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# PERMANENT ADMINISTRATIVE ORDER

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CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILING CAPTION: Toxic Free Kids Modernization Act (HB 3043, 2023) and triennial review of High Priority Chemicals

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RULES:
333-016-2010, 333-016-2020, 333-016-2035, 333-016-2060, 333-016-2070, 333-016-3010, 333-016-3015, 333-016-3020, 333-016-3080

AMEND: 333-016-2010

RULE TITLE: Definitions

NOTICE FILED DATE: 10/31/2024

RULE SUMMARY: Amend OAR 333-016-2010: Adding the term “product model” and its definition to OAR 333-016-2010 Definitions. This relates to the amendment in OAR 333-016-2060 Notification Requirements.

RULE TEXT:
The following definitions apply to OAR 333-016-2001 to 333-016-3080.
(1) "Alternatives Assessment" or "AA" as described in OAR 333-016-3060 means the evaluation of the possibility of replacing chemicals in products or processes with inherently safer alternatives in order to better protect human health.
(2) "Analytical methods" means defined protocols for the analysis of the presence of a high priority chemical of concern to children’s health (HPCCCH) in a sample of a medium, including laboratory testing that can be described and is readily reproducible by another party.
(3) "Bioavailability" means the extent to which a HPCCCH at or above the practical quantification limit for the chemical established in OAR 333-016-2035(2) Exhibit A in leachate or air may be absorbed by a child.
(4) "Chemical" means:
(a) A substance with a distinct molecular composition and the breakdown products of the substance that form through decomposition, degradation or metabolism.
(b) A group of structurally related substances and the breakdown products of the substances that form through decomposition, degradation or metabolism.
(5) "Chemical Abstracts Service Registry Number" means the number assigned for identification of a particular chemical by the Chemical Abstracts Service, a service of the American Chemical Society that indexes and compiles abstracts of worldwide chemical literature called Chemical Abstracts.

(6) "Child" means an individual under 12 years of age.
(7)(a) "Children's cosmetics" means products that are intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, moisturizing, beautifying, promoting attractiveness or altering the appearance.
(b) "Children's cosmetics" does not mean soap, dietary supplements or food and drugs approved by the United States Food and Drug Administration.
(8)(a) "Children's product" means:
(A) Any of the following products that are made for, marketed for use by or marketed to children under 12 years of age:
(i) A product designed or intended by the manufacturer to facilitate sucking, teething, sleep, relaxation, feeding or drinking.
(ii) Children's clothing and footwear.
(iii) Car seats.
(iv) Children's cosmetics.
(v) Children's jewelry.
(vi) Toys.
(B) Any component part of a product specified in paragraph (A) of this subsection.
(b) "Children's product" does not mean:
(A) Athletic shoes with cleats or spikes.
(B) Batteries.
(C) BB guns, pellet guns and air rifles.
(D) Bicycles and tricycles.
(E) Chemistry sets.
(F) Consumer electronic products, including personal computers, audio and video equipment, calculators, wireless telephones and game consoles, handheld devices that incorporate a video screen and are used to access interactive software, and the associated peripherals.
(G) Interactive software intended for leisure and entertainment, such as computer games, and their storage media, such as compact discs.
(H) Model rockets.
(I) Pocketknives and multitools.
(J) Roller skates.
(K) Scooters.
(L) Sets of darts with metallic points.
(M) Slings and catapults.
(N) Snow sporting equipment, including skis, poles, boots, snowboards, sleds and bindings.
(O) Sporting equipment and accessories, including but not limited to bats, balls, gloves, sticks, pucks, pads, helmets and other protective equipment, weight training and exercise aids, protective eyewear, backpacks and tents, raingear, sport bags and luggage, and golf equipment.
(P) Video toys that can be connected to a video screen and are operated at a nominal voltage exceeding 24 volts.
(Q) Food and beverages and food and beverage packaging regulated by the United States Food and Drug Administration or the United States Department of Agriculture.
(9) "Class of chemicals" has the meaning given that term in ORS 431A.253.
(10) "Component part" means a uniquely identifiable material or coating (including ink or dye) that is intended to be included as a part of a finished children's product, including, but not limited to:
(a) Bio-based materials (animal or plant based);
(b) Synthetic polymers (such as but not limited to synthetic rubber, plastics, and foams);
(c) Metals (including alloys);
(d) Glass, ceramic and siliceous material;

(e) Surface coatings (such as but not limited to paints, plating, and waterproofing);
(f) Homogenous mixtures (gels, creams, powders, liquids, adhesives, synthetic fragrances);
(g) Inks/dyes/pigments; and
(h) Textiles (synthetic fibers and blends).
(11) "Contaminant" has the meaning given that term in ORS 431A.253.
(12) "De minimis level" has the meaning given that term in ORS 431A.253.
(13) "Essential use" means a function of a HPCCCH in a children's product considered critical for performance of a product.
(14) "Exposure scenarios" means the mechanisms by which children may be exposed to HPCCCHs found in a children's product.
(15) "Hazard Assessment" or "HA" as described in OAR 333-016-3030 means an evaluation of whether a chemical or chemicals substituted for a HPCCCH in a children's product make that product less hazardous than it was when it contained the HPCCCH.
(16) "HPCCCH" means high priority chemicals of concern to children's health.
(17) "High priority chemicals of concern list" means the high priority chemicals of concern for children's health identified by the Oregon Health Authority in OAR 333-016-2020.
(18) "Intentionally added chemical" has the meaning given that term in ORS 431A.253.
(19) "Leachability" means the extent to which a HPCCCH is reasonably anticipated to migrate from a children's product through normal and reasonably foreseeable use and abuse of such product determined by measuring a HPCCCH at or above the practical quantification limit for the chemical established in OAR 333-016-2035(2) Exhibit A in media during simulated exposure scenarios.
(20) "Manufacturer" has the meaning given that term in ORS 431A.253.
(21) "Manufacturing control program" or "MCP" means a program implemented by the manufacturer or its suppliers to control the amount of a HPCCCH present as a contaminant at or above de minimis levels through the implementation of tools, processes and oversight that support effective chemicals management at all levels to include supply chain management, quality assurance and educational programs. Control includes the minimization, reduction or elimination of contaminants when possible.
(22) "Mouthable" has the meaning given that term in ORS 431A.253.
(23) "Non-essential use" means a function of a HPCCCH in a children's product that is not critical for the performance of a product but is included for other reasons such as market demand.
(24) "Owner" for purposes of clarifying the definition of "manufacturer" means the person or entity, whether an importer or a distributor, that offers the children's product for sale in Oregon.
(25) "Practical quantification limit" has the meaning given that term in ORS 431A.253.
(26) "Product category" means the "brick" level of the GS1 Global Product Classification (GPC) standard, which identifies products that serve a common purpose, are of a similar form and material, and share the same set of category attributes.
(27) "Product model" means the specific product name used by the manufacturer to place the product into the stream of commerce.
(28) "Quantitative Exposure Assessment" or "QEA" means an assessment as described in OAR 333-016-3050 of whether a HPCCCH used in children's products is or is not reasonably anticipated to result in exposure based upon an analysis of leachability and bioavailability of the HPCCCH used in children's products.
(29) "Reasonably foreseeable use and abuse" includes: non-incidental skin contact; swallowing; mouthing; inhalation of gaseous products emitted by a children's product; the aging of a children's product; and may include breaking during typical and reasonable use by children or other situations of a similar nature.
(30) "Subclass of chemicals" has the meaning given that term in ORS 431A.253.
(31) "Substitutable role" means a role for or presence of a HPCCCH that might be regarded as essential but where alternatives to the HPCCCH have been identified that have comparable functionality and performance making the use

of the HPCCCH no longer essential.

