Assessment of regulatory needs

Authority: ECHA

Date: 16 December 2021

Group Name: Bisphenols

General structure:



Figure: Generic "bisphenol" structure (A) with "X" depicting the bridge between the phenyl rings. There may be additional groups attached to the bridging atom(s). (B) General "bisphenol derivative" structure. R_n can be the same/different groups. R_n does not cover halogen substituents.

Revision history

Version	Date	Description
1.0	16 December 2021	

Substances within this group:

Subgroup: BPA and BPA derivatives

EC/List No	CAS No	Substance name and substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)
201-240-0	79-97- 0	4,4'-isopropylidenedi-o-cresol BPC	$H_{A,C} \xrightarrow{OH} CH_{A}$ $H_{A,C} \xrightarrow{H_{A,C}} CH_{A}$	Full, not (publicly) available
201-245-8	80-05- 7	4,4'-isopropylidenediphenol BPA, bisphenol A		Full, >1000
204-137-9	116- 37-0	1,1'-isopropylidenebis(p- phenyleneoxy)dipropan-2-ol BPA 2 PO	CH CH CH	Full, >1000
212-985-6	901- 44-0	2,2'-isopropylidenebis(p- phenyleneoxy)diethanol BPA 2 EO		Full, not (publicly) available
214-590-4	1156- 51-0	4,4'-isopropylidenediphenyl dicyanate BADCy		Full, 1-10
216-823-5	1675- 54-3	2,2'-[(1- methylethylidene)bis(4,1- phenyleneoxymethylene)]bisoxi rane BADGE		Full, >1000

217-121-1	1745- 89-7	4,4'-isopropylidenebis[2- allylphenol] DAB	H_{i}^{C}	Full, 10-100
227-033-5	5613- 46-7	4,4'-isopropylidenedi-2,6-xylol TMBPA		Full, not (publicly) available
235-985-8	13080 -86-9	4,4'-[isopropylidenebis(4,1- phenyleneoxy)]dianiline BAPP		Full, not (publicly) available
242-895-2	19224 -29-4	2,2'-[(1- methylethylidene)bis(4,1- phenyleneoxy)]bisethyl diacetate		Full, not (publicly) available
248-607-1	27689 -12-9	(1-methylethylidene)bis(4,1- phenyleneoxy-3,1-propanediyl) bismethacrylate BIS-PMA		Full, not (publicly) available
253-781-7	38103 -06-9	4,4'-[(isopropylidene)bis(p- phenyleneoxy)]diphthalic dianhydride BPA-DA		Full, not (publicly) available
425-220-8	5945- 33-5	(1-methylethylidene)di-4,1- phenylene tetraphenyl diphosphate BPADP		Full, >1000

432-380-2	14750 4-92-5	4,6-bis[2-(4- hydroxyphenyl)isopropylidene]r esorcinol	$H_{L,C} \rightarrow H_{L,C} \rightarrow H_{L$	NONS
434-000-0		PURAM		NONS
434-010-5		FULLMAP	entropy and a strange	NONS
460-230-6		Oligomeric reaction products of 4,4'-propane-2,2-diyldiphenol and 2-methyloxirane and 2- (chloromethyl)oxirane	UVCB	Full, not (publicly) available
500-082-2	32492 -61-8	4,4'-Isopropylidenediphenol, ethoxylated BPA-EO	UVCB; (Examples of) representative structure(s):	Full, >1000
500-086-4	35238 -34-7	2-Acetone, polymer with phenol	UVCB	Full, not (publicly) available
500-090-6	36425 -16-8	4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3- epoxypropane, reaction products with maleic anhydride and methacrylic acid	UVCB	Full, 100-1000
500-097-4	37353 -75-6	4,4'-Isopropylidenediphenol, propoxylated BPA-PO	UVCB; (Examples of) representative structure(s): (-, -) + (-, -)	Full, >1000
500-130-2	55818 -57-0	4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3- epoxypropane, esters with acrylic acid	UVCB	Full, >1000

		DGEBADA		
500-180-5	67989 -52-0	4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3- epoxypropane, reaction products with fatty acids, C18- unsatd., dimers	UVCB	Full, 100-1000
500-181-0	68002 -42-6	4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3- epoxypropane, reaction products with 2- methylimidazole	UVCB	Full, not (publicly) available
500-240-0	68958 -77-0	4,4'-Isopropylidenediphenol, polymer with 1-chloro-2,3- epoxypropane, propane-1,2-diol acrylate and succinic anhydride	UVCB	Full, 100-1000
500-263-6	77138 -45-5	Formaldehyde, oligomeric reaction products with 4,4'- isopropylidenediphenol and diethylenetriamine	UVCB	Full, not (publicly) available
500-268-3	87041 -44-9	4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3- epoxypropane, reaction products with cyclohex-1,2- ylenediamine	UVCB	Full, not (publicly) available
500-607-5	16127 8-17-7	Formaldehyde, oligomeric reaction products with 4,4'- isopropylidenediphenol and m- phenylenebis (methylamine)	UVCB	Full, not (publicly) available
500-655-7	16130 8-15-2	4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3- epoxypropane, reaction products with biphenyl-4-ol	UVCB	Full, cease manufacture
609-946-4	41637 -38-1	BISPHENOL A POLYETHYLENE GLYCOL DIETHER DIMETHACRYLATE	UVCB	Full, 100-1000
614-657-1	68609 -08-5	Reaction products of 3- aminomethyl-3,5,5- trimethylcyclohexylamine with 2,2'-[(1- methylethylidene)bis(4,1- phenyleneoxymethylene)]bisoxi rane	UVCB	Full, 10-100
701-308-4		Reaction products of methacrylic acid and 2,2'-[(1- methylethylidene)bis(4,1- phenyleneoxymethylene)]bisoxi rane	UVCB	Full, >1000

701-359-2	Oligomerisation products of 2,2'-[(1- methylethylidene)bis(4,1- phenyleneoxymethylene)]bisoxi rane with acrylic acid and fatty acids, C18-unsatd., dimers and nonanoic acid	UVCB	Full, not (publicly) available
701-362-9	Esterification products of acrylic acid and 4,4'- isopropylidenediphenol ethoxylated	UVCB	Full, 100-1000
701-373-9	Oligomerisation products of 2,2'-[(1- methylethylidene)bis(4,1- phenyleneoxymethylene)]bisoxi rane with acrylic acid and lauric acid	UVCB	Full, not (publicly) available
701-404-6	Not (publicly) available BADGE-DETA	UVCB	Full, 10-100
701-405-1	4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3- epoxypropane, reaction products with ethylene diamine BADGE_EDA	UVCB	Full, 10-100
701-406-7	2,2'-[(1- methylethylidene)bis(4,1- phenyleneoxymethylene)]bisoxi rane reaction mass with amines, polyethylenepoly-, triethylenetetramine fraction BADGE-TETA	UVCB	Full, 10-100
701-407-2	Reaction products of 4,4'- methylenebis(cyclohexylamine) and 2,2'-[(1- methylethylidene)bis(4,1- phenyleneoxymethylene)]bisoxi rane	UVCB	Full, not (publicly) available
904-653-0	Reaction mass of 4,4'- isopropylidenediphenol and phenol	ОН но-СЭ-Н-СЭ-Он	Full, not (publicly) available
926-571-4	4-[2-(4-hydroxyphenyl)propan- 2-yl]phenol, reaction product with diphenyl carbonate	UVCB	Full, not (publicly) available
931-252-8	2-Acetone, condensation product with phenol	UVCB	Full, not (publicly) available
941-183-5	Reaction mass of 4,4'- Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane and Orthophosphoric acid,	UVCB	Full, not (publicly) available

	oligomeric reaction products with 4,4'-isopropylidenediphenol -1-chloro-2,3-epoxypropane co- oligomer		
943-503-9	2,6-bis({[bis(2- hydroxyethyl)amino]methyl})- 4-[2-(3-{[bis(2- hydroxyethyl)amino]methyl}-4- hydroxyphenyl)propan-2- yl]phenol; 2,6-bis({[bis(2- hydroxyethyl)amino]methyl})- 4-[2-(4-hydroxyphenyl)propan- 2-yl]phenol; 2-[(2- hydroxyethyl)amino]ethan-1-ol; 2-{[bis(2- hydroxyethyl)amino]methyl}-4- [2-(3-{[bis(2- hydroxyethyl)amino]methyl}-4- [2-(4-hydroxyphenyl)propan-2- yl]phenol; 2-{[bis(2- hydroxyethyl)amino]methyl}-4- [2-(4-hydroxyphenyl)propan-2- yl]phenol; 4-[2-(4- hydroxyphenyl)propan-2- yl]phenol; 4-[2-(4-		Full, cease manufacture
945-830-2	Reaction product of 4,4'- Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane and aqueous phosphoric acid, 2-butoxyethanol, 2- (dimethylamino)ethanol DD80	UVCB	Full, 10-100
946-322-3	Reaction mass of 6,6'-(2,2- Propanediyl)bis(3-phenyl-3,4- dihydro-2H-1,3-benzoxazine) and N-({4-[2-(3-phenyl-3,4- dihydro-2H-1,3-benzoxazin-6- yl)propan-2- yl]phenoxy}methyl)aniline		Full, not (publicly) available
947-794-3	Reaction mass of 2,6- Bis[(dimethylamino)methyl]-4- (1-{3- [(dimethylamino)methyl]-4- hydroxyphenyl}-1- methylethyl)phenol and 4-(1- {3,5- Bis[(dimethylamino)methyl]-4- hydroxyphenyl}-1- methylethyl)-2,6- bis[(dimethylamino)methyl]phe nol	$H_{C} \xrightarrow{H_{C}} (G_{0}) \xrightarrow{H_{C}} (G_{0}$	Full, not (publicly) available
947-984-6	Phenol, 4,4'-(1- methylethylidene)bis-, oligomer with (chloromethyl)oxirane, reaction products with diethylenetriamine and 4methyl-2-pentanone	UVCB	Full, not (publicly) available

