Diisononyl phthalates and related compounds: Human health tier II assessment

13 February 2015

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
1,2-Benzenedicarboxylic acid, diisononyl ester	28553-12-0
1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters	68515-40-2
1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9 rich	68515-48-0

Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted and published separately, using information available at the time, and may be undertaken at different tiers.

This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

For more detail on this program please visit:**www.nicnas.gov.au**

Disclaimer

ACRONYMS & ABBREVIATIONS

Grouping Rationale

The Phthalate Esters Panel of the American Chemistry Council (2006 revised) derived three categories of phthalates based on use, physicochemical and toxicological properties. Low molecular weight phthalates (LMWPs) are defined as those produced from alcohols with carbon side-chain lengths of ≤C3. High molecular weight phthalates (HMWPs) are those produced from alcohols with straight or ring-structured carbon chain lengths of ≥C7. A similar definition of HMWPs is used by the Organisation for Economic Co-operation and Development (OECD, 2004). Transitional phthalates were defined as those produced from alcohols with straight or branched carbon chain lengths of C4–6.

On the basis of the ester side-chain length, the chemicals assessed in this report belong to the HMWP category. In addition, the two chemical formulations of DINP (CAS Nos. 28553-12-0 and 68515-48-0), which have been assessed as Priority Existing Chemicals (PECs) by NICNAS (2012), show no statistically distinguishable differences in their toxicological profiles. In B79P (CAS No. 68515-40-2), the esterifying alcohols (on a molar basis) are benzyl (50 %), carbon chain lengths ≥C7 (48 %) and C4–6 (2 %, which is a lower proportion than for the DINPs) (ACC Phthalate Ester Panel, 2006). This chemical also showed no differences from DINP profiles, based on the unpublished report of developmental toxicity registered with the European Chemicals Agency (ECHA) (REACH). DINPs have been also reviewed and considered valid for read-across (filling data gaps) for other members of the HMWP category (OECD, 2004; ACC Phthalate Esters Panel, 2006).

Import, Manufacture and Use

Australian

The following Australian industrial uses were reported for DINPs under previous mandatory and/or voluntary calls for information.

The chemicals have no reported cosmetic use.

The chemicals have no reported domestic use.

The chemicals have reported commercial uses including in:

- automotive products, cable insulations, laminations, sheets, films;
- adhesives, surfactants, printing inks for T-shirts;
- polyvinyl chloride (PVC) and polymer-related products for indoor use such as gaskets, gumboots, vinyl flooring, and carpet backings; and
- children's PVC toys and childcare articles (in imported articles).

The chemicals have reported site-limited use including in plasticisers and solvents for local formulation and processing.

While the above uses of the chemicals are commercial and/or site-limited, the articles produced in factories in Australia and elsewhere have domestic uses, and the chemicals can, over time, leach out into the environment during use.

Information submitted to NICNAS indicated that the chemical B79P is currently not manufactured or imported as a chemical product in Australia, but may be present in finished articles.

International

Internationally, the chemicals have no reported cosmetic use. The chemicals are not listed in the:

- European Commission's Cosmetic Ingredients and Substances (CosIng) database;
- Personal Care Products Council's International Nomenclature Cosmetic Ingredients (INCI) dictionary; or
- Personal Care Products Council's Compilation of Ingredients Used in Cosmetics in the US (CIUCUS, 2011).

The following international uses have been identified through the European Union Registration, Evaluation, Authorisation and Restriction of Chemicals (EU REACH) dossiers; EU Risk Assessment Report (ECB, 2003); Galleria Chemica; Substances in Preparations in Nordic countries (SPIN) database; United States (US) National Library of Medicine Household Products database; Hazardous Substances Data Bank (HSDB); and eChemPortal.

Members of this group have reported domestic use including:

- DINP (CAS No. 68515-48-0) in lacquers for home maintenance (aerosol, liquid).

The chemicals have reported commercial use including in:

- rubbers and PVC plastic products including fillers, construction materials, insulation materials, transport equipment, building interiors, vinyl floors and walls, vehicle interiors, electrical batteries and accumulators;
- non-polymer applications such as adhesives, sealants, lubricants, coatings, paints, lacquers, varnishes, printing inks for fabrics, textiles and apparel; and
- soft mouthable toys for children.

The chemical has reported site-limited use including in:

- plasticisers for manufacturing PVC and polymer-related applications;
- solvents for diluting organic peroxides; and

- intermediates for manufacture and formulation.

