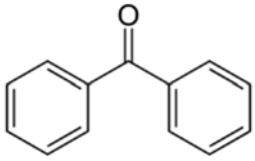
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Benzophenones not alkyl- nor p-amino, and other hydroxy substituted

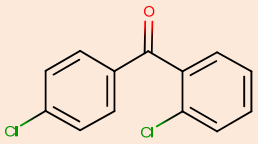
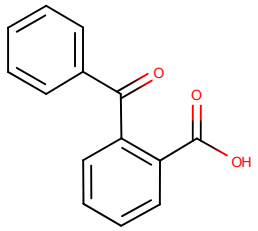
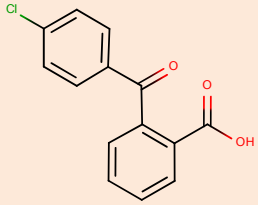
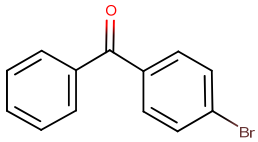
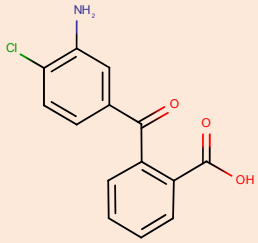
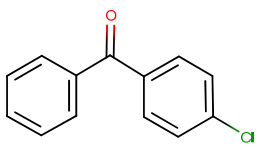
General structure:



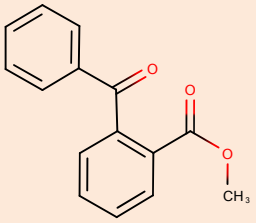
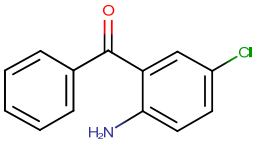
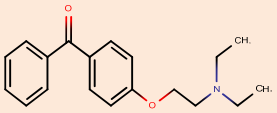
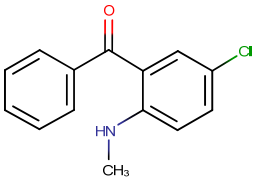
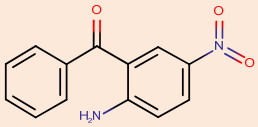
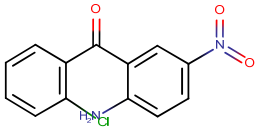
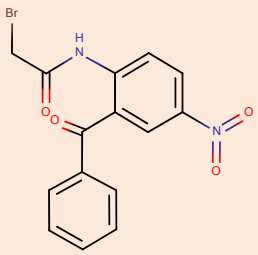
Revision history

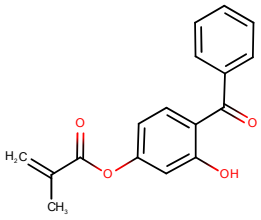
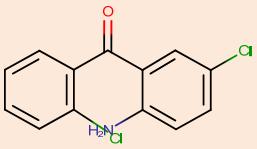
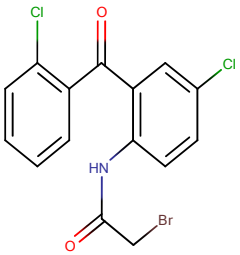
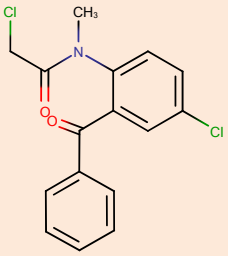
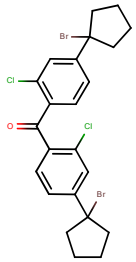
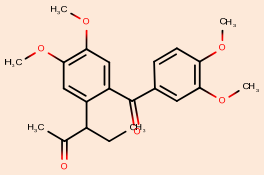
Version	*Date*	*Description*
1.0	13 May 2024	

Substances within this group:

EC/List no	CAS no	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
201-596-7	85-29-0	2,4'-dichlorobenzophenone		C&L notification
201-612-2	85-52-9	2-benzoylbenzoic acid		Full, 10-100
201-615-9	85-56-3	2-(4-chlorobenzoyl)benzoic acid		Full, 10-100
202-024-9	90-90-4	4-bromobenzophenone		C&L notification
204-230-4	118-04-7	2-(3-amino-4-chlorobenzoyl)benzoic acid		OSII or TII
205-160-7	134-85-0	4-chlorobenzophenone		Full, 1-10

[1] The total aggregated tonnage band may be available on ECHA's webpage at https://echa.europa.eu/information-on-chemicals/registered-substances

EC/List no	CAS no	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
210-112-3	606-28-0	Methyl 2-benzoylbenzoate		Full, 100-1000
211-949-7	719-59-5	2-amino-5-chlorobenzophenone		Full, 1-10
212-348-2	796-77-0	4-[2-(diethylamino)ethoxy]benzophenone		OSII or TII
213-822-1	1022-13-5	5-chloro-2-(methylamino)benzophenone		OSII or TII
217-207-9	1775-95-7	2-amino-5-nitrobenzophenone		OSII or TII
217-929-4	2011-66-7	2-amino-2'-chloro-5-nitrobenzophenone		OSII or TII
217-932-0	2011-70-3	N-(2-benzoyl-4-nitrophenyl)-2-bromoacetamide		OSII or TII

EC/List no	CAS no	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
218-000-6	2035-72-5	4-benzoyl-3-hydroxyphenyl methacrylate		C&L notification
220-985-2	2958-36-3	2-amino-2',5-dichlorobenzophenone		OSII or TII
226-844-1	5504-92-7	2-bromo-N-[4-chloro-2-(2-chlorobenzoyl)phenyl]acetamide		OSII or TII
227-875-3	6021-21-2	N-(2-benzoyl-4-chlorophenyl)-2-chloro-N-methylacetamide		OSII or TII
229-803-6	6740-86-9	1-bromocyclopentyl-o-chlorophenyl ketone		OSII or TII
239-479-8	15462-91-6	3-[2-(3,4-dimethoxybenzoyl)-4,5-dimethoxyphenyl]pentan-2-one		OSII or TII

