ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 372

[EPA–HQ–TRI–2022–0262; FRL–2425.1–03–OCSPP]

RIN 2025–AA17

Addition of Diisononyl Phthalate Category; Community Right-to-Know Toxic Chemical Release Reporting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is adding a diisononyl phthalate (DINP) category to the list of toxic chemicals subject to the reporting requirements under the Emergency Planning and Community Right-to-Know Act (EPCRA) and the Pollution Prevention Act (PPA). In this action, EPA is adding the DINP category to the toxic chemical list as a category defined to include branched alkyl di-esters of 1,2 benzenedicarboxylic acid in which alkyl ester moieties contain a total of nine carbons. The DINP category meets the EPCRA chronic human health effects toxicity criterion because the members of the category can reasonably be anticipated to cause serious or irreversible reproductive dysfunctions as well as other serious or irreversible chronic health effects in humans, specifically, developmental, kidney, and liver toxicity.

DATES: The final rule is effective on September 12, 2023.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–TRI–2022–0262, is available at *https://www.regulations.gov.* Additional instructions on visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Rachel Dean, Data Gathering and Analysis Division (7406M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–1303; email: *dean.rachel@epa.gov.*

For general information contact: The Emergency Planning and Community Right-to-Know Hotline; telephone numbers: toll free at (800) 424–9346 (select menu option 3) or (703) 348–5070 in the Washington, DC Area and International; or go to *https://www.epa.gov/home/epa-hotlines.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you own or operate a facility that manufactures, processes, or otherwise uses any chemicals in the diisononyl phthalate (DINP) category. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Facilities subject to reporting under EPCRA section 313 include:

- Facilities included in the following NAICS manufacturing codes (corresponding to Standard Industrial Classification (SIC) codes 20 through 39): 311*, 312*, 313*, 314*, 315*, 316, 321, 322, 323*, 324, 325*, 326*, 327*, 331, 332, 333, 334*, 335*, 336, 337*, 339*, 111998*, 113310, 211130*, 212323*, 212390*, 488390*, 512230*, 512250*, 5131*, 516210*, 519290*, 541713*, 541715* or 811490*. *Exceptions and/or limitations exist for these NAICS codes.
- Facilities included in the following NAICS codes (corresponding to SIC codes other than SIC codes 20 through 39): 211130* (corresponds to SIC code 1321, Natural Gas Liquids, and SIC 2819, Industrial Inorganic Chemicals, Not Elsewhere Classified); or 212114, 212115, 212220, 212230, 212290*; or 2211*, 221210*, 221330 (limited to facilities that combust coal and/or oil for the purpose of generating power for distribution in commerce) (corresponds to SIC codes 4911, 4931, and 4939, Electric Utilities); or 424690, 424710 (corresponds to SIC code 5171, Petroleum Bulk Terminals and Plants); 425120 (limited to facilities previously classified in SIC code 5169, Chemicals and Allied Products, Not Elsewhere Classified); or 562112 (limited to facilities primarily engaged in solvent recovery services on a contract or fee basis (previously classified under SIC code 7389, Business Services, NEC)); or 562211*, 562212*, 562213*, 562219*, 562920 (limited to facilities regulated under the Resource Conservation and Recovery Act, subtitle C, 42 U.S.C. 6921 *et seq.*) (corresponds to SIC code 4953, Refuse Systems). *Exceptions and/or limitations exist for these NAICS codes.
- Federal facilities.
- Facilities that the EPA Administrator has specifically required to report to TRI pursuant to a determination under EPCRA section 313(b)(2).

A more detailed description of the types of facilities covered by the NAICS codes subject to reporting under EPCRA section 313 can be found at: *https://www.epa.gov/toxics-release-inventory-tri-program/tri-covered-industry-sectors.* To determine whether your facility would be affected by this action, you should carefully examine the applicability criteria in 40 CFR part 372, subpart B. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

This action is issued under EPCRA sections 313(d), 313(e)(1) and 328, 42 U.S.C. 11023(d), 11023(e)(1) and 11048. EPCRA is also referred to as Title III of the Superfund Amendments and Reauthorization Act of 1986.

EPCRA section 313, 42 U.S.C. 11023, requires owners/operators of certain facilities that manufacture, process, or otherwise use listed toxic chemicals in amounts above reporting threshold levels to report their facilities' environmental releases and other waste management information on such chemicals annually. These facility owners/operators must also report pollution prevention and recycling data for such chemicals, pursuant to PPA section 6607, 42 U.S.C. 13106.

Under EPCRA section 313(c), Congress established an initial list of toxic chemicals subject to EPCRA toxic chemical reporting requirements that was comprised of 308 individually listed chemicals and 20 chemical categories.

EPCRA section 313(d) authorizes EPA to add or delete chemicals from the list and sets criteria for these actions. EPCRA section 313(d)(2) states that EPA may add a chemical to the list if the Administrator determines, in his judgment, that there is sufficient evidence to establish that any of the listing criteria in EPCRA section 313(d)(2) are met. Therefore, to add a chemical, EPA must determine that at least one criterion is met, but need not determine whether any other criterion is met. Conversely, to delete a chemical from the list, EPCRA section 313(d)(3) dictates that EPA must determine that there is not sufficient evidence to establish any of the criteria described in EPCRA section 313(d)(2). The listing criteria in EPCRA section 313(d)(2)(A)–(C) are as follows:

- The chemical is known to cause or can reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of

continuous, or frequently recurring, releases.

- The chemical is known to cause or can reasonably be anticipated to cause in humans: cancer or teratogenic effects, or serious or irreversible reproductive dysfunctions, neurological disorders, heritable genetic mutations, or other chronic health effects.
- The chemical is known to cause or can be reasonably anticipated to cause, because of its toxicity, its toxicity and persistence in the environment, or its toxicity and tendency to bioaccumulate in the environment, a significant adverse effect on the environment of sufficient seriousness, in the judgment of the Administrator, to warrant reporting under this section.

EPA often refers to the EPCRA section 313(d)(2)(A) criterion as the ''acute human health effects criterion;'' the EPCRA section 313(d)(2)(B) criterion as the ''chronic human health effects criterion;'' and the EPCRA section 313(d)(2)(C) criterion as the ''environmental effects criterion.''

