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Draft Environmental Exposure Assessment for Diisononyl Phthalate (DINP)

Technical Support Document for the Draft Risk Evaluation

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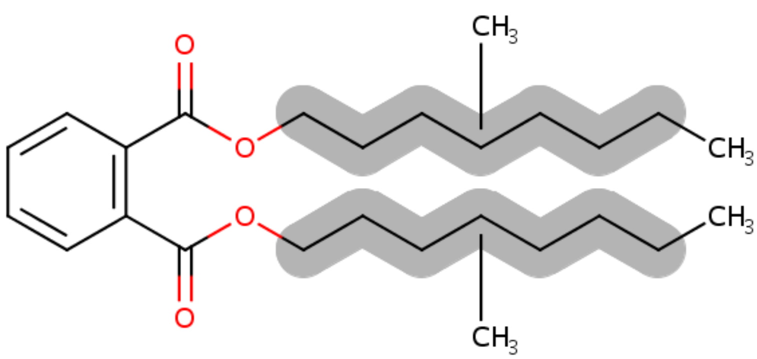

(Representative Structure)

August 2024

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ABBREVIATIONS AND ACRONYMS

7Q10	Lowest 7-day average flow occurring in a 10-year period
AERMOD	AMS/EPA Regulatory Model
AUF	Area Use Factor
BAF	Bioaccumulation factor
BCF	Bioconcentration factor
BSAF	Biota to sediment accumulation factor
COU	Condition of use
DINP	Diisononyl phthalate
DPE	Dialkyl phthalate esters
EPA	U.S. Environmental Protection Agency (or the Agency)
FIR	Feed intake rate
OES	Occupational exposure scenario
PVC	Polyvinyl chloride
SIR	Sediment intake rate
SSL	Soil screening levels
TRV	Toxicity reference value
TSCA	Toxic Substances Control Act
VVWM-PSC	Variable Volume Water Mode – Point Source Calculator
WIR	Water intake rate

SUMMARY

EPA evaluated the reasonably available information for environmental exposures of diisononyl phthalate (DINP) to aquatic and terrestrial species under the Toxic Substances Control Act (TSCA). The key points of the environmental exposure assessment are summarized below:

- EPA expects the main environmental exposure pathway for DINP to be releases to surface water and subsequent deposition to sediment. The ambient air exposure pathway was also assessed for its limited contribution via deposition to soil.
- DINP exposure to aquatic species via surface water and sediment were modeled to estimate concentrations from the TSCA conditions of use/occupational exposure scenarios (COUs/OESs) that resulted in the highest environmental media concentrations. Concentrations of DINP in representative organisms for the screening level trophic transfer analysis were calculated using modeled sediment concentrations from the Variable Volume Water Mode – Point Source Calculator (VVWM-PSC) (Section 3.2.1).
- Based on a solubility of 6.1×10^{-4} mg/L and the predicted bioconcentration factor (BCF) of 5.2 L/kg, the calculated concentration of DINP in fish was predicted to be 3.2×10^{-3} mg/kg, which was one order of magnitude lower than the highest DINP measured concentrations reported in aquatic biota in peer-reviewed literature. The DINP concentration in middle trophic level species (*i.e.*, mussel) calculated using a bioaccumulation factor (BAF) of 209.8 was 1.0×10^{-1} mg/kg-bw across DINP COUs/OESs (Section 3.1).
- Deposition of DINP from air to soil was modeled via the AMS/EPA Regulatory Model (AERMOD) and daily deposition to surface water and sediment was modeled with VVWM-PSC to represent concentrations for the COU/OES that resulted in the highest environmental media concentrations (Section 3.2.1).
- Exposure to terrestrial species through soil via DINP air deposition was assessed using data modeled via AERMOD (Section 4.2).
- DINP is not considered bioaccumulative; however, within the aquatic environment, relevant environmental exposures are possible through incidental ingestion of sediment while feeding and/or ingestion of food items that have become contaminated due to uptake from sediment.
- Exposure through diet was assessed through a trophic transfer analysis (Section 5) with representative species (Figure 5-1), which estimated the transfer of DINP from soil through the terrestrial food web (Table 5-3), and from surface water and sediment through the aquatic food web via releases to surface waters (Table 5-4, Table 5-5).
- The highest COU/OES estimate (Non-PVC material compounding) resulted in DINP exposure concentrations in a modeled terrestrial ecosystem of 0.04 mg/kg-bw/day in the earthworm (*Eisenia fetida*) consuming soil with an estimated dietary intake of 0.02 mg/kg-bw/day in northern shorttail shrews (*Blarina brevicauda*).
    - Within the aquatic modeled ecosystem, the highest COU/OES estimate (Non-PVC material compounding) resulted in a predicted DINP exposure concentration of 263 mg/kg in the blacktail redhorse (*Moxostoma poecilurum*) consuming a middle trophic level species (*i.e.*, mussel) and resulted in a predicted dietary intake of DINP of 62.7 mg/kg-bw/day in American mink (*Mustela vison*).

1 INTRODUCTION

This document provides the technical information and analysis supporting exposure of DINP to environmental organisms in aquatic and terrestrial environments, and includes modeling and monitoring approaches. EPA assessed DINP exposures via surface water, sediment, and soil, which were used to determine exposures to aquatic and terrestrial species (Section 5.1). The media of release for these exposures originate from releases to water and releases to air and subsequent deposition to soil or water and sediment. Approaches for modeled and monitored concentrations of DINP within aquatic (Section 3) and terrestrial (Section 4) biota are presented. Dietary exposure to terrestrial and aquatic-dependent mammals consuming food items and media contaminated with DINP is described.

The screening level trophic transfer analysis was conducted by producing exposure estimates from the high-end exposure scenarios defined as those associated with the industrial and commercial releases from a COU and OES that resulted in the highest environmental media concentrations. Table 1-1 summarizes the high-end exposure scenarios that were considered in this screening level analysis to estimate environmental and dietary exposures. This analysis was performed quantitatively only when environmental media concentrations were quantified for the appropriate exposure scenario. For example, exposure from soil or groundwater resulting from DINP release to the environment via biosolids or landfills was not quantitatively assessed because DINP concentrations in the environment from biosolid and landfill releases were not quantified (U.S. EPA, 2024e, f).

Table 1-1 Exposure Scenarios Representing the Highest Environmental Releases per Media of Release Assessed in the Screening Level Trophic Transfer Analysis

COU (Life Cycle Stage[a]/ Category[b]/ Sub-category[c])	Occupational Exposure Scenario	Media of Release	Exposure Pathway	Receptors
Processing/Incorporation into formulation, mixture, or reaction product/Plasticizers (adhesives manufacturing, custom compounding of purchased resin; paint and coating manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; wholesale and retail trade; all other chemical product and preparation manufacturing; pigments)	Non-PVC material compounding	Water	Water	Aquatic species and aquatic-dependent mammals
Processing/Incorporation into formulation, mixture, or reaction product/Plasticizers (adhesives manufacturing, custom compounding of purchased resin; paint and coating manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; wholesale and retail trade; all other chemical product and preparation manufacturing; pigments)	Non-PVC material compounding	Fugitive or stack air release	Air deposition to surface water, sediment	Aquatic species and aquatic-dependent mammals
Processing/Incorporation into formulation, mixture, or reaction product/Plasticizers (adhesives manufacturing, custom compounding of purchased resin; paint and coating	Non-PVC material compounding	Fugitive or stack air release	Air deposition to soil	Terrestrial mammals

COU (Life Cycle Stage[a]/ Category[b]/ Sub-category[c])	Occupational Exposure Scenario	Media of Release	Exposure Pathway	Receptors
manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; wholesale and retail trade; all other chemical product and preparation manufacturing; pigments)				

[a] Life Cycle Stage Use Definitions (40 CFR 711.3):

"Industrial use" means 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.

Although EPA has identified both industrial and commercial uses here for purposes of distinguishing scenarios in this document, the Agency interprets the authority over "any manner or method of commercial use" under TSCA section 6(a)(5) to reach both.

[b] These categories of COU appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent COUs of DINP in industrial and/or commercial settings.

