

Estimating the number and types of applications for 11 substances added to the Authorisation List in February 2020

February 2020

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Estimating the number and types of applications for 11 substances added to the Authorisation List in February 2020

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European Chemicals Agency

P.O. Box 400, FI-00121 Helsinki, Finland

Table of Contents

EXECUTIVE SUMMARY	5
INTRODUCTION	7
METHODS	10
Literature search and evaluation of ECHA background documents	10
Assessment of current uses	10
Analysis of information on alternatives	
Stakeholder consultation Supply chain description and assessing likelihood of applications for authorisation	
RESULTS AND DISCUSSION	12
Summary of uses and potential suppliers	20
1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters	24 24
Supply chain description	25
CONCLUSIONS	27
REFERENCES	29
APPENDIX A	30
APPENDIX B	33
APPENDIX C	38

Tables

Table 1 – Substances added to the Authorisation List on 6 February 2020	5
Table 2 - Substances added to the Authorisation List in 2020	9
Table 3 - Summary of substance uses compiled from ECHA background documents and literature searc	
Table 4 - Current use of substances in articles on EU market	.19
Table 5 - Potential alternatives to 11 substances being placed on the Authorisation List	.20
Table 6 - Classification and labelling notifications for unregistered substances on the Authorisation List	.23
Table 7 - Patents owned by European companies (including in Switzerland and Norway) by substance	.30
Table 8 - Substance patents by European company (including in Switzerland and Norway)	.32
Table 9 - EU suppliers of 11 substances added to the Authorisation List in 2020	.33
Table 10 - Details of EU chemical suppliers for 11 substances added to the Authorisation List in 2020	.35
Table 11 - List of substances, uses of which in mixtures and articles have been reported in the SPIN database for 2017 by Denmark, Finland, Norway and Sweden	.38

Executive Summary

The European Commission added 11 substances to the Authorisation List (Annex XIV to the REACH Regulation) on 6 February 2020. In the run-up to the new entries' publication in the Official Journal, ECHA and wca^1 , an independent consultancy providing advice on the risk assessment of chemicals in the environment and workplace, have carried out market research to explore the likely numbers of applications for authorisation that might be received for these substances in the future (Table 1).

Anticipating the potential number of applications for authorisation is instrumental for ECHA to be able to plan its staff resources, the meetings of the Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) and to ensure that it has the capacity to provide timely opinions on any applications for these substances.

ECHA can expect to receive few applications for the 11 substances. The only substance for which a potential applicant was found was trixylyl phosphate.

Table 1 - Substances added to the Authorisation List on 6 February 2020

Substance	EC number	Number of applications
1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear*)	271-093-5	0
dihexyl phthalate	201-559-5	0
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	271-094-0; 272-013-1	0
trixylyl phosphate*)	246-677-8	Some**)
sodium perborate*)	239-172-9; 234-390-0	0
sodium peroxometaborate	231-556-4	0
5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof]	-	0
2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328) *)	247-384-8	Possibly some**)
2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	223-383-8	0

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¹ https://www.wca-environment.com/index.php/about-us

2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	253-037-1	0
2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	223-346-6	0

^{*)} Registered substances **) Some = under five applications

However, the market intelligence suggests that small volumes are being placed on the EU market even for the unregistered substances, so it is important to ensure that there is adequate publicity on the announcement of Authorisation List updates and to highlight to importers that these substances should not be placed on the EU market after the sunset date unless they apply for authorisation to continue specific uses of the substances.

A search for information on the presence of the 11 substances in articles on the EU market revealed only limited information but indicated that some of these substances, particularly the UV substances, may be present in imported articles. Therefore, ECHA will need to consider preparing restriction dossiers according to Article 69(2)² of REACH after the sunset dates for the relevant substances incorporated in articles and imported into the EU have passed.

The lead registrant of UV-328 posited that it is very likely that articles containing UV-328, as well as a similar substance UV-327 (and possibly other UV substances), will continue to be imported into the EU market. They, therefore, considered it essential for there to be an EU-wide restriction on articles containing these substances.

Data from the Substances in Preparations in Nordic Countries (SPIN) <u>database</u> suggested that six of these 11 substances were placed on the market in Nordic countries. As many of them have not been registered it is likely that these are manufactured or imported by multiple actors under one tonne each in 2017(see Table 11).

ECHA approached the lead registrants of the four registered Substances of Very High Concern (SVHCs)³. They stated that it is very unlikely that a market exists in the EU for these substances following their sunset dates. The specific findings were:

- **Trixylyl phosphate** (EC 246-677-8): there is some interest in continued use for very specific applications.
- 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328) (EC 247-384-8): UV-328 is currently imported to the EU as a UV absorber and light stabiliser for transparent plastics. A number of suitable alternatives are already available and the co-registrants for the substance are confident that downstream users will switch to plastics containing these substances. The registrants for UV-328 also supply these alternatives. They will cease placing UV-328 on the market after the sunset date, and do not intend to support any applications. One of the co-registrants thought that some of their downstream users, such as those in the automotive industry, may wish to apply for authorisation to support

² After the sunset date has passed for a substance included on the Authorisation List (Annex XIV), Article 69(2) of REACH requires ECHA to consider if the use of the substance in articles is adequately controlled and, if it isn't, prepare a dossier which conforms to the requirements of an Annex XV dossier for restriction.

³ As there were no registrations of the other seven substances, ECHA was unable to approach any registrants.

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the use of this substance in specific plastic components. This might amount to one or two applications.

- **Sodium perborate** (EC 239-172-9; 234-390-0): This substance is currently used in niche applications in the EU. Suitable alternatives are readily available and substitution has apparently already largely occurred. It is unlikely that any applications would be received.
- 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 271-094-0; 272-013-1): This is no longer used in the EU. Suitable alternatives are readily available and substitution has apparently already occurred.

ECHA received useful information from the lead registrants as well as sectoral trade associations – AISE, ATIEL, CEPE, Concawe, Cosmetics Europe, ELISANA, ETRMA, FEICA, Pinfa Plasticisers Plus and Plastics Europe – all representing downstream users. The registrants, as manufacturers or importers of the substances, were able to make definitive statements regarding whether they would place these substances on the EU market after the sunset date.

This information was corroborated by confirmatory statements from sectoral trade associations as well as the main users of the substances, such as lubricant manufacturers, manufacturers of detergents, rubber and plastic products, as well as various other downstream user groups. ECHA asked the stakeholders to verify or corroborate the findings of the market survey⁴.

While ECHA has made efforts to uncover the market situation of the 11 substances and, in particular, to predict the number of applications it would receive, it is possible that it has not been able to reach particular user groups.

By publishing this report, ECHA wants to increase the awareness around the need to apply for substances placed on the Authorisation List. It also hopes that any potential applicants for authorisation would inform ECHA if they find inaccuracies in this report about their intention to apply.

Introduction

Title VII of the REACH Regulation concerning the authorisation procedure aims to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern (SVHCs) are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies, where these are economically and technically feasible (Article 55).

The inclusion of a substance on the 'Candidate List' designates that the substance is an SVHC and that it may be prioritised for placing on the REACH Authorisation List (Annex XIV). The prioritisation is normally based on (1) the inherent properties of the substance, (2) high volume and (3) the use (wide-dispersive).

Before sending its recommendation to the European Commission, ECHA launches a consultation

⁴ Stakeholders were also asked to verify whether the statements attributed to them in the report were accurate. At the request of the stakeholders, ECHA did not mention their names in the report.

which lasts for three months, in particular, on uses which should be exempt from the authorisation requirement (Article 58(4) of REACH).

REACH allows companies to submit applications for authorisation to continue or start using substances included on the Authorisation List. The initial draft recommendation for inclusion of a substance on the Authorisation List includes (among other information) the 'sunset date', after which the placing on the market and the use of a substance is prohibited unless an authorisation is granted (or the use is exempt). It also includes the 'latest application date' (LAD) by which applications must be received if applicants want certainty on continued use of their substances after the sunset date, but when a decision (to grant or refuse the AfA) has not yet been adopted.

It is still possible to submit an AfA after the LAD, but the use of the substance must cease before the sunset date if a decision on the application has not been made before then. It is also possible to submit an application after the sunset date, but it is only possible to use the substance if the authorisation is granted.