Under EPCRA section 313(e)(1), any person may petition EPA to add chemicals to or delete chemicals from the list. EPA issued a statement of policy in the **Federal Register** of February 4, 1987 (52 FR 3479) providing guidance regarding the recommended content of and format for petitions. On May 23, 1991 (56 FR 23703), EPA issued guidance regarding the recommended content of petitions to delete individual members of the metal compounds categories reportable under EPCRA section 313. EPA published in the **Federal Register** of November 30, 1994 (59 FR 61432) (FRL–4922–2) a statement clarifying its interpretation of the EPCRA section 313(d)(2) and (d)(3) criteria for modifying the EPCRA section 313 list of toxic chemicals.

C. What action is the Agency taking?

In response to a petition, EPA is adding DINP as a category to the list of toxic chemicals subject to the reporting requirements under section 313 of EPCRA. As discussed in more detail later in this document, EPA is concluding that the members of the DINP category meet the EPCRA section 313(d)(2)(B) criterion for listing.

Additionally, as indicated in the supplemental proposal and as is now being finalized via this rulemaking, EPA is listing DINP as a chemical category that includes all branched alkyl di-esters of 1,2 benzenedicarboxylic acid in which alkyl ester moieties contain a total of nine carbons. This category includes but is not limited to the chemicals covered by the CAS numbers and names identified by EPA at the time of this rulemaking. In the supplemental proposal, EPA identified the following chemicals: Diisononyl phthalate (CAS Number 28553–12–0), Branched dinonyl phthalate (CAS Number 71549–78–5), Branched dinonyl phthalate (CAS Number 14103–61–8), and Di(C8–10, C9 rich) branched alkyl phthalate (CAS Number 68515–48–0). EPA has since identified that Bis(7-methyloctyl) phthalate (CAS Number 20548–62–3) and Bis(3-ethylheptan-2-yl) benzene-1,2-dicarboxylate (CAS Number 111983–10–9) also meet the definition of DINP being used for this listing and thus are also being included in the listing at 40 CFR 372.65(c) to assist facilities in identifying members of the DINP chemical category.

Further, in response to public comments and further review of available information, EPA has updated the 2022 Technical Review of DINP (Ref. 1) provided with the supplemental notice of proposed rulemaking (87 FR 48128, August 8, 2022). The updated 2023 Technical Review of DINP (Ref. 2) is in the docket for this rule. For the reasons more fully explained in the updated 2023 Technical Review of DINP (Ref. 2), EPA is now listing the DINP category based on our conclusion that it is reasonably anticipated to cause serious or irreversible reproductive dysfunctions and other serious or irreversible chronic health effects in humans, including developmental, kidney, and liver toxicity. EPA has determined that the DINP can reasonably be anticipated to cause serious or irreversible chronic human health effects at moderately low to low doses and thus data show that DINP has moderately high to high human health toxicity.

As indicated previously, EPCRA section 313(d)(2) states that EPA may add a chemical to the list if the Administrator determines, in his judgment, that there is sufficient evidence to establish that any of the listing criteria in EPCRA section 313(d)(2) are met. Therefore, to add a chemical, EPA must determine that at least one criterion is met, but need not determine whether any other criterion is met. Accordingly, EPA is basing this addition on its conclusion that DINP is reasonably anticipated to cause serious or irreversible reproductive dysfunctions and other serious or irreversible chronic health effects in humans, including developmental, kidney, and liver toxicity.

Given multiple endpoint findings of serious or irreversible chronic noncancer health effects, it was not necessary for the Agency to rely on hazards related to cancer concerns as a basis for a TRI listing of a DINP chemical category. The Agency is not, with this action, taking a position as to whether or not DINP presents cancer concerns that would support a TRI listing of the chemical category. In response to comments received on the supplemental proposal, EPA has updated it hazard analysis to include additional literature on cancer-related research on DINP. However, EPA is forgoing further analysis of this particular topic as it relates to the EPCRA 313 listing criteria. Given forthcoming additional hazard analyses being conducted by the EPA (*e.g.,* pursuant to section 6 of the Toxic Substances Control Act) and ensuring that the Agency has adequate resources to conduct its other TRI activities, EPA has determined it appropriate to reduce the scope of analysis for purposes of this listing.

D. Why is the Agency taking this action?

EPA is taking this action in response to a petition submitted under EPCRA section 313(e)(1) (Ref.3). In this case, EPA is granting the petition to list DINP. Additional details about the petition are included in the 2000 proposed rule and the 2022 supplemental proposed rule (87 FR 48128, August 8, 2022).

E. What are the estimated incremental impacts of this action?

EPA prepared an economic analysis for this action entitled, ''Economic Analysis for the Addition of Diisononyl Phthalate Category; Community Right-to-Know Toxic Chemical Release Reporting'' (Ref. 4), which presents an analysis of the costs of the addition of the DINP category. EPA estimates that this action would result in an additional 198 to 396 reports being filed annually. EPA estimates that the costs of this action will be approximately $968,546 to $1,935,041 in the first year of reporting and approximately $461,212 to $921,448 in the subsequent years. In addition, EPA has determined that of the 181 to 365 small businesses affected by this action, none are estimated to incur annualized cost impacts of more than 1%. Thus, this action is not expected to have a significant adverse economic impact on a substantial number of small entities.

II. Summary of Proposed Rule

On September 5, 2000 (65 FR 53681; FRL–6722–3), in response to a petition filed under the EPCRA, EPA issued a proposed rule to add a DINP category to the list of toxic chemicals subject to the reporting requirements under EPCRA section 313 and PPA section 6607. EPA proposed to add this chemical category

to the EPCRA section 313 toxic chemical list based on the Agency's preliminary conclusion that this category met the EPCRA chronic human health effects toxicity criterion. In response to comments on the proposal, EPA revised its hazard assessment for DINP and issued a notice of data availability (NODA) requesting comments on the revised hazard assessment (70 FR 34437, June 14, 2005 (FRL–7532–4)). In the NODA, EPA proposed to list DINP based on serious or irreversible chronic health effects including liver, kidney, and developmental toxicity but reserved judgment on whether cancer was an endpoint of concern for DINP. On August 8, 2022 (87 FR 48128; FRL–2425.1–04–OCSPP), EPA published a supplemental proposal, providing updated supporting materials for the proposal (*e.g.,* hazard assessment for DINP (*i.e.,* 2022 Technical Review of DINP) (Ref. 1)).

