Chapter 173-334 WAC CHILDREN'S SAFE PRODUCTS—REPORTING RULE

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DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

173-334-110 When must manufacturers begin to provide notice? [Statutory Authority: Chapter 70.240 RCW, RCW 70.240.040. WSR 11-16-008 (Order 09-04), § 173-334-110, filed 7/21/11, effective 8/21/11.] Repealed by WSR 17-20-050 (Order 16-08), filed 9/29/17, effective 10/30/17. Statutory Authority: RCW 70.240.060 and 70.240.035.

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 report. The CSPA specifies both the characteristics of these chemicals and the reporting requirements.

[Statutory Authority: RCW 70.240.060 and 70.240.035. WSR 17-20-050 (Order 16-08), § 173-334-010, filed 9/29/17, effective 10/30/17. Statutory Authority: Chapter 70.240 RCW, RCW 70.240.040. WSR 11-16-008 (Order 09-04), § 173-334-010, filed 7/21/11, effective 8/21/11.]

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 reporting is required;

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

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

[Statutory Authority: RCW 70.240.060 and 70.240.035. WSR 17-20-050 (Order 16-08), § 173-334-020, filed 9/29/17, effective 10/30/17. Statutory Authority: Chapter 70.240 RCW, RCW 70.240.040. WSR 11-16-008 (Order 09-04), § 173-334-020, filed 7/21/11, effective 8/21/11.]

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

[Statutory Authority: Chapter 70.240 RCW, RCW 70.240.040. WSR 11-16-008 (Order 09-04), § 173-334-030, filed 7/21/11, effective 8/21/11.]

WAC 173-334-040 What definitions apply to terms used in this chapter? "Chemical Abstracts Service number" or "CAS" 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 byproducts of chemical reactions during the manufacture of the product component, trace impurities in feed-stock, incompletely reacted chemical mixtures, and degradation products.

"De minimis level" means for a chemical that is an intentionally added chemical, a concentration below the practical quantification limit; or for a chemical that is a contaminant, a concentration below 100 parts per million.

"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.

"Internal component" means a children's product component that during reasonably foreseeable use and abuse of the product would not come into direct contact with the child's skin or mouth.

"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 quantitation limit" or "(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.

[Statutory Authority: RCW 70.240.060 and 70.240.035. WSR 17-20-050 (Order 16-08), § 173-334-040, filed 9/29/17, effective 10/30/17. Statutory Authority: Chapter 70.240 RCW, RCW 70.240.040. WSR 11-16-008 (Order 09-04), § 173-334-040, filed 7/21/11, effective 8/21/11.]

WAC 173-334-050 What is the purpose of the CHCC list? The CHCC list identifies the chemicals to which the reporting 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.

[Statutory Authority: RCW 70.240.060 and 70.240.035. WSR 17-20-050 (Order 16-08), § 173-334-050, filed 9/29/17, effective 10/30/17. Statutory Authority: Chapter 70.240 RCW, RCW 70.240.040. WSR 11-16-008 (Order 09-04), § 173-334-050, filed 7/21/11, effective 8/21/11.]

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.

[Statutory Authority: Chapter 70.240 RCW, RCW 70.240.040. WSR 11-16-008 (Order 09-04), § 173-334-060, filed 7/21/11, effective 8/21/11.]

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(9); 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.

[Statutory Authority: RCW 70.240.060 and 70.240.035. WSR 17-20-050 (Order 16-08), § 173-334-070, filed 9/29/17, effective 10/30/17. Statutory Authority: Chapter 70.240 RCW, RCW 70.240.040. WSR 11-16-008 (Order 09-04), § 173-334-070, filed 7/21/11, effective 8/21/11.]

WAC 173-334-080 What must the manufacturer include in its report to the department? (1) The report 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. A manufacturer need not file a report 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 report 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 concentration of the CHCC contained in each product component within each product category. The total concentration may be reported in ranges, rather than the exact concentration. If there are multiple CHCC concentrations for a given component in a particular product category, the manufacturer must use the highest concentration 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 maintain an online reporting database to be used for reporting on CHCCs. This same database may be used by the reporting party to flag the submitted information it thinks should be treated as CBI.

(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.

[Statutory Authority: RCW 70.240.060 and 70.240.035. WSR 17-20-050 (Order 16-08), § 173-334-080, filed 9/29/17, effective 10/30/17. Statutory Authority: Chapter 70.240 RCW, RCW 70.240.040. WSR 11-16-008 (Order 09-04), § 173-334-080, filed 7/21/11, effective 8/21/11.]

WAC 173-334-090 Who is required to report to the department? (1) The manufacturer of a children's product, or a trade organization on behalf of its member manufacturers, must report 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 report 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 report for the children's product:

(a) The person or entity that had the children's product 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.

