

Phthalate esters: Environment tier II assessment

08 March 2019

CAS Registry Number: 84-69-5, 84-74-2, 117-82-8, 84-64-0, 85-68-7, 84-62-8, 84-61-7, 84-75-3, 523-31-9, 27987-25-3, 71486-48-1, 3648-21-3, 117-81-7, 27554-26-3, 117-84-0, 68515-50-4, 68515-51-5, 68515-40-2, 83897-81-8, 71888-89-6, 68515-44-6, 68515-41-3, 68515-42-4.



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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

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Acronyms & Abbreviations

Grouping Rationale

This Tier II assessment considers the environmental risks associated with the industrial uses of twenty four chemicals and substances which are either discrete di-esters of *ortho*-phthalic acid (phthalate esters), or they are variable mixtures of these esters.

The majority of chemicals in this group are di-esters of linear or branched aliphatic alcohols containing four to eight carbon atoms. The assessment of these chemicals and substances has been conducted as a group because they are likely to be more hazardous to the environment than the homologous di-esters of shorter-chain alcohols (alcohols with one to three carbon atoms) or longer-chain alcohols (alcohols with nine or more carbon atoms). A similar grouping approach has been used by other regulatory agencies in their environmental risk assessments of these chemicals and substances.

It is also known that phthalates with ester groups containing a continuous chain of four to six carbon atoms have high reproductive toxicity. This toxicity diminishes rapidly when the continuous chain exceeds six carbon atoms. Some phthalate esters with continuous chains of seven or eight carbon atoms have been included in this assessment because they provide useful supporting evidence for conclusions regarding the trends in toxicity, other than specific reproductive toxicity, across this group of chemicals.

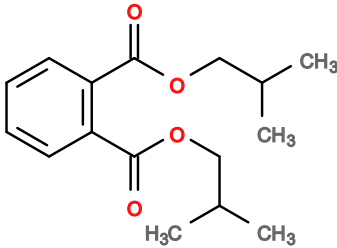
While di(methoxyethyl) phthalate (DMEP) does not strictly meet the above description, its close structural resemblance to dibutyl phthalate makes it appropriate to include in this assessment.

The chemicals in this group share a common major use as plasticisers, particularly in polyvinyl chloride (PVC) products and articles. A variety of other uses have been identified, including construction materials, paints, and adhesives. Phthalate esters are used in significant volumes worldwide, and they are released into the environment as a result of their industrial uses.

Many of the phthalate esters in this group have been subject to regulatory action over the past two decades due to concerns about the risks they pose to human health, particularly to children. As a result, uses of chemicals in this group in cosmetics and in toys and childcare articles have been restricted or prohibited.

The Tier I assessments of chemicals in this group found that they are of potential concern to the environment based on unacceptably high risk quotients for emissions to surface waters in the treated effluent discharged from sewage treatment plants (STP), and because some have endocrine activity. A more in-depth assessment at Tier II level was recommended under the IMAP framework.

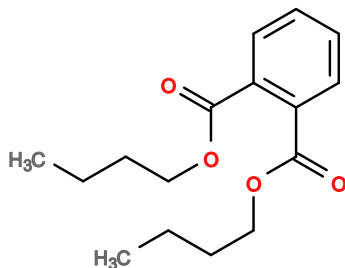
Chemical Identity

CAS RN	84-69-5
Chemical Name	1,2-Benzenedicarboxylic acid, bis(2-methylpropyl) ester
Synonyms	diisobutyl phthalate (DIBP)
Structural Formula	
Molecular Formula	C ₁₆ H ₂₂ O ₄
Molecular Weight (g/mol)	278.34
SMILES	C(=O)(c1c(C(=O)OCC(C)C)cccc1)OCC(C)C

CAS RN	84-74-2
Chemical Name	1,2-Benzenedicarboxylic acid, dibutyl ester

Synonyms dibutyl phthalate (DBP)

Structural Formula



Molecular Formula $C_{16}H_{22}O_4$

Molecular Weight (g/mol) 278.34

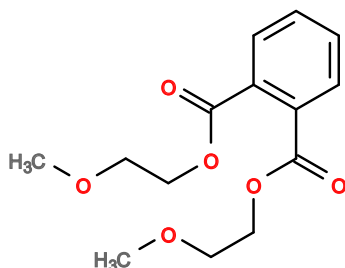
SMILES C(=O)(c1c(C(=O)OCCCC)cccc1)OCCCC

CAS RN 117-82-8

Chemical Name 1,2-Benzenedicarboxylic acid, bis(2-methoxyethyl) ester

Synonyms dimethoxyethyl phthalate (DMEP)

Structural Formula



Molecular Formula $C_{14}H_{18}O_6$

Molecular Weight (g/mol) 282.29

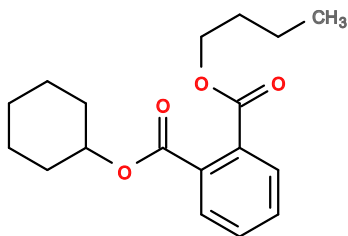
SMILES C(=O)(c1c(C(=O)OCCOC)cccc1)OCCOC

CAS RN 84-64-0

Chemical Name 1,2-Benzenedicarboxylic acid, butyl cyclohexyl ester

Synonyms butyl cyclohexyl phthalate (BCHP)

Structural Formula



Molecular Formula $C_{18}H_{24}O_4$

Molecular Weight (g/mol) 304.38

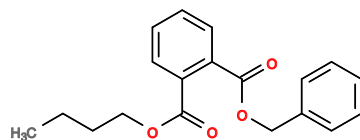
SMILES O=C(OC(CCCC1)C1)c(c(ccc2)C(=O)OCCCC)c2

CAS RN 85-68-7

Chemical Name 1,2-Benzenedicarboxylic acid, butyl phenylmethyl ester

Synonyms butyl benzyl phthalate (BBzP)

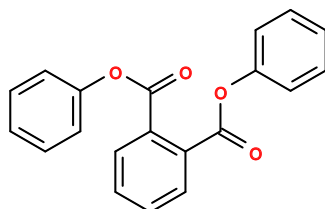
Structural Formula



Molecular Formula	C ₁₉ H ₂₀ O ₄
Molecular Weight (g/mol)	312.36
SMILES	C(=O)(c1c(C(=O)OCc2ccccc2)cccc1)OCCCC

CAS RN	84-62-8
Chemical Name	1,2-Benzenedicarboxylic acid, diphenyl ester
Synonyms	diphenyl phthalate (DPhP)

Structural Formula



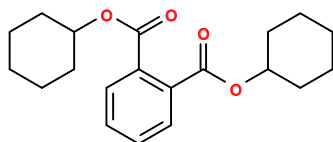
Molecular Formula	C ₂₀ H ₁₄ O ₄
Molecular Weight (g/mol)	318.32
SMILES	O=C(Oc(cccc1)c1)c(c(ccc2)C(=O)Oc(cccc3)c3)c2

CAS RN	84-61-7
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Chemical Name 1,2-Benzenedicarboxylic acid, dicyclohexyl ester

Synonyms dicyclohexyl phthalate (DCHP)

Structural Formula



Molecular Formula $C_{20}H_{26}O_4$

Molecular Weight (g/mol) 330.42

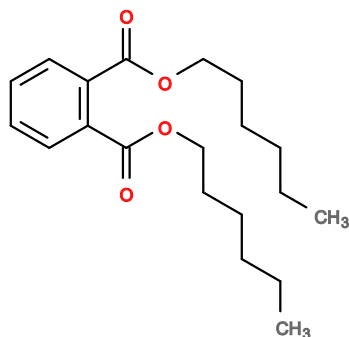
SMILES C(=O)(c1c(C(=O)OC2CCCCC2)cccc1)OC1CCCCC1

CAS RN 84-75-3

Chemical Name 1,2-Benzenedicarboxylic acid, dihexyl ester

Synonyms di-*n*-hexyl phthalate (DNHP)

Structural Formula



Molecular Formula $C_{20}H_{30}O_4$

Molecular Weight (g/mol) 334.45

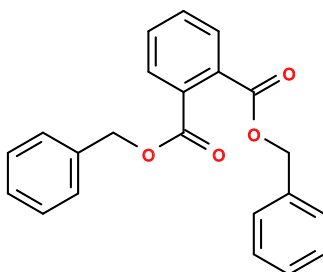
SMILES C(=O)(c1c(C(=O)OCCCCC)cccc1)OCCCCC