[c] These subcategories reflect more specific COUs of DINP.

2 APPROACH AND METHODOLOGY

2.1 Environmental Exposure Scenarios

EPA used two models to assess the environmental concentrations resulting from the industrial and commercial release estimates: VVWM-PSC and AERMOD. Additional information on these models is available in the *Draft Environmental Media and General Population Exposure for Diisononyl Phthalate (DINP)* technical support document (U.S. EPA, 2024d). The Agency modeled DINP in surface water, benthic pore water, and sediment concentrations using VVWM-PSC. Both VVWM-PSC and AERMOD were used to model aquatic media concentrations from air deposition. EPA modeled DINP concentrations in soil via air deposition near facility using AERMOD. Modeled values were then compared to monitoring data found in open literature.

EPA determined exposures of DINP to aquatic-dependent terrestrial species through surface water and sediment using modeled data and to terrestrial species through soil concentrations based on modeled daily air deposition from fugitive and stack releases of DINP. Specifically, exposures to aquatic-dependent wildlife used modeled DINP concentrations in sediment from VVWM-PSC for highest release COU and OES in combination with DINP fish and mid-trophic level species concentrations derived using reasonably available BCF and BAF values, respectively, in a screening level trophic transfer analysis. Soil concentrations from the COU/OES with the highest daily deposition from air to soil were used to demonstrate DINP exposure to terrestrial species via a screening level trophic transfer analysis. Exposure factors for terrestrial organisms used within the screening level trophic transfer analyses are presented in Section 5. Application of exposure factors and hazard values for organisms at different trophic levels is detailed within Section 5.1 and were used in equations as described in the *U.S. EPA Guidance for Developing Ecological Soil Screening Levels* (U.S. EPA, 2005).

3 EXPOSURES TO AQUATIC SPECIES

3.1 Measured Concentrations in Aquatic Species

Studies on DINP concentration in aquatic species within the pool of reasonably available information were primarily coupled with larger investigations on dialkyl phthalate esters (DPE). Concentrations of DINP within several different aquatic species originate from four previously published studies. A larger group of phthalates that include DINP with a similar mode of action could act as an indicator of DINP or phthlate exposure.

Lin et al. (2003) sampled sediment and striped seaperch (*Embiotoca lateralis*) at three locations along False Creek Harbor, Vancouver, British Columbia, Canada. This location was characterized by the study authors as an urbanized marine ecosystem. Mean concentrations of DINP in striped seaperch were graphically represented for the three sites as less than 0.001 mg/kg wet weight. That study provided groundwork for subsequent sampling and analysis of DINP concentrations in biota from the same marine environment and author group (Blair et al., 2009; McConnell, 2007; Mackintosh et al., 2004).

Mackintosh et al. (2004) surveyed 18 species representing 4 trophic levels collected between June and September of 1999 within the marine environment of False Creek Harbor, Vancouver, British Columbia, Canada. Mean DINP concentrations were reported in five out of the eight fish species, ranging from 354.8 ng/g to 776.25 ng/g equivalent lipid in English sole (*Pleuronectes ventulus*) whole embryos and Pacific staghorn sculpin (*Leptocottus armatus*), respectively. Using the authors' reported mean percent lipid values for whole fish allowed for the conversion of lipid equivalent values to comparative values of DINP in mg/kg wet weight. The highest reported value of DINP in whole fishes was 0.0124 mg/kg for juvenile shiner perch. For aquatic invertebrates and algae, mean DINP was recorded in seven out of the nine species sampled, ranging from 436.5 ng/g to 10,964.8 ng/g equivalent lipid in dungeness crabs (*Cancer magister*) and whole plankton samples, respectively. Highest values of DINP in the whole samples adjusted with reported mean percent lipid values indicated the highest whole organism concentrations in geoduck clams (*Panopea abrupta*) and dungeness crabs (*Cancer magister*) were 0.0359 mg/kg and 0.0349 mg/kg wet weight, respectively.

Additional aquatic biota sampled at False Creek Harbor, Vancouver, British Columbia, Canada, were collected from July to September 2005 and resulted in DINP concentrations recorded for seven out of eight aquatic species. The two highest mean concentrations of DINP within whole aquatic organisms were recorded for softshell clam and green algae at 0.048 mg/kg and 0.330 mg/kg wet weight. Grouping DPE congeners, authors noted that dogfish concentrations in muscle were significantly higher in 2005 collections vs. collections from 1999 reported within MacKintosh et al. (2004), while clam DPE concentrations were statistically unchanged between sample periods (McConnell, 2007).

In a study primarily centered on mono-alkyl phthalate ester concentrations within seawater, sediment, and aquatic species collected between 2004 to 2006 at False Creek Harbor, Vancouver, British Columbia, Canada, Blair et al. (2009) reported DINP concentrations for blue mussel (*Mytilus edulis*). Mean DINP concentrations for blue mussel were reported graphically as approximately less than 0.010 mg/kg wet weight. Authors noted that concentrations of DINP within biota were low compared to the predominance of the compounds within water and sediment as graphically reported at approximately less than 1.0×10^{-4} mg/L and 1.0 mg/kg dry weight, respectively.

3.2 Calculated Concentrations in Aquatic Species

3.2.1 Releases to Surface Water

Concentrations of DINP in representative organisms within the screening level trophic transfer analysis were calculated using modeled surface water and sediment concentrations from VVWM-PSC.

Surface water concentrations of DINP modeled with VVWM-PSC by COU/OES water releases exceeded the water solubility limit for DINP, which is approximately 6.1×10^{-4} mg/L (U.S. EPA, 2024f), by up to five orders of magnitude. DINP sorbed onto suspended solids in the water column could lead to DINP amounts greater than solubility concentrations. However, these molecules would not be available for incorporation into aquatic organisms in the water column (*i.e.*, epithelial uptake from skin and/or gills) due to sorption and DINP's physical-chemical properties. DINP has the potential to remain for longer periods of time in soil and sediments due to the inherent hydrophobicity (log K_{ow} = 8.8) and sorption potential (log K_{OC} = 5.5). Furthermore, within the water column, high sorption coefficients indicate that freely dissolved and bioavailable concentrations would be very low and further decreased by DINP's low water solubility (Mackintosh et al., 2006). Therefore, EPA expects that the main pathway for exposure to DINP in the aquatic and terrestrial environments is through direct consumption of contaminated food sources and incidental ingestion of contaminated soil and sediment (Mackintosh et al., 2004).

A predicted fish BCF (Arnot-Gobas method) of 5.2 L/kg was used to represent uptake of DINP from surface water exposure to fishes (U.S. EPA, 2017a). Based on a solubility of 6.1×10^{-4} mg/L and the predicted BCF of 5.2 L/kg, the calculated concentration of DINP in fish is 3.2×10^{-3}, which is within the same order of magnitude as reported for whole fish in the literature. For example, whole body concentrations of DINP reported for juvenile shiner perch and white-spotted greenling were $1.2\times^{-2}$ and 4.9×10^{-3} in Mackintosh et al. (2004) and McConnell (2007), respectively.

An estimated middle trophic level species BAF (Arnot-Gobas method) was used to represent organisms in the benthic aquatic environment. Middle trophic level species DINP concentrations calculated using an estimated BAF of 209.8 L/kg (U.S. EPA, 2017a) were 1.0×10^{-1} mg/kg-bw for the COUs and OES associated with the highest surface water release (Table 3-1), which was one order of magnitude greater than DINP concentrations in geoduck clams and blue mussels reported in Mackintosh et al. (2004) and Blair et al. (2009), respectively.

Modeled values from VVWM-PSC for surface water and sediment based on COU/OES estimated water releases from hypothetical facilities resulted in DINP concentrations within surface water and sediment with a confidence rank of slight as reported within the *DINP Environmental Exposure Media Concentrations Technical Support Document* (U.S. EPA, 2024d). Table 3-1 presents maximum concentrations of DINP in sediments within the reasonably available literature. These values from published literature should be considered to represent DINP concentrations from ambient monitoring and are not directly comparable to COUs and OESs within the current draft risk evaluation.

