



DEPARTMENT OF
ECOLOGY
State of Washington

Concise Explanatory Statement
Chapter 173-334 WAC
Children's Safe Products Reporting Rule

Summary of rulemaking and response to comments

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Publication and Contact Information

This publication is available on the Department of Ecology's website at <https://fortress.wa.gov/ecy/publications/SummaryPages/1704034.html>

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Concise Explanatory Statement

Chapter 173-334 WAC Children's Safe Products Reporting Rule

Hazardous Waste and Toxics Reduction Program
Washington State Department of Ecology
Olympia, Washington 98504-7600

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Introduction

The purpose of a Concise Explanatory Statement is to:

- Meet the Administrative Procedure Act (APA) requirements for agencies to prepare a Concise Explanatory Statement (RCW 34.05.325).
- Provide reasons for adopting the rule.
- Describe any differences between the proposed rule and the adopted rule.
- Provide Ecology's response to public comments.

This Concise Explanatory Statement provides information on The Washington State Department of Ecology's (Ecology) rule adoption for:

Title: Children's Safe Products Reporting Rule

WAC Chapter(s): 173-334

Adopted date: September 29, 2017

Effective date: October 30, 2017

To see more information related to this rulemaking or other Ecology rulemakings please visit our web site: <http://www.ecy.wa.gov/laws-rules/index.html>

Reasons for Adopting the Rule

This rulemaking amends the Children's Safe Products Reporting Rule (CSPA Reporting Rule) – Chapter 173-334 WAC. The CSPA Reporting Rule requires manufacturers to annually report to Ecology the presence of Chemicals of High Concern to Children (CHCCs) in children's products offered for sale in Washington. The CSPA Reporting Rule identifies the CHCCs and details the process for manufacturers to report to Ecology.

Ecology is amending Chapter 173-334 WAC Children's Safe Products Reporting Rule. The 2016 Washington State Legislature's amendment of RCW 70.240 identified six flame retardants to be considered for inclusion on the list of CHCCs (Chapter 173-334 WAC). Ecology and the Washington Department of Health evaluated recent scientific data for the six flame retardants and other chemicals.

Ecology is making the following rule changes:

- Adding 20 chemicals to the CHCC list.
- Changing one grouped nonylphenol listing to three individual CHCC listings.
- Removing three chemicals from the CHCC list.
- Setting a single annual reporting date consistent with reporting in other states.
- Clarifying the total concentration reporting requirement.
- Editing changes for clarification.

Criteria for Chemicals of High Concern to Children

During this rulemaking, changes to the list of CHCCs followed the same basic process that was used to create the original CHCC list in 2011 and update it in 2013. The 2011 CHCC listing process prioritized three toxicity endpoints: carcinogenicity, reproductive/developmental toxicity, and endocrine disruption. Other toxic endpoints (like liver toxicity, neurotoxicity, or aquatic toxicity) were not considered for listing purposes. The process also prioritized potential for exposure as being in children's products or in people.

CHCCs selected for addition or delisting either did or did not meet the listing criteria. CHCC listing criteria are based on authoritative sources that identify chemical toxicity (RCW 70.240.010) and evidence of potential for exposure (RCW 70.240.030(1)). Source references are provided at the end of this document.

Authoritative sources used to determine toxicity:

- California's Proposition 65 list for cancer, birth defects, or other reproductive harm (OEHHA 2017).
- National Toxicology Program (NTP) Center for the Evaluation of Risks to Human Reproduction monographs and Report on Carcinogens (NTP 2016).
- The International Agency for Research on Cancer (IARC 2017).
- Consumer Product Safety Commission's Chronic Hazard Advisory Panel (CHAP) Report on Phthalates (CPSC 2014).
- U.S. EPA sources:

- Alternatives assessments on flame retardants (EPA 2015).
- Integrated Risk Information System (IRIS; EPA 2017).
- European Union sources:
 - Substances restricted or authorized under the EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation (ECHA 2017).
 - Candidate list of Substances of Very High Concern (SVHC) under REACH (ECHA 2017).
 - Existing Substances Regulation (ECHA 2017).
 - Priority list of chemicals identified as suspected endocrine disruptors (EC 2017).

Authoritative sources used to determine potential for exposure:

- Scientific studies published in peer-reviewed journals showing presence in children’s products, house dust, indoor air, or biomonitoring data.
- Danish environmental agency surveys on chemicals in consumer products (DEPA 2017).
- Centers for Disease Control (CDC) National Health and Nutrition Examination Survey (NHANES) (CDC 2015).
- Washington State list of persistent, bioaccumulative, and toxic (PBT) chemicals (Chapter 173-333 WAC).

Differences Between the Proposed Rule and Adopted Rule

RCW 34.05.325(6)(a)(ii) requires Ecology to describe the differences between the text of the proposed rule as published in the *Washington State Register* and the text of the rule as adopted, other than editing changes, stating the reasons for the differences.

There are some differences between the proposed rule filed on March 12, 2017 and the adopted rule filed on September 29, 2017. Ecology made these changes for all or some of the following reasons:

- In response to comments we received.
- To ensure clarity and consistency.
- To meet the intent of the authorizing statute.

The following content describes the changes and Ecology’s reasons for making them. Where a change was made solely for editing or clarification purposes, we did not include it in this section.

- Section 080(e), clarification of the requirement to report total CHCC concentrations:

“The total (~~amount~~) concentration of the CHCC (~~by weight~~) contained in each product component (~~in each children’s product sold or offered for sale~~) within each product category. The (~~amount~~) total concentration may be reported in ranges, rather than exact (~~amount~~) concentration. If there are multiple CHCC (~~values~~) concentrations for a given component in a particular product category, the manufacturer must use the (~~largest value~~) highest concentration for reporting.”
- Section 130 removal of two chemicals that do not meet the CHCC listing criteria:

CAS 78-33-1 Tris(4-tert butylphenyl) phosphate (TBPP)

CAS 220352-35-2 Butylated triphenyl phosphate.

- Section 130 addition of one chemical that meets the CHCC listing criteria:
CAS 117-82-8 Di(2-methoxyethyl) phthalate (DMEP)

List of Topics and Commenters

Ecology accepted comments from March 22, 2017 until May 12, 2017. During this public comment period, Ecology received emails, letters, postcards, and testimony from 362 individuals or organizations. Those comments have been organized into the following 18 topics: 11 topics for chemicals and 7 general rule topics:

Rule content topics	Chemicals
Credible science	BTBPE – 1,2-bis(2,4,6-tribromophenoxy)ethane
Extension	Butylated triphenyl phosphate
Individual comments	D4 - Octamethylcyclotetrasiloxane
Product Name	Dechlorane Plus
Product Testing	DMEP – Di(2-methoxyethyl)phthalate*
Rule update	DIOP – Diisooctyl phthalate
Support CHCC additions	DIPP – Diisopentyl phthalate
	Lead
	PFOA – Perfluorooctanoic acid
	TCE – Trichloroethylene

* comments referred to Bis(2-methoxyethyl)phthalate and used the acronym DEMP.

Note: Ecology received comments on the chemical Bis(2-methoxyethyl)phthalate with the acronym DEMP. Where verbatim comments are provided in this document, the DEMP naming is retained. Ecology uses the alternative chemical name Di(2-methoxyethyl)phthalate and the acronym DMEP. The Ecology chemical name (DMEP) is used throughout this document where comments are summarized, in tables, and in responses to comments.

Table 1 lists the 13 organizations that submitted comments and comment topic. Table 2 lists the 349 individuals who submitted emails and postcards.

Table 1 – Organization Comments

Organization	Comment Topic
American Apparel & Footwear Association	Credible science Extension
Earth Ministry and Washington Interfaith Power and Light	D4 PFOA DMEP, DIOP, DIPP Support CHCC additions
Israeli Chemicals Industrial Products America	Butylated triphenyl phosphate
Juvenile Products Manufacturers Association	Extension
Local Hazardous Waste Management Program in King County	Lead D4 PFOA DMEP, DIOP, DIPP Product name Support CHCC additions TCE
Phillips Burgess Government Relations	Product testing
Public Health Seattle & King County	Rule update

Table 1 – Organization Comments

Organization	Comment Topic
	D4 Lead PFOA DMEP, DIOP, DIPP Product name Support CHCC additions
The ARC of Washington	PFOA DMEP, DIOP, DIPP Support CHCC additions
The Endocrine Disruption Exchange	BTBPE D4 Dechlorane plus DMEP, DIOP, DIPP PFOA Support CHCC additions
Toxic Free Future	BTBPE D4 Dechlorane plus DMEP, DIOP, DIPP PFOA Support CHCC additions
Washington State Legislature	D4 PFOA DMEP, DIOP, DIPP Support CHCC additions
Washington State Nurses Association	D4 PFOA DMEP, DIOP, DIPP Support CHCC additions
Zero Waste Washington	D4 DMEP, DIOP, DIPP Support CHCC additions

Table 2 – Individual Comments

Names of Individuals who submitted rule comments		
Abbot, David	Fradkin, Allison	Mullen, Jen
Abrams-Caras, Randi	Francis, Mary Lou	Murti, Gudrun
Ackerman, Laura	Frederick, Danielle	Musser, Mallory
Adams, Audrey	Frohn, Joyce	Niendorf, John
Adams, Marsha	Fulbright, Kim	Nightingale, Terry
Adkins, Matthew	g, k	Niland, Maureen
Albrecht, Jean	Gabriel , Robert	none , none
Anderson, Glen	Gabriel, Mady	Noorani, Sabrna
Anderson, Julie	Gagney, Aileen	Obst , Pam

