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March 2, 2020

Via Electronic Mail

Hazardous Waste and Toxics Reduction Program
Washington State Department of Ecology
P.O. Box 47600
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Comments on the Safer Products for Washington Priority Consumer Products Draft Report to Legislature (Jan.2020; Publication 20-04-004)

To whom it may concern:

BASF Corporation¹ is pleased to submit these comments to the State of Washington Department of Ecology (DOE) on the Priority Consumer Products Draft Report to Legislature. We appreciate the opportunity to provide public comments on this process.

BASF appreciates DOE's goals in developing and implementing the Safer Products for Washington (SPW) program under the 2019 Safer Products for Washington Act. In support of expected comments from the Resilient Flooring Covering Institute (RFCI), we urge DOE to remove the "vinyl flooring" priority product, which has been included based on now outdated information relating to the past use of ortho-phthalates in these products. This conclusion is largely based on a shift by flooring manufacturers from ortho-phthalates to alternative plasticizers. The following comments focus on one of those alternatives and clarify some important points about ortho-phthalates.

Vinyl Flooring Manufacturers Have Shifted to Alternative Plasticizers

BASF understands that, as a result of market demand and purchasing policies that specify flooring without ortho-phthalates such as DINP, manufacturers of vinyl flooring have largely moved away from the use of the ortho-phthalates to alternatives including terephthalates.² One of the most important and widely used alternatives in North America for flooring and other applications is bis(2-ethylhexyl) terephthalate (CAS 6422-86-2; DOTP or DEHT). A commercial example is BASF's Palatinol® DOTP. DOTP performs well in flooring applications, is well-studied, and has a demonstrated low hazard profile; these are all essential criteria for a valid alternatives assessment.³

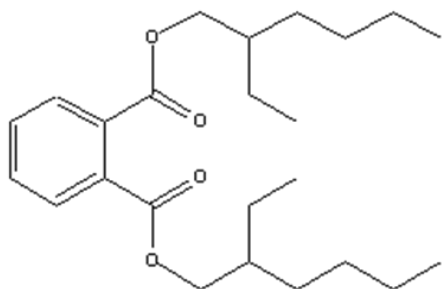
¹ BASF Corporation is a subsidiary of BASF SE and is a manufacturer of plasticizers including some ortho-phthalates as well as di-2-ethylhexyl terephthalate, adipates, trimellitates, and polymeric plasticizers.

² <https://www.floordaily.net/floorfocus/the-greening-of-lvt-mannington-armstrong-tarket>; and <https://www.constructionspecifier.com/walk-this-way-new-trends-in-vinyl-flooring/>.

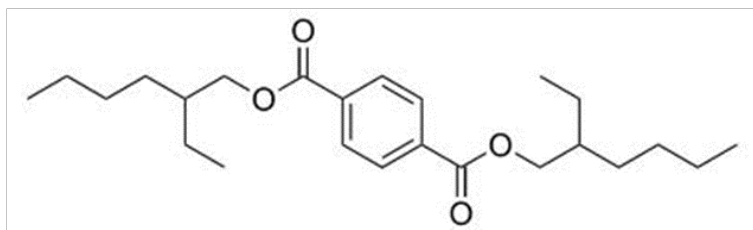
³ For example: http://www.dtsc.ca.gov/SCP/upload/AA-Guide-Version-1-0_June-2017.pdf.

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Terephthalates are different structurally from ortho-phthalates since the two ester groups are in the 1,4 position versus the 1,2 position. This can be seen in the following example comparing DOTP and di-2-ethylhexyl phthalate (DEHP).



DEHP (ortho-phthalate)



DOTP (tere-phthalate)

This structural difference results in a minimal impact on the performance of DOTP compared to DEHP; however, its toxicological behavior is significantly different. DEHP is currently classified in Europe and in California (OEHHA) for reproductive and developmental concerns;⁴ DOTP is not classified and has a demonstrated low hazard profile as discussed in the following section.