III. Summary of Comments Received and EPA Responses

EPA received 15 comments on the supplemental proposed rule. Two comments came from trade associations: the American Chemistry Council (ACC) and the National Association of Chemical Distributors (NACD). Two comments came from environmental/public interest groups: Earthjustice (including Alaska Community Action on Toxics, Breast Cancer Prevention Partners, Center for Environmental Health, Center for Food Safety, Defend Our Health, Learning Disabilities Association of America, Sierra Club) and Environmental Defense Fund (EDF). One comment also came from an individual company: UPC Technology Corporation (UPC). Nine of the on-topic comments came from both private citizens and an anonymous commenter. There was also one off-topic anonymous comment. This unit provides summaries of the most significant comments and EPA's responses. A complete set of comments and EPA's detailed responses can be found in the Response to Comments (RTC) document that is available in the docket for this rulemaking (Ref. 5).

A. Comments Supporting EPA's Proposed Listing of DINP

Earthjustice, EDF, and all private citizens and the anonymous commenter expressed support for EPA's proposed addition of DINP to the TRI list. Additionally, Earthjustice urged EPA to work quickly to publish the rule as EPCRA does not require multiple toxicity endpoints for listing.

B. Comments on the Listing Standard

Comment: UPC disagreed with EPA's proposed listing. UPC claimed that adding DINP to the TRI chemicals list will cause companies to shift away from DINP, instead dealing with chemicals which have not been as well reviewed as DINP, and might be more toxic than DINP, and that listing DINP would create a barrier to international trade. They cited European Chemicals Agency 's (ECHA's) 2018 decision not to label DINP as a hazardous chemical as justification for why DINP would not satisfy EPCRA's requirements for listing.

EPA response: EPA respectfully disagrees with the commenter that DINP does not meet the TRI chemical listing criteria specified in EPCRA section 313(d)(2). Additionally, the fact that a chemical is not on a given organization's ''hazardous chemical'' list does not mean that the chemical fails to meet the EPCRA section 313(d)(2) listing criteria. The Agency's full rationale for listing the DINP category is detailed in the 2023 Technical Review of DINP (Ref. 2) and Response to Comments (Ref. 5).

Comment: ACC also disagreed with EPA's proposed listing of DINP. They asserted that EPA did not apply the correct legal standard because the Agency did not list DINP based on ''cancer, birth defects, or serious or irreversible reproductive dysfunctions, neurological disorders, or heritable genetic mutations.'' ACC also asserts that EPA improperly put the onus on the commenters to prove that DINP *is not* adverse to humans, rather than EPA showing that it *is* adverse to humans; and that EPA is assuming or ''suspects'' that DINP is a hazard, rather than having sufficient information that it does, in fact, meet the listing criteria.

EPA response: Section 313(d)(2) of EPCRA sets out the legal standard for adding new chemicals to the TRI list, and EPA applied this standard when deciding to add DINP. Commenters incorrectly describe this standard, which allows for listing based on sufficient evidence to establish any one of several criteria, including that the chemical is known to cause or can reasonably be anticipated to cause in humans ''cancer or teratogenic effects, or serious or irreversible reproductive dysfunctions, neurological disorders, heritable genetic mutations, or other chronic health effects''. The Agency reasonably relied on hazards identified from animal studies which could plausibly be extrapolated to humans based on a weight of evidence (WoE) evaluation of health hazards posed by DINP in determining that DINP can reasonably be anticipated to cause one or more serious or irreversible chronic health effects in humans.

As documented in the 2023 Technical Review of DINP (Ref. 2), the evidence available to EPA is sufficient to establish that DINP can reasonably be anticipated to cause in humans serious or irreversible reproductive dysfunctions as well as other serious or irreversible chronic health effects in humans, specifically, developmental, kidney, and liver toxicity. This evidence includes evidence of developmental toxicity, such as: reduced pup weights, skeletal variations, and dilated renal pelvises; and also evidence of reproductive dysfunctions such that ''gestational exposure to DINP has been shown to induce effects consistent with the spectrum of effects such as reduced fetal testicular testosterone, decreased AGD, increased male pup nipple retention, altered reproductive organ weight, testicular pathology, and a low incidence of reproductive tract malformation in some studies (such effects are sometimes generally referred to as 'phthalate syndrome').'' (Ref. 2). This evidence also includes evidence of other serious or irreversible chronic health effects; specifically, non-cancer liver and kidney toxicity.

Comment: ACC points to studies in non-human primates to argue that primates are much less sensitive to DINP than are rodents. ACC argues that the timeline of the primate studies was similar to that of rodent studies, so they should be considered.

EPA response: The commenter's argument does not consider the explanation that the short study duration (especially relative to the lifespan of the test species) accounts for the lack of treatment-related effects, and instead attributes the differential toxicity to differences in species sensitivity. ACC was referring to a 14-day study in macaques (Ref. 6) and a 90-day study in marmosets (Ref. 7). The marmoset study did show decreases in body weights and body weight gains in both sexes. However, the non-human primate studies were not further evaluated due to being considered insufficient in study design and duration to evaluate DINP for carcinogenicity as well as for potential reproductive and developmental effects.

C. Comments Related to Hazard: Cancer

Comment: ACC commented on EPA's proposal to list DINP based on cancer as an endpoint, and stated that the EPA could not list DINP on the TRI simply because it was on the California Prop 65 list. ACC further commented that certain animal tumors discussed in the

2022 Technical Review of DINP (Ref. 1) as evidence for listing DINP due to carcinogenicity (including alpha-2u-globulin-mediated kidney cancers in male rats, mononuclear cell leukemia (MNCL), and PPARα-mediated liver tumors) are not indicative of human hazard. The comment claimed that there is significant evidence to show that all three DINP-induced rodent tumors are specific to rodents and not relevant to human cancer.

EPA response: EPA's decision to list DINP on the TRI is based on EPA's analysis of the available data, and not, as the commenter appears to suggest, on a decision made by another regulatory body. Moreover, as explained in greater detail in the Response to Comments (Ref. 5), EPA has decided not to rely on a cancer endpoint for this action to add a DINP chemical category to the TRI chemical list.