(32) "These rules" means OAR 333-016-2001 to 333-016-3080.

(33) "Trade association" has the meaning given that term in ORS 431A.253.

STATUTORY/OTHER AUTHORITY: ORS 413.042, ORS 431A.253 - 431A.280

STATUTES/OTHER IMPLEMENTED: ORS 431A.253 - 431A.280

AMEND: 333-016-2020

RULE TITLE: Chemicals of High Concern to Children

NOTICE FILED DATE: 10/31/2024

RULE SUMMARY: Amend OAR 333-016-2020: Review and revision of OAR 333-016-2020 Chemicals of High Concern to Children is required of the Oregon Health Authority (Authority) under provisions in ORS 431A.255 List of high priority chemicals of concern in children's products. This review is to occur every three years from the date OAR 333-016-2020 became effective (January 1, 2016). The Authority is adding (to OAR 333-016-2020) ten chemicals. The additions are to be effective January 1, 2025, and affect biennial notices made for products sold or offered for sale in Oregon in 2024 and 2025, and beyond.

RULE TEXT:

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

(1) Formaldehyde (50-00-0).
(2) Aniline (62-53-3).
(3) N-Nitrosodimethylamine (62-75-9).
(4) Benzene (71-43-2).
(5) Vinyl chloride (75-01-4).
(6) Acetaldehyde (75-07-0).
(7) Methylene chloride (75-09-2).
(8) Carbon disulfide (75-15-0).
(9) Methyl ethyl ketone (78-93-3).
(10) 1,1,2,2-Tetrachloroethane (79-34-5).
(11) Tetrabromobisphenol A (TBBPA) (79-94-7).
(12) Bisphenol A (BPA) (80-05-7).
(13) Bisphenol S (BPS) (80-09-1).
(14) Dicyclohexyl phthalate (DCHP) (84-61-7).
(15) Diethyl phthalate (DEP) (84-66-2).
(16) Diisobutyl phthalate (DIBP) (84-69-5).
(17) Di-n-butyl phthalate (DBP) (84-74-2).
(18) Di-n-hexyl phthalate (DnHP) (84-75-3).
(19) Butyl benzyl phthalate (BBP) (85-68-7).
(20) N-Nitrosodiphenylamine (86-30-6).
(21) Hexachlorobutadiene (HCDB) (87-68-3).
(22) Propyl paraben (94-13-3).
(23) Butyl paraben (94-26-8).
(24) 2-Aminotoluene (95-53-4).
(25) 2,4-Diaminotoluene (95-80-7).
(26) Methyl paraben (99-76-3).
(27) 4-Hydroxybenzoic acid (99-96-7).
(28) Ethylbenzene (100-41-4).
(29) Styrene (100-42-5).
(30) 4-Nonylphenol (104-40-5); 4-NP and its isomer mixtures including CAS 84852-15-3 and CAS 25154-52-3.
(31) 4-Chloroaniline (106-47-8).
(32) Acrylonitrile (107-13-1).
(33) Ethylene glycol (107-21-1).
(34) Toluene (108-88-3).

(35) Phenol (108-95-2).
(36) 2-Methoxyethanol (109-86-4).
(37) Ethylene glycol monoethyl ether (110-80-5).
(38) Triphenyl phosphate (TPP) (115-86-6).
(39) Tris(2-chloroethyl) phosphate (TCEP) (115-96-8).
(40) Di-2-ethylhexyl phthalate (DEHP) (117-81-7).
(41) Di-(2-methoxyethyl) phthalate (DMEP) (117-82-8).
(42) Di-n-octyl phthalate (DnOP) (117-84-0).
(43) Hexachlorobenzene (118-74-1).
(44) 3,3'-Dimethylbenzidine and Dyes Metabolized to 3,3'-Dimethylbenzidine (119-93-7).
(45) Ethyl paraben (120-47-8).
(46) 1,4-Dioxane (123-91-1).
(47) Tris (2,3-dibromopropyl) phosphate (TDBPP) (126-72-7).
(48) Tri-n-butyl phosphate (126-73-8) (TNBP).
(49) Tetrachloroethene (127-18-4).
(50) Dipentyl phthalate (131-18-0) (DPP)
(51) Benzophenone-2 (Bp-2) (131-55-5)
(52) 4-tert-Octylphenol (140-66-9).
(53) Estragole (140-67-0).
(54) 2-Ethylhexanoic acid (149-57-5).
(55) Perfluorooctanoic acid and related substances (PFOA) (335-67-1).
(56) Pentachlorobenzene (608-93-5).
(57) Bisphenol F (BPF) (620-92-8).
(58) C.I. Solvent yellow 14 (842-07-9).
(59) N-Methylpyrrolidone (872-50-4).
(60) Tricresyl phosphate (TCP) (1330-78-5).
(61) Decabromodiphenyl ether (BDE-209) (1163-19-5).
(62) Ethylhexyl diphenyl phosphate (EHDPP) (1241-94-7).
(63) Perfluorooctane sulfonic acid and its salts; PFOS (1763-23-1).
(64) 4-Octylphenol (1806-26-4).
(65) 2-Ethyl-hexyl-4-methoxycinnamate (5466-77-3).
(66) Mercury & mercury compounds (7439-97-6).
(67) Antimony and Antimony compounds (7440-36-0).
(68) Arsenic and Arsenic compounds (7440-38-2), including arsenic trioxide (1327-53-3) and dimethyl arsenic (75-60-5).
(69) Cadmium and cadmium compounds (7440-43-9).
(70) Cobalt and cobalt compounds (7440-48-4).
(71) Tris(1-chloro-2-propyl) phosphate (TCPP) (13674-84-5).
(72) Tris(1,3-dichloro-2-propyl) phosphate (TDCPP) (13674-87-8).
(73) Butylated hydroxyanisole (BHA) (25013-16-5).
(74) Hexabromocyclododecane (HBCD) (25637-99-4).
(75) Bis (2-ethylhexyl) tetrabromophthalate (TBPH) (26040-51-7)
(76) Diisodecyl phthalate (DIDP) (26761-40-0).
(77) Diisononyl phthalate (unbranched) (DINP) (28553-12-0).
(78) Bis(chloromethyl)propane-1,3-diyl tetrakis-(2-chloroethyl) bis(phosphate) (V6) (38051-10-4).
(79) Isopropylated triphenyl phosphate (IPTPP) (68937-41-7).
(80) Decabromodiphenyl ethane (DBDPE) (84852-53-9).

(81) Short-chain chlorinated paraffins (SCCP) (85535-84-8).

(82) Chlorinated paraffins (108171-26-2).

(83) 2-ethylhexyl-2,3,4,5-tetrabromobenzoate (TBB) (183658-27-7).

