MANUFACTURER REQUEST FOR RISK EVALUATION
DIISODECYL PHTHALATE (DIDP)

Table of Contents

May 23, 2019

Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

Background

The American Chemistry Council's High Phthalates Panel (ACC HPP) represents major producers, importers, and users of DINP, DIDP, and other high molecular weight phthalates. Pursuant to Section 6(b)(4)(C)(ii) of the Toxic Substances Control Act (TSCA) and 40 C.F.R. Section 702.37, ExxonMobil Chemical Company ("the manufacturer"), through the ACC High Phthalates Panel, formally requests that the Agency conduct a risk evaluation of diisodecyl phthalate (DIDP), represented by the two Chemical Abstracts Service Registry Numbers (CASRNs) 26761-40-0 and 68515-49-1. This document and Appendices A-C provide the information to be submitted as set forth in §702.37(b).[1]

Contact information of entity submitting the request

The High Phthalates Panel is comprised of companies that manufacture, compound, convert, or import certain high molecular weight phthalates.[2]

Substance identity

The chemical identity of DIDP is provided in Appendix A. Tables 1-3 of Appendix A include all reasonably known names of the chemical substance, including common or trade names and CAS numbers. Structures of representative isomers of the chemical substance are also provided in figures 1-3 of Appendix A. As noted previously, this substance is represented by two CAS numbers. The structures of DIDP illustrated in figures 1 and 2 of Appendix A represent CAS number 26761-40-0. DIDP identified by CAS number 68515-49-1 refers to a multi-constituent substance comprised of C_9-C_{11} (C_{10}-rich) branched dialkyl phthalate esters, illustrated in figure 3 of Appendix A. Both CAS numbers contain mainly C_{10} dialkyl phthalate esters, having identical molecular formula $C_{28}H_{46}O_4$ (with a molecular weight of approximately 446.7 Da).[3] As noted in Appendix B of this submission, unlike CAS number 68515-49-1, CAS number 26761-40-0 is not currently registered under the European Union (EU) REACH chemical management system. However, U.S. production volumes have been reported for both CAS numbers to EPA's Chemical Data Reporting database, albeit CAS number 26761-40-0 is reported at considerably lower production volumes than CAS number 68515-49-1.

As described in Appendix A, reviewing agencies, including the European Chemicals Bureau/Chemicals Agency (ECHA), Australia NICNAS, Environment Canada and Health Canada, and the US CPSC have considered the two CAS numbers to be toxicologically equivalent and have evaluated them as a single substance. Hence, this request is to evaluate the risk of both CAS numbers as a single substance.

[1] Unless otherwise indicated, all section citations are to 40 C.F.R.
[2] See https://phthalates.americanchemistry.com/About-Us/
[3] *See* Consumer Product Safety Commission. 2010. Toxicity review of Di(isodecyl) Phthalate (Apr. 7, 2010), p. 2. https://www.cpsc.gov/s3fs-public/toxicityDIDP.pdf. The requesting manufacturers agree with this description.

Conditions of use requested for evaluation

The Agency defines conditions of use as "circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of." §702.33. The uses of DIDP are summarized in Appendix B. The primary intended, known or reasonably foreseen use of DIDP is as a plasticizer to impart flexibility to polyvinyl chloride (PVC) in consumer and industrial applications.[4] [5] [6] [7] These applications include building and construction (electrical wire coating, vinyl tiles, resilient flooring, PVC-backed carpeting, roofing, wall coverings etc.), automotive (upholstery and interior finishes such as synthetic leather or PVC skins for car interior seats and dashboards, undercoating, insulation for wire and cable, window glazing etc.), flexible tubes, profiles, and hoses. Other DIDP applications include use in inks, adhesives, sealants, synthetic lubricants and engine oils. This list of uses is consistent with those identified for DIDP in existing European Union (EU) REACH registrations (see Appendix C of this request for links to EU REACH registration dossiers for DIDP).

These uses mirror those reported for DIDP in the US. 2016 CDR data reported for CASRN 26761-40-0 indicates that it is used for industrial and commercial applications such as incorporation into formulation, mixture, or reaction product for making adhesives and sealant chemicals, petroleum lubricating oil and grease manufacturing, as a plasticizer and for use in manufacturing adhesives and sealants. With respect to CASRN 68515-49-1, the 2016 CDR data reports use for industrial, consumer and commercial applications such as incorporation into an article or into formulation, mixture, or reaction product for manufacturing adhesives and sealants, paints and coatings, plastic products, and resins (as a plasticizer).

The manufacturer, through the ACC HPP, requests that the following uses be evaluated under the risk evaluation of DIDP:

- DIDP Manufacturing
- DIDP use as a general purpose plasticizer for PVC used in the following applications;
    - Building and construction – electrical wire coating, vinyl tiles, resilient flooring, PVC-backed carpeting, wall coverings, roofing, etc.
    - Automotive – upholstery and interior finishes (e.g. synthetic leather for car seats, interior PVC skins for dashboards and shift boot covers), window glazing, body-side molding, automotive undercoating, molded interior applications, insulation for wire and cable and wire harnesses.
    - Other consumer applications – flexible tubes, hoses, profiles, etc.
    - Non-PVC applications – inks, adhesives, sealants and paints, synthetic lubricants and engine oils.
- Use in PVC for children's toys and childcare articles – From 2009-2017, the US CPSC placed an interim restriction on the use of DIDP in any children's toys that can be placed in a child's

[4] American Chemistry Council (ACC) (2018). Phthalates: High phthalates uses and applications. https://phthalates.americanchemistry.com/High-Uses-and-Applications.html
[5] IHS Markit. (2018). Chemical Economics Handbook: Plasticizers, pp. 42. 4 May 2018.
[6] European Plasticisers (2018). Plasticisers Information Center: Orthophthalates. https://www.plasticisers.org/plasticisers/orthophthalates/
[7] European Chemicals Agency (ECHA) (2010). Review of New Available Information for di-isodecyl phthalate (DIDP). p. 4. https://echa.europa.eu/documents/10162/13641/didp_echa_review_report_2010_6_en.pdf

mouth or childcare article at levels greater than 0.1%.[8] In 2017, the US CPSC lifted the interim prohibition, on the basis that continuing the prohibition "*is not necessary to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety*".[9] Thus, DIDP may be used in children's toys and childcare articles without restriction in the United States, unless there are restrictions within a specific state. One such state restriction is in California, which prohibits DIDP in concentrations greater than 0.1% in a toy or child care article intended for use by a child under three years of age if that product can be placed in the child's mouth.[10] The manufacturer, through the ACC HPP, requests that potential DIDP exposure of children from toys and childcare articles be evaluated, consistent with the Agency's stated concerns in the US EPA 2012 Phthalate Action Plan.[11]