As explained in greater detail in the 2023 Technical Review of DINP (Ref. 2), in this action EPA is adding DINP to the TRI chemical list based on toxicity data demonstrating that these chemicals can be reasonably anticipated to cause serious or irreversible reproductive dysfunctions and other serious or irreversible chronic human health effects, including developmental, liver, and kidney effects. EPA revised the 2022 Technical Review of DINP (Ref. 1) regarding the evaluation of MNCL and tumors in the liver and kidney, in addition to including a new section on ''Tumors Observed in Other Organs'' under the Conclusions on Carcinogenicity Section of the 2023 Technical Review of DINP (Ref. 2). This section provides a brief discussion of the data for pancreatic islet cell carcinomas, testicular interstitial (Leydig) cell carcinomas and uterine adenocarcinomas. EPA did not, however, base its decision to list DINP on these data.

D. Comments Related to Hazard: Reproductive Dysfunctions and Developmental Toxicity

Comment: ACC asserted that, ''in addition to animal evidence, human evidence, where available, would be crucial to the EPA's evaluation, including the developmental endpoint for DINP. However, neither the EPA's Supplemental Notice nor the Revised Technical Review for DINP includes any of the growing epidemiological evidence''.

EPA response: The Agency acknowledges that the evidence of developmental hazard presented to support the listing of DINP on the TRI focused on the evidence in developmental toxicity and reproduction studies in laboratory animals. The Agency determined that this evidence is extensive and unambiguous in interpretation. EPA notes that the epidemiology data on developmental hazard, although pertinent, do not negate the importance of the animal data, especially given the extent of evidence provided by animal data. Further, inconsistent results make it difficult to draw a definitive conclusion on hazard concerns from epidemiological data on DINP. Therefore, EPA determined that the epidemiological studies are not required to inform the Agency's decision to list DINP on the TRI. EPA's discussion of the epidemiological data referenced by ACC in its comment is addressed further in the Response to Comment document (Ref. 5). Furthermore, the Agency does not consider the lack of presentation of epidemiological evidence to detract from the strength of evidence of both developmental and reproductive hazard posed by DINP represented in the animal studies.

Comment: Reduced pup weights were reversible or transient, inconsistently observed, not statistically significant, and did not cause any adverse effects in older rats, so they should not be considered ''serious or irreversible'' effects.

EPA response: EPA disagrees with the characterization of the body weight decreases as transient, which is typically interpreted in evaluation of toxicology studies as the effect being temporary in the presence of continued exposure. In the two major studies cited (both discussed in Waterman *et al.,* 2000 (Ref. 8)), statistical significance was achieved at multiple timepoints. Particularly in the two-generation study (Ref. 8), the decreased F1 offspring body weights became *more* pronounced in statistical significance and in magnitude difference from controls, and occurred at lower doses as the post-natal period proceeded. The effects of DINP on body weight occurred in both sexes and across generations and generally increased in significance and magnitude with time; and importantly, occurred at lower doses in offspring compared to parents.

Regarding ACC's comment that reduced pup weight results are inconsistent, EPA acknowledges that in some studies with shorter exposure durations, longer term effects on growth may not be apparent. In the study by Clewell *et al.* (Ref. 9), pregnant rats were administered DINP in the diet from gestational day (GD) 12 through postnatal day (PND) 14. However, even with this shorter exposure duration, dams exhibited reduced body weight, body weight gain, and food consumption during gestation and lactation at 750 mg/kg/day. Offspring body weights of males were decreased at PND 14 at the high dose on PND 2 (↓12%) and dose-dependently at both the mid- and high-dose on PND 14 (↓10–27%) at termination of dosing. The fact that the male offspring body weights were not significantly decreased by PND 49–50 (↓4%; NS) with no exposure to DINP since PND 14 (~35 days) does not equate to transient decreases (those that occur with continued exposure).

Furthermore, an additional study showed that decreased body weights persisted after the treated period ended. Masutomi *et al.* (Ref. 10) evaluated developmental effects in the offspring of female Sprague-Dawley rats exposed to DINP in the diet at concentrations of 0, 400, 4,000, or 20,000 ppm from GD 15 to PND 10. Even though treatment ceased on PND 10, prepubertal body weights of offspring were still significantly decreased on PND 27. Importantly, the decreased body weight in male offspring occurred at a lower dose than affected maternal body weights, indicating heightened relative sensitivity of male offspring exposed in utero compared to parents. Finally, it is important to note that these decreases were substantial, with decreases of 18% in mid-dose males and 39–47% in high dose males and females, and were highly significant ($p<0.01$). This supporting evidence shows that adverse effects are seen in prepubertal rats born to exposed pregnant females; it can be reasonably expected that results would persist into adulthood.

In short, the decreases in body weight and weight gain in the animals in the reproduction and developmental toxicity studies on DINP are ''serious,'' in part, because they increase in magnitude and significance with time exposed and across generations and occur at lower doses in offspring than in parents.

Comment: ACC questioned EPA's use of skeletal effects and dilated renal pelvises as evidence of DINP toxicity to developmental health. ACC stated that the conclusions of the ECHA and Australia's National Industrial Chemicals Notification and Assessment Scheme (NICNAS) are that supernumerary ribs are common anomalies in rodents which can only be ''indicative of slight developmental effects.'' ACC asserted that animals in multi-generation studies thrived and there was no evidence of adverse effects related to these variations. ACC also asserted that the agency itself is unsure of the biological relevance of increased

rib variations in rats. For the renal pelvises effects, ACC stated that the dilated renal pelvises reported in Waterman *et al.* (2000) (Ref. 8) and Hellwig *et al.* (1997) (Ref. 11) are transient, of doubtful biological and statistical significance, and occur only at maternally toxic doses.

EPA response: Supernumerary ribs are larger (longer) structures with distal cartilage present and are likely to be permanent, ultimately remaining as distinct ribs; whereas ossification sites are smaller (shorter) structures without distal cartilage and are likely to be transient.