CAS RN 523-31-9

Chemical Name 1,2-Benzenedicarboxylic acid, bis(phenylmethyl) ester

Synonyms dibenzyl phthalate (DBzP)

Structural Formula



Molecular Formula $C_{22}H_{18}O_4$

Molecular Weight (g/mol) 346.38

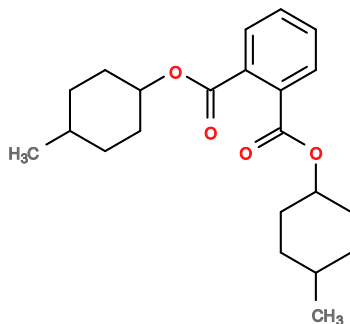
SMILES c1(COC(=O)c2c(C(=O)OCc3ccccc3)cccc2)cccc1

CAS RN 27987-25-3

Chemical Name 1,2-Benzenedicarboxylic acid, bis(methylcyclohexyl) ester

Synonyms dimethylcyclohexyl phthalate (DMCHP)

Structural Formula



Molecular Formula $C_{22}H_{30}O_4$

Molecular Weight (g/mol) 358.48

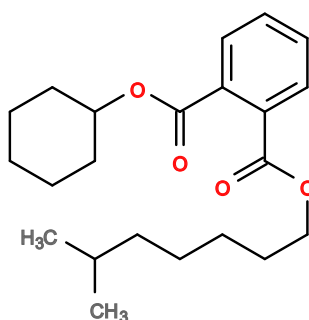
SMILES C1CC(C)CCC1OC(=O)c2ccccc2C(=O)OC3CCC(C)CC3

CAS RN 71486-48-1

Chemical Name 1,2-Benzenedicarboxylic acid, cyclohexyl isooctyl ester

Synonyms cyclohexyl isooctyl phthalate (CHIO)

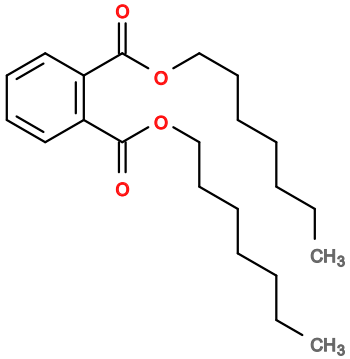
Structural Formula



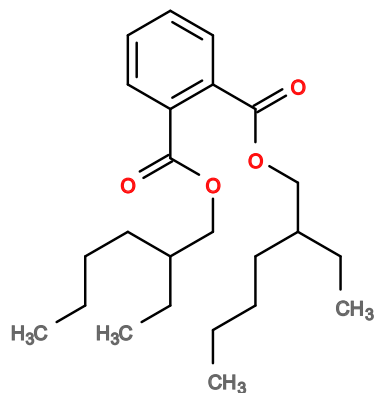
Molecular Formula $C_{22}H_{32}O_4$

Molecular Weight (g/mol) 360.50

SMILES	<chem>O=C(c1ccccc1C(=O)OCCCCC(C)C)OC2CCCCC2</chem>
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CAS RN	3648-21-3
Chemical Name	1,2-Benzenedicarboxylic acid, diheptyl ester
Synonyms	di- <i>n</i> -heptyl phthalate (DNHPP)
Structural Formula	
Molecular Formula	C ₂₂ H ₃₄ O ₄
Molecular Weight (g/mol)	362.50
SMILES	<chem>C(=O)(c1c(C(=O)OCCCCC(C)C)cccc1)OCCCCC(C)C</chem>

CAS RN	117-81-7
Chemical Name	1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester
Synonyms	diethylhexyl phthalate (DEHP)
Structural Formula	



Molecular Formula $C_{24}H_{38}O_4$

Molecular Weight (g/mol) 390.56

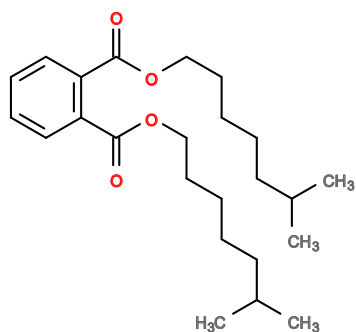
SMILES C(=O)(c1c(C(=O)OCC(CCCC)CC)cccc1)OCC(CCCC)CC

CAS RN 27554-26-3

Chemical Name 1,2-Benzenedicarboxylic acid, diisooctyl ester

Synonyms diisooctyl phthalate (DIOP)

Structural Formula



Molecular Formula $C_{24}H_{38}O_4$

Molecular Weight (g/mol) 390.56

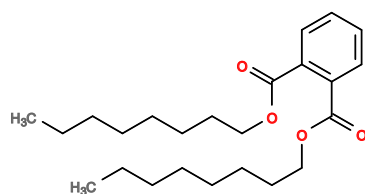
SMILES C(=O)(c1c(C(=O)OCCCCC(C)C)ccc1)OCCCCC(C)C

CAS RN 117-84-0

Chemical Name 1,2-Benzenedicarboxylic acid, dioctyl ester

Synonyms di-*n*-octyl phthalate (DNOP)

Structural Formula



Molecular Formula $C_{24}H_{38}O_4$

Molecular Weight (g/mol) 390.56

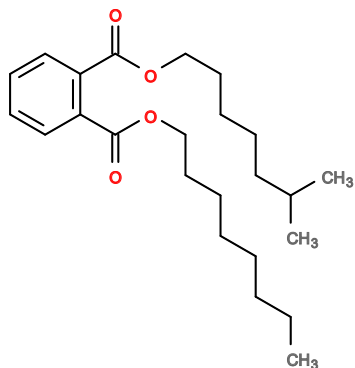
SMILES C(=O)(c1c(C(=O)OCCCCCCCC)ccc1)OCCCCCCCC

CAS RN No CAS RN

Chemical Name 1,2-Benzenedicarboxylic acid, isooctyl capryl ester

Synonyms IOCP

Representative Structural Formula



Molecular Formula $C_{24}H_{38}O_4$

Molecular Weight (g/mol) 390.56

SMILES C(=O)(c1c(C(=O)OCCCCCCC)ccc1)OCCCCC(C)C

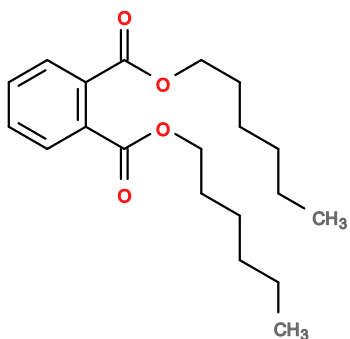
The following group of substances are all substances of unknown or variable composition, complex reaction products, or of biological origin (UVCBs). Representative chemical identify information is provided, but it should be noted that each substance will include a mixture of discrete *ortho*-phthalic acid di-ester isomers and/or homologues.

CAS-RN 68515-50-4

Chemical Name 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear

Synonyms dihexyl phthalate (DHP)

Representative Structural Formula



Molecular Formula $C_{20}H_{30}O_4$

Molecular Weight (g/mol) 334.45

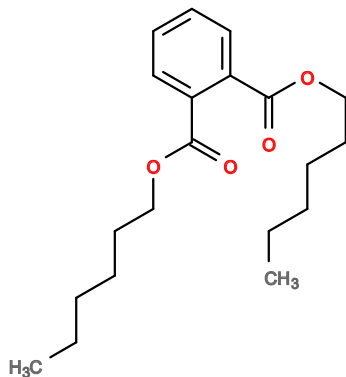
SMILES C(=O)(c1c(C(=O)OCCCCC)cccc1)OCCCCC

CAS RN 68515-51-5

Chemical Name 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters

Synonyms 610P

Representative Structural Formula



Molecular Formula $C_{20}H_{30}O_4$

Molecular Weight (g/mol) 334.45

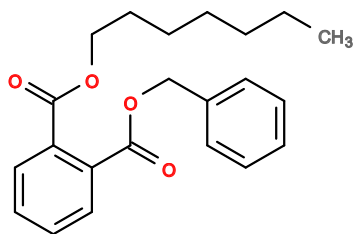
SMILES O=C(c1cccc1C(=O)OCCCCC)OCCCCC

CAS RN 68515-40-2

Chemical Name 1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters

Synonyms Bz79P

Representative Structural Formula



Molecular Formula $C_{22}H_{26}O_4$

Molecular Weight (g/mol) 354.44

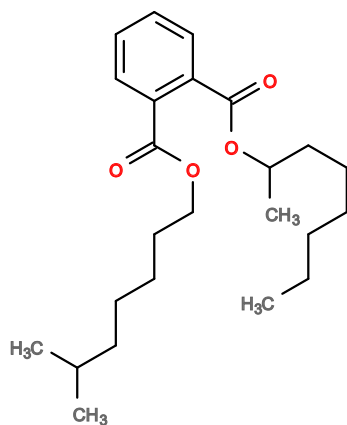
SMILES C(=O)(c1c(C(=O)OCc2ccccc2)cccc1)OCCCCCCC