Table 3-1. Calculated DINP Mussel Concentrations from VVWM-PSC Modeled Values of DINP in Sediment and Published Literature

COU (Life Cycle Stage[a]/ Category[b]/ Sub-category[c])	OES	Flow Rate (m^3/day)	Annual Release per Site (kg/site-yr^{-1})[d]	Sediment Concentration (mg/kg)[e]
Processing/Incorporation into formulation, mixture, or reaction product/Plasticizers (adhesives manufacturing, custom compounding of purchased resin; paint and coating manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; wholesale and retail trade; all other chemical product and preparation manufacturing; pigments)	Non-PVC material compounding	P50 7Q10: 24,822	608	41,000
		P90 7Q10: 15,490,000	608	66.7

Published literature

Sample Collection Conditions/ Location	Reference (Overall Quality Determination)	Sediment Concentration (mg/kg)
Maximum concentration of DINP within sediments/ Industrialized harbor, Kaohsiung Harbor, Taiwan	(Chen et al., 2016) (Medium)	26.5
Maximum concentration of DINP within sediments/ urban areas in Sweden collected by the Swedish National Screening Program, Swedish Environmental Research Institute	(Cousins et al., 2007) (Medium)	3.2
Maximum concentrations of DINP found within several large river basins in Germany	(Nagorka and Koschorreck, 2020) (High)	6.3

[a] Life Cycle Stage Use Definitions (40 CFR 711.3):
"Industrial use" means 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.
Although EPA has identified both industrial and commercial uses here for purposes of distinguishing scenarios in this document, the Agency interprets the authority over "any manner or method of commercial use" under TSCA section 6(a)(5) to reach both.
[b] These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent conditions of use of DINP in industrial and/or commercial settings
[c] These subcategories reflect more specific conditions of use of DINP.
[d] Production volume uses high-end release distribution estimates (95th percentile).
[e] Sediment concentration represented by maximum daily average over the estimated days of release for each COU based on COU/OES characteristics described within the engineering supplement for DINP.

4 EXPOSURES TO TERRESTRIAL SPECIES

4.1 Measured Concentrations in Terrestrial Species

Studies representing measured concentrations in terrestrial species are represented largely by investigations of domesticated mammals such as cats, dogs, and pigs and do not represent ecologically relevant receptors for terrestrial wildlife species for exposure to DINP. One study reported DINP concentrations of less than 0.02 mg/kg wet weight in pooled eggs from three seabird species—the common eider (*Somateria mollisima*), European shag (*Phalacrocorax aristotelis aristotelis*), and European herring gull (*Larus argentatus*) (Huber et al., 2015). Mackintosh et al. (2004), described previously in Section 3.1, reported a marine avian species, surf scooter (*Melanitta perspicillata*), muscle concentration of 0.0057 mg/kg DINP based on a 257.04 ng/g lipid equivalent and mean lipid content of 2.1 percent. Additionally, one study reported DINP concentrations of 0.0004 mg/kg on ant (*Solenopsis saevissima*) cuticles collected from French Guiana (Lenoir et al., 2016).

4.2 Calculated Concentrations in Terrestrial Species

Air deposition to soil modeling is described in Section 2 of *Draft Environmental Media and General Population Exposure for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024d). AERMOD was used to assess the estimated release of DINP via air deposition from specific exposure scenarios to soil. AERMOD modeling represents the highest and lowest COU/OES based estimated daily deposition rate of DINP onto soil via air deposition at 1,000 m from a hypothetical release source. At 1,000 m, the non-PVC material compounding OES fugitive source resulted in the highest deposition rate of 6.8×10^{-3} g/m^2 per day. A full table of deposition rates across all OESs is in U.S. EPA (2024d). Using equations provided in Sections 5.1.1.1 and 5.1.1.2 from the *Draft Environmental Media and General Population Exposure for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024d), the highest daily deposition rate at 1,000 m resulted in a soil concentration of 0.04 mg/kg from the Non-PVC material compound COU/OES (U.S. EPA, 2024d). The highest concentration of DINP reported in rural soil within reasonably available published literature is 0.06 mg/kg (Zhang et al., 2015). The further use of DINP concentrations in soil from AERMOD and published literature is detailed in Section 5.1 of this document.

Air deposition of DINP to water and sediment was assessed qualitatively due to this pathway resulting in low water and sediment concentrations in a previous chemical assessment with very similar fugitive source air deposition and physical-chemical properties (U.S. EPA, 2024d). For example, fugitive source air deposition for DIDP was reported as 8.5×10^{-3} g/m^2-day (compared to the highest DINP deposition rate of 6.8×10^{-3} g/m^2 per day) and resulted in maximum water and sediment concentrations of 9.5×10^{-5} mg/kg and 0.35 mg/kg mg/kg DIDP. Therefore, EPA anticipates air deposition of DINP to not result in appreciable water and sediment concentrations rising to a quantitative analysis.

5 TROPHIC TRANSFER

Trophic transfer is the process by which chemical contaminants can be taken up by organisms through dietary and media exposures and transferred from one trophic level to another. EPA assessed the available studies collected in accordance with the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances* (U.S. EPA, 2021) and *Draft Systematic Review Protocol for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024g) relating to the biomonitoring of DINP. Chemicals can be transferred from contaminated media and diet to biological tissue and accumulate throughout an organisms' lifespan (bioaccumulation) if they are not readily excreted or metabolized. Through dietary consumption of prey, a chemical can subsequently be transferred from one trophic level to another. If biomagnification occurs, higher trophic level predators will contain greater body burdens of a contaminant compared to lower trophic level organisms.

In this trophic transfer analysis, EPA chose representative species to connect the DINP transport exposure pathway via terrestrial trophic transfer from earthworm (*Eisenia fetida*) uptake of DINP from contaminated soil to the representative insectivorous mammal, short-tailed shrew (*Blarina brevicauda*).

Short-tailed shrews primarily feed on invertebrates with earthworms comprising approximately 31 percent (stomach volume) to 42 percent (frequency of occurrence) of their diet. The calculations for assessing DINP exposure from soil uptake by earthworms and the transfer of DINP through diet to higher trophic levels will use maximum soil concentrations from published literature. Because surface water sources for wildlife water ingestion are typically ephemeral, the trophic transfer analysis for terrestrial organisms assumed DINP exposure concentration for wildlife water intake are equal to soil concentrations for each corresponding exposure scenario.

The representative semi-aquatic terrestrial species is the American mink (*Mustela vison*), whose diet is highly variable depending on their habitat. In a riparian habitat, American mink derive 74 to 92 percent of their diet from aquatic organisms, which includes fish, crustaceans, birds, mammals, and vegetation (Alexander, 1977). Sediment concentrations of DINP modeled using VVWM-PSC represent the high-end and central tendency annual release per COU/OES and will be used as a surrogate for the DINP concentration found in the American mink's diet in the form of both water intake, incidental sediment ingestion, and a diet of fish.

The representative fish for the screening level trophic transfer analysis is the blacktail redhorse (*Moxostoma poecilurum*) serving as a prey item for the American mink. This species is within the Catostomidae family of fishes commonly referred to as suckers. Catostomids are represented by approximately 67 species in North America inhabiting lakes, rivers, and streams (Boschung and Mayden, 2004). Taxa within this family are characterized with sub-terminal mouths and feed primarily on benthic associated prey such as chironomids, zooplankton, crayfish, and mollusks, in addition to algae (Dauble, 1986). The representative prey item for the blacktail redhorse will be a mollusk. These fish have the potential to be exposed to DINP within sediment through incidental ingestion of sediment during feeding because of the natural history associated with these fishes. Studies on diet composition within suckers indicates high ingestion of sediment as an incidental effect from benthic feeding. The largescale sucker (*Catostomus macrocheilus*) was observed to have up to 20 percent of its total gut content represented with sand (Dauble, 1986). Gut content composition sampled from March to November in shorthead redhorse (*Moxostoma macrolepidotum*) sampled within the Kankakee River drainage resulted in a mean of approximately 42 percent unidentified inorganic matter and sand (Sule, 1985, 11361932). Sediment within the gut ranged from 19 to 59 percent with a mean of 38 percent sediment for shorthead redhorse using a radionuclide tracer (^{238}U) approach with an adjusted mass balance tracer method equation (Doyle et al., 2011).

