) Musk xylene	81-15-2	2.0	

¹ Washington Department of Ecology has determined the instrumentation used for some applications may not be applicable to all product matrices.

HPLC = high performance liquid chromatography

GC-FID = gas chromatography-

flame ionization detector GC-

MS = gas chromatography-

mass spectrometry

LC-MS/MS = liquid chromatography tandem mass spectrometry

OAR 333-016-4030 Modifications of List for High Priority Chemicals of Concern Used in Cosmetic Products (~~HPCs~~CEPs).

- (1) The Authority may, in its discretion, include a class of chemicals or subclass of chemicals on the list of ~~HPCs~~CEPs identified in OAR 333-016-4020, in accordance with ORS 431A.335(1)(b), if the chemical **is identified by or listed in an Authoritative Source.**
- ~~(a) Is identified in statute, rule or guidance developed by other federal or state agencies as being potentially harmful to human health;~~
- ~~(b) Is currently or subsequently identified by the United States Environmental Protection Agency (USEPA) as being "carcinogenic to humans", or "likely to be carcinogenic to humans" through USEPA's Integrated Risk Information System;~~
- ~~(c) Is currently or subsequently listed on European Chemicals Agency Cosmetic Products Regulation, Annex II – Prohibited Substances.~~
- ~~(d) Is currently or subsequently found to have a reference dose or reference concentration based on neurotoxicity through USEPA's Integrated Risk Information System;~~
- ~~(e) Is currently or subsequently identified in monographs on the Potential Human Reproductive and Developmental Effects, United States Office of Health and Human Services National Toxicology Program, Office of Health Assessment and Translation as a reproductive or developmental toxicant;~~
- ~~(f) Is currently or subsequently identified by the Centers for Disease Control and Prevention in its National Report on Human Exposure to Environmental Chemicals.~~
- ~~(g) Is currently or subsequently found to be included on the European Chemicals Agency Chemicals Database.~~
- ~~(g) **(h)** Is identified in guidance developed by international and nongovernmental organizations as being potentially harmful to human health.~~
- (2) The Authority shall also consider adding a chemical or class of chemicals to the list of ~~HPCs~~CEPs in OAR 333-016-4020 if the chemical, on or after the effective date of these rules.
- (a) Is found to have the potential, as demonstrated by credible, peer-reviewed scientific evidence to:
- (A) Harm the normal development of a fetus or child or cause other developmental toxicity;

- (B) Act as a carcinogen;
 - (C) Cause genetic damage or reproductive harm;
 - (D) Disrupt the endocrine system;
 - (E) Damage the nervous system, immune system or organs;
 - (F) Cause other systemic toxicity;
 - (G) Cause skin or respiratory sensitization
 - (H) Cause skin, eye, or respiratory irritation or damage
 - ~~(G)~~(I) Be a very persistent toxic substance by having a half-life greater than or equal to one of the following:
 - (i) A half-life in soil or sediment of greater than one hundred eighty days.
 - (ii) A half-life greater than or equal to sixty days in water or evidence of long-range transport; or
 - ~~(H)~~(J) Be a bioaccumulative toxic substance by having a bioconcentration factor or bioaccumulation factor greater than or equal to five thousand, or if neither are available, having a **logarithm of the octanol-water partition coefficient ("log Kow")** ~~a log Kow~~ greater than 5.0; and
 - (b) Has been found through:
 - (A) Biomonitoring to be present in human blood, umbilical cord blood, breast milk, urine or other bodily tissues or fluids;
 - (B) Sampling and analysis to be present in household dust, indoor air, drinking water or elsewhere in the home environment; or
 - (C) Monitoring to be present in fish, wildlife or the natural environment.
- (3) Is identified in guidance developed by international and nongovernmental organizations as being potentially harmful to human health;
- (4) The Authority shall review and modify the list of **HPCs**~~CCPs~~ every three years. In completing the modifications under this section, the Authority:
- (a) Shall consider adding or removing a chemical or class of chemicals from the list of high priority chemicals if the chemical or class of chemicals is added to or removed from a list maintained by another state agency, another state or a federal agency that the Authority has identified by rule as a list intended to identify high priority chemicals; and
 - (b) May remove a chemical or class of chemicals from the list of **HPCs**~~CCPs~~ if the Authority determines that the chemical or class of chemicals is no longer being used in cosmetic products.