CAS RN 83897-81-8

Chemical Name 1,2-Benzenedicarboxylic acid, mixed isooctyl and 1-methylheptyl esters

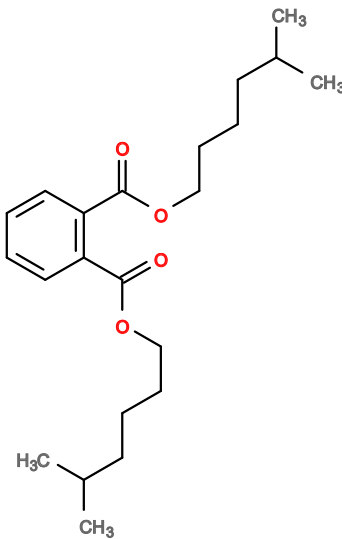
Synonyms 8P

Representative Structural Formula



Molecular Formula $C_{24}H_{38}O_4$

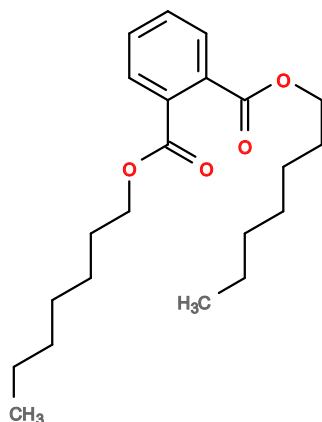
Molecular Weight (g/mol)	390.56
SMILES	<chem>CCCCCCC(C)OC(=O)c1ccccc1C(=O)OCCCCCCC(C)C</chem>

CAS RN	71888-89-6
Chemical Name	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7 rich
Synonyms	diisoheptyl phthalate (DIHpP)
Representative Structural Formula	
Molecular Formula	$C_{22}H_{34}O_4$
Molecular Weight (g/mol)	362.50
SMILES	<chem>C(=O)(c1c(C(=O)OCCCC(C)C)cccc1)OCCCC(C)C</chem>

CAS RN	68515-44-6
Chemical Name	1,2-Benzenedicarboxylic acid, diheptyl ester, branched and linear

Synonyms diheptyl phthalate (DHpP)

Representative Structural Formula



Molecular Formula $C_{22}H_{34}O_4$

Molecular Weight (g/mol) 362.50

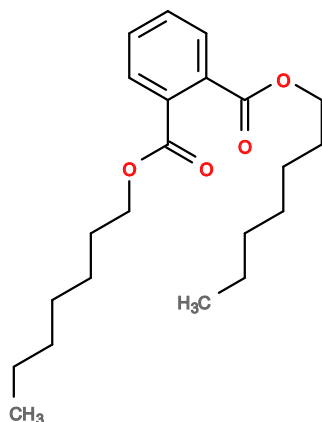
SMILES O=C(c1ccccc1C(=O)OCCCCCCC)OCCCCCCC

CAS RN 68515-41-3

Chemical Name 1,2-Benzenedicarboxylic acid, di-C7-9-branched and linear alkyl esters

Synonyms 79P

Representative Structural Formula



Molecular Formula $C_{22}H_{34}O_4$

Molecular Weight (g/mol) 362.50

SMILES O=C(c1ccccc1C(=O)OCCCCCCC)OCCCCCCC

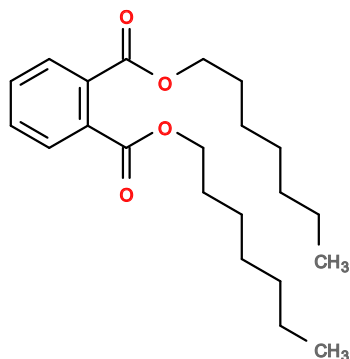
The substance represented by CAS RN 68515-42-4 is a commercial mixture of 6 different phthalate esters, including CAS RN 68515-44-6, which is another chemical in this group. Two of the chemicals, represented by CAS RNs 3648-20-2 and 68515-45-7, are on the Inventory but are not included in this group.

CAS RN 68515-42-4

Chemical Name 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters

Synonyms di-(heptyl, nonyl, undecyl) phthalate (DHNUP)

Representative Structural Formula



Molecular Formula	C ₂₂ H ₃₄ O ₄
Molecular Weight (g/mol)	362.50
SMILES	O=C(c1ccccc1C(=O)OCCCCCCC)OCCCCCCC

Physical and Chemical Properties

The physical and chemical property data for the chemicals in this group were retrieved from the databases included in the OECD QSAR Toolbox (LMC, 2013), and the scientific literature (Sugimoto, et al., 1986; Thomsen, et al., 2001), or they were calculated (US EPA, 2008). Experimental data for a selection of representative di-alkyl esters and a mixed alkyl-aryl di-ester of *ortho*-phthalic acid are presented below:

Chemical	dibutyl phthalate (DBP)	butyl benzyl phthalate (BBzP)	diethylhexyl phthalate (DEHP)	di- <i>n</i> -octyl phthalate (DNOP)
Physical Form	liquid	liquid	liquid	liquid
Melting Point	-35°C	-35°C	-55°C	-4°C
Boiling Point	340°C	370°C	384°C	390°C
Vapour Pressure	2.68 × 10 ⁻³ Pa	1.1 × 10 ⁻³ Pa	1.89 × 10 ⁻⁵ Pa	1.33 × 10 ⁻⁵ Pa
Water Solubility	14.6 mg/L	2.69 mg/L	0.017 mg/L	0.002 mg/L
Ionisable in the Environment?	no	no	no	no
log K _{ow}	4.5	4.73	7.6	8.1

With some exceptions, the chemicals in this group differ by the length and branching of their respective ester alkyl groups. Based on experimental and calculated values for key chemical properties, the water solubility decreases and log K_{ow} increases

as the length of the alkyl chain increases. The longer chain end-members of this series are very hydrophobic chemicals which are only very slightly soluble in water.

The di-methoxyethyl ester of *ortho*-phthalic acid, DMEP, has a calculated log K_{ow} of 1.11 and a measured water solubility of 8500 mg/L. This chemical is much less hydrophobic than the other members of the group because the methoxyethyl ester chain is more polar than the comparable alkyl ester chain.

Several members of this group are esters of aryl or cycloaliphatic alcohols. The physical and chemical properties of these chemicals are broadly represented by the range of values in the table above.

Import, Manufacture and Use

Australia

A range of uses for the chemicals in this group were identified in information collected by NICNAS in 2004 and 2006 (NICNAS, 2018). Following recommendations arising from Priority Existing Chemical (PEC) reviews of these chemicals, some uses were restricted or prohibited.

DMEP, DIBP, DBP and DEHP are listed on Schedule 10 of the Poisons Standard (Therapeutic Goods Administration, 2017), which prohibits their use in cosmetic products. There is a permanent ban on toys, childcare articles, eating vessels, and utensils that are intended for use by children up to and including 36 months of age, where the concentration of DEHP in the article or a component of the article exceeds 1% by weight (ACCC, 2011).

DEHP, DBP, BBzP and DNOP have the highest reported annual introduction volume of the chemicals in this group. DEHP has a reported annual introduction volume between 10 000 and 99 000 tonnes (NICNAS, 2006), while introduction volumes in the range of 100 to 999 tonnes, with volumes decreasing in the order DBP>BBzP>DNOP.

DEHP has reported Australian uses as a plasticiser in PVC products, and in other polymers for coatings, adhesives and resins. A number of companies identified possible use of DEHP in cosmetic products, toys and child care articles. These uses are now prohibited or heavily restricted.

DBP, BBzP and DNOP share a number of reported uses, including as plasticisers in PVC products, and in adhesives, sealants and coatings. Use of DBP in cosmetics and fragrances has also been identified, though these uses are now prohibited.

