

ANNEX XV REPORT

AN ASSESSMENT OF WHETHER THE USE OF TEN PHTHALATES IN ARTICLES SHOULD BE RESTRICTED IN ACCORDANCE WITH ARTICLE 69(2) OF REACH

Annex XIV #	Substance name	EC Number	CAS number
33	Diisopentylphthalate	210-088-4	605-50-5
34	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	276-158-1	71888-89-6
35	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	271-084-6	68515-42-4
36	1,2-Benzenedicarboxylic acid, dipentyl ester, branched and linear	284-032-2	84777-06-0
37	Bis(2-methoxyethyl) phthalate	204-212-6	117-82-8
38	Dipentyl phthalate	205-017-9	131-18-0
39	n-pentyl-isopentylphthalate	933-378-9	776297-69-9
44	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5	68515-50-4
45	Dihexyl phthalate	201-559-5	84-75-3
46	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed decyl and hexyl and octyl diesters with $\geq 0.3\%$ of dihexyl phthalate (201-559-5)	272-013-1 271-094-0	68648-93-1 68515-51-5

CONTACT DETAILS:

EUROPEAN CHEMICALS AGENCY
Telakkakatu 6,
P.O. Box 400,
00121 Helsinki,
Finland
tel: +358-9-686180
www.echa.europa

VERSION NUMBER: 1.0

DATE: 04 April 2022

About the report

This report is prepared according to Article 69(2) of REACH Regulation (EC) No. 1907/2006, which after the sunset date has passed for a substance included in the Authorisation List (Annex XIV), requires ECHA to consider if risks from the use of the substance in articles are adequately controlled and, if this is not the case, prepare an Annex XV restriction dossier.

In general, for the purpose of the Article 69(2) reviews, ECHA gathers information on potential risks to human health and/or the environment for identified uses of the Annex XIV substance in articles from various sources. Information is gathered (if available) from authorisations, recommendation for inclusion in Annex XIV and substance of very high concern (SVHC) identification. Uses identified in the REACH registrations and notifications in substances in articles¹ (in accordance with Article 7(2) of REACH and the Waste Framework Directive's SCIP database²) are also investigated. Information on possible uses of the substance in articles that were not identified during the screening phase can be gathered through a subsequent call for evidence launched via ECHA's website.

In most cases, risks stemming from the incorporation of the substance in an article are not in the scope of this investigation. Incorporation of a substance in articles has to be authorised, unless this use is exempted in accordance with Article 56(1) of REACH.³ The incorporation process carried out in third countries is outside the scope of EU legislation. However, it should be noted that articles if imported to the EU are within the scope of this investigation. The incorporation is regarded to cover two type of uses:⁴

- a) The substance is incorporated into an article during its production, or

¹ Producers and importers have to notify ECHA the substances listed on the Candidate list which are present in their articles, if both the following conditions are met: i) the substance is present in their relevant articles above a concentration of 0.1% w/w; ii) the substance is present in these relevant articles in quantities totalling over 1 tonne per year. Companies have to notify no later than six months after the inclusion of the substance in the Candidate List. For further details see:

<https://echa.europa.eu/regulations/reach/candidate-list-substances-in-articles/notification-of-substances-in-articles>.

² In accordance with the Waste Framework Directive (WFD), companies supplying articles containing substances on the Candidate List in a concentration above 0.1% w/w on the EU market have to submit information on these articles to ECHA, from 5 January 2021. The information provided is included in the SCIP database, i.e., Substances of Concern In articles as such or in complex objects (Products):

<https://echa.europa.eu/scip>.

³ Q&A ID: 0564: <https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/0564> Note that ECHA will investigate for this report whether applications for authorisation/authorisation decisions cover the incorporation of the substance into an article and possible cumulative effects of the substance due to authorisations.

⁴ https://echa.europa.eu/documents/10162/23036412/articles_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c

b) The substance, alone or in a mixture is incorporated into/onto an existing article (isolated or incorporated in a complex object) at a later stage (e.g., coatings, primers, adhesives, sealants) and becomes an integral part of the article (or of the complex object).

It is to be noted that there are several specific exemptions from the authorisation requirements⁵, while only few exemptions are envisaged in case of restrictions. These include manufacture and placing on the market or use of a substance in scientific research and development, risks to human health of the use of the substance in cosmetic products and when a substance is used as an on-site isolated intermediate.

⁵ https://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf/9291ab2a-fe2f-418d-9ce7-4c5abaaa04fc

Contents

A.	Conclusions.....	1
A.1	Conclusions based on the assessment	1
A.2	Targeting.....	2
A.3	Summary of the justification	4
B.	Information on hazard and risk	5
B.1	Identity of the substances and physical and chemical properties.....	5
B.2	Manufacture and uses	13
B.3	Classification and labelling	25
B.4	Environmental fate properties	27
B.5	Human health hazard assessment.....	27
B.6	Human health hazard assessment of physicochemical properties	28
B.7	Environmental hazard assessment	28
B.8	PBT and vPvB assessment	28
B.9	Exposure assessment.....	28
B.10	Risk characterisation	30
C.	Available information on alternatives.....	30
D.	Justification for action on a Community-wide basis	30
E.	Justification why the proposed restriction is the most appropriate Community-wide measure.....	30
F.	Socio-economic Assessment of Proposed Restriction	30
G.	Stakeholder consultation	30
H.	Other information	31
	References	32

Tables

Table 1.	Phthalates in the scope of this screening report: key dates and decisions.....	3
Table 2.	Substance identity.....	6
Table 3.	Substance composition	9
Table 4.	Substance physicochemical properties	11

Table 5. Substances manufactured and/or imported in the EU.....	14
Table 6. Information on uses available in ECHA databases.....	15
Table 7. Applications reported in the SCIP database for Annex XIV entries #34, 35 and 36...	19
Table 8. SCIP database submissions for Bis(2-methoxyethyl) phthalate (entry #37).....	21
Table 9. Harmonised classification according to the CLP Regulation.....	26
Table 10. Notified classifications (aggregated; in addition to the harmonised classification if applicable).....	27
Table 11. Reference DNELs for entry #33 (diisopentylphthalate)	28

A. Conclusions

A.1 Conclusions based on the assessment

The substances subject to this REACH Article 69(2) report include ten phthalates, which represent seven entries in Annex XIV (33-39) of REACH whose sunset date has passed and three entries (44-46) for which no applications for authorisations were submitted before their latest application date of 27 August 2021. They all have similar functions (i.e., additives to polymeric materials) and have similar concern as demonstrated by their harmonised⁶ classification for reproductive toxicity, category 1B. The substances subject to this report are included in table 1 and are herein collectively referred to as “ten phthalates.” Table 1 below gives an overview of the key dates and associated decisions for each of the phthalates in the scope of this review.

ECHA has gathered information on the uses of these ten phthalates in articles from various sources. This includes information gathered during the SVHC listing and recommendation for the inclusion of substances in Annex XIV, as well as uses identified in the REACH registrations. ECHA has not received any applications for authorisations for these substances. This indicates that the uses of these substances in articles have been largely phased out in the EU.

No notifications for substances in articles (SiA, in accordance with Article 7(2) of REACH)⁷ were submitted. Submissions for the presence of the substances in articles to fulfil obligations under the Waste Framework Directive (SCIP database)⁸ indicate that nine out of the ten phthalates (i.e., excluding n-pentyl-isopentylphthalate) are contained in imported articles only, likely in volumes of less than one tonne of the substances per importer.

The call for evidence, which took place between 8 December 2021 and 26 January 2022, did not identify any new uses of the substances in articles placed on the EU market. Several comments were received providing additional information on the ten Annex XIV phthalates in support of the information presented in the report, although one stakeholder questioned whether current use of these phthalates continues internationally. This version of the report takes into account the information received.

Following an assessment of the available evidence, ECHA is of the view that further examination of the risks from the use of the ten phthalates in articles should be considered as part of a larger

⁶ The classification of 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters where they contain dihexyl phthalate $\geq 0.3\%$ (entry #46) is not harmonised. The classification as Repr. 1B (H360FD) applies in accordance with Art. 10 and Table 3.7.2 in Part 3 of Annex I to Regulation (EC) No 1272/2008 (CLP Regulation), on the basis of the entry with index number 607-702-00-1 for dihexyl phthalate in Part 3 of Annex VI to CLP Regulation.

⁷ Producers and importers have to notify ECHA the substances listed on the Candidate list which are present in their articles, if both the following conditions are met: i) the substance is present in their relevant articles above a concentration of 0.1% w/w; ii) the substance is present in these relevant articles in quantities totalling over 1 tonne per year. Companies have to notify no later than six months after the inclusion of the substance in the Candidate List. For further details see: <https://echa.europa.eu/regulations/reach/candidate-list-substances-in-articles/notification-of-substances-in-articles>

⁸ In accordance with the Waste Framework Directive (WFD), companies supplying articles containing substances on the Candidate List in a concentration above 0.1% w/w on the EU market have to submit information on these articles to ECHA, from 5 January 2021. The information provided is included in the SCIP database, i.e., Substances of Concern In articles as such or in complex objects (Products): <https://echa.europa.eu/scip>

investigation to address risks of *ortho*-phthalates,⁹ with suspected similar concerns to human health, as well as to the environment. *Ortho*-phthalates (with a backbone C4-C6) are listed in the Restriction Roadmap (expected to be published by the EU Commission soon), restriction proposal to be initiated by the European Commission under the Chemical Strategy for Sustainability.¹⁰

This final report, updated with information submitted during the call for evidence, was sent to CARACAL/Member States¹¹ in March 2022 as an information document. An Annex XV dossier for restriction is prepared if risks are found not to be adequately controlled.

A.2 Targeting

This report is targeted at the potential release of or exposure to the ten phthalates from articles and throughout their lifecycle (including the waste stage) and whether or not such use should be restricted.