Information relevant to the risk evaluation of DIDP

TSCA requires EPA to conduct risk evaluations to determine whether there is unreasonable risk to humans or the environment using the best available science and weight of the scientific evidence.[12] The definition of weight of the scientific evidence adopted by EPA states:

> "Weight of the scientific evidence means a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance."[13]

These scientific standards apply to manufacturer requests for risk evaluation and any request must include all the existing information relevant to the risk evaluation.[14] Specifically,

> "The request must also include a list of all the existing information that is relevant to whether the chemical substance, under the circumstances identified by the manufacturer(s), presents an unreasonable risk of injury to health or the environment. The list must be accompanied by an explanation as to why such information is adequate to permit EPA to complete a risk evaluation addressing the circumstances identified by the manufacturer(s), The request need not include copies of the information; citations are sufficient, if the information is publically [sic] available. The request must include or reference all available information on the health and

---

[8] Consumer Product Safety Act of 2008 § 108(b)(1), codified at 15 U.S.C. § 2057c(b)(1). https://www.cpsc.gov/s3fs-public/pdfs/blk_pdf_cpsia.pdf. "Children's toy" was defined as a consumer product designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child plays" and "child care article" is defined as "a consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking or teething." 15 U.S.C. § 2057c(g)(1) [as codified after amendment of CPSIA].

[9] US Consumer Product Safety Commission (CPSC). Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates. 82 Fed. Reg. 49938, 49968 (Oct. 27, 2017), https://www.gpo.gov/fdsys/pkg/FR-2017-10-27/pdf/2017-23267.pdf [hereafter "CPSC Phthalate Rule"].

[10] California Health and Safety Code § 108937(b).

[11] US EPA, Phthalates Action Plan (Mar. 14, 2012 revision), pp. 8 & 12, https://www.epa.gov/sites/production/files/2015-09/documents/phthalates_actionplan_revised_2012-03-14.pdf [hereafter "2012 Action Plan"].

[12] 15 U.S.C. 2625(h) and (i); defined at 40 C.F.R. Part 702.33

[13] 40 CFR Part 702.33

[14] 40 CFR Part 702

environmental hazard(s) of the chemical substance, human and environmental exposure(s), and exposed population(s), as relevant to the circumstances identified in the request."[15]

To provide EPA with "all existing information that is relevant" to conduct the manufacturer requested risk evaluation, an extensive literature search was conducted. Appendix C details the protocol used to comprehensively, objectively, transparently, and consistently identify relevant information in several databases. The process used comports with the requirements specified by EPA for a weight of the scientific evidence review method and meets the requirements for submission of a manufacturer requested risk evaluation under 40 CFR Part 702.37.

Specifically, Appendix C contains bibliographic citations to publicly available information that is relevant to whether DIDP, under the circumstances identified above, presents an unreasonable risk of injury to health or the environment. We note that DIDP (and phthalates in general) has been the subject of considerable academic and regulatory interest for several decades. Thus, while the list in Appendix C is robust, it does not necessarily represent all existing hazard and exposure information on DIDP. Nevertheless, it does include all the existing information that is relevant to whether DIDP, under the conditions of use noted herein, presents an unreasonable risk of injury to health or the environment, including the following: information on the hazard and exposure potential of DIDP, information on the persistence and bioaccumulation of DIDP, information on potentially exposed or susceptible subpopulations relevant to the EPA risk evaluation, information on the potential for storage near significant sources of drinking water, and information on DIDP production volumes. The manufacturer, through the ACC HPP, believes that having provided all the existing information listed above, such information is more than adequate for EPA to conduct a thorough risk evaluation addressing the conditions of use we have identified. The following provides an overview of the information referenced in Appendix C.

Information relevant to the human health hazard potential of DIDP –

In its 2012 Phthalates Action Plan 2014 update to the TSCA Work Plan, the Agency indicated that the critical endpoint of concern for DIDP is developmental toxicity (hazard score of 3 – "high" assigned).[16] In addition, in the Action Plan, the Agency indicated that it intended to consider results of risk evaluations being conducted by the US Consumer Product Safety Commission (CPSC), the FDA, and the Agency's IRIS program to inform the extent of any future TSCA Section 6 action addressing the listed phthalates, including DIDP.[17]

Thus, the most relevant information with respect to the reproductive/developmental hazard and risk assessment of DIDP is the recently completed regulatory risk evaluation from the US CPSC's Chronic Hazard Advisory Panel (CHAP) (2014), along with other similar completed risk evaluations from the European Union (2003 and 2013), the Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS) (2015) and Environment Canada and Health Canada (2015). References to these risk evaluations are available on page 2 of Appendix C.

---

[15] Environmental Protection Agency; Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,749 (July 20, 2017)(codified at 40 C.F.R. Pt. 702.37).

[16] 2012 Action Plan, note 11, pp. 1 & 4; TSCA Work Plan for Chemical Assessments: 2014 Update, p. 12, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemical-assessments-2014-update [hereafter "2014 Work Plan"].

[17] 2012 Action Plan, note 11, pp. 10-11 ("Next Steps").

US CPSC –

The CPSC's CHAP conducted an evaluation of the toxicity information available on DIDP, with a focus on reproductive and developmental toxicity.[18] The CHAP concluded that DIDP "*does not appear to possess antiandrogenic potential.*"[19] For all other potential systemic effects, the CHAP concluded that the margin of exposure (MOE) for DIDP in humans "is considered likely to be relatively high."[20] Overall, the CHAP indicated that it did not find "compelling data to justify maintaining the current interim ban on the use of DIDP in children's toys and child care articles" and thus recommended a lifting of the interim ban.[21] In 2017, the US CPSC adopted the recommendation of the CHAP, concluding that DIDP "does not lead to male developmental reproductive toxicity in animals and, therefore, does not contribute to the cumulative risk" and that "continuing the prohibition … *is not necessary to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety*."[22] Thus, DIDP use is now allowed in children's toys, including those that may be placed in a child's mouth, and childcare articles, unless there is a restriction within a specific state.[23] The manufacturer, through the ACC HPP, considers exposure to DIDP in toys and childcare articles to be worst-case, especially in children and pregnant women, who would be considered the most susceptible individuals with respect to DIDP exposure, consistent with the Agency's stated concerns in the 2012 Phthalate Action Plan.[24] The US CPSC's conclusions thus provide adequate confidence that DIDP poses no unreasonable developmental toxicity risk to humans, including the most susceptible populations.