STATUTORY/OTHER AUTHORITY: ORS 413.042, ORS 431A.255

STATUTES/OTHER IMPLEMENTED: ORS 431A.255

AMEND: 333-016-2035

RULE TITLE: Manufacturer Disclosure of High Priority Chemicals of Concern for Children's Health Used in Children's Products: Practical Quantification Limits

NOTICE FILED DATE: 10/31/2024

RULE SUMMARY: Amend Exhibit A of OAR 333-016-2035: Review and revision of OAR 333-016-2035 Manufacturer Disclosure of High Priority Chemicals of Concern for Children's Health Used in Children's Products: Practical Quantification Limits, Exhibit A. Practical Quantification Limits (PQLs) and detection methods were added for the ten high priority chemicals of concern for children's health (HPCCCH) added to OAR 333-016-2020. Detection methods and PQLs for the ten HPCCCH added align with their counterparts on Washington's Chemicals of High Concern to Children's (CHCC)list. Changes are to go into effect January 1, 2025 and affect biennial notices made for products sold or offered for sale in Oregon in 2024 and 2025 and beyond. Changes are only
made to attached Exhibit, not to the rule text.

RULE TEXT:
(1) The practical quantification limit for a chemical 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.

STATUTORY/OTHER AUTHORITY: ORS 413.042

STATUTES/OTHER IMPLEMENTED: ORS 431A.253 – 431A.280

**OAR 333-016-2035**

**Exhibit A: Projected PQLs for the 83 high priority chemicals of concern in children's products**

| | Chemical | CAS | PQL (ppm) | Method |
|---|---|---|---|---|
| 1 | Formaldehyde | 50-00-0 | 5.0 | Total Extraction/EPA 8315 or 8270 |
| 2 | Aniline | 62-53-3 | 1.0 | Total Extraction/EPA 8270 |
| 3 | N-Nitrosodimethylamine | 62-75-9 | 1.0 | Total Extraction/EPA 8270 |
| 4 | Benzene | 71-43-2 | 1.0 | Total Extraction/EPA 8260 |
| 5 | Vinyl chloride | 75-01-4 | 0.5 | Total Extraction/EPA 8260 |
| 6 | Acetaldehyde | 75-07-0 | 1.0 | Total Extraction/EPA 8315 |
| 7 | Methylene chloride | 75-09-2 | 1.0 | Total Extraction/EPA 8260 |
| 8 | Carbon disulfide | 75-15-0 | 1.0 | Total Extraction/EPA 8260 |
| 9 | Methyl ethyl ketone | 78-93-3 | 1.0 | Total Extraction/EPA 8260 |
| 10 | 1,1,2,2-Tetrachloroethane | 79-34-5 | 1.0 | Total Extraction/EPA 8260 |
| 11 | Tetrabromobisphenol A (TBBPA) | 79-94-7 | 50.0 | Total Extraction/EPA 1694 |
| 12 | Bisphenol A (BPA) | 80-05-7 | 1.0 | Total Extraction/EPA 1694 |
| 13 | Bisphenol S (BPS) | 80-09-1 | 1.0 | Total Extraction/EPA 1694 |
| 14 | Dicyclohexyl phthalate (DCHP) | 84-61-7 | 25.0 | CPSC-CH-C1001-09.3 |
| 15 | Diethyl phthalate (DEP) | 84-66-2 | 25.0 | CPSC-CH-C1001-09.3 |
| 16 | Diisobutyl phthalate (DIBP) | 84-69-5 | 25.0 | CPSC-CH-C1001-09.3 |
| 17 | Di-n-butyl phthalate (DBP) | 84-74-2 | 25.0 | CPSC-CH-C1001-09.3 |
| 18 | Di-n-hexyl phthalate (DnHP) | 84-75-3 | 25.0 | CPSC-CH-C1001-09.3 |
| 19 | Butyl benzyl phthalate (BBP) | 85-68-7 | 25.0 | CPSC-CH-C1001-09.3 |
| 20 | N-Nitrosodiphenylamine | 86-30-6 | 1.0 | Total Extraction/EPA 8270 |
| 21 | Hexachlorobutadiene (HCBD) | 87-68-3 | 5.0 | Total Extraction/EPA 8260 |
| 22 | Propyl paraben | 94-13-3 | 5.0 | Total Extraction/EPA 8321 |
| 23 | Butyl paraben | 94-26-8 | 5.0 | Total Extraction/EPA 8321 |
| 24 | 2-Aminotoluene | 95-53-4 | 1.0 | Total Extraction/EPA 8720 |
| 25 | 2,4-Diaminotoluene | 95-80-7 | 1.0 | Total Extraction/EPA 8270 |
| 26 | Methyl paraben | 99-76-3 | 5.0 | Total Extraction/EPA 8321 |
| 27 | 4-Hydroxybenzoic acid | 99-96-7 | 5.0 | Total Extraction/HPLC[i] |
| 28 | Ethylbenzene | 100-41-4 | 1.0 | Total Extraction/EPA 8260 |
| 29 | Styrene | 100-42-5 | 1.0 | Total Extraction/EPA 8260 |
| 30 | 4-Nonylphenol; 4-NP and its isomer mixtures including CAS 84852-15-3 and CAS 25154-52-3 | 104-40-5 | 10.0 | Total Extraction/ EPA 8270/GC-MS[i] |
| 31 | 4-Chloroaniline | 106-47-8 | 1.0 | Total Extraction/EPA 8270 |
| 32 | Acrylonitrile | 107-13-1 | 1.0 | Total Extraction/EPA 8260 |
| 33 | Ethylene glycol | 107-21-1 | 40.0 | Total Extraction/EPA 8015 |
| 34 | Toluene | 108-88-3 | 0.5 | Total Extraction/EPA 8260 |