Table 2 – Individual Comments

Names of Individuals who submitted rule comments		
Angel, Bill	Gale , Maradel	O'Connor, Jeanne
Archer, Elisabeth	Gallotte, Susan	O'Halloran, Kevin
Arnold , Carl	Gayler, Jillian	Olmstead, Michael
Atteridge, Constance	Gendvil, Derek	Olson, Arthur
Auger, Amanda	Giddings, Frances	Olson, Morgan
B, Shary	Gilbert, Steve	Pani, Aarti and Arabinda
Bagley, Christie	Gladstone , David	Paras, Ysabelle
Bailey, Stephen	Gonzales, Marian	Parks, Sharon
Ballestrasse, Cindy	Gonzales-Corbin, Julie	Pearson, Tia
Bangs, Leigh	Gould-Donath, Reisa	Penberthy, Eli
Barr, Nancy	Graham, Margaret	Peterson, Katrina
Bartholet, Mary	Grajczyk, Joyce	Phillips , Jennifer
Bayley, Susan	Green, Antavea	Pino, Dolores
Beach, Victoria	Grigsby, Holly	Polz, Heather
Bean, Joyce	Grisman, Tracy	Provost , Lin
Beatty, Danny	Gunn, Emily	Quinn, Colleen
Beatty, Tara	H, F	Radford, Foster
Bechtholt, Susan	Haggard , Alan	Ramon, Laura
Berenson, Cheryl	Hanley, Erik	Rappold, Julie
Beres, LeeAnne	Hansen, Elizabeth	Rappold, Julie
Bergquist-Moody, Sharon	Hanson, Art	Rathbone, Lora
Beringer, Mark	Hanson, Art	Reeder, Paul
Besaw, Marjorie	Hanson, Natalie	Reifschneider, Jill
blank, blank	Hanson, Natalie	Rezabek, Cynthia
Bolanos, Don	Hass , Susan	Riihimaki, Laura
Bowman, Patty	Hawthorne, Lucinda	Ripka , Bryan
Breiding, Stephanie	Hayden, Nancy	Rivera, Natalie
Breiding, Stephanie	Hayes , Jenny	Robinson, Daliya
Bremer , John	Heath, Elizabeth	Robson, Daliya
Brems , Alison	Higgins, Holly	Rohrbaugh, Taylor
Brieding, Stephanie	Hinchcliffe, Christa	Rolland , Janna
Brookes, Ted	Hokonson, Suzi	Rolland, Janna
Broyhill, Tara	Holland, Elizabeth	Rolland, Seth
Bruckner, Devin	Hombravella, Judith	Rosemeyer, Martha
Bruto da Costa, Michelle	Horn, Freya	Rosenkotter, Barbara
Bryan, Alyssa	Howald, William	Rosinburn, Savahn
Bryan, Teresa	Howell, Andrea	Rosman, Monika
Bubelis, Wally	Huang, Grace	Ross, Adrienne
Buch, Tony	Humphries, Eleanor	S., J.
Burke, James	Iverson, Kim	Sachs, RaeRae

Table 2 – Individual Comments

Names of Individuals who submitted rule comments		
Bushey, Lowell	Jacobs , Bob	Salter , Sarah
Butler , Peggy	Jalbing, M.C.	Samnick, Sarah
Butler, Roberta	Jancoski, Loretta	Sanders , Eric
Cameron, Cami	Janzen, Gayle	Sandry, Narinda
Cameron, Cami	Jenner, Evie	Scavezze, Barb
Campbell, Judy	Johansen, Kristopher	Schanfald, Darlene
Carlton, Jacob	Johnson Leese, J.J.	Schneider, David
Chandra, Arti	Jones , Michael	Schwab, Judith
Charlton, Bronwyn	Jungbluth, Nathaniel	Schwab, Judy
Chen, Chung-Jen	Kamas, Kristin	Schwenger, Stephanie
Chen, Sharon	Kanaga, Mike	Scribner, Denee
Cherney, R.	Kanaga, Peggy	Seidel, Noah
Ciancibelli, Allison	Karageorge, Constantina	Seidel, Noah
Cieters, Yolanda	Kearney-Schupp, Barb	Setzer, Beverly
Clark, Elaine	Keefe, Sandy & George	Shaffer , Rachel
Clark, James	Kehl, Ashley	Shapin, Katie
Clark, Justin	Kehoe, Brendan	Sharer, C
Clark, Marlene	Kelly, Angela	Shay, Brian
Claycomb, Hannah	Kelly, Angela	Sherwood, Shelly
Coffee/Dong, Thomas/Shounan	Kendall, Melissa	Simon, Patricia
Coffey, Patricia	Kenney, Pat	Sloss, Elizabeth
Cohen, Fritzi	Kline, Karla	Smith, Jude
Cohen, Judith	Kohler , Melissa	Smith, Marilyn
Connor , Thomas	Kunz, Daniela	Sodestrom, Jeff
Cornwell, The Rev. Marilyn	Lagerloef, Marcia	Sokol, Elizabeth
Cosman, David	Lahans, Tai	Species , Scott
Costanza, Alison	Lambert, John	Spiltz, Greg
Craig, Laura	Larson, RA	Spivak, Maria
Crum, Joanne	Lawrence, Christopher	St Martin, Darlene
Cruz, Nicolas	Lazerwitx, Jay	Stavis , Alex
Curry, Linda	Leathley, Brad	Stay, Chris
Curtis-Murphy, Megan	Lee, Alex	Stevens , Carol
Dahlgren, Shelley	Lenihan, C	Stitzel, David
Dalton, David	Lindgren, Krista	Stutzman, C
D'Amour, Jules	Lipe, Hillary	Sullivan, John
Dauner, Kellee	Lloyd, Diana	Teed, Cornelia
Dawson, Ann	Lockwood, L Merrick	Teed, Cornelia
De Imus, Roxanne	Lockwood, Sara Ann	Teigen, Rev. Terry
Develle , Stephanie	Lombardozzi, Kim	Thiodet, Briana
Devlin, Felicity	Lovelady, Delorse	Thompsen, Linda

Table 2 – Individual Comments

Names of Individuals who submitted rule comments		
Dickason, Pat	Lujan, Helen	Thorn, Debbie
DiMarco, Diana	Lytle , Denise	Tomhave, Diane
Douma, Barbara	Lytle, Denise	Triggs , Bob
Doumanov, Mihail	Majorowicz, Christina	Turner, Sarah
Dyson, James	Markham, Drew	Valencia, Elizabeth
Eden, Carolyn	Markley, Shannon	Van Dusen, Leigh
Edmison, Sean	Marrs, Marie	Vanderwarren, Jaclyn
Edwards , Willie	Martin, Emily	Varnell, Joann
Ellingham, Nancy	Massoni, Gina	Wahosi, Mare
Elmer, Kay	Massoni, Gina	Wallis, Jean-Paul
Emershly, Chanel	Massoni, Gina	Walsh, Katie
Emiliano, Paola	Masters , Mary	Weinstein, Elyette
Engler, Pamela	Mauch, Victoria	Weis, Marie
Engler, Pamela	McCormick, Helene	Wells , Josie
Engler, Pamela	McDermott, Denise	Wicks, Karen
Ericson, Sylvia	McGinn, Melissa	Wilkinson, Cris
Ervin, Keith	McIntyre, Barbara	Willey, Elaine
Etzel, Sarah	McIntyre, Shelby	Willey, Irene
Evans, Molly & Blair	McIlellan, Rachel	Williams, Beverly
Evenson, Marilyn	McPherson, William	Wilson, Doris
Faley, Robert L.	McRoberts , Jim	Winiecki, David
Fantle, Dena	Mitchell, Elizabeth	Wirth , Mark
Felton, JoAnne	Mohs, Donald	Wirth, Dr. Jason M.
Fisher , Lelah	Montalto, Melissa	Wood , Barbara
Fortman, Scott	Moreton, Kate	Wood , Carolyn
Foshaug, Theodore	Morris , Nancy	Y, Natali
Foster , Gordon	Mulcare , James	Yogev, Yonit
		Zaugg, Linda

Comments and Responses:

Comments and Responses are grouped together and organized by topic. Under each topic heading Ecology provides a summary of comments received or reprints the comment. Ecology's response to the comment is provided for each topic. Table 3 provides a listing of comment topics and the organization or individuals submitting the comments. Responses to comments are organized by rule section.

