

Chapter 6 – Environmental Health Rules
Subchapter 7

CHEMICALS OF HIGH CONCERN IN CHILDREN’S PRODUCTS RULE

1.0 Authority

This rule is adopted pursuant to 18 V.S.A § 1776.

2.0 Purpose

This rule provides the requirements for the disclosure and reporting of toxic substances that are intentionally added to a children’s product at a level above the PQL produced by the manufacturer or are present in a children’s product produced by the manufacturer as a contaminant at concentrations of 100 parts per million or greater. This rule also establishes the process by which a chemical may be added or removed from the list of Chemicals of High Concern to Children and the process by which a chemical might be banned for sale or distribution.

3.0 Scope

This rule applies to manufacturers of children products as defined by 18 V.S.A. § 1772(7) offered for sale in the State of Vermont.

4.0 Definitions

Any terms used in this rule but not defined in this section shall have the meaning found in 18 V.S.A. §1772. Whenever used in this rule, the following terms shall be construed as follows:

4.1 “Department” means the Vermont Department of Health.

4.2 “Commissioner” means the Commissioner of Health.

4.3 “Chemical of high concern to children” means a chemical listed under section 18 V.S.A. §1773 or designated by the Department as a chemical of high concern by this rule.

4.4 “Manufacturer” means any person who manufactures a children's product or whose name is affixed to a children's product or its packaging or advertising, and the children's product is sold or offered for sale in Vermont; or any person who sells a children's product to a retailer in Vermont when the person who manufactures the children's product or whose name is affixed to the children's product or its packaging or advertising does not have a presence in the United States other than

the sale or offer for sale of the manufacturer's products.

- 4.5** “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.
- 4.6** “Product component” means the uniquely identifiable material or coating (including ink or dye) that is intended to be included as part of a finished children’s product.
- 4.7** “Product model” means the specific product name used by the retailer or assembler to place the product into the stream of commerce.
- 4.8** “Contaminant” means a trace amount of a chemical or chemicals that is incidental to manufacturing and serves no intended function in the children's product or component of the children's product, including an unintended by-product of chemical reactions during the manufacture of the children's product, a trace impurity in feed-stock, an incompletely reacted chemical mixture, and a degradation product.

5.0 Chemicals of High Concern to Children

The following chemicals are designated as chemicals of high concern to children:

- (1) Formaldehyde
- (2) Aniline
- (3) N-Nitrosodimethylamine
- (4) Benzene
- (5) Vinyl chloride
- (6) Acetaldehyde
- (7) Methylene chloride
- (8) Carbon disulfide
- (9) Methyl ethyl ketone
- (10) 1,1,2,2-Tetrachloroethane
- (11) Tetrabromobisphenol A
- (12) Bisphenol A
- (13) Diethyl phthalate
- (14) Dibutyl phthalate
- (15) Di-n-hexyl phthalate
- (16) Phthalic anhydride
- (17) Butyl benzyl phthalate (BBP)

- (18) N-Nitrosodiphenylamine
- (19) Hexachlorobutadiene
- (20) Propyl paraben
- (21) Butyl paraben
- (22) 2-Aminotoluene
- (23) 2,4-Diaminotoluene
- (24) Methyl paraben
- (25) p-Hydroxybenzoic acid
- (26) Ethylbenzene
- (27) Styrene
- (28) 4-Nonylphenol; 4-NP and its isomer mixtures including CAS 84852-15-3 and CAS 25154-52-3
- (29) para-Chloroaniline
- (30) Acrylonitrile
- (31) Ethylene glycol
- (32) Toluene
- (33) Phenol
- (34) 2-Methoxyethanol
- (35) Ethylene glycol monoethyl ether
- (36) Tris (2-chloroethyl) phosphate
- (37) Di-2-ethylhexyl phthalate
- (38) Di-n-octyl phthalate (DnOP)
- (39) Hexachlorobenzene
- (40) 3,3'-Dimethylbenzidine and Dyes Metabolized to 3,3'-Dimethylbenzidine
- (41) Ethyl paraben
- (42) 1,4-Dioxane
- (43) Perchloroethylene
- (44) Benzophenone-2 (Bp-2); 2,2',4,4'-Tetrahydroxybenzophenone
- (45) 4-tert-Octylphenol; 4 (1,1,3,3-Tetramethylbutyl) phenol
- (46) Estragole
- (47) 2-Ethylhexanoic acid
- (48) Octamethylcyclotetrasiloxane
- (49) Benzene, Pentachloro

