Personal Care Products Council
Committed to Safety, Quality & Innovation

November 14, 2016

Via Electronic Mail
Kara Steward
Washington State Department of Ecology
HWTR Program
PO Box 47600
Olympia, WA 98504-7600
kara.steward@ecy.wa.gov

Re: Comments on Children's Safe Products Act Rule Update

Dear Ms. Steward:

The Personal Care Products Council (Council)[1] is pleased to submit the following comments in response to the Washington Department of Ecology's (DOE) proposal to update the Reporting List of Chemicals of High Concern to Children (CHCC) contained in the Children's Safe Products Act[2] (CSPA). Our member companies are involved in the manufacture and distribution of over-the-counter (OTC) drug products, cosmetics, toiletries, fragrances, and ingredients in Washington and throughout the United States, and therefore have a strong interest in this process.

As noted, both DOE and the Washington Department of Health will review recent science and data to determine if any chemicals should be added to or deleted from the CHCC list. To that end, the Council respectfully submits the following information in support of removing parabens (methylparaben, ethylparaben, propylparaben, butylparaben); their common metabolite para-hydroxybenzoic acid; and 2-ethyl-hexyl-4-methoxycinnamate as CHCC.

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[1] Based in Washington, DC, the Personal Care Products Council is the leading national trade association representing the global cosmetic and personal care products industry. Founded in 1894, the Council's 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the U.S. As the makers of a diverse range of products millions of consumers rely on every day, from sunscreens, toothpaste and shampoo to moisturizer, lipstick and fragrance, personal care products companies are global leaders committed to product safety, quality and innovation.

[2] Chapter 173-334 WAC Children's Safe Products – Reporting Rule.

General Comments

The Council believes that the continued listing of certain substances does not comport with the rationale underpinning the CHHC. Indeed, the stated rationale for the reporting list of CHCC is "to collect information about the use of these chemicals in children's products."[3] Thus, a plain reading of the rationale demonstrates that the intent of the list was to identify ingredients for additional studies and research. Listing of a particular substance or chemical was not intended to be a declaration of endocrine disruption properties for that particular substance, nor an assertion that the same was fact.

Parabens were originally added to the CHCC largely because of their designation as Category 1 Endocrine Disruptors by the European Union.[4] It is important to stress that designation as a Category 1 substance in that context does not necessarily mean that there is final proof that the substance is an endocrine disruptor; rather, the designation merely indicates that there is at least one study of a living organism which has documented some measure of endocrine activity. Further, continued reliance on the EU designation does not reflect the ongoing debate about the proper definition of "endocrine disruptor."[5] Currently, the European Commission is in the process of refining the definition of "endocrine disruptor," and the method utilized in designating a substance as an endocrine disruptor.[6]

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[3] Rationale for Reporting List of Chemicals of High Concern to Children, "Parabens," prepared by the Washington State Department of Health for the Children's Safe Product Act, prepared April 18, 2011, *available at:* http://www.ecy.wa.gov/programs/hwtr/RTT/cspa/chcc.html (Accessed Aug. 30, 2016).

[4] "The EU List of Potential Endocrine Disruptors", *at* http://eng.mst.dk/topics/chemicals/endocrine-disruptors/the-eu-list-of-potential-endocrine-disruptors/ (Accessed Sept. 14, 2016).

[5] Subsequent to the development of the EU list, comprehensive review of the various parabens in the context of endocrine activity have been published. *See* Golden, R, Gandy, J, and Vollmer, C, (2005) A Review of the Endocrine Activity of Parabens and Implications for Potential Risks to Human Health. Critical Rev Toxicol. Vol. 35, p. 435-458; Boberg, J, Taxvig, C, Christiansen, S, and Hass, U. (2010) Possible endocrine disrupting effects of parabens and their metabolites. Repro. Toxicol., Vol. 30, P. 301-312; Witorsch, RJ. and Thomas, JA. (2010) Personal care products and endocrine disruption: A critical review of the literature. Critical Rev Toxicol. Vol. 40(53), p. 1—30.