On 6 February 2020, the Commission added 11 substances to the Authorisation List. ECHA needs to plan its staff resources and the workload of the Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) to ensure it has the capacity to provide timely opinions on any applications for authorisation relating to these substances. Therefore, ECHA carried out market research in late 2019 and early 2020 to identify relevant industry associations and companies that are likely to be the "movers and shakers" leading the supply chains toward applications or substitution.

The project's primary objective was to generate estimates of the number of applications, the uses covered therein and the types of applications (e.g. by single downstream users, multiple downstream users or upstream actors) that may be submitted for the 11 substances (listed in Table 2).

Of the 11 substances, only four are registered under REACH. This means that the other seven substances can only be placed on the EU market in amounts less than one tonne per year. ECHA has prioritised some of the substances to avoid regrettable substitution with the understanding that these are not currently used in the EU and, therefore, it is unlikely that ECHA would receive applications for these substances.

The tasks of this market research project were to:

- identify the companies and associations leading the supply chains towards any potential applications for authorisation (or if not, substitution);
- describe the supply chains and market structures where the substances are used;
- determine whether substitutes are available and being used;
- describe which uses would authorisations be applied for; and
- if relevant, estimate how many applications would be made, by whom and when, and for how many uses.

Table 2 - Substances added to the Authorisation List in 2020

	LIOIT LISC III 2020		
Substance	Intrinsic properties referred to in Article 57	Latest application date	Sunset date
1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear*) EC 271-093-5; CAS 68515-50-4	Toxic for reproduction (category 1B)	7 August 2021	27 February 2023
Dihexyl phthalate EC 201-559-5; CAS 84-75-3	Toxic for reproduction (category 1B)	7 August 2021	27 February 2023
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 201-559-5) EC 271-094-0; 272-013-1; CAS 68515-51-5; 68648-93-1	Toxic for reproduction (category 1B)	7 August 2021	27 February 2023
Trixylyl phosphate*) EC 246-677-8; CAS 25155-23-1	Toxic for reproduction (category 1B)	27 November 2021	27 May 2023
Sodium perborate; perboric acid, sodium salt*) EC 239-172-9; 234-390-0; CAS 15120-21-5; 11138-47-9	Toxic for reproduction (category 1B)	27 November 2021	27 May 2023
Sodium peroxometaborate EC 231-556-4; CAS 7632-04-4	Toxic for reproduction (category 1B)	27 November 2021	27 May 2023
5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof] EC -; CAS -	vPvB	27 February 2022	27 August 2023
2-(2H-benzotriazol-2-yl)-4,6- ditertpentylphenol (UV-328)*) EC 247-384-8; CAS 25973-55-1	PBT, vPvB	27 May 2022	27 November 2023
2,4-di-tert-butyl-6-(5-chlorobenzotriazol- 2-yl)phenol (UV-327) EC 223-383-8;CAS 3864-99-1	vPvB	27 May 2022	27 November 2023
2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6- (sec-butyl)phenol (UV-350) EC 253-037-1; CAS 36437-37-3	vPvB	27 May 2022	27 November 2023
2-benzotriazol-2-yl-4,6-di-tert- butylphenol (UV-320) EC 223-346-6;CAS 3846-71-7	PBT, vPvB	27 May 2022	27 November 2023

^{*)} Registered substances

This was the first time that ECHA carried out such market research to engage proactively with relevant stakeholders to gauge their interest in applying for authorisations for the concerned substances. This research has helped to build internal capabilities and competences for similar projects in the future.

Methods

This section details how the market research was undertaken to assess the market reaction to the 11 substances being classified as substances of very high concern (SVHCs) and then placed on the Authorisation List (Annex XIV), with the objective of determining the likelihood of applications for authorisation being submitted.

Literature search and evaluation of ECHA background documents

ECHA carried out an initial market research based on the registrations of the substance and by contacting the lead registrants and sector organisations. It then contracted *wca* to follow up certain aspects of the initial research.

The *wca* project team undertook a brief review of available literature (primarily internet resources) to obtain an overview of uses of the substances and screen those within the scope of authorisation. This provided only limited information and more relevant information was obtained from ECHA 'background documents' such as reports detailing the proposal for identification of an SVHC (Annex XV).

Assessment of current uses

Information on substance uses were initially compiled from the following sources:

- Annex XV reports published by ECHA;
- US EPA CPCat Database (21 May 2014 release) this details substance use information categorised by product, function and user group (industrial or consumer) from the United States (various EPA chemical datasets), Australia (NICNAS) and industry (Dow Chemical Company);
- SPIN and KEMI databases (the SPIN database also provides information on the amount of a substance used in Nordic countries); and
- Hazardous Substances DataBank (HSDB) and PubChem.

Industrial uses were collated on the basis of substance CAS numbers. Patent searches were conducted to understand specific substance uses and industrial processes that may be situated in the EU. Searches were conducted on Derwent Innovation, based on substance CAS numbers for all available years (1900 to 2019) and European companies holding active and inactive patents were identified.

Substances in articles

Information on the presence of the substances in articles was gathered by *wca* from internet searches. The main information targeted were manufacturer/supplier declarations under REACH Article 33(1) to identify Candidate List substances in articles.

Searches were conducted using search terms such as 'articles containing [substance name] [CAS number]' (e.g. 'articles containing dihexyl phthalate 84-75-3'). Results from the first five pages were screened and information on the types of product and manufacturer/supplier for each substance were recorded.

Supplier search

Chemical suppliers were identified to gain insight on the availability of substances on the European market as these suppliers may hold information on downstream uses and market demand. Searches were conducted in SciFinder based on substance CAS numbers. The substance record contains information on commercial sources, including the product quantities, purities and seller contact details. The contact details for European sellers were collated and product quantities over 1 kg (bulk) were noted.

Analysis of information on alternatives

The *wca* project team investigated whether substitutes are available for the substances placed on the Authorisation List. By reviewing Annex XV reports, the CHEMSEC database and consultation with trade associations and companies, *wca* could determine if there has already been any substitution (or there are plans) since substances were listed as SVHCs.

Stakeholder consultation

ECHA carried out a number of preliminary tasks for the project. The first of these was to approach the registrants of the substances and ask for their collaboration in this study, in particular to identify the relevant supply chains and actors therein.

An initial letter was sent by ECHA to lead registrants for the 11 substances requesting that they provide information on the supply chain for each substance and their opinion on the likelihood of applications for authorisation being submitted following the substance's inclusion on the Authorisation List.

ECHA also set up a "call for information" to inform stakeholders about this work and urge actors in the supply chain to provide information on the likely response to the inclusion of these substances on the Authorisation List.

ECHA also sent a letter to trade associations representing sectors concerned in the supply chain for these substances requesting them to invite member companies to participate in an online survey that requested information on:

- their contact details;
- whether they manufacture, import, formulate, distribute or use any of the 11 substances within the European Union?;
- what the substance is used for;
- whether the company is a downstream user, manufacturer, importer/only representative or distributor;
- whether there was an intention to apply for authorisation to continue using the substance;

- whether there was a plan to apply for authorisation alone or through an upstream applicant;
- whether the respondent would apply for authorisation on behalf of downstream users;
 and
- if the respondent did not plan to apply for authorisation, what was the reason (i.e. substance will no longer be used or an alternative substance/technology has already been identified to switch to)?

ECHA and the *wca* project team then identified companies and associations leading the supply chains toward applications for authorisation or substitution and used telephone interviews to gather relevant information.

Supply chain description and assessing likelihood of applications for authorisation

Based on the outputs of earlier activities, the basic supply chain and market structures for the substances were identified to help determine whether applications for authorisation are likely to be received for the substances placed on the Authorisation List in 2020.

Both ECHA and the *wca* project team requested information from suppliers on the market for the substances, highlighting the priority uses (and substance functionality) for which authorisation is most likely to be applied for. The *wca* project team also requested information on how companies are organised along the supply chain to assess which are most likely to be applicants for authorisation (either alone or through a joint application).