European Union –

The European Union (EU) has published two detailed risk evaluations of DIDP, in 2003 and 2013.[25, 26] Both risk evaluations concluded that there was no need for further testing or risk mitigation with respect to exposure to DIDP for workers and consumers.[27] The 2013 report evaluated the risk of exposure to DIDP from several uses including toys and childcare articles (e.g. school supplies), skinny vinyl leather pants (assuming these are worn 10 hours/day for 2 weeks per month by pregnant women), indoor air, house dust and food in children and adults.[28] The EU report found no reproductive or developmental toxicity risk with DIDP exposure in any of the uses evaluated, consistent with the US CPSC's conclusions.[29]

---

[18] Chronic Hazard Advisory Panel (CHAP) on Phthalates. 2014. Chronic Hazard Advisory Panel on Phthalates and Phthalate Alternatives Final Report (2014), pp. 100-105, A-26&28, B-13-14. https://www.cpsc.gov/s3fs-public/CHAP-REPORT-With-Appendices.pdf [hereafter "CHAP 2014"].

[19] CHAP 2014, note 18, p. 104.

[20] Id. See also id. Section 5.3.3.4.3, page 104 ("Risk"): "Based on the lowest [point of departure] (15 mg/kg-day), the [margins of exposure] range from 2500 to 10,000 for median intakes and from 586 to 3300 for 95th percentile intakes."

[21] Id. pp 104-105.

[22] CPSC Phthalate Rule, note 9, p. 49968

[23] See note 10 and associated text regarding restrictions in California.

[24] 2012 Action Plan, note 11, pp. 8 & 12.

[25] European Chemicals Bureau. 2003. European Union Risk Assessment Report on 1,2- benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich and di-"isodecyl" phthalate (DIDP). https://echa.europa.eu/documents/10162/190cf4c4-b597-4534-9b71-f79fce55050b [hereafter "ECB 2003"].

[26] European Chemicals Agency (ECHA). 2013. Evaluation of new scientific evidence concerning DINP and DIDP in relation to entry 52 of Annex XVII to REACH Regulation (EC) No 1907/2006. August 2013. https://echa.europa.eu/documents/10162/31b4067e-de40-4044-93e8-9c9ff1960715. [hereafter "ECHA 2013"].

[27] ECB 2003, note 25, pp. VII-VIII; ECHA 2013, note 26, pp. 7-8.

[28] ECHA 2013, note 26, pp. 267-276.

[29] Id., Tables 4.91, 4.94, 4.102, 4.108, 4.113, and 4.117.

Australia NICNAS –

In 2015, the Australian NICNAS published a detailed hazard and risk assessment of DIDP exposure through the use of plastic toys and childcare articles.[30] For their assessment, NICNAS identified two critical health effects observed in rodents: repeated-dose toxicity (increased liver weights) and developmental effects (increased skeletal variations at non-maternotoxic dose).[31] To estimate daily internal oral dose for a child who may be exposed to DIDP in toys or childcare articles, NICNAS assumed a six-month old infant, having the lowest body weight among the group (7.5 kg based on the 50th percentile value for males and females combined), would exhibit the maximum mouthing behavior with a typical and reasonable worst-case mouthing time of 0.8 hours/day and 2.2 hours/day, respectively.[32] Assuming the use of toys and childcare articles containing DIDP by children, NICNAS derived margins of exposure (MOE) of 1980 and 3297 for increased liver weights and increased skeletal variations, respectively.[33] MOEs for worst-case exposure scenarios were 339 and 565 for increased liver weights and increased skeletal variations, respectively.[34] Overall, NICNAS concluded that the derived risk estimates for DIDP indicate a low concern of these adverse effects under the exposure conditions.[35] This report is the basis for the current lack of a restriction for DIDP in children's toys and childcare articles in Australia.[36]

Environment Canada and Health Canada –

Environment Canada and Health Canada have conducted a risk evaluation of DIDP.[37] The report identified three critical systemic effects after oral exposure to DIDP: liver weight increase in male rats accompanied with histological changes at the highest dose in short term studies (300 mg/kg bw/day was a NOAEL in females and LOAEL in males), liver weight increase accompanied with histological changes in subchronic studies in the dog (NOAEL = 15 mg/kg bw/day) and histopathological changes in liver of male rats in chronic studies (LOAEL = 22 mg/kg bw/day).[38] Canada also evaluated the potential evidence of any association between DIDP and health outcomes in humans and found no evidence of an association with changes in sex hormone levels, anogenital distance, birth measures, preterm birth and gestational age and pregnancy loss.[39] Canada derived exposure estimates for DIDP from available biomonitoring data, including measured levels of DIDP in dust, food and plastic items, with male children 6-11 years identified as the highest exposed group and infants 6 months to 4 years

---

[30] Australian Government National Industrial Chemicals Notification and Assessment Scheme (NICNAS). 2015. Diisodecyl phthalate and Di-n-octyl phthalate. Existing Chemical Hazard Assessment Report. May 2015. https://www.nicnas.gov.au/__data/assets/word_doc/0004/34843/PEC39-Diisodecyl-phthalate-and-Di-n-octyl-phthalate.docx [hereafter "NICNAS 2015"].

[31] Id. pp. 2 & 40.

[32] Id. pp. 3, 16 & 17.

[33] Id. pp. 43.

[34] Id.

[35] Id. p. 44.

[36] Australia NICNAS Chemical Information Factsheet on DIDP. https://www.nicnas.gov.au/chemical-information/factsheets/chemical-name/diisodecyl-phthalate-didp-and-di-n-octyl-phthalate-dnop. See "Report recommendations.".

[37] Environment Canada and Health Canada State of the Science Report. 2015. Phthalates Substance Grouping: Long-chain Phthalate Esters, 1,2-Benzenedicarboxylic acid, diisodecyl ester (diisodecyl phthalate; DIDP) and 1,2-Benzenedicarboxylic acid, diundecyl ester (diundecyl phthalate; DUP). http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=D3FB0F30-1 [hereafter "Canada SOS 2015"]. See also Environment Canada and Health Canada. 2017. Draft Screening Assessment Phthalate Substance Grouping: Sections 9 and 10. http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=1E5B3C8F-1 [hereafter "Canada 2017"].

[38] Canada SOS 2015, note 37, sections 9.2.2.5.2 & 9.2.2.5.3; Canada 2017, note 37, Table 9-47.

[39] Canada 2017, note 37, Table 9-49.

old identified as the subpopulation with the highest exposure from dust and food. Using the oral LOAEL of 22 mg/kg bw/day (histopathological changes in male rat liver in chronic studies), Canada derived MOEs (central tendency and upper bound) for all possible age groups. Upper bound MOEs were 10,185 for infants 0-18 months (exposure to plastic articles), 76660 for children 6 months to 4 years (food and dust, oral), 5000 for male children 6-11 years (95th percentile aggregate exposure from NHANES biomonitoring data), and 4490 for female adults 20+ years (95th percentile aggregate exposure from NHANES biomonitoring data).[40] Overall, the Canadian evaluation concluded that the MOEs "are considered adequate to account for uncertainties in the exposure and health effects databases and further, protective of potential developmental and reproductive effects of DIDP toxicity not only in males, but also in females as well as effects in other organ systems. These MOEs are also considered adequate as they address potential carcinogenicity of DIDP that could occur at higher doses".