[6] *See* "Minutes: Ad-Hoc Working Group meeting of the Advisory Group on the Food Chain, Animal, and Plant Health Criteria used to Identify Endocrine Disruptors," European Commission (July 18, 2016) *available at* *http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/docs/dgs-consultations_working-groups_20160630_sum.pdf (Accessed Sept. 15, 2016)* ("The Chair stressed he valued very much the contributions

Finally, if part of the calculus in listing a substance as a CHCC is the relative degree of exposure, parabens have decreasing levels of reported uses based on the manufacturer's surveys collected by the Washington DOE. For example, with a reporting date range between 9/10/2012 and 9/14/2016, there were 234 reported uses of propylparaben. With a more current date range of 9/10/2014-9/14/2016, the reported number of uses for propylparaben is 97.[7]

Parabens

Parabens have been reviewed by international authoritative bodies and found to be safe for use in cosmetics, food and medical products. Information on the individual parabens is below, with links and references provided. The two most commonly used parabens - methylparaben and propylparaben – are considered first.

Methylparaben

Cosmetic Ingredient Review

Methylparaben, along with other parabens, was reviewed by the Cosmetic Ingredient Review (CIR; www.cir-safety.org) and concluded to be safe for use in cosmetic products (CIR, 1984). The conclusion was reaffirmed after considering more recent data and exposure estimates for cosmetic uses (CIR, 2008). References are available at http://www.cir-safety.org/ingredients:

Cosmetic Ingredient Review. J. Amer. Call, Toxicol, Final Report on the Safety Assessment of Methylparaben, Ethylparaben, Propylparaben, and Butylparaben, 147-209,Vol.3(S) (1984).

Cosmetic Ingredient Review. Int'l. J. Toxicol. Final Amended Report on the Safety Assessment of Methylparaben, Ethylparaben, Propylparaben, Isopropylparaben, Butylparaben, Isobutylparaben, and Benzylparaben as used in Cosmetic Products, 1-82, Vol. 27(suppl 4) (2008).

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provided by interested parties. He hoped that the process would result in practical ED criteria that will help to protect the health of people and the environment.")

[7] "Children's Safe Reporting Act Reported Data," *at* https://fortress.wa.gov/ecy/cspareporting/Reports/ReportViewer.aspx?ReportName=ChemicalReportByName (Accessed Sept.14, 2016).

FDA

Methylparaben is approved by FDA as a food preservative, with 'Generally Recognized As Safe' status: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=184.1490

Methylparaben is used as an inactive ingredient in approved over-the-counter drugs. The FDA maintains an on-line listing at http://www.accessdata.fda.gov/scripts/cder/iig/index.cfm

FDA website statement: "At this time, we do not have information showing that parabens as they are used in cosmetics have an effect on human health." (http://www.fda.gov/Cosmetics/ProductsIngredients/Ingredients/ucm128042.htm)

Scientific Committee on Consumer Safety / Scientific Committee on Consumer Products (Europe)

The Scientific Committee on Consumer Products in the European Union (SCCP, now SCCS) affirmed the safety of methylparaben and ethylparaben in 2005, concluding that the two parabens could be safely used at levels up to 0.4% (SCCP, 2005). This conclusion was reaffirmed in 2010.

Specific to the issue of paraben estrogenicity, the SCCP concluded in the same 2005 opinion that "(d)ifferent parabens have varying estrogenic potential in cell cultures and animal studies, but their potency is 1000 to 1,000,000 times lower than the potency of 17β-estradiol or testosterone."