Both ECHA and the *wca* project team sought to determine whether there are likely to be 'upstream applications' (fewer in total but broader applications) or specific 'downstream user applications' (specific to a certain use and likely to result in a greater number of applications).

Results and discussion

Summary of uses and potential suppliers

Information on uses of the 11 substances to be placed on the Authorisation List was compiled by the *wca* project team from ECHA documents and various databases covering Europe, the United States and Australia (see Section 2.1.2 for details) and is summarised in Table 3. Based on the uses identified for each substance, the most relevant European trade associations were identified and these are also detailed in Table 3.

Wide-ranging uses were identified for all 11 substances, indicating the theoretical possibility of numerous applications for authorisation being submitted following the placing of these substances on the Authorisation List, and specifically for the four substances already registered under REACH. This highlighted the need for a targeted stakeholder consultation to gather up-to-date information on the supply chain and market for these substances, to pinpoint the most important uses that could drive applications and identify which actors would most likely make the application, i.e. whether this would come from manufacturers or downstream users acting alone or in a consortium.

Patent searches were conducted to identify European companies holding active and inactive patents (Tables 7 and 8). The results (see Appendix A) revealed that a significant number of patents are held by several European companies for most of the substances, although there are no patents held in the EU for trixylyl phosphate and sodium perborate (and only one patent held in the EU for sodium peroxometaborate).

The patents are generally held by large chemical manufacturing companies and the majority are still live patents. It is uncertain what can be read from this information in terms of predicting the likelihood of applications for authorisation but the holding of live patents for most of the substances would indicate an ongoing commercial interest in them that has the potential to motivate submission of applications for authorisation.

Table 3 - Summary of substance uses compiled from ECHA background documents and literature search

Substance	Regis- tered (Yes/ No)	Use summary	Relevant industry associations
1,2- Benzenedicarboxylic acid, dihexyl ester, branched and linear EC 271-093-5 CAS 68515-50-4	Yes	 Plasticiser (sealant/jointing agents in US market) in polymers. Occurring in consumer articles. Automotive gear lubricant on German market. Possible replacement for other low/transitional phthalates being phased out (ECHA 2014a). Rubber and plastic products. Lubricants and additives, gear oils, automotive. 	Plastics Europe, European Tyre & Rubber Manufacturers' Association (ETRMA), Concawe (petroleum refining), ATIEL (lubricants)
Dihexyl phthalate EC 201-559-5 CAS 84-75-3	No	 Plasticiser for cellulose and vinyl plastics. DnHP is used in the making of plastisols that are subsequently used to manufacture automobile parts (air filters, battery covers) and dipmoulded products (tool handles, dishwasher baskets). Substances containing DnHP may also be used in traffic cones, toys, vinyl gloves, weather stripping, flea collars, shoes, and conveyor belts used in food packaging operations. Due to its similar physicochemical properties to other transitional phthalates with C4-C6 carbon backbone lengths, dihexyl phthalate can possibly be used as a substitute for these phthalates (ECHA 2013a). Rubber and plastic products, inert pesticides, children's products. Commercial phthalate substances containing DnHP may be added to the 	Plastics Europe, ETRMA

Substance	Regis- tered (Yes/ No)	Use summary	Relevant industry associations
		PVC utilised to manufacture flooring, canvas tarps, and notebook covers. DnHP is often found as a minor component (less than 1 %) of C6-10-phthalate mixtures; it may also be an isomer in mixtures of diisohexyl phthalates (DIHP) (CAS RN 68515-50-4) at levels of 25 % or lower.	
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 201- 559-5) EC 271-094-0; 272- 013-1 CAS 68515-51-5; 68648-93-1	No	 Phthalates are well known to be used as plasticisers and lubricants, and the registered uses of the substance are for example in adhesives, lubricants, coatings, building material, cable compounding, polymer foils, PVC compounds and artist supply (ECHA 2015a). Rubber and plastic products, adhesives, sealants, plasticisers, custom compounding of purchased resins (CAS 68648-93-1). Adhesives, binding agents, resins for 1- and 2-component hardening adhesives, softeners (CAS 68515-51-5). Plasticiser in PVC products and in paints and can also be used in adhesive and lubricant materials. 	FEICA (adhesives and sealants), Plasticisers Plus, Plastics Europe, ETRMA
Trixylyl phosphate EC 246-677-8 CAS 25155-23-1	Yes	 TXP is mainly used as a functional fluid (fire resistant fluids, hydraulic fluids, lubricants, lubricant additives, grease products, metal working fluid) and as a flame retardant in the production of plastics. Internet sources recommend TXP mixtures as a plasticiser of vinylite, cellulosic resin and natural and synthetic rubber. It may also be used for anti-mildew cables, electricity and as a plasticiser and flame retardant for PVC convey belts, artificial leather and flooring materials¹ (ECHA 2013b). Greases, petroleum lubricating oil and grease manufacturing. Flame retardant, lubricant and additives, manufacture of computer, electronic and optical products. 	Concawe, ATIEL, Pinfa (flame retardants)

Substance	Regis- tered (Yes/ No)	Use summary	Relevant industry associations
		4. Flame retardant plasticiser for wire and cable insulation usually used in blends with phthalates. The major current area of use is in power generation fluids.	
Sodium perborate; perboric acid, sodium salt EC 239-172-9; 234- 390-0 CAS -	Yes	 Used as a source of oxygen in laundry detergents and peroxide-based bleaches. Mainly used as a bleaching agent in laundry detergents and machine-washing products (clothes). Cosmetic products. Other minor uses include non-agricultural pesticides and preservatives, conductive agents and cleaning/washing agents for dishwashing machines. Also, used as a bleaching agent in denture cleansers and stain removers (cited from 2007 risk assessment report) (ECHA 2014b). Personal care products, fracking, biocides, antimicrobials, fragrances, pharmaceuticals, inert pesticides. Cleaning and washing agents, conductive agents, non-agricultural pesticides/preservatives, bleaching agents, building materials/additives, dyestuff/pigments, textile auxiliaries, photo chemicals. Denture cleaner, oxygen source (e.g. oxidiser in tooth powders and toothpaste). Topical antiseptic. Bleaching agents for textiles; component of detergents, mouthwash; laboratory reagent; agent in neutralising cold wave preparation; electroplating agent; germicide; deodorant; agent in developing vat dye. 	International Association for Soaps, Detergents and Maintenance Products (AISE), Cosmetics Europe, Concawe
Sodium peroxometaborate EC 231-556-4 CAS 7632-04-4	No	 As for sodium perborate (ECHA 2014c). Food additive, inert pesticides, active biocide, fracking. Cleaning agent, laundry and dishwashing products, surface treatment, and cosmetics. 	AISE, Cosmetics Europe

Substance	Regis- tered (Yes/ No)	Use summary	Relevant industry associations
5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof] EC -CAS -	No	 Information on use is 'confidential and therefore cannot be provided' (ECHA 2015b). CAS 117933-89-8 used in cosmetics and PCPs. ECHA has no public registered data indicating whether or in which chemical products the substance might be used^{5.} Stated to be manufactured and/or imported in the European Economic Area in 1-10 tonnes per year. Raw material for cosmetic manufacturing, fragrance (CAS 117933-89-8). PubChem: Cleaning/washing, fragrance (consumer use), chemical manufacturing, raw material for personal care products/cosmetics Known as amber dioxane⁶ and used as a woody fragrance in PCPs. Trade name is Karanal; alternative CAS given as 186309-28-4 (available from China). Recently used in a number of perfumes. 	Cosmetics Europe
2-(2H-benzotriazol- 2-yl)-4,6- ditertpentylphenol (UV-328) EC 247-384-8 CAS 25973-55-1	Yes	 UV absorber. Phenolic benzotriazoles are technically the most important UV absorbers and specifically for transparent plastics. UV stabiliser in plastic shrink films (including food packaging), outdoor furniture and clear coat automotive finishes. UV-328 is also used for light stabilising in coatings, Acrylonitrile butadiene styrene resin, epoxy resin, fibre resin, propylene and polyvinyl chloride. It is also effective in light stabilisation of unsaturated polyester, polyacrylate and polycarbonate (ECHA 2014d). Consumer fragrances, fabric/textile/leather products, furniture/furnishings, inert pesticides, automotive. Construction materials, fillers, surface treatment, adhesives, 	CEPE (inks and pigments), Plastics Europe, FEICA, ETRMA

https://echa.europa.eu/substance-information/-/substanceinfo/100.120.617
 http://www.thegoodscentscompany.com/data/rw1038591.html