Regarding the use of DIDP in non-PVC applications like adhesives, sealants, and coatings, the Canadian evaluation concluded that "exposure would not be considered to be of concern for human health" based on low dermal absorption of DIDP in rats (1-4%), evidence that human skin is less permeable than rat skin to phthalate diesters, low skin retention in humans compared to rat (3 to 6-fold lower in humans), low tissue distribution with no accumulation, and rapid excretion (section 9.3.3).

Other Information –
The manufacturer, through the ACC HPP, notes that DIDP is listed as "*known to the state of California to cause reproductive toxicity*" under California's Proposition 65.[41] California's Office of Environmental Health Hazard Assessment (OEHHA) based this listing the conclusion by the National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR) that DIDP causes developmental toxicity.[42] According to the NTP-CERHR report, two prenatal toxicity studies of DIDP in rats showed evidence of an increase in skeletal variations, while two 2-generation dietary reproductive toxicity studies showed some evidence of an effect on postnatal survival and growth.[43] However, it is important to note that while the NTP-CERHR report acknowledges some evidence of developmental effects in rats, it concludes that DIDP does not affect reproduction in rodents.[44] Taking into consideration the hazards of DIDP identified in rats and potential for exposure in humans, the NTP-CERHR report concluded that "*there is minimal concern for developmental effects in fetuses and children*" and that, "*there is negligible concern for reproductive toxicity in exposed adults.*"[45]

Each of the studies reviewed in the 2003 NTP-CERHR report were also reviewed in the more recent risk evaluations of DIDP by the US CPSC, European Union, Australia NICNAS and Environment Canada/Health Canada. As summarized above, none of those agencies found concern for human developmental or reproductive risk. For example, the US CPSC CHAP summarized developmental and reproductive studies by noting, "[T]the CPSC calculated an [acceptable daily intake (ADI)] of 0.4 mg/kg-day using the lowest developmental NOAEL of 40 mg/kg-day for DIDP-induced supernumerary ribs.

[40] Canada SOS 2015, note 37, Table 9.23.
[41] OEHHA 2007. Notice to Interested Parties: Chemical Listed Effective April 20, 2007 As Known To The State Of California To Cause Reproductive Toxicity. https://oehha.ca.gov/media/downloads/proposition-65/chemicals/42007notice20diisodecyl20phthalate.pdf
[42] Id. p. 1. See National Toxicology Program. 2003. NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Di-Isodecyl Phthalate (DIDP). NIH Publication No. 03-4485. https://www.cpsc.gov/s3fs-public/nihDIDP042003.pdf [hereafter "NTP-CERHR 2003"].
[43] NTP-CERHR 2003, note 42, pp. 1-2 & II-24-25 (Table 5)
[44] Id. p. 2.
[45] Id. p. 3.

Three well-conducted rat studies suggest that oral DIDP exposure is not associated with reproductive toxicity at the levels tested."[46] Using an even lower point of departure (POD) of 15 mg/kg bw/day (liver effects with chronic dietary exposure in rats), the CHAP derived MOEs ranging from 2500 to 10000 for median exposures and 586 to 3300 for exposures in the 95th percentile.[47] These MOEs clearly indicate no concern for developmental risk in humans with exposure to DIDP and are the basis for the US CPSC's ruling lifting the interim restriction on the use of DIDP in children's toys and childcare articles.[48]

Overall, we conclude that the California Proposition 65 listing of DIDP for reproductive toxicity is not relevant to the requested TSCA risk evaluation of DIDP.

To the best of our knowledge, no hazard or risk evaluation of DIDP has been conducted by the Agency or the FDA since the 2012 Phthalate Action Plan was issued. We have included a reference to a publicly available FDA investigation of levels of plasticizers (including DIDP) present in PVC articles authorized as food contact materials in Appendix C (see Carlos et al. 2018).

Information relevant to the exposure potential of DIDP –
According to the 2014 update to the TSCA Work Plan, DIDP is assigned an exposure score of 3 (high), based its common use as a plasticizer in PVC with industrial, commercial and consumer applications. The US Centers for Disease Control and Prevention (CDC)'s National Health and Nutrition Examination Survey (NHANES) has reported urinary levels of DIDP metabolites for the US population from 1999 to 2016.[49] [50] These data have served as the basis for recent risk evaluations of DIDP by regulatory Agencies including the US CPSC and Environment Canada/Health Canada. These values represent a snapshot of DIDP exposure in the general population from various sources (industrial, commercial, and consumer) across a wide range of age, gender and race, and are reflective of the average production/import volume of DIDP in the United States.

The NHANES database only provides biomonitoring information from ages 6 and above. The manufacturer, through the ACC HPP, notes that the US CPSC CHAP (see footnote 9) utilized biomonitoring data from the Study for Future Families (SFF)[51] to estimate exposure to infants from 2 to 36 months, as well as estimating prenatal and postnatal measurements from their mothers.[52] However, the manufacturer, through the ACC HPP, advises that the SFF data be interpreted with caution as the data only track DIDP exposures from 1999-2005 and may not necessarily reflect current exposures.

---

[46] CHAP 2014, note 18, p. 104.
[47] Id. p. 104
[48] CPSC Phthalate Rule, note 9, p. 49968.
[49] Data through the 2013-2014 NHANES cycle are presented in CDC's formal exposure report, which presents absolute and creatinine-adjusted values at various percentiles and according to various subpopulations. CDC 2018. Fourth National Report on Human Exposure to Environmental Chemicals. Updated Tables, March 2018, Volume One. pp. 489-492 https://www.cdc.gov/exposurereport/pdf/FourthReport_UpdatedTables_Volume1_Mar2018.pdf. [hereafter "NHANES 2005-2014"]
[50] Raw data for the 2015-2016 NHANES cycle are provided at https://wwwn.cdc.gov/nchs/nhanes/search/datapage.aspx?Component=Laboratory&CycleBeginYear=2015 [hereafter "NHANES 2015-16"]. These datasets need to be accessed using a SAS software viewer.
[51] Swan, S; Calafat, A; Kruse, R; Lasley, B; Redmon, B; Sparks, A; Wang, C. Final Report: Study of Phthalates in Pregnant Woman and Children (Study for Future Families (SFF)). EPA Grant Number: R829436.
https://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.highlight/abstract/1950
https://www.cpsc.gov/s3fs-public/SFF-Biomonitoring-Data.pdf
[52] See CHAP 2014, note 18, Appendix D.