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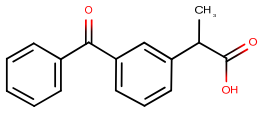
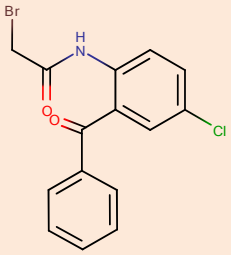
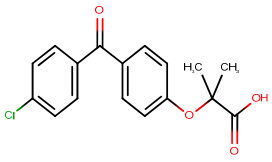
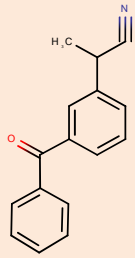
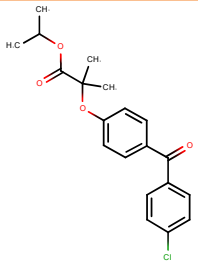
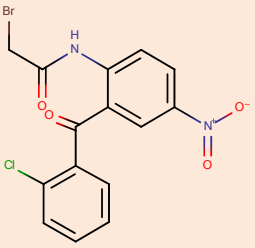
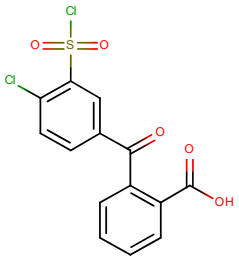
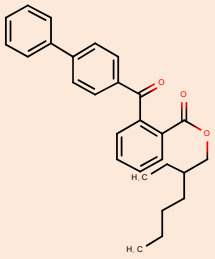
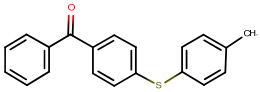
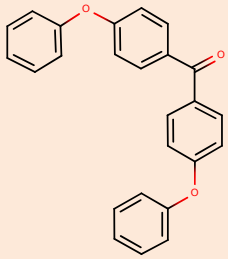
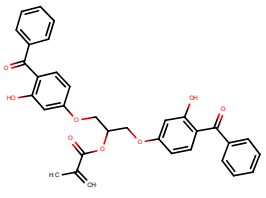
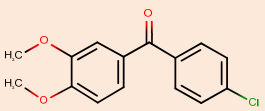
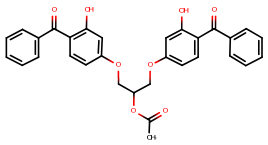
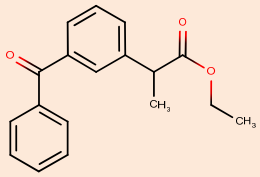
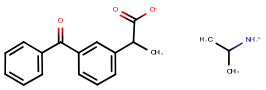
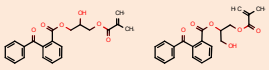
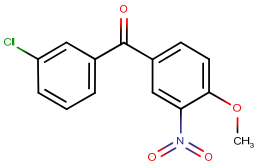
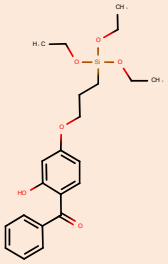
244-759-8	22071-15-4	Ketoprofen		OSII or TII
251-107-6	32580-26-0	N-(2-benzoyl-4-chlorophenyl)-2-bromoacetamide		OSII or TII
255-626-9	42017-89-0	2-[4-(4-chlorobenzoyl)phenoxy]-2-methylpropionic acid		OSII or TII
255-982-5	42872-30-0	2-(m-benzoylphenyl)propionitrile		OSII or TII
256-376-3	49562-28-9	Fenofibrate		OSII or TII
257-681-4	52130-87-7	2-bromo-N-[2-(2-chlorobenzoyl)-4-nitrophenyl]acetamide		OSII or TII

EC/List no	CAS no	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
271-616-7	68592-12-1	2-[4-chloro-3-(chlorosulphonyl)benzoyl]benzoic acid		OSII or TII
278-051-5	75005-95-7	2-ethylhexyl 2-([1,1'-biphenyl]-4-ylcarbonyl)benzoate		Full, 1-10
281-064-9	83846-85-9	4-(4-methylphenylthio)benzophenone		Full, 10-100
403-390-4	-	4,4'-diphenoxybenzophenone		NONS
403-890-2	-	1,3-bis(4-benzoyl-3-hydroxyphenoxy)prop-2-yl methacrylate		NONS
404-610-1	116412-83-0	4-chloro-3',4'-dimethoxybenzophenone		Not registered

EC/List no	CAS no	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
406-990-4	-	1,3-bis(4-benzoyl-3-hydroxyphenoxy)prop-2-yl acetate		NONS
414-920-9	60658-04-0	ethyl 2-(3-benzoylphenyl)propanoate		Full, 1-10
417-970-1	-	isopropylammonium 2-(3-benzoylphenyl)propionate		Not registered
419-000-0	-	reaction mass of: 2-hydroxy-3-(methacryloyloxy)propyl (2-benzoyl)benzoate; 1-hydroxymethyl-2-(methacryloyloxy)ethyl (2-benzoyl)benzoate; x-hydroxy-y-(methacryloyloxy)propyl (or -ethyl) (2-benzoyl)benzoate		Cease manufacture
423-290-4	66938-41-8	(3-chlorophenyl)-(4-methoxy-3-nitrophenyl)methanone		NONS
431-490-8	79876-59-8	4-(3-triethoxysilylpropoxy)-2-hydroxybenzophenone		Full, 1-10

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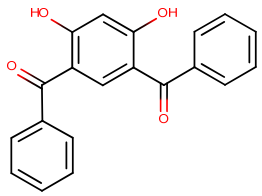
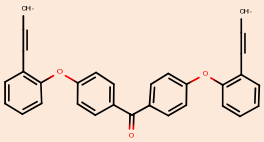
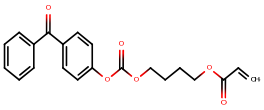
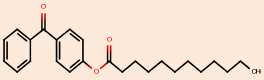
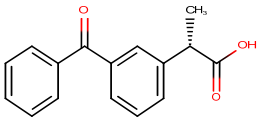
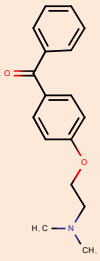
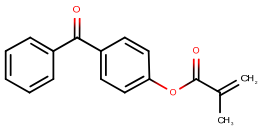
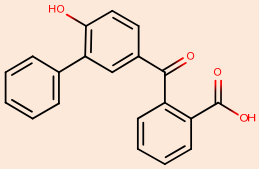
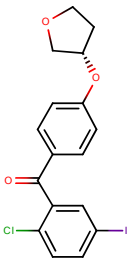
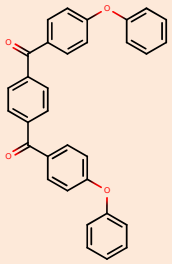
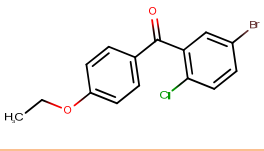
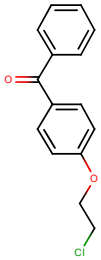
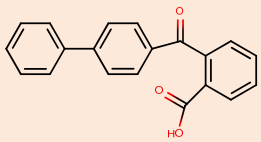
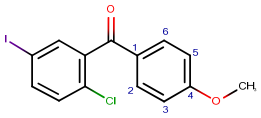
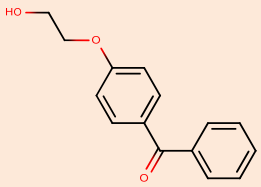
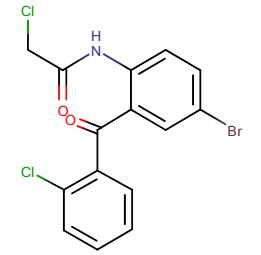
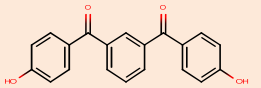
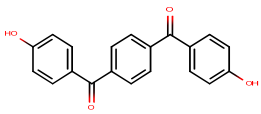
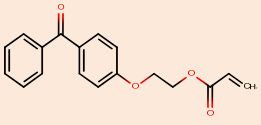
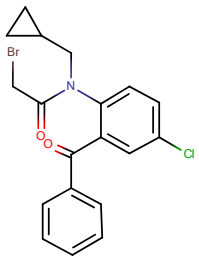
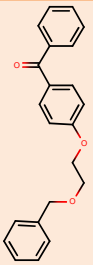
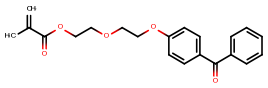
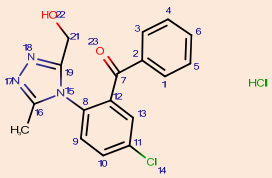
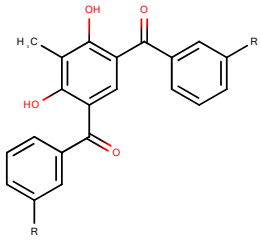
439-680-2	-	DIBENZOYLRESORCIN		NONS
446-450-5	-	[No public or meaningful name is available]	Not (publicly) available	Not registered
447-000-0	-	THBP	Not (publicly) available	Cease manufacture
454-740-8	-	[No public or meaningful name is available]	Not (publicly) available	NONS
472-490-8	-	[No public or meaningful name is available]	Not (publicly) available	NONS
481-100-5	-	bis{4-[2-(prop-1-en-1-yl)phenoxy]phenyl}methanone		Full, 1-10
603-491-5	131513-00-3	Acrylic acid 4-[[(4-benzoylphenoxy)carbonyl]oxy]butyl ester		Full, 10-100
604-316-5	142857-24-7	4-(phenylcarbonyl)phenyl dodecanoate		OSII or TII
606-944-5	22161-81-5	(2S)-2-(3-benzoylphenyl)propanoic acid		OSII or TII
610-729-1	51777-15-2	{4-[2-(Dimethylamino)ethoxy]phenyl}(phenyl)methanone		OSII or TII