This targeting is based on the Article 69(2) of the REACH Regulation that requires ECHA to consider if the use of the substances in articles poses a risk to human health or the environment that is not adequately controlled and prepare an Annex XV dossier for an appropriate restriction if this is the case. The incorporation of an Annex XIV substance into an article is a use which is subject to the authorisation requirement.¹²

⁹ *Ortho*-phthalates are manufactured by reacting phthalic anhydride with alcohol(s) ranging from methanol and ethanol (C1/C2) up to tridecyl alcohol (C13). *Ortho*-phthalates are broadly divided into two main distinct groups: high molecular weight (those with 7-13 Carbon atoms in their chemical backbone) and low molecular weight *ortho*-phthalates with very different applications, toxicological properties, classification and legal requirements (www.plasticiser.org). Further information on the assessment of regulatory needs for *ortho*-phthalates can be found on ECHA's website at: <https://echa.europa.eu/pact>.

¹⁰ [Chemicals Strategy for Sustainability - ECHA \(europa.eu\)](https://echa.europa.eu/pact)

¹¹ Competent Authorities for Registration, Evaluation, Authorisation and restriction of CHemicals (REACH) and Classification, Labelling and Packaging (CLP)

¹² Q&A ID No 564: https://echa.europa.eu/support/qas-support/qas?p_p_id=journalqasearch_WAR_journalqaportlet&p_p_lifecycle=0&p_p_state=normal&p_p_mode=view&p_p_col_id=column-1&p_p_col_pos=2&p_p_col_count=3

Table 1. Phthalates in the scope of this screening report: key dates and decisions

Entry #*	Substance name	EC Number	CAS number	Inclusion in the Candidate list (date; ED decision number)	Inclusion in Annex XIV (date; Commission EU Regulation)	Last application date	Sunset date
33	Diisopentylphthalate	210-088-4	605-50-5	18 December 2012 ED/169/2012	13 June 2017 (EU) No 2017/999	04 January 2019	04 July 2020
34	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	276-158-1	71888-89-6	20 June 2011 ED/31/2011	13 June 2017 (EU) No 2017/999	04 January 2019	04 July 2020
35	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	271-084-6	68515-42-4	20 June 2011 ED/31/2011	13 June 2017 (EU) No 2017/999	04 January 2019	04 July 2020
36	1,2-Benzenedicarboxylic acid, dipentyl ester, branched and linear	284-032-2	84777-06-0	18 December 2012 ED/169/2012	13 June 2017 (EU) No 2017/999	04 January 2019	04 July 2020
37	Bis(2-methoxyethyl) phthalate	204-212-6	117-82-8	19 December 2011 ED/77/2011	13 June 2017 (EU) No 2017/999	04 January 2019	04 July 2020
38	Dipentyl phthalate	205-017-9	131-18-0	17 June 2013 ED/69/2013	13 June 2017 (EU) No 2017/999	04 January 2019	04 July 2020
39	n-pentyl-isopentylphthalate	933-378-9	776297-69-9	18 December 2012 ED/169/2012	13 June 2017 (EU) No 2017/999	04 January 2019	04 July 2020
44	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5	68515-50-4	16 June 2014 ED/49/2014	6 February 2020 (EU) No 2020/171	27 August 2021	27 February 2023
45	Dihexyl phthalate	201-559-5	84-75-3	16 December 2013 ED/121/2013	6 February 2020 (EU) No 2020/171	27 August 2021	27 February 2023
46	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (201-559-5)	272-013-1 271-094-0	68648-93-1 68515-51-5	15 June 2015 ED/39/2015	6 February 2020 (EU) No 2020/171	27 August 2021	27 February 2023

Note: * Entry number in the REACH Annex XIV (Authorisation list), <https://echa.europa.eu/authorisation-list>

A.3 Summary of the justification

A.3.1 Identified uses, hazard, exposure/emissions and risk

Information on uses

Based on the information gathered during the SVHC listing and recommendation for the inclusion of substances in Annex XIV, REACH registrations, SiA, SCIP and other sources, the uses of the ten phthalates in the scope of this review report can be summarised as follows:

- Similar to other low to medium molecular weight *ortho*-phthalates, the ten phthalates are predominantly used as additives (primarily plasticisers) in articles made of polyvinyl chloride (PVC) and other polymeric materials.
- No applications for authorisation¹³ and notifications for substances in articles (SiA) have been received to date for the ten phthalates in the scope of this report. Therefore, also taking into account additional information gathered (e.g., external database searches), it can be concluded that:
 - o The use of substances in entries #33 to #39 has been phased out in the EU.¹⁴
 - o The uses of substances in entries #44, #45 and #46 in the EU/EEA can continue until their sunset date (27 February 2023), unless exempted from authorisation. No information is available (i.e., no applications for authorisation were submitted) to suggest that these substances are currently being used in the EU/EEA (to produce articles or for other uses), although further information was sought during the call for evidence, but no such information was received.
- The use of most of the substances in articles may be continuing internationally and articles containing the substances in a concentration exceeding 0.1% w/w may be placed on the EU market in quantities of less than one tonne of the substance per year per supplier, as evidenced by submissions to the SCIP database (and the absence of notifications to the SiA database). Entry #39 (n-pentyl-isopentylphthalate) may be an exception as only information on limited historical use as a plasticiser was identified and no information was found in the SiA and SCIP databases. Furthermore, no ECHA registrations and no applications for authorisation were submitted for entry #39.
- According to the SCIP database, nine of the ten phthalates (i.e., excluding entry #39) are most commonly found in complex articles, (parts of) machinery and equipment made of a variety of polymeric material, the most common being rubber and soft PVC. Bis(2-

¹³ After the sunset date of an Annex XIV substance passes, only the following uses are allowed in the EU/EEA: i) uses for which an authorisation has been granted, ii) uses for which an application for authorisation was submitted before the latest application date and a decision on the authorisation is pending, ii) uses exempted from authorisation.

¹⁴ Diisopentylphthalate (entry #33) may be a possible exception, as it may potentially be used in military applications under a REACH exemption for military purposes, in the event a Member State grants an exemption for the use in the interest of defence. Further information on the potential continued military used was sought during the call for evidence but no information on military exemptions was submitted.

methoxyethyl) phthalate (entry #37) appears to have the most diverse number of applications (SCIP 2021).

Information on hazards

The ten phthalates are included in Annex XIV based on their Toxic for Reproduction (category 1B) properties (REACH Article 57c). Other endpoints are not relevant for this report.

Information on emissions/release/exposure

No analysis is presented as no restriction is proposed at present.

Characterisation of risk

No analysis is presented as no restriction is proposed at present.

A.3.2 Justification that action is required on a Union-wide basis

No analysis is presented as no restriction is proposed at present.

A.3.3 Justification that the proposed restriction is the most appropriate Union-wide measure

No analysis is presented as no restriction is proposed at present.

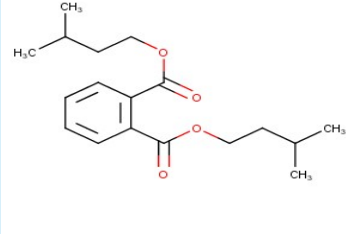
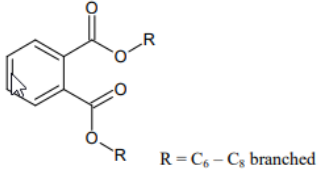
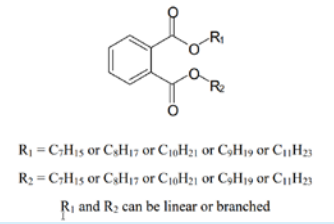
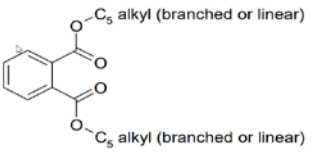
B. Information on hazard and risk

B.1 Identity of the substances and physical and chemical properties

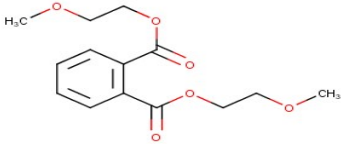
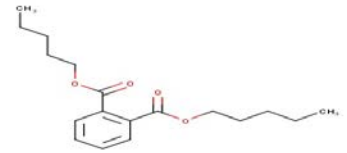
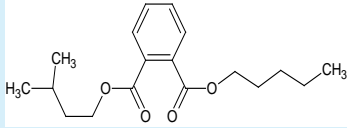
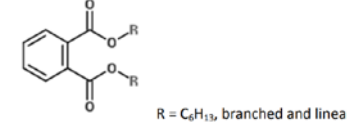
B.1.1 Name and other identifiers of the substances

Table 3 summarises available information on the substance name and other identifiers of the ten phthalates in the scope of this review. The Annex XIV entries # 34, 35, and 46 are UVCB substances (Unknown or Variable Composition, Complex Reaction Products) for which the composition of the substance and the proportions of the different constituents (alkyl groups R) vary. It is therefore not possible to provide a unique molecular formula, nor molecular weight for entries 34, 35 and 46. When specified, the molecular formula, structural formula and molecular weight provided in Table 2 represent only generic information (minimum to maximum number of atoms), but not the exact compositions of the substances.