Substance	Regis- tered (Yes/ No)	Use summary	Relevant industry associations
		intermediates/additives in plastics manufacture, paint/lacquers/varnishes, reprographic agents, printing inks, raw materials for production of plastic, manufacturing of machinery/equipment/transport equipment, manufacture of basic/fabricated metals, serigraphic printing. 4. UV stabiliser in polyolefin films, outdoor furniture and clear coat automotive finishes. Used as a UV absorber in plastic applications. Particularly recommended for polyolefins, polyurethanes, PVC, polyacrylate, epoxy, and elastomers.	
2,4-di-tert-butyl-6- (5- chlorobenzotriazol- 2-yl)phenol (UV- 327) EC 223-383-8 CAS 3864-99-1	No	 One company indicated that 50 % of all of their products of this substance class are used as UV-protection agents in coatings especially for cars and special industrial wood coatings. Ca. 40 % are used as UV-protection agents for plastics, rubber and polyurethanes. The rest is used in cosmetics (e.g. as sun protection agents). UV stabiliser for a wide range of plastics and articles, for example: polycarbonates, acrylic polymers, polyester (saturated and unsaturated), styrene mono- and copolymers, polyvinyl chloride, polyolefins, polyvinylbutyle, and polyurethanes. UV-327 is also a UV stabiliser for rubber and constituents in formulations used for coating of surfaces, e.g. cars or special industrial wood coatings (ECHA 2015c). Drinking water and food contact material. Adhesive, binding agent, automotive, construction material, colouring agent, filler, tightening material (putty), manufacture of rubber and plastic products, paint, lacquers and varnishes, reprographic agent, serigraphic printing, printing inks, 	CEPE (inks and pigments), Plastics Europe, FEICA, ETRMA

Substance	Regis- tered (Yes/ No)	Use summary	Relevant industry associations
		sealing compounds, UV stabilisers, raw material for plastics production.	
2-(2H-benzotriazol- 2-yl)-4-(tert-butyl)- 6-(sec-butyl)phenol (UV-350) EC 253-037-1 CAS 36437-37-3	No	1. As for UV-327 (ECHA 2015d). 2. UV stabiliser.	
2-benzotriazol-2-yl- 4,6-di-tert- butylphenol (UV- 320) EC 223-346-6 CAS 3846-71-7	No	 According to general knowledge on phenolic benzotriazoles, it is expected that UV-320 will be used as UV stabiliser for plastics, polyurethanes and rubber and constituent in formulations used for coating of surfaces, e.g. cars or special industrial wood coatings. Constituent in rubber and plastic products (ECHA 2014e). Manufacturing rubber and plastic products, automotive, absorbent and adsorbent, UV stabiliser. 	

Sources:

- 1. ECHA Annex XV report for the substance.
- 2. Information compiled from US EPA CPCat Database.
- 3. SPIN/KEMI.
- 4. HSDB/PubChem.

An internet search for the presence of the 11 substances in articles on the EU market did not yield results for the majority of the substances, with the exception of the three substances detailed in Table 4.

Two of the phthalates (CAS 84-75-3 and 68515-51-5/68648-93-1) are listed as constituents of Christmas decorations and one of them (dihexyl phthalate) is listed as occurring in consumer electronics and aerospace applications. Sodium perborate is listed as a constituent of a magnetic tripod⁷.

The volume used seems to be low and the production seems to take place outside the EU. As such, this niche use of the substance is unlikely to result in an application. There is also ongoing use of this substance in antiseptic mouth rinse⁸ and as a bleaching agent in a product imported

bocasan?qclid=EAIaIQobChMIo8iE4PqC5QIVD44YCh1ESqjdEAkYAiABEqJePvD BwE#.XZdqj1VKipo

⁷ https://www.festool.ch/de-ch/zubehoer/499814---ma-kal

⁸ <u>https://www.mouthulcers.co.uk/amosan-</u>

from the US⁹ but these uses are unlikely to be continued once the substance is placed on the Authorisation List as virtually all oxygen bleaches now use sodium percarbonate as an alternative to sodium perborate.

Table 4 - Current use of substances in articles on EU market

Substance	Registered (Yes/No)	Articles
Dihexyl phthalate (CAS 84-75-3)	No	Consumer electronics, aerospace applications Christmas decorations
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 (CAS 68515-51-5, 68648-93-1)	No	Christmas decorations
Sodium perborate; perboric acid, sodium salt (CAS 11138-47-9)	Yes	Electric tools

ECHA undertook a search of the SPIN database (Table 11), which indicated that several of the substances are used in Nordic countries alone in volumes of several tonnes per year, including one substance not currently registered under REACH (UV-327). This is likely to be because the substance is imported by multiple importers under one tonne each from outside of the EU.

The list of the substances for which entries have been recorded in the SPIN database for 2017 is given in Appendix C. The latest information available in the SPIN database is from 2017 (i.e. there are no data records for 2018 and 2019). Given the absence of data for the last two years, it is not possible to fully assess the recent trends in the use of the concerned substances or to ascertain whether their uses have been discontinued.

An internet search for commercial suppliers of the 11 substances indicated a number of suppliers worldwide for all substances and the existence of EU suppliers for most of the substances (except sodium perborate), although there was only one EU supplier identified for the following substances:

- 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;
- 5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane; and
- UV-350.

A full list of all suppliers identified by this search is provided in Tables 9 and 10 of Appendix B. The results of this search indicate the existence of an active market for most of the substances although it is uncertain what the actual size of the market is and whether the amount placed on

https://uk.ninthavenue.com/products/sodium-perborate-granular-1-lb?gclid=EAIaIQobChMI-P-pufuC5QIVGomyCh3SIAxKEAkYEiABEgL4GvD_BwE

the EU market exceeds the one tonne per year threshold for registration under REACH (it was only possible to determine where quantities greater than 1 kg are available and this is indicated in Table 10 in Appendix B).

Potential alternatives to substances proposed for the Authorisation List

A brief assessment of potential alternatives indicated that a number of possible alternatives are available for each of the 11 substances placed on the Authorisation List; these are detailed in Table 5.

The consultation with registrants and sectoral trade associations indicated that substitution has already taken place for three of the four substances that are currently registered under REACH, either following or shortly before their designation as substances of very high concern (SVHCs).

Sodium perborate has been replaced by the less toxic but equally effective sodium percarbonate. 1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear has been replaced by other plasticisers, and trixylyl phosphate is no longer placed on the EU market, having been replaced by other flame retardants in its previous main use in lubricants and other functional fluids.

Non-SVHC listed light stabilisers are available as substitutes for UV-328 and it is envisaged that they will be phased in during the run up to the sunset date; with the most appropriate replacement depending upon the specific end use. UV-328 is a phenolic benzotriazole and while other substances from this chemical class have hazardous properties and are also proposed for the Authorisation List, other related benzotriazoles are not SVHCs and can be used as substitutes. Other possible UV absorbers and light stabilisers include benzophenones and hindered amine light stabilisers (HALS), which also protect plastics from UV radiation but are not UV absorbers, instead functioning as degradation inhibitors by acting as proton-donators.

Table 5 - Potential alternatives to 11 substances being placed on the Authorisation List

Substance	Source of information
1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear EC 271-093-5 CAS 68515-50-4	Alternative substances could be other phthalates with short or long carbon backbones, depending on the physicochemical property needed ¹⁰ (ECHA 2014a). Various options depending on phthalate function ¹¹ .

¹⁰ However, these may have similar reprotoxic effects as 1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear.