DMEP, DIBP, DCHP, DHP, 610P, DNHP, DMCHP, DIHpP, DNHpP, DIOP and 79P do not have reported introduction volumes of more than 100 tonnes. Reported uses include as a plasticiser in PVC and in adhesives and sealants. DHP has a reported use in gear box lubricants.

While the import volumes discussed above are only for the chemicals as pure chemicals or in formulations, and not in articles, they are considered likely to reflect the relative extent of use of the chemicals in articles. This does not affect the Predicted Environmental Concentration (PEC) estimates in this assessment, which are derived from monitoring data.

No specific Australian use, import, or manufacturing information has been identified for the other chemicals in this group.

International

Phthalate esters have a wide variety of uses, but are primarily used as plasticisers, especially in polyvinyl chloride (PVC) products and articles. They are also commonly used in adhesives, sealants, paints, filling materials and other construction materials (Nordic Council of Ministers, 2016). These uses are consistent with reported uses in Australia. There is a significant non-industrial use of DEHP in medical devices, such as blood bags and dialysis equipment (Lorz, et al., 2000).

A number of phthalate esters have also been used in cosmetic products, but these uses have declined as a result of regulatory action at both national and international levels.

DHNUP, DMEP, DEHP, and BBzP are on Annex II of the EU Cosmetics Directive (European Commission, 2017c), prohibiting their use in cosmetic products. DIHpP and DIBP are also prohibited in cosmetic products under Article 15 of the EU Cosmetics Directive (European Commission, 2017b).

The remaining chemicals in this group are not listed on the CosIng database, indicating they are not used in cosmetics in the European Union (European Commission, 2017a).

DEHP is listed on the Canadian Cosmetic Ingredient Hotlist (Health Canada, 2015) as prohibited for use in cosmetics.

There is evidence that the industrial use of some of the chemicals in this group is declining. In Japan, the total annual manufactured and/or imported quantity of DEHP consistently decreased between 1996 and 2003, from 285 300 tonnes down to 189 000 tonnes. Between 2012 and 2015, the total annual manufactured and/or imported quantity decreased from 159 599 tonnes to 101 138 tonnes (NITE, 2017).

In 1997, a total of 595 000 tonnes of DEHP was manufactured in Western Europe. In 2007, 187 000 tonnes was manufactured in Western Europe, while the total manufactured volume of DEHP in the EU in the same year was 341 000 tonnes (ECHA, 2009a). In 1994, the manufactured volume of DBP in the EU was 49 000 tonnes, while in 2007 the volume was less than 10 000 tonnes (ECHA, 2009b). The annual manufactured volume of BBzP in Western Europe was 45 000 tonnes between 1994 and 1997, while the volume in 2007 was below 18 000 tonnes (ECHA, 2009c).

Environmental Regulatory Status

Australia

Under the Australian National Pollutant Inventory (NPI), emissions of both DEHP and DBP are required to be reported annually by facilities that use or emit more than 10 tonnes of either chemical during a reporting year (Department of the Environment and Energy, 2018). The emissions may be intentional, accidental or incidental releases arising through industrial processes. Additionally, emissions of these chemicals from diffuse sources, such as landfills, are also periodically estimated by state environment authorities. Diffuse emissions data are updated much less frequently than facility data.

The guideline concentration for DEHP in Australian drinking is 0.01 milligrams per litre (mg/L) (10 micrograms per litre (µg/L)) (NHMRC, 2011). The trigger value for protection of 95% of freshwater species is 26 µg/L for DBP under the National Water Quality Management Strategy (ANZECC, 2000).

The use of the remaining chemicals in this group is not subject to any specific national environmental regulations.

United Nations

No chemicals in this group are currently identified as a Persistent Organic Pollutant (UNEP, 2001), ozone depleting substance (UNEP, 1987), or hazardous substance for the purpose of international trade (UNEP & FAO, 1998).

OECD

DBP, DMEP, BBzP, 79P, DNHP, DHNUP, DIHpP and DEHP have been sponsored under the Cooperative Chemicals Assessment Programme (CoCAP) (OECD, 2017).

DEHP was sponsored by Sweden for assessment at the 20th Screening Information Dataset (SIDS) Initial Assessment Meeting (SIAM 20). The SIDS Initial Assessment Profile (SIAP) concluded that an exposure assessment should be performed for DEHP, focusing specifically on potential for secondary poisoning, due to a combination of bioaccumulation, low NOAEL for reproductive toxicity, and evidence of effects in fish after dietary exposure.

DBP was sponsored by The Netherlands for assessment at SIAM 12. The SIAP indicated that more information is needed on the potential risks of exposure of plants to DBP in the atmosphere.

Publications available for 79P and DIHpP conclude that these chemicals are low priorities for future work based on low hazard profiles for the environment. Publications for DMEP and DHNUP were predominantly focused on human health, and no environmental risk assessment was presented for either chemical. BBzP and DNHP have been sponsored for assessment, but no publication is currently available.

The other chemicals in this group have not been sponsored for assessment under CoCAP.

Canada

DEHP, DBP and DNOP were assessed as part of the First Priority Substances List (PSL1). It was concluded that both DBP and DNOP were not entering the environment under conditions that would have a harmful effect on the environment (Environment Canada and Health Canada, 1993; 1994b). There was insufficient information available at the time to conclude whether DEHP was entering the environment under conditions that would have a harmful effect on the environment (Environment Canada and Health Canada, 1994a).

The environmental hazards of BChP, BBzP, Bz79P, DBzP, DChP and DMChP were categorised as Not Persistent (Not P), Bioaccumulative (B), and Inherently Toxic to the Environment (iT_E) during the Categorization of the Domestic Substances List (DSL) (Environment Canada, 2013).

DIBP, DBP, DNHP, DHP, 79P, DHNUP, DHpP, DIHpP, DEHP, DIOP, and DNOP were categorised as Not P, Not Bioaccumulative (Not B), and iT_E (Environment Canada, 2013).

DMEP was categorised as Not P, Not B, and Not Inherently Toxic to the Environment (Not iT_E) (Environment Canada, 2013).

The remaining chemicals in this group were not categorised.

European Union

DEHP, BBzP, DBP, DIBP, DIHpP, DHNUP, DMEP, DHP, DNHP and 610P are all listed on the Candidate List for Eventual Inclusion in Annex XIV of the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) legislation. These chemicals are identified by the EU as Substances of Very High Concern (SVHC) (ECHA, 2017f). These chemicals are identified as SVHCs due to concerns about their endocrine activity and presumed human reproductive toxicity. DEHP has been identified as an SVHC based on probable serious effects to the environment.

DEHP, BBzP, DBP, DIBP, DIHpP, DHNUP and DMEP have subsequently been listed on Annex XIV (Authorisation) of the REACH legislation (ECHA, 2017e). Authorisation must be obtained for these chemicals to be used in the European Union.

DEHP, DBP, BBzP and DNOP are listed on Annex XVII (Restriction) of the REACH legislation. The use of DBP, BBzP and DEHP in all toys and childcare articles, and the use of DNOP in toys and childcare articles which can be placed in the mouth by children, is restricted to concentrations not exceeding 0.1% by weight of plasticised material (ECHA, 2015a; 2015b; 2017g).

The remaining chemicals in this group are not listed on the Candidate List for Eventual Inclusion in Annex XIV, Annex XIV (Authorisation) or Annex XVII (Restriction) of the REACH legislation. Therefore, these chemicals are not subject to authorisation or restriction, and are not currently identified by the European Union as SVHCs (ECHA, 2017e; 2017f; 2017g).

DBP, BBzP, DEHP, DIBP, 610P, DChP and Bz79P are all registered under REACH. With the exception of IOCP, all of the other chemicals in this group are pre-registered under REACH (ECHA, 2017a; 2017d).

DChP and Bz79P are currently listed on the Community Rolling Action Plan (CoRAP), indicating that these chemicals are considered as priorities for evaluation by a Member State (ECHA, 2017b). In addition, DBP, 610P and DChP are listed on the Public Activities Coordination Tool (PACT) as appropriate for informal hazard assessment and/or risk management option analysis (RMOA) under the SVHC Roadmap (ECHA, 2017c).

United States of America

DBP, DIBP, BBzP, DEHP and DNOP all belong to the US EPA Phthalates chemical class Action Plan (US EPA, 2012).

DBP, DIBP, BBzP, DEHP, DCHP, DNOP, DIOP, Bz79P, 79P, 610P, DNHP, DHNUP, DHpP, DHP, DNHpP and DIHpP are all on the United States (US) High-production Volume (HPV) chemicals list (US EPA, 2018b).

