



Guidance for Requesting Exemption from Removal or Substitution Requirements per Oregon Administrative Rule (OAR) 333-016-3015

Under Oregon’s Toxic-Free Kids Act (TFKA) ([Oregon Revised Statute \(ORS\) 431A.250](#)) beginning January 1, 2018, manufacturers¹ of children’s products sold or offered for sale in Oregon were required to notify the Oregon Health Authority (Authority) of products that contain one or more [High Priority Chemicals of Concern for Children’s Health](#) (HPCCCH) in an amount at or above the de minimis level.² Notifications must be made biennially; be at the ‘product category’ (GS1 ‘brick’) level; and completed using the [High Priority Chemicals Data System](#) (HPCDS). OAR 333-016-2060. Manufacturers are responsible for knowing the concentrations of HPCCCHs in their children’s products.

On or before the date on which a manufacturer of a children’s product submits the third biennial notice for a product category(ies), that manufacturer must remove or substitute HPCCCH(s) present in a subset of children’s products in that product category(ies), if these products are to be offered for sale in Oregon after that date. OAR 333-016-3010(1). That subset of children’s products are the following:

- “Mouthable” as that is defined in [ORS 431A.253](#); or
- A children’s cosmetic; or
- Made for, marketed for use by or marketed to children under three years of age.

Products in this subset, whose product category/HPCCCH combination has been reported in their third Biennial Notice/Reporting period, cannot be sold or offered for sale in Oregon on **January 1st** of their fourth Biennial Notice Period and beyond, unless a manufacturer has been granted for those

¹ As defined in Oregon’s Toxic-Free Kids statute (ORS 431A.253), “manufacturer” means any person that produces a children’s product or an importer or domestic distributor of a children’s product. This statute applies only to manufacturers with annual worldwide sales of \$5 million or more. See statute for additional details on reporting.

² Per ORS 431A.253, “de minimis level” means: (a) for a chemical that is an intentionally added chemical, that chemical’s practical quantification limit in OAR [333-016-2035](#) ; or (b) for a chemical that is a contaminant, a concentration of 100 parts per million.

products, one or more of the following: an exemption under OAR [333-016-2070](#) or OAR [333-016-3015](#) ; a chemical substitution request under OAR [333-016-3020](#); or a waiver under OAR [333-016-3040](#). Enforcement of OAR [333-016-3010\(5\)](#) is “paused” for such products and they may continue to be sold in Oregon until OHA’s review of these requests is complete.

Exemption Process under OAR 333-016-3015

Manufacturers can apply for an exemption from the removal or substitution requirement upon a simple showing that they comply with other laws.

OAR [333-016-3015\(2\)](#) has four exemption categories or pathways -- by which manufacturers may request an exemption from the HPCCCH removal or substitution requirements for specified products.

An exemption request must:

- Specify the products for which an exemption is being requested.
- Identify the appropriate exemption category in OAR 333-016-3015 [\(2\)\(a\),\(b\),\(c\) or \(d\)](#); and
- Provide documentation required under the corresponding rule section, OAR 333-016-3015 [\(4\)\(a\),\(b\),\(c\) or \(d\)](#).

More than one product model may be submitted in a single exemption request and the \$1500 exemption fee may cover multiple products.

Please see [Frequently Asked Question #41](#) for information on submitting requests under OAR 333-016-3015. The Authority must approve or disapprove the request in writing within 180 days of receipt of the documentation and fee, or the request is deemed approved. OAR [333-016-3015\(7\)](#).

Documentation to Satisfy OAR 333-016-3015(4)

The four exemption categories in OAR [333-016-3015\(2\)](#) allow for children’s products containing HPCCCHs, which have already met specific regulatory standards, to be exempt from the removal or substitution requirements of the TFKA. The categories and the documentation required in their corresponding subsections of OAR [333-016-3015\(4\)](#) are specific to certain HPCCCHs and children’s products.

The examples below may assist manufacturers in applying for an exemption:

- OAR [333-016-3015\(4\)\(a\)](#): *For an exemption request under subsection (2)(a) of this rule, a manufacturer must include a citation for the section of the Consumer Product Safety Improvement Act of 2008 (CPSIA), P.L. 110-314, 122 Stat. 3016, in effect on July 27, 2015, naming the HPCCCH, that the manufacturer is in compliance with.*

Federal law permits concentrations of some HPCCCHs in children's products that are higher than the de minimis levels defined by the TFKA (ORS 431A.253). The Consumer Product Safety Commission (Commission) requires that a manufacturer have a children's product certificate (CPC) stating that its product complies with all applicable Commission safety rules for children's products. Certification of children's products must be based upon the passing test results of third-party testing. A CPC will identify separately each children's product safety rule that applies to the children's product. The CPC will serve as sufficient documentation that a manufacturer is in compliance with the CPSIA.

- OAR [333-016-3015\(4\)\(b\)](#): *For an exemption request under subsection (2)(b) of this rule, a manufacturer must include 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 product, that the manufacturer is in compliance with.*

This pathway is broader than that of OAR [333-016-3015\(4\)\(a\)](#).

Mechanisms for locating federal consumer product safety standards in effect include:

- <https://www.ecfr.gov/>
- <https://www.federalregister.gov/>
- OAR [333-016-3015\(4\)\(c\)](#): *For an exemption request under subsection (2)(c) of this rule, a manufacturer must include a copy of the manufacturer's request for exemption under the applicable State of Washington law and the exemption approval from that state.*

Consumer products, including children's products, sold in Oregon are often sold in the State of Washington. If a Washington state agency has

granted an exemption as described above, that request and the agency's approval may be submitted as documentation to satisfy this exemption pathway.

- Exemptions granted under the [Revised Code of Washington Chapter 70.365](#) may be utilized to satisfy OAR [333-016-3015\(4\)\(c\)](#).
- OAR [333-016-3015\(4\)\(d\)](#): *For an exemption request under subsection (2)(d) of this rule, a manufacturer must provide an electronic copy of a certificate 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.*

EN-71 is the standard that all children's toys sold in the European Union (EU) must meet. Some HPCCCHs are also regulated under the current EN-71 standard. If a children's toy containing a HPCCCH sold or offered for sale in Oregon meets the applicable EN-71, it may exempt under OAR [333-016-3015\(2\)\(d\)](#).

To be approved for an exemption under OAR [333-016-3015\(2\)\(d\)](#), an electronic copy of the actual certificate of conformity/declaration of conformity issued by an accredited laboratory for the specified product must be submitted in a manufacturer's request.

EN-71 resources include:

- <https://www.en-standard.eu/>
- Internet searches of "EN-71 accredited laboratories" will yield candidate laboratories that may be accredited to do such conduct such testing. It is the responsibility of the manufacturer to confirm that the laboratory with which they contract is accredited per OAR [333-016-3015\(2\)\(d\)](#).

Questions?

Please contact the Authority's [Toxic-Free Kids Program](#) at toxicfreekids.program@odhsoha.oregon.gov or 971-673-0977.