

Chapter 173-334 WAC

CHILDREN'S SAFE PRODUCTS - REPORTING RULE

NEW SECTION

WAC 173-334-010 Introduction. Under the Children's Safe Product Act (CSPA), chapter 70.240 RCW, manufacturers of children's products are required to notify the department of ecology when a chemical of high concern to children (CHCC) is present in their products or, if the product contains more than one component, each product component.

The presence of a CHCC in a children's 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. The reported information will help fill a data gap that exists for both consumers and agencies.

The CSPA requires the department of ecology in consultation with the department of health to identify a list of chemicals for which manufacturers of children's products are required to provide notice. The CSPA specifies both the characteristics of these chemicals and the notice requirements.

NEW SECTION

WAC 173-334-020 What is the purpose of this chapter? The purpose of this chapter is to:

(1) Establish the list of chemicals for which manufacturer notice is required;

(2) Establish what manufacturers of children's products must do to comply with the notice requirements created by the CSPA; and

(3) Clarify the enforcement processes the department of ecology will use if manufacturers fail to provide notice as required.

NEW SECTION

WAC 173-334-030 To whom does this chapter apply? This chapter applies to manufacturers of children's products.

NEW SECTION

WAC 173-334-040 What definitions apply to terms used in this chapter? "Chemical Abstracts Service 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*.

"CHCC list" means the reporting list of chemicals that the department has identified as high priority chemicals of high concern for children.

"Child" means an individual under twelve.

"Children's product" has the same meaning as defined in RCW 70.240.010.

(a) For the purposes of this rule, children's products only include products that are sold, or are to be offered for sale, to consumers in the state of Washington.

(b) In addition to the exemptions specified in RCW 70.240.010, for the purposes of this rule, "children's product" does not include over the counter drugs, prescription drugs, food, dietary supplements, packaging, medical devices, or products that are both a cosmetic and a drug regulated by the Food and Drug Administration.

(c) A product label that includes usage instructions for use of a product that apply to children does not in and of itself establish that the product is a children's product.

"Contaminant" means trace amounts of chemicals that are incidental to manufacturing. They serve no intended function in the product component. They can include, but are not limited to, unintended by-products of chemical reactions during the manufacture of the product component, trace impurities in feed-stock, incompletely reacted chemical mixtures, and degradation products.

"Department of health" means the Washington state department of health.

"Intentionally added chemical" means a chemical in a product that serves an intended function in the product component.

"Manufacturer" means the producer, importer, or wholesale domestic distributor of a children's product and is more specifically defined in RCW 70.240.010. For the purposes of this rule, a retailer of a children's product is not a manufacturer unless it is also the producer, manufacturer, importer, or domestic distributor of the product.

"Mouthable" means able to be brought to the mouth and kept in

the mouth by a child so that it can be sucked and chewed. If the product can only be licked, it is not able to be placed in the mouth. If a product or part of a product in one dimension is smaller than five centimeters, it can be placed in the mouth.

"Practical quantification limit (PQL)" means the lowest concentration that can be reliably measured within specified limits of precision, accuracy, representativeness, completeness, and comparability during routine laboratory operating conditions. This value is based on scientifically defensible, standard analytical methods. The value for a given chemical could be different depending on the matrix and the analytical method used.

"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.

"Product component" 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.

NEW SECTION

WAC 173-334-050 What is the purpose of the CHCC list? The CHCC list identifies the chemicals to which the notice requirements apply. A manufacturer must notify the department in accordance with WAC 173-334-080 if a chemical on the CHCC list is present in a children's product component. The current CHCC list is set forth in WAC 173-334-130.

NEW SECTION

WAC 173-334-060 How can the department revise the CHCC list? The department can only add chemicals to, or remove chemicals from, the CHCC list by amending this rule in accordance with the requirements of the Administrative Procedure Act, chapter 34.05 RCW.