DBP and DEHP are both on the US EPA Toxics Release Inventory (US EPA, 2018a).

Environmental Exposure

The major industrial use of the chemicals in this group is as plasticisers in synthetic rubbers and plastics, and in polyvinyl chloride plastics in particular. Release of these chemicals into the environment is expected from the migration of these chemicals to the surface of rubber and plastic articles, including imported articles, as well as from abrasion and wear of these articles during their normal use. At the end of their service life, these articles are likely to be disposed of in landfill. The environmental exposure resulting from the use of these chemicals in articles can be significant, as plasticised PVC articles have been variously reported to be composed of 30–60% plasticiser by weight (Mersiowsky, et al., 2001; Thornton, 2002).

The use of agricultural plastics can result in direct release of these chemicals to the soil compartment (Gao and Wen, 2016).

Environmental release may also result from use at industrial sites. Information from the NPI indicates several sites in Victoria, NSW and Queensland that report emissions of DEHP and DBP, though at low total volumes (well below the 10 tonne threshold) (Department of the Environment and Energy, 2014).

Frequent indoor use of articles containing phthalate ester plasticisers has led to the high occurrence of these chemicals in household dust. In one study, DEHP is noted to be the predominant phthalate ester in dust, occurring at concentrations up to 10 milligrams per gram (mg/g), while BBzP is present at up to 1.3 mg/g (Kolarik, et al., 2008). Phthalate esters in household dust can be released to waste water through cleaning and washing of surfaces and fabrics.

Environmental Fate

The environmental fate assessment of DEHP, DBP and BBzP, the highest volume members of this group, is provided below. As these chemicals broadly cover the range of structural and physicochemical properties of the rest of the chemicals in this group, it is expected that the remaining chemicals will have an environmental fate similar to these three representative members. Exceptions are noted and discussed.

Partitioning

The chemicals in the group are neutral organic chemicals that are expected to partition mostly to soil, with increasing partitioning to the sediment compartment and decreasing partitioning to the water compartment as the hydrophobicity increases.

Most of the chemicals and substances in this group are oily liquids at room temperature. DBP is moderately soluble and slightly volatile, BBzP is slightly soluble and slightly volatile, and DEHP is very slightly soluble and very slightly volatile. DBP, BBzP and DEHP are expected to be moderately volatile from water and moist soil (LMC, 2013; US EPA, 2008).

Calculations with a standard multimedia partitioning (fugacity) model assuming equal and continuous distributions to air, water and soil compartments (Level III approach) predict that, for DBP, BBzP and DEHP under steady state conditions, partitioning to the soil compartment predominates (65–72%), followed by the water compartment (16–26%), with minor partitioning to the air compartment (0.5–2.9%). Partitioning to the sediment compartment was most variable, with 0.7% partitioning for DBP increasing to 18% for DEHP. When released solely to water, partitioning to the sediment compartment increases with increasing log K_{ow} , from DBP (2.7%) through BBzP (18%) to DEHP (53%) (US EPA, 2008).

Degradation

The hydrophilic members of this group are not expected to be persistent in the environment. The more hydrophobic chemicals in this group are expected to be persistent in sediment and under anaerobic conditions.

A study investigated rates of degradation of phthalate esters under sunlight irradiation in water (Lertsirisopon, et al., 2009). Primary degradation half-lives at pH 7 of 360 days, 480 days and 1600 days were observed for DBP, BBzP and DEHP, respectively. The rate of degradation increased under both acidic and basic conditions: half-lives of 50 and 57 days observed for DBP at pH 5 and 9, respectively; 58 and 68 days for BBzP at pH 5 and 9, respectively; and 390 and 460 days for DEHP at pH 5 and 9, respectively. These findings suggest that abiotic degradation will not contribute significantly to environmental transformation of these chemicals.

The chemicals in this group are expected to degrade rapidly in the atmosphere. In air, the chemicals in this group are calculated to have half-lives of approximately 1 day or less due to oxidation by hydroxyl radicals (US EPA, 2008).

A number of screening biodegradation studies have been conducted for DEHP, BBzP and DBP. Studies conducted according to OECD Test Guideline (TG) 301C found that 69% of DEHP was degraded after 28 days, while 81% of BBzP and 69% of DBP were mineralised after 14 days as measured by biological oxygen demand. The same experiment showed 89% primary degradation of DEHP, 98% primary degradation of BBzP, and 100% primary degradation of DBP (NITE, 2017). Two replicate tests with DEHP and four replicate tests with DBP according to OECD TG 301B found an average of 82% and 81% degradation over 28 days respectively; all results met the 60% degradation within a 10-day window requirement for ready biodegradability (Scholz, et al., 1997). A non-standard test using lake water as the inoculant found that DEHP was mineralised to between 35% and 71% after 40 days (Subba-Rao, et al., 1982).

These studies indicate that DEHP, BBzP and DBP are likely to be rapidly degradable in water under aerobic conditions. However, the more hydrophobic chemicals in this group are likely to partition to sediment and suspended solids during STP processes, and therefore may be present in river sediment or in agricultural soils treated with biosolids.

The rate of primary degradation in creek sediment was investigated for several phthalate esters (Kickham, et al., 2012). Measured sediment half-lives for DBP, BBzP, DEHP and DNOP were reported to be 46, 2.9, 347 and 173 days, respectively. The reported sediment half-life for DEHP exceeds the domestic threshold for persistence in the sediment compartment (half-life \geq 6 months). The study found that the rate of degradation tended to decrease with increasing lipophilicity, and suggested that the inherent biodegradation rate constants for the phthalate esters are comparable, but that the higher sorption of the more lipophilic phthalate esters to sediment reduces their bioavailability to microorganisms, which results in slower biodegradation.

A study (Ejlertsson, et al., 1997) investigated the degradation of a number of phthalate esters in water under methanogenic conditions at 37°C. The more water-soluble phthalate esters such as DBP, BBzP and DNHP were degraded under these conditions, with primary degradation of DBP and BBzP complete within 30 days of incubation; the more hydrophobic phthalate esters such as DEHP and DNOP did not degrade. The concentration of DEHP was largely unchanged after 92 days of incubation.

A study was conducted to measure degradation of DEHP in moist agricultural soils amended with sludge from an STP located in Denmark (Madsen, et al., 1999). Soil was combined with sewage sludge in a 58:1 ratio and spiked with radiolabelled DEHP to several different concentrations, and DEHP mineralisation was calculated based on $^{14}\text{CO}_2$ release. Under aerobic conditions, mineralisation half-lives in soil were calculated to be 150 days at 20°C, 337 days at 10°C and much greater than 1 year at 5°C. Mineralisation was slower under anaerobic conditions, with a mineralisation half-life of much greater than 1 year at 10°C.

These studies indicate that the more hydrophilic phthalate esters such as DBP and BBzP are degradable in sediment and under anaerobic conditions. DEHP undergoes slow mineralisation in soil, and it may be persistent in sediment and under anaerobic conditions.

However, a study conducted by Chang, et al. (2005) measuring the primary degradation of phthalate esters in Taiwanese river sediment under anaerobic conditions found the primary degradation half-life of DEHP to be between 25.7 and 34.7 days when incubated at 30°C. This is not consistent with the above studies. The difference in degradation rate may be due to adaptation of the inoculum to phthalate esters or the high incubation temperature used in this study. A study by Tabak, et al. (1981) found negligible degradation of DEHP in the first week of a culture using settled domestic wastewater as an inoculum, but subsequent cultures which were inoculated with the previous culture showed adaptation to the substrate such that with the fourth culture, 95% primary degradation of DEHP occurred after 7 days.

The chemicals in this group are expected to degrade in water and soil under aerobic conditions. In sediment and under anaerobic conditions, DBP and the more hydrophilic phthalate esters are expected to degrade, while there is evidence that DEHP and other phthalate esters containing chains with eight carbon atoms degrade slowly. The rate of degradation varies with both temperature and inoculum. Abiotic degradation processes are not expected to be a major degradation pathway for the chemicals in this group.

Bioaccumulation

The chemicals in this group are not expected to bioaccumulate.