- (5) The list of ~~HPCs~~~~CCPs~~ in OAR 333-016-4020 may only be modified by following the rulemaking process as provided for in ORS Chapter 183.

OAR 333-016-4040 Notice Requirements

- (1) A manufacturer of a cosmetic product sold or offered for sale in this state that contains a ~~HPC~~ ~~CCPs~~ listed in OAR 333-016-4020 as an individual chemical or a member of a class or subclass of chemicals, in an amount at or above the de minimis level shall include a Prominently Displayed notice for Oregon consumers on the manufacturer's website. The notice must contain, in this order:
- (a) The words "Oregon Toxic-Free Cosmetics Act – Warning" that are hyperlinked and are ~~prominently displayed~~ **Prominently Displayed on the product's detail page on the manufacturer's website. This phrase is not considered to be Prominently Displayed if the purchaser must search for it in the general content of the manufacturer's website.**
- (b) The link in (1)(a) must lead to one of the following blocks of text on the manufacturer's website. (A) "This product may expose you to _____ [list all HPCs found in product, separated by commas]. These substances may cause the health effects listed by the substance name at healthoregon.org/toxicfreecosmetics." **This block of text may be located in a different section of the manufacturer's website than the phrase required in subsection (a).**
- (c) **The** ~~The content of the text block is dependent on the HPC~~CCP~~'s potential effects on human health as determined by Authority, and the number of HPC~~CCPs~~ present in the particular cosmetic product. The HPC~~CCPs~~ and their potential effects are found at www.healthoregon.org/toxicfreecosmetics.~~
- (A) ~~For HPC~~CCPs~~ listed as carcinogens, the words, "This product can expose you to _____, _____, or _____, which recognized is may cause cancer as determined by a Authoritative Sources recognized by the State of Oregon. For more information go to www.healthoregon.org/toxicfreecosmetics."~~
- (B) ~~For HPC~~CCPs~~ listed as reproductive toxicants, the words, "This product can expose you to _____, _____, or _____, which is recognized may cause birth defects or other reproductive harm as determined by Authoritative Sources recognized by State of Oregon. For more information go to www.healthoregon.org/toxicfreecosmetics."~~

~~(C) For HPCCCPs listed as endocrine disruptors the words, “This product can expose you to _____, _____, or _____, which may cause endocrine disruption as determined by Authoritative Sources recognized by State of Oregon. For more information go to www.healthoregon.gov/toxicfreecosmetics.”~~

~~(D) For HPCCCPs listed as carcinogens, endocrine disruptors or reproductive toxicants, the words “This product can expose you to _____, _____, or _____, which may cause cancer, endocrine disruption, birth defects or other reproductive harm as determined by Authoritative Sources recognized by the State of Oregon. For more information go to www.healthoregon.gov/toxicfreecosmetics.”~~

~~(d)~~ (c) Information that satisfies all the labeling requirements pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq.;

~~(e)~~ (d) Information that satisfies all the labeling requirements pursuant to the federal Fair Packaging and Labeling Act, 15 U.S.C. 1451 et seq.

~~(2) For purposes of Section (1)(a), a notice must be on the product’s detail page on the manufacturer’s website.~~

~~(3) For purposes of Section (1)(a), a notice is not Prominently Displayed if the purchaser must search for it in the general content of the website. The block of text for (1)(b) may be in a different section of the manufacturer’s website than the words of (1)(a).~~

~~(4)~~ (2) This rule does not apply to the packaging of a cosmetic product that is intended to be discarded before the product is used.

~~(5)~~ (3) This rule does not apply to the applicator, container, or case in which the cosmetic product itself is found. Subsection (4) will apply if one or more HPCCCPs transfers ~~red~~ to the cosmetic product itself as contaminants at or above de minimis and are detected through testing.