948-520-5		Reaction products of Soya and Linseed Oil Fatty Acids with Bisphenol A diglycidylether	UVCB	Full, not (publicly) available
Not registered substances				
216-367-7	1565- 94-2	(1-methylethylidene)bis[4,1- phenyleneoxy(2-hydroxy-3,1- propanediyl)] bismethacrylate		C&L notification
223-123-3	3739- 67-1	4,4'- isopropylidenebis[(allyloxy)benz ene]		C&L notification
225-144-3	4687- 94-9	(1-methylethylidene)bis[4,1- phenyleneoxy(2-hydroxy-3,1- propanediyl)] diacrylate	Jog O'Ogge	C&L notification
246-263-7	24448 -20-2	(1-methylethylidene)bis(4,1- phenyleneoxy-2,1-ethanediyl) bismethacrylate	funditional	C&L notification
500-033-5	25068 -38-6	4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane	UVCB	C&L notification
500-072-8	31326 -29-1	4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3- epoxypropane, reaction products with diethylenetriamine	Not (publicly) available	C&L notification
500-089-0	36425 -15-7	4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3- epoxypropane, reaction products with methacrylic acid	Not (publicly) available	C&L notification
500-103-5	38294 -67-6	4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3- epoxypropane, reaction products with 4,4'- methylenebis(cyclohexylamine)	Not (publicly) available	C&L notification
500-104-0	38294 -69-8	4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3- epoxypropane, reaction products with triethylenetetramine	Not (publicly) available	C&L notification
500-253-1	72480 -18-3	4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3- epoxypropane, reaction products with ethylenediamine	Not (publicly) available	C&L notification

605-281-9	16224 -36-5	4,4-(1-Methylethyliden)-bis- [2,6-bis- (dimethylaminomethyl)-phenol]	$\begin{array}{c} CH_1 \\ CH_2 \\ OH \\ CH_2 \\ CH_3 \\ CH_3$	C&L notification
605-913-3	18102 8-79-5	Bisphenol A diphosphate	Not (publicly) available	C&L notification
607-500-3	25036 -25-3	Poly(Bisphenol A-co- epichlorohydrin) glycidyl end- capped	Not (publicly) available	C&L notification
607-501-9	25037 -45-0	Not (publicly) available	Not (publicly) available	C&L notification
607-535-4	25085 -75-0	Not (publicly) available	Not (publicly) available	C&L notification
607-537-5	25085 -99-8	1-Chloro-4 Trifluromethyl Bisphenol A Epoxy Resin	Not (publicly) available	C&L notification
609-251-6	36484 -54-5	Phenol, 4,4'-(1- methylethylidene)bis-, polymer with 2-(chloromethyl)oxirane and 2-methyloxirane	Not (publicly) available	C&L notification
609-402-6	37312 -33-7	Epichlorohydrin, bisphenol A, toluenediisocyanate polymer	Not (publicly) available	C&L notification
609-663-6	39382 -25-7	2-Butenedioic acid (2E)-, polymer with .alpha.,.alpha.'- (methylethylidene)di-4,1- phenylene)bis(.omega hydroxypoly(oxy(methyl-1,2-et	Not (publicly) available	C&L notification
613-584-2	64401 -02-1	Poly(oxy-1,2-ethanediyl), .alpha.,.alpha.'-[(1- methylethylidene)di-4,1- phenylene]bis[.omega[(1-oxo- 2-propen-1-yl)oxy]-	Not (publicly) available	C&L notification
614-177-2	67924 -34-9	Phenol, 4-(1,1-dimethylethyl)-, polymer with 2- (chloromethyl)oxirane and 4,4'- (1-methylethylidene)bis[phenol]	Not (publicly) available	C&L notification
614-207-4	68002 -44-8	Phenol, 4,4'-(1- methylethylidene)bis-, polymer with 2-(chloromethyl)oxirane, 2-methyl-2-propenoate, reaction products with formaldehyde-phenol polymer	Not (publicly) available	C&L notification
614-255-6	68071 -07-8	Phenol, 4,4'-(1- methylethylidene)bis-, polymer with 2-(chloromethyl)oxirane, dodecanoate 2-propenoate	Not (publicly) available	C&L notification
620-316-8	28906 -96-9	Formaldehyde, polymer with 2- (chloromethyl)oxirane and 4,4'- (1-methylethylidene)bis[phenol]	Not (publicly) available	C&L notification

641-007-4	36704 -31-1	Phenol, 4,4'-(1- methylethylidene)bis-, polymer with 2-(chloromethyl)oxirane and 1,2-ethanediamine	Not (publicly) available	C&L notification
678-196-8	127- 54-8	2,2-Bis(4-hydroxy-3- isopropylphenyl)propane BPG	ОН	C&L notification
678-197-3	24038 -68-4	2,2-Bis(2-hydroxy-5- biphenylyl)propane BPPH	ОН	C&L notification
680-511-9	68610 -41-3	2-PROPENENITRILE, POLYMER WITH 1,3-BUTADIENE, CARBOXY-TERMINATED, POLYMERS WITH BISPHENOL A AND EPICHLOROHYDRIN	Not (publicly) available	C&L notification
686-711-2	68954 -74-5	Phenol, 4,4'-(1- methylethylidene)bis-, polymer with (chloromethyl) oxirane 2- (1methylethyl)-1H-imidazole- modified	Not (publicly) available	C&L notification
800-098-2	60684 -77-7	Oxirane, 2,2'-[(1- methylethylidene)bis(4,1- phenyleneoxymethylene)]bis-, polymer with 1,1'- methylenebis[isocyanatobenzen e]	Not (publicly) available	C&L notification
806-676-0	21668 9-76-8	Fatty acids, C18-unsatd., dimers, polymers with acrylic acid, bisphenol A, epichlorohydrin and nonanoic acid	Not (publicly) available	C&L notification
947-250-5		Poly(1-Iminodimethene-3,5,5- trimethylcyclohexane-3- methyl/methylimino/2- hydroxypropane-1,3-diyl/2,2- bis(4- phenoxy)propane/methyloxiran e)-blend-2-(4-{2-[4-(oxiran-2- ylmethoxy)phenyl]propan-2- yl}phenoxymethyl)oxirane	Not (publicly) available	C&L notification
EC/List no 1		Not (publicly) available	Not (publicly) available	Not (publicly) available
EC/List no 2		Not (publicly) available	Not (publicly) available	Not (publicly) available
EC/List no 3		Not (publicly) available	Not (publicly) available	Not (publicly) available

EC/List number	CAS number	Substance name and Substance name acronyms	Substance structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)
201-250-5	80-09-1	4,4'- sulphonyldiphenol BPS	HO O=SOOH	Full, >1000
235-986-3	13080-89-2	4,4'- [sulphonylbis(4,1- phenyleneoxy)]dia niline	H ₂ N O O O O O O O O O O O O O O O O O O O	C&L notification
263-920-3	63134-33-8	p-[[p- benzyloxyphenyl]s ulphonyl]phenol BPS-MPE	Сс	C&L notification
277-962-5	74665-14-8	Phenol, sulfonated	UVCB	Full, not (publicly) available
405-520-5	95235-30-6	4-(4- isopropoxyphenyls ulfonyl)phenol D8 (D88)		Full, 100-1000
411-570-9	41481-66-7	2,2'-diallyl-4,4'- sulfonyldiphenol TG-SB, TG-SH, TG- SH(H)	H ₂ C HO HO HO HO HO HO HO HO HO HO HO HO HO	Full, not (publicly) available
427-620-8	-	Not (publicly) available D-90	Not (publicly) available	NONS
479-880-7	97042-18-7	4-(4-Allyloxy- benzenesulfonyl)- phenol BPS-MAE		NONS
680-791-2	9017-72-5	Naphthalenesulfoni c acid polymer with formaldehyde and 4,4'- sulfonylbis[phenol]	Not (publicly) available	C&L notification
941-992-3	-	Reaction product of Phenol, Sulphuric acid and Sodium hydroxide	UVCB	TII or OSII
EC/List no 4	Not (publicly) available	Not (publicly) available	Not (publicly) available	Not (publicly) available

Subgroup: BPS and BPS derivatives

EC/List number	CAS number	Substance name and substance name acronyms	Substance structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)
204-279-1	118-82-1	2,2',6,6'-tetra-tert-butyl- 4,4'-methylenediphenol TBMD	H_3C CH_3 OH H_3C CH_3 H_1C H_3C CH_3 H_3C CH_3 H_3C CH_3 H_3C CH_3 H_3C CH_3 CH_3	Full, 100-1000
210-658-2	620-92-8	4,4'-methylenediphenol BPF	ОН	C&L notification
218-257-4	2095-03-6	2,2'-[methylenebis(p- phenyleneoxymethylene)]b isoxirane Bisphenol F diglycidyl ether		C&L notification
226-378-9	5384-21-4	4,4'-methylenedi-2,6- xylenol Tetramethyl Bisphenol F		Full, >1000
405-790-4	101657-77-6	4,4'-methylenebis(2,6- dimethylphenyl cyanate)		NONS
432-740-9	-	BIS26X-MBOC		NONS

