

OREGON ADMINISTRATIVE RULES  
OREGON HEALTH AUTHORITY, PUBLIC HEALTH DIVISION  
CHAPTER 333

**DIVISION 16**

**HAZARDOUS SUBSTANCES**

**333-016-2035**

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

- (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. [Exhibit A not included. See ED. NOTE.]

[ED. NOTE: Exhibit A referenced is not included in rule text. [Click here for PDF copy of Exhibit A](#)]

Stat. Auth: ORS 413.042

Stats. Implemented: ORS 431A.253–431A.280

**333-016-2040**

**Purpose and Scope**

OAR 333-016-2035 through 333-016-2090:

- (1) Require manufacturers of children's products to disclose high priority chemicals of concern for children's health used in children's products, unless the manufacturer is exempt;
- (2) Establish requirements for disclosure;
- (3) Establish a process for a manufacturer to apply for an exemption from the disclosure requirements; and
- (4) Describe the Authority's civil penalty authority and enforcement process.

Stat. Auth: ORS 413.042

Stats. Implemented: ORS 431A.253–431A.280

**333-016-2050**

**Definitions**

- (1) "Authority" means the Oregon Health Authority.
- (2) "Chemical" has the meaning given that term in ORS 431A.253.
- (3) "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.
- (4) "Child" means an individual under 12 years of age.
- (5) "Children's product" has the meaning given that term in ORS 431A.253.
- (6) "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).
  - (7) "Contaminant" has the meaning given that term in ORS 431A.253.
  - (8) "De minimis level" has the meaning given that term in ORS 431A.253.
  - (9) "HPCCCH" means high priority chemicals of concern to children's health.
  - (10) "High priority chemicals of concern list" means the high priority chemicals of concern for children's health identified by the Authority in OAR 333-016-2020.
  - (11) "Intentionally added chemical" has the meaning given that term in ORS 431A.253.
  - (12) "Manufacturer" has the meaning given that term in ORS 431A.253
  - (13) "Manufacturing control program" means a program implemented by the manufacturer or its suppliers to control the amount of a high priority chemical of concern in children's products present as a contaminant at or above de minimis 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.
  - (14) "Mouthable" has the meaning given that term in ORS 431A.253.
  - (15) "Owner" for purposes of clarifying the definition of "manufacturer" means the first person or entity, whether an importer or a distributor, that first offers the children's product for sale in Oregon.
  - (16) "Practical quantification limit" has the meaning given that term in ORS 431A.253.
  - (17) "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.
  - (18) "These rules" means OAR 333-016-2040 to 333-016-2100.
  - (19) "Trade association" has the meaning given that term in ORS 431A.253.
- Stat. Auth: ORS 413.042  
Stats. Implemented: ORS 431A.253–431A.280

### **333-016-2060**

#### **Notification Requirements**

- (1) No later than January 1, 2018, and every other year thereafter, a manufacturer of a children's product sold or offered for sale in this state that contains a HPCCCH listed in OAR 333-016-2020 in an amount at or above a de minimis level must submit a notice to the Authority that contains all the information required in these rules, unless the manufacturer or product is exempt.
- (2) 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.
- (3) Future notices apply to children's products sold or offered for sale during the previous two year period. For example, for the reporting year 2020, a manufacturer must include children's products sold or offered for sale between January 1, 2018, and December 31, 2019, that contain a HPCCCH listed in OAR 333-016-2020.
- (4) The notice required in section (1) 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) A description of the function of the chemical in the children's product;
  - (d) The amount of the chemical used in each unit of the children's product reported as a range rather than an exact amount;
  - (e) The name and address of the manufacturer, and the name, address and telephone number of the contact person for the manufacturer; or
  - (f) The name, address and contact information for the trade association submitting the notification on behalf of the affected industry; and
  - (g) Any other information that the manufacturer deems relevant to the appropriate use of the children's product.
- (5) The second biennial notice will cover the period of January 1, 2018 through December 31, 2020.
- (6) 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 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.
- (7) A trade association may provide the notice required in these rules on behalf of a member manufacturer.
- (8) A trade association who fulfills the notice or exemption requirements of 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.
- (9) 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.

Stat. Auth: ORS 413.042, 431A.258

Stats. Implemented: ORS 431A.258

### **333-016-2070**

#### **Exemptions from Notice Requirement**

- (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 Authority a request for an exemption from these rules if the HPCCCH in a children's product is present only as a contaminant at or above the de minimis level, and a manufacturing control program is in place.
- (4) In order to meet the standards for an exemption a manufacturing control program 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 must document in its exemption request the specific HPCCCH present as a contaminant at or above the de minimis level that the manufacturing control program is intended to address and the product categories where the HPCCCH are found.
- (6) In order for the manufacturer to demonstrate that a manufacturing control program meets the minimum standards for an exemption, the manufacturing control program 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), EN 79.
  - (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) In addition to meeting one of the requirements of subsections (6)(a) through (d) of this rule a manufacture 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 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;
  - (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.
- (8) 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.
- (9) 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.
- (10) 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.
- (11) At any time the Authority may request additional information from a manufacturer requesting an exemption.
- (12) If a manufacturer submits information to the Authority as part of its request for an exemption under this rule that the manufacturer believes is a trade secret, the manufacturer must mark the information "confidential – trade secret."
- (a) If the Authority receives a public records request for records related to a request for an exemption under this rule, it will review all documents submitted by the manufacturer to determine whether the documents contain trade secrets that would be exempt from disclosure under Oregon's Public Records Act, ORS 192.501(2).
- (b) For purposes of this section "trade secret" has the meaning given that term in ORS 192.501(2).

Stat. Auth: ORS 413.042, 431A.258, 431A.268

Stats. Implemented: 431A.258, 431A.268

### **333-016-2090**

#### **Enforcement and Civil Penalties**

- (1) The Authority may impose a civil penalty on a manufacturer for a violation of any provision of ORS 431A.258 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 this state.
- (3) 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.
  - (a) 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. 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) If the Authority has reason to believe that a children's product that contains a HPCCH used in children's products is being sold or offered for sale in this state in violation of ORS 431A.258

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 days after receipt of a request. To prove compliance with ORS 431A.258 the manufacturer must provide:

- (a) Evidence that the children's product does not contain the HPCCCH used in children's products;
  - (b) Evidence that the manufacturer has previously provided the Authority with notice as required by ORS 431A.258 and these rules; or
  - (c) Provide the Authority with notice as required by ORS 431A.258 and OAR 333-016-2060.
- (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 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 was in place prior to the violation and that the manufacturer has exercised due diligence.
- (6) Civil penalties will be imposed in the manner provided in ORS 183.745.

Stat. Auth: ORS 431A.275

Stats. Implemented: ORS 431A.275