5.1 Dietary Exposure

EPA conducted screening level approaches for aquatic and terrestrial risk estimation based on exposure via trophic transfer using conservative assumptions for factors such as area use factor as well as DINP absorption from diet, soil, sediment, and water. The *Draft Fate Assessment for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024f) details how DINP is expected to be found predominantly in sediments near point sources based on sorption, with a decreasing trend in sediment concentrations downstream. DINP is not considered bioaccumulative; however, within the aquatic environment relevant environmental exposures are possible through incidental ingestion of sediment while feeding and ingestion of food items that have become contaminated due to uptake from sediment. Due to a lack of reasonably available measured data, a predicted BCF (Arnot-Gobas method) of 5.2 L/kg was used to represent uptake of DINP from exposure to surface water for fish (U.S. EPA, 2017a). Concentration of DINP within a middle level trophic species were calculated by EpiSuite™ using a predicted bioaccumulation factor (BAF; Arnot-Gobas method) of 209.8 L/kg as reported within (U.S. EPA, 2017a). EpiSuite™ calculations represent general trophic levels (*i.e.*, not for a particular fish species) and are derived for "representative" environmental conditions (*e.g.*, dissolved and particulate organic carbon content in the water column, water temperature). Thus, it provides general estimates for these conditions in absence of site-specific measurements or estimates.

The use of this predicted value was more conservative than the upper trophic level as high-quality empirical values for BCF in aquatic biota were not available. This conservative approach complements the use of the absorbed fraction of the contaminate within sediment (AFsj), water (AFwj), and biota (AFij) and are all set to one. For representation of DINP within a middle level trophic species, BAF is preferred in estimating exposure because it considers the animal's uptake of a chemical from both diet and the water column. Section 3 reports estimated concentrations of DINP within representative fish and middle level trophic species tissue based on the estimated BCF and BAF, respectively. A screening level analysis was conducted for trophic transfer. The screening level approach employs a combination of conservative assumptions (*i.e.*, conditions for several exposure factors included within Equation 5-1 below) and utilization of the maximum values obtained from modeled and/or monitoring data from relevant environmental compartments.

Following the basic equations provided in Chapter 4 of the *U.S. EPA Guidance for Developing Ecological Soil Screening Levels* (U.S. EPA, 2005), wildlife receptors may be exposed to contaminants in soil by two main pathways: (1) incidental ingestion of soil while feeding, and (2) ingestion of food items that have become contaminated due to uptake from soil. The general equation used to estimate dietary exposure via these two pathways is provided below. It has been adapted to include consumption of water contaminated with DINP—and for semi-aquatic mammals, incidental ingestion of sediment instead of soil:

Equation 5-1. Terrestrial and Aquatic Mammals

$$E_j = \left(\left[S_j * P_s * \mathrm{FIR} * \mathrm{AF}_{sj} \right] + \left[W_j * WIR * AF_{wj} \right] + \left[\sum_{i=1}^{N} B_{ij} * P_i * \mathrm{FIR} * \mathrm{AF}_{ij} \right] \right) * AUF$$

Equation 5-2. Fish

$$E_j = \left(\left[S_j * P_s * \mathrm{FIR} * \mathrm{AF}_{sj} \right] + \left[\sum_{i=1}^{N} B_{ij} * P_i * \mathrm{FIR} * \mathrm{AF}_{ij} \right] \right) * AUF$$

Where:

E_j = Dietary exposure for contaminant (j) (mg/kg-bw/day)

S_j = Concentration of contaminant (j) in soil or sediment (mg/kg dry weight)
P_s = Proportion of total food intake that is soil or sediment (kg soil/kg food; SIR/((FIR)(body weight [bw])))
SIR = Sediment intake rate (kg of sediment [dry weight] per day)
FIR = Food intake rate (kg of food [dry weight] per kg body weight per day)
AF_{sj} = Absorbed fraction of contaminant (j) from soil or sediment (s) (for screening purposes set equal to 1)
W_j = Concentration of contaminant (j) in water (mg/L); assumed to equal water solubility for the purposes of terrestrial trophic transfer
WIR = Water intake rate (kg of water per kg body weight per day)
AF_{wj} = Absorbed fraction of contaminant (j) from water (w) (for screening purposes set equal to 1)
N = Number of different biota type (i) in diet
B_{ij} = Concentration of contaminant (j) in biota type (i) (mg/kg dry weight)
P_i = Proportion of biota type (i) in diet
AF_{ij} = Absorbed fraction of contaminant (j) from biota type (i) (for screening purposes set equal to 1)
AUF = Area use factor (for screening purposes set equal to 1)

Table 5-1. Terms and Values Used to Assess Potential Trophic Transfer of DINP for Terrestrial Risk Characterization

Term	Earthworm (*Eisenia fetida*)	Short-Tailed Shrew (*Blarina brevicauda*)
P_s	1	0.03[a]
FIR	1	0.555[b]
AF_{sj}	1	1
P_i	1	1
WIR	1	0.223[b]
AF_{wj}	1	1
AF_{ij}	1	1
N	1	1
AUF	1	1
S_j [c]	*x* mg/kg DINP[d]	*x* mg/kg DINP[d]
B_{ij}	*x* mg/kg DINP[d] (soil)	*x* mg/kg DINP (worm)

[a] Soil ingestion as proportion of diet represented at the 90th percentile sourced from EPA's *Guidance for Developing Ecological Soil Screening Levels* (U.S. EPA, 2005).
[b] Exposure factors (*FIR* and *WIR*) sourced from EPA's *Wildlife Exposure Factors Handbook* (U.S. EPA, 1993).
[c] DINP concentration in soil and soil pore water for earthworm and short-tailed shrew
[d] Highest daily soil concentration of DINP reported from Non-PVC material compounding OES

Table 5-2. Terms and Values Used to Assess Potential Trophic Transfer of DINP for Aquatic Risk Characterization

Term	Blacktail Redhorse (*Moxostoma poecilurum*)	American Mink (*Mustela vison*)
P_s	0.32 [a]	5.35E−04 [b]
FIR	0.02 [c]	0.22 [d]
AF_{sj}	1	1
P_i	1	1
WIR	NA[e]	0.105 [d]
AF_{wj}	1	1
AF_{ij}	1	1
SIR	9.5E−04 [f]	1.20E−04 [g]
Bw	0.148 kg [h]	1.0195 kg [i]
N	1	1
AUF	1	1
S_j [f]	*x* mg/kg [j] DINP	*x* mg/kg[j] DINP
W_j	0.00061 mg/L[k] DINP	0.00061 mg/L[k] DINP
B_{ij}	*x* mg/kg [l] Mussel	*x* mg/kg [m] Fish

[a] Sediment ingestion as proportion of diet, calculated from the geometric mean of sediment as a proportion of diet reported in published literature for catostomids (Doyle et al., 2011; Dauble, 1986; Sule and Skelly, 1985).
[b] Sediment ingestion as proportion of diet, calculated by dividing the SIR by kg food, where kg food = FIR multiplied by body weight of the mink.
[c] Daily feed rate reported from apparent satiation in laboratory growth study for juvenile black buffalo (*Ictiobus niger*) (Guy et al., 2018).
[d] Exposure factors (FIR and WIR) sourced from EPA's *Wildlife Exposure Factors Handbook* (U.S. EPA, 1993) for mink.
[e] The BCF for fish used to calculate an estimated fish DINP concentration, replacing the WIR term.
[f] SIR reported as kg of sediment in diet at a *FIR* of 0.02 based on a mean body weight of 148g (Guy et al., 2018) and sediment ingestion rate of 0.32
[g] Exposure factor (SIR) for mink sourced from EPA's *Second Five Year Review Report Hudson River PCBs Superfund Site Appendix 11 Human Health and Ecological Risks* (U.S. EPA, 2017b).
[h] Fish body weight used to calculate FIR (Guy et al., 2018).
[i] Mink body weight used to calculate P_s sourced from EPA's *Wildlife Exposure Factors Handbook* (U.S. EPA, 1993).
[j] Sediment concentration of DINP obtained using VVWM-PSC modeling.
[k] Surface water concentration of DINP (VVWM-PSC).
[l] Middle level trophic species concentration (mg/kg) calculated from surface water concentration of DINP (VVWM-PSC) and BAF of 209.8 (U.S. EPA, 2017a).
[m] Fish concentration (mg/kg) calculated from benthic pore water concentration of DINP (VVWM-PSC) and estimated BCF of 5.2 (U.S. EPA, 2017a).