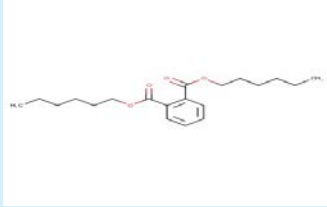
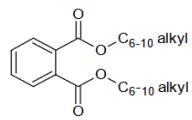
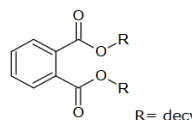
Table 2. Substance identity

Entry #	Substance name	EC Number	CAS number	Substance type	Structural formula	Molecular formula	Molecular weight
33	Diisopentylphthalate	210-088-4	605-50-5	Mono-constituent		C ₁₈ H ₂₆ O ₄	306.40 g/mol
34	1,2-Benzenedicarboxylic acid, di-C ₆ -8-branched alkyl esters, C ₇ -rich	276-158-1	71888-89-6	UVCB	 R = C ₆ – C ₈ branched	C ₂₀ H ₃₀ O ₄ –C ₂₄ H ₃₈ O ₄	334 – 390 g/mol
35	1,2-Benzenedicarboxylic acid, di-C ₇ -11-branched and linear alkyl esters	271-084-6	68515-42-4	UVCB	 R ₁ = C ₇ H ₁₅ or C ₈ H ₁₇ or C ₁₀ H ₂₁ or C ₉ H ₁₉ or C ₁₁ H ₂₃ R ₂ = C ₇ H ₁₅ or C ₈ H ₁₇ or C ₁₀ H ₂₁ or C ₉ H ₁₉ or C ₁₁ H ₂₃ R ₁ and R ₂ can be linear or branched	C ₂₂ H ₃₄ O ₄ –C ₃₀ H ₅₀ O ₄	362 – 474 g/mol
36	1,2-Benzenedicarboxylic acid, dipentyl ester, branched and linear	284-032-2	84777-06-0	UVCB	 C ₅ alkyl (branched or linear)	C ₁₈ H ₂₆ O ₄	306 g/mol

Annex XV report – Article 69(2)

Entry #	Substance name	EC Number	CAS number	Substance type	Structural formula	Molecular formula	Molecular weight
37	Bis(2-methoxyethyl) phthalate	204-212-6	117-82-8	Mono-constituent		C ₁₄ H ₁₈ O ₆	282.29 g/mol
38	Dipentyl phthalate	205-017-9	131-18-0	Mono-constituent		C ₁₈ H ₂₆ O ₄	306.397 g/mol
39	n-pentyl-isopentylphthalate	933-378-9	776297-69-9	Mono-constituent		C ₁₈ H ₂₆ O ₄	306 g/mol
44	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5	68515-50-4	UVCB		C ₂₀ H ₃₀ O ₄	334 g/mol

Annex XV report – Article 69(2)

Entry #	Substance name	EC Number	CAS number	Substance type	Structural formula	Molecular formula	Molecular weight
45	Dihexyl phthalate	201-559-5	84-75-3	Mono-constituent		C ₂₀ H ₃₀ O ₄	334 g/mol
46	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (201-559-5)	272-013-1, ¹⁵ 271-094-0 ¹⁶	68648-93-1, 68515-51-5	UVCB	 EC No. 271-094-0  EC No. 272-013-1 R= decyl, h	unspecified	unspecified

Sources: ECHA Dissemination portal (2021) for entry #33, ECHA 2012b for entry #33; (ECHA, 2011a) for entry #34, (Danish EPA, 2011) for entry #35, (BAuA, 2012) for entry #36, ECHA 2011d for entry #37, ECHA 2013a for entry #38, ECHA 2012d and ECHA for entry#39, (KEMI, 2014) for entry #44, ECHA Dissemination portal (2021) for entry #45, (ECHA, Member State Committee support document for the identification of 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC no. 201-559-5), 2015) for entry #46.

¹⁵ 1,2-Benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters

¹⁶ 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters

B.1.2 Composition of the substances

Table 3 gives an overview of the available composition information. The data is scarce. When available, information is provided on the main constituents, impurities and additives, as well as typical concentration or a concentration range.

Table 3. Substance composition

Entry#	Substance name	EC Number	Substance type	Composition information
33	Diisopentylphthalate	210-088-4	Mono-constituent	Confidential
34	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	276-158-1	UVCB	No information available in the Annex XV SVHC identification dossier. According to US EPA ¹⁷ , the UVCB contains ≥ 99% of C7 isomers.
35	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	271-084-6	UVCB	No information available
36	1,2-Benzenedicarboxylic acid, dipentyl ester, branched and linear	284-032-2	UVCB	No information available
37	Bis(2-methoxyethyl) phthalate	204-212-6	Mono-constituent	≥99.5% (based on C&L notifications)
38	Dipentyl phthalate	205-017-9	Mono-constituent	95-99%
39	n-pentyl-isopentylphthalate	933-378-9	Mono-constituent	No information available
44	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5	UVCB	No information available
45	Dihexyl phthalate	201-559-5	Mono-constituent	≥ 80%
46	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (201-559-5)	272-013-1, 271-094-0	UVCB	The upper concentration level in C6, C7, C8, C9 and C10 within the alcohols of "C6-10 alcohols" and the upper concentration level in C6, C8 and C10 of "C6-10 (even numbered) alcohols" is normally expected to be ≥10% and <80%. Any substance having a composition equivalent to the diesterification reaction products between 1,2-benzenedicarboxylic acid and "C6-10 alcohols" or "C6-10 alcohols (even numbered)" is in the scope.

Sources: ECHA 2012c for entry #33, (ECHA, 2011a) for entry #34, (Danish EPA, 2011) for entry #35, (BAuA, 2012) for entry #36, ECHA 2011d for entry #37, ECHA 2013a for entry #38, ECHA 2012d for entry #39, (KEMI, 2014) for entry #44, (BAuA, 2013) for entry #45, (ECHA, Member State Committee support document for the identification of 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC no. 201-559-5), 2015) for entry #46

¹⁷ <https://comptox.epa.gov/dashboard/dsstoxdb/results?search=71888-89-6>

B.1.3 Physicochemical properties

Available information on the physicochemical properties of the group of ten phthalates is summarised in Table 4.

No information on the physicochemical properties is available for Annex XIV entries #36, #39, and #44 therefore these substances are not listed in the table below.

Table 4. Substance physicochemical properties

Entry #/ REACH ref Annex	VII, 7.1 Physical state at 20 °C and 101.3 kPa	VII, 7.2 Melting / freezing point	VII, 7.3 Boiling point	VII, 7.5 Vapour pressure	VII, 7.7 Water solubility	VII, 7.8 Partition coefficient octanol/water [log value]	XI, 7.16 Dissociation constant	VII, 7.4 Density
33	Liquid (100%)	25 °C	339 °C @ 101.6 kPa	<0.025 Pa at 25 °C	1.1 mg/L at 20 °C pH 6.9 to 7.1	Log P _{ow} : ca. 5.6 @ 25 °C	-	1.02 at 20 °C (relative density)
34	-	-	-	-	0.017 mg/L	Log K _{ow} : 6.15	-	-
35	Liquid	-57 °C (pour point)	235-278 °C at 7 hPa	<10 Pa at 20 °C	0.1 mg/L at 20 °C pH neutral	Log K _{ow} : ca. 4.8	-	969-973 kg/m ³ at 20 °C
37	Oily liquid	-45 °C	340 °C (pressure not indicated)	0.00028 mm Hg at 25 °C	8500 mg/L at 25 °C	Log P _{ow} : ca. 1.11 (temperature not indicated)	-	1.1596 g/cm ³ at 20 °C
38	Oily liquid	-55 °C	342 °C (pressure not indicated)	1.96 x10 ⁻⁴ mm Hg at 25 °C	0.8 mg/L at 25 °C	Log P _{ow} : ca. 5.62 at 20 °C	-	1.03 g/cm ³
45	Oily liquid	-58 °C	662 °F at 735 mm Hg {350 °C at 98 kPa}	1.4 x 10 ⁻⁵ mm Hg at 25 °C	0.03 mg/L	Log K _{ow} : 6.82	-	1.010-1.016 g/cm ³ at 20 °C
46	EC 271-094-0: liquid	EC 272-013-1: -4 °C EC 271-094-0: -48 °C	EC 271-094-0: 277 °C	EC 271-094-0: <0.001 mBar at 38 °C	EC 272-013-1: 0.03 mg/L EC 271-094-0: 11	EC 272-013-1: Log K _{ow} : 8.17 EC 271-094-0: 8.2 at 20 °C and pH 7	-	EC 271-094-0: 976 g/L at 20 °C

Annex XV report – Article 69(2)

Entry #/ REACH ref Annex	VII, 7.1 Physical state at 20°C and 101.3 kPa	VII, 7.2 Melting / freezing point	VII, 7.3 Boiling point	VII, 7.5 Vapour pressure	VII, 7.7 Water solubility	VII, 7.8 Partition coefficient noctanol/water [log value]	XI, 7.16 Dissociation constant	VII, 7.4 Density
					mg/L at 23 °C and pH 5.5			

Sources: ECHA Dissemination portal for entry #33, <https://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=723C9007-1> for entries #34, 45 and 46, Annex XV SVHC identification proposal: (Danish EPA, 2011) for entry #35, (BAuA, 2012) for entry #36, ECHA 2011d for entry #37, ECHA 2013a for entry #38, ECHA 2012d for entry #39, (KEMI, 2014) for entry #44, registration dossier of EC 271-094-0, (Health Canada, 2020 (molecular weight, water solubility, Log K_{ow}; National Library of Medicine (physical state, melting point, boiling point, vapour pressure, density)) for entry #45, CompTox for entry #46 (melting point).

B.1.4 Justification for grouping

The ten phthalates subject to this review belong to the *ortho*-phthalate family and have structural similarities. They all have similar concern to human health, as demonstrated by their harmonised⁶ classification as toxic to reproduction, category 1B. In addition, according to the information gathered, there are indications that these substances have a similar technical function (plasticiser) in variety of consumer, professional and industrial uses. Grouping of these substances was therefore considered relevant for this screening report.

B.2 Manufacture and uses

B.2.1 Manufacture, import and export of a substance

None of the ten phthalates are manufactured or imported to the EU in quantities above 1 tonne per year per company, in accordance with Article 5, 6(1) and 7(1)) of REACH.

The registration for diisopentylphthalate (EC 210-088-4) (entry #33) became inactive in 2021 and for 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters (EC No. 271-094-0) (entry #46) in 2018. SPIN data (SPIN database, 2021) for both EC numbers included in entry #46 suggest that no products are placed on the market in northern Europe and that the annual tonnage is lower than 100 kg¹⁸. Information on entry #33 in the SPIN database is marked as confidential.