Subgroup: BPF and BPF derivatives

439-910-1	93705-66-9	Oxirane, 2,2'- [methylenebis[(2,6- dimethyl-4,1- phenylene)oxymethylene]] bis-		NONS
500-770-2	64448-68-6	4,4'- methylenediphenololigomer ic reaction products with 1- chloro-2,3-epoxypropane, reaction products with acrylic acid	Not (publicly) available	C&L notification
608-164-0	28064-14-4	Phenol, polymer with formaldehyde, glycidyl ether	Not (publicly) available	C&L notification
632-557-6	93705-66-9	Not (publicly) available	Not (publicly) available	C&L notification
700-487-6	-	reaction products of diglycidyl ether bisphenol F (DGEBF) and oligomeric phenol diglycidyl ethers with acrylic acid Epoxy half acrylate	UVCB	Full, cease manufacture
701-263-0	-	Reaction mass of 2,2'- [methylenebis(2,1- phenyleneoxymethylene)]b is(oxirane) and 2,2'- [methylenebis(4,1- phenyleneoxymethylene)]b is(oxirane) and 2-({2-[4- (oxiran-2- ylmethoxy)benzyl]phenoxy }methyl)oxirane		Full, >1000
908-912-9	1333-16-0	2-[(2- hydroxyphenyl)methyl]phe nol; 2-[(4- hydroxyphenyl)methyl]phe nol; 4-[(4- hydroxyphenyl)methyl]phe nol	(1) (1) (1) (1) (1) (1) (1) (1) (1) (1)	Full, 1-10
941-357-0	-	Reaction mass of 2,2'- {methylenebis[(2,6- dimethyl-4,1- phenylene)oxymethylene]} dioxirane and 1,3-bis{4- [3,5-dimethyl-4-(oxiran-2- ylmethoxy)benzyl]-2,6- dimethylphenoxy}propan- 2-ol and 3,3'- {methylenebis[(2,6- dimethyl-4,1- phenylene)oxy]}bis(1-{4- [3,5-dimethyl-4-(oxiran-2- ylmethoxy)benzyl]-2,6- dimethylphenoxy}propan- 2-ol)	à da à da à da à da a da a da a da a da	Full, not (publicly) available
941-435-4	-	Reaction products of Bisphenol F and phenol with aniline and formaldehyde	Not (publicly) available	C&L notification

946-144-6	-	Reaction mass of 3-phenyl- 6-[(3-phenyl-3,4-dihydro- 2H-1,3-benzoxazin-8- yl)methyl]-3,4-dihydro-2H- 1,3-benzoxazine and 6,6'- methanediylbis(3-phenyl- 3,4-dihydro-2H-1,3- benzoxazine)	ante atta	Full, not (publicly) available
680-136-0	68492-67-1	2-METHYL -2-PROPENOIC ACID, POLYMER WITH (CHLOROM	Not (publicly) available	C&L notification

Subgroup: Miscellaneous bisphenols

EC/List number	CAS number	Substance name and substance name acronyms	Substance structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)
Bisphenol AP	P (BPAP) der	ivatives		
433-130-5	1571-75-1	1,1-bis(4-hydroxyphenyl)-1- phenylethane BPAP		NONS
811-683-7	1799707- 26-8	4,4'-(1-phenylethane-1,1- diyl)bis(heptyloxybenzene)		Full, not (publicly) available
Bisphenol B	(BPB) deriva	itives		
201-025-1	77-40-7	4,4'-(1- methylpropylidene)bisphenol; bisphenol B BPB	H ₃ C + CH ₃ OH	C&L notification
Bisphenol BP	P (BPBP) der	ivatives		
679-999-6	1844-01-5	4,4'- Dihydroxytetraphenylmethane BPBP		C&L notification

Bisphenol C2	2 (BPC2) deri	ivatives		
238-940-0	14868-03- 2	4,4'-(dichlorovinylidene)diphenol BPC2 (BPCl2)	CI C	C&L notification
945-909-1	69415-01- 6	Reaction mass of meso-2-{[4- (2-{4-[(oxiran-2- yl)methoxy]phenyl}-1,1- dichloroethylidene-2 yl)phenoxy]methyl}oxirane and 2RS)-2-({4-[2-(4-{[(2RS)- oxiran-2-yl]methoxy}phenyl)- 1,1-dichloroethylidene-2- yl]phenoxy}methyl)oxirane		Full, not (publicly) available
Bisphenol E	(BPE) deriva	tives		
627-637-2	2081-08-5	4,4'-Ethylidenebisphenol BPE	но ОН	C&L notification
405-740-1	47073-92- 7	4,4'-ethylidenediphenyl dicyanate	N=-O HaC	Full, not (publicly) available
Bisphenol FL	. (BPFL) deri	vatives		
404-470-1		EPIKOTE 1079		NONS
406-950-6	3236-71-3	9,9-bis(4- hydroxyphenyl)fluorene BPFL	HO	NONS
Bisphenol M	(BPM) deriva	atives	ÓН	
428-970-4	13595-25- 0	4,4'-(1,3-phenylene-bis(1- methylethylidene))bis-phenol BPM	H ₃ C H ₃ C CH ₃ CH ₃ C	NONS
944-616-6		Reaction products of 4,4'-(1,3- phenylene-bis(1- methylethylidene))bis-phenol and cyanogen bromide	UVCB	Full, not (publicly) available
Bisphenol P	(BPP) deriva	tives		
606-820-0	2167-51-3	4,4'-(1,4- Phenylenediisopropylidene)bisph enol BPP		C&L notification

Bisphenol TM	ІС (ВР-ТМС)	derivatives		
404-140-7		BISPHENOL TMC BP-TMC	HO HO HO HO HO HO HO HO HO HO HO HO HO H	NONS
Bisphenol Z	(BPZ) deriva	tives		
212-677-1	843-55-0	4,4'-cyclohexylidenebisphenol BPZ	HO	C&L notification
219-110-7	2362-14-3	4,4'-cyclohexylidenedi-o-cresol	HO H ₃ C CH ₃	Full, not (publicly) available
810-464-3	13446-84- 9	2,2'-[cyclohexane-1,1- diylbis(4,1- phenyleneoxymethylene)]dioxira ne	2008	Full, not (publicly) available

Subgroup: Bisphenol AF (BPAF) and BPAF derivatives

EC/List number	CAS number	Substance name and substance name acronyms	Substance structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)
216-036-7	1478-61- 1	4,4'-[2,2,2-trifluoro-1- (trifluoromethyl)ethylide ne]diphenol BPAF	HO F F F F F F F F F F F F F F F F F F F	Full, 10-100
278-305-5	75768- 65-9	benzyltriphenylphosphon ium, salt with 4,4'- [2,2,2-trifluoro-1- (trifluoromethyl)ethylide ne]bis[phenol] (1:1)		Full, 1-10
425-060-9		T-6627		NONS

443-330-4		COMPOUND 7518		NONS
468-740-0		Tributyl-2- methoxypropylphosphoni um salt with 4,4'-[2,2,2- trifluoro-1- (trifluoromethyl)ethylide ne]bis[phenol]	$(0) \longrightarrow \left(\begin{array}{c} 1 \\ 1 \\ 1 \\ 1 \\ 1 \\ 1 \\ 1 \\ 1 \\ 1 \\ 1 $	NONS
469-080-6		Not (publicly) available	HO-FFF FFFFFFFFFFFFFFFFFFFFFFFFFFFFFFFFF	NONS
479-100-5	577705- 90-9	benzyl(diethylamino)diph enylphosphonium 4- [1,1,1,3,3,3-hexafluoro- 2-(4- hydroxyphenyl)propan- 2-yl]phenolate	ja jo	Full, cease manufacture
943-265-6		Reaction mass of 4,4'- [2,2,2-trifluoro-1- (trifluoromethyl)ethylide ne]diphenol and benzyl(diethylamino)diph enylphosphonium 4- [1,1,1,3,3,3-hexafluoro- 2-(4- hydroxyphenyl)propan- 2-yl]phenolate (1:1)		Full, 10-100
947-368-7		Reaction mass of 4,4'- [2,2,2-trifluoro-1- (trifluoromethyl)ethylide ne]diphenol and benzyltriphenylphosphon ium, salt with 4,4'- [2,2,2-trifluoro-1- (trifluoromethyl)ethylide ne]bis[phenol] (1:1)		Full, 10-100

EC/List number	CAS number	Substance name and substance name acronyms	Substance structures	Registratio n type (full, OSII or TII, NONS), highest tonnage band among all the registration s (t/y)
201-618-5	85-60-9	6,6'-di-tert-butyl-4,4'- butylidenedi-m-cresol	CH_3 H_3C CH_3 HO CH_3 CH_3 CH_3 H_3C CH_3 H_3C CH_3 H_3C CH_3 CH_3 CH_3 H_3C CH_3 CH_3 CH_3 CH_3 CH_3 CH_3 CH_3 CH_3 CH_3 CH_3 CH_3 CH_3 $CH_$	Full, 100- 1000
210-039-7	603-41-8	p,p'-(2- pyridylmethylene)bisphenol	нотон	TII or OSII
217-420-7	1843-03-4	4,4',4''-(1-methylpropanyl-3- ylidene)tris[6-tert-butyl-m- cresol]	$H_{3}C \xrightarrow{(H_{3})} CH_{3} ($	Full, not (publicly) available
255-002-6	40615-36- 9	1,1'- (chlorophenylmethylene)bis[4- methoxybenzene]		Full, not (publicly) available
255-003-1	40615-39- 2	5'-O-(p,p'- dimethoxytrityl)thymidine	H ₃ C ^{-O} (CH ₃) (CH ₃)	Full, not (publicly) available
401-720-1		2,2-bis(4'-hydroxyphenyl)-4- methylpentane	H ₃ C CH ₃ CH ₃ CH ₃ OH	NONS

Subgroup: Other aliphatic or aryl bridged bisphenol derivatives

405-800-7	27955-94- 8	4,4',4''-(ethan-1,1,1- triyl)triphenol	OH H ₃ C OH OH	Full, not (publicly) available
433-980-7		CHEMICAL CODE NO 1592		NONS
610-104-3	43100-47- 6	5',5''''-(1,1,1-trifluoropropane- 2,2-diyl)bis(1,1':3',1''-terphenyl- 2'-ol)		Full, not (publicly) available
680-046-1	74462-02- 5	4,4'-(2-ethylhexane-1,1- diyl)diphenol	СН ₃ Но-СН ₃ -СН ₃ -СН ₃ -ОН	Full, not (publicly) available

This table contains also group members that are only notified under the CLP Regulation. However, the list is not necessarily exhaustive. Should further regulatory risk management action on one or more substances in the group be considered, ECHA may make an additional search for related C&L notified substances to be included in the group and develop an assessment of regulatory needs for them.