| | Chemical | CAS | PQL (ppm) | Method |
|---|---|---|---|---|
| 35 | Phenol | 108-95-2 | 1.0 | Total Extraction/EPA 8270 |
| 36 | 2-Methoxyethanol | 109-86-4 | 10.0 | Total Extraction/EPA 8015 |
| 37 | Ethylene glycol monoethyl ether | 110-80-5 | 10.0 | Total Extraction/EPA 8015 |
| 38 | Triphenyl phosphate (TPP) | 115-86-6 | 50.0 | Total Extraction/EPA 8270 |
| 39 | Tris(2-chloroethyl) phosphate (TCEP) | 115-96-8 | 50.0 | Total Extraction/EPA 8270 |
| 40 | Di-2-ethylhexyl phthalate (DEHP) | 117-81-7 | 25.0 | CPSC-CH-C1001-09.3 |
| 41 | Di-(2-methoxyethyl) phthalate (DMEP) | 117-82-8 | 25.0 | CPSC-CH-C1001-09.3 |
| 42 | Di-n-octyl phthalate (DnOP) | 117-84-0 | 25.0 | CPSC-CH-C1001-09.3 |
| 43 | Hexachlorobenzene | 118-74-1 | 1.0 | Total Extraction/EPA 8270 |
| 44 | 3,3'-Dimethylbenzidine and Dyes Metabolized to same | 119-93-7 | 1.0 | Total Extraction/EPA 8270 |
| 45 | Ethyl paraben | 120-47-8 | 5.0 | Total Extraction/EPA 8321 |
| 46 | 1,4-Dioxane | 123-91-1 | 20.0 | Total Extraction/EPA 8260 |
| 47 | Tris (2,3-dibromopropyl) phosphate (TDBPP) | 126-72-7 | 50.0 | Total Extraction/ EPA 8270 |
| 48 | Tri-n-butyl phosphate (TNBP) | 126-73-8 | 50.0 | Total Extraction/ EPA 8270 |
| 49 | Tetrachloroethene | 127-18-4 | 0.5 | Total Extraction/EPA 8260 |
| 50 | Dipentyl phthalate (131-18-0) (DPP) | 131-18-0 | 50.0 | CPSC-CH-C1001-09.3 |
| 51 | Benzophenone-2 (Bp-2) | 131-55-5 | 5.0 | Total Extraction/ GC-FID[i] |
| 52 | 4-tert-Octylphenol | 140-66-9 | 10.0 | Total Extraction/ GC-MS[i] |
| 53 | Estragole | 140-67-0 | 10.0 | Total Extraction/ GC-MS[i] |
| 54 | 2-Ethylhexanoic Acid | 149-57-5 | 5.0 | Total Extraction/ GC-MS[i] |
| 55 | Perfluorooctanoic acid and related substances (PFOA) | 335-67-1 | 0.001 | Total Extraction/ LC-MS/MSi |
| 56 | Pentachlorobenzene | 608-93-5 | 1.0 | Total Extraction/EPA 8270 |
| 57 | Bisphenol F (BPF) | 620-92-8 | 1.0 | Total Extraction/ EPA 1694 |
| 58 | C.I. Solvent Yellow 14 | 842-07-9 | 1.0 | Total Extraction/ LC-M/MS[i] |
| 59 | N-Methylpyrrolidone | 872-50-4 | 1.0 | Total Extraction/ 8015/8270 |
| 60 | Tricresyl phosphate (TCP) | 1330-78-5 | 50.0 | Total Extraction/ GC-MSi |
| 61 | Decabromodiphenyl ether (BDE-209) | 1163-19-5 | 10.0 | Total Extraction/ 8270 |
| 62 | Ethylhexyl diphenyl phosphate (EHDPP) | 1241-94-7 | 50.0 | Total Extraction/ GC-MS[i] |
| 63 | Perfluorooctane sulfonic acid and its salts; (PFOS) | 1763-23-1 | 0.001 | Total Extraction/ LC-M/MS[i] |
| 64 | 4-Octylphenol | 1806-26-4 | 10.0 | Total Extraction/ GC-MS[i] |
| 65 | 2-Ethyl-hexyl-4-methoxycinnamate | 5466-77-3 | 5.0 | Total Extraction/ HPLC |
| 66 | Mercury & mercury compounds | 7439-97-6 | 0.5 | Total Digestion/ EPA[ii] |
| 67 | Antimony & Antimony compounds | 7440-36-0 | 1.0 | Total Digestion (EPA 3052)/ EPA 6020[iii] |
| 68 | Arsenic & Arsenic compounds including arsenic trioxide (1327-53-3) and dimethyl arsenic (75-60-5) | 7440-38-2 | 1.0 | Total Digestion (EPA 3052)/ EPA 6020[ii] |

| | Chemical | CAS | PQL (ppm) | Method |
|---|---|---|---|---|
| 69 | Cadmium & cadmium compounds | 7440-43-9 | 1.0 | Total Digestion (EPA 3052)/ EPA 6020[ii] |
| 70 | Cobalt & Cobalt compounds | 7440-48-4 | 1.0 | Total Digestion (EPA 3052)/ EPA 6020[ii] |
| 71 | Tris(1-chloro-2-propyl) phosphate (TCPP) | 13674-84-5 | 50.0 | Total Extraction/ EPA 8270 |
| 72 | Tris(1,3-dichloro-2-propyl) phosphate (TDCPP) | 13674-87-8 | 50.0 | Total Extraction/ EPA 8270 |
| 73 | Butylated hydroxyanisole (BHA) | 25013-16-5 | 10.0 | Total Extraction/ GC-MS[i] |
| 74 | Hexabromocyclododecane (HBCD) | 25637-99-4 | 50.0 | Total Extraction/ EPA 1694 |
| 75 | Bis (2-ethylhexyl) tetrabromophthalate (TBPH) | 26040-51-7 | 50.0 | Total Extraction/ EPA 8270 |
| 76 | Diisodecyl phthalate (DIDP) | 26761-40-0 | 25.0 | CPSC-CH-C1001-09.3 |
| 77 | Diisononyl phthalate (unbranched) (DINP) | 28553-12-0 | 25.0 | CPSC-CH-C1001-09.3 |
| 78 | Bis(chloromethyl)propane-1,3-diyl tetrakis- (2-chloroethyl) bis(phosphate) (V6) | 38051-10-4 | 50.0 | Total Extraction/ EPA 1694 |
| 79 | Isopropylated triphenyl phosphate (IPTPP) | 68937-41-7 | 50.0 | Total Extraction/ GC-MS[i] |
| 80 | Decabromodiphenyl ethane (DBDPE) | 84852-53-9 | 50.0 | CPSC-CH-C1001-09.3 |
| 81 | Short-chain chlorinated paraffins (SCCP) | 85535-84-8 | 50.0 | Total Extraction/ GC-MS[i] |
| 82 | Chlorinated paraffins | 108171-26-2 | 50.0 | Total Extraction/ GC-MS[i] |
| 83 | 2-ethylhexyl-2,3,4,5-tetrabromobenzoate (TBB) | 183658-27-7 | 50.0 | Total Extraction/ EPA 8270 |

[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

[ii] EPA = SW-846 general method 6020 or appropriate SW-846 7000 metal specific analysis, https://www.epa.gov/hw-sw846

[iii] Hydrofluoric acid only needed with a glass matrix

AMEND: 333-016-2060

RULE TITLE: Notification Requirements

NOTICE FILED DATE: 10/31/2024

RULE SUMMARY: Amending OAR 333-016-2060 Notification Requirements per ORS 431A.258 (HB 3043, SECTION 4) by adding brand name, product model to specify the level at which children's products must be reported.

RULE TEXT:

(1) For purposes of this rule, "unit" has the same meaning as "component part" as that is defined in OAR 333-016-2010.

(2) A manufacturer of a children's product sold or offered for sale in this state that contains a high priority chemical of concern to children's health (HPCCCH) listed in OAR 333-016-2020 as an individual chemical or a member of a class or subclass of chemicals, in an amount at or above a de minimis level must submit:

(a) A notice to the Oregon Health Authority (Authority) that contains all the information required in these rules, unless the manufacturer or product is exempt; and

(b) A nonrefundable fee of $250 for the notification of each HPCCCH as specified in OAR 333-016-2080.

(3) The first manufacturer's notice due on January 1, 2018, applies to children's products sold or offered for sale in this state between January 1, 2017 and December 31, 2017. For the reporting years 2018, 2020, and 2022, reports are due on January 1st.

(4) On and after January 1, 2024, manufacturer reports are due on January 31st of even numbered years for the previous two-year biennial notice period. For example, for the reporting year 2024, a manufacturer must include children's products sold or offered for sale between January 1, 2022, and December 31, 2023, that contain a HPCCCH listed in OAR 333-016-2020.