Table 3 – List of Comment Categories

Comment Topic	Rule Section	Organization Commenting
Rule Text		
Credible science	070	American Apparel & Footwear Association
Product Name	080	Local Hazardous Waste Management Program in King County Public Health Seattle & King County
Product Testing	080	Phillips Burgess Government Relations
Extension	100	American Apparel & Footwear Association Juvenile Products Manufacturers Association
Rule update	130	Public Health Seattle & King County
General Chemicals		
Individual comments	130	349 individual emails and postcards
Support CHCC Additions	130	Earth Ministry and Washington Interfaith Power and Light Local Hazardous Waste Management Program in King County Public Health Seattle & King County The ARC of Washington The Endocrine Disruption Exchange Toxic Free Future Washington State Legislature Washington State Nurses Association Zero Waste Washington
Specific chemicals		
BTBPE	130	The Endocrine Disruption Exchange Toxic Free Future
Butylated triphenyl phosphate	130	Israeli Chemicals Industrial Products America
D4	130	Earth Ministry and Washington Interfaith Power and Light Local Hazardous Waste Management Program in King County Public Health Seattle & King County The Endocrine Disruption Exchange Toxic Free Future Washington State Legislature Washington State Nurses Association Zero Waste Washington
Dechlorane Plus	130	The Endocrine Disruption Exchange Toxic Free Future
DMEP	130	Earth Ministry and Washington Interfaith Power and Light Local Hazardous Waste Management Program in King County

Table 3 – List of Comment Categories

Comment Topic	Rule Section	Organization Commenting
		Public Health Seattle & King County The ARC of Washington The Endocrine Disruption Exchange Toxic Free Future Washington State Legislature Washington State Nurses Association Zero Waste Washington
DIOP	130	Earth Ministry and Washington Interfaith Power and Light Local Hazardous Waste Management Program in King County Public Health Seattle & King County The ARC of Washington The Endocrine Disruption Exchange Toxic Free Future Washington State Legislature Washington State Nurses Association Zero Waste Washington
DIPP	130	Earth Ministry and Washington Interfaith Power and Light Local Hazardous Waste Management Program in King County Public Health Seattle & King County The ARC of Washington The Endocrine Disruption Exchange Toxic Free Future Washington State Legislature Washington State Nurses Association Zero Waste Washington
Lead	130	Local Hazardous Waste Management Program in King County Public Health Seattle & King County
PFOA	130	Earth Ministry and Washington Interfaith Power and Light Local Hazardous Waste Management Program in King County Public Health Seattle & King County The ARC of Washington The Endocrine Disruption Exchange Toxic Free Future Washington State Legislature Washington State Nurses Association
TCE	130	Local Hazardous Waste Management Program in King County

Ecology Responses By Topic

Ecology's responses to comments are organized as listed in Table 3. Some comments are summarized and some are included verbatim.

Credible science

Ecology received a comment urging the Washington Department of Ecology to adhere to WAC 173-334-070, which states that in order for a chemical to be considered for addition to or removal from the list of CHCC, "credible peer-reviewed scientific information" is required.

Ecology Response
Changes to the CHCC list during this rulemaking were based on information from authoritative sources and credible peer-reviewed scientific data.
The comment did not result in changes to the rule.

Product Name

Ecology received two comments requesting manufacturers be required to report the CHCCs list chemicals for all product names and categories that they sell in Washington State.

Ecology Response
Changing the rule to require reporting at the product level is outside the scope of this rulemaking. Currently manufacturers report at the "brick" level, which at the product category level.
The comment did not result in changes to the rule.

Product Testing

Ecology received one comment requesting clarification of the testing methodology in WAC 173-334-080(2)(e).

Ecology Response
The language in the rule was modified to clarify that the total concentration of a CHCC in a product component is required to be reported.
The comment resulted in the following text changes:
<i>WAC 173-334-080(2)(e) The total (amount) concentration of the CHCC (by weight) contained in each product component (in each children's product sold or offered for sale) within each product category. The (amount) total concentration may be reported in ranges, rather than the exact (amount) concentration. If there are multiple CHCC (values) concentrations for a given component in a particular product category, the manufacturer must use the (largest value) highest concentration for reporting.</i>

Extension

Ecology received two comments noting that 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. In one comment Ecology

was urged to work with manufacturers on an individual basis to understand the challenges associated with reporting.

Ecology Response

Ecology will work individually with manufacturers requesting additional time to submit the January 2019 report.

The comment did not result in changes to the rule.

Rule Update

Ecology received a comment requesting more frequent updates of the Children's Safe Products Reporting Rule and CHCC list. The request suggested a 2 to 3 year frequency to allow quick updates on chemicals based on new or changing information. The comment suggested the scope of the rule updates could be smaller to allow for the frequency of review.

Ecology Response

The current plan for the next rule update is to initiate the process in 3 years.

The comment did not result in changes to the rule.

Individual Comments

Ecology received 349 emails and postcards from interested individuals. These messages included the following general comments:

- Support for the addition of 21 chemicals to the CHCC list.
- Request for addition of three phthalates: DIPP, DMEP, DIOP
- Request for addition of PFOA related compounds
- Request to keep D4 on the CHCC list.

Ecology Response

Ecology appreciates the comments from these interested individuals. After review of multiple comments from stakeholders, including these individuals, the following changes were incorporated into the rule:

- DMEP was added to the CHCC list.
- Two flame retardants were removed from the proposed CHCC list: Tris(4-tertbutyl phenyl) phosphate and Butylated triphenyl phosphate.
- D4 was delisted from the CHCC list.
- The phrase “and related chemicals” was added to the PFOA listing.

These changes are described in the comment/response for individual chemicals.

Support for CHCC Additions

Ecology received multiple comments supporting the addition of twenty-one chemicals to the CHCC list – those comments referred to the proposed addition of the following chemicals:

<u>CAS</u>	<u>Name</u>	<u>Acronym</u>
78-33-1	Tris(4-tert-butylphenyl) phosphate	TBPP
80-09-1	Bisphenol S	BPS

84-61-7	Dicyclohexyl phthalate	DCHP
84-69-5	Diisobutyl phthalate	DIBP
115-86-6	Triphenyl phosphate	TPP
126-72-7	Tris (2, 3-dibromopropyl) phosphate	TDBPP
126-73-8	Tri-n-butyl phosphate	TNBP
131-18-0	Dipentyl phthalate	DPP
335-67-1	Perfluorooctanoic acid	PFOA
620-92-8	Bisphenol F	BPF
1241-94-7	Ethylhexyl diphenyl phosphate	EHDPP
1330-78-5	Tricresyl phosphate	TCP
13674-84-5	Tris (1-chloro-2-propyl) phosphate	TCPP
25154-52-3	Nonylphenol	
26040-51-7	Bis (2-ethylhexyl) tetrabromophthalate	TBPH
38051-10-4	Bis(chloromethyl)propane-1,3-diyl tetrakis-(2-chloroethyl) bis(phosphate)	V6
68937-41-7	Isopropylated triphenyl phosphate	IPTPP
84852-15-3	4-Nonylphenol (branched)	
84852-53-9	Decabromodiphenyl ethane	DBDPE
85535-84-8	Short-chain chlorinated paraffins	SCCP
108171-26-2	Chlorinated paraffins	
183658-27-7	2-ethylhexyl-2,3,4,5-tetrabromobenzoate	TBB
220352-35-2	Butylated triphenyl phosphate	

Ecology Response

These comments of support did not result in any changes to the rule.

After review of other comments on the rule Ecology determined that two flame retardants did not meet the CHCC listing criteria. Tris(4-tertbutyl phenyl) phosphate and Butylated triphenyl phosphate were removed from the proposed CHCC list. Specific reasons for these two changes are provided in the response to Butylated Triphenyl Phosphate.

BTBPE

Ecology received two comments requesting the addition of 1,2-Bis(2,4,6-tribromophenoxy)ethane (BTBPE) to the CHCC list. (note: the comment from Toxic Free Future uses the acronym BDBPE) Those comments are provided below.

Toxic Free Future:

We also request that Ecology add Dechlorane Plus (CAS # 13560-89-9) and BDBPE (CAS # 37853-59-1) to the list as we requested in 2013 and 2016. There is new information showing that a breakdown product of BDBPE is bioaccumulating in people and affecting thyroid hormone levels (Leonetti, Butt et al. 2016). Researchers found the breakdown product 2,4,6-tribromophenol in human placenta at levels higher than those of PBDEs. Both of these chemicals meet the toxicity and exposure criteria for listing, and information on their use is needed.

1,2-bis(2,4,6-tribromophenoxy) ethane (BTBPE) (CAS # 37853-59-1)

TFF requested the addition of 1,2-bis(2,4,6-tribromophenoxy)ethane (BTBPE) in our August 2016 petition. BTBPE is an additive flame retardant introduced to replace octa-BDE and used in various plastic resins including polystyrene and thermoplastics. This compound has been detected in house dust, in children's toys, and in human serum. We again request the addition of this compound, which appears to disrupt thyroid hormone. Evidence of thyroid impacts include the

following: tests on chicken eggs and hepatocytes found that BTBPE exposure depressed expression of a key enzyme related to thyroid hormone (Egloff et al. 2011). In addition, BTBPE's metabolite 2,4,6-tribromophenol (2,4,6-TBP) is a thyroid-disrupting compound (Hamers et al. 2006, Butt et al. 2011, Lee et al. 2016). In an epidemiological study, dust concentrations of BTBPE were positively and significantly associated with levels of T3 in adult men (Johnson et al. 2010).

Children's Exposure: BTBPE has been detected in household dust in Washington state as well as Boston, California and the UK (Harrad et al. 2008) (Stapleton et al. 2008) (Dodson et al. 2012) (Schreder and La Guardia 2014). It has been detected in children's toys in China at levels up to 117 ug/g as well as in food samples in Sweden and Ireland (Chen et al. 2009) (EFSA Panel on Contaminants in the Food Chain 2012) (Sahlstrom et al. 2015). BTBPE has been detected in human serum in two studies, in Norway and in Canada (Zhou et al. 2014) (Cequier et al. 2015). Sampling in the Great Lakes region and the Arctic has detected BTBPE in outdoor air at levels up to 1pg/m³ (Salamova and Hites 2011) (Salamova et al. 2014). Higher concentrations in air were seen in Louisiana, up to 70 ng/m³ (EFSA Panel on Contaminants in the Food Chain 2012).

