### Nontechnical Summary of the TSCA Risk Evaluation for Diisononyl Phthalate (DINP)

(Representative Structure) C<sub>26</sub>H<sub>42</sub>O<sub>4</sub> (CASRNs: 28553-12-0 and 68515-48-0)

### Why Is EPA Providing This Document?

EPA evaluated the risks of DINP to human health and the environment under the Toxic Substances Control Act (TSCA). This document summarizes the results of the completed risk evaluation for DINP.

#### What Is DINP and How Is It Used?

DINP is a clear, oily mixture used primarily as a plasticizer to produce flexible polyvinyl chloride (PVC) for a variety of consumer, commercial, and industrial applications. DINP is also used to manufacture building and construction materials, automotive articles, and other commercial and consumer products such as paints, adhesives, and electronics. There are other domestic uses of DINP that are specifically excluded from TSCA, including medical devices, food contact materials, and cosmetics. EPA's unreasonable risk findings for DINP (described below) cannot be extrapolated to uses of DINP that are not subject to TSCA and that the Agency did not evaluate.

#### **How Might Persons be Exposed to DINP?**

Workers can be exposed to DINP when making or using DINP-containing products in the workplace. During manufacturing, DINP can be released into the water—although most will end up in the sediment of rivers and lakes rather than in sources of drinking water. If DINP is released into the air, it will attach to dust and be deposited

on land or into water. DINP can also be released from indoor products and adhere to dust. If this happens, people could inhale or ingest dust that contains DINP. EPA evaluated all these exposures to determine if there was unreasonable risk to human health.

#### Can DINP Harm People Who Are Exposed?

EPA found that exposure to DINP can harm the developing male reproductive system in laboratory animals, causing what is known as phthalate syndrome. This condition results when male fetuses from DINP-treated rodents produce lower testosterone levels in their testes than in controls. Based on laboratory animal models, high levels of exposure to DINP could also cause cancer, liver, and kidney toxicity.

#### Can DINP Harm the Environment?

DINP is not expected to be harmful to the environment. The 2024 risk evaluation assessed risks to the environment, including to aquatic vertebrates, invertebrates, and plants, such as fish, mussels, and algae. It also assessed risks to terrestrial animals that could be exposed to DINP. EPA found that DINP is not expected to persist in water, sediment, or soil based on its physical and chemical properties. Although DINP might be present in air, concentrations are expected to be well below those that could cause harm to the environment.

### How Has EPA Assessed DINP under TSCA?

In August 2024, EPA published the <u>Draft Risk</u> <u>Evaluation for Diisononyl Phthalate (DINP)</u> that assessed risks to the following groups of people—including potentially exposed or susceptible subpopulations who have higher exposures to DINP or are more likely to be harmed by exposure to DINP:

- workers, including those employed in manufacturing DINP or otherwise use DINP in the workplace;
- consumers, from infants to adults, who have DINP-containing products in their homes;

- subsistence fishers and tribal populations whose diets include large amounts of fish;
- members of the general population who may be exposed through releases of DINP to the environment; and
- people who are more susceptible to the risk of DINP, specifically women of reproductive age/pregnant women, male infants, and male children.

# What Is EPA's Final Risk Determination for DINP under TSCA?

DINP presents an unreasonable risk of injury to human health. EPA did not identify risk of injury to the environment that would contribute to the unreasonable risk determination for DINP.

The Agency is also including DINP in its forthcoming draft cumulative risk assessment of six phthalate chemicals that can cause phthalate syndrome in laboratory animals. EPA has not yet accounted for or considered its cumulative phthalate risk assessment in its risk calculations for DINP. However, based on the draft cumulative risk analysis technical support document, the Agency does not expect any significant changes to risk conclusions for DINP.

Between release of the draft risk evaluation and the finalization of the DINP risk evaluation, EPA updated the risk determination to find that four conditions of use (COUs)<sup>1</sup> significantly contribute to the unreasonable risk of DINP. These updates were based on new information identified by the Agency, information provided by public commenters, and recommendations of the Science Advisory Committee on Chemicals (SACC). These changes stem from consideration of

- multiple factors impacting occupational exposure during spray application of DINP; and
- a determination that the liver effects associated with chronic exposure to DINP are relevant to adult workers, adult consumers, and adult members of the

general population—but not infants and children.

The following TSCA COUs, representing about 3 percent of the U.S. production volume of DINP, significantly contribute to the unreasonable risk of injury to human health of workers:

- Industrial use in adhesives and sealants;
- Industrial use in paints and coatings;
- Commercial use in adhesives and sealants; and
- Commercial use in paints and coatings.

The remaining assessed COUs do *not* significantly contribute to unreasonable risk. For a complete list of COUs, see the Executive Summary of the *Risk Evaluation for Diisononyl Phthalate (DINP)*. These 43 COUs account for the vast majority (about 97%) of DINP production volume in the United States.

# How Will EPA Protect Human Health from DINP under TSCA?

Following a final determination of unreasonable risk, TSCA requires EPA to propose regulations to address the unreasonable risk of DINP. After taking public comment on the proposed regulations, TSCA requires EPA to finalize risk management regulations for DINP. Such regulations could include banning or restricting DINP for specific uses, worker protections, or labeling or recordkeeping requirements.

# For More Technical Information, Including Previous EPA Actions, See the Following:

- Risk Evaluations for Existing Chemicals under TSCA
- <u>Draft Risk Evaluation for Diisononyl</u> <u>Phthalate (DINP)</u>
- <u>Draft Technical Support Document for</u>
   the Cumulative Risk Analysis of DEHP,
   <u>DBP, BBP, DIBP, DCHP, and DINP</u>
   <u>Under the Toxic Substances Control Act</u>
   (TSCA)

manufactured, processed, distributed in commerce, used, or disposed of."

<sup>&</sup>lt;sup>1</sup> Under TSCA, COUs are the specific circumstances, "as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be