- (50) C.I. Solvent yellow 14
- (51) N-Methylpyrrolidone
- (52) 2,2',3,3',4,4',5,5',6,6'-Decabromodiphenyl ether; BDE-209
- (53) Perfluorooctanyl sulphonic acid and its salts; PFOS
- (54) Phenol, 4-octyl
- (55) 2-Ethyl-hexyl-4-methoxycinnamate
- (56) Mercury and mercury compounds including methyl mercury (22967-92-6)
- (57) Molybdenum and molybdenum compounds
- (58) Antimony and Antimony compounds
- (59) Arsenic and Arsenic compounds, including arsenic trioxide (1327-53-3) and dimethyl arsenic (75-60-5)
- (60) Cadmium and cadmium compounds
- (61) Cobalt and cobalt compounds
- (62) Tris (1,3-dichloro-2-propyl) phosphate
- (63) Butylated hydroxyanisole; BHA
- (64) Hexabromocyclododecane
- (65) Diisodecyl phthalate (DIDP)
- (66) Diisononyl phthalate (DINP)
- (67) Bisphenol S
- (68) Dicyclohexyl phthalate
- (69) Diisobutyl phthalate
- (70) Triphenyl phosphate
- (71) Tris (2,3-dibromopropyl) phosphate
- (72) Tri-n-butyl phosphate
- (73) Dipentyl phthalate
- (74) Perfluorooctanoic acid
- (75) Bisphenol F
- (76) Ethylhexyl diphenyl phosphate
- (77) Tricresyl phosphate
- (78) Tris (1-chloro-2-propyl) phosphate
- (79) Bis (2-ethylhexyl) tetrabromophthalate
- (80) Bis (chloromethyl) propane-1,3-diyl tetrakis-(2-chloroethyl) bis (phosphate)
- (81) Isopropylated triphenyl phosphate

- (82) Decabromodiphenyl ethane
- (83) Short-chain chlorinated paraffins; Chlorinated paraffins
- (84) 2-ethylhexyl-2,3,4,5-tetrabromobenzoate
- (85) Lead and lead compounds
- (86) Di-(2-methoxyethyl) phthalate

6.0 Disclosure Notice

6.1 Any notice submitted under 18 V.S.A. § 1775 shall contain the following information:

- 6.1.1** The name of the chemical used or produced and its chemical abstracts service registry number (18 V.S.A. § 1775(b)(1));
- 6.1.2** A description of the product or product component containing the chemical. This description must include Global Product Classification (GPC) product brick description;
- 6.1.3** The brand name, product model, and the universal product code (UPC) if the product has such a code (18 V.S.A. § 1775(b)(2));
- 6.1.4** The amount of the chemical contained in each unit of the product or product component, reported by weight or parts per million as authorized by the Commissioner (18 V.S.A. § 1775(b)(3));
- 6.1.5** The name and address of the manufacturer of the children's product and the name, address, and telephone number of a contact person for the manufacturer (18 V.S.A. § 1775(b)(4));
- 6.1.6** Any other information the manufacturer deems relevant to the appropriate use of the product (18 V.S.A. § 1775(b)(5));
- 6.1.7** The function of the chemical in the product;

7.0 Reporting Ranges

7.1 A manufacturer may report ranges of the amount of a chemical in a children's product, rather than the exact amount, provided that if there are multiple chemical values for a given component in a particular product category, the manufacturer shall use the largest value for reporting.

7.2 The ranges are as follows:

- 7.2.1** Equal to or more than the PQL but less than 100 ppm (0.01%).
- 7.2.2** Equal to or more than 100 ppm (0.01%) but less than 500 ppm (0.05%).
- 7.2.3** Equal to or more than 500 ppm (0.05%) but less than 1,000 ppm (0.1%).
- 7.2.4** Equal to or more than 1,000 (0.1%) ppm but less than 5,000 ppm (0.5%).
- 7.2.5** Equal to or more than 5,000 ppm (0.5%) but less than 10,000 ppm (1.0%).

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

8.0 Reporting Years and Periods

8.1 On or before August 31, 2020 and annually thereafter, a manufacturer of a children's product or a trade association representing a manufacturer of children's products, shall submit to the Department the notice described in Section 6.0 of this rule. The submission schedule is:

8.1.1 Submission on or prior to August 31, 2020 for products offered for sale between September 1, 2018 and August 31, 2020;

8.1.2 Submissions shall continue annually thereafter.

8.2 Any manufacturer required to submit notices to the Department pursuant to 18 V.S.A. § 1775, must provide notices prior to August 31 of each year.