As illustrated in Figure 5-1, a representative mammal species was chosen to connect the DINP transport exposure pathway via trophic transfer from earthworm uptake of DINP from contaminated soil through invertivore mammal (short-tailed shrew) species. For semi-aquatic terrestrial species, a representative mammal (American mink) is chosen to connect the DINP exposure pathway via trophic transfer from fish uptake of DINP from contaminated sediment. Additional uptake of DINP in the diet of blacktail redhorse is represented with a diet of mollusk species.

At the screening level, the conservative assumption is that the invertebrate diet for the short-tailed shrew comprises 100 percent earthworms from contaminated soil. The screening level analysis uses the highest monitored soil contaminate level to determine if a more detailed assessment is required.

Exposure factors for food intake rate (FIR) and water intake rate (WIR) were sourced from the EPA's *Wildlife Exposure Factors Handbook* (U.S. EPA, 1993); the exposure factor for sediment intake rate (SIR) was sourced from the EPA's *Second Five Year Review Report Hudson River PCBs Superfund Site Appendix 11 Human Health and Ecological Risks* (U.S. EPA, 2017b). FIR for the blacktail redhorse is represented with daily feed rate reported from apparent satiation in a laboratory growth study for juvenile black buffalo (*Ictiobus niger*) (Guy et al., 2018). The proportion of total food intake that is soil (P_s) is represented at the 90th percentile for short-tailed shrew and was sourced from calculations and modeling in EPA's *Guidance for Developing Ecological Soil Screening Levels* (U.S. EPA, 2005). The proportion of total food intake that is sediment (P_s) for representative taxa (American mink) was calculated by dividing the SIR by food consumption, which was derived by multiplying the FIR by the body weight of the mink (sourced from *Wildlife Exposure Factors Handbook* (U.S. EPA, 1993)). The SIR for American mink was sourced from calculations in EPA's *Second Five Year Review Report Hudson River PCBs Superfund Site Appendix 11 Human Health and Ecological Risks* (U.S. EPA, 2017b).

For the purposes of the current screening level trophic transfer analysis using the blacktail redhorse, EPA has chosen to use a geometric mean of 0.32 for P_s as the proportion of total food intake that is soil (kg soil/kg food) from previously detailed studies (Doyle et al., 2011; Dauble, 1986; Sule and Skelly, 1985). As a conservative assumption, 100 percent of the American mink's diet is predicted to come from fish while 100 percent of the fish diet is predicted to come from a representative middle level trophic species. Similarly, the short-tailed shew was assumed to have a 100 percent diet of earthworm.

The highest concentrations of DINP in soil reported within reasonably available published literature were used to represent DINP concentrations in media for terrestrial trophic transfer. Sediment concentrations modeled via VVWM-PSC were used to represent DINP concentrations in media for trophic transfer to a semi-aquatic mammal (mink) and from fish consuming a middle level trophic species. Additional assumptions for this analysis have been considered to represent conservative screening values (U.S. EPA, 2005). Within this model, incidental oral soil or sediment exposure is added to the dietary exposure (including water consumption at DINP water solubility) resulting in total oral exposure to DINP. In addition, EPA assumes that 100 percent of the contaminant is absorbed from both the soil (AF_{sj}), water (AF_{wj}) and biota representing prey (AF_{ij}). The proportional representation of time an animal spends occupying an exposed environment is known as the area use factor (AUF) and has been set at one for all biota.

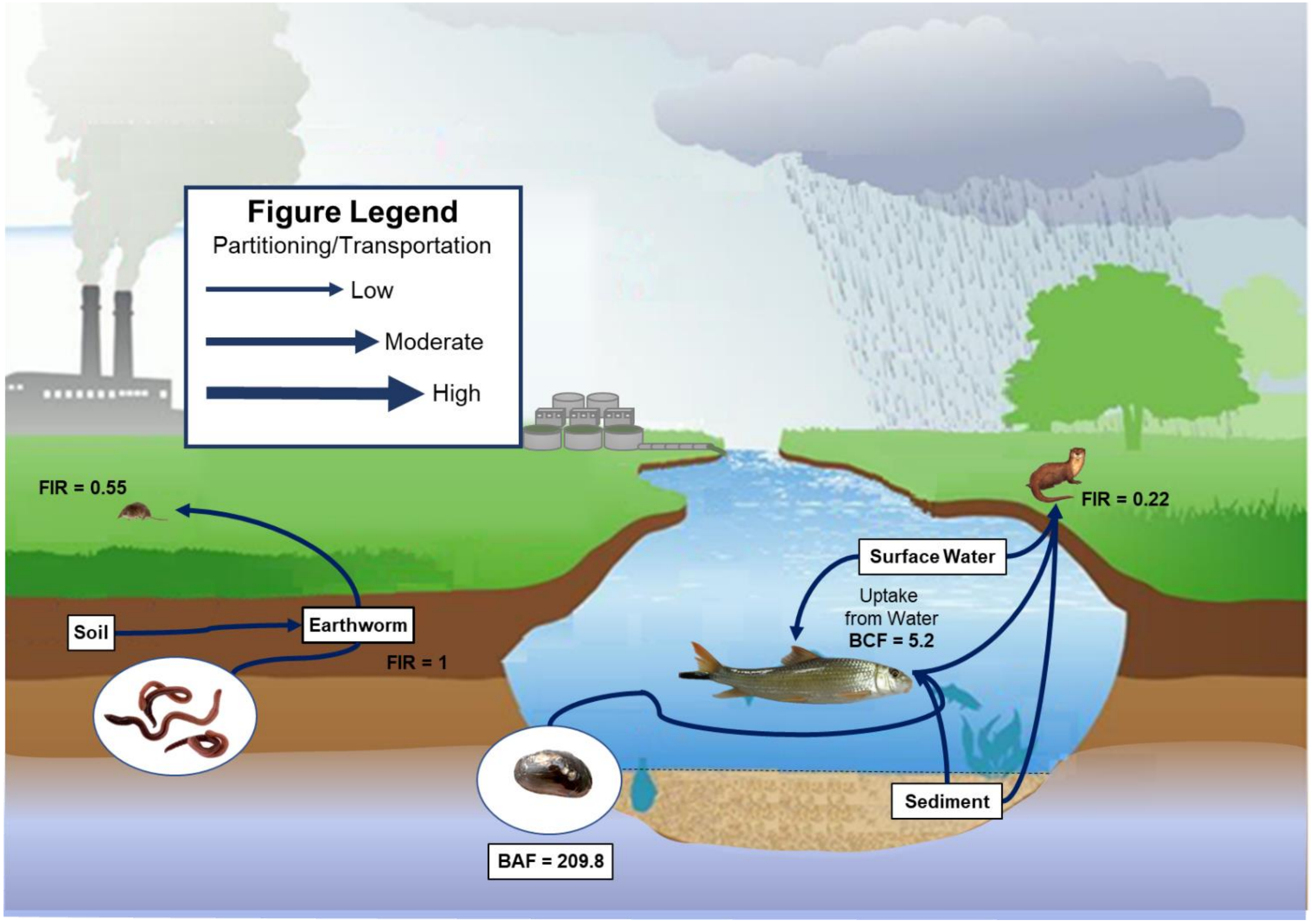

Figure 5-1. Trophic Transfer of DINP in Aquatic and Terrestrial Ecosystems

Values for calculated dietary exposure are shown in Table 5-3 for trophic transfer to shrew from the maximum monitored soil concentration available in published literature. Similarly, Table 5-4 and Table 5-5 show trophic transfer to mink consuming fish and fish consuming a middle level trophic species, respectively. Fish and middle level trophic species concentrations (mg/kg) were calculated using surface water concentrations of DINP from VVWM-PSC.