EC/List no	CAS no	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
611-390-2	56467-43-7	2-propenoic acid, 2-methyl-, 4-benzoylphenyl ester		Full, 10-100
617-597-4	84627-04-3	2-{6-hydroxy-[1,1'-biphenyl]-3-carbonyl}benzoic acid		OSII or TII
619-598-5	915095-87-3	(2-Chloro-5-iodophenyl)[4-[[(3S)-tetrahydro-3-furanyl]oxy]phenyl]methanone		OSII or TII
620-097-9	54299-17-1	1,4-phenylene bis[(4-phenoxyphenyl)-methanone]		Full, 100-1000
630-623-9	461432-22-4	(5-Bromo-2-chloro-phenyl)-(4-ethoxy-phenyl)-methanone		OSII or TII
641-467-6	60658-04-0	[No public or meaningful name is available]	Not (publicly) available	C&L notification
690-635-5	3439-73-4	4-(2-Chloroethoxy)benzophenone		OSII or TII
Not (publicly) available	-	Substance 1 [No public or meaningful name is available]	Not (publicly) available	Cease manufacture

EC/List no	CAS no	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
Not (publicly) available	-	Substance 2 [No public or meaningful name is available]	Not (publicly) available	Cease manufacture
700-862-4	42797-18-2	2-(4-Phenylbenzoyl)benzoic acid		Full, 10-100
810-422-4	1459754-39-2	4-methoxy-2'-chloro-5'-iodo-benzophenone		OSII or TII
810-808-2	14814-17-6	[4-(2-hydroxyethoxy)phenyl](phenyl)methanone		Cease manufacture
814-736-2	285158-15-8	N-[4-bromo-2-(2-chlorobenzoyl)phenyl]-2-chloroacetamide		OSII or TII
816-325-3	5436-05-5	1,3-phenylenebis((4-hydroxyphenyl)methanone)		Full, 10-100
816-326-9	15517-46-1	1,4-phenylene bis((4-hydroxyphenyl)methanone)		Full, 10-100
836-681-3	22421-66-5	4-(2-acryloyloxy-ethoxy) benzophenone		Full, 1-10

EC/List no	CAS no	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
920-284-8	1184768-58-8	N-(2-Benzoyl-4 Chlorophenyl)-2-Bromo-N-(Cyclopropylmethyl)-Acetamide		OSII or TII
938-331-6	341527-03-5	4-(2-Benzyloxyethoxy)-benzophenone		OSII or TII
943-359-7	-	2-(2-(4-benzoyl-phenoxy)ethoxy)ethyl 2-methylprop-2-enoate		Full, 1-10
951-488-5	-	[5-chloro-2-[3-(hydroxymethyl)-5-methyl-1,2,4-triazol-4-yl]phenyl]-phenylmethanone-chlorohydrate		OSII or TII
952-088-3	-	Reaction mass of benzoyl chloride, toluoyl chloride and 2-methyl resorcinol		Full, 1-10

This table contains also group members that are only notified under the CLP Regulation, however, the list is not necessarily exhaustive.

Contents

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The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA, the Member States or other regulatory agencies may initiate at a later stage. Assessments of regulatory needs and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

Foreword

The assessment of regulatory needs of a group of substances is an iterative, informal process to help authorities consider the most appropriate way to address an identified concern for a group of substances or a single substance and decide whether further regulatory risk management activities are necessary.

The grouping is mainly based on structural similarity and associations made by the registrants between substances through read-across and category approaches as well as category associations from external sources (e.g. OECD categories)[2]. These methods are different from grouping as defined in Section 1.5 of Annex XI to REACH because the scope and intended use of ECHA's grouping is different. Thus, in this context, grouping does not aim to validate read-across and category approaches according to the Annex XI requirements but rather to support a faster and more consistent approach for regulating chemicals and avoid regrettable substitution.

The focus of the assessment is largely based on information available in the registration dossiers and on properties requiring regulatory risk management action at EU level[3]. The information reported on uses is from the registration dossiers (IUCLID) and is used as a proxy for assessing how widespread uses are and whether potential for exposure to humans and releases to the environment can be expected. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

The outcome of these assessments are proposals for immediate (the first action) and subsequent regulatory action(s), including the foreseen ultimate regulatory action (last foreseen regulatory action) to address the identified concern(s) in case the potential hazards are confirmed. For example, further data generation through compliance check is suggested as a first action, to confirm the identified hazard.

Where hazards are confirmed, regulatory risk management actions could be considered for the whole group, for a subgroup or for individual substances within the group. The robustness of the group depends on the stage of assessment and the level of certainty this stage requires. For example, the needs for grouping under restriction may differ from the needs for grouping for the purpose of harmonised classification. Group membership is reconsidered accordingly throughout the iterative assessment of regulatory needs, for example, after further information is generated and the hazard has been clarified or when new insights on uses and risks are available.

The assessment of regulatory needs in itself does not represent a regulatory action, but rather a preparatory step to consider further possible regulatory actions at the level of individual substances or groups/subgroups of substances.

[2] Working with Groups - ECHA (europa.eu)

[3] Regarding hazard properties the focus is for instance on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the report. This does not mean that the substances do not have other known or potential hazards. In some specific cases, ECHA may consider additional hazards (e.g. neurotoxicity, STOT RE).

Publication of ARNs makes it easier for companies to follow the latest status of their substances of interest, anticipate potential regulatory actions and make strategic choices in their chemicals portfolio.

For more information on assessments of regulatory needs please consult ECHA's website[4].

[4] https://echa.europa.eu/understanding-assessment-regulatory-needs

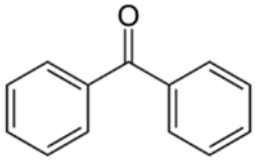
Glossary

ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic / very persistent and very bioaccumulative
PMT/vPvM	Persistent, mobile, and toxic / very persistent and very mobile
RDT	Repeated dose toxicity
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern
TPE	Testing proposal evaluation

1 Overview of the group

Explanations on the scope of this assessment is available in the foreword to this document. Please read it carefully before going through the report.

ECHA has grouped together structurally similar substances based on the presence of the benzophenone moiety shown in the figure below. Benzophenones that are alkyl- nor p-amino, and other hydroxy substituted are excluded from the group, these are covered in the group 'Benzophenones alkyl-, hydroxy- or p-amino substituted'.



Benzophenone fragment always present in the structure

The group consists of 68 benzophenone derivatives, mainly mono-constituent substances where substituents include halogens, carboxylic acids (i.e. esters, salts), amides, substituted anilines, methacrylates, alkoxy groups, alkoxyamines, ethoxylates, di-, trihydroxyl groups and biphenyls. Benzophenones may be mono-, di-, tri-, tetra or pentasubstituted and the substituents can be in the same ring or distributed within both rings.

Out of the 68 substances in the group, 19 have a full registration. Based on information reported in the REACH registration dossiers, three substances in the group (EC 210-112-3, 281-064-9 and 278-051-5) are used in applications such as coatings and paints, thinners, paint removes, ink and toners, adhesives, sealants, fillers, putties, plasters, modelling clay. In these applications, uses by professional workers are commonly reported. In addition, article service life is often relevant (either via the presence of the substances or of their reaction products in the manufactured/treated article manufactured/treated). Therefore, these uses can be considered widespread with a potential for exposure and releases.