More recent summary data on mono (carboxy-isononyl) phthalate (MCiNP) DIDP metabolite collected in The Infant Development and the Environment Study (TIDES) has been published.[53, 54] According to the study authors, TIDES is a prospective cohort study of phthalate metabolites in urine samples of pregnant women over 18 years old and <13 weeks pregnant, recruited from 2010-2012 and collected in the first, second and third trimesters. Mean urinary concentrations of MCiNP (ng/mL) for each trimester have been published for a limited dataset (N = 167-168).[55] Mean values were well below the 90th percentile for all age groups 20 years and older and all females (regardless of age) reported for the US population from NHANES, suggesting that the NHANES data is an appropriate surrogate for estimating potential prenatal exposures to DIDP.

Limited data on urinary levels of DIDP metabolites are available for occupational workers and are referenced in Appendix C. For example, in one study, levels of DIDP metabolites were assessed in spot urine samples of 5 employees in a car manufacturing plant in German, refinishing plastisol seam sealants.[56] The refinishing was performed at room temperature with a brush or with fingers. Creatinine-adjusted urinary levels of mono-(carboxylnonyl) phthalate (MCNP) ranged from 1.0-7.1 µg/g for pre-shift workers (median – 2.5 µg/g) and 0.8-8.7 µg/g for post-shift workers (median – 5.3 µg/g). Although the sampling period was not provided in the paper, the upper range of MCNP was similar to the 90th percentile reported by NHANES for the US population ages 20 years and older between 2005 and 2014.[57] Thus, it can be inferred that the higher percentile ranges of the NHANES dataset can be used as an upper bound estimate or worst-case estimate of exposures to DIDP across the population, including occupational workers.

One use that the manufacturer, through the ACC HPP, is requesting for risk evaluation is the use of DIDP in children's toys, including those that could be placed in a child's mouth, and childcare articles. Compared to DINP, evaluations of potential exposures of children to DIDP in toys is limited. Some regulatory agencies (for example, the European Chemicals Agency) have assumed that the level of exposure to DIDP from toys would be equivalent to that of DINP.[58] However, published estimates of DIDP exposure from toys are considerably lower than those for DINP.[59] Several phthalate migration and PVC toy mouthing studies in infants are available and have been reviewed by other regulatory agencies. In one study, the US CPSC conducted an assessment to identify the types and migration of plasticizers used in component parts of various children's toys and childcare articles on the market after 2008.[60] The CPSC identified 129 component parts from 63 samples, 38 of which were composed of

[53] Swan, S.H., T.S.T. the, S. Sathyanarayana, T.S.T. the, E.S. Barrett, T.S.T. the et al.: First trimester phthalate exposure and anogenital distance in newborns. *Human Reproduction* 30(4): 963-972 (2015). https://academic.oup.com/humrep/article/30/4/963/613595.
[54] Martino-Andrade AJ, Liu F, Sathyanarayana S, Barrett ES, Redmon J, Nguyen RH, Levine H, Swan SH; TIDES Study Team. Timing of prenatal phthalate exposure in relation to genital endpoints in male newborns. Andrology. 2016 Jul;4(4):585-93. doi: 10.1111/andr.12180. Epub 2016 Apr 7. https://www.ncbi.nlm.nih.gov/pubmed/27062102
[55] Id. p. 588 (Table 1).
[56] Koch, H.M., A. Haller, T. Weiß, H.-U. Käfferlein, J. Stork, and T. Brüning: Phthalate exposure during cold plastisol application—a human biomonitoring study. *Toxicology Letters* 213(1): 100-106 (2012).
[57] See NHANES 2005-2014, note 49, pp. 489-492 for urinary MCNP (in µg/g creatinine) for the 2005/2006 to 2013/2014 NHANES cycles.
[58] ECHA 2013, note 26, p. 202.
[59] Compare Table 4.65 and 4.66 in id. pp. 204-205.
[60] US CPSC (2010). Phthalates and Phthalate Substitutes in Children's Toys. https://www.cpsc.gov/s3fs-public/phthallab.pdf

PVC. [61] DIDP was not identified in any of the items.[62] DINP was only found in 1 item; the majority of the items contained other plasticizers such as di-2-ethylhexyl terephthalate (DOTP) and 1, 2-cyclohexanedicarboxylic acid, di-isononyl ester (DINCH).[63]

All documents and data summarized above are referenced in Appendix C of this request for the Agency's review.

Information relevant to the persistence and bioaccumulation of DIDP –
According to the Agency's 2012 Phthalates Action Plan and 2014 TSCA Work Plan, DIDP exhibits low toxicity to aquatic organisms and is ranked low for persistence and bioaccumulation.[64]

The most relevant and thorough ecological hazard and risk evaluations of DIDP are available in the European Union (EU) 2003 risk assessment and Environment Canada and Health Canada's 2015 State of the Science Report on long-chain phthalate esters.[65] Tables 7-3 and 7-4 of Canada's State of the Science report provide an extensive summary of the biodegradation data available for DIDP. Canada summarizes that DIDP is rapidly biodegraded in aerobic conditions (and even under conditions of low oxygen), with 68% removal within 1 day and 90-100% removal of parent substance within 10-28 days.[66] With respect to bioaccumulation, Canada states, "Empirical bioconcentration factors (BCFs) of <14 and 147 L/Kg wet weight and biota-soil/sediment accumulation factors (BSAFs) of 0.015 and 0.16 suggest that DIDP has low potential to bioaccumulate in aquatic and terrestrial organisms."[67]

A detailed review of the biodegradation of DIDP is also available in the 2003 EU risk assessment report.[68] Overall, the data support Canada's conclusion that DIDP is readily biodegraded and is hence unlikely to persist in the environment.[69] Bioaccumulation data for DIDP itself were limited, but overall the EU report supports Canada's finding that DIDP has "low bioaccumulation and biomagnification potential".[70]

Test results and robust summaries pertaining to DIDP's persistence and bioaccumulation are referenced in Appendix C under the data sets submitted to the European Chemicals Agency.