¹¹ https://chemsec.org/publication/endocrine-disruptors,substitution/replacing-phthalates

Substance	Source of information
Dihexyl phthalate EC 201-559-5 CAS 84-75-3	Alternative substances might be phthalates with short or long carbon backbones, depending on the physicochemical property needed. Depending on the functionality needed, chemicals like citrates (biodegradable and not toxic), adipates, phosphates (resistant to ignition and burning), trimellitates (exceptional thermal properties.) etc. could be used as alternatives of dihexyl phthalate. Potential alternatives as assessed in the case of the restriction proposal for bis(2-ethylhexyl)phthalate (DEHP, CAS 117-81-7), Benzyl butyl phthalate (BBP, CAS 85-68-7), Dibutyl phthalate (DBP, CAS 84-74-2), and Diisobutyl phthalate (DIBP, CAS 84-69-5) could be of interest for dihexyl phthalate (ECHA 2013a).
	Various options depending on phthalate function ¹⁵ .
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 201-559-5) EC 271-094-0; 272-013-1 CAS 68515-51-5; 68648-93-1	Substance itself containing less than 0.3 % (w/w) of dihexyl phthalate (ECHA 2015a). Various options depending on phthalate function ¹⁵ .
Trixylyl phosphate EC 246-677-8 CAS 25155-23-1	Other phosphate esters, e.g. BuTTP (less problematic triarylphosphate) or polyol esters are alternatives as hydraulic fluids. Isopropylphenyl diphenyl phosphate (IPDPP) and tris-(isopropylphenyl) phosphate (IPPP) are alternatives for PVC products and lubricants (ECHA 2013b).
Sodium perborate; perboric acid, sodium salt EC 239-172-9; 234-390-0 CAS - 15120-21-5; 11138-47-9	In the EU, sodium perborates have almost exclusively been replaced by the alternative sodium percarbonate, which is less toxic (ECHA 2014b).
Sodium peroxometaborate EC 231-556-4 CAS 7632-04-4	As for sodium perborate (ECHA 2014c).

Substance	Source of information
5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof] EC / CAS -	Information on alternatives is 'confidential and therefore cannot be provided' (ECHA 2015b).
2-(2H-benzotriazol-2-yl)-4,6- ditertpentylphenol (UV-328) EC 247-384-8 CAS 25973-55-1	Other phenolic benzotriazoles (but may also have PBT/vPvB properties). Benzophenones are other technically important UV absorbers for transparent plastic materials but may be potential endocrine disruptors. Hindered amine light stabilisers (HALS) also protect plastics from UV radiation – not UV absorbers but function as degradation inhibitors by being proton-donators (ECHA 2014d).
2,4-di-tert-butyl-6-(5- chlorobenzotriazol-2-yl)phenol (UV- 327) EC 223-383-8 CAS 3864-99-1	As above for UV-328 and other potential alternative substances acting as UV stabilisers are triazines, oxanilides, and cyanoacrylates (ECHA 2015c).
2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) EC 253-037-1 CAS 36437-37-3	As for UV-327 (ECHA 2015d).
2-benzotriazol-2-yl-4,6-di-tert- butylphenol (UV-320) EC 223-346-6 CAS 3846-71-7	As for UV-328 (ECHA 2014e).

Sources: ECHA Annex XV report for the substance and ChemSec Marketplace¹².

Stakeholder consultation

The stakeholder consultation led by ECHA focused on four of the 11 substances to be placed on the Authorisation List that had active REACH registrations when the project commenced at the beginning of September 2019, i.e.

EC	CAS	EC Name
271-094-0	68515-51-5	1,2-benzenedicarboxylic acid, di-c6-10-alkyl esters
246-677-8	25155-23-1	trixylyl phosphate
234-390-0	11138-47-9	perboric acid, sodium salt
247-384-8	25973-55-1	2-(2h-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)

The results of the stakeholder consultation detailed in this section of the report for these four substances are a combination of responses received by both ECHA and the *wca* project team.

¹² https://chemsec.org/business-tool/marketplace

ECHA investigated PPORD₁₃, substances in articles₁₄, and C&L notifications¹⁵ for the seven unregistered substances. ECHA investigated PPORD16, substances in articles17, and C&L notifications¹⁸ for the seven unregistered substances. It has been observed that ECHA has received only one substance in article notification for 2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327), whereas no PPORD notification has been received for any of the substances. On the other hand, C&L notifications have been received for the six substances detailed in Table 6.

Table 6 - Classification and labelling notifications for unregistered substances on the Authorisation List

EC Number	EC Name	Number of group notifications	Total number of members part of the group notifications	Number of notifications not submitted on behalf of a group
201-559-5	dihexyl phthalate	3	27	5
223-346-6	2-benzotriazol-2-yl-4,6-di- tert-butylphenol	3	104	15
223-383-8	2,4-di-tert-butyl-6-(5- chlorobenzotriazol-2- yl)phenol	16	373	54
231-556-4	sodium peroxometaborate	6	159	18
253-037-1	2-(2h-benzotriazol-2-yl)-4- (tert-butyl)-6-(sec- butyl)phenol	5	147	8
271-093-5	1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear	2	14	2

It is impossible to infer from C&L notifications whether any of the notifiers still use the substance, even more so, whether they intend to submit an application for authorisation. ECHA sent a short survey to the notifiers to gauge their potential interest in submitting an application for authorisation in the future. Only one response was received.

Given the absence of responses it may be inferred with some degree of certainty that the notifiers did not have a particular interest in applying for authorisation for the given substances. It is also possible that the notifiers no longer use the substances.

1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters

The lead registrant for this substance indicated to ECHA that they ceased production of the substance in the EU approximately two years ago, after the substance was identified as a

¹³ https://echa.europa.eu/support/dossier-submission-tools/reach-it/ppord

¹⁴ https://echa.europa.eu/regulations/reach/candidate-list-substances-in-articles/notification-of-substances-in-articles

¹⁵ https://echa.europa.eu/regulations/clp/cl-inventory/notification-to-the-cl-inventory

¹⁶ https://echa.europa.eu/support/dossier-submission-tools/reach-it/ppord

¹⁷ https://echa.europa.eu/regulations/reach/candidate-list-substances-in-articles/notification-of-substances-in-articles

¹⁸ https://echa.europa.eu/regulations/clp/cl-inventory/notification-to-the-cl-inventory

substance of very high concern (SVHC) and it became apparent that it was likely to be placed on the Authorisation List. The lead registrant was the only manufacturer of the substance in the EU (and worldwide) and their registration status is currently "inactive".

1,2-benzenedicarboxylic acid, di-c6-10-alkyl esters was used as plasticiser for very niche and specific applications and the registrant manufactures other (non-SVHC listed) plasticisers that are suitable alternatives for the required functions. They, therefore, consider that there is no need to continue manufacturing the substance and were definitive in their assertion that there would not be any applications for authorisation for this substance, especially as imported articles cannot contain this substance, as the lead registrant was the only global manufacturer.

Trixylyl phosphate

Regarding trixylyl phosphate, ECHA received opinions from both the current lead registrant, and the trade association ATIEL (representative body of the European lubricants industry). The lead registrant does not intend to support any applications for authorisation. However, one of the customers of the co-registrant intends to make a downstream application for the use of the substance in power plant turbines.

ATIEL reported that the use of trixylyl phosphate has been discontinued by all of its members (i.e. manufacturers of lubricants). Evaluation of EU downstream uses has shown that acceptable alternatives are available and are already being used in the EU.

At the appropriate time before an established sunset date, the registration dossier will be updated by the lead registrant to delete all authorisable uses. Discussions within the Phosphate ester Flame Retardants (PFR) Consortium will be held to transfer the lead registration to another member if one does intend to support end uses within the EU.

Perboric acid, sodium salt (sodium perborate)

ECHA determined that there are currently only two manufacturers of sodium perborate in the EU. Both manufacturers largely export outside the EU. However, one of them still continues to supply the substance for very few specific applications in the EU. One former manufacturer, and original member of the REACH Registration Consortium for sodium perborate, completely stopped manufacturing sodium perborate before the substance was identified as a substance of very high concern (SVHC) and added to the Candidate List in 2014. This was largely their business decision unrelated to REACH. The main uses for sodium perborate nowadays are in the oil and gas industry, whereas formerly they were widely used in powder detergents below specific concentration limits.

Several sources have confirmed to ECHA that sodium percarbonate is the main alternative substance to replace sodium perborate and that it fully meets functionality/performance requirements without the hazards associated with sodium perborate. A former manufacturer stated that they switched to manufacturing sodium percarbonate after discontinuing the manufacture of sodium perborate. Another company manufactures both sodium perborate and sodium percarbonate.