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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 purpose of the assessment of regulatory needs of a group of substances is to help authorities conclude on the most appropriate way to address the identified concerns for a group of substances or a single substance, i.e. the combination of the regulatory risk management instruments to be used and any intermediate steps, such as data generation, needed to initiate and introduce these regulatory measures.

An assessment of regulatory needs can conclude that regulatory risk management at EU level is required for a (group of) substance(s) (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. While the assessment is done for a group of substances, the (no) need for regulatory action can be identified for the whole group, a subgroup or for single substance(s).

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is voluntary, i.e., it is not part of the processes defined in the legislation but aims to support them.

The assessment of regulatory needs can be applied to any group of substances or single substance, i.e., any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, more extensive set of information can be available, e.g. assessment done under REACH/CLP or other EU legislation, or can be generated in some cases (e.g. further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult the ECHA website¹.

¹ <u>https://echa.europa.eu/understanding-assessment-regulatory-needs</u>

Glossary

ССН	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
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
UVCB	Substances of Unknown or Variable composition, Complex reaction products or Biological materials

1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of the "bisphenol" moiety shown in the figure in the beginning of the report. The group consists of 148 substances, including 17 "bisphenols" with the generic "bisphenol" structure, and "bisphenol derivatives" that have constituents with structural features common to bisphenols.

The substances were sub-grouped according to specific bisphenol types, defined by the nature of the bridge between the two phenol rings, see figure on page 1:

- BPA and BPA derivatives
- BPS and BPS derivatives
- BPF and BPF derivatives
- BPAF and BPAF derivatives
- Miscellaneous bisphenols: Heterogeneous subgroup with bisphenols and bisphenol derivatives addressed as one subgroup for practical reasons
- Other aliphatic or aryl bridged bisphenol derivatives: Heterogeneous subgroup addressed as one subgroup for practical reasons.

2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (tetrabromobisphenol A, TBBPA, EC 201-236-9) and TBBPA derivatives were excluded from the group due to their specific use as flame retardant and the information suggesting a possible distinct hazard profile.

The derivatives for each bisphenol type include as constituent(s) structures with the same bridge between the two phenyl rings as the specific bisphenol, e.g. BPA derivatives sharing the BPA bridge. The phenolic hydroxyl groups are on the para position to the bridge. The derivatives may have different substituents at the phenyl rings or may have the phenolic hydroxyls derivatised (hydrogens substituted, e.g. ether bonded groups (R-O-R')). The Molecular weights of the constituent structures was arbritarily set to bebelow 600.

For the bisphenols and their derivatives specifically, the main human health hazards are their potential endocrine disrupting properties, reproductive toxicity and skin sensitisation. In addition to these, many of the bisphenols have a concern for endocrine disrupting properties for the environment and for PBT/vPvB based on REACH Annex XIII screening criteria.

BPA has a harmonised classification as reproductive toxicant for fertility (Repr. 1B, H360F) and as skin sensitiser (Cat 1, H317). It is identified as a substance of very high concern (SVHC) and included in the Candidate List for reproductive toxicity and for endocrine disrupting properties (for human health and the environment)². BPA is also restricted under REACH for use in thermal paper (Annex XVII, entry 66). Exposure to BPA may also result in effects on the immune system, due to which the European Food Safety Authority (EFSA) recently proposed to lower the tolerable daily intake (TDI) of BPA to 0.04 nanograms per kilogram of body weight

² In the latest COM regulation amending Annex XIV (voted but not yet published in the OJ, https://op.auropa.au/op/publication_dotail/_/publication_(15f08b31_2c0f_11ac_bd8a_01ac75ad71a

https://op.europa.eu/en/publication-detail/-/publication/15f08b31-2c0f-11ec-bd8e-01aa75ed71a1/language-

en/format-HTML/source-search), the COM gives the following reason not to include BPA to Annex XIV (recital 17): "An Annex XV dossier is under preparation to restrict the use of Bisphenol A and structurally related bisphenols of similar concerns for the environment. That restriction is to cover the uses of Bisphenol A that would fall under the authorisation regime. It is therefore appropriate to postpone the inclusion of that substance in Annex XIV to Regulation (EC) 1907/2006.Regulation (EC) No 1907/2006 should therefore be amended accordingly."

per day (previously set at 4 μ g/kg body weight per day)³.

BPB is included on the Candidate list as SVHC for its endocrine disrupting properties for human health and the environment. Reproductive toxicity is confirmed and addressed by harmonised classification as Repr. 1B for EC 401-720-1. For BPS and BPAF and its salts, Repr. 1B has been confirmed by ECHA's Risk Assessment Committee (RAC) but this classification has not yet been included in the ATP of the CLP. EC 401-720-1 is also on the Candidate List as SVHC based on its reproductive toxicity. RMOAs have been conducted by France and Germany for BPA, France for BPB and EC 226-378-9, Sweden for BPF and EC 401-720-1, and an RMOA for BPS is currently under development by Belgium.

For most of the other group members, ED properties, reproductive potential and/or PBT/vPvB properties are still to be confirmed and for many data generation is ongoing, either via a compliance check (CCH), testing proposal (TPE) or substance evaluation (SEv). However, there are also around 30 bisphenols for which no further data can be generated to clarify their possible ED properties, reproductive toxicity and/or PBT/vPvB properties due to their registration status⁴.

Most of the BPA and BPF-derivatives (67 bisphenol derivatives) are skin sensitisers, 1/1A/1B based on harmonised or self-classification⁵. Some of these are also under investigation for ED or reproductive toxicity (11 substances), and/or for PBT/vPvB (5 substances).

Most of the substances (approximately 90) have a classification for aquatic toxicity. Nine substances have a harmonised classification for aquatic toxicity⁶. For BPA a harmonised classification as Aquatic Acute 1, M-factor=1, and Aquatic Chronic 1, M-factor=10 (based on the ED effects) has been agreed on by RAC in Oct 2020⁷.

Based on information reported in the REACH registration dossiers, the substances across the different sub-groups have several similar use profiles. Most substances are used as intermediates in the manufacture of polymers or polymer resins (with some specifying use in epoxy resins or polycarbonate). Generally, relatively low exposure potential of humans and the environment is expected from such uses when they occur at industrial sites. For professional uses, this exposure potential is generally expected to be higher. Other main uses indicated in the registration dossiers include use in thermal paper or photo-lithography, inks and coatings, adhesives and in textile, paper and board. Exposure of industrial and professional workers, consumers and the environment may be expected from these uses, and some bisphenols have been monitored in humans⁸. Similarities in uses and to some extent also in the technical functionality generally suggest a possibility for substitution across many of the different bisphenols and subgroups. One exception appears to be the subgroup of BPAF and its salts which have intermediate uses and

³ <u>https://www.efsa.europa.eu/en/topics/topic/bisphenol;</u> Link to the EFSA draft opinion that open for public consultation until February 2022:

https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0l1v00000E8BRD/pc0109

⁴ Most of these substances are registered below 10 t/y, as NONS, not registered (C&L notified only) or registered as intermediate under Art. 17/18.

⁵ 14/67 substances (BPA-derivatives) are not registered and have only notified classification

⁶Aquatic acute 1 and chronic 1: EC 433-130-5, 405-740-1, EC 406-950-6, EC 401-720-1. Aquatic chronic 2: EC 405-520-5, 411-570-9, 428-970-4, 405-800-7. Aquatic chronic 3; EC 405-790-4.

⁷ https://echa.europa.eu/documents/10162/54613cb3-b022-e58e-296f-37de7bf36e5d

⁸ https://www.hbm4eu.eu/hbm4eu-substances/bisphenols/

are used as vulcanising agent in fluorelastomers (synthetic rubber) and plastic in industrial settings with low exposure potential. However, exposure of humans and the environment during article service life is possible.

Note on the scope of ECHA's assessment of regulatory needs

Regarding hazards, the focus of ECHA's assessment is 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 table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (e.g. neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. Harmonised classification are presented in Annex 1.

On the exposure side, ECHA is mainly using the information on uses reported in the registration dossiers (IUCLID) as a proxy for assessing the potential for exposure to humans and releases to the environment. The potential for release / exposure is generally considered high for "widespread" uses, i.e. professional and consumer uses and uses in articles. For these uses, normally happening at many places, the expected level of control is *à priori* considered limited. The chemical safety reports are not necessarily consulted at the stages of assessment where the hazards are not yet clarified, and no quantitative exposure assessment is performed.

2 Justification for the need for regulatory risk management action at EU level

The main potential hazards for this group of 148 substances are ED for human health and the environment, reproductive toxicity and skin sensitisation, and for some also PBT/vPvB. Effects on the immune system could not be established for the group of bisphenols due to a general lack of information⁹. In this assessment of regulatory needs, a stepwise approach is proposed.

Based on the potential for widespread use and the information available on the potential endocrine disruptive, reproductive and PBT/vPvB properties, 34 substances were identified with a need for restriction (see section 2.1). Depending on the scope of the eventual restriction(s) put in place, authorisation could be further considered as complimentary measure, e.g. to avoid regrettable substitution and possibly regulate uses for which restriction was considered not the appropriate tool. Other bisphenols for which i) hazards are currently inconclusive with data generation to be started or ongoing (section 2.2), or ii) for which hazards cannot be clarified (section 2.4), may act as substitutes for those to be regulated. Regulatory risk management on these potential substitutes may follow the work on the first subgroup of bisphenols that are identified with a need for RRM already. 27 bisphenols are identified with skin sensitisation as most severe hazard for which discussion on possible generic restrictive measures is already ongoing (section 2.3).