~~(6)~~ (4) If the Authority has reason to believe that a cosmetic product that contains a HPCCCP is being sold or offered for sale in this state in violation of ORS 431A.340, the Authority may issue a written notice of such violation and require that the manufacturer provide a statement of compliance using the form available on the Authority Website. The manufacturer must submit

the statement of compliance within 10 calendar days after receipt of a request from the Authority.

(7) (5) To prove compliance under section (5), the manufacturer must:

(a) Demonstrate through submission of test results from a third-party laboratory that the cosmetic product does not contain the HPCGP at or above a de minimis level; or

(b) Show that the manufacturer complied with the notice requirements of section (1).

(7) (5) The Authority may impose civil penalties against a manufacturer for each failure to comply with the requirements of this rule that is not resolved within 90 calendar days of written notice by the Authority. If a manufacturer does not come into compliance within 90 calendar days of written notification by the Authority, civil penalties will be assessed in accordance with OAR 333-016-4080.

OAR 333-016-4045

Formal Communications Regarding Toxic Free Cosmetics

Formal communication between manufacturers and the Authority relating to notice requirements and prohibited chemicals shall be to and from ToxicFreeCosmetics@dhsosha.state.or.us-

OAR 333-016-4060 List of Prohibited Chemicals, Subclasses or Classes of Chemicals

(1) Manufacturers may not knowingly manufacture, sell, offer for sale, distribute for sale or distribute for use in this state any cosmetic product that contains any of the following intentionally added chemicals or classes of chemicals above the practical quantification limit:

(a) Ortho-phthalates, including but not limited to:

(A) Dimethyl phthalate (131-11-3)

(B) Diethyl phthalate (84-66-2)

(C) Dibutyl phthalate (84-74-2)

(D) Diisononyl phthalate (28553-12-0), (68515-48-0)

(E) Diethylhexyl phthalate (DEHP) (117-81-7)

(F) Acryloyloxyethyl phthalate (30697-40-6)

(G) Butyl phthalyl butyl glycolate (85-70-1)

(H) Butyl benzyl phthalate (85-8-7)

(b) Perfluoroalkyl and polyfluoroalkyl substances, including but not limited to:

(A) Perfluorodecalin (306-94-5)

(B) Polytetrafluoroethylene acetoxypopyl betaine (123171-68-6)

(C) Dioctyldodecyl fluoroheptyl citrate (214334-16-4)

(D) Tetrafluoropropene (29118-24-9)

(E) Polytetrafluoroethylene (PTFE) (9002-84-0)

(F) Perfluorononyl dimethicone NA

(G) Methyl perfluorobutyl ether (163702-07-6)

(H) Methyl perfluoroisobutyl ether (163702-08-7)

(I) Perfluorohexane (355-42-0)

(J) Perfluorohexylethyl triethoxysilane (51851-37-7)

(K) Pentafluoropropane (460-73-1)

(L) Perfluoroperhydrophenanthrene (306-91-2)

(M) Perfluorononylethyl stearyl dimethicone NA*

(N) Perfluorooctylethyl triethoxysilane (101947-16-4)

(O) Dioctyldodecyl fluoroheptyl citrate NA

(P) Perfluorooctylethyl trimethoxysilane (83048-65-1)

(Q) Perfluorohexylethyl triethoxysilane (51851-37-7)

(R) Polysilicone-7 (146632-08-8)

(c) Formaldehyde (CAS Registry Number 50-00-0) and formaldehyde releasing agents, including but not limited to:

(A) DMDM Hydantoin (6440-58-0)

(B) Diazolidinyl Urea (78491-02-8)

(C) Imidazolidinyl Urea (39236-46-9)

(D) Quaternium-15 (4080-31); (51229-78-8)

(E) Tosylamide/Formaldehyde Resin (PTSAF) (25035-71-6)

(F) 2-Bromo-2-Nitropropane-1,3-Diol (Bronopol) (52-51-7)