Both manufacturers had many EU-based customers, but when discussions started that the substance might be listed as an SVHC, the detergent industry started slowly moving away from sodium perborate and they lost most of their EU customers. Additionally, the detergent industry has moved rapidly towards liquid detergent (as opposed to powder-based products) meaning that overall demand for both sodium perborate and its main alternative sodium percarbonate

has seen a rapid decline as both substances are used as solids.

Given these developments, both existing manufacturers of sodium perborate stated that they do not see any business sense in applying for authorisation in the hope of 'winning back the lost customers'. These customers would not want to switch back to sodium perborate anyway, given that a safer (non-SVHC listed) alternative is already readily available on the market at a reasonable/competitive price.

2-(2h-benzotriazol-2-yl)-4,6-bis(1,1-dimethylpropyl)phenol [UV-328]

Both registrant and co-registrant stated that 100 % of the UV-328 is imported into the EU, mainly from Asia as a pure substance or in mixtures. The substance is not used as an intermediate or monomer.

One registrant stated that they will supply the substance until the sunset date but they will not apply for authorisation on their own as they already have several viable alternatives to UV-328 that are not substances of very high concern (SVHCs) (e.g. phenolic benzotriazoles that are non-PBT and non-vPvB) and see little value in preparing an application given the number of economically/technically feasible alternatives. However, there is a possibility that some of their downstream users (e.g. the automotive industry) may submit an application if they were confronted with a lengthy and involved 'recertification process' for parts. This was thought to result in no more than one or two applications from the automotive industry.

The registrant expressed a concern that after UV-328 and the other phenolic benzotriazoles stabilisers (e.g. UV-327 and UV-350, which are unregistered) are officially added to the Authorisation List, the import of articles containing these substances will continue from outside the EU. The registrant, therefore, expressed the view that industry should strongly advocate for EU-wide measures to address this.

The co-registrant for UV-328 confirmed that they had similar views and stated that they will not continue to import and supply UV-328 after the sunset date. They will not submit an application on their own and do not expect any of their downstream users to submit it either, as there are readily available alternatives as UV stabilisers, which they also market (these were stated to be non-benzotriazoles but further details were considered commercially sensitive and confidential).

Following discussion with the *wca* project team, the sectoral trade association for downstream users of this type of substance, ELiSANA (European Light Stabilisers and Antioxidants Association) publicised this project to their members and encouraged them to make contact if they anticipated submitting an application for UV-328 or other related substances to be placed on the Authorisation List. No responses were received, which is another indication that ECHA is unlikely to receive applications for continued use of these substances.

Supply chain description

There is no supply chain to consider for 1,2-benzenedicarboxylic acid, di-c6-10-alkyl as it is no longer manufactured in the EU.

Sodium perborate is no longer placed on the EU market by one of the two existing European manufacturers, who only exports their product to countries outside of the EU. The other manufacturer still supplies the substance for very niche applications in the EU and may continue to do so until the sunset date. It appears that there is a small residual market for bleaching

products containing this substance, such as denture cleaners, which are likely to be old stock or imported from outside of the EU.

Trixylyl phosphate is no longer used in lubricants – previously its main market sector in the EU. The lead registrant will continue to manufacture the substance for export only. As such, only one application is expected to be received from a downstream user based in France for use in turbines in power plants.

UV-328 is imported and placed on the EU market as the pure substance or in mixtures. Manufacturers who responded to the stakeholder consultation emphasised that they have no clear picture of the supply chain as it very complex; they largely provide masterbatches containing stabilisers such as UV-328 down the supply chain to converters (these are their main clients) for further processing, who in turn supply plastics producers, who then deliver finished plastic products to end-users (for instance, to the automotive industry).

Conclusions

The Commission added 11 substances to the Authorisation List (Annex XIV to the REACH Regulation) in 2020, meaning that an authorisation would be needed to continue a specific use of the substance after the sunset date.

ECHA needs to plan its staff resources and the work of its two scientific committees to ensure that it has the capacity to provide timely opinions on any applications relating to these substances. The market survey described in this report was ECHA's first attempt to estimate the likely number of applications it would receive for these substances.

The overall conclusion of this market survey is that ECHA can expect to receive very few applications (less than five) for the 11 substances, which were placed on the Authorisation List in 2020. The market survey on the presence of the 11 substances in articles on the EU market revealed only limited information but indicated the possibility that some of these substances may be presented in imported articles such as Christmas decorations and consumer electronics.

Attention in this market survey largely centred on the four substances with active REACH registrations. Unregistered substances are not manufactured or imported into the EU at volumes exceeding one tonne per year. Therefore, as no other indications were received, it seems plausible that no applications for authorisation will be received for these seven substances.

As expected, the consultation with registrants, sectoral industry associations and key market operators proved to be the most important way of getting additional information in the market survey. Overall, the main finding was that the use of these substances will in all likelihood be insignificant after their sunset dates. Specifically the findings of this market survey were as follows:

- 1,2-benzenedicarboxylic acid, di-c6-10-alkyl is no longer being placed on the EU market.
- Trixylyl phosphate has been also largely phased out in the EU and its use may only be continued in small quantities for niche applications. The lead registrant for trixylyl phosphate is withdrawing its lead status and it seems unlikely that the co-registrant will take over, though they will support their customer throughout the authorisation process. Feedback from the trade association for end users indicated that the market for this substance has ceased and is unlikely to be reactivated. ECHA has received information that a French downstream user is planning to apply for an authorization to use the substance in power plant turbines.
- **Sodium perborate** continues to be placed on the EU market for niche applications as well in spite of the fact that a safer and economically viable alternative is readily available on the EU market.
- **UV-328** is still being imported and supplied to the EU market as a UV absorber and light stabiliser for transparent plastics. A number of suitable alternatives are already available and the co-registrants for the substance are confident that downstream users will switch to plastics containing these substances. The registrants for UV-328 also supply these alternatives and will cease placing UV-328 on the market after the sunset date. They do not intend to support any applications for authorisation themselves. One of the co-registrants thought that some of their downstream users, such as those in the automotive industry, may wish to apply for authorisation to support the use of this substance in specific plastic components. This would likely only amount in one to two applications.

It should be noted that UV-327 was also used in Nordic countries in 2017 (Table 11) suggesting that it was imported into the EU by several actors.

It is important to increase awareness about the Authorisation List and to highlight the requirement for importers to comply with the authorisation requirement of also unregistered substances. This report contributes to this aim. Furthermore, ECHA will need to consider preparing restriction dossiers for the 11 substances, in particular for UV-237 and UV-238, in accordance with Article 69(2).

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Appendix A

Table 7 - Patents owned by European companies (including in Switzerland and Norway) by substance

Substance	Papers on SciFinder	Patents on Derwent
1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear EC 271-093-5 CAS 68515-50-4	No papers	164 - 28 patents from EU companies: 17 BASF (Germany) 8 Evonik Oxeno Degussa (Germany) 2 Construction Research & Technology (Germany) 1 Styrosolution Europe (Germany)
Dihexyl phthalate EC 201-559-5 CAS 84-75-3	1 349 (435 papers with uses)	62 – 5 patents from EU companies: 2 CARTINA (Italy) 3 Nitrochemie (Germany)
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 201-559-5) EC 271-094-0; 272-013-1 CAS 68515-51-5; 68648-93-1	No papers	155 (68515-51-5) – 27 patents from EU companies: 16 BASF (Germany) 8 Evonik Oxeno Degussa (Germany) 2 Construction Research & Technology (Germany) 1 Styrolution Europe (Germany) 155 (68648-93-1) – 26 patents from EU companies: 15 BASF (Germany) 8 Evonik Oxeno Degussa (Germany) 2 Construction Research & Technology (Germany) 1 Styrolution Europe (Germany)
Trixylyl phosphate EC 246-677-8 CAS 25155-23-1	847 (700 papers with uses)	118 – No patents from EU companies
Sodium perborate; perboric acid, sodium salt EC 239-172-9; 234-390-0 CAS -	2 514 (1 959 papers with uses)	No patents
Sodium peroxometaborate EC 231-556-4 CAS 7632-04-4	2 299 (1 434 papers with uses)	11 – 1 patent from EU companies: 1 Robert McBride (UK)
5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof] EC - CAS -	33 (29 papers with uses)	164 – 7 patents from EU companies: 5 Givaudan (Switzerland) 1 Aqdot (UK) 1 Proctor & Gamble (Switzerland)
2-(2H-benzotriazol-2-yl)-4,6- ditertpentylphenol (UV-328)	2 205 (1 971 papers with	327 – 26 patents from EU companies:

Substance	Papers on SciFinder	Patents on Derwent
EC 247-384-8 CAS 25973-55-1	uses)	9 BASF (Germany) 8 Bayer Covestro (Germany) 1 Eckhart/Altana (Germany) 1 Beneke-Kaliko (Germany) 1 Icopal Kunststoffe Entwicklungs (Germany) 4 Borealis (Austria) 1 Unilever (UK/Netherlands) 1 Charite Universitatsmedizin Berlin (Germany)
2,4-di-tert-butyl-6-(5- chlorobenzotriazol-2-yl)phenol (UV-327) EC 223-383-8 CAS 3864-99-1	3 100 (2 804 papers with uses)	223 – 19 patents from EU companies: 7 BASF (Germany) 2 Ciba/Novartis/BASF (Germany) 2 Bayer/Covestro (Germany) 1 Unilever (UK/Netherlands) 6 Borealis (Austria) 1 Eckhardt/Altana (Germany)
2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) EC 253-037-1 CAS 36437-37-3	174 (154 papers with uses)	158 – 19 patents from EU companies: 9 BASF (Germany) 8 Covestro Bayer (Germany) 1 Arkema (France) 1 Charite Universitatsmedizin Berlin (Germany)
2-benzotriazol-2-yl-4,6-di-tert- butylphenol (UV-320) EC 223-346-6 CAS 3846-71-7	1 024 (873 papers with uses)	170 - 15 patents from EU companies: 4 BASF (Germany) 2 Borealis (Austria) 3 Bayer/Covestro (Germany) 3 NOR-X (Norway) 1 Arkema (France) 2 Royal DSM (Netherlands)

Sources: SciFinder; Derwent

Table 8 - Substance patents by European company (including in Switzerland and Norway) $\,$

Company	Substances with natents
Company	Substances with patents
	68515-50-4 (17 patents, 11 alive)
	68515-51-5 (16 patents, 11 alive)
DACE (C.)	68648-93-1 (15 patents, 10 alive)
BASF (Germany)	25973-55-1 (9 patents, 3 alive)
	3864-99-1 (7 patents, 3 alive)
	36437-37-3 (9 patents, 3 alive)
	3846-71-7 (4 patents, 1 alive)
Evonik/Oxeno/Degussa/RAG Foundation	68515-50-4 (8 patents, 7 alive)
(Germany)	68515-51-5 (8 patents, 7 alive)
(Comany)	68648-93-1 (8 patents, 7 alive)
Construction Research & Technology/BASF	68515-50-4 (2 patents. 2 alive)
(Germany)	68515-51-5 (2 patents, 2 alive)
(Germany)	68648-93-1 (2 patents, 2 alive)
	68515-50-4 (1 patent, 1 alive)
Styrolution Europe/Ineos/BASF (Germany)	68515-51-5 (1 patent, 1 alive)
	68648-93-1 (1 patent, 1 alive)
Cartina (Italy)	84-75-3 (2 patents, 2 alive)
Nitrochemie/Rheinmetall (Germany)	84-75-3 (3 patents, 1 alive)
Robert McBride (UK)	7632-04-4 (1 patent, 0 alive)
Givaudan (Switzerland)	117933-89-8 (5 patents, 4 alive)
Aqdot (UK)	117933-89-8 (1 patent, 1 alive)
Proctor & Gamble (Switzerland)	117933-89-8 (1 patent, 1 alive)
·	25973-55-1 (8 patents, 5 alive)
Bayer Cayastra (Cayasan)	3864-99-1 (2 patents, 1 alive)
Bayer Covestro (Germany)	36437-37-3 (8 patents, 6 alive)
	3846-71-7 (3 patents, 2 alive)
Foldowt (Altono (Common))	25973-55-1 (1 patent, 1 alive)
Eckhart/Altana (Germany)	3864-99-1 (1 patent, 1 alive)
Beneke-Kaliko (Germany)	25973-55-1 (1 patent, 1 alive)
Icopal Kunststoffe Entwicklungs (Germany)	25973-55-1 (1 patent, 1 alive)
	25973-55-1 (4 patents, 4 alive)
Borealis (Austria)	3864-99-1 (6 patents, 4 alive)
,	3846-71-7 (2 patents, 2 alive)
Hadleson (IIIC/Nathandan d.)	25973-55-1 (1 patent, 1 alive)
Unilever (UK/Netherlands)	3864-99-1 (1 patent, 1 alive)
	25973-55-1 (1 patent, 1 alive)
Charite Universitatsmedizin Berlin (Germany)	36437-37-3 (1 patent, 1 alive)
BASF/Ciba/Novartis (Germany)	3864-99-1 (2 patents, 1 alive)
	36437-37-3 (1 patent, 1 alive)
Arkema (France)	3846-71-7 (1 patent, 1 alive)
NOR-X (Norway)	3846-71-7 (3 patents, 2 alive)
Royal DSM (Netherlands)	3846-71-7 (2 patents, 2 alive)
,	55.5717 (E paconco/ 2 anvo)

Sources: Derwent

Appendix B

Table 9 - EU suppliers of 11 substances added to the Authorisation List in 2020

Substance	Number of suppliers worldwide	European suppliers (*bulk and/or >1kg available)
1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear EC 271-093-5 CAS 68515-50-4	23	abcr GmbH (Germany) Carbosynth Limited (UK) LGC (UK) Zerenex Molecular Ltd. (UK)
Dihexyl phthalate EC 201-559-5 CAS 84-75-3	56	abcr GmbH (Germany) *Thermo Fisher (Kandel) GmbH (Germany) *Alfa Aesar, Part of Thermo Fisher Scientific (UK) *Aurora Fine Chemicals Ltd. (Austria) FUJIFILM Wako Chemicals Europe GmbH (Germany) LGC (UK) *TCI Europe N.V. (Belgium) *TCI Deutschland GmbH (Germany) *Tokyo Chemical Industry UK Ltd. (UK) Zerenex Molecular Ltd. (UK)
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 201-559-5) EC 271-094-0; 272-013-1 CAS 68515-51-5; 68648-93-1	8 (68515-51-5) 6 (68648-93-1)	LGC (UK)
Trixylyl phosphate EC 246-677-8 CAS 25155-23-1	33	abcr GmbH (Germany) *Biosynth AG (Switzerland) Zerenex Molecular Ltd. (UK)
Sodium perborate; perboric acid, sodium salt EC 239-172-9; 234-390-0 CAS -	5 (Sodium perborate -> 11138-47-9)	No European suppliers, all from China
Sodium peroxometaborate EC 231-556-4 CAS 7632-04-4		Carbosynth Limited (UK)