(5) The notice required in section (2) of this rule must include the following:

(a) The name and Chemical Abstracts Service Registry Number of the chemical contained in the children's product;

(b) The product category of the children's product that contains the chemical;

(c) The brand name and product model;

(d) A description of the function of the chemical in the children's product;

(e) The amount of the chemical used in each unit. The amount of the chemical used in each unit of the children's product is to be reported as a range rather than an exact amount;

(f) The target age category for whom the children's product is intended, either ages 0-3, 3-12 or 0-12 years-old;

(g) The number of the children's product that contain the high priority chemical either sold or offered for sale in Oregon during the biennial notice period;

(h) The name and address of the manufacturer, and the name, address and telephone number of the contact person for the manufacturer;

(i) The name, address and contact information for the trade association submitting the notification on behalf of the affected industry; and

(j) Any other information that the manufacturer deems relevant to the appropriate use of the children's product.

(6) No later than January 1, 2020, and every other year thereafter, notices to the Authority shall be submitted utilizing the Interstate Chemicals Clearinghouse's High Priority Chemicals Data System (HPCDS) or alternate data system designated by the Authority. A link to the data system will be made available on the Toxic Free Kids Program website: www.healthoregon.org/toxicfreekids.

(7) If a manufacturer, required to report under ORS 431A.258, is acquired by another business entity, merges into another business entity or separates into distinct business entities, the new controlling entity must submit the required biennial notices to the Authority.

(8) If a manufacturer has included a children's product in a notice required under these rules, and determines that there is no change to the information for the product except the number of products sold or offered for sale submitted to the Authority in the previous notice, the manufacturer may, in lieu of including the children's product again in a subsequent notice, submit a written statement, or if available, an electronic notification indicating that the previous reported data is

still valid for that children's product. The notification shall include the number of products sold or offered for sale during the biennial notice period.
(9) A trade association may provide the notice required in these rules on behalf of a member manufacturer. If a trade association reports on a member manufacturer's behalf, the trade association must specify which member or members the association is reporting on behalf of, including the name and contact information of a representative for each of those members, and must submit the fees for each member as required in OAR 333- 016-2080.
(10) A trade association who fulfills the notice or exemption from notice requirements as well as waiver or hazard assessment requests in these rules on behalf of a member manufacturer will not be held liable for a violation or penalty as a result of the member manufacturer's noncompliance with the requirements of these rules.
(11) A manufacturer may, during the notification process, submit to the Authority recommendations regarding technical, financial or logistical support considered necessary for the implementation of innovation and green chemistry solutions related to HPCCCH used in children's products.
(12) Only one person or entity that falls within the definition of manufacturer is required to report with respect to a particular children's product. The Authority will hold the following primarily responsible for ensuring that it receives a complete, accurate, and timely notice for the children's product, in the following order:
(a) Any person or entity that manufactured the children's product, unless it has no presence in the United States.
(b) Any person or entity that distributed or made available for distribution the children's product, unless it has no presence in the United States.
(c) The importer or owner of the children's product in the United States.
(13) The Authority will enforce the reporting requirements in this rule against a manufacturer in the same order as the priority order for reporting in section (12) of this rule.
(14) If a manufacturer has included a children's product in a notice required under these rules, and removes the HPCCCH from that children's product it shall, within 180 days of removal, submit a written statement, or if available, an electronic notification indicating the HPCCCH that was removed, whether another HPCCCH was substituted and the date the removal was effective, unless the Authority has already been notified under OAR 333-016-3010(1). Such notification will help the Authority avoid any unnecessary enforcement actions because of a failure to report or failure to comply with the other requirements of these rules.

STATUTORY/OTHER AUTHORITY: ORS 413.042, 431A.258

STATUTES/OTHER IMPLEMENTED: ORS 431A.258

AMEND: 333-016-2070

RULE TITLE: Exemptions from Notice Requirement

NOTICE FILED DATE: 10/31/2024

RULE SUMMARY: Amends OAR 333-016-2070 Exemptions from Notice Requirement. This modifies the date by which a request made under this rule must be received by the Oregon Health Authority (Authority). This amendment aligns this date with the date on which biennial notices/reports must be made under OAR 333 016-2060 Notification Requirements, as required by ORS 431A.258.

RULE TEXT:

(1) A manufacturer of children's products with annual worldwide gross sales of less than $5 million, as reported on the most recent tax return filed by the manufacturer before the notification required under OAR 333-016-2060, is exempt from all the requirements of these rules.

(2) If, following the filing of the most recent tax return, a manufacturer's annual worldwide gross sales are $5 million or more, the manufacturer must submit a notice as required under OAR 333-016-2060. The notice must be submitted during the next applicable reporting period or within 180 days of the filing, whichever is later.

(3) A manufacturer or trade association may submit to the Oregon Health Authority (Authority) a request for an exemption from these rules if the high priority chemical of concern to children's health (HPCCCH) in a children's product is present only as a contaminant at or above the de minimis level, and a manufacturing control program (MCP) is in place. A request for an exemption must be accompanied by any applicable fees in OAR 333-016-2080.

(a) An exemption request submitted by a trade association on behalf of its members must identify each member for which the exemption is being requested, including the name and contact information of a representative for each of those members.

(b) A request for an exemption from these rules by any entity must be received by the Authority on or before January 31st of even numbered years for the previous two-year biennial notice period.

(4) In order to meet the standards for an exemption an MCP must be structured using at least one of the following categories:

(a) Manufacturing processes, for example polymerization of plastic resin, injection-molding of plastic, pad-transfer printing, silk screening;

(b) Materials or group of materials, for example multiple styrenic plastics;

(c) Component parts;

(d) A HPCCCH present as a contaminant at or above the de minimis level; or

(e) Finished products.

(5) In addition to the information provided in section (4) of this rule a manufacturer or a trade association must document in its exemption request the specific HPCCCH present as a contaminant at or above the de minimis level that the MCP is intended to address and the product categories where the HPCCCH are found. MCPs submitted in support of an exemption request by a trade association on behalf of a member or members must include the product categories for which each member is seeking an exemption.

(6) In order for the manufacturer to demonstrate that an MCP meets the minimum standards for an exemption, the MCP must meet generally-recognized industry best manufacturing practices and processes for the control of a HPCCCH, such as but not limited to:

(a) The most current and appropriate International Standards Organization (ISO) requirements for a specific manufacturing process or facility. The manufacturer must demonstrate how the ISO certification held by the manufacturer or supplier is controlling the contaminant in a component part or in the finished children's product.

(b) Another established certification or standards manufacturing control program such as, but not limited to, Sony Corporations Green Partners Standards, the European ROHS (Restriction of Hazardous Substances in Electronic Parts), and EN-71.