Less common applications reported for some substances in the group include anti-freeze and de-icing, washing and cleaning, cosmetics, personal care, non-metal-surface treatment, paper and board treatment, textile dyes, and impregnating. In these applications, uses by professional worker are reported. In addition, article service life can be relevant for some of these applications (either via the presence of the substances or of their dissolution products in the article manufactured/treated). Although these uses are less frequently reported, they can be considered widespread with a potential for exposure and releases.

Some substances are used as laboratory chemicals or pharmaceuticals, mostly in industrial setting. In these cases, the potential for exposure and releases is likely to be much lower.

Most of the substances in the group (46 out of 53 registered substances) are also used as intermediate in industrial setting. Out of these 46, 33 substances are registered as intermediate only.

Potential substitution was considered based on structural similarity for the substances in the group that reported widespread uses. EC 210-112-3 could be potentially substituted by EC 204-230-4 and EC 271-616-7, given that both contain a carboxylic group in ortho position.

A potential substitute for EC 278-051-5 could be EC 617-597-4, due to the presence of a biphenyl ring and a carboxylic group in ortho position. No intermediate in the group was found as potential substitute for EC 281-064-9.

According to general knowledge[5], benzophenone can be used as a photo initiator in UV-curing applications such as inks, imaging, and clear coatings in the printing industry. Benzophenone can also be added to plastic packaging as a UV blocker to prevent photo-degradation of the packaging polymers or its contents.

[5] Ullmann's Encyclopedia of Industrial Chemistry, Wikipedia

2 Conclusions and proposed actions

The conclusions and actions proposed in the table below are based mainly on the REACH and CLP information available at the time of the assessment by ECHA. The conclusions are preliminary suggestions from a screening-level assessment done by ECHA with the aim to propose the next steps for further work (e.g., strengthening of the hazard conclusions, clarification of the uses and/or potential for exposure). The main source of information is the registration dossiers. Relevant public assessments may also be considered. When new information (e.g., on hazards through evaluation processes, or on uses) will become available, the document may be updated, and conclusions and actions revisited.

Table 1: Conclusions and proposed actions

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
210-112-3 **281-064-9** **204-230-4** **271-616-7**	Known or potential hazard for carcinogenicity for all substances Known or potential hazard for STOT RE for 210-112-3 Known or potential hazard for ED for 281-064-9	Known or potential hazard for aquatic toxicity for 210-112-3, 281-064-9 Known or potential hazard for PBT/vPvB for 281-064-9 Known or potential hazard for PMT/vPvM for 210-112-3 Inconclusive hazard for aquatic toxicity	210-112-3 and 281-064-9 are used in professional and industrial setting in many application with potential for exposure and releases (adhesives and sealants, finger paint, fillers, coatings and paints, inks and toners, etc.). 204-230-4, 271-616-7 are currently registered as	**First step:** CCH for 210-112-3, 281-064-9 **Potential next steps (if hazard confirmed after data generation):** CLH 210-112-3, 204-230-4, 271-616-7 for PMT 281-064-9 for PBT **Potential last action:** **Restriction** <u>Justification</u>: For EC 281-064-9 releases to the environment from widespread professional uses cannot be avoided. Widespread professional uses are typically non-contained

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
		for PBT/vPvB for PMT/vPvM For 204-230-4, 271-616-7 Known or potential hazard for ED for 281-064-9	intermediates only. However, due to their structural similarity to 210-112-3, they could potentially be used as substitute to that substance. They are included here for this reason.	and non-automated leading to releases to the environment. For EC 210-112-3, since there is high release potential to surface waters, soil and ground water due to the use as e.g., adhesives and sealants, finger paint, fillers, coatings and paints, CLH is proposed to confirm the potential PMT/vPvM hazards. Until more clarity is available on how to regulate PMT/vPvM substances, we would suggest to consider including this substance as well as EC 204-230-4 and 271-616-7 (due to structural similarity) in a restriction on EC 281-064-9 as well Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses. Industrial uses to be considered as part of the restriction. Potential exposure from articles needs further investigation, restriction for use in articles to be considered together with the restriction of professional uses.
201-612-2	Known or potential hazard	Inconclusive hazard for PBT/vPvB	The substances are mostly used in	**First step:** CCH

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
816-325-3 **816-326-9**	for carcinogenicity for all substances Known or potential hazard for reproductive toxicity for ED for 816-325-3, 816-326-9 Known or potential hazard for STOT RE for mutagenicity for skin sensitisation for 201-612-2	for PMT/vPvM for aquatic toxicity for 201-612-2 Known or potential hazard for PMT/vPvM for 816-325-3, 816-326-9 Known or potential hazard for aquatic toxicity for 816-325-3, 816-326-9 Known or potential hazard for ED for 816-325-3, 816-326-9	application where exposure or releases are likely to be relatively low (intermediates, polymers, laboratory)	**Potential last action (if hazard confirmed after data generation):** **CLH** 201-612-2 for Muta 816-325-3 and 816-326-9 for Repr, ED, PMT/vPvM <u>Justification</u>: If the CLH process confirms these hazards for these substances then the CLH will require company level risk management measures (RMM) for workers to be in place.
700-862-4 **201-615-9**	Known or potential hazard for carcinogenicity For all substances	Known or potential hazard for aquatic toxicity For 700-862-4 Inconclusive hazard for PBT/vPvB	The substances are mostly used in application where exposure or releases are likely to be relatively low	**First step:** CCH **Potential last action (if hazard confirmed after data generation):** **Currently not possible to assess the regulatory needs**

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
	Known or potential hazard for skin sensitisation for 201-615-9	for PMT/vPvM for all substances Inconclusive hazard for aquatic toxicity for 201-615-9	(intermediates, polymers, laboratory)	<u>Justification</u>: It is not possible to assess the needs for regulatory risk management for the substances as information on hazard is not sufficient to conclude on PBT/vPvB and PMT/vPvM, and the information for carcinogenicity is insufficient to act on. The needs for regulatory risk management actions will be assessed once generation of data is completed (CCH).
620-097-9	Known or potential hazard for carcinogenicity	Known or potential hazard for aquatic toxicity	The substance is used in application where exposure or releases are likely to be relatively low (intermediates, polymers, laboratory)	**First step:** CCH **Potential last action:** **Currently no need for EU RRM** <u>Justification</u>: Considering the type of uses, self-classification followed by implementation of necessary RRMs should be sufficient to ensure safe use by workers.
278-051-5 **611-390-2** **205-160-7**	Known or potential hazard for carcinogenicity For all substances	Known or potential hazard for PBT/vPvB for 278-051-5, 414-920-9, 431-490-8,	Widespread uses with potential for exposure and releases for 278-051-5 (adhesives and sealants, finger paint, fillers, etc.), and to a	No action <u>Justification</u>: Due to the registration status of these substances (low tonnage, intermediate

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
431-490-8 **481-100-5** **836-681-3** **952-088-3** **943-359-7** **603-491-5** **211-949-7** **414-920-9** **212-348-2** **213-822-1** **217-207-9** **217-929-4** **217-932-0** **220-985-2** **226-844-1** **227-875-3** **229-803-6**	Known or potential hazard for mutagenicity for 423-290-4 Known or potential hazard for skin sensitisation for 481-100-5, 952-088-3, 414-920-9, 836-681-3, 419-000-0, 603-491-5, 943-359-7, 211-949-7, 641-467-6 Known or potential hazard for STOT RE for 414-920-9, 417-970-1, 641-467-6	472-490-8, 481-100-5, 952-088-3, Known or potential hazard for PMT/vPvM for 211-949-7, 278-051-5, 414-920-9, 417-970-1, 419-000-0, 423-290-4, 439-680-2, 447-000-0, 454-740-8, 836-681-3, 943-359-7, Known or potential hazard for aquatic toxicity for 205-160-7, 211-949-7, 278-051-5, 414-920-9, 431-490-8, 481-100-5, 603-491-5, 611-390-2, 836-681-3, 943-359-7, 952-088-3, 255-626-9, 255-982-5, 256-376-3, 611-390-2, 617-597-4, 619-598-5, 814-736-2, 417-970-1, 419-000-	lesser extent for 611-390-2, 431-490-8, 481-100-5, 952-088-3 (adhesives and sealants or coatings). The other registered substances are mostly used in application where exposure or releases are likely to be relatively low (intermediates, polymers, laboratory, pharmaceutical)	registration, not registered) no data generation is possible to clarify the hazards currently. Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status and/or uses change. Data generation is proposed to verify the aquatic toxicity of EC 952-088-3. However this will not allow to clarify the potential PBT/vPvB hazard.