Potentially exposed or susceptible subpopulations relevant to the EPA risk evaluation –
The Agency has indicated that it considers children and the developing fetus as the susceptible subpopulations for which the health risks of DIDP should be assessed.[71] The CDC report of NHANES data on urinary metabolites of DIDP (reported as geometric means and selected percentiles) is stratified by gender (males and females), race/ethnicity (Mexican American; Non-Hispanic Black; Non-Hispanic White) and age group (6-11 years, 12-19 years and ≥20 years).[72] Additional refinements can be made by directly accessing the NHANES database to obtain relevant information on DIDP exposures in the subpopulation that the Agency considers to be most susceptible, children and women of childbearing

[61] Id. p. 4.
[62] Id.
[63] Id.
[64] 2012 Action Plan, note 11, pp. 5-6; 2014 Work Plan, note 16, p. 12.
[65] ECB 2003, note 25, pp. 23-106; Canada SOS 2015, note 37, Sections 7 & 8.
[66] Canada SOS 2015, note 37, Section 7.2.1.
[67] Id. section 7.3.
[68] ECB 2003, note 25, pp. 23-26.
[69] Canada SOS 2015, note 37, Synopsis.
[70] Id.; ECB 2003, note 25, p. 27-33
[71] 2012 Action Plan, note 11, pp. 8.
[72] NHANES 2005-2014, note 49, pp. 489-492

age. As earlier mentioned, NHANES does not include data on infants and children <6 years of age. The SFF data, with a smaller subset of infants (2-37 months) may be considered as a surrogate, with caution, as noted previously.[73]

With respect to evaluation of DIDP exposure from mouthing toys and childcare articles (the worst-case exposure scenario for children), minimal data is available and certain regulatory agencies (like the European Chemicals Agency) have extrapolated from data available for DINP. These are summarized in the exposure section.

Potential for storage of chemical substance near significant sources of drinking water, including storage facility location and nearby drinking water source(s) –
DIDP is used primarily as a plasticizer in finished flexible PVC products. As the conditions of use in Appendix B (Production and Use) involve the end use products into which DIDP is incorporated, none include storage of DIDP next to significant sources of drinking water or otherwise. Any significant storage of the chemical is likely restricted to manufacturing and/or storage terminals for DIDP. A detailed evaluation of the fate and behavior of DIDP in environmental media, including water, has been conducted by Environment Canada and Health Canada.[74] A summary of a Level III fugacity modeling with a detailed evaluation of partitioning, transport, degradation and transformation processes for DIDP when released into environmental media, is available.[75] Canada concludes that a high solid phase partition coefficient (log K_{ow} >8-12) and low water solubility (7.1×10^{-7} to 1.2 mg/L at 20 to 25 ºC) for DIDP suggests that DIDP released into water will distribute primarily into sediment (90-94%), with <20% expected to remain in the water column.[76] Due to low vapor pressure (4.97×10^{-7} to 3.77×10^{-2} Pa at 25 ºC), 0% of DIDP released into water is expected to distribute to air.[77] With respect to release into soil, the high solid phase partition coefficient, combined with low water solubility, suggests that the substance sorbs strongly to organic matter in soil, and will have low mobility.[78] The model prediction of low mobility for DIDP means that it is unlikely to leach through soil to groundwater or a surface source of drinking water.

According to the Canadian report, and as summarized above, DIDP is rapidly biodegraded in aerobic aqueous environments, with 68% of the parent substance removed within 1 day and 90-100% removed within 105-28 days.[79] Overall, the physico/chemical properties of DIDP (low water solubility and high partition coefficient/high hydrophobicity) are such that it is rapidly degraded in water and primarily partitions to suspended particulate fraction of surface waters in the event of spillage into water. In the event of spillage into a water source that serves as a source of drinking water, since DIDP tends to sorb to sediment particles, treatment with flocculants and filters would separate out the DIDP prior to distribution in the drinking water system. In the event of soil spillage, the high partition coefficient and low mobility of DIDP suggests that it is primarily adsorbed to soil and unlikely to migrate to ground water. Therefore, should there be a spill of DIDP into water or soil, the potential for significant contamination of sources of drinking water is very low.

[73] See note 51 and associated text.
[74] Canada SOS 2015, note 37, Section 7.
[75] Id. Table 7-1.
[76] Id. Section 7.1.
[77] Id.
[78] Id.
[79] Canada SOS 2015, note 37, Section 7.2.1.

In that respect, the manufacturer, through the ACC HPP, is aware of the following:

All manufacturing and storage locations have developed Spill Prevention Control & Countermeasure (SPCC) plans prepared in accordance with requirements and guidelines set forth in 40 CFR 112. The purpose of this SPCC Plan is to establish procedures and methods in accordance with best management practices to prevent and control the discharge of pollutants resulting from a spill event into navigable waters.

DIDP production volume –
DIDP production volumes for 2012-2015 for both DIDP CASRNs, as reported in the Agency's Chemical Data Reporting database, are provided in Appendix B of this request. No significant changes in production volume were observed for the reported years.

Addendum

As noted above, the manufacturer, through the ACC HPP, believes that, to the best of our knowledge, it has provided the Agency with all the existing information that is relevant to whether DIDP, under the conditions of use identified herein, presents an unreasonable risk of injury to health or the environment. As all of the information is publicly available, HERO database or bibliographic citations are provided, rather than actual copies of the information. The manufacturer, through the ACC HPP, commits to provide to the Agency any referenced information upon request.

Certification

I certify, on behalf of the American Chemistry Council High Phthalates Panel, that to the best of my knowledge and belief:

The ACC HPP represents major companies that manufacture, compound, convert, or import DIDP, the chemical substance identified for risk evaluation.

All information provided in the notice is complete and accurate as of the date of the request.

On behalf of the ACC HPP, I have either identified or am submitting all information in my possession and control as ACC HPP manager, and a description of all other data known to or reasonably ascertainable by me as required for this request under this part. I am aware it is unlawful to knowingly submit incomplete, false and/or misleading information in this request and there are significant criminal penalties for such unlawful conduct, including the possibility of fine and imprisonment.

Sincerely,

Eileen Conneely

Eileen Conneely
on behalf of the American Chemistry Council
High Phthalates Panel

Certification

I certify that to the best of my knowledge and belief:

ExxonMobil Chemical Company manufactures the chemical substance identified for risk evaluation.

All information provided in the notice is complete and accurate as of the date of the request.

I have either identified or am submitting all information in my possession, control, and a description of all other data known to or reasonably ascertainable by me as required for this request under this part. I am aware it is unlawful to knowingly submit incomplete, false and/or misleading information in this request and there are significant criminal penalties for such unlawful conduct, including the possibility of fine and imprisonment.

Sincerely,

M. David Adenuga

M. David Adenuga
on behalf of ExxonMobil Chemical Company

APPENDIX A – SUBSTANCE IDENTITY INFORMATION
DIISODECYL PHTHALATE (DIDP)

Name and substance identifiers

The substance “di-isodecyl phthalate” is described by two CAS numbers based on the composition of the alkyl side chains.