⁹ With the exception of BPA, there is a general lack of information on possible immunotoxic effects of bisphenols and their potential for immunotoxicity is not expected to be further clarified via the compliance checks initiated. However, if new information is included in the registration dossiers, it will be followed up. At this point of time, this hazard is not further considered as a potential main hazard for the group (but should be considered for BPA specific).

There is currently only one substance (BPA-PO EC 500-097-4) for which effects were considered not severe enough by the evaluating Member State to trigger further regulatory action at the moment (section 2.3).

2.1 Restriction as last foreseen regulatory action

Based on the currently available information, there is a need for (further) EU regulatory risk management – Restriction for 34 bisphenols¹⁰ that are known or potential endocrine disruptors for the environment or for human health, or that can be identified as toxic for reproduction.

At the moment, the German Competent Authority on REACH is developing a proposal to restrict the emissions of BPA based on its endocrine disrupting properties in the environment¹¹. Also other bisphenols of similar ED ENV concern are to be included in the restriction. The restriction may address the use of these substances as such, in mixtures and in articles, and may cover the presence of these substances as constituent or impurity in other substances. Examples of materials/articles expected to be in scope are thermal paper, plastics, textiles, leather and fur.

BPAF and its eight salts furthermore meet the OECD definition of being PFAS (Perand PolyFluoroAlkyl Substances)¹² and may thereby also be in scope of the universal PFAS restriction that is currently under development.

Pending the eventual scope of the German proposal for restricting bisphenols, and the scope of the PFAS restriction, further restriction of uses to protect workers and consumers against endocrine effects and toxic effects on reproduction may be considered, should any EU wide risks for human health remain. This further consideration of regulatory needs should then also reflect on e.g. intermediate uses and reconsider authorisation as a possible option for regulating uses that are not in scope of the proposed restriction. For BPA, assessment of further regulatory needs should also consider possible risks arising due to immunotoxic effects in a substance specific manner. **ECHA proposes to consider any further need for regulatory action on bisphenols once further clarity is obtained on the scope of the German proposal and the universal PFAS restriction** (see draft Restriction Roadmap¹³).

¹³ CARACAL 42, 17-18 November 2021, AP_8

¹⁰ EC/List No. 201-245-8 (BPA), 201-025-1 (BPB), 401-720-1 (4,4'-Isobutylethylidenediphenol), 216-036-7 (BPAF) and its 8 salts (278-305-5; 425-060-9; 443-330-4; 468-740-0; 469-080-6; 479-100-5; 943-265-6; 947-368-7), 201-250-5 (BPS), 201-240-0 (BPC), 204-279-1 (TBMD), 201-618-5 (6,6'-di-tert-butyl-4,4'-butylidenedi-mcresol), 242-895-2, 248-607-1, 405-520-5 (D8), 217-121-1 (DAB), 227-033-5 (TMBPA), 210-658-2 (BPF), 411-570-9, 277-962-5 (contains BPS, 500-086-4 (contains BPA), 500-263-6 (contains BPA), 500-607-5 (contains BPA), 701-362-9, 904-653-0 (contains BPA), 908-912-9 (contains BPF), 926-571-4 (contains BPA), 931-252-8 (contains BPA), 941-992-3 (contains BPS), 943-503-9 (contains BPA).

¹¹ <u>https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1853413ea</u>

¹² Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance; Series on Risk Management No.61. ENV/CBC/MONO(2021)25 https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/CBC/MONO(2021)25&docLangu age=En

https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp?FormPrincipal: idcl=FormPrincipal: id 1&FormPrincipal_SUBMIT=1&id=5a4771e2-6e46-44de-bff4-

¹⁷⁸c035d2c5d&javax.faces.ViewState=A3sZ4bdgS3K72mWq7ozQX6cKIpe5ALOTrCxpEJKQ52EX8S0A7y1Qz %2BmvDosnOePjPu6h4Hk8krbKfXtkVMTL3g%2B0vGD1wP4191FYT8W%2FxFLHlfDcIUcEP7rA8w%2Bmr Nf4Q%2B4Q8nrXES8yVDHfhGWiIdiM7NE%3D; https://echa.europa.eu/hot-topics/chemicals-strategy-for-

2.1.1 Hazard confirmation as a first step towards restriction

ECHA considers that hazard confirmation via either SVHC identification to confirm ED ENV/HH or Harmonised classification and labelling for Repr. 1B to facilitate further regulatory management actions is a preferable first step before a restriction

Bisphenols classified as Repr. 1B will be restricted for use in consumer mixtures through the generic entry 30 in Annex XVII, and risk management measures at the workplace will be triggered through OSH (Directive 98/24/EC, 92/85/EEC and 94/33/EC) to protect industrial and professional workers (including also pregnant and young workers). Also, use in textiles, leather and fur may be restricted for Repr. 1B harmonised classified bisphenols via entry 72 (this would require addition of the relevant substances to Appendix 12 by the Commission through Article 68(2)). Several possible future restrictions proposed in the Restrictions Roadmap may further affect the uses of bisphenols. One is the use in thermal paper, which may be further restricted by expanding the already existing restriction on BPA in thermal paper to include bisphenols that may be used as BPA alternatives and that have ED HH or Repr. 1B properties. Another possible one may be the proposed idea to restrict CMRs in childcare articles.

2.1.1.1 Substances for which hazards are already confirmed

Three substances, BPA (EC 201-245-8), BPB (EC 201-025-1) and 4,4'-Isobutylethylidenediphenol (EC 401-720-1), are already identified as substances of very high concern (SVHC); BPA for reproductive toxicity and for endocrine disrupting properties (HH and ENV), BPB for endocrine disrupting properties (HH and ENV), and EC 401-720-1 for reproductive toxicity. BPA and EC 401-720-1 also have a harmonised classification as reproductive toxicant (Repr. 1B).

2.1.1.2 Substances for which sufficient information may be available to confirm hazards

For **BPAF** (EC 216-036-7) **and its eight salts** (EC/List. 278-305-5; 425-060-9; 443-330-4; 468-740-0; 469-080-6; 479-100-5; 943-265-6; 947-368-7) the information available on BPAF may be sufficient to identify ED ENV/HH properties for all these 9 substances. Identification as SVHC for ED for human health and the environment has not yet been initiated.

Harmonised classification for Repr. 1B has been agreed on by RAC in 2021 for BPAF and several of its salts (EC/List 216-036-7, 278-305-5, 479-100-5, 947-368-7, and 943-265-6¹⁴), but not yet for all. For the remaining salts of BPAF, two of them could be self-classified as Repr. 1B already based on the RAC opinion. For EC 425-060-9 (sodium salt of BPAF) and EC 469-080-6 (UVCB with BPAF as an organic counter ion) where BPAF may be released via dissociation, the RAC opinion would not necessarily trigger self-classification and harmonised classification would be required still to confirm Repro 1B. A proposal for harmonised classification needs to be submitted to initiate this process.

For **BPS** (EC 201-250-5), the assessment of data generated though SEv is ongoing. During its 19th meeting, the ED Expert Group expressed the opinion that 'there is sufficient evidence to conclude that the substance acts as ED for human health,

 $[\]frac{sustainability, and https://echa.europa.eu/documents/10162/1459379/Restrictions+Roadmap+++ECHA+input.pdf/5b460553-1401-9b90-2e3d-662587dae77b?t=1639047513926}{}$

¹⁴ <u>https://echa.europa.eu/documents/10162/d4b588a0-d1e2-9978-a65b-3ebe209d16fa</u>

and that the observed hazards (estrogenic mode of action linked to reduced fertility) are also population relevant for mammalian wildlife thus supporting identification as ED for environment. Based on this assessment of the ED Expert Group, SVHC identification could be considered as the next step. A Repr. 1B hazard has already be confirmed for BPS by RAC (though this is not yet included in the ATP of CLP). For **BPF** (EC 210-658-2), in vitro and in vivo data indicates potential ED properties which need to be further investigated to be confirmed. As a followup of their RMOA, Sweden is currently exploring the possibilities to read-across information from other bisphenols, like BPA, to inform on possible hazards of BPF. Since BPF is not registered, possibilities for further data generation are limited. List No 908-912-9 contains BPF as a constituent and shows effects on the thyroid that could be ED mediated. Substance evaluation on this substance may therefore potentially inform also on BPF (unless other constituents are the hazard driver). However, as this substance is registered at Annex VII for intermediate use in the production of polymers or other chemicals, Substance Evaluation is not proposed at the moment.

List no 701-362-9 is used in dental sealants and is self-classified as Repr. 2, however the information available in the registration dossier suggests that classification as Repr. 1B may be warranted. Harmonising the classification as Repr. 1B would trigger further risk management for workers under the Occupational Safety and Health Directive and for consumers under the Directive for Medical Devices (EU) 2017/745. Possible exposure of consumers via uses in adhesives will be addressed through the generic restriction on mixtures, Annex XVII entry 30.

2.1.1.3 Substances for which further data generation may be required to confirm hazards

Several substances have positive *in vitro* and/or *in vivo* data suggesting ED properties for ENV and HH. However, further data generation may be required (via CCH or SEv) to allow their confirmation as ED ENV/HH and/or reproductive toxicant. Substance Evaluation is already on-going for **BPC** (EC 201-240-0) and **6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol** (EC 201-618-5). Data generation through CCH has been initiated for **TBMD** (EC 204-279-1) and **D8** (EC 405-520-5) **D8** is on the CoRAP and is planned for evaluation in 2023.