References and links to the opinions:

Scientific Committee on Consumer Products, Scientific Committee on Consumer Products Extended Opinion on the Safety Evaluation of Parabens. SCCP/0873/05, http://ec.europa.eu/health/archive/ph_risk/committees/04_sccp/docs/sccp_o_019.pdf

Scientific Committee on Consumer Products, Opinion on Parabens. SCCS/1348/10, http://ec.curopa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_041.pdf

European Medicines Agency

Methylparaben was reviewed in 2015 by the Committee for Medicinal Products for Human Use (CMPH) of the European Medicines Agency, and was found safe for use in oral pharmaceutical

formulations. The review concluded that 'Methylparaben has not been associated with adverse effects on the male and female reproductive organs in juvenile rats or in embryo-foetal development studies. This allows concluding that the use of methylparaben in oral formulations up to 0.2% of the product (as within the recommended effective concentrations as a preservative) is not a concern for humans including the paediatric population whatever the age group." The link to the review is available at http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2015/11/WC500196733.pdf

Propylparaben

Cosmetic Ingredient Review

Propylparaben, along with other parabens, was reviewed by the Cosmetic Ingredient Review (CIR) and concluded to be safe for use in cosmetic products (CIR, 1984). The conclusion was reaffirmed after considering more recent data and exposure estimates for cosmetic uses (CIR, 2008). References are available at http://www.cir-safety.org/ingredients:

Cosmetic Ingredient Review. J. Amer. Call, Toxicol, Final Report on the Safety Assessment of Methylparaben, Ethylparaben, Propylparaben, and Butylparaben, 147-209,Vol.3(S) (1984).

Cosmetic Ingredient Review. Int'l. J. Toxicol. Final Amended Report on the Safety Assessment of Methylparaben, Ethylparaben, Propylparaben, Isopropylparaben, Butylparaben, Isobutylparaben, and Benzylparaben as used in Cosmetic Products, 1-82, Vol. 27(suppl 4) (2008).

FDA

Propylparaben is approved by FDA as a food preservative, with 'Generally Recognized As Safe' status: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=184.1670

Propylparaben is used as an inactive ingredient in approved over-the-counter drugs. The FDA maintains an on-line listing at http://www.accessdata.fda.gov/scripts/cder/iig/index.cfm

FDA website statement: "At this time, we do not have information showing that parabens as they are used in cosmetics have an effect on human health."
(http://www.fda.gov/Cosmetics/ProductsIngredients/Ingredients/ucm128042.htm)

Scientific Committee on Consumer Safety (Europe)

Propylparaben was reviewed by the Scientific Committee on Consumer Safety (SCCS) in 2010 along with butylparaben. The conclusion of the review was that the two parabens were safe for use as long as the sum of the individual concentrations of propyl- and butylparaben do not exceed 0.19%, based on a "conservative choice for the calculation of the Margin-of-Safety (MOS) of Butyl- and Propylparaben". This conclusion was reaffirmed in 2013. Links to the opinions are available at:

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_041.pdf
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_132.pdf

A particularly important study of propylparaben was conducted at Ricerca Biosciences in 2012 and discussed in the SCCS 2013 opinion (publication reference: Gazin, V., Marsden, E., and Marguerite, F. (2013) Oral Propylparaben Administration to Juvenile Male Wistar Rats Did Not Induce Toxicity in Reproductive Organs, Toxicol. Sci. 136 (2), 392-401). The SCCS opinion states "the GLP study on reproductive toxicity has been well conducted and is considered appropriate to refute the study of Oishi which reported reproductive toxicity in juvenile male rats" (reference: Oishi S. [2002] Effects of propylparaben on the male reproductive system, Food Chem Toxicol., 1807-13, Vol.40).

Specific to the issue of paraben estrogenicity, the SCCS concluded in a 2005 opinion that "(d)ifferent parabens have varying estrogenic potential in cell cultures and animal studies, but their potency is 1000 to 1,000,000 times lower than the potency of 17β-estradiol or testosterone." The link to the opinion is http:// ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_019.pdf

European Medicines Agency

Propylparaben was reviewed in 2015 by the Committee for Medicinal Products for Human Use (CMPH) of the European Medicines Agency, and was found safe for use in oral pharmaceutical formulations. The review concluded that 'a conservative NOEL of 100 mg/kg/day has been determined for propylparaben' based on effects on the female reproductive system. The link to the review is available at:

