



September 15, 2016

Ms. Kara Steward
Washington Department of Ecology
Hazardous Waste & Toxics Reduction Program
P.O. Box 47600
Olympia, WA 98504-7600

Re: Children's Safe Products Reporting Rule, Chapter 173-334 WAC - Review of the inclusion of phthalic anhydride on the existing list of Chemicals of High Concern to Children (WAC-173-334-130)

Dear Ms. Steward:

The Phthalic Anhydride Producers Panel (Panel) of the American Chemistry Council (ACC) submits the following information in response to the Department of Ecology's request for comment on revisions to the Children's Safe Products (CSP) Reporting Rule and the list of Chemicals of High Concern to Children (CHCCs). The Panel represents the North American manufacturers of phthalic anhydride (CAS No. 85-44-9) which is used as a chemical intermediate in the manufacture of materials (e.g., phthalate ester plasticizers, polyester and alkyd resins, copolymers) that are subsequently used in the production of consumer and commercial products. Based on the current classification of the chemical under global labeling criteria and the information on the potential for children's exposure collected through CSP reporting, the Panel requests that phthalic anhydride be removed from the CHCC list.

Under the Children's Safe Product Act (CSPA),¹ manufacturers of children's products are required to notify the Department when a CHCC is present in their products or product components. Section 70.240.030 defines a CHCC as a "high priority chemical" to which a child or developing fetus may be exposed.² Section 70.240.010 identifies high priority chemicals as those that have been "identified by a state agency, federal agency, or accredited research university, or other scientific evidence deemed authoritative . . . on the basis of credible scientific evidence as known to" cause developmental toxicity, cancer, genetic damage or reproductive harm, disrupt the endocrine system, cause nervous, immune, or other systemic toxicity, be persistent, bioaccumulative and toxic, or be very persistent and very bioaccumulative.

¹ Chapter 70.240 RCW

² Section 70.240.030 RCW identifies criteria for considering potential exposure to children and fetuses, which include data from biomonitoring studies or environmental sampling from home environments or the presence in a consumer product or the home.



In the subsequent Reporting Rule implementing the CSPA requirements,³ the Department established additional criteria for considering petitions to add or remove substances from the CHCC list. Among these criteria is a requirement that petitioners provide “credible peer-reviewed scientific information documenting why the chemical meets or fails to meet the criteria required for inclusion on the list.”

The background information provided at the time of the creation of the CHCC list indicates that phthalic anhydride meets the criteria for classification as a Category 2 reproductive toxicant or germ cell mutagen under the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).⁴ The documentation further suggests that the substance is present in children’s products and has the potential for individual child exposure. In a subsequent review of the framework for evaluating chemicals employed by Ecology for its analysis, the WA Department of Health (WDOH) indicated that the source of GHS criteria was “less robust” than other information used by the Department in part because it did not consider the 2007 and 2009 amendments to GHS.⁵

Toxicity

The sole basis for the toxicity scoring for phthalic anhydride in the Department’s original analysis was a screening analysis of the application of the GHS criteria by the Japanese government in 2006 suggesting that the chemical would be identified in Category 2 for reproductive toxicity or germ cell mutagenicity. Since that time, the GHS criteria have been revised and industry and governments have developed considerably more experience implementing GHS. Based on these developments, and as evidenced by the enclosed summary from the European Chemical Agency (ECHA),⁶ phthalic anhydride is not classified for either reproductive toxicity or germ cell mutagenicity under the GHS criteria. The ECHA summary further notes that phthalic anhydride does not meet the GHS criteria for classification for carcinogenicity or for repeated dose toxicity to an organ system.⁷

The review of the DOE scoring by WDOH as part of Phase 3 of the rule development process – in addition to highlighting the preliminary nature of the Japanese analysis of the GHS criteria –

³ Chapter 173-334 WAC

⁴ WA Department of Ecology. Children’s Safe Product Act Reporting Requirements – Pilot Rule Development Process. Phase 2 – Prioritization. Score sheet for phthalic anhydride (CAS: 85-44-9).

⁵ WA Department of Health. Report to WA Department of Ecology - Phase 3 work conducted under Children’s Safe Products Act (CPSA). Submitted by Barbara Morrissey and Jim White (July 23, 2010). Available at www.ecy.wa.gov/programs/hwtr/rtt/cspa/pdf/p3doh.pdf.

⁶ ECHA. REACH Registration Dossier – Phthalic Anhydride. Classification & Labelling & PBT Assessment. Available at <https://www.echa.europa.eu/web/guest/registration-dossier/-/registered-dossier/15845>.

⁷ See also Table 3.1 of Annex VI of the European Commission Classification, Labeling and Packaging regulation (EC No. 1272/2008). Available at <https://echa.europa.eu/information-on-chemicals/annex-vi-to-clp>.



cited evidence of reproductive and developmental effects with phthalic anhydride from reviews conducted by other public organizations.⁸ None of the entities determined these data to be sufficient to designate the chemical as a reproductive or developmental toxicant, however. The most recent of these reviews by the Organization of Economic Cooperation and Development (OECD) in 2005 reported that, while no fertility study was available, there was “no evidence of toxicity to reproductive organs . . . in comprehensive carcinogenicity studies in rats and mice.”⁹ The OECD review further concluded that “in the absence of maternal toxicity, phthalic anhydride is not a developmental toxicant.”

Removal of the GHS classification means that phthalic anhydride no longer meets the criteria for designation as a high priority chemical under Section 70.240.010. As a consequence, the chemical should no longer be considered a candidate for listing as a CHCC.

Exposure

Information collected by the Department since the inception of the reporting requirement in June 2012 confirms the previous finding that there is no direct use of phthalic anhydride in children’s products.¹⁰ Of the 113 products reported to Ecology as containing the substance in 2016, 102 indicate that the concentration is below 100 parts per million and/or that it is present as a contaminant. The remaining 11 reports indicate that phthalic anhydride may be present as a component of a synthetic polymer, copolymer or ink/dye/pigment. The reported concentrations are further complicated by an uncertainty over whether the chemical was actually present in the component or was formed as part of the analytical procedure.¹¹ Available information suggests that phthalic anhydride can form during thermal degradation of other materials in the injection port of a gas chromatograph.

In a recent analysis of the information reported under the CSPA, Smith *et al.* (2016) assigned phthalic anhydride the second lowest exposure score and a total priority index (based on toxicity and exposure scores) of zero (0).¹² Based on this analysis, one can conclude that exposure to phthalic anhydride is of little or no concern to children’s health.

⁸ These include the United Nations Environment Programme (UNEP), the US Environmental Protection Agency (USEPA), the European Commission, and the California EPA.

⁹ UNEP. OECD Screening Information Dataset (SIDS) initial assessment report for Phthalic Anhydride, at 5 (2005). Available at <http://webnet.oecd.org/hpv/ui/handler.axd?id=ce1be9d2-c97e-414a-b21f-60e9f4923a38>.

¹⁰ *Ibid*, at 5.

¹¹ *Ibid*, at 17.

¹² Smith MN *et al.* A toxicological framework for the prioritization of Children’s Safe Product Act data. *Int. J. Environ. Res. Public Health* 13(4): 431 (2016). Available at <http://www.mdpi.com/journal/ijerph>.



Summary

Information that has become available since the Department compiled the list of CHCCs for CSP reporting shows that phthalic anhydride does not meet the criteria for toxicity or exposure established by the Act. It should be removed from the CHCC list.

Sincerely,

Steve

Stephen P. Risotto
Senior Director

Enclosure