Substance Evaluation is furthermore proposed to clarify the ED and reproductive toxicity concern for DAB (EC 217-121-1), TMBPA (EC 227-033-5), EC 242-895-2, EC 248-607-1and EC 411-570-9.

Structural similarity to BPA for EC 242-895-2 and 248-607-1 raises concern for possible ED and reproductive toxic properties, and for possible regrettable substitution. Substance evaluation is suggested to clarify this concern. Clarifying the hazard is also considered necessary because of the possibility that these substances may substitute List 701-362-9 (all three registered for use in dental sealants) as soon as the latter would be regulated (see section 2.1.1.2).

TBMD (EC 204-279-1) and 6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol (EC 201-618-5) have an additional concern for PBT/vPvB which is being clarified in already ongoing SEv processes. In both cases, the German restriction proposal under development may already sufficiently address concerns for these substances when their ED ENV properties get confirmed. Pending the SEv conclusion, we therefore propose to only consider any further need for regulatory measures once further clarity is obtained on the scope of the German proposal for a restriction.

2.1.2 Substances containing BPA, BPF or BPS

An additional ten substances likely contain BPA, BPF or BPS in concentrations that could warrant SVHC identification as ED or classification as reproductive toxicant. All are registered as UVCBs or multi-constituents. We propose that inclusion of these substances in the restriction under development by Germany is considered based on their BPA, BPF or BPS presence, once confirmed. Since hazard confirmation is already in place for BPA and is ongoing for BPS and BPF, hazard confirmation prior to restriction of substances containing these may not be necessary.

These substances have intermediate uses in the production of polymers, polymer resins or plastics. **EC/List 500-086-4**, **500-263-6**, **500-607-5**, **904-653-0**, and **941-992-3** are only registered for use at industrial sites with low exposure potential. For the others, potential for exposure may be higher due to professional uses and because consumer exposure may be anticipated via article service life. Of these, **EC 277-962-5** is registered for use in textiles and may therefore (also) be addressed under the restriction(s) for textile articles (i.e. entry 72 for CMR substances or the restriction under development on skin sensitisers in textile articles the basis of its skin sensitising properties¹⁵ (see also section 2.3.1).

2.2 No hypothesis yet – data generation

Based on currently available information, it is not possible to assess the need for regulatory risk management as information on hazard is not sufficient to conclude on mutagenicity, reproductive toxicity, ED, skin sensitiser, STOT RE, PBT/vPvB and/or aquatic toxicity hazards of 22 substances in the group.

Hazards are inconclusive for EC/List 212-985-6 (BPA-2EO), 219-110-7, 226-378-9, 253-781-7, 405-800-7, 425-220-8 (BPA-DP), 500-082-2, 609-946-4, 610-104-3 and 811-683-7. Hazards for ED and/or reproductive toxic properties are also inconclusive for another 12 substances that are already classified as skin sensitiser. This concerns EC/List 204-137-9, 701-404-6, 701-406-7, 500-130-2, 701-308-4, and 701-359-2. EC/List 217-420-7, 701-407-2, 500-240-0, 701-405-1, 701-373-9, and 947-794-3 have additionally a PBT concern. Regulatory measures are already being discussed/under development to address concerns for skin sensitisation in mixtures and textile articles (see section 2.3.1).

Data generation (i.e. through compliance checks or testing proposals by the registrant(s)) is ongoing to further inform on these properties. Until results become available it is not possible to conclude on a need for further EU regulatory risk management for ED, reproductive toxicity and/or PBT/vPvB. We propose that these substances follow the regulatory actions described above should their ED ENV/HH, PBT/vPvB, and/or reproductive toxic properties get confirmed. Clarifying these possible hazards might require Substance Evaluation before any further regulatory action is initiated. Immediate next steps for these substances may therefore only be concluded once results from ongoing data generation will become available.

Exposure of humans (consumers, and/or professionals and/or industrial workers) and/or the environment may be expected for most of the substances due to uses in e.g. polymers and polymer preparations, inks, coatings, adhesives and sealants, and thermal paper.

¹⁵ <u>https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e182446136</u>

2.3 Currently no need for (further) EU regulatory risk management

Based on currently available information, there is no need for (further) EU regulatory risk management for substances with a skin sensitiser hazard (and no ED or reproductive toxicity or other hazards) because regulatory action is already being considered.

2.3.1 Skin sensitisers

Twenty-six (26) bisphenols have skin sensitisation as the most important hazard to consider for a possible need for EU RRM. Most of them are already indicated as Skin sensitiser 1/1A/1B via a harmonised, self-, or notified classification. Among these is BADGE (EC 216-823-5), for which SEv was concluded without confirming ED properties, but at the same time leaving residual concern for ED.

For 2out of the 26 substances generation of data is needed to clarify the skin sensitisation properties (i.e. EC/List 945-909-1 and 810-464-3,).

The majority of the bisphenols only with skin sensitising properties are only used by industrial or professional workers, and limited consumer exposure is expected. For industrial and professional uses, sufficient and consistent self-classification as applied by the registrants should trigger adequate risk management measures according to workplace legislation. Adequate product labelling should in principle provide consumers with sufficient information to manage risks arising from the use of mixtures. However, there is a concern related to skin sensitisers (potentially) present in consumer mixtures and the need to further investigate whether further regulatory actions are needed and what would be the best options to address such concern. Four (4) of the 25 bisphenols with skin sensitising properties are registered for use in mixtures by consumers e.g. in paints, coatings, inks, adhesives and/or lubricants (i.e. EC/List 216-823-5 (BADGE), 614-657-1, 701-263-0 and 810-464-3).

The concern of consumer exposure to skin sensitisers in mixtures has already been identified in other groups of substances and was brought for further discussion to Member States. Work is ongoing on this generic issue by both Member States and ECHA and may affect the regulatory actions on substances in this group. Pending the outcome of the current data generation and the ongoing work on restricting skin sensitisers in mixtures for consumer use, no further action is proposed for these bisphenols at this moment in time¹⁶.

2.3.2 Substances for which hazards are concluded not severe enough

BPA-PO (EC 500-097-4) is registered for use in inks and toners and has been under Substance Evaluation because of suspected ED properties. The SEV was recently concluded. Effects were concluded as being ambiguous without a clear adversity and were considered not severe enough by the evaluating Member State to trigger

¹⁶ BPF (EC 210-658-2) may also be used in textile and leather, for which a targeted restriction (skin sensitiser use in textile and leather articles) is under development. A harmonised classification for Skin Sens would be needed to include BPF in this restriction. However, since it is expected that BPF will already be restricted based on its ED ENV/HH and/or Repro properties both in mixtures and in articles, pursuing harmonised classification of Skin Sensitisation (in the presence of the available notified classification) is considered not of priority for now. It may however be included also when CLH for reproductive toxicity is proposed.

further regulatory risk management measures at present. Hence, currently there is no need for further action.

2.4 No hypothesis and no possibility to generate data

Based on currently available information, it is not possible to assess the need for regulatory risk management as information on hazard is not sufficient to conclude on reproductive toxicity, ED properties, skin sensitisation and PBT/vPvB for 65 bisphenols and information relevant to these properties cannot be generated. Data that is currently being generated on other bisphenols may inform on a possible need for further regulatory action. However, differences in, for example, structure and functional groups reactivity may impact the feasibility of any future readacross approaches.

These substances have either a full registration at Annex VII, are inquiries on possible future registrations, are inactive registrations, are NONS without tonnage upgrades, or substances with no registration. Only few are registered >10t/y. Approximately half of the substances are inconclusive for reproductive toxic and ED properties, and about a third is inconclusive for PBT/vPvB. EC 210-039-7 is registered as an intermediate under Art. 17/18. Their registration status prevents further data generation under Dossier Evaluation. Also, data generation through Substance Evaluation is likely challenging due to a general lack of any close structural relation to other bisphenols to justify concern and their either low tonnages and/or low exposure potential¹⁷. However, for few, the potential for exposure may be higher due to registered professional, consumer uses or possible exposure during article service life. This may be the case for EC 432-380-2, 433-130-5 (BPAP)¹⁸, 434-000-0 and "EC/List no 4". For group members that are not registered and only have one or more C&L notifications under CLP or have a PPORD notification there is no hazard information available.

For BPZ (EC 212-677-1) and BP-TMC (EC 404-140-7) there is data available to identify a potential for reproductive toxicity and ED properties. For BPZ, there is *in vitro* information on possible ED properties, and for BP-TMC there is information from a 28d repeated dose toxicity screening study. In both cases it is not possible to follow-up on these concerns.

3 Conclusions and actions

The conclusions and actions proposed in the table below are based on the REACH and CLP information available at the time of the assessment by ECHA. 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 will be updated and conclusions and actions revisited.

¹⁷ Based on the information available on the uses, potential for exposure is expected be limited for most due to the low registered tonnages, intermediate uses and/or uses only at industrial sites.

¹⁸ A potential for ED properties has been identified (in vitro data) but may not be possible to follow up on due to the absence of widespread uses as a consequence of its low tonnage band.