The non-registered phthalates (or with inactive registration) could still be manufactured or imported to the EU/EEA if the total amount of the substance as such is below 1 tonne per year per company, in accordance with Article 5, 6(1) and 7(1)) of REACH. It is likely manufacturing of at least nine of the ten phthalates continues internationally as the substances have been reported present in imported articles in the SCIP database (all except entry #39).

¹⁸ Tonnages are reported as "0.0" which means that the volume is below the limit of accuracy, 100 kg.

Table 5. Substances manufactured and/or imported in the EU

Entry#	Name	EC Number	Estimated quantity manufactured and/or imported in Europe [tpa]
33	Diisopentylphthalate	210-088-4	manufacture ceased (inactive registration)*
34	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	276-158-1	No information available (no REACH registration)
35	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	271-084-6	No information available (no REACH registration)
36	1,2-Benzenedicarboxylic acid, dipentyl ester, branched and linear	284-032-2	No information available (no REACH registration)
37	Bis(2-methoxyethyl) phthalate	204-212-6	No information available (no REACH registration)
38	Dipentyl phthalate	205-017-9	No information available (no REACH registration)
39	n-pentyl-isopentylphthalate	933-378-9	No information available (no REACH registration)
44	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5	No information available (no REACH registration)
45	Dihexyl phthalate	201-559-5	No information available (no REACH registration)
46	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed decyl and hexyl and octyl diesters with $\geq 0.3\%$ of dihexyl phthalate (201-559-5)	272-013-1, 271-094-0	272-013-1: No information available (no REACH registration) 271-094-0: manufacture ceased (inactive registration)*

Note: *Sourced from ECHA dissemination portal

B.2.2 Uses in articles

The Table 6 gives an overview of the information on uses in articles gathered from various ECHA sources: REACH registration dossiers, applications for authorisation (AfA), SiA, and the SCIP databases. Whenever uses were identified, substance-specific details are provided in Table 6.

Table 6. Information on uses available in ECHA databases

Entry#	Name	EC Number	REACH registration*	REACH AfA**	REACH SiA‡	WFD SCIP‡
33	Diisopentylphthalate	210-088-4	historical uses before cease of manufacture: propellants	-	-	Yes
34	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	276-158-1	-	-	-	Yes
35	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	271-084-6	-	-	-	Yes
36	1,2-Benzenedicarboxylic acid, dipentyl ester, branched and linear	284-032-2	-	-	-	Yes
37	Bis(2-methoxyethyl) phthalate	204-212-6	-	-	-	Yes
38	Dipentyl phthalate	205-017-9	-	-	-	Yes
39	n-pentyl-isopentylphthalate	933-378-9	-	-	-	No
44	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5	-	- [1]	-	Yes
45	Dihexyl phthalate	201-559-5	-	- [1]	-	Yes
46	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (201-559-5)	272-013-1, 271-094-0	272-013-1: - 271-094-0: historical uses before cease of manufacture: PVC compounds, cables, artist supply ^[2] , coatings, polymer foils, adhesives, lubricants, building materials	- [1]	-	Yes

Notes:

[1]: the latest application date has not passed yet (27 August 2021)

[2] coatings and paints, thinners, paint removes, fillers, putties, plasters, modelling clay, finger paints, ink and toners

Sources: * ECHA Dissemination portal

**ECHA submitted applications for authorisation database

‡ ECHA Substances in Articles database

¥ ECHA SCIP database

In addition, searches were also performed in various other databases¹⁹ in order to identify any information on the substances presence in articles. Uses identified during the process of SVHC

¹⁹ Danish Chemicals in Consumer Products Database, Consumer Product Information Database (USA & Canada); US EPA CompTox; OECD Global Products Recall; Children's Safe Product Act Reported Data; ChemSec SIN list; RAPEX notifications database (EU Safety Gate); Phthalate substance grouping information from Health Canada; CPCat of US EPA; Substances in preparations in Nordic countries (SPIN database). Searches by a known substance identifier combined with the word "product" were performed in Google Scholar, Web of Science, and PubChem, as the purpose of the search focused on the identification of the use of the substances in articles. Based on a screening of the results from the last ten years displayed on the first two web pages, it was concluded that these search engines appear to provide information primarily on analytical methods, hazards (toxicology) and exposure. As the total search results exceeded

listing and prioritisation for inclusion in Annex XIV are also reported. Although these uses may not be relevant anymore in the EU/EEA, they may still exist outside the EU/EEA and thus, can lead to the import of articles in the EU/EEA. Below is a summary of the findings:

- Similar to other low to medium molecular weight *ortho*-phthalates, the ten phthalates are predominantly used as additives (primarily plasticisers) in articles made of PVC and other polymeric materials. However, none of the ten phthalates were identified in commercial use in high volumes in a recent joint ECHA and industry plastic additive mapping exercise.²⁰
- No applications for authorisation²¹ and notifications for substances in articles (SiA) have been received to date for the ten phthalates in the scope of this report. Therefore, taking into account additional information (e.g., from external database searches), it can be concluded that:
 - o The use of substances (in articles or other uses) in entries #33 to #39 has been phased out in the EU. Diisopentylphthalate (entry #33) may be a possible exception, as it may potentially be used in military applications under a REACH exemption for military purposes, in the event a Member State grants an exemption for the use in the interest of defence.²²
 - o The uses of substances in entries #44, #45 and #46 in the EU/EEA can continue until their sunset date (27 February 2023), unless exempted from authorisation. No information is available to suggest (i.e., no applications for authorisation have been submitted) that these substances are currently being used in the EU/EEA (for production of articles or other uses), although further information was sought during the call for evidence, but no such information was received.
- The use of most of the substances in articles may be continuing internationally and articles containing the substances in a concentration exceeding 0.1% w/w may be placed on the EU market in quantities of less than one tonne of the substance per year per supplier, as evidenced by submissions to the SCIP database (and the absence of notifications to the SiA database). Entry #39 (n-pentyl-isopentylphthalate) may be a notable exception as only information on limited historical use was identified and no information was found in the SiA and SCIP databases. Furthermore, no ECHA registration and no applications for authorisation were submitted for entry #39.

The conclusion on the limited presence of the substances in articles in the EU is also supported from information on enforcement. An enforcement project conducted by Nordic

36 000 and additional investigation of uses of *ortho*-phthalate will likely be performed in the context of a restriction proposal, further assessment was not performed for the purpose of this review report.

²⁰ For further information see Plastic Additives Initiative (<https://echa.europa.eu/plastic-additives-initiative>) and Mapping Exercise (<https://echa.europa.eu/mapping-exercise-plastic-additives-initiative>)

²¹ After the sunset date of an Annex XIV substance passes, only the following uses are allowed in the EU/EEA: i) uses for which an authorisation has been granted, ii) uses for which an application for authorisation was submitted before the latest application date and a decision on the authorisation is pending, ii) uses exempted from authorisation.

²² No information has been received to confirm this assumption, including during the call for evidence.

countries on give-away products (Norden, 2019) investigated the presence of a number of substances, including entries #34, 35, 37, 38, 44, 45, and 46. It appears that these substances were not found in the tested articles. No recent alerts also have been made in EU Safety Gate (RAPEX)²³ for the ten phthalates in the scope of this review report.²⁴

- According to the SCIP database, the nine phthalates (i.e., excluding entry #39) are most commonly found in complex articles, (parts of) machinery and equipment made of a variety of polymeric material, the most common being rubber and soft PVC. Bis(2-methoxyethyl) phthalate (entry #37) appears to have the most diverse number of applications (SCIP 2021).

The sections below provide more detailed overview of the uses of the ten phthalates in articles:

Entry #33: Diisopentylphthalate

Diisopentylphthalate has an inactive registration for industrial, professional and consumer uses in (the manufacture of) propellants (and explosives) to coat them to regulate the rate of burn. In general, phthalates are used in nitrocellulose propellants as plasticisers (to reduce danger of low temperature embrittlement) and for surface conditioning (reduction of burn rate). According to ECHA 2012c, a typical formulation for propellants contains 3-5 % of phthalates. According to information submitted in the call for evidence, diisopentylphthalate was present in concentration below 3 % weight by weight, although a different amount of propellant is present per ammunition round depending on the ammunition type. The propellants are used for the production of ammunition. Most of the uses of ammunition are military; however, a part is also used for civil applications and by consumers (e.g., sport shooters and hunters) for ammunition of different size (calibre) (ECHA 2012c).

In the past, diisopentylphthalate has been reported to be used in a similar manner to di-n-butyl phthalate (DBP) and diisobutyl phthalate (DIBP). DBP and DIBP are used in many PVC formulations, principally for ease of gelation. Because of their relatively high volatility, in comparison with other phthalates, they are often used in conjunction with higher molecular mass esters (ECHA 2012c). While there were no registrations for that use, ECHA 2012c concluded that diisopentylphthalate can potentially be used as a plasticiser and it has the potential to substitute other phthalates. No information is available on the amounts of diisopentylphthalate potentially present in the final articles and possible releases. The SPIN database reports the use of the substance in consumer preparations in Sweden between 2015 and 2019 (no use/volume is reported for reasons of confidentiality). US EPA lists fragrance and preservative with the highest predicted probability for associated functional uses for diisopentylphthalate in 2015 (Comptox 2021).

No authorisation for use of diisopentylphthalate in propellants and explosives or other uses of the substance have been submitted to ECHA to date. However, it is possible that some Member States have granted an exemption from REACH (as per Article 2 (3) of the REACH Regulation) in the interest of defence.²⁵ Information submitted during the call for evidence suggests that stocks of propellant and ammunition produced prior to the sunset date may be available and still sold to EU customers today. In addition, military ammunition with diisopentyl phthalate containing propellant produced before the sunset date may still be refurbished or dismantled.

²³ <https://ec.europa.eu/safety-gate-alerts/screen/search>

²⁴ Recalls have also not been reported in the OECD global product database: <https://globalrecalls.oecd.org/>

²⁵ No information has been received to confirm this assumption, including during the call for evidence.