Values were not calculated for dietary exposure from air deposition to surface water/sediment due to very low water and sediment concentrations resulting from air deposition of a similar chemical with very similar maximum deposition rate (U.S. EPA, 2024a). For example, fugitive air release emissions from a similar chemical (diisodecyl phthalate [DIDP]) were comparable to DINP at 8.5×10^{-3} and 6.8×10^{-3} g/m^2/day at 1,000 m for DIDP and DINP, respectively. When air deposition to water and sediment was quantified in the case of DIDP, the mink dietary exposure through fish consumption was 1.19×10^{-3} mg/kg-bw/day, far below a comparable toxicity reference value (TRV) of 128 mg/kg-bw/day. Therefore, EPA anticipates a similar low dietary exposure of DINP to mink from air deposition to water and sediment and is assessing this pathway qualitatively for DINP.

Table 5-3 Dietary Exposure Estimates Using EPAs Wildlife Risk Model for Eco-SSLs for Screening Level Trophic Transfer of DINP (Air Deposition to Soil) to the Short-Tailed Shrew

COU (Life Cycle Stage/Category/ Sub-category)	OES	Earthworm DINP Concentration (mg/kg-bw) [a]	DINP Dietary Exposure (mg/kg-bw/day) [b]
Processing/Incorporation into formulation, mixture, or reaction product/Plasticizers (adhesives manufacturing, custom compounding of purchased resin; paint and coating manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; wholesale and retail trade; all other chemical product and preparation manufacturing; pigments)	Non-PVC material compounding	0.04	0.02
Published literature [c]			
(Zhang et al., 2015)		0.06	0.03

[a] Estimated DINP concentration in representative soil invertebrate, earthworm, assumed equal to aggregated highest and lowest calculated soil via air deposition to soil (Section 4.2).
[b] Dietary exposure (Equation 5-1) to DINP includes consumption of biota (earthworm), incidental ingestion of soil, and ingestion of water.
[c] The highest concentration of DINP reported in rural soil within reasonably available published literature is 0.06 mg/kg (Zhang et al., 2015).

Table 5-4 Dietary Exposure Estimates Using EPA's Wildlife Risk Model for Eco-SSLs for Screening Level Trophic Transfer of DINP (Releases to Surface Water) to the Fish Eating a Middle Level Trophic Species

COU (Life Cycle Stage/ Category/ Sub-category)	OES	Flow Rate (m^3/day)	DINP Concentration from Ingestion of Sediment (mg/kg-bw/day) [a]	DINP in Middle Level Trophic Species Consumed (mg/kg-bw/d) [b]	Fish DINP Dietary Exposure (mg/kg-bw/day) [c]
Non-PVC Material Compounding	Non-PVC material compounding	P50 7Q10: 24,822	263.0	0.003	263.0
		P90 7Q10: 15,490,000	0.4	0.003	0.4
Published literature					
Sample Collection Conditions/ Location	**Reference (Overall Quality Determination)**				
Maximum concentration of DINP within sediments/ Industrialized harbor, Kaohsiung Harbor, Taiwan	(Chen et al., 2016) (Medium)		0.17	0.003	0.17
Maximum concentration of DINP within sediments/urban areas in Sweden collected by the Swedish National Screening Program, Swedish Environmental Research Institute	(Cousins et al., 2007) (Medium)		0.040	0.003	0.042
Maximum concentrations of DINP found within several large river basins in Germany	(Nagorka and Koschorreck, 2020) (High)		0.021	0.003	0.023

[a] Calculated from Equation 5-2 with factors representing: concentration of DINP in sediment, proportion of food intake that is sediment, food intake rate, and absorbed fraction of DINP from sediment.
[b] Calculated from Equation 5-2 with factors representing: concentration of DINP in prey, proportion of prey in diet, feed intake rate, and absorbed fraction of DINP from prey.
[c] Dietary exposure (Equation 5-2) to DINP includes consumption of biota and ingestion of sediment during feeding.

Table 5-5 Dietary Exposure Estimates Using EPAs Wildlife Risk Model for Eco-SSLs for Screening Level Trophic Transfer of DINP (Releases to Surface Water) to the Mink Eating Fish

COU (Life Cycle Stage/ Category/ Sub-category)	OES	DINP Concentration from Ingestion of Sediment (mg/kg-bw/day) [a]	DINP Concentration in Mink from Water Intake (mg/kg-bw/day) [b]	DINP Concentration in Fish Consumed (mg/kg-bw/day) [c]	Mink DINP Dietary Exposure (mg/kg-bw/day) [d]
Non-PVC Material Compounding	Non-PVC material compounding, P50	4.8	0.00006	57.9	62.7
	Non-PVC material, P90	0.01	0.00006	0.09	0.1
Published literature					
Sample Collection Conditions/ Location	**Reference (Overall Quality Determination)**				
Maximum concentration of DINP within sediments/ Industrialized harbor, Kaohsiung Harbor, Taiwan	(Chen et al., 2016) (Medium)	0.0031	0.00006	0.03	0.041
Maximum concentration of DINP within sediments/ urban areas in Sweden collected by the Swedish National Screening Program, Swedish Environmental Research Institute	(Cousins et al., 2007) (Medium)	0.0007	0.00006	0.009	0.010
Maximum concentrations of DINP found within several large river basins in Germany	(Nagorka and Koschorreck, 2020) (High)	0.0004	0.00006	0.005	0.006

[a] Calculated from Equation 5-2 with factors representing: concentration of DINP in sediment, proportion of food intake that is sediment, food intake rate, and absorbed fraction of DINP from sediment.
[b] Calculated from Equation 5-2 with factors representing: water intake rate, concentration of DINP in surface water, and absorbed fraction of DINP from water.
[c] Calculated from Equation 5-2 with factors representing: concentration of DINP in prey, proportion of prey in diet, feed intake rate, and absorbed fraction of DINP from prey.
[d] Dietary exposure (Equation 5-2) to DINP includes consumption of biota (fish), incidental ingestion of sediment, and ingestion of water.

6 WEIGHT OF SCIENTIFIC EVIDENCE CONCLUSIONS FOR ENVIRONMENTAL EXPOSURE ASSESSMENT

EPA uses several considerations when weighing and weighting the scientific evidence to determine confidence in the dietary exposure estimates. These considerations include the quality of the database, consistency, strength and precision, and relevance (see Appendix A, (U.S. EPA, 2024b)). This approach is in agreement with the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances* (U.S. EPA, 2021). For exposure through trophic transfer EPA considers the evidence for soil invertebrate-eating terrestrial mammals to be moderate and the evidence for fish-consuming aquatic-dependent mammals to be moderate (Table 6-1).

6.1 Strengths, Limitations, Assumptions, and Key Sources of Uncertainty for the Environmental Exposure Assessment

The current environmental exposure and screening level trophic transfer analysis utilized both modeled and monitored data from published literature as a comparative approach. Modeled values from VVWM-PSC for surface water and sediment based on COU/OES estimated water releases from hypothetical facilities resulted in DINP concentrations within surface water and sediment with a confidence rank of slight as reported within the *Draft Environmental Media and General Population Exposure for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024d). EPA has slight confidence in modeled DINP concentrations from AERMOD for air deposition to soil as reported within the above technical support document. EPA has slight confidence in the modeled concentrations as being representative of actual releases, due to the bias toward over-estimation, but robust confidence that no surface water release scenarios exceed the concentrations presented in this evaluation. Other model inputs were derived from reasonably available literature collected and evaluated through EPA's systematic review process for TSCA risk evaluations. All monitoring and experimental data included in this analysis were from articles that received overall quality determinations of "medium" or "high" from this process. Modeled data for aquatic species over-estimated risk to aquatic organisms compared to monitoring values while modeled and monitoring values were less than an order of magnitude different for terrestrial organisms.