[Statutory Authority: RCW 70.240.060 and 70.240.035. WSR 17-20-050 (Order 16-08), § 173-334-090, filed 9/29/17, effective 10/30/17. Statutory Authority: Chapter 70.240 RCW, RCW 70.240.040. WSR 11-16-008 (Order 09-04), § 173-334-090, filed 7/21/11, effective 8/21/11.]

WAC 173-334-100 When must manufacturers report and for what time period? (1) On January 31, 2019, and annually thereafter, a manufacturer of a children's product sold or offered for sale in Washington that contains a CHCC listed in WAC 173-334-130 in an amount above a de minimis level must submit the information detailed in WAC 173-334-080 to the department.

(a) The report submitted on January 31, 2019, applies to children's products sold or offered for sale in Washington between September 1, 2017, and December 31, 2018.

(b) A manufacturer of a children's product containing a CHCC above the de minimis level may request an extension for submission of the report required on January 31, 2019, if this would be the first report required by the manufacturer and the manufacturer will be reporting more than one product or chemical.

(c) Reports submitted on January 31, 2020, and annually thereafter, apply to children's products sold or offered for sale during the prior calendar year.

(2) If the reporting party determines that there has been no change in the information required to be reported since the prior annual report, the party must copy the prior year's report and resubmit the same data into the online reporting database.

(3) If a CHCC is subsequently removed from the children's product component for which a report was given, the manufacturer may report to the department. Such updated reports will be documented in the department's records.

(4) Annual reporting for internal components will not be required, except by amendment of this rule.

[Statutory Authority: RCW 70.240.060 and 70.240.035. WSR 17-20-050 (Order 16-08), § 173-334-100, filed 9/29/17, effective 10/30/17. Statutory Authority: Chapter 70.240 RCW, RCW 70.240.040. WSR 11-16-008 (Order 09-04), § 173-334-100, filed 7/21/11, effective 8/21/11.]

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)(b), 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 report for the presence and accurate amount of each CHCC, in each applicable product category, in each applicable product component.

[Statutory Authority: RCW 70.240.060 and 70.240.035. WSR 17-20-050 (Order 16-08), § 173-334-120, filed 9/29/17, effective 10/30/17. Statutory Authority: Chapter 70.240 RCW, RCW 70.240.040. WSR 11-16-008 (Order 09-04), § 173-334-120, filed 7/21/11, effective 8/21/11.]

WAC 173-334-130 The reporting list of chemicals of high concern to children (CHCC list). (1) The current list of CHCCs identifies the chemicals that must be reported to the department in accordance with WAC 173-334-080 if a chemical on the CHCC list is present in a children's product component. (2) Changes to the list of CHCCs occurs only by amendment of this rule as required by WAC 173-334-060. The year a CHCC was added to the list by rule amendment is provided in the third column. Chemicals removed by rule amendment are identified at the end of this list.

		N.Z
CAS	Chemical	Year Added
50-00-0	Formaldehyde	2011
62-53-3	Aniline	2011
62-75-9	N-Nitrosodimethylamine	2011
71-43-2	Benzene	2011
75-01-4	Vinyl chloride	2011
75-07-0	Acetaldehyde	2011
75-09-2	Methylene chloride	2011
75-15-0	Carbon disulfide	2011
78-93-3	Methyl ethyl ketone	2011
79-34-5	1,1,2,2-Tetrachloroethane	2011
79-94-7	Tetrabromobisphenol A (TBBPA)	2011
80-05-7	Bisphenol A (BPA)	2011
80-09-1	Bisphenol S (BPS)	2017
84-61-7	Dicyclohexyl phthalate (DCHP)	2017
84-66-2	Diethyl phthalate (DEP)	2011
84-69-5	Diisobutyl phthalate (DIBP)	2017
84-74-2	Di-n-butyl phthalate (DBP)	2011
84-75-3	Di-n-hexyl phthalate (DnHP)	2011
85-68-7	Butyl benzyl phthalate (BBP)	2011
86-30-6	N-Nitrosodiphenylamine	2011
87-68-3	Hexachlorobutadiene	2011
94-13-3	Propyl paraben	2011
94-26-8	Butyl paraben	2011
95-53-4	2-Aminotoluene	2011
95-80-7	2,4-Diaminotoluene	2011
99-76-3	Methyl paraben	2011
99-96-7	4-Hydroxybenzoic acid	2011
100-41-4	Ethylbenzene	2011
100-42-5	Styrene	2011
104-40-5	4-Nonylphenol	2011
106-47-8	4-Chloroaniline	2011
107-13-1	Acrylonitrile	2011
107-21-1	Ethylene glycol	2011
108-88-3	Toluene	2011
108-95-2	Phenol	2011
109-86-4	2-Methoxyethanol	2011
110-80-5	Ethylene glycol monoethyl ether	2011