Such refurbished ammunition, when shipped back to the military customers, would still contain the old propellant (e.g., in cases where only the primer is exchanged). Given that in old ammunition, there is a very specific interaction of the pyrotechnic substances used in its components, it is difficult to use alternative propellants when refurbishing the ammunition.

Other uses of the substance reported in the past include cosmetics (in Europe),²⁶ flooring and food contact materials (internationally).

Submissions to the SCIP database reveal limited use of diisopentylphthalate in articles (expected to be imported judging by the lack of applications for authorisations). The substance is reported as used in:

- rubber (acrylonitrile-butadiene or chloroprene or rubber combined with soft PVC) articles (e.g., tubes, pipes, hoses)
- soft PVC or epoxide resins in parts of electrical machinery and equipment, such as static convertors, electronic integrated circuits, printed circuits, and insulated fittings
- soft PVC and chloroprene rubber for refrigerators, freezers, heat pumps and other conditioning equipment; transmission shafts, gears, and other parts for machinery.

No SiA notifications (and applications for authorisation) have been submitted for the substance to date, indicating that the diisopentylphthalate is contained in imported articles in less than one tonne per importer per year.

On the basis of information described above, it can therefore be concluded that the use in articles of diisopentylphthalate in the EU/EEA has largely been phased out, unless uses exempted from authorisation continue, including in propellants for ammunition for military uses in the event a Member State may have granted exemptions from REACH in the interest of defence.²⁷ The substance appears to be used internationally and may be present in a limited number of imported articles in a concentration above 0.1% w/w (e.g., rubber articles, machinery and equipment), placed on the EU market in less than one tonne of the substance per year per supplier.

Entries #34: 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich, #35: 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters, and #36: 1,2-Benzenedicarboxylic acid, dipentyl ester, branched and linear

Before their addition to the authorisation list, the substances covered by the entries #34, 35 and 36 were not produced anymore in Europe, but were potentially used, in quantities below one tonne per year, for the following types of applications ((ECHA, 2011a) for entry #34, (Danish EPA, 2011) for entry #35, (BAuA, 2012) for entry #36):

- Use as plasticiser in PVC (industrial site), e.g., in construction building, in the manufacture of flooring products, in extrusion, injection moulding and calendaring applications requiring improved processability, in the manufacture of electric and communication cables/wires insulation, or in the maintenance and repair of vehicles.

²⁶ Analysis of plasticizers and synthetic musks in cosmetic and personal care products by matrix solid-phase dispersion gas chromatography–mass spectrometry, *Journal of Chromatography*, [Volume 1293](#), 7 June 2013, Pages 10-19, Llompart et al.

²⁷ No information has been received to confirm this assumption, including during the call for evidence.

- Use in mixtures such as sealants, coatings and printing inks (industrial, professional and consumer uses) in various types of application (e.g., cardboard, automotive, pesticides etc.)

Since their addition to the Annex XIV authorisation list, these three phthalates have not been registered and considering that no applications for authorisations have been submitted for the use of these substances in the EU to date, it is likely that the three phthalates covered by entry #34, 35 and 36 are no longer used in the EU.

When looking at the use of the substances outside Europe, Entry #34 is listed in the TSCA (Toxic Substances Control Act) database which means that the substance is considered an "existing" chemical substance manufactured or processed in the United States for uses under the TSCA. Entry #34 was also identified in at least one consumer mixture (Multipurpose Acrylic Paintable Caulk²⁸ containing 10 - 30% (w/w) of entry #34) which is still available on the US market, but also surprisingly on the EU market from web-retailers (e.g., from eBay²⁹). As the sunset date for this substance has already passed, the substance covered by entry #34 should indeed not be placed on the market unless an authorisation is granted, or the use is exempted from authorisations.

With regard to the uses in articles: in principle, imported articles, which are not within the scope of the applications for authorisations, might contain the substances of concern above the concentration limit of 0.1% w/w (e.g., articles made of flexible plastic, or coated, printed, sealed with mixtures containing the phthalate of interest). No SiA notifications for these substances have been received. However, uses in articles have been reported in the SCIP database. An overview is provided in Table 7 below.

Table 7. Applications reported in the SCIP database for Annex XIV entries #34, 35 and 36

Entry#	Name	Main types of applications	Reported material where the substance is included
34	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	Rubber articles	Various plastics and polymers
35	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	Main applications in: <ul style="list-style-type: none"> - Electrical machines and apparatus - Electrical transformers, static converters (for example, rectifiers) and inductors - Parts and accessories of motor vehicles including seats. Other minor applications include uses in nuclear applications, oscilloscopes, spectrum analysers and other instruments and apparatus for measuring or checking electrical quantities, rubber articles	Various plastics and polymers

²⁸ Source: <https://www.whatsinproducts.com/chemicals/view/1/4042/071888-89-6/Diisoheptyl%20phthalate> – The caulk may be used for sealing interior and exterior windows, replacing window panes, sealing cracks in the doorjamb or window seal.

²⁹ The mixture (shipped from the US) was still placed on the EU market on 8 April 2021.

Entry#	Name	Main types of applications	Reported material where the substance is included
36	1,2-Benzenedicarboxylic acid, dipentyl ester, branched and linear	Main application in (ignition) wiring sets used in vehicles, aircraft or ships. Other minor applications include uses in vehicle seats, and nuclear applications	Non-halogenated (co)polymers (plastic and polymers)

Source: ECHA SCIP database (extracted in June 2021)

A 2019 report (Andersson et Al., 2019) on restricted chemical substances in recycled plastics originating from ELV (End-of-Life Vehicles) and WEEE (Waste Electrical and Electronic Equipment) collected in Europe, reports the presence of the phthalates covered by entry #34 in plastics pellets made of recycled plastics in concentration < 0.01% (w/w). This might be explained by the recycling of plastics that contained the phthalates covered by entry #34. It should be noted as well that substances covered by entries #35 and #36 were not detected in the analysed samples (n=17). Nevertheless, the report indicates as well that 'poor' quality plastics are usually not recycled and were therefore not sampled and tested to identify the presence of restricted chemicals.

On the basis of information from the SCIP database, the external database and the literature searches, it can therefore be concluded that the uses of the phthalates covered by entries #34, 35 and 36 continue internationally, and that the substances are contained in imported articles (imported in quantities of less than 1 tonne per year per producer or importer) supplied to the EU market.

Information submitted during the call for evidence revealed that the only manufacturer in the EU and internationally of entry #34 decommercialised the substance in 2008-2009 after its identification as a Category 1B reproductive agent. As a result, the substance was phased out from commercial use in the EU and internationally.

Entry #37: Bis(2-methoxyethyl) phthalate

Bis(2-methoxyethyl) phthalate is not registered and considering that no applications for authorisations have been submitted for the use of the substance to date, it is likely that the substance is no longer used in the EU/EEA in articles or other uses (unless potentially for uses exempt from REACH authorisation requirements). No SiA notifications for the substance have been received but the substance has been reported to be contained in articles in the SCIP database. The reported uses in articles placed on the EU market are primarily in parts of electrical machinery and equipment such as accumulators, insulators, resistors, boards, panels, etc., as well as in wiring sets for vehicles, aircraft or ships. This suggests that the substance is contained in imported articles (imported in quantities of the substance contained in these articles of less than 1 tonne per year per importer) supplied to the EU market. The substance is reportedly used in the following materials and mixtures supplied to the EU market: copolymers of ethylene-vinyl acetate; cellulose and its chemical derivatives; polycarbonates (PCS), including copolymers; poly(ethylene terephthalate) (PET), including copolymers; high density polyethylene (HDPE); other rubber (SCIP 2021). Further information on the applications of bis(2-methoxyethyl) phthalate reported in the SCIP database are included in Table 8.

Table 8. SCIP database submissions for Bis(2-methoxyethyl) phthalate (entry #37)

CN* Section	CN* Chapter	Material Category
SECTION IV (16 - 24) Prepared foodstuffs; beverages, spirits and vinegar; tobacco and manufactured tobacco substitutes	Preparations of vegetables, fruit, nuts or other parts of plants	polyethylene, high density (hdpe)
SECTION VII (39 - 40) Plastics and articles thereof; rubber and articles thereof	Plastics and articles thereof	cellulose and its chemical derivatives (not elsewhere specified)
		polyethylene, high density (hdpe)
SECTION XVI (84 - 85) Machinery and mechanical appliances; electrical equipment; parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles	Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles	copolymers of ethylene-vinyl acetate
		ferroelectric perovskites based ceramic
		other special glass
		poly(ethylene terephthalate) (pet), including copolymers
		polycarbonates (pcs), including copolymers
	Nuclear reactors, boilers, machinery and mechanical appliances; parts thereof	other rubber
other: ()		

Notes: * Combined Nomenclature

Source: SCIP database (date of extraction June 2021)

Previously reported general global applications include use as a plasticiser in the production of nitrocellulose, acetyl cellulose, polyvinyl acetate, polyvinyl chloride and polyvinylidene chloride intended for contact with food or drink. It can be used in enamelled wire, film, high-strength varnish, additive in printer inks, adhesive as well as in pesticide products internationally. Specific reported advantages of bis(2-methoxyethyl) phthalate include improving the durability and toughness of cellulose acetate (e.g., in laminated documents). The substance was also reportedly used in the past in the EU in a number of consumer products, e.g., in a material used to cover floors, in leather care products (e.g. for shoes), or in paints, lacquers and varnishes (ECHA 2011d). The SPIN database reports the use of the substance in construction in Denmark until 2014, and historically in paint, flooring and wall covering (SPIN 2021). ChemSec reported uses include plasticiser or solvent in moulding compositions, adhesives, laminating cements, and flash bulb lacquers (ChemSec 2021).

Internationally, it was also reportedly used in balls for playing and exercise, hoppers and children's toys (e.g., as inflatable water products) (ECHA 2011d). US EPA lists UV absorber and fragrance as the most common uses for bis(2-methoxyethyl) phthalate in 2015 (Comptox 2021).