6.2 Trophic Transfer Confidence

Quality of the Database; Strength (Effect Magnitude) and Precision

Measured concentrations within aquatic species were represented with empirical biomonitoring data within four studies while measured concentration within terrestrial species were limited to three avian species and ants. Empirical biomonitoring data for aquatic organisms were reasonably available with biota concentrations represented within a variety of aquatic taxa inhabiting False Creek Harbor, Vancouver, British Columbia, Canada, a location characterized by the authors as an urbanized marine ecosystem Lin et al. (2003). Overall, there were four different publications from this same site with sampling conducted on aquatic organisms representing four different trophic levels Mackintosh et al. (2004). The highest DINP concentration within whole fish was observed for juvenile shiner perch, at 588.84 ng/g lipid equivalent, which represents 0.012 mg/kg in the whole fish with a mean lipid content of 2.1 percent (Mackintosh et al., 2004). Within the reasonably available published literature terrestrial species were largely represented by domesticated mammals residing within agricultural and indoor environments and these mammals are not ecologically relevant. One study reported DINP concentration within the muscle of an avian species, surf scooter, at 257.04 ng/g lipid equivalent, which represents 0.0057 mg/kg within the muscle tissue with a mean lipid content of 2.2 percent (Mackintosh et al., 2004). Because some empirical data with several species is represented, the confidence in quality of the database for the chronic mammalian assessment using aquatic-dependent terrestrial species consuming fishes that prey on a middle level trophic species is moderate.

Applying BCF and BAF values for aquatic species was accomplished using predicted and calculated values, respectively. A calculated value was available for a BAF value within a middle level trophic species from (U.S. EPA, 2017a). A predicted BCF was used to represent DINP from surface water exposure to fishes (U.S. EPA, 2017a). Although an empirical BCF was available for earthworm from ECJRC (2003) these data were determined to have an overall quality ranking of low and were not used within this screening level trophic transfer analysis. As a result, the concentration for the earthworm was conservatively set as equivalent to the soil concentration from the AERMOD modeling of air to soil deposition of DINP results with the highest COU/OES based estimated daily deposition rate of DINP (Section 4.2). Because of uncertainty surrounding actual earthworm BCF values in addition to the lack of quality data, the confidence in quality of the database for the chronic mammalian assessment using a worm-eating mammal consuming earthworms as a prey item is moderate.

The use of species-specific exposure factors (*i.e.*, feed intake rate, water intake rate, the proportion of soil or sediment within the diet) from reliable resources assisted in obtaining dietary exposure estimates (U.S. EPA, 2017b, 1993), thereby increasing the confidence for strength and precision, resulting in a moderate confidence for the dietary exposure estimates in terrestrial trophic transfer. Exposure factors for the fish species were obtained to represent potential sediment uptake from feeding activity and included: diet composition (Boschung and Mayden, 2004; Dauble, 1986), feed intake rate (Guy et al., 2018), and the proportion of sediment in diet (Doyle et al., 2011; Dauble, 1986; Sule and Skelly, 1985).

Consistency

The confidence in consistency for the chronic mammalian assessment using a terrestrial invertebrate-eating mammal consuming earthworms as a prey item is moderate. Inputs for DINP concentrations in soil displayed similarities among modeled and monitored concentrations. The highest daily deposition rate for soil concentrations modeled via AERMOD (Section 4.2) is roughly the same order of magnitude to the highest soil concentrations reported within published literature. The modeled concentration was represented by the Non-PVC material compounding OES with deposition to soil 1,000 m from a fugitive source, while the highest concentration within literature was collected from soil characterized as originating from agricultural facilities in the black soil region of northeast China (Zhang et al., 2015). There is no reasonably available literature on daily deposition of DINP from stack or fugitive emissions to soil that can serve as a comparison between modeling results and monitored soil concentrations.

The confidence in consistency for the chronic mammalian assessment using aquatic-dependent terrestrial species consuming fishes that prey on a middle level trophic species (*i.e.*, mussel) is moderate. A moderate confidence ranking is due to uncertainty associated with the predicted BCF value used for fish. There is a large disparity between measured and modeled concentrations of DINP within a middle level trophic species from a modeled BAF value and modeled sediment DINP concentrations for each water release-based COU/OES. This disparity, however, was consistent between the three monitoring values reported. The predicted sediment concentrations were three to four orders of magnitude greater than the highest concentrations of DINP reported within aquatic biota. The modeled data represent estimated concentrations near hypothetical facilities that are actively releasing DINP to surface water, whereas the reported measured concentrations within biota represent sampled taxa with ambient water and sediment concentrations of DINP. Differences in magnitude between modeled and measured concentrations within biota may be due to collections of aquatic species not being geographically or temporally close to known releasers of DINP.

Relevance (Biological and Environmental)

The short-tailed shrew and American mink were selected as appropriate representative mammals for the soil- and aquatic-based trophic transfer analysis, respectively (U.S. EPA, 1993). Overall, the use of exposure factors (*i.e.*, feed intake rate, water intake rate, the proportion of soil within the diet) from a consistent resource assisted in addressing species specific differences for dietary exposure estimates (U.S. EPA, 1993). For this reason, the confidence in biological relevance for the chronic mammalian assessment using a worm-eating mammal consuming earthworms as a prey item is moderate. Selection of a benthic oriented fish species increases confidence with considerations made for sediment ingestion due to feeding behavior and further increases confidence in representing exposure pathways from sediment to aquatic species. The application of conservative assumptions at each trophic level ensures a cautious approach to determining potential risk. Conversely, conservative assumptions associated with a lack of metabolic transformation within prey items such as earthworms and fish decrease the confidence in biological relevance resulting in a slight confidence for biological relevance for the chronic mammalian assessment using an aquatic-dependent terrestrial species.

The screening level trophic transfer analysis investigated dietary exposure resulting from DINP in biota and environmentally relevant media such as soil, sediment, and water. The analysis used equation terms (*e.g.*, area use factor and the proportion of DINP absorbed from diet, and soil or sediment), all set to the most conservative values, emphasizing a conservative approach to estimating exposure to DINP. Assumptions within the trophic transfer equations (Equation 5-1, Equation 5-2) represent conservative screening values (U.S. EPA, 2005), and those assumptions were applied similarly for each trophic level and representative species. The AUF—defined as the home range size relative to the contaminated area (*i.e.*, site ÷ home range = AUF)—was designated as 1 for all organisms, which assumes a potentially longer residence within an exposed area or a large exposure area. These conservative approaches likely overrepresent DINP ability to transfer among the trophic levels; however, this increases confidence that risks are not underestimated. As a result, there is an overall moderate confidence for environmental relevance of the dietary exposure estimates.

The confidence in relevance for the chronic mammalian assessment using a worm-eating mammal consuming earthworms as a prey item is moderate. The confidence in relevance for the chronic mammalian assessment using an aquatic-dependent terrestrial species consuming fishes that prey on a middle level trophic species is moderate.

Table 6-1. DINP Evidence Table Summarizing Overall Confidence Derived for Trophic Transfer

Types of Evidence	Quality of the Database	Strength and Precision	Consistency	Relevance[a]	Trophic Transfer Confidence
Aquatic					
Acute Aquatic Assessment	N/A	N/A	N/A	N/A	N/A
Chronic Aquatic Assessment	N/A	N/A	N/A	N/A	N/A
Aquatic plants (vascular and algae)	N/A	N/A	N/A	N/A	N/A
Terrestrial					
Chronic Avian Assessment	N/A	N/A	N/A	N/A	N/A
Chronic Mammalian Assessment (fish consumption)	++	++	++	++	Moderate
Chronic Mammalian Assessment (terrestrial invertebrate-eating)	++	++	++	++	Moderate

[a] Relevance includes biological and environmental relevance.
+ + + Robust confidence suggests thorough understanding of the scientific evidence and uncertainties. The supporting weight of scientific evidence outweighs the uncertainties to the point where it is unlikely that the uncertainties could have a significant effect on the hazard estimate.
+ + Moderate confidence suggests some understanding of the scientific evidence and uncertainties. The supporting scientific evidence weighed against the uncertainties is reasonably adequate to characterize hazard estimates.
+ Slight confidence is assigned when the weight of scientific evidence may not be adequate to characterize the scenario, and when the assessor is making the best scientific assessment possible in the absence of complete information. There are additional uncertainties that may need to be considered.