Restrictions

Australian

No known restrictions have been identified.

International

DINPs (CAS No. 28553-12-0 and 68515-48-0) are listed in the European Commission (EC) Annex XVII to REACH Regulation (Entry 52; EC, 2014): DINPs 'shall not be used as substances or in mixtures, in concentrations greater than 0.1 % by weight of the plasticised material, in toys and childcare articles which can be placed in the mouth by children. Such toys and childcare articles containing these phthalates in a concentration greater than 0.1 % by weight of the plasticised material shall not be placed on the market.'

These chemicals are also candidates for further restrictions as they are listed on:

- the US Environmental Protection Agency's (EPA) Phthalates Action Plan (US EPA, 2012a revised), which is an initiative to address the manufacturing, processing, distribution in commerce, and/or use of eight phthalates, including DINP;
- the US EPA's Universe of Chemicals list for potential endocrine disruptor screening and testing (DINP CAS No. 28553-12-0) (US EPA, 2012b); and
- Environment Canada's Categorisation Results of Domestic Substances List (DSL) as moderate priorities for further work (DINP CAS No. 28553-12-0) (Environment Canada).

Existing Worker Health and Safety Controls

Hazard Classification

The chemicals are not listed on the Hazardous Substances Information System (HSIS) (Safe Work Australia).

Exposure Standards

Australian

No specific exposure standards are available.

International

Workplace Exposure Standards:

TWA (time weighted average) = 5 mg/m^3 (New Zealand; United Kingdom)

STEL (short-term exposure limit) = 5 mg/m^3 (Sweden)

LTEL (long-term exposure limit) = 5 mg/m^3 (United Kingdom)

Health Hazard Information

The hazard findings for DINPs (NICNAS, 2012) will be taken to be representative of this group.

Toxicokinetics

Orally administered DINPs and related compounds are rapidly absorbed. Following high single doses or repeated dosing in rodents, the oral absorption of the chemicals may become saturated and incomplete. No information on the total excretion via all routes and/or the extent of faecal excretion (whether as the result of bile elimination or saturated urinary excretion) is available. Therefore, the oral bioavailability of the chemicals is considered to be 100 % for both adults and children. Bioavailability from dermal absorption is unlikely to exceed 4 % of the applied dose in humans. Absorption of inhaled DINPs is considered negligible due to their low vapour pressure.

Tissue distribution of the chemicals is widespread, however there is no evidence of accumulation in the body.

The chemicals are also rapidly hydrolysed to a corresponding phthalate monoester, which is further metabolised to form oxidative metabolites and a small quantity of phthalic acid. The chemicals DINPs are metabolised to monoisononyl phthalate (MINP), then to carboxy-MINP, hydroxy-MINP, and oxo-MINP. These metabolites are rapidly and almost completely excreted in urine and faeces, as well as the unabsorbed and unmetabolised parent chemicals (NICNAS, 2012).

Acute Toxicity

Oral

The chemicals are expected to have low acute oral toxicity. The median lethal doses (LD50) of DINPs in rodents are >2000 mg/kg bw and consistent across the group (ACC Phthalate Esters Panel, 2006; NICNAS, 2012; REACH).

Dermal

The chemicals are expected to have low acute dermal toxicity. The median lethal doses (LD50) of DINPs in rodents are >2000 mg/kg bw and consistent across the group where data are available (ACC Phthalate Esters Panel, 2006; NICNAS, 2012; REACH).

Inhalation

The chemicals are expected to have low acute inhalational toxicity. No mortalities, body weight changes, gross lesions or microscopic alterations of the lungs, liver or kidneys were observed in rats following aerosol exposure of DINP at 4.4 mg/L/4 hour (NICNAS, 2012; REACH).

Corrosion / Irritation

Skin Irritation

The available data suggest that the chemicals cause minimal skin irritation (NICNAS, 2012; REACH).

Eye Irritation

The available data suggest that the chemicals cause minimal eye irritation (NICNAS, 2012; REACH).

Sensitisation

Skin Sensitisation

The available data suggest that the chemicals are not likely to be skin sensitisers in humans (NICNAS, 2012).

Repeated Dose Toxicity

Oral

Repeated oral exposure to DINPs caused adverse effects to the liver and kidneys of rodents, including increased organ weights, and biochemical and histopathological changes. These effects were found to be less pronounced in dogs and primates. Therefore, they are considered indicative of adaptative effects or associated with the peroxisomal proliferation, which are not relevant to humans (ECB, 2003; NICNAS, 2012). According to OECD (2004), the findings were consistent across the HMWP category.