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
239-479-8 **244-759-8** **251-107-6** **255-626-9** **255-982-5** **256-376-3** **257-681-4** **604-316-5** **606-944-5** **610-729-1** **617-597-4** **619-598-5** **630-623-9** **690-635-5** **Substance 1** **Substance 2** **810-422-4**		0, 423-290-4, 447-000-0, 641-467-6 Inconclusive hazard for PBT/vPvB for 212-348-2, 213-822-1, 212-348-2, 213-822-1, 217-207-9, 217-929-4, 217-932-0, 220-985-2, 226-844-1, 227-875-3, 229-803-6, 239-479-8, 244-759-8, 251-107-6, 255-626-9, 255-982-5, 256-376-3, 257-681-4, 604-316-5, 606-944-5, 610-729-1, 617-597-4, 619-598-5, 630-623-9, 690-635-5, Substance 1, Substance 2, 810-422-4, 810-808-2, 814-736-2, 920-284-8, 938-331-6, 951-488-5, 201-596-7, 202-024-9, 403-390-4, 403-890-2, 404-610-1, 406-990-4, 641-467-6		

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
810-808-2 **814-736-2** **920-284-8** **938-331-6** **951-488-5** **201-596-7** **202-024-9** **218-000-6** **403-390-4** **403-890-2** **404-610-1** **406-990-4** **417-970-1** **419-000-0** **423-290-4** **439-680-2** **446-450-5**		Inconclusive hazard for PMT/vPvM for 212-348-2, 213-822-1, 212-348-2, 213-822-1, 217-207-9, 217-929-4, 217-932-0, 220-985-2, 226-844-1, 227-875-3, 229-803-6, 239-479-8, 244-759-8, 251-107-6, 255-626-9, 255-982-5, 256-376-3, 257-681-4, 604-316-5, 606-944-5, 610-729-1, 617-597-4, 619-598-5, 630-623-9, 690-635-5, Substance 1, Substance 2, 810-422-4, 810-808-2, 814-736-2, 920-284-8, 938-331-6, 951-488-5, 201-596-7, 202-024-9, 403-390-4, 403-890-2, 404-610-1, 406-990-4, 472-490-8, 641-467-6		

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
447-000-0 **454-740-8** **472-490-8** **641-467-6**		Inconclusive hazard for aquatic toxicity for 212-348-2, 213-822-1, 212-348-2, 213-822-1, 217-207-9, 217-929-4, 217-932-0, 220-985-2, 226-844-1, 227-875-3, 229-803-6, 239-479-8, 244-759-8, 251-107-6, 257-681-4, 604-316-5, 606-944-5, 610-729-1, 630-623-9, 690-635-5, Substance 1, Substance 2, 810-422-4, 810-808-2, 920-284-8, 938-331-6, 951-488-5, 201-596-7, 202-024-9, 403-390-4, 403-890-2, 404-610-1, 406-990-4, 439-680-2, 454-740-8, 472-490-8,		

3 Justification for the (no) need for regulatory risk management action at EU level (if hazards confirmed)

Hazard

Based on currently available information, there is a potential hazard for **carcinogenicity (Carc. 2)** for all substances in the group. This is based on chemical structure similarity with benzophenone (not a member of this group of substances). Benzophenone has a harmonised classification as Carc. 1B (RAC opinion, 2020[6]). Data generation to clarify this hazard is difficult and is proposed only for the few substances where explicitly mentioned in the following subsections.

This hazard hypothesis (i.e. Carc 2) is extrapolated to the entire group of substances. We do not extrapolate Carc 1B, but to Carc. 2 because of the high uncertainties due to the limited available data and the expectation that this uncertainty will remain for the foreseeable future. The available repeated dose studies of this group of substances do not provide compelling evidence of a possible carcinogenicity effect. It is not expected that the uncertainty can be resolved, perhaps with the exception of EC 210-112-3 (see further). Only one OECD TG 422 study (EC 210-112-3) provided evidence of hepatocellular hypertrophy of the liver, and degeneration in the cortical/corticomedullary tubules of the kidney in the mid and the high dose in both sexes. The incidence and severity suggested dose relationship in both alterations. Hypertrophy occurred in the liver with centrilobular zonation, minimal and mild severity in both sexes at the high dose, and with minimal intensity in the mid dose males. This change was regarded as non-adverse adaptive response. No hypertrophy was observed in the mid and low dose females and in the low dose males. Moreover, the presence of additional functional groups (such as acrylates, amides, halogens) as compared to benzophenone may lead to differences in metabolism. Notably as a worst case scenario, this hazard is extrapolated also to ketoprofen, ketoprofen ester and fenofibrate, widely used susbtances registered under REACH as intermediates and with no relevant data in their dossiers.

Based on currently available information, there is a known/potential hazard for **skin sensitiser** hazard. This is based on CLH for Skin Sensitisation 1 (ECs 414-920-9, 641-467-6 (CLH)), self classification as Skin Sens 1/1B (ECs 201-612-3, 201-615-9, 211-949-7, 481-100-5, 603-491-5, 836-681-3, 943-359-7, 952-088-3) or group extrapolation based on the presence of metacrylate moiety (ECs 403-890-2, 419-000-0), unless negative data were available. The hazard is unlikely for the rest of the substances in the group based on five TG 429, four TG 406, and a few in vitro and non TG studies. For the other substances with no data, the hazard is extrapolated as unlikely because no structural alert has been identified and the majority of the sustbances in the group are not skin sensitisers.

Based on currently available information, there is a known hazard for **STOT RE 1**: for ECs 414-920-9 and 641-467-6 with STOT RE 1 CLH. There is a known hazard for EC 417-970-1 with **STOT RE 2** CLH. There is potential STOR RE 2 for EC 210-112-3 with a self classified as STOT RE 2. This conclusion is based on one TG 422 study reporting effects on liver and kidney at 125 and 500 mkd in m/f with histopathological changes, hepatocellular hypertrophy of liver, the data are suggestive of a dose-response effect. This conclusion is extrapolated to EC 201-612-2 due to chemical structure similarity (corresponding ester). This conclusion is

[6] https://echa.europa.eu/documents/10162/63078b71-7c88-afa0-241c-ffef8fbdd3bd

not extrapolated to other susbtances in the group because of negative studies, including four TG 422 screening studies and one TG 407.

Based on currently available information, there is a known hazard for **mutagenicity**: for EC 423-290-4 with Muta 2 CLH. There is potential hazard for mutagenicity for EC 201-612-2. This conclusion is based on a positive chromosomal aberration study with no in vivo follow-up. This conclusion is extrapolated to the following substances with ECs 217-932-0 (intermediate), 217-207-9 (intermediate), 217-929-4 (intermediate) because of structural similarity with EC 423-290-4. This hazard is unlikely for the rest of the substances in the group based on about 20 negative genotoxicity studies.