Persistence and Bioaccumulation: In its analysis, the European Food Safety Authority identified BTBPE as having high persistence and high potential for bioaccumulation (EFSA Panel on Contaminants in the Food Chain 2012). BTBPE has been detected in various biota, including marine mammals in the South China sea and the Canadian Arctic as well as in Glaucous gulls from the Norwegian Arctic, juvenile sole from the French Atlantic coast, and trout and other fish in Lake Ontario (EFSA Panel on Contaminants in the Food Chain 2012) (Zhu et al. 2014). A study in juvenile trout given an environmentally relevant dose of BTBPE found fish accumulated the compound and concluded it has a high potential for biomagnification in aquatic food webs (Tomy et al. 2007). Researchers also found BTBPE accumulated in fathead minnows (de Jourdan et al. 2014).

Other effects: Inhalation exposure of rats to BDBPE resulted in behavioral, respiratory, and gastrointestinal effects as well as dermatitis (Harju et al. 2009). Dermal exposure of rabbits resulted in "nutritional and gross metabolic changes" (Harju et al. 2009).

Since the submittal of the petition, additional research has been published raising the level of concern about the potential health impacts of this chemical. In November 2016, Leonetti et al. published a paper titled "Brominated flame retardants in placental tissues; associations with infant sex and thyroid hormone end points" in Environmental Health (Leonetti et al. 2016). In the analysis of placental tissues (n= 102), the authors found PBDEs as well as 2,4,6-TBP in all placentas; suprisingly, mean 2,4,6-TBP levels were higher than those of PBDEs, an unexpected finding. These results indicate that 2,4,6-TBP bioaccumulates in placenta and suggest there are substantial sources of this compound. The study also found lower T3 levels in placentas with greater brominated flame retardant levels. The authors conclude that brominated flame retardants may be associated with thyroid hormone changes that differ between the sexes, which may explain the sex-specific manner, which may explain the sex-specific associations seen in other epidemiological studies. Thus, available studies show that exposure occurs in children and that the metabolite has endocrine activity that may be detrimental to developing children.

The Endocrine Disruption Exchange

1,2-Bis(2,4,6-tribromophenoxy)ethane (BTBPE: 37853-59-1): In humans BTBPE dust concentrations are associated with T3 levels in men [88]. The metabolite of BTBPE, 2,4,6-tribromophenol (2,4,6-TBP) is a thyroid disrupting chemical and bioaccumulates in the placenta [89, 90].

Ecology Response
We agree that exposure criteria are met for BTBPE. We did not locate, nor was information provided that identified BTBPE as meeting toxicity criteria by an authoritative source. See page 2 for the listing criteria used in this rulemaking.

These comments did not result in changes to the rule.

The European Food Safety Authority found insufficient information for classification of this chemical for carcinogenicity, developmental and reproductive toxicity, or endocrine disruption (EFSA, 2012).

Regarding a potential human metabolite of BTBPE, 2,4,6-tribromophenol, we agree that this metabolite is of potential concern to children's health. Reproductive toxicity is reported in rodent testing and there is emerging evidence that it can alter hormone signaling and may therefore have developmental neurotoxicity in mammals (NIOSH 2016, Leonetti et al 2016, Norwegian Environment Agency 2016). However, 2,4,6-tribromophenol is not currently listed by an authoritative source as a reproductive or developmental toxicant. While 2,4,6-tribromophenol is detected in people, biota, and the environment the extent to which BTBPE contributes to its presence is not known. There are a number of possible sources of 2,4,6-tribromophenol in the environment and biota beside BTBPE. No current manufacturing or use information is available in EPA's Chemical Data Reporting database but according to PubChem, 2,4,6-tribromophenol is a globally-produced chemical with a high production volume in the U.S. It is used in the production of a number of brominated flame retardants, may be used as a reactive flame retardant itself, and can also be formed naturally in the marine environment. According to Wikipedia it is also used as a wood preservative and fungicide. It has been detected in fish and shellfish and human exposure may occur via direct dietary exposure.

Butylated Triphenyl Phosphate

Ecology received the following comment:

Israeli Chemicals Industrial Products America:

A large number of studies have been performed over the last decades with butylated triphenyl phosphate (TBTPP), including acute, (semi)chronic and reproductive toxicity, neurotoxicity, genotoxicity and inhalation and dermal studies. Acute oral and dermal toxicity studies showed that the product has very low acute toxicity by both routes. This low toxicity was confirmed in an acute inhalation study in which rats exposed to the highest attainable air concentration showed minimal signs of toxicity. TBTPP can cause very mild irritation to the skin and eyes, but non sensitization was confirmed in a Human Patch. Repeated exposure in rats via the diet did not result in any adverse effects and a combined one-generation reproductive/developmental toxicity screening test in rats by the oral route, showed no treatment-related effects. TBTPP was tested separately for developmental toxicity in other studies and the data show it does not adversely affect fetal development. TBTPP did not show a potential to induce genetic mutations or chromosomal aberrations, as shown in a battery of mutagenicity tests. Various studies with hens have been performed to study the neurotoxicity potential of TBTPP, high doses caused significant plasma cholinesterase inhibition, which is a fully reversible biochemical effect. Treatment with TBTPP did not cause the percent inhibition of NTE necessary for the induction of delayed peripheral neurotoxicity and thus indicates low potential for neurotoxicity. Based on the results from the reproductive testing, it can be assumed that TBTPP does not cause any endocrine disruption when released into the environment.

EPA confirmed these conclusions in the study published in July 2008, in the Initial Risk-Based Prioritization of High Production Volume Chemicals, where the agency stated "The potential health hazard of butylated triphenyl phosphate is low." The agency also found potential exposure to children was low, as no uses in products specifically intended to be used by children were reported nor found.

Ecology Response

Further information provided by industry participants in the rulemaking process clarified the CAS numbers used for chemicals and mixtures with butylated triphenyl phosphate flame retardants. The sole domestic manufacturer of CAS No. 78-33-1 clarified that this chemical is not used as an independent flame retardant. Rather, it is one component (usually 1-10%) generated during production of a butylated triphenyl phosphate commercial mixture (CAS no. 56803-37-3 and 68937-40-6). These mixtures always contains triphenyl phosphate as a component and as such would already trigger CSPA reporting. Two European government evaluations of the commercial butylated phenyl phosphate mixtures rated the reproductive and developmental toxicity of the commercial mixtures as low based on available data (UK 2009, DEPA 2016).

The commercial mixtures (68937-40-6 and 56803-37-3) were considered for listing but do not meet toxicity criteria because they are not considered toxic by an authoritative source for carcinogenicity, reproductive/developmental toxicity, or endocrine disruption.

Exposure criteria were met for listing the commercial mixtures. DOH confirmed with the Stapleton laboratory that their reported detection in residential furniture and children's products is evidence of use of the commercial mixture. Although industry participants were unaware of any uses of this commercial mixture in children's products, a company that did not participate in the CSPA rulemaking process, lists the mixture (CAS No 68937-40-6) in the EPA Chemical Data Reporting database 2016 reporting cycle as being used in consumer and children's products for foam seating and bedding products.

Based on the clarification above, Ecology removed butylated triphenyl phosphate (CAS No 78-33-1 and associated CAS No. 220352-35-2 listed in the proposed rule documents) from the CHCC list.

D4

Ecology received multiple comments requesting that D4 be retained on the CHCC list. Many of these comments did not provide references to authoritative sources or credible peer-reviewed scientific data. Two requests to retain D4 on the CHCC list did include references. Those comments are provided below.

Toxic Free Future:

Octamethylcyclotetrasiloxane (D4) (CAS # 556-67-2)

TFF urges the Department of Ecology to reconsider its proposal to remove octamethylcyclotetrasiloxane (D4) from the CHCC reporting list. There is evidence that this chemical has endocrine-disrupting properties in industry-sponsored as well as in government and independent studies (McKim et al. 2001) (Quinn et al. 2007) (Quinn et al. 2007) (Meeks et al. 2007) (Siddiqui et al. 2007) (He et al. 2003) (Lee et al. 2015) and there is new evidence of D4 exposure to children through CSPA reporting itself. D4's presence in children's products reported under CSPA indicates that products other than personal care products are a significant and unexpected source of D4 exposure to children. Washington's families and policymakers need the continued presence of D4 on the CHCC list while this exposure is evaluated.

Toxicity: D4 is described as having been placed on the CHCC list in 2011 because it is classified as a Category 1 endocrine disruptor by the European Union, it has been demonstrated to have estrogenic activity in rat and mice uterotrophic assays, and because it was identified by the Danish EPA as a listed ingredient in personal care products marketed to children (DOH, 2011).