(G) Sodium Hydroxymethylglycinate (70161-44-3)

(H) Polyoxymethylene Urea (9011-05-6); (68611-64-3)

(I) Polyoxymethylene Melamine (9003-08-1)

(J) 5-Brom-5-Nitro-1,3-Dioxane (Bronidox) (30007-47-7)

(K) 7-Ethylbicyclo-oxazolidine (Bioban CS1246) (7747-35-5)

(L) Benzylhemiformal (14548-60-8)

(M) Dimethylhydantoinormaldehyde (DMHF) (26811-08-5); (9065-13-8)

(N) Dimethylol Glycol (3586-55-7)

(O) Dimethylol Urea (140-95-4)

(P) Dimethyl Oxazolidine (51200-87-4)

(Q) MDM Hydantoin (116-25-6); (27636-82-4); (16228-00-5)

(R) Methemamine (100-97-0)

(S) Methylal (109-87-5)

(T) Polyoxymethylene (30525-89-4)

(U) Polyoxmethylen (9002-81-7)

(V) Tetramethylolglycoluril (5395-50-6)

(W) Timonac (When used in heat-activated hair straighteners (444-27-9))

(X) Tris-Hydroxymethylnitromethane (126-11-4)

(Y) Urea, polymer with formaldehyde, isobutylated (68002-18-6)

(d) Methylene glycol (463-57-0);

(e) Mercury and mercury compounds (7439-97-6);

(f) Triclosan (3380-34-5);

(g) m-Phenylenediamine and its salts (108-45-2); and

(h) o-Phenylenediamine and its salts (95-54-5).

(2) A manufacturer may not knowingly manufacture, sell, offer for sale, distribute for sale or distribute for use in this state any cosmetic product that contains lead or lead compounds (CAS Registry Number 7439-92-1) at 10 parts per million or above, or as otherwise determined by the Authority by rule.

(3) This rule does not apply to the packaging of a cosmetic product that is intended to be discarded before the product is used.

(4) This rule does not apply to the applicator, container, or case in which the cosmetic product itself is found. The rule will apply if one or more HPCGPs transferred to the cosmetic product itself as contaminants at or above de minimis and are detected through testing.

(5) If a manufacturer continues to manufacture, sell, offer for sale, distribute for sale, or distribute for use in this state any cosmetic product that contains an intentionally added chemical or classes of chemicals prohibited by this rule, the Authority shall provide the manufacturer with written notice informing the manufacturer of the violation and requiring that the manufacturer provide a statement of compliance using the form available on the Authority Website. The notice shall state that the manufacturer may avoid a civil penalty by submitting proof to the Authority that it is not in violation as alleged in the notice. The manufacturer must submit the statement of compliance within 10 calendar days after receipt of a request from the Authority.

(6) To prove compliance under section (5), the manufacturer must demonstrate through submission of test results from a third-party laboratory that the cosmetic product does not contain the intentionally added chemicals or class of chemicals at or above the practical quantification limit.

(7) The Authority may impose civil penalties against a manufacturer for each failure to comply with the requirements of this rule that is not resolved within 90 calendar days of written notice by the Authority. If a manufacturer does not come into compliance within 90 calendar days of written notification by the Authority, civil penalties will be assessed in accordance with OAR 333-016-4080.

Inclusion of a chemical under this rule (OAR 333016-4060) is contingent on OHA determining a practical quantification limit for the chemical

333-016-4075 List of Prohibited Intentionally Added Chemicals or Classes of Chemicals: Practical Quantification Limits

Chemical	CASRN	Practical Quantification Limit (PQL) in parts per million (ppm)	Method
(a) Ortho-phthalates class	All CASRN in Class	25.0	CPSC-CH-C1001-09.3
(b) Perfluoroalkyl and polyfluoroalkyl substances	All CASRN in Class	0.001	Total Extraction/LC-MS/MS ¹
(c) Formaldehyde (CAS Registry Number 50-00-0) and formaldehyde releasing agents	All CASRN in Class	5.0	Total Extraction/EPA 8315 or 8270
(d) Methylene glycol	463-57-0	5.0	

(e) Mercury and mercury compounds	7439-97-6	0.5	Total Digestion/ EPAii
(f) Triclosan	3380-34-5	0.5 0.0001	
(g) m-Phenylenediamine and its salts (108-45-2);	108-45-2	100 ppm	
(h) o-Phenylenediamine and its salts (95-54-5);	95-54-5	100 ppm	

ⁱ Washington Department of Ecology has determined the instrumentation used for some applications may not be applicable to all product matrices.