NEW SECTION

WAC 173-334-070 How will the department identify chemicals for inclusion in the CHCC list? (1) The department will consult with the department of health during the modification of the CHCC list.

(2) A chemical that the department determines to meet all of the following criteria may be included on the CHCC list:

(a) The toxicity, persistence, or bioaccumulativity criteria specified in RCW 70.240.010(6); and

(b) The exposure criteria specified in RCW 70.240.030(1).

(3) The department will consider both the parent chemical and its degradation products when deciding whether a chemical meets the criteria of this section. If a parent chemical does not meet the criteria in this section but degrades into chemicals that do, the parent chemical may be included on the CHCC list.

(4) A person may submit a petition for consideration by the department to add a chemical to or remove a chemical from the CHCC list. The petition must provide the following information:

(a) Chemical Abstracts Service registry number;

(b) Chemical prime name; and

(c) Credible peer-reviewed scientific information documenting why the chemical meets or fails to meet the criteria required for inclusion on the list.

(5) The department shall review petitions in accordance with RCW 34.05.330, the Administrative Procedure Act.

NEW SECTION

WAC 173-334-080 What must the manufacturer include in its notice to the department? (1) The notice required by RCW 70.240.040 must be filed annually with the department in accordance with the following:

(a) Each chemical on the CHCC list that is an intentionally added chemical present in a product component must be reported at any concentration above the PQL.

(b) Each chemical on the CHCC list that is a contaminant present in a product component must be reported at any concentration above 100 ppm.

(c) A manufacturer need not file a notice with respect to any CHCC that occurs in a product component only as a contaminant if the manufacturer had in place a manufacturing control program and exercised due diligence to minimize the presence of the contaminant in the component.

(2) The notice must include all of the following information:

(a) The name of the CHCC and its Chemical Abstracts Service registry number.

(b) The product category or categories in which it occurs.

(c) The product component or components within each product category in which it occurs.

(d) A brief description of the function, if any, of the CHCC in each product component within each product category.

(e) The total amount of the CHCC by weight contained in each product component within each product category. The amount may be reported in ranges, rather than the exact amount. If there are multiple CHCC values for a given component in a particular product category, the manufacturer must use the largest value for reporting.

For the purpose of this rule, the reporting ranges are as follows:

(i) Equal to or more than the PQL but less than 100 ppm (0.01%);

(ii) Equal to or more than 100 ppm (0.01%) but less than 500 ppm (0.05%);

(iii) Equal to or more than 500 ppm (0.05%) but less than 1,000 ppm (0.10%);

(iv) Equal to or more than 1,000 ppm (0.10%) but less than 5,000 ppm (0.5%); or

(v) Equal to or more than 5,000 ppm (0.5%) but less than 10,000 ppm (1.0%); or

(vi) Equal to or more than 10,000 ppm (1.0%).

(f) The name and address of the reporting manufacturer or trade organization and the name, address and phone number of the contact person for the reporting manufacturer or trade organization. When a trade organization is the reporting party, the report must include a list of the manufacturers on whose behalf the trade organization is reporting, and all of the information that would otherwise be required of the individual manufacturers.

(g) Any other information the manufacturer deems relevant to the appropriate use of the product.

(3) Reporting parties are not required to include either:

(a) Any specific formula information; or

(b) The specific name and address of the facility which is responsible for the introduction of a CHCC into a children's product or product component.

(4) If a reporting party believes the information being provided is confidential business information (CBI), in whole or in part, it may request that the department treat the information as confidential business information as provided in RCW 43.21A.160. The department will use its established procedures to determine how it will handle the information.

(5) The department will make available the current version of the web form to be used for reporting on CHCCs. This same form may be used by the reporting party to flag the submitted information it thinks should be treated as CBI. The web form must be used when providing notification.

(6) Any information that is not determined to be confidential business information will be available to the public. As resources allow, the department will post this information on the department's web site.