TFF supports the continued listing of D4 on the CHCC list for its endocrine-disrupting properties:

- Washington's Department of Ecology confirmed the use of the European Union's priority list of chemicals identified as suspected endocrine disruptors, specifically those designated as Category 1, for this current CSPA rule update (Ecology, 2016a). D4 is identified as a Category 1 chemical (DHI 2007) because there is evidence that it has endocrine-disrupting effects in intact organisms.
- New evidence (Lee et al. 2015) gives evidence of D4's disrupting properties in an vivo study. In one of several studies reported on in this paper, an uterotrophic assay (an in vivo estrogenicity assay) was carried out by administering subcutaneous injections of 500 mg/kg (ppm) D4 or 1,000 mg/kg to immature rats for 4 days. Treatment uterine weights were not significantly different from control uterine weights in the uterotrophic assay. Having seen significant results in an in vitro estrogenicity assay prior to the uterotrophic assay, the authors stated that, "Since the estrogenic effect of D4 was not shown by UT assay, we used a more sensitive method." They looked at CaBP-9K, ER alpha, and PR expression in immature rats' uteruses. Results demonstrated that the estrogenic biomarker CaBP-9K mRNA expression was significantly increased by D4 in a dose-dependent manner. CaBP-9K mRNA expression was up-regulated 2- or 3- fold by 500 and 1000 mg/kg D4. The authors concluded from their research that D4 has estrogenic potential proven under both in vitro and in vivo experimental conditions. This paper shows mixed in vivo evidence, which is not compelling new evidence, and does not provide proof that D4 is no longer estrogenic.

D4 also shows evidence of reproductive toxicity and therefore should remain on the CHCC list:

- A European Union Harmonized Classification and Labelling has been assigned to D4: Reproduction Category 2 with a hazard statement code H361f (suspected of damaging fertility) and R62 (possible risk of impaired fertility) and R63 (possible risk of harm to the unborn child) risk phrases (EHCA 2008e).
- (Siddiqui et al. 2007) reports results on the reproductive toxicity of D4. This study evaluated the reproductive toxicity in two generations of Sprague-Dawley rats (30/sex/group) exposed to whole body vapor inhalation of D4 at concentrations of 0, 70, 300, 500, or 700 ppm 6 hours per day for 70 consecutive days prior to mating and lasted through weaning. Prolonged estrous cycles, decreased mating and fertility indices were observed in the F1 generation exposed to D4. Significant reductions in the mean number of pups born and mean live litter size were observed in the 500 and 700 ppm groups for both the FO and F1 generations. Implantation sites were also reduced at 700 ppm for both FO and F1 generations. The NOAEL for male reproduction was considered to be 700 ppm and the NOAEL for female reproduction was considered to be 300 ppm.
- (Meeks et al. 2007) exposed rats to D4 by whole body vapor inhalation and evaluated the phase of the female reproductive cycle affected by D4. For the overall phase study female rats were exposed to 0, 70, 300, 500, or 700 ppm D4 in vapor for 6 hours per day. A statistically significant decrease in maternal body weight was observed in the 700 ppm group during gestation. Mean absolute adrenal gland weight was significantly increased in the 700 ppm group. The mean numbers of corpora lutea were statistically significantly reduced in the 300 and 500 ppm exposure groups. There was increased implantation loss at 500 and 700 ppm.

There was a significant reduction in the mean number of viable fetuses in the 500 and 700 ppm exposure groups. In the fertilization phase study (exposures were 0 and 700 ppm only), absolute maternal ovarian weight was decreased at 700 ppm. There were also lower numbers of implantation sites and a significant increase in early resorptions and significantly reduced mean number of viable fetuses.

Exposure: The argument for delisting D4 is also based on the assumption that D4 is no longer in use in personal care products. However, evidence does exist for D4's presence in personal care and other products that children are exposed to:

- There have been over 2,300 reports to date of D4 in children's products reported to the state of Washington under the Children's Safe Products Act in concentrations up to 500 ppm. Most of these reports are of products other than personal care products such as clothing, footwear, toys, baby care items, and bedding (Ecology 2017). Companies reporting these products include large companies such as Walmart, Carter's, Nike, Gap, Gymboree, and VF Corporation. Based on this evidence alone children's exposure to D4 is widespread and in products not generally associated with D4. This points to the need to investigate more fully the sources of exposure of children to D4, as well as to the importance of keeping D4 on the CSPA reporting list in order to continue collecting important information about the chemical.
- (Capela et al. 2016) analyzed for 04 in cosmetics and personal care products purchased in Portugal. 6 out of 6 baby and children lotion/milk/ cream moisturizer samples contained 04 with levels ranging from 0.03 - 0.14 ug/g (ppm). 8 out of 9 baby and children shower gels contained 04 with levels ranging up to 5.34 ug/g (ppm). 5 out of 8 baby and children shampoo contained 04 with levels ranging up to 20.13 ug/g (ppm). 6 out of 6 baby and children toothpaste samples contained 04 with levels ranging from 0.02 - 0.30 ug/g (ppm).

The Endocrine Disruption Exchange

We do not support the removal of D4 from the CHCC list.

Octamethylcyclotetrasiloxane (D4; 556-67-2) is used as an intermediate to produce silicone polymers. There have been over 2,300 reports of D4 in children's products to Ecology since 2008, indicating the potential for exposure in children. In Publication No. 17-04-021 Ecology states that "Based on the mixed results on a single assay, there is not sufficient evidence for CSPA of D4 toxicity" [91]. From this, it appears that Ecology has proposed to delist D4 based largely on a 2015 report by Lee et al. that reported that D4 did not induce a uterotrophic response [92]. We do not feel that this is a strong enough rationale for delisting a potentially hazardous EDC. Our reasons are listed below.

- Despite the lack of a uterotrophic response, Lee et al. (2015) concluded that D4 was estrogenic based on its induction of other estrogen regulated endpoints in vivo and in vitro including induction of gene and protein expression of the classic estrogen responsive genes calbindin-D9k (CaBP-9K) and progesterone receptor. The increased expression of CaBP-9K and progesterone receptor was blocked when treatment occurred in the presence of the potent estrogen receptor antagonist ICI 182 780 (ICI), which indicates that D4 was acting through an estrogen receptor mediated mechanism.
- **Earlier studies have all reported that D4 induces a uterotrophic response [93-95].** This finding holds across species (rat and mouse), strains (Sprague Dawley or F-344 rat) and exposure paradigms (oral and inhalation routes; juvenile or ovariectomized adults).
- The in vivo study by Lee et al. (2015) is the only study that utilized a subcutaneous route of exposure. It is possible that the route-specific differences in

pharmacokinetics of D4 could account for the negative findings in the uterotrophic assay [96].

- Additional support for estrogenic activity is that the uterotrophic response can be blocked by the estrogen receptor specific antagonist ICI [95] and D4 increases epithelial cell height in the uterus, which is another indicator of estrogenic activity [93, 94].
- The potential for estrogenic effects is further supported by the findings of Quinn et al. (2007) and He et al. (2003) who reported binding of D4 to estrogen receptor alpha *in vitro*. Ecology did not acknowledge these findings in document 17-04-021, focusing rather on the lack of binding of D4 to the estrogen receptor in the US EPA's high throughput testing system ToxCast. It has been noted, however, that the negative finding in ToxCast is potentially due to the volatility of D4 and it is possible that "the concentration of the compound actually tested in the high-throughput assays was lower than the calculated nominal concentration" [97].

Upon evaluation of this body of research, we see no reason for the single negative finding in a single assay by Lee et al. to be given more weight than the previous studies in determining the potential toxicity of D4. There is no reason to disregard existing data across species, strains, and routes of exposure that indicates that D4 is estrogenic by measurement in the uterotrophic assay, as well as additional *in vivo* and *in vitro* assays.

Perhaps more important, yet not mentioned in document 17-04-021, is that **D4 has consistently been reported to be a reproductive toxicant, causing fetal loss in pregnant rats.** Exposure to D4 causes changes to pregnancy-related hormone concentrations including estradiol, follicle stimulating hormone, and luteinizing hormone [95, 98]. According to the authors of the papers reporting fetal loss [99, 100] the loss is most likely caused by disruption of the luteinizing hormone surge required for ovulation [98, 99]. The suggestion from these papers is that if the pregnancy loss is not a result of D4's estrogenicity, then the fact that D4 is estrogenic can be disregarded. However, regardless of the mechanism, **the fact that D4 caused up to a 38% loss in the number of live pups per litter should not be ignored.** Further, Siddiqui et al. (2007) also reported effects in other estrogen sensitive tissues, such as the mammary gland. Yet Siddiqui et al. (2007) made no attempt to determine the mechanism or the subsequent functional consequences of the mammary gland disruption, which included increased cellular proliferation, secretions, and milk cysts [100]. **Environmental chemicals including EDCs often act on multiple target tissues through more than one mechanism, and it is not necessary to have a fully elucidated mechanism to consider a chemical a potential hazard. D4 clearly has the potential to act as an endocrine disruptor and a reproductive toxicant, as demonstrated by independent academic, government, and industry scientists, and as such, should remain listed on the CHCC under the CSPA.**

Ecology Response

Ecology conducted a detailed review and analysis of the information and references provided by Toxic Free Future and The Endocrine Disruption Exchange.

D4 is present on the European Commission (EC) Category 1 list, based on a single study, showing an increase in uterine weight (McKim et al, 2007). However, a more recent study shows no effect on uterine weight by D4 (Lee et al, 2015). These mixed results, along with biomarker and *in vitro* data for D4 (He et al, 2003; Quinn et al, 2007; Lee et al, 2015) are not sufficient for CHCC listing.