Based on the information above, it can be concluded that bis(2-methoxyethyl) phthalate is no longer used in the EU (unless uses exempted from authorisation are continuing) but imported articles containing the substance in concentration above 0.1% w/w are still placed on the EU market likely in quantities below one tonne per year per supplier.

Entry #38: Dipentyl phthalate

The primary reported use for dipentyl phthalate in articles in the past has been as a plasticiser for PVC. Additional use reported in the past included as a component of gunpowder (ECHA 2013a). The SPIN database reports the use of the substance in gunpowder and explosives in Sweden until 2019 (SPIN 2021). US EPA lists fragrance, preservative and UV absorber with the

highest predicted probabilities of associated functional use for dipentyl phthalate in 2015 (Comptox 2021).

As there are no registrations and applications for authorisation for dipentyl phthalate, it can be concluded that the substances are no longer used in the EU (unless uses exempted from authorisation are continuing). No SiA notifications have been submitted for the substance to date, indicating that the dipentyl phthalate is not contained in imported articles in concentrations of more than 0.1% w/w in more than 1 tonne per importer per year.

Submissions to the SCIP database reveal limited use of dipentyl phthalate in articles. The substance is reportedly used in various plastic articles (e.g., artificial flowers) made of other acrylic polymers and copolymers. Other reported uses include parts of electrical machinery and equipment, such as electric conductors, headphones, switches, monitors, etc. made of soft PVC, other polyesters, elastomultiester and other.

These findings suggest that dipentyl phthalate can be found in a limited number of imported articles placed on the EU market, likely containing less than one tonne per year of the substance per supplier.

Entry #39: n-pentyl-isopentylphthalate

The primary reported use for n-pentyl-isopentylphthalate in articles in the past has been as a plasticiser for PVC. There are no registrations for the substance, applications for authorisation as well as no reported uses in the SCIP or SiA databases, implying that currently n-pentyl-isopentylphthalate is not used or placed on the EU market, including in imported articles.

Entry #44: 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear

Previously reported applications include use as sealant/jointing agents, and as a component in engine oil stabilizer, and as lubricant in automotive gear (BAuA, 2012). According to the ChemSec SIN List, this phthalate is used as lubricant in steering fluid and as plasticiser as well; applications include rubber and plastics products.

When looking at the use of this substance outside Europe, entry #44 is imported for use in auto transmission lubricants in Australia (ChemSec SIN List) and is listed in the TSCA database which means that the substance is considered an "existing" chemical substance manufactured or processed in the United States for uses under the TSCA.

Entry #44, according to the SPIN database, was identified in four different preparations used as lubricants and additives in the maintenance and repair of motor vehicles and motorcycles in Sweden until 2019. The quantity reported for 2019 were below 100 kg/year.

Submissions to the SCIP database reveal limited use in complex articles of this phthalate. The substance is reported to be used in two main types of application:

- Electrical machinery and equipment such as electronic integrated circuits, monitors and projectors, or reception apparatus for television
- Nuclear reactors, boilers, machinery and mechanical appliances, such as automatic data-processing machines and units; magnetic or optical readers.

The main material where the substance is reported to be contained is poly(ethylene terephthalate) (PET), including copolymers.

No registration, no applications for authorisation and no SiA notifications have been submitted for the substance to date, indicating that the substance covered by entry #44 may only be contained in imported articles in less than 1 tonne per importer per year.

On the basis of information from the SCIP database and the external database searches, it can therefore be concluded that the uses by entry #44 continue internationally, and that the substance is contained in imported complex articles (imported in quantities of less than 1 tonne per year per producer or importer) supplied to the EU market.

Entry #45: Dihexyl phthalate

This substance (a mono-constituent) is not registered and there is no registration information available relating to the use of the substance in articles.³⁰ According to the European sector association European Plasticisers, the substance is not manufactured by their members.³¹ Furthermore, no SiA notifications have been received. Submissions in the SCIP database concern use in polymeric materials, i.e., PVC, non-halogenated (co)polymers and/or polyurethanes, predominantly in electrical equipment such as wiring insulation and switches. In addition, it is reported in a number of (soft) PVC articles, e.g., seamless tubing, as well as in accessories in vehicles, and certain copper-based articles like pins and tacks).

No applications for authorisation were received for dihexyl phthalate by the latest application date for authorisation of 27/08/2021. No exempted categories of uses apply.

The Annex XV report (BAuA, 2013) proposing the identification of dihexyl phthalate as an SVHC reported that dihexyl phthalate can be used in the making of plastisols that are subsequently used in the manufacture of automobile parts (air filters, battery covers) and dip-moulded products (tool handles, dishwasher baskets). Additionally, it may be added to the PVC utilised in the manufacture of flooring, canvas tarps, and notebook covers. Substances containing dihexyl phthalate may also be used in traffic cones, toys, vinyl gloves, weather stripping, flea collars, shoes, and conveyor belts used in food packaging operations and potentially in applications where high solvating plasticisers and stain resistance are required, for example, foamed leather cloth and flooring.

Within Europe, the Nordic countries' SPIN database reports no use/volume data in the period 2003-2019 (last year of reporting, for reasons of confidentiality). That said, SPIN concludes dihexyl phthalate has a very narrow range of applications and an amount used annually which equates to <0.01 tonnes per year, maximum.

Some uses of dihexyl phthalate are reported internationally as plasticiser/softener (for most synthetic polymers, occasional reinforcement/strength) in various soft toys/dolls, cosmetics (nails, glitters), jewellery (rings, necklaces, brooches, bracelets) & clothing accessories, boots/shoes, painting and drawing supplies, colouration in pigments/dyes/inks. The substance is also reportedly used as a component of plastic resin or polymer process aid in inks/dyes/pigments, surface coatings and synthetic polymers (for the latter up to 1000 ppm).³²

Based on the information above, it can be concluded that dihexyl phthalate is no longer used as such in the EU (unless uses exempted from authorisation are continuing) but imported articles

³⁰ Dihexyl phthalate was pre-registered with an indication of registration by 30 November 2010.

³¹ [European Plasticisers](#) – a sector group of Cefic (web page accessed 19.06.2021)

³² <https://theic2.org/hpcds#gsc.tab=0> accessed 17/06/2021.

containing the substance in concentration above 0.1% w/w are still placed on the EU market, likely in quantities below one tonne per year per supplier.

Entry #46: 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed decyl and hexyl and octyl diesters with \geq 0.3% of dihexyl phthalate

Entry #46 covers 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed decyl and hexyl and octyl diesters with \geq 0.3% of dihexyl phthalate, and therefore only the articles incorporating substances containing \geq 0.3% of dihexyl phthalate are targeted in this Article 69(2) report. Thus, it is the amount of dihexyl phthalate in articles that has to be considered. However, the available information on uses in articles does not allow to distinguish cases where articles incorporate substances containing more than 0.3% of dihexyl phthalate. Therefore, for the purpose of this screening report, it is assumed that all articles reported to contain substances EC 271-094-0 and EC 272-013-1 fall within the scope of this screening.

Substance EC 271-094-0 was registered but the registration has been inactive since 2018. The registration referred to uses in: coatings, artist supplies (coatings, paints, thinners, paint removes, fillers, putties, plasters, modelling clay, finger paints, ink and toners, rubber and plastic articles), PVC compounds, polymer foils, cables, building materials (polymer preparations and plastic compounds), lubricants and adhesives (lubricants, greases, release products, polymer preparations and compounds, included in vehicles, machinery, mechanical appliances, electrical/electronic articles, fabrics, textiles and apparel, plastic articles), articles obtained by calendaring (plastic, rubber articles, textiles, parts or vehicles, part of machines, electrical/electronic articles) (KEMI, 2015). EC 272-013-1 is not registered, however, as the two substances are closely related, information on the use of substance with EC 271-094-0 is considered relevant also for the substance with EC 272-013-1 (KEMI, 2015).

SPIN data (SPIN database, 2021) reveals use of substance EC 271-094-0 (with a decrease in the number of preparations and tonnage over the years) related to the repair of motor vehicles and motorcycles (most recent data in 2017), as adhesives, binding agents (most recent data in 2011). Data from CPCAT (USA) do not contradict the information from the registration dossier and the SPIN database.

All these uses are in the scope of REACH authorisation, but no applications for authorisation have been submitted to date. Furthermore, no SiA notifications were received. However, several SCIP submissions were received which indicate that the substances are used in plastics (in silicones, in polyethylene, and in the insulating fitting of soft PVC plastic in electrical appliances), in paper pulp (filters) and pig iron in silicate ceramics, and in unspecified material in service vehicles for railway/tramway maintenance.

(KEMI, 2015) identified a US safety data sheet for a polyurethane product containing 15-40% of substance EC 271-094-0, intended for adhesives and sealants for windshields. This product is still available on the distributor website³³. A reiteration of the search³⁴ for the two CAS numbers associated with entry #46: 68515-51-5 and 68648-93-1 coupled with the keyword "MSDS" showed only a few relevant hits, namely (not an exhaustive list) several (M)SDS from the USA

³³ <https://www.finishmaster.com/prod/assets/08609.pdf>, accessed 28/05/2021

³⁴ Search performed on Google on 28/05/2021, only first 5 pages of results considered.

for a polyurethane curing foam³⁵, a paste resin³⁶, a polyurethane sealant³⁷, an optical gel³⁸ containing respectively 0-19%, 30-60%, 0-25%, 20-40% of substance EC 272-013-1. This reveals that some products which, although mixtures, can be incorporated in complex articles, are available outside the EU/EEA and it cannot be excluded that articles containing the substance may be imported to the EU/EEA.

A search in various databases¹⁹ did not provide any hits.

Therefore, the substance may be contained only in imported articles, i.e., below the limit for notification for SiA (i.e., less than 1 tonne per supplier), as evidenced by a few SCIP submissions and MSDS. Therefore, it cannot be ruled out that some (complex) articles may contain the substances in e.g., sealants used to attach pieces together, plastic parts, silicate ceramic parts.