The developmental variations seen in Waterman *et al.* (1999) (Ref. 12) include significantly increased incidences of rudimentary lumbar ribs at 500 and 1,000 mg/kg-day, compared to controls. Additionally, incidences of supernumerary cervical ribs were significantly increased at 1000 mg/kg-day, compared to controls. The authors noted that supernumerary lumbar ribs ''have been associated with nonspecific maternal toxicity''; however, this does not preclude its relevance, and it is important to note that significantly increased incidences of rudimentary lumbar ribs were noted at a dose lower than that at which maternal toxicity was observed. Furthermore, no corroborating findings of delayed fetal ossification, which would suggest that fetal effects were secondary to maternal effects, were reported at the high dose in this study. ACC has taken the Agency's statement from the 2022 Technical Review of DINP (Ref. 1) out of context. The full statement was: ''Therefore, although the biological significance of a statistically significant increase in rib variations is uncertain, the Agency believes that the dose-related response observed in the Waterman *et al.* (1999) (Ref. 12) study may represent growth alterations that are indicative of DINP's potential to disrupt normal developmental patterns and produce a developmental hazard.'' The Agency reiterates its conclusion that DINP can reasonably be anticipated to be developmentally toxic to humans.

EPA acknowledges that the dilated renal pelvises observed in Hellwig *et al.* (1997) (Ref. 11) were consistently increased over controls only at the high dose of 1000 mg/kg-day. However, the fact that this fetal finding in this study was noted at a dose that was toxic to the maternal animals does not preclude its toxicological relevance to offspring. And it is important to note that, for DINP–3, increased dilated renal pelvises observed at 1000 mg/kg-day were accompanied in some instances by renal malformations (*e.g.,* hydroureter, agenesis or absence of kidney). Furthermore, in the developmental toxicity study in rats conducted by Waterman *et al.* (1999) (Ref. 12), fetal and litter incidences of dilated renal pelvis were statistically significant and dose-dependently increased in *all* treated groups, whereas maternal toxicity, as evidenced by decreased body weights and weight gains during treatment, was affected only at the high dose of 1000 mg/kg-day. EPA disagrees with the characterization that dilated renal pelvis is a ''normal developmental phenomenon'' (as stated by NICNAS), but acknowledges that the toxicological relevance is dependent upon the incidence and severity. Nevertheless, the commenters mischaracterized NICNAS's conclusion on these variations. The full statement from NICNAS reads: ''These variations are relatively common in rodents; *however,* the induced frequencies (78% vs 25% control for rudimentary lumbar ribs, and 26% vs 0% control for dilated renal pelvises) were outside historical control ranges and thus interpreted as indicative of slight developmental effects.'' (Ref. 13, emphases added). Therefore, NICNAS also interpreted the renal pelvis and additional lumbar ribs to be indicative of adverse effects of DINP.

To summarize, dilated renal pelvises incidences in these studies are treatment-related, and it remains to be seen whether the findings are reversible/transient because that depends on the severity of the effects. However, it is the Agency's determination that dilated renal pelvises, in addition to renal malformations, even at doses with observed maternal toxicity, are biologically significant, and contribute to the WoE for DINP as a developmental toxicant.

Comment: ACC asserted that DINP does not cause a serious or irreversible effect on anogenital distance (AGD) or nipple retention in animals, citing a lack of statistical significance in Clewell *et al.* (2013) (Ref. 14) for AGD and Gray *et al.* (2000) (Ref. 15) for nipple retention. ACC stated that these effects, if they occur, are only transient and do not persist into adulthood. Finally, ACC asserts that DINP is not associated with male reproductive malformations in humans.

EPA response: EPA acknowledges that there is some inconsistency in reporting of significant effects on AGD across available studies of DINP and that permanent, statistically significant reductions in AGD have not been reported in adult offspring following gestational exposure to DINP. However, reduced AGD in males is only one of many effects that make up phthalate syndrome (or androgen insufficiency syndrome). As described in EPA's 2023 Technical Review of DINP (Ref. 2), gestational exposure to DINP has been shown to induce effects consistent with the spectrum of effects that comprise phthalate syndrome (*e.g.,* reduced fetal testicular testosterone, decreased AGD, increased male pup nipple retention, altered reproductive organ weight, testicular pathology, and a low incidence of reproductive tract malformation in some studies). Therefore, EPA still considers a decrease in AGD to be a potential adverse and serious outcome of DINP exposure and a reflection of the suite of effects that comprise phthalate syndrome.

EPA also acknowledges that there is some inconsistency in reporting of nipple retention across available studies of DINP. In Gray *et al.* (2000) (Ref. 15), the finding of permanent nipples in DINP-treated rats was accompanied by several abnormalities in the testes, including testicular atrophy, epididymal agenesis with hypospermatogenesis, and scrotal fluid-filled testis devoid of spermatids. This syndrome may result from inhibition of fetal testis hormone production during sexual differentiation, a process that is critical in all mammals including humans. Furthermore, the finding of nipple retention was not exclusively noted in Gray *et al.* (2000) (Ref. 15). For example, Boberg *et al.* (2011) (Ref. 16) demonstrated a dose-dependent and statistically significant increase in the number of retained nipples in DINP-exposed (GD 7 to PND 19) male pups on PND 13 at 750 mg/kg-day (3.14) and 900 mg/kg-day (3.17) compared to controls (1.98), which ACC failed to mention when citing the findings in the study at PND 90.

In addition to the male reproductive malformations noted in the two studies by Gray *et al.* (2000 (Ref. 15), 2023 (Ref. 17)), EPA discussed the findings of ten additional studies in its 2023 Technical Review of DINP (Ref. 2) which support the WoE for serious adverse impacts on the male reproductive tract. Such effects include: decreased body weight at the onset of puberty; decreased weights of the testes, levator ani plus bulbocavernosus muscles (LABC), and seminal vesicles; decreased testosterone, percent motile sperm, and AGD; increased incidences of multinucleated gonocytes (MNGs) in testes, large Leydig cell aggregates, degeneration of stage XIV meiotic spermatocytes, vacuolar degeneration of Sertoli cells, and scattered cell debris in the epididymal ducts; and effects on male copulatory

behavior (reduced number of mounts, intromissions, and ejaculations).

Phthalate syndrome may result from inhibition of fetal testis hormone production during sexual differentiation, a process that is critical in all mammals including humans. EPA concludes that humans can reasonably be anticipated to be affected if exposed to sufficient concentrations of DINP or its metabolites at critical stages of reproductive development.