CAS	Chemical	Year Added
115-86-6	Triphenyl phosphate (TPP)	2017
115-96-8	Tris(2-chloroethyl) phosphate (TCEP)	2011
117-81-7	Di-(2-ethylhexyl) phthalate (DEHP)	2011
117-82-8	Di-(2-methoxyethyl) phthalate (DMEP)	2017
117-84-0	Di-n-octyl phthalate (DnOP)	2011
118-74-1	Hexachlorobenzene	2011
119-93-7	3,3'-Dimethylbenzidine and Dyes Metabolized to 3,3'-Dimethylbenzidine	2011
120-47-8	Ethyl paraben	2011
123-91-1	1,4-Dioxane	2011
126-72-7	Tris (2,3-dibromopropyl) phosphate (TDBPP)	2017
126-73-8	Tri-n-butyl phosphate (TNBP)	2017
127-18-4	Tetrachloroethene	2011
131-18-0	Dipentyl phthalate (DPP)	2017
131-55-5	Benzophenone-2 (Bp-2)	2011
140-66-9	4-Octylphenol	2011
140-67-0	Estragole	2011
149-57-5	2-Ethylhexanoic acid	2011
335-67-1	Perfluorooctanoic acid (PFOA) and related substances	2017
608-93-5	Pentachlorobenzene	2011
620-92-8	Bisphenol F (BPF)	2017
842-07-9	C.I. solvent yellow 14	2011
872-50-4	N-Methylpyrrolidone	2011
1163-19-5	Decabromodiphenyl ether (BDE-209)	2011
1241-94-7	Ethylhexyl diphenyl phosphate (EHDPP)	2017
1330-78-5	Tricresyl phosphate (TCP)	2017
1763-23-1	Perfluorooctane sulfonic acid (PFOS) and its salts	2011
1806-26-4	4-Octylphenol	2011
5466-77-3	2-Ethyl-hexyl-4- methoxycinnamate	2011
7439-97-6	Mercury & mercury compounds including methyl mercury (22967-92-6)	2011
7440-36-0	Antimony & Antimony compounds	2011

CAS	Chemical	Year Added			
7440-38-2	Arsenic & Arsenic compounds including arsenic trioxide (1327-53-3) & dimethyl arsenic acid (75-60-5)	2011			
7440-43-9	Cadmium & cadmium compounds	2011			
7440-48-4	Cobalt & cobalt compounds	2011			
13674-84-5	Tris (1-chloro-2-propyl) phosphate (TCPP)	2017			
13674-87-8	Tris(1,3-dichloro-2- propyl)phosphate (TDCPP)	2013			
25013-16-5	Butylated hydroxyanisole (BHA)	2011			
25154-52-3	Nonyl phenol	2011			
25637-99-4	Hexabromocyclododecane (HBCD)	2011			
26040-51-7	Bis (2-ethylhexyl) tetrabromophthalate (TBPH)	2017			
26761-40-0	Diisodecyl phthalate (DIDP)	2011			
28553-12-0	Diisononyl phthalate (unbranched) (DINP)	2011			
38051-10-4	Bis (chloromethyl) propane-1,3-diyl tetrakis-(2-chloroethyl) bis(phosphate)(V6)	2017			
68937-41-7	Isopropylated triphenyl phosphate (IPTPP)	2017			
84852-15-3	4-Nonyl phenol branched	2011			
84852-53-9	Decabromodiphenyl ethane (DBDPE)	2017			
85535-84-8	Short-chain chlorinated paraffins (SCCP)	2017			
108171-26-2	Chlorinated paraffins	2017			
183658-27-7	2-ethylhexyl-2,3,4,5- tetrabromobenzoate (TBB)	2017			
List of CHCCs removed by Rule Amendment					
CAS	Chemical	Year Removed			
71-36-3	1-Butanol	2013			
85-44-9	Phthalic anhydride	2017			
556-67-2	Octamethylcyclotetrasiloxa ne (D4)	2017			
7439-98-7	Molybdenum & molybdenum compounds	2017			

[Statutory Authority: RCW 70.240.060 and 70.240.035. WSR 17-20-050 (Order 16-08), § 173-334-130, filed 9/29/17, effective 10/30/17. Statutory Authority: Chapter 70.240 RCW. WSR 13-21-123 (Order 12-02), § 173-334-130, filed 10/22/13, effective 11/22/13. Statutory Authority:

Chapter 70.240 RCW, RCW 70.240.040. WSR 11-16-008 (Order 09-04), § 173-334-130, filed 7/21/11, effective 8/21/11.]