NEW SECTION

WAC 173-334-090 Who is required to provide notice to the department? (1) The manufacturer of a children's product, or a trade organization on behalf of its member manufacturers, must provide notice to the department that the manufacturer's children's product component contains a chemical on the CHCC list.

(2) The definition of manufacturer in RCW 70.240.010 includes any person or entity that produces a children's product, any importer that assumes ownership of a children's product, and any domestic distributor of a children's product. However, it is only necessary for one person or entity to provide notice with respect to a particular children's product.

The following hierarchy will determine which person or entity the department will hold primarily responsible for ensuring that the department receives a complete, accurate, and timely notice for the children's product:

(a) The person or entity that had the children's product designed or manufactured, unless it has no presence in the United States.

(b) The person or entity that marketed the children's product under its name or trademark, unless it has no presence in the United States.

(c) The first person or entity, whether an importer or a distributor, that owned the children's product in the United States.

NEW SECTION

WAC 173-334-100 What time period is covered by the notice? Manufacturers must provide notice as required by WAC 173-334-110 on an annual basis for children's products that have been manufactured for sale in Washington during the twelve-month period that precedes the applicable due date for first notices set out in WAC 173-334-110(2). If the reporting party determines that there has been no change in the information required to be reported since the prior annual notice, the party may submit a written statement indicating that the previous reported data is still valid, in lieu of a new duplicate complete notice.

If a CHCC is subsequently removed from the children's product component for which notice was given, the manufacturer may provide notice to the department. Such updated notices will be documented in the department's records.

NEW SECTION

WAC 173-334-110 When must manufacturers begin to provide notice? (1) This section establishes when manufacturers must first provide notice to the department if a children's product contains a chemical on the CHCC list. The notice requirement will be phased in as provided in the schedule set out in subsection (2) of this section based on the manufacturer categories and children's product tiers established in subsections (3) and (4) of this section. Manufacturers conducting safer alternative assessments for CHCCs may obtain an extension of the first notice date as provided in subsection (5) of this section. After the first notice date, notice must be provided annually on the anniversary of the first notice.

(2) The following table specifies when the first annual notice must be provided to the department in compliance with RCW 70.240.040. The due date will be determined by counting the number of months specified in the table, beginning with the first calendar month following the calendar month in which this rule is adopted. The notice will be considered delinquent if not received by the department by the last day of the month indicated.

Notice due dates from adoption date of rule, values are in months.

Manufacturer categories	Product Tier 1	Product Tier 2	Product Tier 3	Product Tier 4
Largest	12	18	24	case-by-case
Larger	18	24	36	case-by-case
Medium	24	36	48	case-by-case
Small	36	48	60	case-by-case
Smaller	48	60	72	case-by-case
Tiny	60	72	84	case-by-case

(3) For the purpose of this rule the department recognizes six categories of manufacturers. The categories of manufacturers are as follows:

(a) "Largest manufacturer" means any manufacturer of children's products with annual aggregate gross sales, both within and outside of Washington, of more than one billion dollars, based on the manufacturer's most recent tax year filing.

(b) "Larger manufacturer" means any manufacturer of children's products with annual aggregate gross sales, both within and outside of Washington, of more than two hundred fifty million but less than or equal to one billion dollars, based on the manufacturer's most recent tax year filing.

(c) "Medium size manufacturer" means any manufacturer of children's products with annual aggregate gross sales, both within and outside of Washington, of more than one hundred million but less than or equal to two hundred fifty million dollars, based on the manufacturer's most recent tax year filing.

(d) "Small manufacturer" means any manufacturer of children's products with annual aggregate gross sales, both within and outside of Washington, of more than five million but less than or equal to one hundred million dollars, based on the manufacturer's most

recent tax year filing.

(e) "Smaller manufacturer" means any manufacturer of children's products with annual aggregate gross sales, both within and outside of Washington, of more than one hundred thousand but less than or equal to five million dollars, based on the manufacturer's most recent tax year filing.