The European Union Harmonized Classification and Labeling listing is not an authoritative source for CHCC listing. D4 is not listed by any of the other CSPA authoritative sources. D4

does not meet the CHCC listing criteria. See page 2 for the listing criteria used in this rulemaking.

D4 was removed from the CHCC list.

Dechlorane plus

Ecology received two comments requesting the addition of Dechlorane plus to the CHCC list. Those comments are provided below.

Toxic Free Future:

We also request that Ecology add Dechlorane Plus (CAS # 13560-89-9) and BDBPE (CAS # 37853-59-1) to the list as we requested in 2013 and 2016.

On September 6, 2013 TFF (then known as Washington Toxics Coalition) submitted a petition to the Department of Ecology requesting that the flame retardant Dechlorane Plus (CAS # 13560-89-9) and several other chemicals be added to the CHCC list. On August 5, 2016 TFF (then known as Washington Toxics Coalition) submitted a petition to Ecology requesting that the flame retardant BTBPE (CAS # 37853-59-1) and several other chemicals be added to the CHCC list. TFF respectfully requests that Ecology consider adding Dechlorane Plus and BTBPE to the CHCC list in this rule update. TFF's rationale for listing Dechlorane Plus and BTBPE are given below:

Dechlorane Plus (CAS # 13560-89-9)

Dechlorane Plus is a chlorinated flame retardant used in wires, cables, and connectors and in paper laminates, with typical levels in the range of 20-25% (Weil and Levchik 2004). It can be used in multiple polymers including ABS, HIPS, epoxy, nylon, and polypropylene (Oxychem 2007). A significant use is reported to be in television enclosures (Weil and Levchik 2007).

Children's Exposure: Dechlorane Plus is used in consumer products and has been detected in house dust in California and Canada (Dodson et al. 2012) (Shoeib et al. 2012). It has also been detected in outdoor air in the Great Lakes region as well as in Europe and the Arctic (Peverly et al. 2015) (Salamova et al. 2014) (Sverko et al. 2011). A Canadian study detected the compound in breast milk, and European and Chinese studies have detected it in human serum (Siddique et al. 2015) (He et al. 2013) (Cequier et al. 2015). It has also been found to cross the placenta (Ben et al. 2014).

Persistence and Bioaccumulation: The predicted half-life of Dechlorane Plus is 360 days in soil and 1600 days in sediment (Office of Environmental and Health Hazard Assessment 2008). The bioaccumulation appears to differ between the two isomers (syn- and anti-), but the predicted bioconcentration factor (BCF) is 3.2 (Office of Environmental and Health Hazard Assessment 2008). Modeling and detections in sediment and biota suggest that Dechlorane Plus may be persistent, bioaccumulative, and subject to long-range transport (Sverko et al. 2011).

Reproductive Toxicity: In a 28-day dermal toxicity study in rabbits, there was a significant decrease in absolute ovarian weights at the lowest dose tested, 500 mg/kg-day. This result places Dechlorane Plus in the "severe" category for reproductive toxicity (US EPA 2011).

Endocrine Disruption: Serum levels of Dechlorane Plus were associated with higher total T3 levels in women living more than 20 years in an e-waste recycling region of China (Ben et al. 2014).

Organ Toxicity: In a 28-day day inhalation study in rats, at the lowest dose tested, 0.64 mg/L (dust), both male and female rats showed significant increases in absolute liver weights. Females also had significantly greater lung weights and slightly increased numbers of macrophages in the alveoli (US EPA 2011).

Additional Considerations: Dechlorane Plus has a high degree of structural similarity to organochlorine pesticides including heptachlor, chlordane, nonachlor, and aldrin, substances restricted due to persistence, bioaccumulation, and toxicity (Zhu et al. 2007).

The Endocrine Disruption Exchange

Dechlorane Plus (DP: 13560-89-9): In zebrafish, embryonic exposure to DP causes neurobehavioral defects at non-teratogenic doses [86]. In adult zebrafish, DP causes increased circulating plasma T4 and expression of corticotropin releasing hormone and thyroid stimulating hormone b genes in brain [87].

Ecology Response

We agree that exposure criteria are met for Dechlorane Plus. Available toxicity data are limited and there are important data gaps for carcinogenicity, endocrine disruption and other endpoints of concern to children. Based on available data, EPA in 2014 rated reproductive and development toxicity of DP as “very low.” In repeated-dose studies, adverse effects on the liver including mild pathology, altered gene expression, altered liver enzyme levels in serum were reported. (EPA 2011, EPA 2014, Li et al 2013, Wu et al 2012).

Dechlorane Plus does not currently meet the agency’s CHCC criteria due to the lack of an authoritative source listing the chemical as toxic for cancer, endocrine disruption, or reproductive and developmental toxicity. See page 2 for the listing criteria used in this rulemaking.

These comments did not result in changes to the rule

DMEP

Ecology received multiple comments requesting that Di(2-methoxyethyl) phthalate (DMEP) be added to the CHCC list. Many of these comments did not provide references to authoritative sources or credible peer-reviewed scientific data. Two requests to add DMEP to the CHCC list did include references. (note: the comments from Toxic Free Future and The Endocrine Disruption Exchange use the acronym DEMP) Those comments are provided below.

Toxic Free Future:

Bis (2-methoxy ethyl phthalate) phthalate (DEMP) (CAS # 117-82-81)

Use: Bis (2-methoxyethyl phthalate) (DEMP) is used as a plasticizer in cellulosic resins, some vinyl ester resins, PVC, and as a solvent, a molding component in adhesives, and laminating cements (CPSC 2011).

Children's exposure: DEMP can be present at up to 40% (possibly in combination with other phthalates) in toys, including inflatable water products, hoppers, play and exercise balls according to Australian industry sources (NICNAS 2008b). In children's toys and childcare articles made from polyvinyl chloride (PVC), DEMP may also be used as a secondary plasticizer or be present as a contaminant (NICNAS 2008b). DEMP was detected in indoor dust in Hamburg, Germany, between 1998 and 2000 (BAuA Bis(2-methoxyethyl)phthalate). It was also detected in indoor air in Australia (BAuA Bis(2-methoxyethyl)phthalate). DEMP was detected in Germany in T-shirts (10-30 ug/kg), diapers (10-20 ug/kg) and house carpets (10-50 ug/kg) (Environment Canada 2009).

Toxicity: DEMP is found on the following authoritative lists:

- EU REACH Candidate List of Substances of Very High Concern for Authorisation (SVHC list), Reason for listing: Toxic for Reproduction (ECHA 2011).
- EU - Annex VI CMRs: Reproductive Toxicity Category 1B (ECHA 2008c).
- EU R-phrases: R61 May cause harm to the unborn child (ECHA 2008c).
- EU R-phrases: R62 Possible risk of impaired fertility (ECHA 2008c).
- EU GHS H-statements: H360Df May damage the unborn child. Suspected of damaging fertility (ECHA 2008c).

- EU - REACH Annex XVII CMRs: Repr. Category 18 (ECHA Annex VI CLP spreadsheet).

Reproductive Toxicity: In an oral exposure (gavage) repeated dose study in Sprague-Dawley rats DEMP metabolite 2-methoxyethanol (2-ME) was reported to have an LOAEL of 100 mg/kg bw-day for degeneration of spermatocytes, and an LOAEL of 250 mg/kg bw-day for decreased relative testis weight, seminal tube atrophy and sperm degeneration (NICNAS 2008b). In two DEMP oral exposure by gavage studies in rats an LOAEL of 1000 mg/kg bw-day was reported for decreased testes weight and an LOAEL of 1000 mg/kg bw-day was reported for decreased testes weight and abnormal sperm heads (NICNAS 2008b). In a study on oral exposure of Sprague-Dawley rats to DEMP metabolite methoxyacetic acid (MAA) an LOAEL of 592 mg/kg bw-day was reported for decreased testes weight, however this was the lowest dose tested (NICNAS 2008b).

Developmental Toxicity: In a study in which Wistar rats were exposed to DEMP metabolite 2-methoxyethanol (2-ME) orally by gavage an LOAEL of 158 mg/kg bw-day was reported for the effect of increased fetal resorptions and increased gross and skeletal malformations (NICNAS 2008b). In another study in which female monkeys were exposed to 2-ME orally by gavage an LOAEL of 12 mg/kg bw-day was reported for increased intrauterine death with 100% intrauterine death at 36 mg/kg/bw-day (NICNAS 2008b). In a study in which Sprague-Dawley rates were exposed orally by gavage to DEMP metabolite MAA an LOAEL of 187 mg/kg bw-day was reported for increased fetal resorptions and increased gross and skeletal malformations (NICNAS 2008b). Developmental effects of DEMP were observed in rats following oral (gavage) administration on gestation days 6 to 16. Significantly reduced pup body weight gain and slightly reduced pup survival were observed at the lowest dose tested (60 mg/kg-bw per day, LOAEL). At a higher dose level (180 mg/kg-bw per day), significantly reduced pup survival and pup body weight gain as well as pup abnormalities, including a shortened lumbosacral region, acauda and filamentous tails, were observed (Environment Canada 2009).