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2015/11/WC500196733.pdf

Butylparaben

Butylparaben, along with other parabens, was reviewed by the Cosmetic Ingredient Review (CIR) and concluded to be safe for use in cosmetic products (CIR, 1984). The conclusion was reaffirmed after considering more recent data and exposure estimates for cosmetic uses (CIR, 2008). References are available at http://www.cir-safety.org/ingredients:

Cosmetic Ingredient Review. J. Amer. Call, Toxicol, Final Report on the Safety Assessment of Methylparaben, Ethylparaben, Propylparaben, and Butylparaben, 147-209,Vol.3(S) (1984).

Cosmetic Ingredient Review. Int'l. J. Toxicol. Final Amended Report on the Safety Assessment of Methylparaben, Ethylparaben, Propylparaben, Isopropylparaben, Butylparaben, Isobutylparaben, and Benzylparaben as used in Cosmetic Products, 1-82, Vol. 27(suppl 4) (2008).

FDA

Butylparaben is used as an inactive ingredient in approved over-the-counter drugs. The FDA maintains an on-line listing at http://www.accessdata.fda.gov/scripts/cder/iig/index.cfm

FDA website statement: "At this time, we do not have information showing that parabens as they are used in cosmetics have an effect on human health."
(http://www.fda.gov/Cosmetics/ProductsIngredients/Ingredients/ucm128042.htm)

Scientific Committee on Consumer Safety (SCCS)

Butylparaben was reviewed by the Scientific Committee on Consumer Safety (SCCS) in 2010 along with propylparaben. The conclusion of the review was that the two parabens were safe for use as long as the sum of the individual concentrations of propyl- and butylparaben do not exceed 0.19%, based on a "conservative choice for the calculation of the Margin-of-Safety (MOS) of Butyl- and Propylparaben". This conclusion was reaffirmed in 2013. The links to the opinions are:

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_041.pdf

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_132.pdf

Ethylparaben

Cosmetic Ingredient Review

Ethylparaben, along with other parabens, was reviewed by the Cosmetic Ingredient Review (CIR) and concluded to be safe for use in cosmetic products (CIR, 1984). The conclusion was reaffirmed after considering more recent data and exposure estimates for cosmetic uses (CIR, 2008). References are available at http://www.cir-safety.org/ingredients:

Cosmetic Ingredient Review. J. Amer. Call, Toxicol, Final Report on the Safety Assessment of Methylparaben, Ethylparaben, Propylparaben, and Butylparaben, 147-209,Vol.3(S) (1984).

Cosmetic Ingredient Review. Int'l. J. Toxicol. Final Amended Report on the Safety Assessment of Methylparaben, Ethylparaben, Propylparaben, Isopropylparaben, Butylparaben, Isobutylparaben, and Benzylparaben as used in Cosmetic Products, 1-82, Vol. 27(suppl 4) (2008).

Scientific Committee on Consumer Safety / Scientific Committee on Consumer Products (Europe)

The Scientific Committee on Consumer Products in the European Union (SCCP, now SCCS) affirmed the safety of methylparaben and ethylparaben in 2005, concluding that the two parabens could be safely used at levels up to 0.4% (SCCP, 2005). This conclusion was reaffirmed in 2010. Links to the opinions are:

Scientific Committee on Consumer Products, Scientific Committee on Consumer Products Extended Opinion on the Safety Evaluation of Parabens. SCCP/0873/05, available at http://ec.europa.eu/health/archive/ph_risk/committees/04_sccp/docs/sccp_o_019.pdf

Scientific Committee on Consumer Products, Opinion on Parabens. SCCS/1348/10, http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_041.pdf

2-Ethyl-Hexyl-4-Methoxycinnamate Safety

DOE also lists 2-ethyl-hexy-4-methoxycinnamate (also known as octinoxate when used as an active drug ingredient) on its list of CHCC. Ethylhexyl Methoxycinnate is an ester of 2-ethylhexyl alcohol and methoxycinnamic acid.