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	· · · · · · · · · · · · · · · · · · ·	st foreseen tion	Action		
Section 2.1: Bisphenols for wh	Section 2.1: Bisphenols for which further EU RRM is proposed – restriction						
201-025-1 (BPB)	Known or	Known or potential	Widespread use with	Need for EU	CLH ongoing for BPS, TBMD		
201-240-0 (BPC)	potential hazard	hazard for ED	possibility for exposure of workers (professional	RRM: Restriction	(204-279-1), 405-520-5 (D8; CORAP 2023) and BPAF and		
201-245-8 (BPA)	for reproductive	all substances Known or potential	and industrial), consumers and/or the	Justification:	its salts (i.e. 216-036-7, 278- 305-5, 479-100-5, 947-368-		
201-250-5 (BPS)	toxicity and/or ED:	hazard for PBT/vPvB: EC/List 204-279-1,	environment for many of the substances, except	Emissions of bisphenols	7, and 943-265-6). RAC opinions published		
201-618-5	all	201-618-5.	for EC/List 201-025-1,	with ED ENV			
204-279-1 (TBMD)	substances	Known or potential	217-121-1, 278-305-5, 425-060-9, 469-080-6,	properties may lead to	Substance evaluation ongoing to clarify ED and/or Repr.		
210-658-2 (BPF)		hazard for aquatic toxicity:	479-100-5, 500-086-4, 500-263-6, 500-607-5,	risks to the environment.	properties for BPS, BPC, TMBA, 201-618-5		
216-036-7 (BPAF)		201-025-1, 201-250-5,	904-653-0, 926-571-4,	Exposure to			
217-121-1 (DAB)		201-240-0, 201-245-8, 201-618-5, 204-279-1,	931-252-8, 941-992-3, that are used as	bisphenols with ED HH	Substance evaluation ongoing to clarify PBT/vPvB for 204-		
227-033-5 (TMBPA)		210-658-2, 216-036-7, 217-121-1, 227-033-5,	intermediates at industrial sites only.	and/or Repr. properties	279-1, 201-685-5		
242-895-2		248-607-1, 278-305-5, 401-720-1, 411-570-9,	Use in dental sealants	may lead to risks of	First steps prior to restriction:		
248-607-1		425-060-9, 443-330-4,	and adhesives with	workers and			
277-962-5		468-740-0, 469-080-6, 479-100-5, 500-607-5,	possibility for exposure of professional workers	consumers.	CLH for BPAF salts (i.e. 425- 060-9, 469-080-6) and 701-		
278-305-5 (BPAF-salt)		701-362-9, 931-252-8, 943-265-6, 943-503-9,	and consumers for 242- 895-2, 248-607-1 and	Restriction of emissions to	362-9		
401-720-1 (4,4'-		947-368-7	701-362-9.	the	ED assessment and Candidate		
Isobutylethylidenediphenol)				environment of bisphenols	listing when hazards confirm for BPAF and its 8 salts and		
				with ED ENV	for BPF, BPS, TBMD, EC 201-		

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
405-520-5 (D8) 411-570-9 (TG-SA) 425-060-9 (BPAF-salt) 443-330-4 (BPAF-salt) 468-740-0 (BPAF-salt) 469-080-6 (BPAF-salt) 479-100-5 (BPAF-salt) 500-086-4 500-263-6 500-607-5 701-362-9 904-653-0 908-912-9 926-571-4				properties is under consideration by the German Competent Authority. Depending on the scope and level of protection of the German restriction proposal, and depending on the scope of the PFAS restriction possibly affecting uses of BPAF and its salts,	618-5 and D-8 (in CoRAP for evaluation in 2023) Substance evaluation to clarify ED and Repr. properties for DAB, TMBPA, 242-895-2, 248-607-1 and EC 411-570-9 (followed by CLH and/or Candidate listing when hazards confirm) Next steps: Restriction for all substances with ED ENV properties and or ED HH or Repr. 1B properties SVHC identification for PBT/vPvB for EC 204-279-1 and 201-618-5 to be considered once restriction based on ED ENV becomes clearer.
931-252-8 941-992-3				further regulatory action could be	
941-992-3 943-265-6 (BPAF-salt)				considered, such as a restriction	

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action		
943-503-9				for human			
947-368-7 (BPAF-salt)				health based on ED HH/Repr. and/or an extension of the BPA restriction in thermal paper to other bisphenols. For EC/List 204-279-1, 201-618-5 a restriction based on PBT/vPvB could be considered.			
Section 2.2: No hypothesis yet but data generation ongoing							
204-137-9	Inconclusive hazard	Known or potential hazard	Widespread use with	No hypothesis	CCH/TPE ongoing to inform on inconclusive hazards for		
212-985-6 (BPA-2EO)	for	for aquatic toxicity:	possibility for exposure of workers	yet	204-137-9, BPA-2EO, 217-		
217-420-7	reproductive toxicity and	204-137-9, 219-110-7, 226-378-9, 253-781-7,	(professional and industrial),		420-7, 219-110-7, 226-378- 9, 253-781-7, 405-800-7,		
219-110-7	ED: all substances	405-800-7, 701-404-6, 500-082-2, 701-407-2	consumers and/or the environment for		BPA-DP, 701-404-6, 500-082- 2, 701-407-2, 701-406-7,		
226-378-9		701-406-7, 500-130-2, 500-240-0, 701-405-1,	many of the substances, except		500-240-0, 500-130-2, 701- 405-1, 609-946-4, 610-104-		

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
253-781-7	Known or	500-263-6, 610-104-3,	for EC/List 204-137-		3, 701-373-9, 701-308-4,
405-800-7	potential hazard	701-373-9, 811-683-7, 904-653-0, 947-368-7,	9, 212-985-6, 219- 110-7, 226-378-9,		701-359-2, 811-683-7, and 947-794-3. Further
425-220-8 (BPA-DP)	for skin sensitisation:		253-781-7, 610-104- 3, 701-373-9, 811-		actions to be considered once results suggest ED,
701-404-6	204-137-9, 217-420-7,	Inconclusive hazard for	683-7, 947-794-3 that are used as		reproductive toxic and/or PBT/vPvB properties.
500-082-2	701-404-6, 701-407-2,	PBT/vPvB: EC/List 217-420-7, 226-378-9,	intermediates at industrial sites only		
701-407-2	701-406-7,	701-407-2, 500-240-0,	industrial sites only		
701-406-7	500-130-2, 500-240-0,	701-405-1, 610-104-3, 701-373-9, 811-683-7			
500-130-2	701-405-1, 701-373-9,				
500-240-0	701-308-4,				
701-405-1	701-359-2, 947-794-3				
609-946-4					
610-104-3					
701-373-9					
701-308-4					
701-359-2					
811-683-7					
947-794-3					
Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
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Section 2.3: Currently no need	for (further) I	EU regulatory risk mana	gement		
214-590-4	Known or	Known or potential	Most are used by	Currently no	No action needed for now
216-823-5	potential hazard	hazard for aquatic toxicity: EC	industrial or professional workers	need for EU RRM for this endpoint	
235-985-8	for skin sensitisation	List 214-590-4, 216- 823-5, 255-002-6,	in the preparation of polymers, polymer		CCH ongoing for 945-909-1 and 810-464-3 to clarify skin
255-002-6	except for BPA-PO	255-003-1, 405-790-4, 428-970-4, 439-910-1,	resins and plastics, in paints, coatings,	Justification: All substances	sensitising properties
255-003-1		460-230-6, 500-097-4,	inks, in adhesives	are indicated as	
405-790-4	No hazard or unlikely	500-180-5, 500-181-0, 500-268-3, 609-946-4,	and in lubricants. Few are also used in	skin sensitiser 1/1B/1A, either	
428-970-4	hazard for BPA-PO	614-657-1, 680-046-1, 701-263-0, 810-464-3.	consumer mixtures with a potential for	by classification or C&L	
439-910-1		941-183-5, 945-830-2,	consumer exposure.	notification. Self-	
460-230-6		945-909-1, 947-250-5, 947-984-6, 948-520-5		classification is thought sufficient to facilitate safe	
500-090-6		Inconclusive hazard for		work for	
500-097-4 (BPA-PO)		PBT/vPvB: EC/List, 609-946-4		industrial and professional	
500-180-5				workers. Work is	
500-181-0				ongoing to protect	
500-268-3				consumers by restricting skin	
614-657-1				sensitisers in mixtures for	
680-046-1				consumer use.	

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
701-263-0				Pending this ongoing work,	
810-464-3				we see no need	
941-183-5				to propose further EU RRM	
941-357-0				for now.	
944-616-6					
945-830-2					
945-909-1					
947-250-5					
947-984-6					
948-520-5					
Section 2.4: No hypothesis yet established- no data generatio			Bisphenols for which	the need for furth	er EU RRM cannot be
210-039-7	Inconclusive hazard	Known or potential hazard	Low exposure potential expected	Currently no need for EU RRM	No action
212-677-1 (BPZ)	for	for aquatic toxicity:	for most of the		
216-367-7	reproductive toxicity and	212-677-1, 216-367-7, 218-257-4, 223-123-3,	substances because of their low	Justification: The information	
218-257-4	ED	404-140-7, 404-470-1, 405-740-1, 427-620-8,	registered tonnage, use at industrial sites	available does not allow to	
223-123-3	Known or	432-380-2, 433-130-5,	only, use as	identify nor to	
225-144-3	potential hazard for	500-072-8, 500-103-5, 500-104-0, 500-253-1,	intermediate, or because the	conclude on the absence of an ED	

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
235-986-3	skin	500-655-7, 605-913-3,	substances are only	or Repr. hazard,	
238-940-0	sensitisation: 216-367-7	607-500-3, 607-535-4, 607-537-5, 608-164-0,	C&L notified. Few substances may	and does not allow generation	
246-263-7	218-257-4 223-123-3	613-584-2, 620-316-8, 632-557-6, 679-999-6,	have higher exposure potentials	of further information to	
263-920-3	225-144-3 246-263-7	680-511-9, 680-791-2, 700-487-6, 941-435-4,	due to their registered use in	inform on a possible need for	
404-140-7 (BP-TMC)	500-072-8 500-103-5	946-322-3	thermal paper, inks and toners or in	regulatory action.	
404-470-1	500-103-5		photo lithography.	action.	
405-740-1	500-253-1 500-770-2				
406-950-6	607-500-3				
432-380-2	607-535-4 607-537-5				
432-740-9	608-164-0 609-663-6				
427-620-8 (D90)	613-584-2 614-177-2				
433-130-5	615-255-6				
433-980-7	620-316-8 632-557-6				
434-000-0	641-007-4 678-197-3				
434-010-5	680-511-9 700-487-6				
479-880-7 (BPA-MAE)	800-098-2				
500-033-5	806-676-0				