(c) The most current American Society for Testing and Materials (ASTM) International standards that provide the

recommended industry standards for materials used or produced in the manufacturing process;
(d) Any proven alternative methodology that will enable the manufacturer to demonstrate:
(A) That the methodology controls the contaminant to the lowest practicable levels in the finished children's product; and
(B) That the alternative methodology is as or more effective at controlling the contaminant than the standards in subsections (a) through (c) of this section.
(7) For any category described in section (4) of this rule a manufacturer must provide adequate evidence that the contaminant is being controlled, including but not limited to:
(a) Periodic laboratory test reports from a third-party laboratory accredited to the current ISO/IEC 17025 standards by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) mutual recognition arrangement. The laboratory must be accredited for the method used to conduct the testing. The testing must show the presence, if quantifiable, and the amount of a HPCCCH, including documentation that characterizes the test methodology.
(b) A supplier's certificate of analysis documenting the maximum levels of contaminant in any category described in section (4) of this rule for which the exemption is being requested. A certificate of analysis must include:
(A) The name and address of the laboratory that performed the tests;
(B) The name and description of the product or material being tested, including, if known, the batch number used by the original manufacturer;
(C) The date of the batch's manufacture;
(D) A description of methodology employed to take samples from the batch to ensure that samples are representative of the product or material being tested;
(E) A reference to the analytical laboratory test method used, including the data quality assurance criteria and reporting limits;
(F) The results of all analytical laboratory tests performed on the batch for which the certificate is issued (in numerical form, where applicable) and a comparison with the established acceptance criteria (limits);
(G) The date or dates on which the test or tests were performed; and
(H) The signature of an authorized representative of the laboratory, and the contact information for that individual.
(c) Documentation demonstrating that the instituted control measures are able to control the contaminant, as appropriate for the category described in section (4) of this rule, including but not limited to, the quantification of the degree of contaminant control occurring because of contaminant control measures instituted.
(8) In addition to meeting one of the requirements of section (6) of this rule a manufacturer must document and describe, in its exemption request, whether the manufacturer's or the manufacturer's supplier's manufacturing control process, include any of the following:
(a) Procedures to ensure the quality and purity of feedstock, whether raw or recycled;
(b) Contract specifications for manufacturing process parameters, for example material purity, drying and curing times when relevant to the presence of high priority chemicals in the finished children's product components;
(c) Periodic testing that is for the presence and amount of HPCCCH in the finished children's product, including documentation of how tests were conducted and applicable lab results from an accredited third-party laboratory that meets the standards in subsection (7)(a) of this rule;
(d) Procedures and approaches to audit the methods used by contractors or suppliers to control a HPCCCP present as a contaminant in a children's product; and
(e) Education and outreach to members of a supply chain about the importance to the manufacturer of controlling the amount of HPCCCH in supplied materials through activities such as discussions with suppliers, oral presentations, written materials or webinars.
(9) The Authority, upon receipt of an exemption request will date stamp the document. Once date stamped the Authority must approve or deny an exemption request within 180 days.
(a) If the Authority does not approve or disapprove the exemption request within 180 days the manufacturing control

program exemption is deemed approved.
(b) If the Authority approves the exemption the Authority will notify the manufacturer of the approval, in writing.
(c) If an exemption request is disapproved, the Authority will provide written notice to the manufacturer of the disapproval and the reason for the disapproval.
(10) If the Authority disapproves an exemption request, the manufacturer may submit a revised exemption request for consideration within 180 days after the Authority's notice of disapproval.
(11) If the exemption request is denied a second time, the manufacturer will have 90 days from the date of the written notification of disapproval to submit a notification in accordance with OAR 333-016-2060.
(12) A manufacturer who has been denied an exemption request a second time may submit a new exemption request under section (3) of this rule during future biennial notice periods.
(13) At any time the Authority may request additional information from a manufacturer requesting an exemption, and may specify the time period by which the manufacturer must provide the requested information
(14) A manufacturer or trade association may request an amendment of an MCP previously approved by the Authority. A request must be made at least 30 days before the next biennial notice period. Such amendments are limited to the following:
(a) The addition of product categories to an MCP provided that the HPCCCH in the manufacturing of products in these added categories is monitored and controlled, at all stages, with the specific mechanisms, tests and processes itemized in the approved MCP.
(b) Changes in the specific mechanisms, tests and processes identified in an approved MCP that are used to control an HPCCCH.
(c) The inclusion of additional members for specific product categories on an MCP approved by the Authority provided those members use all specific mechanisms, tests and processes itemized on the approved MCP for those product categories.
(15) The Authority may impose an MCP review fee under OAR 333-016-2080(1)(b)(B) for review of a request to amend an approved MCP.
(16) Within 90 days the Authority will inform the holder of the approved exemption request if the proposed amendment to the MCP still meets the standards for exemption as described in these rules.
(17) Trade associations seeking to include additional members on an MCP approved by the Authority in accordance with subsection (14)(c) of this rule shall submit a new exemption request as specified in section (3) of this rule. A request to add a member manufacturer to an approved MCP must include the product categories for which each member manufacturer is seeking exemption from these rules.
(18) A trade association must notify the Authority within 90 days of the date it determines a manufacturer member listed on an approved MCP is no longer party to an approved MCP.
(19) An approved MCP is only valid for the manufacturer that submitted it for approval. If a manufacturer with an approved MCP merges with or is acquired by another business entity the new controlling entity must send a notice to the Authority within 90 days confirming that the specific mechanisms, tests and processes itemized in the previously approved MCP will continue to be utilized, or the exemption will be considered by the Authority to be invalid.

STATUTORY/OTHER AUTHORITY: ORS 413.042, 431A.258, 431A.268

STATUTES/OTHER IMPLEMENTED: ORS 431A.258, 431A.268

AMEND: 333-016-3010

RULE TITLE: Removal or Substitution of High Priority Chemicals

NOTICE FILED DATE: 10/31/2024

RULE SUMMARY: Amends OAR 333-016-3010 Removal or Substitution of High Priority Chemicals. This clarifies the date on which manufacturers must submit notice under this rule.

RULE TEXT:

(1) On or before the date on which a manufacturer of a children's product must submit the third biennial notice required under OAR 333-016-2060 for a high priority chemical of concern to children's health (HPCCCH) that is present in a children's product, the manufacturer must remove or make a substitution, or seek a waiver under OAR 333-016-3040 if the HPCCCH is present in a children's product that is:

(a) Mouthable;

(b) A children's cosmetic; or

(c) Made for, marketed for use by or marketed to children under three years of age.

(2) A manufacturer with 25 or fewer employees may apply for a two-year extension of the date specified in ORS 431A.260 to meet the requirements of these rules. To apply for an extension a manufacturer must submit a request for an extension. A request for an extension must:

(a) Be received by the Oregon Health Authority (Authority) on or before the date on which the manufacturer of a children's product is obligated to submit the third biennial notice required under ORS 431A.260.

(b) Include documentation that the manufacturer had an average of 25 or fewer employees on its payroll during the third biennial notice period and the number of employees currently employed by the manufacturer.

(3) A manufacturer that has previously reported a HPCCCH to the Authority and later removes the HPCCCH from a children's product sold or offered for sale in Oregon and does not substitute another chemical or is no longer manufacturing such a product, must submit notice to the Authority that the manufacturer is no longer using the chemical or a substitute chemical or manufacturing the product. The notice must be submitted on or before the date (January 31st) on which the requirement to remove or substitute a HPCCCH from a children's product is triggered under ORS 431A.260. The notice shall include

(a) The product category of the children's product;

(b) The brand names under which it is sold in Oregon and the model numbers of the children's product associated with those brand names; and

(c) Universal Product Code or Stock Keeping Unit codes, style codes or other mechanisms sufficient to identify product models sold in Oregon, which have been assigned by the manufacturer.