Experimental values for the bioconcentration factor (BCF) for DBP and DEHP of 176 L/kg and 30 L/kg respectively in the Japanese rice fish (*Oryzias latipes*) were determined according to a MITI bioaccumulation test method (LMC, 2013; NITE, 2017). In the cases of BBzP, BCF values in the range 135–663 L/kg are reported in the European Union Risk Assessment Report for this chemical (ECB, 2007). One study investigated the temperature dependence of DEHP bioaccumulation, with measured concentrations of DEHP in sheepshead minnow (*Cyprinodon variegatus*) increasing 6-fold over the temperature range of 10°C to 35°C in a short-term exposure experiment with this marine species (Barron, et al., 1987). Calculated BCF values based on this experiment ranged from 45 L/kg at 10°C to 6510 L/kg at 35°C. However, the model used by the study author predicts that the BCF for DEHP would not exceed the domestic threshold for bioaccumulation (BCF \geq 2000 L/kg) until the water temperature exceeds 30°C, which is not considered relevant for categorisation purposes.

A study investigating the bioaccumulation potential of phthalates esters in a marine aquatic food web found either no relationship between trophic level and lipid concentration for lower molecular weight phthalate esters, or a negative correlation (Food Web Magnification Factor $<$ 1) for higher molecular weight phthalate esters (Mackintosh, et al., 2004). The phthalate esters detected include DBP, BBzP, DIHP, DIHPp, DEHP, DNOP, and DIOP. The authors concluded that phthalate esters have low potential to biomagnify.

Phthalate esters undergo biotransformation in biota, which typically increases with increasing trophic level (Staples, et al., 1997). In fish, rapid metabolism of DEHP has been observed in the gills of rainbow trout through esterase conversion to the corresponding anionic monoester (Berg, et al., 2003).

While the log K_{ow} of the majority of chemicals in this group are above that of the domestic categorisation threshold for bioaccumulation (log $K_{ow} \geq 4.2$), experimental evidence suggests low potential for these chemicals to bioaccumulate. There is evidence of rapid biotransformation of these chemicals, especially in biota of higher trophic levels. Therefore, the chemicals in this group are not expected to bioaccumulate.

Transport

The chemicals in this group have low potential for long-range transport.

The expected rapid degradation of these chemical in the troposphere indicates that they will be unlikely to undergo long-range transport through the atmosphere. In addition, the chemicals in this group are expected to have only moderate volatility from water and moist soil (US EPA, 2008), resulting in limited partitioning to the air compartment.

Predicted Environmental Concentration (PEC)

Environmental concentrations of the chemicals in this group were estimated from available domestic and international monitoring data, as well as calculated data. Based on domestic monitoring data, the most abundant chemical in the environment is expected to be DEHP with a maximum concentration of 0.93 $\mu\text{g/L}$ in Australian rivers.

A number of phthalate esters have been detected in the Australian environment, with DEHP, DBP and BBzP being some of the most commonly detected members of this group (Clara, et al., 2010; Gao and Wen, 2016; Peijnenburg and Struijs, 2006; Suzuki, et al., 2001). A study of influent and effluent waters in five STPs in Queensland from 2007 quantified BBzP, DBP and DEHP in effluents. DEHP was generally present at higher concentrations than BBzP or DBP, with a maximum effluent concentration (the mean concentration plus one standard deviation) of 0.93 $\mu\text{g/L}$. DBP and BBzP had maximum effluent concentrations of 0.12 $\mu\text{g/L}$ and 0.14 $\mu\text{g/L}$ respectively (Tan, et al., 2007). At one STP, water samples were also taken 1 km downstream of the effluent discharge site, giving similar phthalate ester concentrations in surface waters to the effluent samples.

Based on these maximum measured concentrations, the riverine PECs for DEHP, DBP and BBzP are taken to be 0.93, 0.12 and 0.14 $\mu\text{g/L}$, respectively.

DEHP, DBP and BBzP have, respectively, the highest, second highest and third highest reported annual introduction volumes among the chemicals in this group, and it is considered unlikely that the other chemicals in this group will be present at higher concentrations in the Australian riverine environment. This is reflected in international monitoring studies: monitoring of a number of phthalate esters in water samples taken from the Tama River in Japan found DEHP, DBP and BBzP at respective concentrations up to 3.6, 0.54, and 0.06 µg/L. In the same study, DIBP was found at up to 0.03 µg/L, while DCHP and DNOP were not detected (Suzuki, et al., 2001). Another study analysing phthalate esters in treated wastewater in Austria found DEHP, DBP and BBzP at concentrations up to 6.6, 2.4 and 1.4 µg/L, respectively, while DNOP was found at up to 0.26 µg/L (Clara, et al., 2010). Based on these monitoring data, the other chemicals in this group are not expected to be present in the Australian riverine environment at concentrations exceeding those for DBP (0.12 µg/L).

Phthalate ester concentrations in sludge samples taken from two STPs in Australia were also investigated in a study from 2007 (Tan, et al., 2007). DEHP was present in sludge taken from the aerobic and anaerobic bioreactors up to a maximum (mean concentration plus one standard deviation) of 12 micrograms per gram (µg/g) (12 milligrams per kilogram (mg/kg)), while the less lipophilic DBP and BBzP were present at low nanograms per gram (ng/g) levels. Following application of biosolids to land, the maximum concentration of DEHP predicted in soil is 0.37 mg/kg (Langdon, et al., 2010).

Environmental Effects

Effects on Aquatic Life

Experimental acute and chronic ecotoxicity data are presented below for DBP, BBzP and DEHP. With the exception of the fish chronic toxicity study, the acute and chronic ecotoxicity values for DEHP all exceed the water solubility of this hydrophobic chemical. Parkerton and Konkell (2000) report that acute effects of phthalate esters appear to result from a narcotic mode of toxic action, with very hydrophobic phthalate esters not exhibiting acute aquatic toxicity up to the limit of their solubility in water. The toxicity data presented in the tables below were obtained from databases included in the OECD QSAR Toolbox (LMC, 2013) and from the scientific literature (Zanotelli, et al., 2010).

Acute toxicity

Taxon	Endpoint	Method
Fish	DBP: 96 h LC50 = 0.48 mg/L	<i>Lepomis macrochirus</i> (bluegill) Static EPA-660/3-75-009
	DEHP: 96 h LC50 > 0.16 mg/L	<i>Pimephales promelas</i> (fathead minnow) Static EPA-660/3-75-009
	BBzP: 96 h LC50 = 0.51 mg/L	<i>Cymatogaster aggregata</i> (shiner perch) Flow-through Saltwater conditions
Invertebrate	DBP: 96 h LC50 = 0.50 mg/L	<i>Mysidopsis bahia</i> (mysid shrimp) Static EPA-660/3-75-009

Taxon	Endpoint	Method
	DEHP: 48 h EC50 = 0.133 mg/L	<i>Daphnia pulex</i> Static Immobilisation test
	BBzP: 96 h LC50 = 0.9 mg/L	<i>Mysidopsis bahia</i> (mysid shrimp) Static EPA-660/3-75-009
Algae	DBP: 96 h EC50 = 0.4 mg/L	<i>Selenastrum capricornutum</i> Static EPA-600/9-78-018
	DEHP: 96 h EC50 > 0.10 mg/L	
	BBzP: 96 h EC50 = 0.21 mg/L	

It has been reported that monoester compounds resulting from partial degradation of the chemicals in this group are generally less acutely toxic than the parent compound (Jonsson and Baun, 2003).

Chronic toxicity

Taxon	Endpoint	Method
Fish	DBP: 99 d NOEC = 0.1 mg/L	<i>Oncorhynchus mykiss</i> (rainbow trout) Semi-static ASTM E1241-90
	DEHP: 91 d LOEC = 0.001 mg/L	<i>Poecilia reticulata</i> (guppy fish) Semi-static - weekly replacement Growth inhibition observed
	BBzP: 30 d NOEC = 0.15 mg/L	<i>Oryzias latipes</i> OECD TG 210
Invertebrates	DBP: 21 d NOEC = 0.33 mg/L	<i>Daphnia magna</i> OECD TG 211
	DEHP: 21 d NOEC = 0.077 mg/L	<i>Daphnia magna</i> ASTM E-1193
	BBzP: 21 d NOEC = 0.28 mg/L	

Taxon	Endpoint	Method
Algae	DBP: 96 h NOEC = 0.21 mg/L	<i>Selenastrum capricornutum</i> Static EPA-600/9-78-018
	DEHP: 96 h NOEC = 0.1 mg/L	
	BBzP: 96 h NOEC < 0.1 mg/L	

Several other members of this group have been shown to have high aquatic toxicity. The 72 h EC₅₀ for DIBP is 0.64 mg/L for *Pseudokirchneriella subcapitata* in a study conducted according to OECD TG 201. The 21 d NOECs for DNHP and DIOP in an invertebrate study with *Daphnia magna* conducted according to ASTM E-1193 are 0.084 mg/L and 0.062 mg/L, respectively. These values are used in the domestic categorisation of environmental hazard.