The identification of compounds falling in the scope of entry #46 is rather complex, and thus, it cannot be excluded that some compounds corresponding to the definition of “substance having a composition equivalent to the diesterification reaction products between 1,2-benzenedicarboxylic acid and “C6-10 alcohols” or “C6-10 alcohols (even numbered)” can still be present in imported articles.

B.2.3 Uses advised against by the registrants

No uses advised against were reported by registrants for diisopentylphthalate (EC 210-088-4) and 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters (EC 271-094-0)³⁹.

The remaining phthalates of interest have no REACH registrations.

B.2.4 Description of targeting

This Annex XV report under Article 69(2) is targeted on the potential release of the ten phthalates from articles and exposure to these substances when used in articles and whether or not such use should be restricted. Furthermore, targeting is based on the hazard for which the substances were included on Annex XIV, i.e., toxic to reproduction, Category 1B.

B.3 Classification and labelling

B.3.1 Harmonised classification according to CLP

Table 9 provides an overview of the harmonised classification according to the CLP Regulation. Nine of the ten phthalates have a harmonised classification for toxic to reproduction, category 1B, with applicable generic concentration limits of equal or greater than 0.3% w/w. In addition, according to registration information, diisopentylphthalate is additionally classified as Skin Sens. 1, H317 (ECHA 2012b).

³⁵ <http://www.emseal.com/wp-content/uploads/2016/06/security-seal-ssw2-sds-package-2-hour-fire-rated-expansion-joint-pick-resistant-emseal.pdf>, accessed 28/05/2021

³⁶ <https://www.buildsite.com/pdf/escoweld/Phillymastic-TG-7B-SDS-1469062.pdf>

³⁷ https://www.pecora.com/wp-content/uploads/2015/12/NR-200-Urexpand-Part-B-SDS_8-26-14.pdf

³⁸ <https://cargille.com/wp-content/uploads/2018/10/Cargille-Sub-Lux-Gel-Code-081160C-USA.pdf>

³⁹ Registrations for these substances are not active.

Table 9. Harmonised classification according to the CLP Regulation

Entry#	Substance name	EC Number	Index number	Harmonised classification
33	Diisopentylphthalate	210-088-4	607-426-00-1	Repr. 1B (H360FD) Aquatic acute 1 (H400)
34	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	276-158-1	607-483-00-2	Repr. 1B (H360D***)
35	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	271-084-6	607-480-00-6	Repr. 1B (H360Df)
36	1,2-Benzenedicarboxylic acid, dipentyl ester, branched and linear	284-032-2	607-426-00-1	Repr. 1B (H360FD) Aquatic acute 1 (H400)
37	Bis(2-methoxyethyl) phthalate	204-212-6	607-228-00-5	Repr. 1B (H360Df)
38	Dipentyl phthalate	205-017-9	607-426-00-1	Repr. 1B (H360FD) Aquatic acute 1 (H400)
39	n-pentyl-isopentylphthalate	933-378-9	607-426-00-1	Repr. 1B (H360FD) Aquatic acute 1 (H400)
44	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5	607-710-00-5	Repr. 1B (H360FD)
45	Dihexyl phthalate	201-559-5	607-702-00-1	Repr. 1B (H360FD)
46	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (201-559-5)	272-013-1, 271-094-0	-	Repr. 1B (H360FD) (not harmonised) ‡

Notes according to the CLP regulation (Annex VI):

***: Hazard statements H360 and H361 indicate a general concern for effects on fertility and/or development: 'May damage/Suspected of damaging fertility or the unborn child'. According to the criteria, the general hazard statement can be replaced by the hazard statement indicating the specific effect of concern in accordance with Section 1.1.2.1.2. of the CLP regulation. When the other differentiation is not mentioned, this is due to evidence proving no such effect, inconclusive data or no data and the obligations in Article 4(3) shall apply for that differentiation.

In order not to lose information from the harmonised classifications for fertility and developmental effects under Directive 67/548/EEC, the classifications have been translated only for those effects classified under that Directive. These hazard statements are indicated by the reference ***

D: May damage the unborn child

F: May damage fertility

f: Suspected of damaging fertility

‡ Classification of 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters where they contain dihexyl phthalate ≥ 0.3 % according to Art. 10 and Table 3.7.2 in Part 3 of Annex I to Regulation (EC) No 1272/2008 (CLP Regulation), on the basis of the entry with index number 607-702-00-1 for dihexyl phthalate in Part 3 of Annex VI to CLP Regulation

Source: ECHA Dissemination portal

B.3.2 Classification according to the Classification and Labelling Inventory

In general, the classifications notified to the C&L inventory match the harmonised one in the CLP Regulation. Table 10 indicates the notified classification in case the C&L notifications deviate from the harmonised one.

Table 10. Notified classifications (aggregated; in addition to the harmonised classification if applicable)

Entry#	Substance name	EC Number	Number of aggregated notifications	Classification (Number of notifiers with different to harmonised classification)
33	Diisopentyl phthalate	210-088-4	115	See "Harmonised classifications"
34	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	276-158-1	179	Repr. 1B (H360D)*
35	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	271-084-6	179	Repr. 1B (H360Df)**
36	1,2-Benzenedicarboxylic acid, dipentyl ester, branched and linear	284-032-2	116	Repr. 1B (H360FD)*** Aquatic acute 1 (H400)
37	Bis(2-methoxyethyl) phthalate	204-212-6	3	See "Harmonised classifications"
38	Dipentyl phthalate	205-017-9	250	Repr. 1B (H360FD) or Repr. 1A (2) Aquatic acute 1 (H400)
39	n-pentyl-isopentylphthalate	933-378-9	116	See "Harmonised classifications"
44	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5	28	Repr.2 (H361) (28)
45	Dihexyl phthalate	201-559-5	46	Repr. 1B (H360FD)*** or no classification (7)
46	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (201-559-5)	272-013-1, 271-094-0	-	Repr. 1B (H360FD)

Source: ECHA dissemination website consulted in March 2021

* D indication omitted in some cases

** Df indication omitted in some cases

*** FD indication omitted in some cases

B.4 Environmental fate properties

Not relevant.

B.5 Human health hazard assessment

All the ten phthalates of interest are included in Annex XIV based on their Toxic for Reproduction (category 1B) properties (REACH Article 57c). Other human health endpoints are not relevant for this report.

In preparation for reviewing potential applications for authorisation, RAC prepared reference DNELs based on the reproductive toxicity of diisopentylphthalate. These are presented in Table 11.

Table 11. Reference DNELs for entry #33 (diisopentylphthalate)

	Inhalation route	Dermal route	Oral route
General population	0.02 mg/m ³ /d (24 hrs)	0.07 mg/kg bw/d	0.007 mg/kg bw/d
Workers	0.13 mg/m ³ /d (8 hrs)	19 mg/kg bw/d	-

Source: ECHA 2016

B.6 Human health hazard assessment of physicochemical properties

Not relevant.

B.7 Environmental hazard assessment

Not relevant.

B.8 PBT and vPvB assessment

Not relevant.

B.9 Exposure assessment

B.9.1 General discussion on releases and exposure

Phthalates are not covalently bound to the PVC/polymer matrix and can migrate into the surrounding environment. Migration of phthalates depends on type of contact, contact duration, temperature, plasticiser concentration difference, plasticiser concentration level, molecular weight and molecular structure. Another element that seems important in determining the migration rate is the process conditions for article manufacturing. Phthalates are highly lipophilic, and therefore fatty simulants, such as olive oil, can produce significant migration in contrast with non-lipophilic media (ECHA 2017).

The general population and workers may be exposed to variety of articles made from PVC or other polymeric materials which may contain one or more of the ten phthalates. Similar to other *ortho*-phthalate plasticisers, exposure could not only occur via different sources but also via different routes. Oral exposure can occur from ingestion of food and dust, and from mouthing of articles. Exposure can also occur from inhalation of air and dust and from dermal contact with articles and dust. The main sources of exposure are considered to be food, indoor environment and direct contact with articles.

B.9.1.1 Summary of the existing legal requirements

REACH Regulation:

REACH has several requirements for substances on the Candidate List including the notification of its presence in Articles if the concentration exceeds $\geq 0.1\%$ and 1 tonne per year (Article 7(2)); and the obligation for suppliers to inform their customers on request if an article contains more than 0.1% by weight of the substances (Article 33(b)).

The entries in Annex XIV for Authorisation set the latest application dates and sunset dates as described in table 1. The substances cannot be used in the EU after their sunset date has passed (except in uses covered by a granted authorisation, uses for which applications for authorisations have been submitted before the latest application deadline and whose decision is pending, or uses exempted from authorisation).

Due to their harmonised classification as Repro 1B, five of the phthalates in the scope of this review: diisopentylphthalate (#33) 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (#34), bis(2-methoxyethyl) phthalate (#37), dipentyl phthalate (#38), and dihexyl phthalate (#45) are restricted under entry #72 of Annex XVII. The five phthalates are restricted in consumer clothing or related accessories; textiles other than clothing which, under normal or reasonably foreseeable conditions of use, come into contact with human skin to an extent similar to clothing and footwear in concentrations above 0.1% w/w, individually or in combination with other phthalates in entry #72 or in other entries of Annex XVII that are classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 in any of the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B.

The ten phthalates are also restricted under entry #30 of Annex XVII for supply to the general public as a substance, constituent of a substance or in mixtures, when the concentration exceeds relevant concentration limit specified in Part 3 of Annex VI to the CLP Regulation (EC) No 1272/2008.