Since the submittal of Toxic-Free Future's petition in 2016 requesting DEMP be added to the CHCC list, additional sources on DEMP exposure in humans were located. Researchers in Hong Kong published a study in which 153 samples of blood were collected from 153 individuals (Wan et al. 2013). DEMP was detected in 100% of the individuals sampled with a mean concentration of 11.01 ng/ml. In comparison DEHP was detected in 96% of the individuals sampled with a mean concentration of 11.13 ng/ml. DEMP is generally not included in the list of analytes in human biomonitoring studies. In another study (Bao et al. 2015), researchers detected DEMP in 1 out of 7 samples of baby shampoo at a concentration of 24.3 mg/kg. DEMP is infrequently included in consumer product and house dust testing. This new information raises concern about DEMP exposures, and with data gaps in the literature, Toxic-Free Future requests further consideration of this chemical for inclusion on the CHCC list.

The Endocrine Disruption Exchange

Bis(2-methoxyethyl) phthalate (DEMP: 117-82-8): DEMP and its metabolite methoxyacetic acid (MAA) are developmental toxicants. A single exposure to DEMP on gestational days 10-14 (0.6ml/kg) is embryotoxic causing an increase in the number of resorptions. DEMP is also fetotoxic causing reduced fetal weight and an increase in skeletal and congenital brain malformations [79, 80]. In 10 week old rats a single exposure to 1500 or 2000 mg/kg DEMP decreased testis weight and increased abnormal sperm [81]. Additionally, the metabolite of DEMP, MAA, disrupts early embryo growth and development in culture and is teratogenic in vivo [82, 83].

Ecology Response
Ecology conducted a detailed review and analysis of the information and references provided by Toxic Free Future and The Endocrine Disruption Exchange.

DMEP has been identified as toxic by an authoritative source (ECHA SVHC listing, BAuA undated). DMEP has been reported in biomonitoring samples (Wan 2013). Ecology concluded that DMEP meets the CHCC listing criteria. See page 2 for the listing criteria used in this rulemaking.

Therefore, DMEP was added to the CHCC list.

DIOP

Ecology received multiple comments requesting that DIOP be added to the CHCC list. Many of these comments did not provide references to authoritative sources or credible peer-reviewed scientific data. Two requests to add DIOP to the CHCC list did include references. Those comments are provided below.

Toxic Free Future:

Diisooctyl phthalate (DIOP) (CAS # 27554-26-3)

Uses: Plasticizer for vinyl, cellulosic and acrylate resins, and synthetic rubber, additive in plastics that will come into contact with food (HSDB 2009).

Exposure: In one study the use of DIOP has been reported in teething rings (10.2%) and pacifiers (17.1%) (Stringer et al. 2000). In the US, it is also reported in shower mats. The FDA has approved DIOP for use in adhesives or surface resin and polymer coatings for products that have contact with food (products intended to be used in production, manufacturing, packing, transport, or holding of food) (CPSC 2010b).

Reproductive and Developmental Toxicity: Female CD-1 mice were exposed to 0, 44, 91, 190.6, or 292.5 mg/kg bw DIOP in their diet during gestation. The number and percent of resorptions, late fetal deaths, and dead and malformed fetuses were all increased in response to 190.6 and 292.5 mg/kg bw treatments. Female fetal weight and the number of live fetuses per litter for both sexes were significantly reduced at 190.6 and 292.5 mg/kg bw doses. A significant increase in both the percentage of fetuses with external, visceral, and skeletal malformations and the percentage of malformed fetuses per litter were observed with dosing as low as 91 mg/kg bw (HSDB 2009). In a two-generation study, male/female Swiss CD-1 mice were exposed daily to 0, 14, 140, or 420 mg/kg of DIOP in their diet throughout a cohabitation period. When the F1 litters were sexually mature, they were mated with animals from different litters within the same group. At necropsy the F1 animals showed a significant decrease in the number of litters/pair, live pups/litter, mean live pup weight and proportion of live pups at 140 mg/kg/day. Exposure to 420 mg/kg/day resulted in significant infertility during the continuous breeding phase of the study which was seen in both sexes. Exposure to the high dose in the crossover study also resulted in male specific effects including reduced testis, epididymis, prostate weights, percentages of motile sperm and abnormal sperm, and sperm concentration in the males. In females effects included reduced combined weight of ovaries, oviducts and uterus. Both sexes exhibited increased liver weights. The majority of high-dose male mice evidenced some degree of bilateral atrophy of the seminiferous tubules (HSDB 2009).

Additional Considerations: The Chronic Hazard Advisory Panel on Phthalates and Phthalate Alternatives (CHAP) recommended to the U.S. Product Safety Commission in July, 2014 that DIOP should be subject to an interim ban from use in children's toys and child care articles at levels greater than 0.1% (CHAP 2014).

Since Toxic-Free Future submitted a petition in 2016 requesting Ecology add DIOP to the CHCC list, additional information on DIOP toxicity and exposure has been located. A study published in 2013 (Saillenfait et al. 2013) show that in utero exposure of Sprague-Dawley rats produced fetal growth retardation at 500 and 1000 mg/kg/day as evidenced by reduced body weight and/or ossification delay. Short supernumerary lumbar rib skeletal variant was significantly increased at 500 and 1000mg/kg/day. In addition there was abnormal position of the testes in DIOP-exposed fetuses, a dose-dependent decrease in ex vivo testosterone production by the fetal testis with the

NOAEL and LOAEL for this endpoint being 10 and 100 mg/kg/day, permanent postnatal alterations in androgen-dependent structures of male offspring, and reproductive tract malformations in a few adult males at 500 mg/kg/day and at higher incidences at 1000 mg/kg/day. A recent study on phthalates in house dust carried out in Canada (Kubwabo et al. 2016) reported detections of DIOP in 87% of 126 house dust samples taken from 38 Canadian homes. Reported DIOP levels ranged from <MDL to 1170 ug/g, with a median of 6.6 ug/g. Phthalates not commonly monitored were focused on in this study. These papers confirm exposure to DIOP and provide additional toxicity evidence.

The Endocrine Disruption Exchange

Diisooctyl phthalate (DIOP: 27554-26-3): DIOP has already been detected in some children's toys [84]. DIOP is a reproductive and developmental toxicant. At higher doses (0.5 and 1 g/kg-day) developmental exposure to DIOP increases resorptions and reduces fetal weight, whereas lower doses (0.1 g/kg-day) reduce testicular testosterone production. Importantly, hypospadias, undescended testes, and skeletal malformations are increased in the offspring of developmentally exposed males [85].

Ecology Response

Ecology conducted a detailed review and analysis of the information and references provided by Toxic Free Future and The Endocrine Disruption Exchange.

The CHAP report recommendation states that “human exposure appears to be negligible,” based on the reference to data collected in 1998 (Stringer 2009). The CHAP Report is an authoritative source for CSPA, however the recommendation for DIOP is not sufficiently robust for a CHCC listing (CHAP 2014). DIOP does not meet the CHCC listing criteria. See page 2 for the listing criteria used in this rulemaking.

These comments did not result in changes to the rule.

DIPP

Ecology received multiple comments requesting that DIPP be added to the CHCC list. Many of these comments did not provide references to authoritative sources or credible peer-reviewed scientific data. Two requests to add DIOP to the CHCC list did include references. Those comments are provided below.

Toxic Free Future:

Diisopentyl phthalate (DIPP) (CAS # 605-50-5)

Use: DIPP is a plasticizer used to ensure flexibility of PVC (Environment Agency Austria, DIPP). It is also used in the manufacture of propellants and explosives, and has been found in cosmetics (Environment Agency Austria, DIPP) (Llompert et al. 2013). It is considered to be a potential substitute for other C4 - C6 phthalates and is similar in structure to other banned phthalates known for their toxicity effects (especially to DNPP CAS # 131-18-0) (Environment Agency Austria, DIPP).

Children's exposure: An Austrian environmental agency study of consumer products detected DIPP in one sample; since it has not routinely included in phthalate measurements in products, its presence may be underestimated (Environment Agency Austria, DIPP).

Toxicity: DIPP is found on the following authoritative lists:

- EU REACH Candidate List of Substances of Very High Concern for Authorisation (SVHC list). Reason for listing: Toxic for Reproduction (ECHA 2012).
- EU - Annex VI CMRs - Reproductive Toxicity Category 18 (ECHA 2008d).
- EU R-phrases: R61 May cause harm to the unborn child (ECHA 2008d).

- EU R-phrases: R60 May impair fertility (ECHA 2008d).
- EU GHS H-statements: H 360FD May damage fertility, may damage the unborn child (ECHA 2008d).

Developmental effects: In a toxicity study in which an oral mixture of Di-n-pentylphthalate (DNPP) with di-iso-pentylphthalate (DIPP) was administered to pregnant Wistar rats in doses of 40, 200 and 1,000 mg/kg, results showed at the highest dose all fetuses were resorbed (100% post-implantation loss). No effects were observed at the lower doses (ECHA Support Document DIPP). Two other studies provide strong evidence that dipentylphthalate (DIPP) (CAS 131-18-0) is an equal or even more potent testicular toxicant than DEHP. This is likely to be valid also for other structurally related pentyl phthalates, like DIPP (ECHA Support Document DIPP). This is supported by the study on the mixture of DNPP and DIPP mentioned above. This mixture of pentyl phthalates caused a 100% resorption at 1000 mg/kg/d ay while DEHP caused malformations in 70% of the litters at the same dose (ECHA Support Document DIPP).