Based on currently available information, there is a potential hazard for **reproductive toxicity / ED**: for the following substances: List 816-325-3 and 816-326-9. This hypothesis is based on developmental effects reported for 816-325-3 at 1000 mg/ kg / d (i.e. decreased body weight for females and males pups with no recovery, shift sex ratio in most litters (7 out of 8), but on effects on AGD and thyroid hormone levels). This conclusion is extrapolated to List 816-326-9 based on chemical structure similarity. This hazard is unlikely for the rest of the substances based on five TG 422 studies. Notable there are no prenatal developmental and/or extended one generation studies available for the entire group of substances.

Based on currently available information, there is a potential hazard for **ED,** with uncertainty, for the following substance: EC 281-064-9. This hypothesis is based on a screening and developmental toxicity study OECD 422 showing a decrease concentration of T4 in F1 offspring at Day 13 post-partum (male pups of all dose and female pups of mid (200 mg/kg) and high dose (600 mg/kg), and increased retention of areolae at mid dose (200 mg/kg).

Based on currently available information, there is a potential hazard for **aquatic toxicity** hazard for most of the substances in the group. A high number of substances in the group have either a harmonised classification and/or a classification in the registration dossier.

Based on ECHA's screening assessment of currently available information, there is a potential hazard for **PBT / vPvB** and/or **PMT / vPvM** for some members in the group having the following properties:

- these substances are potentially persistent or very persistent (P/vP) as they are not readily biodegradable (*i.e.,* <60/70% degradation in an OECD TG 301 or equivalent);
- some substances are potentially bioaccumulative or very bioaccumulative (B/vB) as they have a high potential to partition to lipid storage (e.g., log Kow > 4.5);
- some substances are potentially mobile (M) as the log Koc is less than 3 or log Kow <4.5, or very mobile (vM) as the log Koc is less than 2;
- these substances may meet the T criteria as they are known/potentially toxic to aquatic environment.

Therefore, the substances EC/List no. 278-051-5, 281-064-9, 414-920-9, 431-490-8, 472-490-8, 481-100-5, 952-088-3 are considered as potential PBT/vPvB substances.

The substances EC/List no. 210-112-3, 211-949-7, 278-051-5, 417-970-1, 419-000-0, 423-290-4, 439-680-2, 447-000-0, 454-740-8, 816-325-3, 816-326-9, 836-681-3, 943-359-7 are considered as potential PMT/vPvM substances.

Based on currently available information, there is a potential hazard for **ED for environment** hazard for some substances in the group. The ED potential is extrapolated from the HH assessment with uncertainty. Therefore, the substances EC/List no. 281-064-9, 816-325-3 and 816-326-9 are considered as potential ED substances.

Based on currently available information, PBT/vPvB and PMT/vPvM hazards are inconclusive for most of the other substances in the group as there is not sufficient information to make a holistic view of available information for the substances.
Data are lacking for most of the TII/OSII and NONS substances, for which the persistency, bioaccumulation and mobility potential is considered inconclusive. Considering the high structural variability within the group and the lack of a clear trend, no extrapolation is feasible.
For EC/List no. 201-612-2, 201-615-9, 700-862-4 no dissociation constant is available, but they have the carboxyl moiety in the structure, therefore they can potentially ionise in the environment. No experimental BCF data are available, and considering that both bioaccumulation and mobility cannot be adequately predicted with log Kow and log Koc, respectively, B and M are inconclusive. Moreover, the available ready biodegradability studies (OECD TG 301 D,F) showed a low degradation, therefore these substances are potentially persistent.
Compliance check is suggested for the following specific substances to clarify PBT/vPvB and/or PMT/vPvM hazards: EC/List no. 201-612-2, 201-615-9, 210-112-3, 281-064-9, 700-862-4, 816-325-3, 816-326-9, 952-088-3.

Regulatory Needs

Suggested regulatory risk management action for substances 210-112-3, 281-064-9, 204-230-4, 271-616-7 if PMT or PBT hazards are confirmed: CLH followed by Restriction

Based on currently available information, there is a potential hazard for PMT/vPvM for 210-112-3, and for PBT for 281-064-9.

Although EC 204-230-4 and 271-616-7 are currently registered as intermediates only, they have been included here as they could potentially be used as alternatives for 210-112-3.

EC 210-112-3 and 281-064-9 are used in uses/applications such as adhesives and sealants, coatings / paints / thinners, ink and toners, etc., where exposure to workers in both industrial and professional setting is likely to be significant and releases to the environment is likely (either during the use of the substance or during article service life).

Data generation is proposed to clarify the hazards (Carc via repeated dose studies, PMT for EC 210-112-3 and PBT/vPvB for 281-064-9).

The first step of the suggested regulatory risk management action, should the hazard exist, is the confirmation of hazard via harmonised classification (CLH) as PBT for EC 281-064-9 and PMT for 210-112-3, 204-230-4 and 271-616-7.

CLH as PBT/vPvB will require company level risk management measures (RMM) for environment to be in place. It will require manufacturers and importers of the substance to recommend, to downstream users, risk management measures that minimise exposure and emissions to humans and the environment throughout the lifecycle of the substances.

Confirmation of the hazard properties via CLH is not considered sufficient to minimise potential releases of the substances in the environment for the PBT properties of EC 281-064-9. Although it is difficult to draw conclusions regarding possible additional EU regulatory risk management for EC 210-112-3, 204-230-4 and 271-616-7 until more clarity is available on how to regulate PMT/vPvM substances, we would suggest to consider including these substances (EC 204-230-4 and 271-616-7 due to structural similarity) in a restriction on EC 281-064-9 as well.

A restriction is seen as the most appropriate option as potential for exposure is expected from the professional uses in adhesives and sealants, coatings / paints / thinners, ink and toners. These uses are expected to be widespread (at many sites and by many users) and typically non-contained and non-automated leading to releases to the environment.

Furthermore, potential for exposure and releases to the environment from articles is uncertain based on available information.

Therefore, a restriction of the substances as such or in mixtures (concentration limit in mixtures) used by consumers, professional workers, industrial workers is suggested after CLH, with the aim to minimise exposures and emissions to humans and the environment.

The use of PBT and vPvB substances by consumers and professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability[7].

Moreover, **restricting substances in articles** used by professionals or consumers (reported for substances EC 210-112-3 and 281-064-9) should be considered in the context of the restriction of consumer/professional uses as potential exposure from articles needs further investigation first.

It is suggested to cover possibly also industrial uses as part of the restriction. However, the need for authorisation might be considered for industrial uses excluded from the scope of the restriction as it may not be proportionate to restrict all uses.

Suggested regulatory risk management action for substances EC 201-612-2, 816-325-3, 816-326-9 if Muta, Repro, PMT, PBT hazards is/are confirmed: CLH

Based on currently available information, there is a potential hazard for mutagenicity (EC 201-612-2), Reproductive toxicity, ED, PMT/vPvM (List 816-325-3 and 816-326-9). However, the data available for EC 201-612-2 does not allow to conclude on PBT/vPvB and PMT/vPvM hazards.

These substances do not have a very wide use pattern. They are used in either polymer preparations and compounds, laboratory chemicals or as intermediate mostly in industrial setting where the potential for exposure to workers or releases to the environment is not likely to be significant. EC 201-612-2 is also used in coatings and paints in industrial setting.