HPLC = high performance liquid chromatography

GC-FID = gas chromatography flame

ionization detector GC-MS = gas

chromatography mass

spectrometry

LC-MS/MS = liquid chromatography tandem mass spectrometry

ⁱⁱEPA = SW-846 general method 6020 or appropriate SW-846 7000 metal specific analysis, <https://www.epa.gov/hw-sw846>

333-016-4080 Enforcement and Civil Penalties

(1) The Authority may impose a civil penalty on a manufacturer for a violation of any provision of ORS 431A.340 or 431A.345, or these rules. A civil penalty may not exceed:

(a) \$5,000 for the first violation.

(b) \$10,000 for the second and each subsequent violation.

(2) For purposes of assessing civil penalties under this section, a violation consists of a single course of conduct with regard to an entire cosmetic product line that is sold or offered for sale in this state.

(3) (a) If a manufacturer violates the notification requirement described in OAR 333-016-4040 the Authority shall provide the manufacturer with written notice informing the manufacturer of the violation and stating that the manufacturer may avoid a civil penalty for the violation by providing the proper notice required under OAR 333-016-4040 within 90 calendar days or providing a statement of compliance in accordance with OAR 333-016-4040(5) and (6).

(b) If the manufacturer fails to cure the violation within the first 90 days, the Authority may impose a civil penalty not to exceed \$5,000.

(c) For a continuing violation, each 90-day period that the violation continues after the preceding imposition of a civil penalty is considered a separate offense subject to a separate civil penalty not to exceed \$10,000. The Authority is not required to provide the

manufacturer with an opportunity to cure the continuing violation before imposing the separate civil penalty.

(4)(a) If a manufacturer continues to manufacture, sell, offer for sale, distribute for sale, or distribute for use in this state any cosmetic product that contains an intentionally added chemical or classes of chemicals prohibited by OAR 333-016-4060, the Authority shall provide the manufacturer with written notice informing the manufacturer of the violation. The notice shall state that the manufacturer may avoid a civil penalty by submitting the statement of compliance no later than 10 calendar days from the date of the Authority's written notice to the manufacturer in accordance with OAR 333-016-4060(3) and (4).

(b) If the manufacturer does not submit proof that it is in compliance with the requirements of OAR 333-016-4060 or fails to cure the violation within 90 days, the Authority may impose a civil penalty not to exceed \$5,000.

(c) For a continuing violation, each day that the violation continues after the preceding imposition of a civil penalty is considered a separate offense subject to a civil penalty not to exceed \$10,000. The Authority is not required to provide the manufacturer with an opportunity to cure the continuing violation before imposing the separate civil penalty.

(5) In imposing a penalty under these rules, the Authority must consider the following factors:

(a) The past history of the manufacturer in taking all feasible steps or following all feasible procedures necessary or appropriate to correct any violation.

(b) Any prior violations of statutes, rules, orders or permits pertaining to ~~HPCCCHP~~ used in children's products.

(c) Any prior violations of statutes, rules, orders or permits pertaining to intentionally added chemicals or classes of chemicals prohibited by OAR 333-016-4060.

(d) The gravity and magnitude of the violation.

(e) Whether the violation was a sole event, repeated, or continuous.

(f) Whether the violation was a result of an unavoidable accident, negligence, or an intentional act.

(g) The violator's cooperativeness and efforts to correct the violation.

(h) The economic and financial conditions of the manufacturer incurring a penalty.

(6) Civil penalties will be imposed in the manner provided in ORS 183.745.