The fish chronic toxicity endpoint value for DEHP in the table above was derived from an early life-stage test conducted with *Poecilia reticulata* (guppy fish), which revealed significant dose-responsive effects of DEHP upon growth when exposure began while the fish were less than 1 week old (Zanotelli, et al., 2010). After 91 days, guppies had significantly reduced body length and weight at both 1 and 10 µg/L DEHP nominal concentrations. In addition, mortality had increased relative to the control at 10 µg/L DEHP, with 35% survival compared to 85% survival in the control. The sexual development of the fish appeared to be unaffected.

Endocrine Activity

There is evidence that endocrine activity of DEHP results in adverse outcomes in fish exposed to this chemical. Long-term exposure to the chemical led to reproductive effects in Chinese rare minnow, while zebrafish were highly susceptible to inhibition of both male and female germ cell development, leading to decreases in reproductive ability. These effects occurred at DEHP exposure concentrations that have previously been measured in the Australian aquatic environment. There is also evidence of endocrine activity for BBzP and DBP in fish.

A study investigated mechanisms of toxicity in fish both *in vitro* and *in vivo* for several phthalate esters, including DEHP, DBP and BBzP, (Mankidy, et al., 2013). Toxicity mechanisms investigated included (o)estrogenic activity, oxidative stress, steroidogenesis, and aryl hydrocarbon receptor (AhR) activation. DEHP, DBP and BBzP were all found to weakly activate the AhR. DEHP was able to significantly affect concentrations of 17-β estradiol in media, while both DEHP and DBP were able to decrease the concentration of testosterone, though DEHP was more potent. Oxidative stress was identified as the critical mechanism of toxicity for DEHP.

Wang, et al. (2013) conducted a study of the endocrine effects of DEHP on *Gobiocypris rarus* (Chinese rare minnow) over a 21 day period. The majority of effects on plasma sex hormone concentration and transcription of related genes was seen at concentrations in excess of 39.4 µg/L, which exceeds the water solubility of DEHP. A second study (Guo, et al., 2015) was conducted as a long-term study on the effects of DEHP on reproduction in Chinese minnow over 6 months. Concentrations in exposure water were measured to be 0 µg/L, 4.2 µg/L, 13.3 µg/L and 40.8 µg/L. At an exposure concentration of 13.3 µg/L, egg production was decreased by 32.7% relative to the control and ovarian germ cell development was inhibited.

Carnevali, et al. (2010) conducted a study exposing female zebrafish to several environmentally relevant concentrations of DEHP. Exposure resulted in a significant increase in serum vitellogenin levels, indicating (o)estrogenic activity. Significant decreases in embryo production at all concentrations of DEHP tested was also observed. At 0.02 µg/L DEHP, embryo production decreased to roughly 50% of the control, decreasing further to less than 10% of control at 20 µg/L. The study identified a number of factors affecting oocyte development and maturation that were negatively affected by DEHP exposure, contributing to the large decrease in reproductive success.

Another series of tests was conducted to study the effects of DEHP in male zebrafish (Corradetti, et al., 2013). Male zebrafish were exposed to 0.2 and 20 µg/L of DEHP for three weeks before being mated with untreated females in a separate tank. Reproductive capacity was substantially decreased at both exposure levels. The authors observed an inhibition of germ cell development from spermatogonia to spermatocytes in the fish testes, and evidence of oxidative stress leading to DNA

fragmentation after DEHP exposure. When DEHP exposure was halted, the reproductive ability of the male zebrafish recovered within 2 weeks, suggesting that the inhibition of spermatogenesis was temporary.

Harries, et al. (2000) conducted a reproductive performance test for BBzP using breeding pairs of fathead minnow (*Pimephales promelas*). After 3 weeks of exposure to BBzP at measured concentrations between 69 and 82 µg/L, no effects on fish growth or survival were observed compared to the control, nor were the total number of eggs spawned by breeding pairs affected. No vitellogenin induction was observed in male or female fish, though it was noted that vitellogenin induction in fish has previously been observed at higher concentrations of BBzP.

A study investigated the effects of DBP in female Murray rainbowfish (*Melanotaenia fluviatilis*) (Bhatia, et al., 2013). After 7 days of exposure at DBP concentrations in the range 250–1000 µg/L, effects on a number of reproductive biomarkers including circulating vitellogenin concentrations and ovary histology were observed, indicating an anti(o)estrogenic effect. Exposure at 125 µg/L did not produce significant effects on these biomarkers and did not affect the survival of the adult fish. A second study (Bhatia, et al., 2014) used similar methodology to investigate the effect of DBP on male Murray rainbowfish. Effects on a number of reproductive biomarkers including circulating vitellogenin concentrations, size of germ cells and a number of transcriptional markers were observed, which the authors attributed to an (o)estrogenic mode of action for DBP. At the lowest measured DBP concentration of 62 µg/L, the main effect observed was a decrease in the size of germ cells (spermatogonia, spermatocytes A and B and spermatids).

A follow-up study was conducted to assess the effects of long-term DBP exposure on juvenile Murray rainbowfish (Bhatia, et al., 2015). Fish that were at least 44 days old were exposed to 5, 15 and 50 µg/L DBP for up to 90 days. After 90 days at 5 µg/L DBP, reduced body length and bodyweight was observed along with a change to Fulton's condition factor. Further effects included feminisation of the gonad, increase in E2 (estradiol), and a decrease in 11-KT (11-ketotestosterone) and thus a change in the ratio of sex hormones (E2/11-KT ratio). At higher exposure concentrations, these effects were either more severe or apparent after shorter timeframes. Although fish survival was unaffected, this study demonstrates that low concentrations of DBP can cause significant physiological effects following prolonged exposure.

Effects on Terrestrial Life

In terrestrial mammals exposure through ingestion is likely to be the main exposure pathway (Smith, et al., 2007). Toxicity in model terrestrial organisms has been well characterised for several members of this group, with noted reproductive and developmental toxicity of DBP, DEHP and BBzP occurring through a likely antiandrogenic mode of action involving alteration of steroidogenesis and gene expression critical for development of the reproductive system (NICNAS, 2008; 2015). However, effects were generally seen at higher exposures than would be expected in the environment, especially given the low potential for bioaccumulation and low predicted soil concentration of this group of chemicals.

Predicted No-Effect Concentration (PNEC)

The PNECs for select members of this group were calculated using the range of available ecotoxicity endpoints and the appropriate assessment factor.

An assessment factor of 50 was used for DEHP. A range of acute and chronic ecotoxicity data were available for these chemicals across three trophic levels. Standard ecotoxicity screening tests for DEHP generally gave endpoints beyond the water solubility of this chemical, but chronic effects on fish development and reproduction were observed in several studies over extended timeframes at concentrations below the water solubility. A threshold effect concentration for DEHP of 1 µg/L was selected based on the weight of evidence from available studies. A PNEC of 0.02 µg/L was derived for DEHP.

An assessment factor of 50 was used for DBP. A range of acute and chronic toxicity data are available for this chemical across three trophic levels. A PNEC of 0.1 µg/L was derived for this chemical based on the effects observed on juvenile Murray rainbowfish.

An assessment factor of 50 was used for BBzP. A range of acute and chronic toxicity data are available for this chemical across three trophic levels. It was considered appropriate to use a more conservative assessment factor as the chronic toxicity endpoint selected was the lowest concentration used in the study (Adams, et al., 1995), and still elicited a significant effect on the test organism compared to the control. A PNEC of 2 µg/L was derived for this chemical.

Categorisation of Environmental Hazard

The categorisation of the environmental hazards of the chemicals in this group according to domestic environmental hazard thresholds is presented below (EPHC, 2009; NICNAS, 2017):

Persistence

DEHP, DNOP

Persistent (P). Based on a measured sediment half-life greater than 6 months for DEHP, and very slow degradation under anaerobic conditions, DEHP and DNOP are categorised as Persistent.

DIOP, 8P, DHNUP, 79P, 610P, IOCP, Bz79P, CHIOP

Persistent (P). Based on the recalcitrance towards degradation of representative C8 alkyl chain-containing members of this group in sediment and under anaerobic conditions these chemical are all categorised as Persistent.