Spongiosis hepatis was also observed after long-term DINP exposure, although this effect is not considered relevant for a human health risk assessment. This is addressed in detail in the DINP PEC assessment (NICNAS, 2012).

A no observed adverse effect level (NOAEL) of 88 mg/kg bw/d is determined for DINP based on liver changes unrelated to peroxisome proliferation and on increased kidney weights in both sexes (ECB, 2003; NICNAS, 2012). Read-across of this NOAEL can be applied to other members in this group.

Dermal

Repeated dermal exposure to DINPs caused no systemic effects (ECB, 2003; NICNAS, 2012). Thus, the chemicals are not expected to be hazardous via dermal route.

Genotoxicity

The available data do not support a mutagenic or genotoxic potential of the chemicals in humans.

In vitro bacterial, mammalian or cytogenetic mutations assays showed that DINPs were not mutagenic. DINPs were also not clastogenic in an in vivo bone marrow assay (ECB, 2003; OECD, 2004; NICNAS, 2012; REACH). Similarly, B79P was also not mutagenic in all strains in an Ames test (US EPA HPVIS).

Carcinogenicity

Based on the weight of evidence, the available data do not support a carcinogenic potential for the chemicals in humans.

Although incidences of mononuclear cell leukaemia (MCL), and kidney and liver neoplasia were observed with DINP exposure in rodent carcinogenicity studies, they are considered species specific and not relevant to humans (ECB, 2003; OECD, 2004; NICNAS, 2012; REACH).

Reproductive and Developmental Toxicity

DINPs have been well characterised for the reproductive and developmental toxicity endpoints.

According to the NICNAS (2013) PEC assessment, DINPs have no effects on mating, fertility, fecundity, gestational length or index in rat studies. Although quantitatively being less potent than C4–6 phthalates (e.g. diethylhexyl phthalate (DEHP) and dibutyl phthalate (DBP)), DINPs have exhibited adverse effects on the male reproductive system and sexual differentiation during development in a number of rodent studies. They include increased nipple retention, reduced testosterone and testes weight, testicular pathology and decreased anogenital distance (AGD) and/or anogenital index (AGI), which are components of the antiandrogenic pattern observed with DEHP, the well-studied potent phthalate. Foetal expression of genes involved in androgen synthesis such as StAR and Cyp11a was also reduced. There was also a report of increased gene expression of Insl3 (a foetal Leydig cell product critical for testes descent) that might indicate impaired testicular steroidogenesis following exposure to DINPs at high doses (e.g. =750 mg/kg bw/d).

For fertility-related (or sexual developmental) effects, an overall NOAEL of 50 mg/kg bw/d is determined based on the collective study results and weight of evidence.

Pup weight was reduced at approximately 100 mg/kg bw/d in both sexes, both in one- and two-generation reproductive studies in rats, in the absence of overt maternal toxicity. The pup weight reduction was also sustained after birth and continued to postnatal day (PND) 21, and is not considered solely related to low birth weight. In a postnatal toxicity study, reduced pup weight was also observed at =250 mg/kg bw/d on PND 14. Therefore, this adverse effect of DINPs is assessed as the most sensitive endpoint on offspring growth and development.

For developmental effects, a NOAEL of 50 mg/kg bw/d is established based on the reduced pup weight =100 mg/kg bw/d.

Overall, the available human data do not provide sufficient evidence for a causal relationship between exposure to DINP and possible adverse health effects in humans. There are also uncertainties regarding the exact mechanism by which DINPs affect male reproductive tract development and sexual function in comparison with well-studied transitional C4–6 phthalates. However, elements of a plausible mode of action for the DINP effects on the male reproductive system, offspring growth and sexual differentiation are considered parallel in rats and humans if the exposure to DINP is high and within a critical window of development. Therefore, the reproductive and developmental toxicity effects of DINPs observed in animal studies are regarded as relevant to humans.

Other Health Effects

Neurotoxicity

DINPs at ≥900 mg/kg bw/d affected spatial learning and increased masculinisation of behaviour in female offspring. However, these findings are preliminary (NICNAS, 2012).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include increased kidney and liver weights with histopathological changes in the liver unrelated to peroxisome proliferation (repeated dose toxicity) and reduced pup weight, testosterone and altered sexual differentiation (developmental and fertility-related toxicity).