(f) "Tiny manufacturer" means any manufacturer of children's products with annual aggregate gross sales, both within and outside of Washington, of less than one hundred thousand dollars, based on the manufacturer's most recent tax year filing.

(4) For the purpose of this rule the department recognizes four tiers of products. The tiers or products are as follows:

(a) Tier 1 - children's products intended to be put into a child's mouth (e.g., children's products used for feeding, sucking, some toys) or applied to the child's body (e.g., children's products used as lotions, shampoos, creams), or any mouthable children's product intended for children who are age three or under.

(b) Tier 2 - children's products intended to be in prolonged (more than one hour) direct contact with a child's skin (e.g., clothes, jewelry, bedding).

(c) Tier 3 - children's products intended for short (less than one hour) periods of direct contact with child's skin (e.g., many toys).

(d) Tier 4 - children's product components that during reasonable foreseeable use and abuse of the product would not come into direct contact with the child's skin or mouth (e.g., inaccessible internal components for all children's products). Any reporting requirements for Tier 4 components will be based on a case-by-case evaluation by the department and may be required by amendment of these rules.

(5) If a manufacturer presents documentation to show that it is conducting safer alternative assessments for CHCCs contained in its children's products and that these assessments are intended to result in the elimination or significant reduction of CHCCs from the manufacturer's products, the department may extend by twelve months the reporting requirement for that manufacturer.

NEW SECTION

WAC 173-334-120 How will this chapter be enforced? (1) The department may collect children's products subject to possible reporting, and analyze their components for the presence of CHCCs. If the department finds that a children's product component contains a chemical on the CHCC list that the manufacturer either has not reported, or has reported at a lesser amount, the department will notify the manufacturer in writing. The department will then afford the manufacturer forty-five days from receipt of the department's notification to respond to the findings before the

department takes further enforcement action.

In determining whether a violation of the CSPA or these rules has occurred, the department will consider the manufacturer's timely explanation as to why it did not report the presence or accurate amount of the CHCC in the product component. If the manufacturer asserts that the CHCC is present in the component only as a contaminant, and that the manufacturer did not report the CHCC's presence based on WAC 173-334-080 (1)(c), then the manufacturer must present evidence that it conducted a reasonable manufacturing control program for the CHCC contaminant and exercised due diligence as described in subsections (2) and (3) of this section.

If the manufacturer contests the department's findings regarding the presence or amount of the CHCC in the product component, the manufacturer may further analyze the component in question for presence of CHCC and provide the department with a copy of its own laboratory findings for the component.

(2) Manufacturing control program. A reasonable manufacturing control program must include industry best manufacturing practices for the minimization of the CHCC in the children's product. Those practices may include, but are not limited to, methods and procedures for meeting relevant federal regulations, International Standards Organization (ISO) requirements, American Society for Testing and Materials (ASTM) standards, and other widely established certification or standards programs.

(3) Due diligence. Actions demonstrating due diligence in ensuring the effectiveness of a manufacturing control program may include the use and enforcement of contract specifications, procedures to ensure the quality/purity of feedstock (whether raw or recycled), the use and enforcement of contract specifications for manufacturing process parameters (e.g., drying and curing times when relevant to the presence of high priority chemicals in the finished children's product components), periodic testing for the presence and amount of CHCCs, auditing of contractor or supplier manufacturing processes, and other practices reasonably designed to ensure the manufacturer's knowledge of the presence, use, and amount of CHCCs in its children's product components.

(4) If the department determines based on the process described in subsection (1) of this section, or on other grounds, that a manufacturer has violated a requirement of the CSPA or these rules, it may require the manufacturer to pay a civil penalty. A manufacturer of children's products in violation of this chapter is subject to a civil penalty not to exceed five thousand dollars for each violation in the case of a first offense. Manufacturers who are repeat violators are subject to a civil penalty not to exceed ten thousand dollars for each repeat offense. Penalties collected under this section must be deposited in the state toxics control account created in RCW 70.105D.070.