EU legislation other than REACH:

The classification under the CLP Regulation of the ten phthalates subject to this report trigger obligations under a wide range of EU-wide legislation. The following concern the concentration of the ten substances in articles in particular:

- Active Implantable Medical Devices Directive (90/385/EEC)
- Construction Products Regulation (305/2011/EU)
- Ecolabel Regulation (66/2010/EC)
- End-of-Life Vehicles Directive (2000/53/EC)
- General Product Safety Directive (2001/95/EC)
- Active and Intelligent Materials and Articles Intended to Come into Contact with Food (450/2009/EC)
- In Vitro Diagnostic Medical Devices Directive (2001/95/EC)
- Medical Devices Directive (93/42/EEC)
- Marine Environmental Policy Framework Directive (2008/56/EC)
- Toy Safety Directive (2009/48/EC)
- Waste Framework Directive (2018/851/EU).⁴⁰

Other EU legislation concerns the presence of the substances at workplaces (e.g., Protection of pregnant and breastfeeding women directive 92/85/EEC, Protection of young people at work directive 94/33/EC, Workplace signage: EU Directive 92/58/EEC, Safety and Health of Workers at Work Directive 89/391/EEC, Chemical Agents Directive 98/24/EC) and their concentration in mixtures (e.g., Cosmetics Products Regulation, 1223/2009/EC). Further information on existing EU legislation relevant for the ten phthalates is available on ECHA's website under EU Chemicals

⁴⁰ The ten substances subject to this review are included in Annex II of the Directive due to their harmonised classification under the CLP Regulation of Repro 1B. The revised WFD (July 2018) gave ECHA the task to develop a database with information on articles containing SVHCs on the Candidate List. Companies supplying articles containing these substances in a concentration above 0.1% w/w on the EU market have to submit information on these articles to ECHA from 5 January 2021. The SCIP database (for information on Substances of Concern In articles as such or in complex objects (Products) established under the WFD) complements the existing information requirements for the presence of hazardous substances in articles under REACH (ECHA 2021). Information on the submissions to the SCIP database reporting the use of the ten phthalates is reported in section B.2.2.

Legislation Finder (EUCLEF): <https://echa.europa.eu/fi/legislation-obligation/-/obligations/100.001.062>.

B.10 Risk characterisation

No analysis is presented as no restriction is proposed at present.

C. Available information on alternatives

As no restriction is proposed at present, detailed analysis of the alternatives is not presented. Alternatives to the 10 phthalates are anticipated to exist as there is no information on applications where they have particular advantages, and worldwide their use appears limited.

A number of substances have been identified as alternative plasticisers on the market. Recent trend has been pointing to substitution of low molecular weight plasticisers to high molecular weight such as DINP, DINCH, but also terephthalates, citrates, sebacates, adipates and phosphates. Similar to the phthalates these alternative plasticisers are not chemically bound to the polymer and can leach out of products. In ammunition, currently DBP is authorised in the EU. The suitability of alternatives for every application depends not only on the inherent properties but also on the performance requirements (temperature, viscosity, ageing, fogging, price) of the article being manufactured (ECHA 2012c).

A recent joint ECHA and industry plastic additive mapping exercise identified a number of plastic additives registered under REACH at above 100 tonnes per year and used as plasticisers, flame retardants, pigments, antioxidants, antistatic agents, nucleating agents and various types of stabilisers.⁴¹

SWECO 2018 identified more than 150 substitutes to regulated plasticisers, i.e., on REACH Candidate, Authorisation or Restrictions list, ECHA CoRAP list, or Swedish PRIO List or the Restricted database in Sweden.

D. Justification for action on a Community-wide basis

Not relevant, as no restriction is proposed at present.

E. Justification why the proposed restriction is the most appropriate Community-wide measure

Not relevant, as no restriction is proposed at present.

F. Socio-economic Assessment of Proposed Restriction

Not relevant, as no restriction is proposed at present.

G. Stakeholder consultation

The call for evidence, which took place between 8 December 2021 and 26 January 2022, did not identify any new uses of the substances in articles placed on the EU market. Several comments

⁴¹ For further information see Plastic Additives Initiative (<https://echa.europa.eu/plastic-additives-initiative>) and Mapping Exercise (<https://echa.europa.eu/mapping-exercise-plastic-additives-initiative>)

were received providing additional information on the ten Annex XIV phthalates in support of the information in the report. In total, two comments were received by Member State competent authorities and three industry associations. In summary,

- Two comments provided results of previous screening of the presence of the ten phthalates subject to this report. In 2006 report by the Danish Environmental Agency, entry #38 was identified in several plastic foam toy and childcare products such as sword, activity carpet, book, mask, surfboard, ball and floor puzzles. The concentration did not exceed more than 0.5 mg/kg for all products except the ball, where entry #38 did not exceed 2.5 mg/kg (Danish EPA 2006). 2017 report identified phthalates entry #38 and entry #45 in five samples of pizza boxes in concentration of respectively less than 2 µg/dm² and 3 µg/dm² (Danish EPA 2017). A 2014 survey of phthalates by Sweden identified five out of nine of the Annex XIV phthalates as registered in the Swedish product register (entry 45 was not in the scope of the Swedish report): i.e., entries number: 34, 35, 36, 38, and 44 (KEMI 2014a).
- One comment summarised the uses of the ten phthalates in military applications
- One comment provided an overview of uses and alternatives of the ten phthalates as well as other *ortho*-phthalates with C4-C6 backbone
- Three comments were explicitly supportive of the conclusions of the report, although one stakeholder called into question the need to further examine the risks from the use of these ten phthalates in articles as part of a larger investigation to address risks from *ortho*-phthalates, with suspected similar concern to human health and the environment. In the opinion of the stakeholder, the uses of these phthalates have been largely phased out and further regulatory action would not lead to significant risk reduction.

This final report takes into account the information received on the ten Annex XIV phthalates during the call for evidence. The information on other *ortho*-phthalates with C4-C6 backbone will be taken into account in the examination for the need of restriction to address risks arising from their presence in articles.

H. Other information

Not relevant.

References

- Andersson et Al. (2019). *Mapping and evaluation of some restricted chemical substances in recycled plastics*. RISE IVF AB, ISBN: 978-91-88907-54-7. Retrieved from <https://www.diva-portal.org/smash/get/diva2:1295690/FULLTEXT02.pdf>
- BAuA. (2012). *Annex XV report - Proposal for identification of a substance as an SVHC for 1,2-Benzenedicarboxylic acid dipentylester, branched and linear*. Submitted by the BAuA - Germany, August 2012. Retrieved from <https://echa.europa.eu/documents/10162/be72273c-858b-6c5a-1239-85ebb7c76e7c>
- BAuA. (2013). *Annex XV report - Proposal for identification of a substance as an SVHC for Dihexyl phthalate*. Submitted by the BAuA - Germany, 2012. Retrieved from <https://echa.europa.eu/documents/10162/9a8b4fa6-c852-48bd-b561-c727b8d197ff>.
- Canada, E. a. (2020). *Screening Assessment. Phthalate Substance Grouping*. Health Canada, December 2020. Retrieved from <https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/screening-assessment-phthalate-substance-grouping.html>.
- Danish EPA. (2011). *Annex XV report - Proposal for identification of a substance as an SVHC for 1,2-Benzenedicarboxylic acid, di-C7-11 -branched and linear alkyl esters (DHNUP)*. Submitted by the Danish Environmental Protection Agency - Denmark, January 2011. Retrieved from <https://echa.europa.eu/documents/10162/90b30344-9d14-15ad-c5fe-9dadd4a8af8a>
- ECHA. (2011a). *Annex XV report - Proposal for identification of a substance as an SVHC for 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich*. Submitted by ECHA on request of the Commission, February 2011. Retrieved from <https://echa.europa.eu/documents/10162/eec0b364-e29e-48f8-970c-a4cdb78465b8>
- ECHA. (2011b). *Comments on an annex xv dossier for identification of a substance as svhc and responses to these comments*. Retrieved from <https://echa.europa.eu/fr/registry-of-svhc-intentions/-/dislist/details/0b0236e180e4a232>
- ECHA. (2011c). *Member State Committee support document for identification of 1,2-benzenedicarboxylic acid, di-c6-8-branched alkyl esters, c7-rich (dihp) as a substance of very high concern because of its cmr properties; adopted on 20 may 2011*. Retrieved from <https://echa.europa.eu/documents/10162/cbbf42b0-a111-c54c-42d2-9b5c13135d7b>
- ECHA. (2015). *Member State Committee support document for the identification of 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with $\geq 0.3\%$ of dihexyl phthalate (EC no. 201-559-5)*. Retrieved from <https://echa.europa.eu/documents/10162/2b4a5011-39c9-4eb0-9309-9aa6b10981ab>
- ECHA. (2018). *Background document for 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with $\geq 0.3\%$ of dihexyl phthalate (EC No. 201-559-5) - 8th recommendation for inclusion in Annex XIV*. Retrieved from <https://echa.europa.eu/documents/10162/d9ac49aa-6ca8-381e-c9df-38c053a42a79>

- KEMI. (2014). *Annex XV report - Proposal for identification of a substance as an SVHC for 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear*. Submitted by KEMI-Swedish Chemicals Agency, February 2014. Retrieved from <https://echa.europa.eu/documents/10162/06da7989-d9f9-85fd-098b-30cd13e9f5de>
- KEMI. (2015). *Annex XV report - Proposal for identification of a SVHC for 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters and 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters*. Submitted by the Swedish Chemicals Agency - February 2015. Retrieved from <https://echa.europa.eu/documents/10162/6b8c38f1-6d8c-470d-6f0a-78c8b393fe99>
- Medicine, N. L. (2021). *Hazardous Substances Data Bank*. Accessed 20/06/2021. <https://pubchemdocs.ncbi.nlm.nih.gov/about>.
- Norden. (2019). *Nordic enforcement project on give-away products*. Nordic Council of Ministers (Norden).
- SPIN database. (2021). *Database on substances in preparations in Nordic Countries*. Retrieved from <http://www.spin2000.net>, accessed 2021-05-27
- SWECO (2018) *Substitutes for regulated phthalates*. Swedish Environmental Protection Agency. 2018