Ethylhexyl Methoxycinnamate was originally listed as a CHCC because of possible estrogenic properties, and its designation as a Category 1 Endocrine Disruptor by the European Union in a 2002 Report ("2002 EU Report"). At the time of the 2002 EU Report, designation as a Category 1 Endocrine Disrupter only required "at least one study providing evidence of endocrine disruption in an intact organism."[8] At the same time, a 2002 EU Report also acknowledged that such an approach was "*not a formal weight of evidence approach*" (emphasis added).[9]

Ethylhexyl Methoxycinnamate has been reviewed by international authoritative bodies and found to be safe for use as an over-the-counter drug, and as a cosmetic ingredient. Information on those reviews is provided below, with links and references provided.

Ethylhexyl Methoxycinnamate is approved by the U.S. FDA as an active ingredient in OTC drug products, including use in sunscreen formulations up to a concentration of 7.5 percent. Furthermore, FDA has recognized and approved of the combination of various active drug ingredients, including octinoxate, in sunscreen formulations provided that the applicable concentrations and required SPF levels are met. The reference and link is available at:
Title 21-Food and Drugs, Sec. 352, Sunscreen Drug Products for Over-the-Counter Human Use,
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=352

In studies completed in 2011-2012 and sponsored by the U.S. National Institutes of Environmental Health, it was concluded that oral administration of octylmethoxycinnamate, up to the limit dose level of 1000 mg/kg did not demonstrate estrogenic or androgen agonist/antagonist activity (studies referenced at http://ntp.niehs.nih.gov/testing/status/agents/ts-m20239.html - the full report and its data can be requested through the relevant and applicable public disclosure statutes).

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[8] European Commission DG Environment. *Endocrine disruptors: study on gathering information on 435 substances with insufficient data. Final report B4-3040/2001/325850/MAR/C2*, page ix, *available at* http://ec.europa.eu/environment/chemicals/endocrine/pdf/bkh_report.pdf (2002).

[9] European Commission DG Environment, *Endocrine disruptors: study on gathering information on 435 substances with insufficient data. Final report B4-3040/2001/325850/MAR/C2*, page ix, *available at* http://ec.europa.eu/environment/chemicals/endocrine/pdf/bkh_report.pdf (2002).

Ethylhexyl Methoxycinnamate is approved as a UV filter in the European Union as well as in the U.S. The evaluation of its safety by the Scientific Committee on Cosmetic and Non-food Products (SCCNFP) included specific consideration of endocrine disruption. The review reports the results of a uterotrophic assay, noting that 2-ethyl-hexyl-4-methoxycinnamate "did not induce a uterotrophic effect and no histopathologic changes could be shown in the uteri concerned." The review concluded that 2-ethyl-hexyl-4-methoxycinnamate had an acceptable margin of safety for all endpoints, including estrogenicity. The reference and link are:

Opinion on the Evaluation of Potentially Estrogenic Effects of UV-Filters, adopted June 12, 2001, http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/sccnfp_opinions_97_04/sccp_out145_en.htm

Conclusion

As stated previously, the aim and focus of the program should be on maintaining a list of CHCCs that is based upon sound scientific data and principles. This type of approach would address both the public safety and health concern, while also providing assurance to industry that the regulations are not implemented on an ad hoc basis. When there is a consistent absence of *scientifically valid* data about a chemical's potential for harm, despite years of inclusion as a CHHC, continuing to list such a substance frustrates the aim of the CSPA, diverts public funding and research from consideration of new priority chemicals, and creates an unnecessary burden upon manufacturers and distributors.

The Council would like to thank DOE for the opportunity to provide comments, and welcomes the opportunity to work with DOE on this and future rulemakings. Our industry recognizes the critical need to update a chemical management program in order to improve public health and the environment in the State of Washington.

Sincerely,

Thomas Myers
EVP – Legal & General Counsel