Table 1: Substance Identity

CAS Number	Systematic Name	EPA Registry Name	Molecular formula	Molecular weight range (g/mol)
26761-40-0*	1,2-benzenedicarboxylic acid, 1,2-diisodecyl ester	Diisodecyl phthalate	$C_{28}H_{46}O_4$	446.67
68515-49-1**	1,2-Benzenedicarboxylic acid, di-C_{9-11}-branched alkyl esters, C_{10}-rich	C_{10}-Rich di-C_{9-11}-branched alkyl phthalates	$C_{28}H_{46}O_4$***	447

* EPA Substance Registry Service
** EPA Substance Registry Service
*** EU REACH Chemical Safety report – DIDP (CASRN 68515-49-1)

Structure[1]

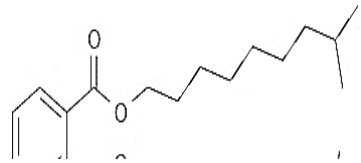

Figure 1: CAS Number – 26761-40-0

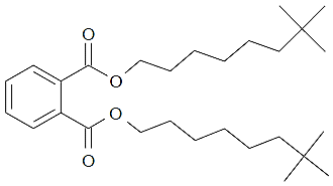

Figure 2: CAS Number – 26761-40-0

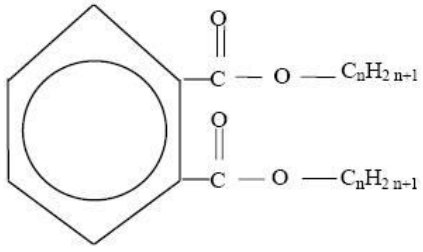

Figure 3: CAS Number – 68515-49-1 (Source: EU REACH Chemical Safety Report)

Table 2: Other Names Used (European Chemicals Agency [ECHA] REACH information)

CAS Number	Regulatory Process Names	Trade Names	IUPAC Names

[1] European Chemicals Bureau. 2003. European Union Risk Assessment Report on 1,2- benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich and di-“isodecyl” phthalate (DIDP). https://echa.europa.eu/documents/10162/190cf4c4-b597-4534-9b71-f79fce55050b [hereafter “ECB 2003”].

EINECS Number			
26761-40-0 247-977-1*	○ Di-''isodecyl'' phthalate ○ di-''isodecyl'' phthalate ○ Di-“isodecyl” phthalate (DIDP)	○ DIDP	○ 1,2-Benzenedi-carboxylic acid, diisodecyl ester ○ 1,2-bis(8-methylnonyl) benzene-1,2-dicarboxylate ○ bis(7,7-dimethyloctyl) phthalate ○ di-''isodecyl'' phthalate ○ Diisodecyl phthalate ○ Diisodecyl Phthalate (mixture of branched chain isomers)
68515-49-1 271-091-4**	○ 1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich ○ 1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich	○ JAYFLEX DIDP-E	○ 1,2-Benzenedicarboxylic acid di(C=9-11) branched alkyl esters, (C=10)-rich ○ 1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich ○ bis(8-methylnonyl) phthalate ○ Didodecylphthalate, DIDP

NR – Not registered under EU REACH

*****ECHA substance information – https://echa.europa.eu/substance-information/-/substanceinfo/100.043.601. Note, this substance is not registered under EU REACH.

******ECHA substance information – https://echa.europa.eu/substance-information/-/substanceinfo/100.064.609

Table 3: Other Names Used (US NLM TOXNET data)

CAS Number	Synonyms
26761-40-0*	1,2-Benzenedicarboxylic acid, diisodecyl ester; Bis(isodecyl) phthalate; Bis(isodecyl)phthalate; BRN 2171889; CCRIS 6194; Di(i-decyl) phthalate; Didp; DIDP (plasticizer); Diisodecyl phthalate; HSDB 930; Palatinol Z; Phthalic acid, bis(8-methylnonyl) ester; Phthalic acid, diisodecyl ester; Plasticized ddp; PX 120; Sicol 184; UNII-WF93T741QI; Vestinol DZ
68515-49-1**	1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich;

	C10-Rich di-C9-11-branched alkyl phthalates; Diisodecyl phthalate; 1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich; Di(C9-C11) branched alkyl phthalate; Phthalic acid, di-C9-11-branched alkyl esters, C10-rich

*https://chem.nlm.nih.gov/chemidplus/rn/26761-40-0

** https://chem.nlm.nih.gov/chemidplus/rn/68515-49-1

N/A – No number identified.

Considerations for Evaluating both CAS Numbers as a Single Substance[2]

As shown in Table 1, two di-isodecyl phthalate (DIDP) products are identified by two different CAS numbers. Both substances are manufactured from the same feed, through an identical olefin oligomerization process and through similar oxo alcohol manufacturing and phthalate esterification processes. According to the EU risk assessment report for DIDP, both CAS numbers represent complex substances that contain mainly C_{10}-branched isomers (see footnote 1). The structure of DIDP illustrated in figures 1 and 2 represent CAS number 26761-40-0. DIDP identified by CAS number 68515-49-1 refers to a multi-constituent substance comprised of C_9-C_{11} (C_{10}-rich) branched dialkyl phthalate esters, illustrated in figure 3. The C_9-, C_{10}-, and C_{11}-dialkyl groups have methyl branching, which on the average includes 2 methyl branches per molecule, typically found on the 2nd, 3rd and/or 4th carbons of the alkyl chain closest to the aromatic ring. Both CAS numbers contain mainly C_{10} dialkyl phthalate esters, having identical molecular formula $C_{28}H_{46}O_4$ (with a molecular weight of approximately 446.7 Da).[3] DIDP is manufactured by the esterification of phthalic anhydride with C_9-C_{11} (C_{10}-rich) branched alcohols, with a final concentration range comprised of >70% C_{10} isomers and <20% each of C_9 and C_{11} isomers. Both CAS numbers are considered to be fully interchangeable, and have been considered to possess toxicologically equivalent properties and evaluated as a single substance by other regulatory agencies.[4, 5, 6, 7]

[2] See note 1.

[3] Chronic Hazard Advisory Panel (CHAP) on Phthalates. 2010. Toxicity review of DIDP [page 2] - https://www.cpsc.gov/s3fs-public/toxicityDIDP.pdf

[4] Australia NICNAS (2015): Priority Existing Chemical Assessment Report 39 – Diisodecyl phthalate and Di-n-octyl phthalate – https://www.nicnas.gov.au/__data/assets/word_doc/0004/34843/PEC39-Diisodecyl-phthalate-and-Di-n-octyl-phthalate.docx

[5] Environment Canada and Health Canada State of the Science Report. 2015. Phthalates Substance Grouping: Long-chain Phthalate Esters, 1,2-Benzenedicarboxylic acid, diisodecyl ester (diisodecyl phthalate; DIDP) and 1,2-Benzenedicarboxylic acid, diundecyl ester (diundecyl phthalate; DUP). http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=D3FB0F30-1 [hereafter "Canada SOS 2015"].

[6] See note 1.

[7] See note 3.