Data generation is proposed for all substances to clarify the hazards (Muta for 201-612-2; Repr, ED, PMT/vPvM for 816-325-3 and 816-326-9). Data generation is also

[7] European Commission, *Chemical Strategy for Sustainability Towards a Toxic-Free Environment*, available at https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

expected to allow concluding on the PBT/vPvB and PMT/vPvM hazards of 201-612-2.

The first step of the regulatory risk management action proposed, should the hazard exist, is to confirm via harmonised classification (CLH) the potential properties flagged above for the different substances.

If the CLH process confirms these hazards for these substances then the CLH will require company level risk management measures (RMM) for workers to be in place.

For EC 201-612-2, the needs for regulatory risk management actions for the PBT/vPvB and PMT/vPvM hazards will be assessed once generation of data is completed (CCH).

Currently not possible to suggest regulatory risk management actions for substances EC 201-615-9 and List 700-862-4.

It is not possible to assess the needs for regulatory risk management for 201-615-9, 700-862-4 as information on hazard is not sufficient to conclude on PBT/vPvB and PMT/vPvM hazards. The needs for regulatory risk management actions will be assessed once generation of data is completed (CCH).

These substances have a narrow use pattern. They are used in industrial setting either in polymer preparations and compounds, laboratory chemicals or as intermediate. The potential for exposure to workers or releases to the environment is likely to be moderate.

Currently no need to suggest (further) regulatory risk management actions for 620-097-9

Data generation is proposed for to clarify the hazards

For industrial and professional uses, it is expected that following data generation registrants would adequately self-classify the substances and implement necessary RMMs to ensure safe use at the workplace. In addition, a harmonised classification as CMR cat.2 would not impact any known legislations based on the uses of the substances. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.

Currently no need to suggest (further) regulatory risk management actions for all other substances

Due to their registration status, it is not possible to clarify the hazard of the other substances of the group and read-across does not seem possible.

Low tonnage: EC/List 278-051-5, 611-390-2, 205-160-7, 431-490-8, 481-100-5, 836-681-3, 952-088-3, 943-359-7, 603-491-5, 211-949-7, 414-920-9. Data generation is proposed to verify the aquatic toxicity of EC 952-088-3. However this will not allow to clarify the PBT/vPvB hazard.

Intermediate only registrations: EC/List 212-348-2, 213-822-1, 217-207-9, 217-929-4, 217-932-0, 220-985-2, 226-844-1, 227-875-3, 229-803-6, 239-479-8, 244-759-8, 251-107-6, 255-626-9, 255-982-5, 256-376-3, 257-681-4, 604-316-5, 606-944-5, 610-729-1, 617-597-4, 619-598-5, 630-623-9, 690-635-5,

Substance 1, Substance 2, 810-422-4, 810-808-2, 814-736-2, 920-284-8, 938-331-6, 951-488-5.

Not registered substances: EC/List 201-596-7, 202-024-9, 218-000-6, 403-390-4, 403-890-2, 404-610-1, 406-990-4, 417-970-1, 419-000-0, 423-290-4, 439-680-2, 446-450-5, 447-000-0, 454-740-8, 472-490-8, 641-467-6.

Therefore, it is proposed that there is currently no need for EU RRM action on these substances. If the registration status changes, data generation and potentially follow up actions will be re-considered when the assessment will be revisited.

Annex 1: Overview of classifications

Data extracted on 14/06/2023

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
201-596-7	85-29-0	2,4'-dichlorobenzophenone	-	-
201-612-2	85-52-9	2-benzoylbenzoic acid	-	STOT Single Exp. 3 H335, affected organs: respiratory organs [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)] Acute Tox. 4 H302 Skin Sens. 1B H317
201-615-9	85-56-3	2-(4-chlorobenzoyl)benzoic acid	-	Acute Tox. 4 H302 Eye Damage 1 H318 Skin Sens. 1B H317
202-024-9	90-90-4	4-bromobenzophenone	-	-
204-230-4	118-04-7	2-(3-amino-4-chlorobenzoyl)benzoic acid	-	Eye Irrit. 2 H319 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)] STOT Single Exp. 2 H335, affected organs: Respiratory tract [intermediate (active)]
212-348-2	796-77-0	4-[2-(diethylamino)ethoxy]benzophenone	-	-
213-822-1	1022-13-5	5-chloro-2-(methylamino)benzophenone	-	Eye Irrit. 2 H319 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: High respiratory tract [intermediate (active)]
217-207-9	1775-95-7	2-amino-5-nitrobenzophenone	-	Eye Irrit. 2 H319 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: high respiratory tract [intermediate (active)]

217-929-4	2011-66-7	2-amino-2'-chloro-5-nitrobenzophenone	-	-
217-932-0	2011-70-3	N-(2-benzoyl-4-nitrophenyl)-2-bromoacetamide	-	-
218-000-6	2035-72-5	4-benzoyl-3-hydroxyphenyl methacrylate	-	-
220-985-2	2958-36-3	2-amino-2',5-dichlorobenzophenone	-	-
226-844-1	5504-92-7	2-bromo-N-[4-chloro-2-(2-chlorobenzoyl)phenyl]acetamide	-	-
227-875-3	6021-21-2	N-(2-benzoyl-4-chlorophenyl)-2-chloro-N-methylacetamide	-	-
229-803-6	6740-86-9	1-bromocyclopentyl-o-chlorophenyl ketone	-	-
239-479-8	15462-91-6	3-[2-(3,4-dimethoxybenzoyl)-4,5-dimethoxyphenyl]pentan-2-one	-	-
244-759-8	22071-15-4	ketoprofen	-	Acute Tox. 3 H301 [intermediate (active)]
251-107-6	32580-26-0	N-(2-benzoyl-4-chlorophenyl)-2-bromoacetamide	-	-
257-681-4	52130-87-7	2-bromo-N-[2-(2-chlorobenzoyl)-4-nitrophenyl]acetamide	-	-
271-616-7	68592-12-1	2-[4-chloro-3-(chlorosulphonyl)benzoyl]benzoic acid	-	Skin Corr. 1B H314 [intermediate (active)]
404-610-1	116412-83-0	4-chloro-3',4'-dimethoxybenzophenone	Index number: 606-056-00-8 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	
406-990-4	-	1,3-bis(4-benzoyl-3-hydroxyphenoxy)prop-2-yl acetate	Index number: 607-340-00-4 Aquatic Chronic 2 H411	
414-920-9	-	414-920-9	Index number: 607-534-00-9 Acute Tox. 3 * H301 Skin Sens. 1 H317 STOT RE 1 H372 ** Aquatic Chronic 2 H411	Acute Tox. 3 H301 Skin Sens. 1 H317 STOT Rep. Exp. 1 H372 Aquatic Chronic 2 H411
419-000-0	-	419-000-0	Index number: 607-672-00-X	Aquatic Chronic 2 H411 [Article 10 (inactive)]

			Skin Sens. 1 H317 Aquatic Chronic 2 H411	Skin Sens. 1 H317 [Article 10 (inactive)]
423-290-4	66938-41-8	(3-chlorophenyl)-(4-methoxy-3-nitrophenyl)methanone	Index number: 606-061-00-5 Muta. 2 H341 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	
431-490-8	79876-59-8	431-490-8	Index number: 606-102-00-7 Aquatic Chronic 2 Statement: H411	Aquatic Chronic 2 H411
604-316-5	142857-24-7	604-316-5	-	Skin Irrit. 2 H315 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: Voies respiratoires [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)]
606-944-5	22161-81-5	(2S)-2-(3-benzoylphenyl)propanoic acid	-	Acute Tox. 3 H311 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)] Acute Tox. 3 H331 [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)] Acute Tox. 3 H301 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: GI tract, liver, kidneys [intermediate (active)]
610-729-1	51777-15-2	610-729-1	-	Acute Tox. 4 H332 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Acute Tox. 4 H312 [intermediate (active)]
630-623-9	461432-22-4	(5-bromo-2-chlorophenyl)(4-ethoxyphenyl)methanone	-	STOT Single Exp. 1 H335, affected system: respiratory system: lower respiratory tract, affected organs: lungs [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: Respiratory tracts [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)]
641-467-6	60658-04-0	641-467-6	Index number: 607-534-00-9 Acute Tox. 3 Hazard Statement: H301 (Minimum classification) STOT RE 1 Hazard	-

