

Oregon Toxic-Free Cosmetics Act ([SB546](#)) – Draft OARs for RAC Review

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

(1) “Authoritative Source” means a source listed in OAR 333-016-4030.

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

More draft definitions to be added for RAC review.

333-016-4020

High Priority Chemicals of Concern Used in Cosmetic Products (HPCCCP)*

The following chemicals are designated as high priority chemicals of concern for children’s health when used in cosmetic products:

(1) Allyl isothiocyanate (57-06-7)

(2) N-Nitrosodimethylamine (62-75-9)

(3) Benzene (71-43-2)

(4) Acetaldehyde (75-07-0)

(5) Trichloroacetic acid (76-03-9)

(6) 2-chloracetamide (79-07-2)

(7) Lily aldehyde (80-54-6)

(8) Musk ketone (81-14-1)

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- (9) Musk xylene (81-15-2)
- (10) Musk ambrette (83-66-9)
- (11) Anthraquinone (84-65-1)
- (12) N- N-Nitrosodiphenylamine (86-30-6)
- (13) Pyrogallol (87-66-1)
- (14) Propyl paraben (94-13-3)
- (15) Butyl paraben (94-26-8)
- (16) Methyl paraben (99-76-3)
- (17) 4-Hydroxybenzoic acid (99-96-7)
- (18) Styrene (100-42-5)
- (19) Boric acid (10043-35-3)
- (20) Acrylonitrile (107-13-1)
- (21) Vinyl acetate (108-05-4)
- (22) Cyclohexylamine (108-91-8)
- (23) 2-Methoxyethanol (109-86-4)
- (24) Triphenyl phosphate (TPP) (115-86-6)
- (25) Musk moskene (116-66-5)
- (26) Ethyl paraben 120-47-8
- (27) 1,4-dioxane (123-91-1)
- (28) Benzophenone-2 (Bp-2) (131-55-5)
- (29) Tricresyl phosphate (1330-78-5)
- (30) Estragole (140-67-0)

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- (31) Musk tibetene (145-39-1)
- (32) Malachite green (569-64-2)
- (33) Basic green 1 (633-03-4)
- (34) N-Methylpyrrolidone (872-50-4)
- (35) C.I. disperse blue 3 (2475-43-6)
- (36) C.I. disperse blue 1 (2475-45-8)
- (37) Butylated hydroxyanisole (BHA) (25013-16-5)
- (38) Isopropyl-paraben (4191-73-5)
- (39) Isobutyl-paraben (4247-02-3)
- (40) Trisodium nitrilotriacetate (5064-31-3)
- (41) 2-Ethyl-hexyl-4- methoxycinnamate (5466-77-3)

 *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 HPCCCP: Practical Quantification Limits

(1) The practical quantification limit for a HPCCCP 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.

[ED. NOTE: To view attachments referenced in rule text, click here for PDF copy.]

TBD

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

- (1) The Oregon Health Authority (Authority) shall consider adding a chemical to the list of high priority chemicals of concern used in cosmetic products in OAR 333-016-4020 and practical quantification limits for the chemical if the chemical:
- (a) Is identified in **statute, rule or** guidance developed by the **State of** Washington Department of Ecology or Washington Department of Health as being potentially harmful to human health;
 - (b) Is identified in statute, rule or guidance developed by the State of California as being potentially harmful to human health.**
 - (c) Is identified in statute, rule or guidance developed by the State of New York as being potentially harmful to human health.**
 - (d) 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;
 - (e) Is currently or subsequently listed on European Chemicals Agency Cosmetic Products Regulation, Annex II – Prohibited Substances
 - (f) Is currently or subsequently found to have a reference dose or reference concentration based on neurotoxicity through USEPA's Integrated Risk Information System;
 - (g) 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; or
 - ~~(h)~~ (h) Is currently or subsequently identified by the Centers for Disease Control and Prevention in its National Report on Human Exposure to Environmental Chemicals. ~~The Authority shall also consider adding a chemical or class of chemicals to the list of~~

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~~HPCCCHs 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) 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) 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 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.~~

(2) Is identified in guidance developed by other federal, state, international and nongovernmental organizations with applicable expertise, as being potentially harmful to human health;

(3) The Authority may, in its discretion, include a class of chemicals or subclass of chemicals on the list of high priority chemicals of concern used in cosmetic products, in accordance with ORS 431A.335(1)(b). In making a decision whether to include a class or subclass of chemicals in the list, the Authority will consider the provisions in sections (1) of this rule.