E. Comments Related to Hazard: Liver Toxicity

Comment: ACC commented on EPA's identification of spongiosis hepatis as a treatment-related lesion in rats exposed to DINP, and the Agency's position that the occurrence is relevant to human health; more specifically, ACC asserted that the mere fact that a lesion is treatment-related in a rat does not mean it will occur in humans. ACC further stated that the effect did not occur in mice exposed to similar levels of DINP, and that it is not a serious or irreversible effect, even in rats, because EPA did not state whether spongiosis hepatis is linked to any other adverse pathological or toxicological process detrimental to the health of affected rats. ACC added that liver enzyme changes in studies appeared to be sporadic and not indicative of serious liver damage. ACC concluded that spongiosis hepatis is not relevant to human health.

Response: EPA disagrees with ACC's conclusion and maintains that the finding of spongiosis hepatis in rats has human relevance as one of multiple indicators of adverse outcomes to the liver post-DINP exposure. While the human relevance of spongiosis hepatis, in particular, is unclear, that does not preclude its relevance in a WoE evaluation of evidence of hepatotoxicity in the rat, and the Agency does not consider the lack of evidence of a direct human correlate of spongiosis hepatis to detract from the extrapolation of that evidence in animals to relevance to human health. The Agency references Lington *et al.* (1997) (Ref. 18) for the co-occurring findings of other histopathology effects in the liver due to DINP treatment including focal necrosis, hepatopathy associated with leukemia, and hepatocellular enlargement in both sexes, in addition to sinusoid ectasia in males. The Agency also references Moore *et al.* (1998a) (Ref. 19) and Bio/dynamics (1987) (Ref. 20) for co-occurring findings in the liver, including cytoplasmic eosinophilia, diffuse hepatocellular enlargement, and increased pigment in both sexes, and additionally individual cell degeneration/necrosis in the males. Moore *et al.* (1998b) (Ref. 21) also conducted a 2-year study in mice and found similar adverse treatment-related effects on the liver. In all these studies, increases in key indicator enzymes were also observed.

The Agency acknowledges that treatment-related effects on the liver are often along a continuum, with effects early on and at lower doses reflecting an adaptive response (often indicated by increased liver weights and/or hepatocellular hypertrophy) but progressing to an adverse response at prolonged or higher doses, characterized by adverse findings in clinical chemistry and histopathology. While induction of CYP450s as a metabolic activation response of the liver may be an adaptive response, increases in ALT are indicative of liver damage and inherently adverse, and the clinical interpretation of this finding is conserved across species, including humans. For certain enzymes (*e.g.,* ALT), increases, as well as various enzymatic activities when considered with other effects such as histopathology lesions, are adverse effects and support the conclusion that DINP induces serious chronic effects in the liver beyond liver enlargement. Thus, the Agency disagrees with ACC's assertion that the increases in liver weights and enzymes seen in these studies are an adaptive response or are non-serious in the total weight of evidence.

F. Comments Related to Hazard: Kidney Toxicity

Comment: ACC commented that: (a) DINP does not cause and cannot reasonably be anticipated to cause rodent chronic progressive nephropathy (CPN) in human kidneys, as no human analog exists; (b) while EPA may ''speculate,'' per ACC's characterization, that chemicals that cause CPN in rodents may cause other kidney effects in humans, such ''speculation'' is not appropriate for a TRI listing; and (c) even the EPA's ''speculation'' is unlikely to be supported, as there is minimal evidence that DINP is associated with any kidney disease in humans. ACC further points to the lack of adverse effects seen in primate studies as evidence that DINP is not relevant to human health.

EPA response: Although the *mechanism* of DINP-induced kidney toxicity may not be clear, the kidneys are clearly a target of DINP-induced toxicity which can reasonably be anticipated to cause serious or irreversible chronic health effects in humans, as evidenced by increases in absolute and relative kidney weights, clinical chemistry (*e.g.,* increased blood urea nitrogen), urinalysis changes, and findings in gross pathology (*e.g.,* granular pitted/rough kidneys), and histopathology (*e.g.,* reduction in the tubular space and oedema of epithelial cells in the glomeruli, a loss of loop points in the glomerular capillaries, increased granular casts and regenerative/basophilic tubules) in rats and mice. EPA disagrees with ACC's conclusion that the changes in kidney weights in rats are not relevant to human kidney toxicity, and asserts that the lack of an effect in the primate studies ACC mentioned is plausibly related to the shorter duration of dosing relative to the life span of the animal instead of indicating a lack of relevance to humans. (See the ''Generally: EPA has Failed to Apply the Correct Legal Standard in this Case'' section.) Given that increased kidney weight appears as a consistent effect among other kidney injuries following DINP exposure, EPA believes it to be relevant in the WoE supporting DINP kidney toxicity. EPA acknowledges that, in a letter to the U.S. EPA IRIS Program (NIEHS 2019) (Ref. 22), U.S. NTP concluded that the ''morphological spectrum of CPN have no analog in the human kidney and that CPN is distinct entity in the rat (Hard *et al.,* 2009) (Ref. 23).'' However, NTP also acknowledged that ''The etiology of CPN is unknown and represents a complex disease process in rats. Given the fact that there is no definitive pathogenesis for this multifactorial disease process, it cannot be fully ruled out that chemicals which exacerbate CPN in rats may have the potential to exacerbate disease processes in the human kidney.'' Subsequently, the EPA IRIS Program in its toxicological reviews of tert-Butanol (EPA 2021a) (Ref. 24) and ethyl tertiary butyl ether (EPA 2021b) (Ref. 25) (chemicals which cause CPN in male and female rats) concluded that ''a chemical that exacerbates CPN in rats could also exacerbate disease processes in the human kidney'' and that other effects in the kidney were observed that were not confounded by alpha 2u-globulin related processes, and kidney toxicity was selected as the basis of the oral noncancer reference doses that were derived. Similarly, for DINP, available studies demonstrate a spectrum of effects on the kidney. Given the WoE when considering the other effects involving the kidney, and EPA's position, based on the Agency's technical expertise, that chemicals which exacerbate CPN in rodents could also exacerbate disease processes in the human kidney, DINP can reasonably be anticipated to cause serious and/or

irreversible harm to the kidney based on the literature reviewed.