Public Risk Characterisation

For children, the NICNAS PEC assessment has indicated that the risks of DINP adverse effects from direct exposure in consumer products (via handling and mouthing toys and childcare articles containing up to 43 % DINP) are low (NICNAS, 2012).

For adults, the risks from direct exposure are expected to be negligible given the average concentration of DINPs in the PVC material is about 13–16 % w/w (Cousins et al., 2014). There is no reported use of DINPs and B79P in home maintenance products in Australia.

The public health risks for the general population (without occupational sources) and children (with or without mouthing toys) from all exposure sources (including indirect exposures via the environment) to the chemicals are also considered low, based on the evaluation of margins of exposure (MOEs). This approach compares the NOAEL of 50 mg/kg bw/d for reproductive effects with the following intake estimates of DINP, deriving MOEs of >100 (i.e. adequate safety margin):

—from biomonitoring data (95th percentile)

- <LOD (limit of detection) to 39.62 µg/kg bw/d (reviewed by Kransler et al., 2012)
- 11.7–13.9 µg/kg bw/d (measured as oxidative metabolites of DINP) (Christensen et al., 2014)

—from exposure models (worst-case estimates)

- 0.28–410 µg/kg bw/d (ECB 2003; Kransler et al., 2012).

The above estimates are cumulative, including all sources of exposure. Modelling shows that exposure without mouthing behaviour places individuals at the low end of the range.

Occupational Risk Characterisation

During product formulation, dermal and inhalational exposure of workers to the chemicals might occur, particularly where manual or open processes are used. These may include transfer and blending activities, quality control analysis, and cleaning and maintenance of equipment. Worker exposure to the chemicals at lower concentrations may also occur while using formulated products containing the chemicals. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the critical long-term systemic and reproductive effects, the chemicals could pose an unreasonable risk to workers (especially pregnant and breastfeeding women) unless adequate control measures to minimise occupational exposures are implemented.

NICNAS Recommendation

Based on the currently available data, there are clear indications of effects associated with development of male offspring of dams treated with DINPs and B79P. However, NICNAS does not consider reversible effects on components of the endocrine system or reversible outcomes of these hormonal perturbations or other related measurements to be necessarily adverse. Where these changes can be shown to lead to adverse outcomes affecting the ongoing functioning of the organism, it is these adverse outcomes that are used as the driver for recommending risk management measures. The available data do not conclusively demonstrate the presence of adverse effects. Therefore, provision of further information, in particular a new standardised two-generation study (preferably using a dose range sufficient for dose-response characterisation and containing high doses of around 1000 mg/kg bw/d) would be required in order to ascertain the adverse outcomes of these observed antiandrogenic effects of DINPs and B79P.

It is recommended that, should the new information become available, a Tier III assessment of hazard properties of DINPs, B79P and related compounds and subsequent effects on male offspring development be conducted to ascertain an appropriate GHS/HSIS classification.

Regulatory Control

Advice for consumers

Products containing the chemicals should be used according to the instruction on the label.

Advice for industry

Control measures

Control measures to minimise the risk from dermal and inhalational exposure to the chemicals should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate or minimise risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemical is used. Examples of control measures which may minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- health monitoring for any worker who is at risk of exposure to the chemical if valid techniques are available to monitor the effect on the worker's health;
- minimising manual processes and work tasks through automating processes;
- work procedures that minimise splashes and spills;
- regularly cleaning equipment and work areas; and
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemicals.

Guidance on managing risks from hazardous chemicals are provided in the *Managing risks of hazardous chemicals in the workplace—Code of practice* available on the Safe Work Australia website.

Personal protective equipment should not solely be relied upon to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selecting personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Obligations under workplace health and safety legislation

Information in this report should be taken into account to assist with meeting obligations under workplace health and safety legislation as adopted by the relevant state or territory. This includes, but is not limited to:

- ensuring that hazardous chemicals are correctly classified and labelled;
- ensuring that (material) safety data sheets ((m)SDS) containing accurate information about the hazards (relating to both health hazards and physicochemical (physical) hazards) of the chemicals are prepared; and
- managing risks arising from storing, handling and using a hazardous chemical.

Your work health and safety regulator should be contacted for information on the work health and safety laws in your jurisdiction.