Low Hazard Profile for DOTP

DOTP has a full toxicological profile and no relevant hazards. It has been reviewed by the European Food Safety Authority (EFSA),⁵ ANSES under the EU Regulatory Management Option Analysis (RMOA) process,⁶ NSF International,⁷ and more recently by the U.S. Consumer Product Safety Commission (CPSC).⁸

DOTP has been assessed using the GreenScreen® methodology based on hazard classifications for 18 human health, environmental, and physical hazard endpoints.⁹ It received a Benchmark score of 3_{DG} in an assessment in 2012¹⁰ and an updated assessment in

⁴ It should be noted that the reproductive and developmental effects depend upon the alcohol chain length and not all ortho-phthalates show the same adverse effects. See Fabjan, E.; Hulzebos, E.; Mennes, W.; Piersma, A. W. "A Category Approach for Reproductive Effects of Phthalates," *Crit. Rev. Tox.*, **2006**, 36, 695-726.

⁵ European Food Safety Authority (EFSA), "Opinion of the Scientific Panel on Food Additives, Flavorings, Processing Aids and Materials in Contact with Food (SFC). The EFSA Journal 628-633:1-19," 2008.

⁶ ANSES, "Risk Management Options Analysis (RMOA) - Diethylhexyl Terephthalate," January 2016. [Online]. Available: <https://www.echa.europa.eu/documents/10162/dd0220b0-1187-4c2b-8991-51ddbbc9d462>. [Accessed 18 May 2016].

⁷ Ball, G. L.; McLellan, C. J.; Bhat, V. S. "Toxicological Review and Oral Risk Assessment of Terephthalic Acid and Its Esters: a Category Approach," *Crit. Rev. Tox.*, 2012, 42, 28-67. DOI: 10.3109/10408444.2011.623149.

⁸ <https://www.cpsc.gov/s3fs-public/Toxicity%20Review%20of%20DEHT.pdf?FObpuBBqgypVtw7gIEGMFXHN5H7vbeEz>.

⁹ For more details see, <http://www.greenscreenchemicals.org/>.

¹⁰ ToxServices, "Di(2-ethylhexyl) Terephthalate (DEHT) (CAS #6422-86-2)," 11 October 2012. [Online]. Available: http://www.greenchemistryandcommerce.org/documents/DEHTVERIFIEDASSESSMENT_final.pdf. [Accessed 11 September 2017].

2016/17.¹¹ This means that the product was classified as a low hazard for all endpoints and met the criteria for Benchmark 4 (the highest), except for one or more allowed data-gaps. In the most recent assessment, the only identified data gap was for endocrine activity. As noted in Harmon and Otter (2018), BASF has concluded there is no data gap for this end point based on in vitro data and in vivo data from various chronic and subchronic studies.¹² It is important to note that DOTP clearly shows no evidence of adverse endocrine effects based on the following data:

- No anti-androgenic effects similar to those observed with some ortho-phthalates¹³
- No estrogenic effects in vitro or in vivo¹⁴
- Inactive in a number of US EPA ToxCast and EDSP21 assays¹⁵
- No suggestion of thyroid or adrenal gland effects from sub-chronic and chronic studies¹⁶

In addition, ANSES under the EU RMOA process determined that there was “no alert . . . on potential endocrine disruption properties of the substance” and concluded there were no risk management measures necessary.¹⁷

The two commercial U.S. made products also are listed in the CleanGredients® database, which is based on the US EPA Safer Choice criteria.

¹¹ NSF International, "GreenScreen Assessment for Bis(2-ethylhexyl) terephthalate (6422-86-2)," 2017. The assessment is currently not publicly available but can be provided to Washington DOE upon request.

¹² Harmon, J. P. and Otter, R. "Green Chemistry and the Search for New Plasticizers," *ACS Sustainable Chem. Eng.* **2018**, 6, 2078 – 2085.

¹³ Gray, Jr., L. E.; Ostby, J.; Furr, J.; Price, M.; Veeramachaneni, D. N.; Parks, L. "Perinatal Exposure to the Phthalates DEHP, BBP, and DINP, but Not DEP, DMP, or DOTP, Alters Sexual Differentiation of the Male Rat," *Toxicol. Sci.*, **2000**, 58, 350-365; and Furr, J. R.; Lambright, C. S.; Wilson, V. S.; Foster, P. M.; Gray, Jr., L. E. "A Short-Term In Vivo Screen Using Fetal Testosterone Product, a Key Event in the Phthalate Adverse Outcome Pathway, to Predict Disruption of Sexual Differentiation," *Toxicol. Sci.*, **2014**, 140, 403-424.