Reproductive effects: A fertility reducing action is suspected because of the structural relationship of DIPP to di-n-pentyl phthalate (DNPP) and dibutylphthalate (DBP) and the findings available for these substances. The monoesters of phthalic acid esters of medium chain length (C4 - C6) cause damage to the germinal epithelium in the testis. Sertoli cells in the seminiferous tubules are the primary site of attack. They exhibit considerable vacuolization of the smooth endoplasmatic reticulum resulting in a reduced fertility. As a consequence the germinal epithelium may be lost (ECHA Support Document DIPP).

The Endocrine Disruption Exchange

Diisopentyl phthalate (DIPP: 605-50-5): Though DIPP is not routinely tested in consumer products, it has been detected in a cosmetic sample, which suggests that it may already be in use on the marketplace [77]. The European Chemicals Agency (ECHA) classifies DIPP as a Category 1A and 1B reproductive toxicant stating that it may impair fertility and harm the unborn child due to its structural similarity to other phthalates, specifically di-n-pentyl phthalate (DNPP) and dibutylphthalate (DBP) [78].

Ecology Response
<p>Ecology conducted a detailed review and analysis of the information and references provided by Toxic Free Future and The Endocrine Disruption Exchange.</p> <p>DIPP has been identified as toxic by an authoritative source (ECHA SVHC listing). The references provided for exposure potential were insufficient for CHCC listing.</p> <p>Cosmetic sample tests did not report presence of DIPP in children’s products (Llompart 2013). The Austrian study reported detection of DIPP in one product, but the result was below the limit of quantification (Environment Agency Austria, undated). These study results are not sufficient to establish potential for exposure for CHCC listing. DIPP does not meet the CHCC listing criteria. See page 2 for the listing criteria used in this rulemaking.</p> <p>These comments did not result in changes to the rule.</p>

Lead

Ecology received two comments requesting that Lead be added to the CHCC list. These comments did not provide references to authoritative sources or credible peer-reviewed scientific data.

Ecology Response

Ecology appreciates these comments. The comments did not provide references to authoritative sources nor credible peer-reviewed scientific data.

These comments did not result in changes to the rule.

PFOA

Ecology received multiple comments requesting that related substances that degrade into PFOA be added to the CHCC list. Many of these comments did not provide references to authoritative sources or credible peer-reviewed scientific data. Two requests to add PFOA related substances to the CHCC list did include references. Those comments are provided below.

Toxic Free Future:

Perfluorooctanoic Acid (PFOA) (CAS # 335-67-1) and Related Substances

TFF strongly supports the proposed addition by the Department for Ecology of perfluorooctanoic acid (PFOA) to the CHCC; however, TFF respectfully requests that the Department of Ecology change the proposed listing of PFOA to include PFOA and related compounds.

PFOA and related compound are used in the production of stain-resistance compounds used on textiles, polymers with numerous applications, fire-fighting foams, coatings, surfactants, and other products. The European Chemical Agency (ECHA) has classified PFOA as toxic for reproduction (ECHA, 2015b) and the International Agency for Research on Cancer has designated PFOA as a possible carcinogen based on epidemiological evidence linking exposure to kidney and testicular cancer (IARC, 2016), (Lau et al. 2007), (Barry et al. 2013), (Benbrahim-Tallaa et al. 2014). These compounds are widespread in the environment as a result of industrial releases and from their use in consumer products. Precursor chemicals used commercially can degrade to PFOA biotically and abiotically after their release during production or from in-use products (Butt et al. 2013) (D'eon and Mabury 2011). PFOA does not degrade in the environment and has been designated by the European Union as persistent, bioaccumulative, and toxic (PBT) (ECHA, 2013b). Despite the US EPA PFOA Stewardship Program challenging manufacturers to end releases of PFOA, recent testing has detected the compound in consumer products. PFOA has been detected in house dust, surface water, drinking water, sediment, outdoor air, fish, marine mammals, polar bears and other biota, and human blood (Calafat et al. 2007) (Furl et al. 2011) (Fraser et al. 2013) (Houde et al. 2011) (Ahrens and Bundschuh 2014) (Dinglasan-Panlilio et al. 2014).

There is precedent on the CHCC list for listing chemicals and related compounds. For instance, several metals, including arsenic and cadmium, are listed along with related compounds, and 3,3'-dimethylbenzidine is listed with dyes metabolized to 3,3'-dimethylbenzidine. For a sufficient understanding of the use of chemicals likely to degrade to PFOA, it is necessary to list PFOA along with related compounds. This is the approach taken in restrictions being considered by the European Union Committee in September, 2015. The approach was to restrict "manufacturing, use, and placing on the market of Perfluorooctanoic Acid (PFOA) and its salts, also including substances that may degrade to PFOA (PFOA-related substances) (ECHA, 2015b)."

The use of PFOA-related substances in consumer products is largely unknown by the public and by policymakers. By requiring disclosure of PFOA related compounds, the Department of Ecology would obtain information on the presence of chemicals in children's products that break down into PFOA. This approach would provide the public and policymakers critical information on potential exposure routes for kids, and be consistent with the European Union.

The Endocrine Disruption Exchange

Perfluorooctanoic acid (PFOA: 335-67-1): PFOA has a relatively long reported half life of 3.8 years in humans [5] and has numerous endocrine disrupting effects, some of which are highlighted here. PFOA is a thyroid hormone signaling disruptor. A recent systematic review of epidemiological evidence found that childhood exposure was inversely related to serum levels of

thyroid stimulating hormone (TSH) in two studies in girls [6]. PFOA also activates the peroxisome proliferator-receptor alpha and disrupts normal mammary gland development, though the mechanism for this disruption is not clear [7]. Another recent systematic review concluded that "PFOA is "known to be toxic" to human reproduction and development based on sufficient evidence of decreased fetal growth in both human and nonhuman mammalian species" [8]. PFOA is also of high concern as it was recently "presumed to be an immune hazard to humans based on a high level of evidence that PFOA suppressed the antibody response from animal studies and a moderate level of evidence from studies in humans" [9]. **We respectfully suggest that Ecology consider expanding this listing to "PFOA and related substances" because there is now evidence [10] that substitutes for PFOA may degrade into PFOA**, and there is a lack of transparency around what these shorter chain substitutes are, as well as data gaps on toxicity and exposure information on them.

Ecology Response
The addition to the CHCC list of chemicals that degrade into PFOA is outside the scope of this rulemaking.
The term "and related compounds" was added to the CHCC listing for PFOA.

TCE

Ecology received one comment requesting that TCE be added to the CHCC list.

Ecology Response
Ecology appreciates these comments. This comment did not provide references to authoritative sources nor credible peer-reviewed scientific data.
The comment did not result in changes to the rule.

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Appendix A - List of Acronyms

APA	Administrative procedures act (WA)
BAuA	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (German Institute for Occupational Safety and Health)
CAS	Chemical abstract service
CDC	Centers for Disease Control (US)
CHAP	Chronic Hazard Advisory Panel on Phthalates and Phthalate Alternatives (US)
CHCC	Chemicals of High Concern to Children (WA)
CPSC	Consumer Product Safety Commission (US)
CSPA	Children's Safe Products Act (WA)
ECHA	European Chemicals Agency (EU)
EPA	U. S. Environmental Protection Agency
ESR	Existing substances registry (EU)
EU	European Union
IARC	International Agency for Research on Cancer (WHO)
IRIS	Integrated Risk Information System (EPA)
NHANES	National Health and Nutrition Examination Survey (CDC)
NTP	National Toxicology Program (US)
OEHHA	Office of Environmental Health Hazard Assessment (California)
PBT	Persistent, bioaccumulative and toxic
Prop 65	Proposition 65 (California)
RCW	Revised code of Washington
REACH	Registration, Evaluation, Authorisation, and Restriction of Chemicals (EU)
SVHC	Substances of Very High Concern (EU)
WAC	Washington Administrative Code
WHO	World Health Organization
	CHEMICAL ACRONYMS
BPF	Bisphenol F
BPS	Bisphenol S
BTBPE	1,2-bis(2,4,6-tribromophenoxy)ethane
D4	Octamethylcyclotetrasiloxane
DBDPE	Decabromodiphenyl ethane
DCHP	Dicyclohexyl phthalate
DIBP	Diisobutyl phthalate
DIOP	Diisooctyl phthalate
DIPP	Diisopentyl phthalate
DMEP	Di(2-methoxyethyl)phthalate
DPP	Dipentyl phthalate
EHDPP	Ethylhexyl diphenyl phosphate
IPTPP	Isopropylated triphenyl phosphate

PFOA	Perfluorooctanoic acid
SCCP	Short-chain chlorinated paraffins
TBB	2-ethylhexyl-2,3,4,5-tetrabromobenzoate
TBPH	Bis (2-ethylhexyl) tetrabromophthalate
TBPP	Tris(4-tert-butylphenyl) phosphate
TCE	Trichloroethylene
TCP	Tricresyl phosphate
TCPP	Tris (1-chloro-2-propyl) phosphate
TDBPP	Tris (2, 3-dibromopropyl) phosphate
TNBP	Tri-n-butyl phosphate
TPP	Triphenyl phosphate
V6	Bis(chloromethyl)propane-1,3-diyl tetrakis-(2-chloroethyl) bis(phosphate)