Substance	Number of suppliers	European suppliers (*bulk and/or >1kg available)
5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof] EC -CAS -	worldwide 17 - (5-sec-butyl-2-(2,4-dimethylcyclohe x-3-en-1-yl)-5-methyl-1,3-dioxane -> 117933-89-8) 5-sec-butyl-2-(4,6-dimethylcyclohe x-3-en-1-yl)-5-methyl-1,3-dioxane = same as above	*Aurora Fine Chemicals Ltd. (Austria)
2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328) EC 247-384-8 CAS 25973-55-1	77	abcr GmbH (Germany) *Aurora Fine Chemicals Ltd. (Austria) *BIONET/Key Organics Ltd. (UK) Biosynth AG (Switzerland) Carbosynth Limited (UK) *TCI Europe N.V. (Belgium) *TCI Deutschland GmbH (Germany) *Tokyo Chemical Industry UK Ltd. (UK) Zerenex Molecular Ltd. (UK)
2,4-di-tert-butyl-6-(5- chlorobenzotriazol-2-yl)phenol (UV-327) EC 223-383-8 CAS 3864-99-1	67	abcr GmbH (Germany) *Aurora Fine Chemicals Ltd. (Austria) Biosynth AG (Switzerland) Carbosynth Limited (UK) Inochem, Ltd. (UK) LivChem GmbH & Co. KG (Germany) LGC (UK) *TCI Europe N.V. (Belgium) *TCI Deutschland GmbH (Germany) *Tokyo Chemical Industry UK Ltd. (UK) Zerenex Molecular Ltd. (UK)
2-(2H-benzotriazol-2-yl)-4- (tert-butyl)-6-(sec- butyl)phenol (UV-350) EC 253-037-1 CAS 36437-37-3	30	*Biosynth AG (Switzerland)
2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320) EC 223-346-6 CAS 3846-71-7	65	abcr GmbH (Germany) *Aurora Fine Chemicals Ltd. (Austria) *BIONET/Key Organics Ltd. (UK) Biosynth AG (Switzerland) Carbosynth Limited (UK) Fluorochem Ltd. (UK) LGC (UK) Zerenex Molecular Ltd. (UK)

Source: SciFinder

Table 10 - Details of EU chemical suppliers for 11 substances added to the Authorisation List in 2020

Note: Registered substances highlighted in **bold**

Supplier	Substances (*bulk and/or >1kg available)
abcr GmbH (Germany)	68515-50-4
Im Schlehert 10, Karlsruhe, Germany, D-76187	84-75-3
info@abcr.de	25155-23-1
Phone: +49-(0)721-95061-0	25973-55-1
Fax: +49-(0)721-95061-80	3864-99-1
	3846-71-7
Alfa Aesar, Part of Thermo Fisher Scientific (UK)	*84-75-3
Shore Road, Port of Heysham Industrial Park, Heysham, Lancashire, UK, LA3 2XY	
uksales@alfa.com	
Phone: 0800 801812	
Phone: +44 (0)1524 850506	
Fax: +44 (0)1524 850508	
Aurora Fine Chemicals Ltd. (Austria)	*84-75-3
Herrengasse 13, Graz, Austria, A-8010	*117933-89-8
aurora@aurorafinechemicals.com	*25973-55-1
<u> </u>	*3864-99-1
	*3846-71-7
BIONET/Key Organics Ltd. (UK)	*25973-55-1
Highfield Road Industrial Estate, Camelford, Cornwall, UK, PL32 9RA	*3846-71-7
enquiries@keyorganics.net	
Phone: +44(0) 1840 212137	
Fax: +44(0) 1840 213712	
Biosynth AG (Switzerland)	*25155-23-1
Rietlistr. 4, Staad, Switzerland, 9422	25973-55-1
welcome@biosynth.ch	3864-99-1
sales@biosynth.ch	*36437-37-3
Phone: +41 71 858 20 20	3846-71-7
Fax: +41 71 858 20 30	
Carbosynth Limited (UK)	68515-50-4
7, 8 & 9 Old Station Business Park, Compton, Berkshire, UK, RG20 6NE	7632-04-4
sales@carbosynth.com	25973-55-1
Phone: +44 (0)1635 578444	3864-99-1
Fax: +44 (0)1635 579444	3846-71-7

Supplier	Substances (*bulk and/or >1kg available)
Fluorochem Ltd. (UK)	3846-71-7
Unit 14 Graphite Way, Rossington Park, Hadfield, Derbyshire, SK13 1QH	
enguiries@fluorochem.co.uk	
Phone: +44 (0)1457 860111	
Fax: +44 (0)1457 892799	
FUJIFILM Wako Chemicals Europe GmbH (Germany)	84-75-3
Fuggerstrasse 12, Neuss, Germany, D-41468	
labchem_wkeu@fujifilm.com	
Contact: Dietrich Sost	
Phone: +49-2131-311-271	
Fax: +49-2131-311-100	
Inochem, Ltd. (UK)	3864-99-1
Unit 3, Kellet Road Industrial Estate, Boundary Way, Carnforth, Lancashire, UK, LA61DE	
sales@inochem.co.uk	
Phone: +44 (0)1524 730551	
Fax: +44 0)1524 730551	
Notes: Europe Distributor for Frontier Scientific, Inc. and exclusive UK Distributor	
LGC (UK)	68515-50-4
Queens Road, Teddington, Middlesex, UK, TW11 0LY	84-75-3
askus@lgcstandards.com	68515-51-5/ 68648-93-1
Phone: +44 (0)20 8943 7000	3864-99-1
	3846-71-7
LivChem GmbH & Co. KG (Germany)	3864-99-1
Stroofstr. 27, Geb. 2901, 65933, Frankfurt am Main, Germany	
<u>customerservice@livchem-logistics.com</u>	
Phone: +49 (0)069 3800 2685	
Fax: +49 (0)069 3800 2320	
Notes: Europe Distributor for Frontier Scientific, Inc.	
TCI Deutschland GmbH (Germany)	*84-75-3
Mergenthalerallee 79-81, Eschborn, Germany, D-65760	*25973-55-1
Sales-DE@TCIchemicals.com	*3864-99-1
Phone: +49 6196 64053-00	
Fax: +49 6196 64053-01	
TCI Europe N.V. (Belgium)	*84-75-3
Boerenveldseweg 6, Haven 1063, Zwijndrecht, Belgium, 2070	*25973-55-1
Sales-EU@TCIchemicals.com	*3864-99-1
Phone: +32-3-735-0700	
Fax: +32-3-735-0701	

Supplier	Substances (*bulk and/or >1kg available)
Thermo Fisher (Kandel) GmbH (Germany)	*84-75-3
Postfach 11 07 65, Karlsruhe, Germany, 76057	
EuroSales@alfa.com	
Phone: (00) 800 4566 4566	
Phone: +49 (0)721 84007 280	
Fax: (00) 800 4577 4577	
Fax: +49 (0)721-84007 300	
Tokyo Chemical Industry UK Ltd. (UK)	*84-75-3
The Magdalen Centre, Robert Robinson Avenue, The Oxford Science Park, Oxford, UK, OX4	*25973-55-1
4GA	*3864-99-1
Sales-UK@TCIchemicals.com	
Phone: +44 (0)1865 784560	
Fax: +44 (0)1865 784561	
Zerenex Molecular Ltd. (UK)	68515-50-4
12 Manningham Road, Greater Manchester, United Kingdom, BL3 5QS	84-75-3
sales@zerenex-molecular.com	25155-23-1
Phone: +44 (0) 845 2993935	25973-55-1
Fax: +44 1204 441363	3864-99-1
	3846-71-7

Source: internet searches; SciFinder

Appendix C

Table 11 - List of substances, uses of which in mixtures and articles have been reported in the SPIN database for 2017 by Denmark, Finland, Norway and Sweden

Substance	EC number	Total Volume (tons)	Country	Description of reported uses/product categories
1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5	0.8	Sweden	Lubricants and additives Gear oils
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 201-559-5)	271-094-0; 272-013-1	0.019	Denmark	Adhesives, binding agents
Trixylyl phosphate	246-677-8	0.0	Finland	Hydraulic fluids and additives Lubricants and additives
Sodium peroxometaborate	231-556-4	0.9	Sweden	Cleaning/washing agents
2-(2H-benzotriazol-2-yl)- 4,6-ditertpentylphenol (UV- 328)	247-384-8	4.3	Finland (2.3t) Sweden (1.4t) Denmark (0.4t) Norway (0.2t)	Adhesives, binding agents Paints, lacquers and varnishes Fillers Construction materials Intermediates
2,4-di-tert-butyl-6-(5- chlorobenzotriazol-2- yl)phenol (UV-327)	223-383-8	2.4	Sweden (2.3t) Denmark (0.1t) Norway (0.0t)	Fillers

Source: Substances in Preparations in Nordic Countries (SPIN) database

¹⁹ The value of "0.0" means that the volume is below the limit of accuracy, which is 100 kg.

EUROPEAN CHEMICALS AGENCY P.O. BOX 400, FI-00121 HELSINKI, FINLAND ECHA.EUROPA.EU