¹⁴ Ball, G. L.; McLellan, C. J.; Bhat, V. S. "Toxicological Review and Oral Risk Assessment of Terephthalic Acid and Its Esters: a Category Approach," *Crit. Rev. Tox.*, **2012**, 42, 28-67.

¹⁵ US EPA, "Endocrine Disruptor Screening Program (EDSP) Estrogen Receptor Bioactivity," 2015. [Online]. Available: <https://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-edsp-estrogen-receptor-bioactivity>. [Accessed 20 June 2016]; and US EPA, "EDSP21 Dashboard," [Online]. Available: <https://actor.epa.gov/edsp21/>. [Accessed 11 September 2017].

¹⁶ See reference in Footnote 14.

¹⁷ ANSES, "Risk Management Options Analysis (RMOA) - Diethylhexyl Terephthalate," January 2016. [Online]. Available: <https://www.echa.europa.eu/documents/10162/dd0220b0-1187-4c2b-8991-51ddb9d462>. [Accessed 18 May 2016].

Alternatives Assessment – Avoid Regrettable Substitution

As discussed in Lavoie, et al., “substitution that is not informed by the best available information and science can lead to unintentional and undesired consequences,” or what some have called “regrettable substitution”.¹⁸ The choice of DOTP as a plasticizer by vinyl flooring manufacturers is a good example of responsible and science-based alternative selection. The positive assessments and regulatory approvals for DOTP described above support the goal of avoiding “regrettable substitution” and its broad use as an alternative to general purpose ortho-phthalates.

Ortho-Phthalates as a Class

It is inappropriate to regulate ortho-phthalates as a class. As noted in Footnote 4, the reproductive and developmental effects that have driven most of the regulatory action depend upon the alcohol chain length, and not all ortho-phthalates show the same adverse effects. For example, the results of a U.S. EPA screening test for effects on fetal rat testosterone and subsequent anti-androgenic effects are summarized in the following table (Fuhr, et al., 2014).¹³

Observed effect on rat fetal testis testosterone production

Plasticizers	Alcohol		Outcome
	Carbon chain	C Backbone	
DMP	1	1	Negative
DEP	2	2	Negative
DIBP	4	3	Positive
DBP	4	4	Positive
BBP	4/7	4	Positive
DPenP	5	5	Positive
DHexP	6	6	Positive
DEHP	8	6	Positive
DINP	9	6-9	Weak positive
DPHP	10	7	Negative
DIDP	10	7-9	Negative
Alternatives			
TOTM	8	6	Negative
Hexamoll® DINCH	9	7-9	Negative
DOTP/DEHT	8	6	Negative

¹⁸ Lavoie, E. T.; Heine, L. G.; Holder, H.; Rossi, M. S.; Lee, II, R.E.; Connor, E. A.; Vrabel, M. A.; Difiore, D. M.; Davies, C. L. "Chemical Alternatives Assessment: Enabling Substitution to Safer Chemicals," *Environ. Sci. Tech.*, **2010**, *44*, 9244-9249.



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The products that were inactive (negative) in these tests are not classified in Europe or other regions for fertility or developmental effects; however, the ones that are active (positive) are classified.

Authoritative government agencies also recognize the differences in the behavior of the various ortho-phthalates. U.S. CPSC lifted the restriction on diisodecyl phthalate (DIDP) and di-n-octyl phthalate (DNOP) in toys and childcare articles based on the absence of these effects.¹⁹ The EU ECHA Risk Assessment Committee (RAC) recently concluded that “no classification for DINP [diisononyl phthalate] for either effects on sexual function and fertility, or for developmental toxicity is warranted.”²⁰

If you have any questions, please contact me at 346-252-4123 or patrick.harmon@basf.com.

Sincerely yours,

A handwritten signature in cursive script that reads "J P Harmon".

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BASF Corporation

¹⁹ <https://www.federalregister.gov/documents/2017/10/27/2017-23267/prohibition-of-childrens-toys-and-child-care-articles-containing-specified-phthalates>.

²⁰ <https://echa.europa.eu/documents/10162/56980740-fcb6-6755-d7bb-bfe797c36ee7>.