Furthermore, the EPA disagrees with ACC's assertion that the kidney toxicity seen in female mice is irrelevant to human health. Although α-2u-globulin MOA is male rat-specific and has been shown not to be relevant to humans, the MOA for kidney toxicity for female rats and male and female mice remains unclear and so in order to be protective of human health, EPA maintains that CPN is relevant to human health and contributes to the WoE for kidney toxicity for this non-cancer endpoint. A study by Ma *et al.* (Ref. 26) found that oxidative stress may be involved in the hepatic and renal toxicities associated with DINP exposure. In order to be protective of human health, the EPA maintains that oxidative stress-related mechanism are relevant to human health. EPA would like to direct ACC's attention to the ''Conclusions on Chronic Non-cancer Toxicity'' section 2.5.6.2 on ''Kidney Effects'' in the 2023 Technical Review of DINP (Ref. 2) for further details.

G. Comments Related to Exposure

Comment: ACC argued that due to its physico/chemical properties, community exposure to DINP via environmental release is negligible.

EPA response: As EPA has previously stated, including in the supplemental proposal for this rulemaking (87 FR 48128), it is not appropriate to consider exposure for chemicals that are moderately high to highly toxic based on a hazard assessment when determining if a chemical should be added for chronic human health effects pursuant to EPCRA section 313(d)(2)(B) (see 59 FR 61440–61442). EPA concludes that DINP can reasonably be anticipated to cause serious or irreversible chronic human health effects at moderately low to low doses including serious or irreversible reproductive dysfunctions as well as other serious or irreversible chronic health effects in humans, specifically, developmental, kidney, and liver toxicity. The data for DINP demonstrates that DINP has moderately high to high human health toxicity. For listings pursuant to EPCRA section 313(d)(2)(A), EPA must consider whether ''chemical is known to cause or can reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently recurring, releases.'' However, even pursuant to such listings, the Agency need not confirm that communities are actually exposed to the given chemical, but rather that concentration levels of concern are reasonably likely to exist beyond a facility's boundaries as a result of releases. Further, listings based on EPCRA section 313(d)(2)(B) (as well as EPCRA section 313(d)(2)(C)) do not require an exposure assessment, but rather are based on hazard alone.

Therefore, in accordance with EPA's standard policy on the use of exposure assessments (see November 30, 1994 (59 FR 61432, FRL–4922–2), an exposure assessment is neither necessary nor appropriate for determining whether DINP meets the criteria of EPCRA section 313(d)(2)(B).

Additionally, EPA notes that EPCRA indicates that TRI reporting forms are intended to provide information to governments and the public to inform persons about releases of toxic chemicals to the environment, assist in the conduct of research and data gathering, and to aid in the development of regulations and other similar purposes (see EPCRA section 313(h)). Accordingly, even if releases are very small, the data reported is still useful. For example, such reporting might indicate that a toxic chemical being used in the community is not being released at levels of concern, which would be reassuring to residents. Further, how the public or any particular entity may make use of TRI data on a particular chemical need not factor into whether or not that chemical is on the TRI list of chemicals.

IV. Summary of the Final Rule

EPA is finalizing the addition of a DINP category to the EPCRA section 313 list of toxic chemicals. Based on EPA's review of the available toxicity data, EPA has determined that these chemicals can be reasonably anticipated to cause serious or irreversible reproductive dysfunctions as well as serious or irreversible chronic human health effects in humans, including developmental, kidney, and liver toxicity. Therefore, EPA has determined that the evidence is sufficient for listing the DINP category on the EPCRA section 313 toxic chemicals list pursuant to EPCRA section 313(d)(2)(B).

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not itself physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. USEPA. Technical Review of Diisononyl Phthalate. Office Pollution Prevention and Toxics, Data Gathering and Analysis Division and Existing Chemicals Risk Assessment Division. April 11, 2022.
2. USEPA. Technical Review of Diisononyl Phthalate [updated]. Office Pollution Prevention and Toxics, Data Gathering and Analysis Division and Existing Chemicals Risk Assessment Division. June 2023.
3. Letter to EPA Administrator Carol M. Browner, Re: Petition to Add Diisononyl Phthalate (DINP) to the Emergency Planning and Community Right-to-Know Act Section 313 List of Toxic Chemicals. From Laurie Valeriano, Policy Director, Wastington Toxics Coalition. February 24, 2000.
4. USEPA. Economic Analysis for the Addition of Diisononyl Phthalate Category; Community Right-to-Know Toxic Chemical Release Reporting. Prepared by Abt Associates. April 20, 2023.
5. USEPA. Response to Comments Received on the August 8, 2022, Proposed Rule (87 FR 48128): Addition of Diisononyl Phthalate Category; Community Right-to-Know Toxic Chemical Release Reporting. June 2023.
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12. Waterman, S.J.; Ambroso, J.L.; Keller, L.H.; Trimmer, G.W.; Nikiforov, A.I.; Harris, S.B. 1999. Developmental toxicity of di-isodecyl and di-isononyl phthalates in rats. Reprod. Toxicol. 13(2):131–136.
13. Australia NICNAS, Priority existing chemical assessment report no. 35. Diisononyl phthalate. September 2012, Australian Government Department of Health and Ageing: Sydney, Australia. *https://www.industrialchemicals.gov.au/sites/default/files/PEC35-Diisononyl-phthalate-DINP.pdf.*
14. Clewell, R.A., *et al.,* 2013. A dose response study to assess effects after dietary administration of diisononyl phthalate (DINP) in gestation and lactation on male rat sexual development. Reprod Toxicol. 35:70–80.
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VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and 14094: Modernizing Regulatory Review

This action is not a significant regulatory action as defined in Executive Order 12866 (58 FR 51735, October 4, 1993), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023), and was therefore not subject to a requirement for Executive Order 12866 review.

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA, 44 U.S.C. 3501 *et seq.* Burden is defined in 5 CFR 1320.3(b). OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control numbers 2070–0212 and 2050–0078.

Currently, the facilities subject to the reporting requirements under EPCRA section 313 and PPA section 6607 may use either EPA Toxic Chemicals Release Inventory Form R (EPA Form 9350–1), or EPA Toxic Chemicals Release Inventory Form A (EPA Form 9350–2). The Form R must be completed if a facility manufactures, processes, or otherwise uses any listed chemical above threshold quantities and meets certain other criteria. For the Form A, EPA established an alternative threshold for facilities with low annual reportable amounts of a listed toxic chemical. A facility that meets the appropriate reporting thresholds, but estimates that the total annual reportable amount of the chemical does not exceed 500 pounds per year, can take advantage of an alternative manufacture, process, or otherwise use threshold of 1 million pounds per year of the chemical, provided that certain conditions are met, and submit the Form A instead of the Form R. In addition, respondents may designate the specific chemical identity of a substance as a trade secret pursuant to EPCRA section 322, 42 U.S.C. 11042, 40 CFR part 350.