(4) From the date that the notice under section (3) of this rule is submitted, the manufacturer has 90 calendar days to:

(a) Cease selling or offering for sale in Oregon the children's product; and

(b) Provide notice to all known distributers and retailers to whom the product was distributed that the product may no longer be sold or offered for sale in Oregon. To identify affected units of such children's products, the notice shall include Universal Product Code, Stock Keeping Unit codes, style codes or other mechanisms sufficient to identify the affected product models.

(5) Units identified in this rule may no longer be sold or offered for sale in Oregon.

(6) Manufacturers shall provide the Authority with the notice in subsection (4)(b) of this rule and a list of known distributers and retailers to whom notice was given.

(7) A manufacturer that intends to substitute a HPCCCH pursuant to ORS 431A.263 must comply with OAR 333-016-3030.

STATUTORY/OTHER AUTHORITY: ORS 413.042, ORS 431A.260, ORS 431A.268

STATUTES/OTHER IMPLEMENTED: ORS 431A.260

AMEND: 333-016-3015

RULE TITLE: Exemptions from Removal or Substitution Requirements

NOTICE FILED DATE: 10/31/2024

RULE SUMMARY: Amends OAR 333-016-3015 Exemptions from Removal or Substitution Requirements. This clarifies the requirements for exemptions under this rule. It specifies the requirements for a manufacturer, which already has an approved list of products exempted under this rule, to add additional product models, which are chemically identical to one or more models on the approved list.

RULE TEXT:

(1) For purposes of this rule "children's product" is a children's product as defined in ORS 431A.253 that is:

(a) Mouthable;

(b) A children's cosmetic; or

(c) Made for, marketed for use by or marketed to children under three years of age.

(2) A manufacturer is exempt from meeting the requirement of removal or substitution of a high priority chemical of concern to children's health (HPCCCH) in a children's product under ORS 431A.260 if one or more of the following is met:

(a) The children's product contains a HPCCCH used in children's products at levels that are at or below allowable levels for children's products as established by the Consumer Product Safety Improvement Act of 2008, P.L. 110-314, 122 Stat. 3016, as in effect on July 27, 2015.

(b) A manufacturer is in compliance with a federal consumer product safety standard adopted under federal law that establishes allowable levels for children's products of a high priority chemical of concern for children's health used in children's products.

(c) The State of Washington has granted an exemption for the removal or substitution of a HPCCCH in the same children's product model for which the exemption is requested under OAR 333-016-3015.

(d) A children's product has been tested under applicable EN-71 standards, by a laboratory that is accredited to conduct such testing under the current edition of ISO/IEC 17025 by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation mutual recognition arrangement.

(3) More than one product model may be submitted in a single exemption request.

(4) In order to be exempt under one or more of the categories in section (2) of this rule a manufacturer must submit:

(a) An exemption request on a form prescribed by the Oregon Health Authority (Authority);

(b) The fees specified in OAR 333-016-2080(1)(e);

(c) The information required in OAR 333-016-3010(3)(a) through (c), for the product models as they are sold in Oregon for which exemption is being requested; and

(d) Written documentation supporting the exemption request, including but not limited to an electronic copy of the certificate of conformity issued by the applicable authority or an authorized designate, if available, and evidence that the children's product meets the standards described in the applicable exemption category including:

(A) For an exemption request under subsection (2)(a) of this rule, the citation for the section of the Consumer Product Safety Improvement Act of 2008, P.L. 110-314, 122 Stat. 3016, in effect on July 27, 2015, naming the HPCCCH.

(B) For an exemption request under subsection (2)(b) of this rule, a citation to the federal consumer product safety standard adopted under federal law that establishes an allowable level of a HPCCCH in children's products, specific to allowable levels of the HPCCCH in children's products.

(C) For an exemption request under subsection (2)(c) of this rule, a copy of the manufacturer's request for exemption under the applicable State of Washington law and the exemption approval from that state.

(D) For an exemption request under subsection (2)(d) of this rule, an electronic copy of an actual European Community/European Union Declaration of Conformity issued for the product or products for which exemption is being requested, establishing that the product or products meets current EN-71 standards applicable to the HPCCCH and product type for which an exemption is being sought.

(5) This written documentation must be submitted in its entirety to the Authority on or before the date on which the manufacturer is required to submit the third biennial notice under ORS 431A.258 and OAR 333-016-2060.
(6) The Authority will approve or disapprove an exemption request made under section (2) of this rule in writing within 180 days from receipt of all of the documentation required in the rule, explaining the basis of the approval or denial.
(a) If the Authority does not approve or disapprove the exemption request made under section (2) of this rule within 180 days of its submission, the exemption is deemed approved.
(b) If disapproved, a manufacturer may not resubmit an exemption request.
(7) If a manufacturer is granted an exemption under subsection (2)(c) of this rule and subsequently the State of Washington withdraws the approval for the exemption, the manufacturer must immediately notify the Authority and come into compliance with ORS 431A.260 and these rules.
(8) A manufacturer may request to add additional children's products to an approved list of exempted products if the following apply:
(a) The chemical composition of the new product is uniform in composition and chemically identical to those specified in the approved request and differ only in ways that do not affect the HPCCCH's behavior in the product;
(b) There are not any HPCCCHs at or above de minimis in the new product in addition to those in the approved list of exempted product(s); and
(c) Neither the concentration of the HPCCCH nor its mobility from the product has increased from those products in the approved list of exempted product(s).
(9) To request an addition to an approved list of exempted products, manufacturers shall submit the following to the Authority:
(a) A copy of the current Oregon Health Authority approved list of exempted products;
(b) An application form, provided by the Authority, with the signature of an authorized representative of the manufacturer, with the knowledge and authority to attest to the veracity of the information submitted under section (9) of this rule; and
(c) Identification of products proposed to be added, consistent with section (4)(c) of this rule

STATUTORY/OTHER AUTHORITY: ORS 413.042, ORS 431A.260

STATUTES/OTHER IMPLEMENTED: ORS 431A.260

AMEND: 333-016-3020

RULE TITLE: Requirements for Chemical Substitution

NOTICE FILED DATE: 10/31/2024

RULE SUMMARY: Amends OAR 333-016-3020 Requirements for Chemical Substitution per ORS 431A.263 (HB 3043, SECTION 5), by requiring that a Hazard Assessment (HA), approved or deemed approved, under this rule is valid for three years after submitted to the Oregon Health Authority (Authority). At the end of that period, manufacturers must resubmit a valid HA for the products with the substitute chemical to be in compliance with the chemical substitution provision in statute (ORS 431A.260). Under current rule, HAs for products containing substitute chemicals are approved in perpetuity. The amendment also clarifies that selling or offering for sale products with a substitute chemical that are not specified in an approved HA is a violation of this rule and subjects the manufacturer to penalties.

RULE TEXT:

(1) For purposes of this rule a "children's product" is a children's product as defined in OAR 333-016-3015(1) that is:

(a) Mouthable;

(b) A children's cosmetic; or

(c) Made for, marketed for use by or marketed to children under three years of age.