7 CONCLUSION OF ENVIRONMENTAL EXPOSURE AND SCREENING LEVEL TROPHIC TRANSFER ANALYSIS

Dietary exposure estimates were calculated based on water and air releases from the COU/OES with the highest modeled environmental releases as reported within the *Draft Environmental Media and General Population Exposure for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024d). The Non-PVC material compounding OES (which encompasses the Non-PVC material compounding COU) resulted in the highest environmental media concentrations from the following media of release/exposure pathways: (1) surface water or wastewater/surface water, sediment; and (2) fugitive or stack air release/air deposition to soil. Although terrestrial hazard data for DINP were not available for mammalian wildlife species, studies in laboratory rodents were used to derive hazard values for mammalian species (U.S. EPA, 2024c). Specifically, empirical toxicity data for mice and rats were used to estimate a TRV for terrestrial mammals of 139 of mg/kg-bw/day (U.S. EPA, 2024c) based on *Guidance for Developing Ecological Soil Screening Levels (Eco-SSLs)* (U.S. EPA, 2003).

Results for calculated dietary exposures of DINP to mammals from modeled concentrations within relevant pathways such as water, sediment, and soil indicated exposure concentrations below the TRV. The conclusion of screening level trophic transfer analyses for aquatic-dependent mammals with exposure pathways for surface water/sediment and air deposition to surface water/sediment are presented within Table 7-1. Maximum concentrations of DINP in surface water and sediment reported within the reasonably available literature were also used to calculate dietary exposure estimates, describing no intersection of exposure of DINP with the calculated TRV from the screening level trophic transfer analysis. The P50 7Q10 flow rate was used in the calculations of modeled dietary estimates as a conservative estimate to aquatic organisms. However, the P90 7Q10 flow rate was also modeled for aquatic exposure and was within an order of magnitude to monitoring values (Table 5-4). Similarly, the screening level trophic transfer analysis for terrestrial mammals based on the highest modeled releases of DINP from air and subsequent deposition to soil also resulted in dietary exposure concentrations below the TRV (Table 7-2). Comparative maximum soil concentrations of DINP in soil (6.0×10^{-2} mg/kg), resulted in dietary exposure concentrations very similar to that of the TRV (Zhang et al., 2015). Exposure pathways with aquatic-dependent mammals and terrestrial mammals as receptors were not examined further since, even with conservative assumptions, dietary DINP exposure concentrations from this analysis are not equal to or greater than the TRV. These results align with previous studies indicating that DINP is not bioaccumulative and will not biomagnify as summarized within U.S. EPA (2024f).

The screening level trophic transfer analyses were conducted with both modeled DINP concentrations from COU/OESs for different media of release and exposure pathways in addition to maximum values reported within reasonably available literature for soil and sediment. Modeled concentrations of DINP within surface water and sediment from hypothetical facility surface water releases have a confidence rank of slight as reported within the *Draft Environmental Media and General Population Exposure for Diisononyl Phthalate (DINP)* (U.S. EPA, 2024d). Maximum concentrations from published literature should be considered to represent DINP concentrations from ambient monitoring within industrialized and urban ecosystems and not direct releases. Conservative approaches within both environmental media modeling (*e.g.*, AERMOD and VVWM-PSC) and the screening level trophic transfer analysis likely overrepresent DINP ability to transfer among the trophic levels; however, this increases confidence that risks are not underestimated. The utilization of these different sources of information as a comparative approach with similar results ensures, with a high degree of confidence, that dietary exposure of DINP does not approach concentrations that cause hazard within mammals.

Table 7-1. Dietary Exposure Estimates for Aquatic-Dependent Mammals Representing the Highest Modeled Environmental Releases to Surface Waters and DINP in Sediment within Published Literature

COU (Life Cycle Stage[a]/Category[b]/ Sub-category[c])	Occupational Exposure Scenario	Media of Release/ Exposure Pathway	Mink DINP Dietary Exposure (mg/kg-bw/day)[d]	DINP TRV for Mammals (mg/kg-bw/day)[e]
Processing/Incorporation into formulation, mixture, or reaction product/Plasticizers (adhesives manufacturing, custom compounding of purchased resin; paint and coating manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; wholesale and retail trade; all other chemical product and preparation manufacturing; pigments)	Non-PVC material compounding, P50	Surface water/ Surface water, sediment	62.7	139
Published literature				
Sample Collection Conditions/Location	**Reference (Overall Quality Determination)**			
Maximum concentration of DINP within sediments/ Industrialized harbor, Kaohsiung Harbor, Taiwan	(Chen et al., 2016) (Medium)		0.040	
Maximum concentration of DINP within sediments/ urban areas in Sweden collected by the Swedish National Screening Program, Swedish Environmental Research Institute	(Cousins et al., 2007) (Medium)		0.010	
Maximum concentrations of DINP found within several large river basins in Germany	(Nagorka and Koschorreck, 2020) (High)		0.006	

[a] Life Cycle Stage Use Definitions (40 CFR 711.3):
"Industrial use" means 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.
Although EPA has identified both industrial and commercial uses here for purposes of distinguishing scenarios in this document, the Agency interprets the authority over "any manner or method of commercial use" under TSCA section 6(a)(5) to reach both.
[b] These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent conditions of use of DINP in industrial and/or commercial settings.
[c] These subcategories reflect more specific conditions of use of DINP.
[d] RQ values calculated for aquatic-dependent terrestrial receptors based on DINP releases to water, wastewater, and/or Wastewater to onsite treatment or discharge to POTW (with or without pretreatment)
[e] Toxicity reference value (TRV) for mammals calculated using empirical toxicity data for rats as detailed within the *Draft Environmental Hazard Assessment Diisononyl Phthalate (DINP)* technical support document (U.S. EPA, 2024d).

Table 7-2. Dietary Exposure Estimates for Terrestrial Mammals Representing the Highest Modeled Environmental Releases of Air and DINP in Soil from Published Literature

<table>
<tr><th>COU (Life cycle stage[a]/Category[b]/ Sub-category[c])</th><th>Occupational Exposure Scenario</th><th>Media of Release/ Exposure Pathway</th><th>Shrew DINP Dietary Exposure (mg/kg-bw/day)[d]</th><th>DINP TRV for Mammals (mg/kg-bw/day)[e]</th></tr>
<tr><td>Processing/Incorporation into formulation, mixture, or reaction product/Plasticizers (adhesives manufacturing, custom compounding of purchased resin; paint and coating manufacturing; plastic material and resin manufacturing; synthetic rubber manufacturing; wholesale and retail trade; all other chemical product and preparation manufacturing; pigments)</td><td>Non-PVC material compounding</td><td>Fugitive air/ Air deposition to soil</td><td>0.02</td><td rowspan="4">139</td></tr>
<tr><td colspan="4">Published literature</td></tr>
<tr><th>Sample Collection Conditions/ Location</th><th colspan="2">Reference (Overall Quality Determination)</th><td></td></tr>
<tr><td>Agriculture facilities distributed across the black soil region of northeast China</td><td colspan="2">(Zhang et al., 2015)</td><td>0.03</td></tr>
<tr><td colspan="5">[a] Life Cycle Stage Use Definitions (40 CFR 711.3):
“Industrial use” means 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.
Although EPA has identified both industrial and commercial uses here for purposes of distinguishing scenarios in this document, the Agency interprets the authority over “any manner or method of commercial use” under TSCA section 6(a)(5) to reach both.
[b] These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent conditions of use of DINP in industrial and/or commercial settings.
[c] These subcategories reflect more specific conditions of use of DINP.
[d] RQ values calculated for terrestrial receptors based on DINP releases to fugitive or stack air and air deposition to soil
[e] TRV for mammals calculated using empirical toxicity data for rats as detailed within the Draft Environmental Hazard Assessment Diisononyl Phthalate (DINP) technical support document (U.S. EPA, 2024d).</td></tr>
</table>

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