			Statement: H372 (No information to prove exclusion of certain routes of exposure) Aquatic Chronic 2 Statement: H411 Skin Sens. 1 Statement: H317	
690-635-5	3439-73-4	[4-(2-chloroethoxy)phenyl](phenyl)methanone	-	-
Substance 1	Not (publicly) available	[No public or meaningful name is available]	-	-
Substance 2	Not (publicly) available	[No public or meaningful name is available]	-	-
810-422-4	1459754-39-2	(2-chloro-5-iodophenyl)(4-methoxyphenyl)methanone	-	-
810-808-2	14814-17-6	[4-(2-hydroxyethoxy)phenyl](phenyl)methanone	-	STOT Single Exp. 3 H335, affected organs: Respiratory system [intermediate (inactive)] Eye Irrit. 2 H319 [intermediate (inactive)] Skin Irrit. 2 H315 [intermediate (inactive)]
816-325-3	5436-05-5	1,3-phenylenebis[(4-hydroxyphenyl)methanone]	-	-
816-326-9	15517-46-1	1,4-phenylenebis[(4-hydroxyphenyl)methanone]	-	-
920-284-8	1184768-58-8	N-(2-benzoyl-4-chlorophenyl)-2-bromo-N-(cyclopropylmethyl)acetamide	-	-
938-331-6	341527-03-5	{4-[2-(benzyloxy)ethoxy]phenyl}(phenyl)methanone	-	-
951-488-5	-	{5-chloro-2-[3-(hydroxymethyl)-5-methyl-4H-1,2,4-triazol-4-yl]phenyl}(phenyl)methanone hydrochloride (1:1)	-	-
952-088-3	-	Reaction mass of (5-benzoyl-2,4-dihydroxy-3-methylphenyl)(3-methylphenyl)methanone and (4,6-dihydroxy-5-methyl-1,3-phenylene)bis[(3-methylphenyl)methanone] and (4,6-	-	Skin Sens. 1 H317

		dihydroxy-5-methyl-1,3-phenylene)bis(phenyl methanone)		

Annex 2: Overview of uses based on information available in registration dossiers

Data extracted on 14/06/2023

If it is possible that the substance itself or its reaction/ dissolution products end-up in articles, the registrant should report article service life in their dossier. This is particularly relevant for substances used in applications/uses such as:

- PC 15: Non-metal-surface treatment products
- PC 32: Polymer preparations and compounds
- PC 1: Adhesives, sealants
- PC 9c: Finger paint
- PC 9b: Fillers, putties, plasters, modelling clay
- PC 9a: Coatings and paints, thinners, paint removes
- PC 18: Ink and toners
- PC 26, Paper and board treatment products
- PC 34, Textile dyes, and impregnating products

In the dossiers screened, article service life was identified by registrants for some substances/uses, but not consistently. In most cases, the analysis conducted during the screening exercise did not allow to exclude the presence of the substances or of their reaction/dissolution products in articles manufactured/treated. Therefore, a worst-case approach was taken, and article service life was added where not reported by the registrant to substances used in the product categories (PC) mentioned above, unless a sufficient justification could be found in the data screened.

It should however be noted that this cannot directly be understood as an indication for potential exposure or potential releases to the environment. This potential will depend on factors such as the presence of the substance on the surface of the article or its concentration and migration rate in the matrix.

According to the information screened for EC 611-390-2, this substance is used in cosmetics and personal care products at industrial sites. Similar use by professional workers or consumers was not reported. Without further justification, it is difficult to exclude that cosmetics and personal care products used at industrial sites would not be used by professional workers. Therefore, a worst-case approach was taken and professional use was added.

Industry should update their registration dossiers and clarify whether these uses should be reported for the substances and if not, bring sufficient justification for not considering those uses. For substances where article service life is justified, the registrants should also clarify its relevance in terms of potential for exposure and releases to the environment and, where necessary, provide an exposure assessment. If no additional information is provided at the next iteration of the assessment, those uses will be considered for further regulatory risk management.

EC/ List Main types of applications structured by product or article types	PC 4: Anti-freeze and de-icing products	PC 35: Washing and cleaning products	PC 39: Cosmetics, personal care products	PC 29: Pharmaceuticals	PC 15: Non-metal-surface treatment products	PC 32: Polymer preparations and compounds	PC 1: Adhesives, sealants	PC 9c: Finger paint	PC 9b: Fillers, putties, plasters, modelling clay	PC 9a: Coatings and paints, thinners, paint removes	PC 18: Ink and toners	PC 26: Paper and board treatment products	PC 34: Textile dyes, and impregnating products	PC 21: Laboratory chemicals	PC 19: intermediate (precursor)	PC 30: Photo-chemicals
201-612-2										I, A					I	
201-615-9															I	
204-230-4															I	
205-160-7						I, A								I, A	I	
210-112-3	P					F, I, P, A	F, I, P, A	I, P, A	F, I, P, A	F, I, P, A	F, I, P, A				I	
211-949-7				I											I	
212-348-2															I	
213-822-1															I	
217-207-9															I	
217-929-4															I	
217-932-0															I	
220-985-2															I	
226-844-1															I	
227-875-3															I	
229-803-6															I	

239-479-8														I	
244-759-8														I	
251-107-6														I	
255-626-9														I	
255-982-5				I										I	
256-376-3				I										I	
257-681-4														I	
271-616-7														I	
278-051-5							P, A	I, A	I, A	I, P, A	F, I, P, A				
281-064-9		F, I, P			F, I, P, A	F, I, P, A	I, P, A		F, I	F, I, P, A	F, I, P, C, A	F, I, P, A	I, P, A		F, I
414-920-9				I										I	
431-490-8										I, A					
481-100-5						F, I, A	F, I, A							I	
603-491-5						I, A									
604-316-5														I	
606-944-5				I										I	
610-729-1														I	
611-390-2			I, P			I, A	I, A						I	I	
617-597-4														I	
619-598-5														I	
620-097-9						I, A							I, P	I	
630-623-9														I	
690-635-5														I	
Substance 1														I	
Substance 2														I	

700-862-4						I, A								I	
810-422-4														I	
810-808-2														I	
814-736-2														I	
816-325-3						I, A									
816-326-9						I, A									
836-681-3						I, A								I	
920-284-8														I	
938-331-6														I	
943-359-7						I, A								I	
951-488-5														I	
952-088-3										I, A					

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; P, C and A are highlighted in red to indicate widespread use with potential for exposure/release

Annex 3: Overview of completed or ongoing regulatory risk management activities

Data extracted on 21/07/2023

EC / List No	RMOA, ARN	Authorisation		Restric-tion*	CLH	Actions not under REACH / CLP
		Candidate List	Annex XIV	Annex XVII	Annex VI (CLP)	
404-610-1					YES	
406-990-4					YES	
414-920-9					YES	
417-970-1					YES	
419-000-0					YES	
423-290-4					YES	Cosmetics
431-490-8					YES	
641-467-6					YES	

*Some of the broad restriction entries in the Annex XVII of REACH are not represented in the overview, e.g. when the scope of the restriction is defined by its classification or the substance identification is broad (e.g. entries 3, 28-30, 40 and 75).

There are no relevant completed or ongoing regulatory risk management activities for the other substances.