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(4) The Authority shall review and revise the list of high priority chemicals every three years.

In completing the revisions under this subsection, 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 high priority chemicals if the Authority determines that the chemical or class of chemicals is no longer being used in cosmetic products.

(5) The list of HPCCCPs in OAR 333-016-4020 may only be modified by following the Administrative Procedures Act rulemaking process.

OAR 333-016-4040 Notice Requirements

(1) A manufacturer of a cosmetic product sold or offered for sale in this state that contains a high priority chemical of concern used in cosmetic products (HPCCCP) listed in OAR 333-016-4040 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.

(b) The link in (1)(a) must lead to one of the following blocks of text on the manufacturer's website. The content of the text block is dependent on the HPCCCP's potential effects on human health as determined by Oregon Health Authority, and the number of HPCCCPs present in the particular cosmetic product. The HPCCCPs and their potential effects are found at www.healthoregon/toxicfreecosmetics.

(A) For HPCCCPs listed as carcinogens, the words, "This product can expose you to _____, _____, or _____, which ~~recognized is~~ **may cause cancer as determined by authoritative sources recognized** by the State of Oregon. For more information go to www.healthoregon/toxicfreecosmetics."

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- (B) For HPCCCPs listed as reproductive toxicants, the words, “This product can expose you to _____, _____, or _____, which ~~is recognized [are]~~ may **cause birth defects or other reproductive harm as determined by authoritative sources** recognized by State of Oregon ~~to cause birth defects or other reproductive harm~~. For more information go to www.healthoregon/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/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 by authoritative sources** recognized by the State of Oregon ~~to cause cancer, birth defects or other reproductive harm~~. For more information go to www.healthoregon/toxicfreecosmetics.”
- (c) Information that satisfies all the labeling requirements pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq.;
- (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 display** 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) This rule does not apply to the packaging of a cosmetic product that is intended to be discarded before the product is used.

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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)

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(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)

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- (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))

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(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 Oregon Health Authority by rule.

 *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

TBD

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.

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- (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 ORS 431A.340 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 ORS 431A.340 within 90 calendar days.
- (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) If the Authority has reason to believe that a cosmetic product that contains a high priority chemical of concern used in cosmetic products is being sold or offered for sale in this state in violation of ORS 431A.340, the Authority may request that the manufacturer provide a statement of compliance on a form provided by the Authority. The manufacturer must submit the statement of compliance within 10 calendar days after receipt of a request.
- (5) To prove compliance with ORS 431A.340, the manufacturer must:
- (a) Demonstrate through submission of test results from a third-party laboratory that the cosmetic product does not contain the high priority chemical of concern used in cosmetic products at or above a de minimis level; or
- (b) Show that the manufacturer complied with the notice requirements of ORS 431A.340.
- (6) 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 ORS 431A.345, 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 proof to the Authority that it is not in violation as alleged in the notice.

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- (a) If the manufacturer does not submit proof that it is in compliance or fails to cure the violation within 90 days, the Authority may impose a civil penalty not to exceed \$5,000.
- (b) 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.
- (7) 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 HPCCCH used in children's products.
 - (c) The gravity and magnitude of the violation.
 - (d) Whether the violation was a sole event, repeated, or continuous.
 - (e) Whether the violation was a result of an unavoidable accident, negligence, or an intentional act.
 - (f) The violator's cooperativeness and efforts to correct the violation.
 - (g) The economic and financial conditions of the manufacturer incurring a penalty.

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