(5) A single violation consists of a manufacturer failing to provide the required notice for the presence and accurate amount of each CHCC, in each applicable product category, in each applicable product component.

NEW SECTION

WAC 173-334-130 The reporting list of chemicals of high concern to children (CHCC list).

CAS	Chemical
50-00-0	Formaldehyde
62-53-3	Aniline
62-75-9	N-Nitrosodimethylamine
71-36-3	n-Butanol
71-43-2	Benzene
75-01-4	Vinyl chloride
75-07-0	Acetaldehyde
75-09-2	Methylene chloride
75-15-0	Carbon disulfide
78-93-3	Methyl ethyl ketone
79-34-5	1,1,2,2-Tetrachloroethane
79-94-7	Tetrabromobisphenol A
80-05-7	Bisphenol A
84-66-2	Diethyl phthalate
84-74-2	Dibutyl phthalate
84-75-3	Di-n-Hexyl phthalate
85-44-9	Phthalic anhydride
85-68-7	Butyl benzyl phthalate (BBP)
86-30-6	N-Nitrosodiphenylamine
87-68-3	Hexachlorobutadiene
94-13-3	Propyl paraben
94-26-8	Butyl paraben
95-53-4	2-Aminotoluene
95-80-7	2,4-Diaminotoluene
99-76-3	Methyl paraben
99-96-7	p-Hydroxybenzoic acid
100-41-4	Ethylbenzene
100-42-5	Styrene
104-40-5	4-Nonylphenol; 4-NP and its isomer mixtures including CAS 84852-15-3 and CAS 25154-52-3
106-47-8	para-Chloroaniline
107-13-1	Acrylonitrile
107-21-1	Ethylene glycol
108-88-3	Toluene
108-95-2	Phenol
109-86-4	2-Methoxyethanol
110-80-5	Ethylene glycol monoethyl ester
115-96-8	Tris(2-chloroethyl) phosphate
117-81-7	Di-2-ethylhexyl phthalate
117-84-0	Di-n-octyl phthalate (DnOP)

CAS	Chemical
118-74-1	Hexachlorobenzene
119-93-7	3,3'-Dimethylbenzidine and Dyes Metabolized to 3,3'-Dimethylbenzidine
120-47-8	Ethyl paraben
123-91-1	1,4-Dioxane
127-18-4	Perchloroethylene
131-55-5	Benzophenone-2 (Bp-2); 2,2',4,4'- Tetrahydroxybenzophenone
140-66-9	4-tert-Octylphenol; 1,1,3,3-Tetramethyl- 4-butylphenol
140-67-0	Estragole
149-57-5	2-Ethylhexanoic acid
556-67-2	Octamethylcyclotetrasiloxane
608-93-5	Benzene, pentachloro
842-07-9	C.I. solvent yellow 14
872-50-4	N-Methylpyrrolidone
1163-19-5	2,2',3,3',4,4',5,5',6,6'- Decabromodiphenyl ether; BDE-209
1763-23-1	Perfluorooctanyl sulphonic acid and its salts; PFOS
1806-26-4	Phenol, 4-octyl-
5466-77-3	2-Ethyl-hexyl-4-methoxycinnamate
7439-97-6	Mercury & mercury compounds including methyl mercury (22967-92-6)
7439-98-7	Molybdenum & molybdenum compounds
7440-36-0	Antimony & Antimony compounds
7440-38-2	Arsenic & Arsenic compounds including arsenic trioxide (1327-53-3) & dimethyl arsenic (75-60-5)
7440-43-9	Cadmium & cadmium compounds
7440-48-4	Cobalt & cobalt compounds
25013-16-5	Butylated hydroxyanisole; BHA
25637-99-4	Hexabromocyclododecane
26761-40-0	Diisodecyl phthalate (DIDP)
28553-12-0	Diisononyl phthalate (DINP)