APPENDIX B – PRODUCTION AND USE
DIISODECYL PHTHALATE (DIDP)

Production volume

According to the 2015 US EPA Chemical Data Reporting (CDR) database[1], between 1 and 260 million pounds of DIDP was imported or manufactured in the United States as follows (note that this volume has remained constant since 2012):

Table 1: US DIDP Production volumes for 2012 to 2015, by CAS Number

Reporting Year		2012	2013	2014	2015
Total Aggregate Production Volume (lbs.)	CASRN 26761-40-0	1 – 10 million	1 – 10 million	1 – 10 million	1 – 10 million
	CASRN 68515-49-1	100 – 250 million	100 – 250 million	100 – 250 million	100 – 250 million

2016 CDR data reported for CASRN 26761-40-0 indicates that it is used for industrial and commercial applications.[2] Listed industrial uses include incorporation into formulation, mixture, or reaction product for making adhesives and sealant chemicals, petroleum lubricating oil and grease manufacturing and as a plasticizer. One commercial use is listed in the CDR report, for use in manufacturing adhesives and sealants. With respect to CASRN 68515-49-1, the 2016 CDR data reports use for industrial, consumer and commercial applications. All listed applications involve incorporation into an article or into formulation, mixture, or reaction product for manufacturing adhesives and sealants, paints and coatings, plastic products and resins (as a plasticizer).

Uses

For the purpose of this document, the term DIDP represents Chemical Abstract Service Registry Numbers (CASRNs) 26761-40-0 and 68515-49-1. However, it should be noted that the CASRN 26761-40-0 is not currently registered under EU REACH and we are not aware of any commercial production of the material. DIDP is used primarily as a plasticizer to impart flexibility to polyvinyl chloride (PVC) in consumer and industrial applications.[3] [4] [5] [6] These PVC products are used in automotive products such as upholstery and interior finishes (e.g. synthetic leather for car interiors), interior PVC skins (dashboards and shift boot covers), window glazing (urethane glass bonding adhesives and PVC window encapsulate), body-side molding, automotive undercoating, molded interior applications, insulation for wire and cable and wire harnesses and synthetic lubricants and engine oils. DIDP-

[1] US EPA Chemical Data Access Tool (CDAT). https://chemview.epa.gov/chemview. Last accessed – December 12, 2018.

[2] CDR defines “industrial use” as use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed. “Commercial use” means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services. “Consumer use” means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use. – Public database 2016 chemical data reporting (Data last updated 12/9/2018). Washington, DC: US Environmental Protection Agency, Office of Pollution Prevention and Toxics.

[3] American Chemistry Council (ACC) (2018). Phthalates: High phthalates uses and applications. https://phthalates.americanchemistry.com/High-Uses-and-Applications.html

[4] IHS Markit. (2018). Chemical Economics Handbook: Plasticizers, pp. 42. 4 May 2018.

[5] European Plasticisers (2018). Plasticisers Information Center: Orthophthalates. https://www.plasticisers.org/plasticisers/orthophthalates/

[6] European Chemicals Agency (ECHA) (2010). Review of New Available Information for di-isodecyl phthalate (DIDP). p. 4. https://echa.europa.eu/documents/10162/13641/didp_echa_review_report_2010_6_en.pdf

plasticized PVC is also used in building and construction, particularly in adhesives and sealants, electrical wire coating, vinyl tiles, resilient flooring, PVC-backed carpeting, pool liners, roofing and wall coverings. Other uses include use flexible tubes, profiles, hoses, and inks.

The most recent assessment of United States (US) consumption of DIDP (Figure 1) indicates that the largest share is used for building wire and power cable jacketing and electrical insulation and appliance cords. Other uses include jacketing for communications, electronics and automotive wire, automotive interiors and undercoats and coated fabrics.

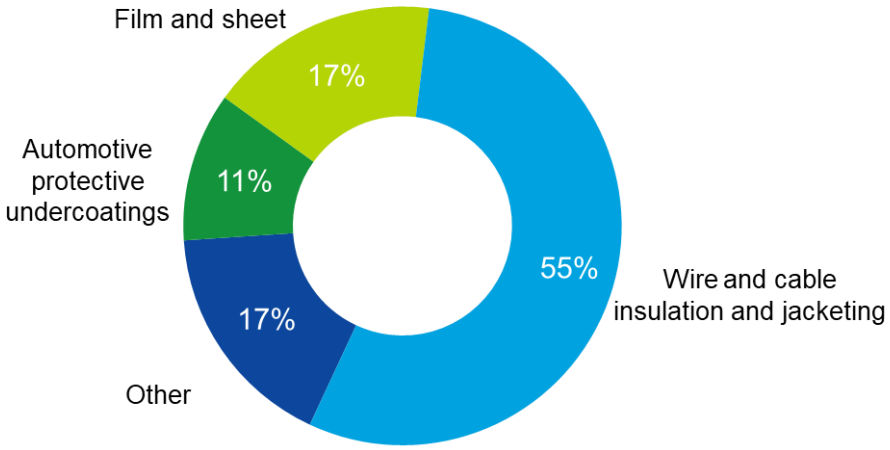

Figure 1: US Consumption of diisodecyl phthalate (percent) – 2017 (Source – IHS Markit. Plasticizers. 4 May 2018). Note, film and sheet applications include use in roofing, wall coverings, pool liners etc.).

Prior regulations restricting use

From 2009 to 2017, there were certain restrictions on DIDP use in children's toys and childcare articles. In 2008, the United States Congress passed the Consumer Product Safety Improvement Act (CPSIA) that placed an interim restriction on the use of DIDP in children's toys that can be placed in a child's mouth and childcare articles at concentrations no greater than 0.1%[7]. On the 27th of October 2017, the US Consumer Product Safety Commission (CPSC) issued a final ruling in the Federal Register (82 FR 49938) that lifted this restriction on the basis that DIDP is not antiandrogenic and a continued prohibition is not necessary to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety.[8]

Intended uses requested for evaluation

- DIDP Manufacturing
- DIDP use as a general purpose plasticizer for PVC used in the following applications;
  - Building and construction – electrical wire coating, vinyl tiles, resilient flooring, PVC-backed carpeting, wall coverings, roofing etc.
  - Automotive – upholstery and interior finishes (e.g. synthetic leather for car seats, interior PVC skins for dashboards and shift boot covers), window glazing, body-side molding,

[7] Consumer Product Safety Act of 2008 – https://www.cpsc.gov/s3fs-public/pdfs/blk_pdf_cpsia.pdf

[8] US Consumer Product Safety Commission (CPSC) (2017). Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates. https://www.gpo.gov/fdsys/pkg/FR-2017-10-27/pdf/2017-23267.pdf

automotive undercoating, molded interior applications, insulation for wire and cable and wire harnesses.
    - Other consumer applications – flexible tubes, hoses and profiles etc.
    - Non-PVC applications – inks, adhesives, sealants and paints, synthetic lubricants and engine oils.
- Use in PVC for children's toys and childcare articles