OMB has approved the reporting and recordkeeping requirements related to Forms A and R, supplier notification, and petitions under OMB Control number 2070–0212 (EPA Information Collection Request (ICR) No. 2613.02) and those related to trade secret designations under OMB Control 2050–0078 (EPA ICR No. 1428). As provided in 5 CFR 1320.5(b) and 1320.6(a), an Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers relevant to EPA's regulations are listed in 40 CFR part 9 and displayed on the information collection instruments (*e.g.,* forms, instructions).

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* The small entities subject to the requirements of this action are small manufacturing facilities. The Agency has determined that no small governments or small organizations are expected to be affected by this action; and that of the 198 to 396 entities estimated to be impacted by this action, 181 to 365 are small businesses. All small businesses affected by this action are estimated to incur annualized cost impacts of less than 1%. Thus, this action is not expected to have a significant adverse economic impact on a substantial number of small entities. A more detailed analysis of the impacts on small entities is located in EPA's economic analysis (Ref. 4).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments and EPA did not identify any small governments that would be impacted by this action. EPA's economic analysis indicates that the total industry cost of this action is estimated to be $968,546 to $1,935,041 in the first year of

reporting and $461,212 to $921,448 in subsequent years (Ref. 4).

E. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. This action relates to toxic chemical reporting under EPCRA section 313, which primarily affects private sector facilities. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of Executive Order 13045. This action is not subject to Executive Order 13045, because it does not concern an environmental health or safety risk. Since this action does not concern human health, EPA's Policy on Children's Health also does not apply.

Although this action does not concern an environmental health or safety risk, the data collected as a result of this action will provide information about releases to the environment that could be used to inform the public on potential exposures to toxic chemical releases, pursuant to the right-to-know principles. EPA also believes that the information obtained as a result of this action could be used by government agencies, researchers, and others to identify potential problems, set priorities, and take appropriate steps to reduce any potential exposures and related human health or environmental risks identified as a result of increased knowledge of exposures to DINP.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards under the NTTAA section 12(d), 15 U.S.C. 272.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color and/or indigenous peoples) and low-income populations.

EPA believes that it is not practicable to assess whether the human health or environmental conditions that exist prior to this action result in disproportionate and adverse effects on people of color, low-income populations and/or indigenous peoples. This action adds a chemical category to the EPCRA section 313 reporting requirements; it does not directly address any human health or environmental risks and does not affect the level of protection provided to human health or the environment. However, EPA believes that the information obtained as a result of this action could be used by the public (including people of color, low-income populations and/or Indigenous peoples) to inform their behavior as it relates to sources of DINP exposure, or by government agencies and others to identify potential problems, set priorities, and take appropriate steps to reduce those exposures, as well as assess any potential human health or environmental risks.

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.,* and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 372

Environmental protection, Community right-to-know, Reporting and recordkeeping requirements, and Toxic chemicals.

Dated: July 6, 2023.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, for the reasons set forth in the preamble, EPA is amending 40 CFR part 372 as follows:

PART 372—TOXIC CHEMICAL RELEASE REPORTING: COMMUNITY RIGHT–TO–KNOW

■ 1. The authority citation for part 372 continues to read as follows:

Authority: 42 U.S.C. 11023 and 11048.

■ 2. In § 372.65, adding in alphabetical order an entry to Table 3 in paragraph (c) for ''Diisononyl Phthalates (DINP)'' to read as follows:

§ 372.65 Chemicals and chemical categories to which this part applies.

* * * * *

(c) * * *

TABLE 3 TO PARAGRAPH (c)

Category name	Effective date
* * * * * * *	
Diisononyl Phthalates (DINP): Includes branched alkyl di-esters of 1,2 benzenedicarboxylic acid in which alkyl ester moieties contain a total of nine carbons. (This category includes but is not limited to the chemicals covered by the CAS numbers and names listed here) 28553–12–0 Diisononyl phthalate. 71549–78–5 Branched dinonyl phthalate.	1/1/2024

TABLE 3 TO PARAGRAPH (c)—Continued

Category name		Effective date
14103–61–8	Bis(3,5,5-trimethylhexyl) phthalate.	
68515–48–0	Di(C8–10, C9 rich) branched alkyl phthalates.	
20548–62–3	Bis(7-methyloctyl) phthalate.	
111983–10–9	Bis(3-ethylheptan-2-yl) benzene-1,2-dicarboxylate.	
*	* * * * * * *	

[FR Doc. 2023–14642 Filed 7–13–23; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 230224–0053; RTID 0648–XD061]

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Ocean Perch in the West Yakutat District of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific ocean perch in the West Yakutat District of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the 2023 total allowable catch of Pacific ocean perch in the West Yakutat District of the GOA.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), July 11, 2023, through 2400 hours, A.l.t., December 31, 2023.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR parts 600 and 679.

The 2023 total allowable catch (TAC) of Pacific ocean perch in the West Yakutat District of the GOA is 1,370 metric tons (mt) as established by the final 2023 and 2024 harvest specifications for groundfish of the GOA (88 FR 13228, March 2, 2023).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2023 TAC of Pacific ocean perch in the West Yakutat District of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 1,270 mt, and is setting aside the remaining 100 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific ocean perch in the West Yakutat District of the GOA. While this closure is effective the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of directed fishing of Pacific ocean perch in the West Yakutat district of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of July 10, 2023.

The Assistant Administrator for Fisheries, NOAA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

Authority: 16 U.S.C. 1801 *et seq.*

Kelly Denit,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2023–14952 Filed 7–11–23; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 230224–0053; RTID 0648–XD062]

Fisheries of the Exclusive Economic Zone Off Alaska; Dusky Rockfish in the West Yakutat District of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for dusky rockfish in the West Yakutat District of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the 2023 total allowable catch of dusky rockfish in the West Yakutat District of the GOA.

DATES: Effective noon Alaska local time (A.l.t.), July 11, 2023, through midnight, A.l.t., December 31, 2023.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR parts 600 and 679.

The 2023 total allowable catch (TAC) of dusky rockfish in the West Yakutat District of the GOA is 90 metric tons