DBP, BBzP, DNHP

Not Persistent (Not P). Based on rapid biodegradation under both aerobic and anaerobic conditions all three chemicals are categorised as Not Persistent.

All remaining chemicals

Not Persistent (Not P). Based on observed degradability of representative members of this group in a number of media under both aerobic and anaerobic conditions all remaining chemicals are categorised as Not Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). While measured or calculated log K_{ow} values are greater than the domestic categorisation threshold for bioaccumulation ($\log K_{ow} \geq 4.2$) for many of the chemicals in this group, low measured BCF values and evidence of rapid metabolism in biota for representative members of this group indicate low potential for bioaccumulation.

Toxicity

DIBP, DBP, DNHP, BBzP, DEHP, DIOP

Toxic (T). Based on measured acute toxicity values less than 1 mg/L, or measured chronic toxicity values less than 0.1 mg/L, these chemicals are categorised as Toxic.

All remaining chemicals

Uncertain (Uncertain T). There is currently insufficient information to conclude whether these chemicals have acute or toxic effects. There are some concerns that they may have chronic toxicity based on the chronic toxicity and endocrine activity of other chemicals in this group. Therefore, the toxicity of these chemicals is categorised as Uncertain.

Summary

1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester (DEHP); and 1,2-benzenedicarboxylic acid, diisooctyl ester (DIOP) are categorised as:

- P
- Not B
- T

1,2-Benzenedicarboxylic acid, dioctyl ester (DNOP); 1,2-benzenedicarboxylic acid, di-C7-9-branched and linear alkyl esters (79P); 1,2-benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP); 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters (610P); 1,2-benzenedicarboxylic acid, mixed isooctyl and 1-methylheptyl esters (8P); 1,2-benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters (Bz79P); 1,2-benzenedicarboxylic acid, cyclohexyl isooctyl ester (CHIOP); and 1,2-benzenedicarboxylic acid, isooctyl capryl ester (IOCP) are categorised as:

- P
- Not B
- Uncertain T

1,2-Benzenedicarboxylic acid, bis(2-methylpropyl) ester (DIBP); 1,2-benzenedicarboxylic acid, dibutyl ester (DBP); 1,2-benzenedicarboxylic acid, dihexyl ester (DNHP); and 1,2-benzenedicarboxylic acid, butyl phenylmethyl ester (BBzP) are categorised as:

- Not P
- Not B
- T

1,2-Benzenedicarboxylic acid, diphenyl ester (DPhP); 1,2-benzenedicarboxylic acid, dicyclohexyl ester (DCHP); 1,2-benzenedicarboxylic acid, diheptyl ester (DNHpP); 1,2-benzenedicarboxylic acid, bis(methylcyclohexyl) ester (DMCHP); 1,2-benzenedicarboxylic acid, diheptyl ester, branched and linear (DHpP); 1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear (DHP); 1,2-benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7 rich (DIHpP); 1,2-benzenedicarboxylic acid, butyl cyclohexyl ester (BCHP); 1,2-benzenedicarboxylic acid, bis(2-methoxyethyl) ester (DMEP); and 1,2-benzenedicarboxylic acid, bis(phenylmethyl) ester (DBzP) are categorised as:

- Not P
- Not B
- Uncertain T

Risk Characterisation

Based on the PEC and PNEC values determined above, the following Risk Quotients (RQ = PEC ÷ PNEC) have been calculated for release into rivers:

Chemical	PEC (µg/L)	PNEC (µg/L)	RQ
DEHP	0.93	0.02	46

Chemical	PEC (µg/L)	PNEC (µg/L)	RQ
BBzP	0.14	2	0.07
DBP	0.12	0.1	1.2

The RQ value for BBzP is below 1. This indicates that environmental concentrations are unlikely to exceed levels which cause ecotoxic effects in exposed organisms. The RQ value for DBP is slightly in excess of 1, which suggests a marginal risk to aquatic life in rivers. However, the estimated exposure concentration for this chemical is conservative and the risk may be overestimated at current exposure levels. Studies investigating possible endocrine effects of these chemicals indicated that DBP and BBzP may have endocrine activity, but effects were only observed at concentrations well beyond the expected Australian environmental concentrations.

The RQ value for DEHP is significantly greater than 1, indicating that this chemical may pose an unreasonable risk to the environment, as the environmental concentration may exceed levels that cause harmful effects. These harmful effects include growth inhibition and reduction of reproductive success by a number of proposed mechanisms, including oxidative damage and alteration of gene transcription.

It is noted that Australian monitoring data for DEHP were obtained in 2007, and that a number of uses for DEHP have since been restricted. Internationally, use of DEHP is being phased out by some industries, usually in favour of very hydrophobic phthalate esters with alkyl chains containing nine or more carbon atoms. In Australia, voluntary initiatives are in place to reduce uses of this chemical in PVC applications. Some environmental release of DEHP may also be due to non-industrial uses in medical equipment. Taking these factors into consideration, the PEC used in this assessment may overestimate the current typical concentrations of DEHP in the riverine environment in Australia. Nevertheless, current environmental monitoring information for DEHP is considered necessary to quantify the risks arising from on-going industrial uses of this chemical in Australia.

Based on currently available information, the remaining chemicals in this group are expected to have lower potential for exposure to the Australian environment, and have equivalent or lower hazard than the chemicals covered in more detail above. Therefore, these chemicals are not expected to pose an unreasonable risk to the environment.

Key Findings

Phthalate esters are widely used plasticisers with a large variety of alternate uses. Available data indicate industrial uses of some of the chemicals in this group in Australia include in PVC materials and products, in construction materials, paints, and adhesives. These chemicals can be released to the environment as a result of these uses.

Many phthalate esters, including DBP and BBzP, are degradable, have low bioaccumulation potential, and have moderate acute and chronic aquatic toxicity. They are also weakly endocrine active.

Some phthalate esters, including DEHP and DNOP, are persistent in sediments, but they are degradable under aerobic conditions in water, soil and air. They also have low bioaccumulation potential. These chemicals are expected to have no acute aquatic toxicity at water saturation.

DEHP has high chronic toxicity to fish and it has endocrine activity that is sufficient to cause adverse outcomes in fish at environmentally relevant exposure concentrations. The concentrations of DEHP in river water measured in Australia in 2007 significantly exceed the PNEC for this chemical. It is uncertain whether emissions of DEHP are continuing at these levels, and it is therefore unclear what the current risks are to the aquatic compartment.

The absence of current aquatic monitoring data for DEHP in Australia is a significant gap in the available environmental information for this chemical which would inform the application of effective risk reduction measures. It is recommended that

agencies and organisations responsible for water quality management in Australia prioritise addressing this information gap by conducting environmental monitoring of DEHP in STP effluents and surface waters receiving effluents from STPs.

Further assessment of DEHP may be required under the IMAP framework if information becomes available to indicate that the concentrations of this chemical in surface waters are comparable with the levels measured in 2007.

The chemicals in this group are not PBT substances according to domestic environmental hazard criteria.

Recommendations

It is recommended that DEHP be added to the list of organic contaminants that are routinely monitored in sewage treatment effluents and surface waters in Australia.

Advice for industry

There are many alternative plasticisers to DEHP available for specific uses, and there has been ongoing international research into alternatives to this chemical. Considering the environmental hazards of this chemical, it is recommended that companies evaluate safer, viable alternatives to DEHP.

Environmental Hazard Classification

In addition to the categorisation of environmental hazards according to domestic environmental thresholds presented above, the classification of the environmental hazards of the chemicals in this group according to the third edition of the United Nations' Globally Harmonised System of Classification and Labelling of Chemicals (GHS) is presented below (UNECE, 2009).

1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester:

Hazard	GHS Classification (Code)	Hazard Statement
Acute Aquatic	Not classified	-
Chronic Aquatic	Category 1 (H410)	Very toxic to aquatic life with long lasting effects

1,2-Benzenedicarboxylic acid, dibutyl ester; and 1,2-benzenedicarboxylic acid, butyl phenylmethyl ester:

Hazard	GHS Classification (Code)	Hazard Statement
Acute Aquatic	Category 1 (H400)	Very toxic to aquatic life
Chronic Aquatic	Category 2 (H411)	Toxic to aquatic life with long lasting effects

These classifications have been made based on the ecotoxicity data presented in this assessment.

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