9.0 Evaluation of Chemicals for Listing as a Chemical of High Concern to Children

9.1 Adding a Chemical

The Commissioner may by rule add additional chemicals to the list of chemicals of high concern to children, provided that the Commissioner of Health, on the basis of credible, scientific evidence, including peer-reviewed studies, has determined that a chemical proposed for addition to the list meets both of the following:

9.1.1 An authoritative governmental entity or accredited research university has demonstrated that the chemical:

9.1.1.1 Harms the normal development of a fetus or child or causes other developmental toxicity;

9.1.1.2 Causes cancer, genetic damage, or reproductive harm;

9.1.1.3 Disrupts the endocrine system;

9.1.1.4 Damages the nervous system, immune system, or organs or causes other systemic toxicity; or

9.1.1.5 Is a persistent bioaccumulative toxic as defined in 18 V.S.A. § 1772 (14).

9.1.2 The chemical has been found through:

9.1.2.1 Biomonitoring to be present in human blood, umbilical cord blood, breast milk, urine, or other bodily tissues or fluids;

9.1.2.2 Sampling and analysis to be present in household dust, indoor air, drinking water, or elsewhere in the home environment; or

9.1.2.3 Monitoring to be present in fish, wildlife, or the natural environment.

9.2 Removing a Chemical

The Commissioner may by rule remove a chemical from the list of chemicals of high concern to children established under 18 V.S.A. § 1773 and this rule if the Commissioner determines that the chemical no longer meets the criteria found therein.

9.3 Process and Procedure to Add or Remove a Chemical

The Commissioner shall prepare a summary of evidence on the basis of credible, scientific evidence, including peer-reviewed studies. The summary shall reference all sources and shall be available to the public. The Commissioner may consult with the Chemicals of High Concern to Children Working Group for feedback on the summary of evidence.

10.0 Prioritization for Chemical Review

10.1 Beginning on July 1, 2017 and biennially thereafter, the Commissioner of Health shall recommend at least two chemicals of high concern to children in children's products for review by the working group.

10.2 The Commissioner may recommend chemicals for review based on the degree of human health risks, exposure pathways, and impact on sensitive populations presented by a chemical of high concern to children, including but not limited to the following criteria:

10.2.1 Whether the chemical has been listed as a chemical of concern in statute or regulation or otherwise restricted by other states, the federal government, other countries, or other governmental bodies;

10.2.2 The disclosure data submitted to the Department of Health for the chemical.

11.0 Regulation of Sale or Distribution

11.1 The Commissioner, after consultation with the Chemicals of High Concern to Children Working Group, may adopt a rule to regulate the sale or distribution of a children's product containing a chemical of high concern to children upon a determination that:

11.1.1 Children may be exposed to a chemical of high concern to children in the children's product; and

11.1.2 There is a possibility that, due to the degree of exposure or frequency of exposure of a child to a chemical of high concern to children in a children's product, exposure could cause or contribute to one or more of the adverse health impacts listed under subsection 9.1.1.

- 11.2** In determining whether children may be exposed to a chemical of high concern in a children's product, the Commissioner shall review available, credible information regarding:
- 11.2.1** The market presence of the children's product in the State;
 - 11.2.2** The type or occurrence of exposures to the relevant chemical of high concern to children in the children's product;
 - 11.2.3** The household and workplace presence of the children's product; or
 - 11.2.4** The potential and likelihood of exposure of children to the chemical of high concern to children in the children's product.
- 11.3** A rule adopted under this section may:
- 11.3.1** Prohibit the children's product containing the chemical of high concern to children from sale, offer for sale, or distribution in the State; or
 - 11.3.2** Require that the children's product containing the chemical of high concern to children be labeled prior to sale, offer for sale, or distribution in the State.
- 11.4** In any rule adopted under this subsection, the Commissioner shall adopt reasonable time frames for manufacturers, distributors, and retailers to comply with the requirements of the rules. No prohibition on sale or manufacture of a children's product in the State shall take effect sooner than two years after the adoption of a rule adopted under this section unless the Commissioner determines that an earlier effective date is required to protect human health and the new effective date is established by rule.

12.0 Notice of Removal of Chemical

A manufacturer that submitted the notice required by law may at any time submit to the Department notice that a chemical of high concern to children has been removed from the manufacturer's children's product or that the manufacturer no longer sells, offers for sale, or distributes in the State the children's product containing the chemical of high concern to children. Upon verification of a manufacturer's notice, the Commissioner shall promptly remove from the Department website any reference to the relevant children's product of the manufacturer, for data that is reported prior to the offer for sale.

13.0 Disclosure of Information on Chemicals of High Concern

Notice of chemical of high concern to children. A manufacturer of a children's product or a trade association representing a manufacturer of children's products shall submit notice to the Department for each chemical of high concern to children in a children's product if a chemical of high concern to children is:

- (1) intentionally added to a children's product at a level above the PQL produced by the manufacturer; or

(2) present in a children's product produced by the manufacturer as a contaminant at a concentration of 100 parts per million or greater.