Information on how to prepare an (m)SDS and how to label containers of hazardous chemicals are provided in relevant codes of practice such as the *Preparation of safety data sheets for hazardous chemicals— Code of practice* and *Labelling of workplace hazardous chemicals—Code of practice*, respectively. These codes of practice are available from the Safe Work Australia website.

A review of the physical hazards of the chemical(s) has not been undertaken as part of this assessment.

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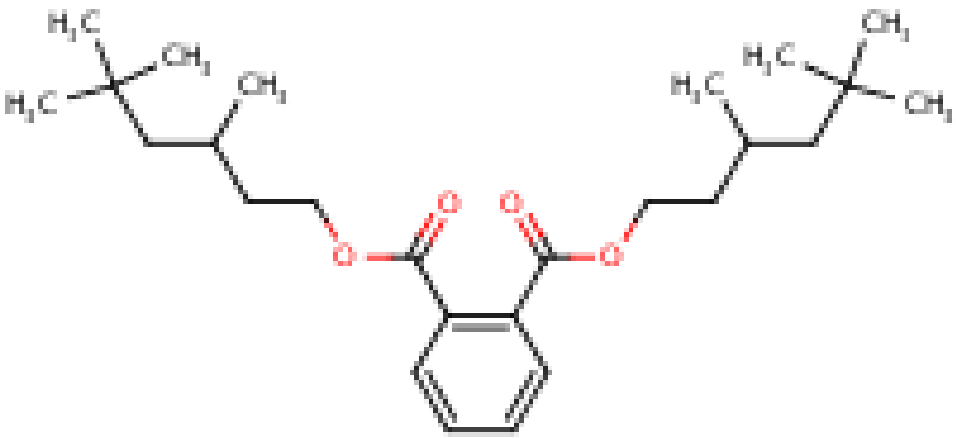
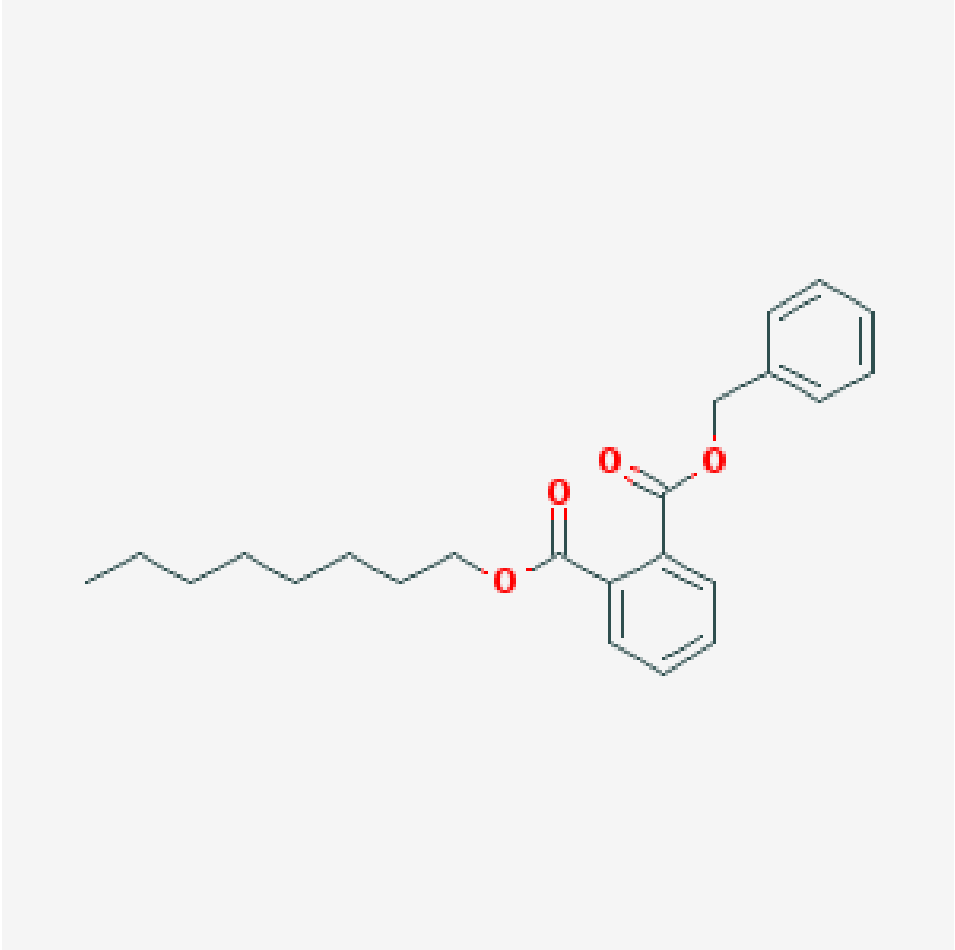
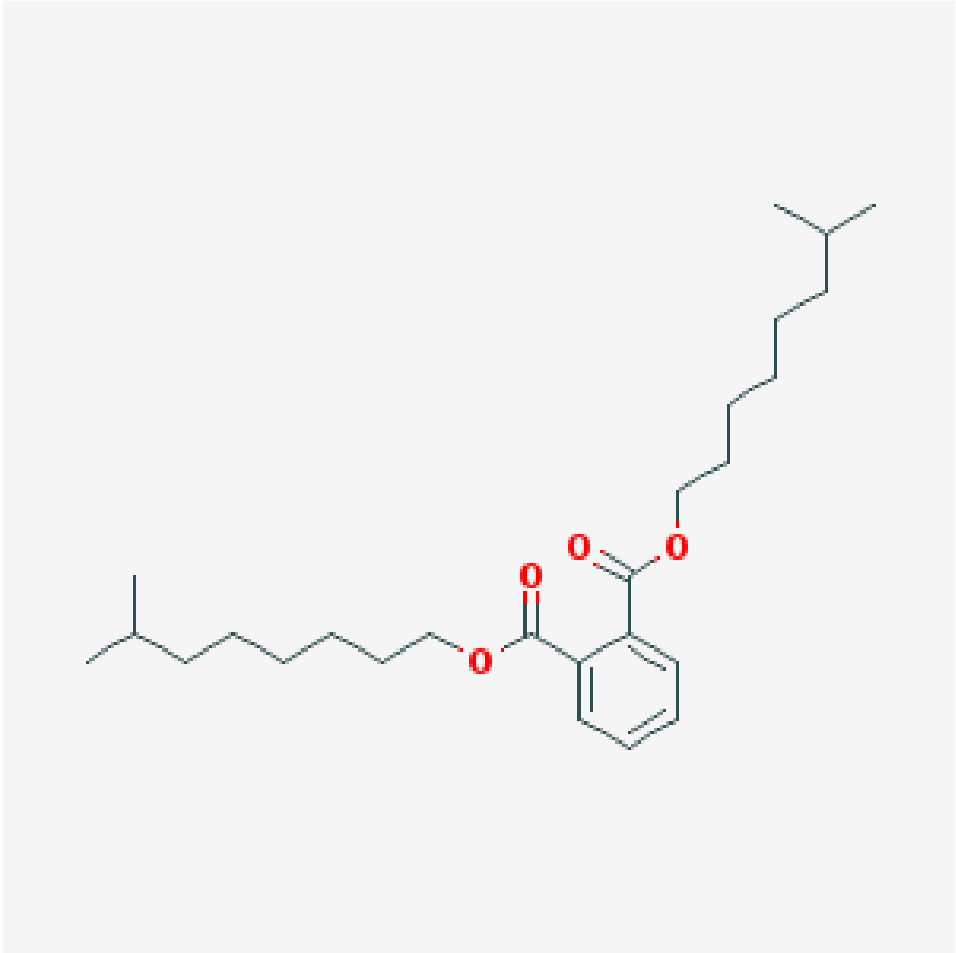
Chemical Identities

Chemical Name in the Inventory and Synonyms	**1,2-Benzenedicarboxylic acid, diisononyl ester** DINP Diisononyl phthalate Phthalic acid, diisononyl ester
CAS Number	28553-12-0
Structural Formula	
Molecular Formula	C26H42O4
Molecular Weight	418.61

Chemical Name in the Inventory and Synonyms	**1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters**

	B79P Benzyl C7-9-branched and linear alkyl phthalates Phthalic acid, benzyl alkyl(C7-C8) ester
CAS Number	68515-40-2
Structural Formula	
Molecular Formula	Unspecified
Molecular Weight	549.81

Chemical Name in the Inventory and Synonyms	**1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9 rich** DINP Di(isononyl) phthalate branched Diisononyl phthalate, technical grade Di(C8-10, C9 rich) branched alkyl phthalates
CAS Number	68515-48-0
Structural Formula	

	
Molecular Formula	Unspecified
Molecular Weight	415.61

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