(2) When a manufacturer of a children's product that is sold or offered for sale in Oregon removes a high priority chemical of concern to children's health (HPCCCH) as required in ORS 431.260 and intends to sell the product in Oregon with a substitute chemical, the manufacturer must provide or submit to the Oregon Health Authority (Authority) no later than the date (January 31st) on which the requirement to remove or substitute a HPCCCH from a children's product is triggered under ORS 431A.260:

(a) A Hazard Assessment (HA) that meets the requirements in OAR 333-016-3030; and

(b) The fees specified in OAR 333-016-2080.;

(3) The Authority must either approve or disapprove a HA within 180 days of the receipt of a HA and the information and fees required in section (2) of this rule.

(4) During its review of the HA the Authority may request additional information from the manufacturer at any time and must specify the time period by which the manufacturer must provide the requested information.

(5) If the Authority does not approve or disapprove the HA within 180 days from receipt of all of the information and fees required in section (2) of this rule the HA is deemed approved and the manufacturer may continue to sell or offer for sale in Oregon the children's product for which the manufacturer submitted a HA.

(6) A HA approved or deemed approved under this rule is valid for a period of three years after the date of submittal of the HA. A manufacturer must resubmit a HA at the end of the three-year period. Any report upon which the resubmitted HA is based must contain a statement that evidence is of such a nature that it can be relied upon, based on current and credible scientific evidence, as specified by the entity conducting the HA, and that the evidence is of such a nature that it can be relied upon for a minimum of three years from the date the report was issued. A HA that has been approved or deemed approved for the same substitute chemical for a total of six years does not need to be submitted a third time.

(7) If the Authority approves the HA it will notify the manufacturer of the approval, in writing.

(8) If the Authority disapproves a HA it will provide written notice to the manufacturer of the disapproval and the basis for the disapproval.

(9) If the Authority disapproves a HA the manufacturer may submit a revised HA within 180 days after the date of the Authority's notice of disapproval that meets the requirements of this rule. The payment of non-refundable fees in OAR 333-016-2080 is not required for a resubmitted HA.

(10) A revised HA is subject to the same requirements as an initial HA under this rule and the Authority will review and approve or disapprove a revised HA in the same manner as an initial HA.

(11) If the Authority disapproves an initial HA and no revised HA is submitted, the manufacturer has 90 calendar days to comply with OAR 333-016-3010(4) through (6).

(12) The Authority will not consider any additional information it did not request that has been provided by a manufacturer and received by the Authority more than seven business days after the revised HA conducted with an alternative hazard assessment methodology (OAR 333-016-3030(4)) is submitted to the Authority.
(13) A manufacturer may request a HA for one or more product models or styles.
(14) If a manufacturer requests a HA for more than one product model or style, the Authority may approve or disapprove a request in whole or in part, based on criteria established in these rules.
(15) Trade associations may submit a HA on behalf of specified member manufacturers if the following conditions are met for each HA submitted:
(a) The HA meets the requirements in OAR 333-016-3030;
(b) The fees are paid as specified in OAR 333-016-2080; and
(c) The products are identified on which a HA has been conducted for each participating manufacturer as specified in OAR 333-016-3010(3)(a) through (c). This list of identified products shall include the name and contact information of a representative for each specified member manufacturer.
(16) It is a violation of this rule to continue to sell or offer for sale in Oregon a children's product with a substitute chemical without an approved or deemed approved HA.

STATUTORY/OTHER AUTHORITY: ORS 413.042, ORS 431A.263

STATUTES/OTHER IMPLEMENTED: ORS 431A.263

AMEND: 333-016-3080

RULE TITLE: Enforcement and Civil Penalties

NOTICE FILED DATE: 10/31/2024

RULE SUMMARY: Amends OAR 333-016-3080 Enforcement and Civil Penalties to clarify the conditions under which a manufacturer may be in violation of the high priority chemicals of concern for children's health (HPCCCH) removal provision of the Toxic Free Kids Act (ORS 431A.260).

RULE TEXT:

(1) The Oregon Health Authority (Authority) may impose a civil penalty on a manufacturer for a violation of any provision of ORS 431A.258, 431A.260 or 431A.263, or these rules. A civil penalty may not exceed:

(a) $2,500 for the first violation.

(b) $5,000 for the second and each subsequent violation.

(2) For purposes of assessing civil penalties under these rules a violation consists of a single course of conduct with regard to an entire children's product line that is sold or offered for sale in Oregon.

(3)(a) If a manufacturer violates the notification requirement described in ORS 431A.258 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.258 within 90 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 $2,500.

(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 $5,000. 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 sell or offers for sale a product for which a chemical was required to be removed under ORS 431A.260, and the manufacturer does not have an approved, or deemed approved waiver or hazard assessment request, 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:

(A) Ceasing to sell or offer the product for sale; and

(B) Contacting any known entities who are distributing or selling the product in Oregon, advising them that the product can no longer be sold in Oregon, and providing documentation of those notifications to the Authority in accordance with OAR 333-016-3010(4) through (6); or

(C) Submitting proof to the Authority that it is not in violation as alleged in the notice.

(b) 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 $2,500.

(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 $5,000. The Authority is not required to provide the manufacturer with an opportunity to cure the continuing violation before imposing the separate civil penalty.

(5) If the Authority has reason to believe that a children's product that contains a high priority chemical of concern to children's health (HPCCCH) used in children's products is being sold or offered for sale in Oregon in violation of ORS 431A.258, 431A.260 or 431A.263 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 30 days after receipt of a request. To prove compliance with ORS 431A.258, 431A.260 and 431A.263, the manufacturer must provide the Authority with proof that:

(a) The children's product does not contain the HPCCCH at or above de minimis levels; or

(b) The manufacturer has previously provided the Authority with notice as required by ORS 431A.258; or

(c) The manufacturer is providing notice as required by ORS 431A.258; or

(d) The manufacturer or trade association has provided the Authority with an exemption request approved by the

Authority under ORS 431A.260; or
(e) The manufacturer possesses a hazard assessment for a substitution approved by the Authority for the HPCCCH and products in question under ORS 431A.263; or
(f) The manufacturer possesses a waiver for the HPCCCH and products in question approved by the Authority under ORS 431A.265.
(6) Providing a notice under subsection (5)(c) of this rule does not exempt the manufacturer from compliance with the timelines for removal or substitution under ORS 431A.260, OAR 333-016-3015, ORS 431A.263, or OAR 333-016-3030.
(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.
(h) The manufacturer's declaration that a HPCCCH used in a children's product is present only as a contaminant, and the manufacturer is able to provide evidence that a manufacturing control program for the contaminant that meets or exceeds the minimum requirements for a manufacturing control program in OAR 333-016-2070, which was approved by the Authority, was in place prior to the violation and that the manufacturer has exercised due diligence.
(i) Civil penalties will be imposed in the manner provided in ORS 183.745.
(8) The Authority will enforce the reporting requirements against a manufacturer in the same order as the priority order for reporting in OAR 333-016-2060(11).

STATUTORY/OTHER AUTHORITY: ORS 413.042, ORS 431A.275

STATUTES/OTHER IMPLEMENTED: ORS 431A.275