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
500-072-8					
500-089-0					
500-103-5					
500-104-0					
500-253-1					
500-655-7					
500-770-2					
605-281-9					
605-913-3					
606-820-0					
607-500-3					
607-501-9					
607-535-4					
607-537-5					
608-164-0					
609-251-6					
609-402-6					

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
609-663-6					
613-584-2					
614-177-2					
614-207-4					
614-255-6					
620-316-8					
627-637-2					
632-557-6					
641-007-4					
678-196-8					
678-197-3					
679-999-6					
680-136-0					
680-511-9					
680-791-2					
686-711-2					
EC/List no 4					

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
700-487-6					
800-098-2					
806-676-0					
EC/List no 1					
941-435-4					
946-144-6					
946-322-3					
EC/List no 2					
EC/List no 3					

Annex 1: Harmonised classifications

The table lists the bisphenols with harmonized classification adopted (included in Annex VI to the CLP Regulation) or with an opinion for classification agreed by RAC (information up to date until 26/11/2021). For self-classifications in the registration dossier or C&L notifications please consult ECHA's website at this link: https://echa.europa.eu/regulations/clp/cl-inventory

EC/List number	Substance name	Harmonised classification
201-245-8	(BPA)	Eye damage 1 H318 Skin Sens 1 H317 Repr 1B H360F STOT SE 3 H335
		RAC opinion adopted for classification as Aquatic Acute 1, H400 Aquatic Acute 1, M-factor=1 Aquatic Chronic 1, H410 Aquatic Chronic 1, M-factor=10
216-823-5	2,2'-[(1-methylethylidene)bis(4,1- phenyleneoxymethylene)]bisoxirane (BADGE)	Skin Irrit 2 H315 Eye Irrit 2 H319 Skin Sens 1 H317
201-250-5	4,4'-sulphonyldiphenol (BPS)	RAC opinion adopted for classification as Repr. 1B H360FD
405-520-5	4-(4- isopropoxyphenylsulfonyl)phenol	Aquatic chronic 2 H411
411-570-9	2,2'-diallyl-4,4'-sulfonyldiphenol	Skin Sens. 1 H317 Aquatic Chronic 2 H411
405-790-4	4,4'-methylenebis(2,6- dimethylphenyl cyanate)	Skin Sens. 1 H317 Aquatic Chronic 3 H412
433-130-5	1,1-bis(4-hydroxyphenyl)-1- phenylethane	Aquatic Acute 1 H400 Aquatic Chronic 1 H410
405-740-1	4,4'-ethylidenediphenyl dicyanate	Acute Tox 4 H302 Eye Dam 1 H318 Acute Tox 4 H332 STOT RE 2 H373** Aquatic Acute 1 H400 Aquatic Chronic 1 H410
406-950-6	9,9-bis(4-hydroxyphenyl)fluorene	Skin Irrit 2 H315 Eye Irrit 2 H319 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
428-970-4	4,4'-(1,3-phenylene-bis(1- methylethylidene))bis-phenol	Skin Sens 1 H317 Aquatic Chronic 2 H411 Repr. 2 H361f
216-036-7, 278- 305-5, 479-100- 5, 947-368-7, and 943-265-6.	4,4'-[2,2,2-trifluoro-1- (trifluoromethyl)ethylidene]diphenol (BPAF) and its salts	RAC opinion adopted for classification as Repr. 1B, H360F
401-720-1	2,2-bis(4'-hydroxyphenyl)-4- methylpentane	Eye Irrit 2 H319 Aquatic Acute 1 H400 Aquatic Chronic 1 H410 Repr 1B H360F
405-800-7	4,4',4"-(ethan-1,1,1-triyl)triphenol	Aquatic chronic 2 H411

Annex 2: Overview of uses based on information available in registration dossiers (information ranges from 2020 - 2021)

Information on uses has been collected at the time that the respective bisphenol subgroups were assessed and has not been reviewed since:

- BPA and BPA derivatives: 15 Jan 2020
- BPS and BPS derivatives: 16 March 2020
- BPF and BPF derivatives: 08 May 2020
- BPAF and BPAF derivatives: 08 Oct 2020
- Miscellaneous bisphenols: 02 July 2020
- Other aliphatic or aryl bridged bisphenol derivatives: 09 Oct 2020

The overview of main uses is given in the tables below. This overview is structured along the regulatory actions proposed and not according to the respective bisphenol subgroups.

Overview of main uses

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

Table 9a: Need for EU regulatory risk management - Restriction

sub-group	EC/List number	acronyms	(Intermediate in) the manufacture of polymers, polymer resins, epoxy resins	Inks and toners	Flame retardant polymer articles	Anti-oxidant for processing pvc	Epoxy resin hardeners	Thermal paper	Polycarbonate articles	Paints and coatings	Adhesives and sealants	Lubricant and greases/functional fluids	ctrical/electronic engineering ceramic boards	Washing and cleaning	Textile, Leather Paper and board	Perfume and fragrance	Plant protection products	Fuel Additive	Rubber products	Dental sealant	Rigid foam
Bisphenol B (BPB)	201-025-1	BPB			Fla	A						Гир	Ele		Te						
derivatives BPA derivatives	201-240-0	BPC	F, I			F, I, P,	F, I, P, A	I, P, A													
BPA derivatives	201-245-8	BPA	F, I			F, I, P, A	F, I, P, A	F, P, A	I, P, A												
BPS derivatives	201-250-5	BPS	I					F, I, A							I, P, A						

sub-group	EC/List number	acronyms	(Intermediate in) the manufacture of polymers, polymer resins, epoxy resins	Inks and toners	Flame retardant polymer articles	Anti-oxidant for processing pvc	Epoxy resin hardeners	Thermal paper	Polycarbonate articles	Paints and coatings	Adhesives and sealants	Lubricant and greases/functional fluids	Electrical/electronic engineering ceramic boards	Washing and cleaning	Textile, Leather Paper and board	Perfume and fragrance	Plant protection products	Fuel Additive	Rubber products	Dental sealant	Rigid foam
Other aliphatic aryl bridged bisphenols	201-618-5		F, A	I, P, C, A						I, P, C, A	F, I, P, C,		F, I, P, C, A								
BPF derivatives	204-279-1	TBMD								F, I, P, C		F, I, P, C, A		F, I, P, C		F	F, I				
BPF derivatives	210-658-2	BPF	I, P, C, A							F, I, P, C, A					F, P, C, A						
BPAF derivatives	216-036-7	BPAF	F, I, A																F, I, A		
BPA derivatives	217-121-1	DAB	F, I																		

sub-group	EC/List number	acronyms	(Intermediate in) the manufacture of polymers, polymer resins, epoxy resins	Inks and toners	Flame retardant polymer articles	Anti-oxidant for processing pvc	Epoxy resin hardeners	Thermal paper	Polycarbonate articles	Paints and coatings	Adhesives and sealants	Lubricant and greases/functional fluids	Electrical/electronic engineering ceramic boards	Washing and cleaning	Textile, Leather Paper and board	Perfume and fragrance	Plant protection products	Fuel Additive	Rubber products	Dental sealant	Rigid foam
BPA derivatives	227-033-5	ТМВРА	I, A		(?)																
BPA derivatives	242-895-2																			F, P, A	
BPA derivatives	248-607-1																			F, P, A	
BPS derivatives	277-962-5		F, I												I, P, A					~	
BPAF derivatives	278-305-5		F,I																F,I		
Other aliphatic aryl bridged bisphenols	401-720-1							I, P, A													
BPS derivatives	405-520-5	D8						I, A													

sub-group	EC/List number	acronyms	(Intermediate in) the manufacture of polymers, polymer resins, epoxy resins	Inks and toners	Flame retardant polymer articles	Anti-oxidant for processing pvc	Epoxy resin hardeners	Thermal paper	Polycarbonate articles	Paints and coatings	Adhesives and sealants	Lubricant and greases/functional fluids	Electrical/electronic engineering ceramic boards	Washing and cleaning	Textile, Leather Paper and board	Perfume and fragrance	Plant protection products	Fuel Additive	Rubber products	Dental sealant	Rigid foam
BPS derivatives	411-570-9	TG-SB, TG-SH, TG-SH(H)						I, A													
BPAF derivatives	425-060-9		-																-		
BPAF derivatives	443-330-4		I, A																I, A		
BPAF derivatives	468-740-0		I,F, A																I,F, A		
BPAF derivatives	469-080-6																		Ι		
BPAF derivatives	479-100-5		Ι																Ι		
BPA derivatives	500-086-4		F, I												F, I				F, I		
BPA derivatives	500-263-6		I																		
BPA derivatives	500-607-5		I																		

sub-group	EC/List number	acronyms	(Intermediate in) the manufacture of polymers, polymer resins, epoxy resins	Inks and toners	Flame retardant polymer articles	Anti-oxidant for processing pvc	Epoxy resin hardeners	Thermal paper	Polycarbonate articles	Paints and coatings	Adhesives and sealants	Lubricant and greases/functional fluids	Electrical/electronic engineering ceramic boards	Washing and cleaning	Textile, Leather Paper and board	Perfume and fragrance	Plant protection products	Fuel Additive	Rubber products	Dental sealant	Rigid foam
BPA derivatives	701-362-9		F, I, P								F, C									F, P , A	
BPA derivatives	904-653-0		F, I																		
BPF derivatives	908-912-9		F, I, P																		
BPA derivatives	926-571-4																	Ι			
BPA derivatives	931-252-8		F, I															Ι			
BPS derivatives	941-992-3		I																		
BPAF derivatives	943-265-6																		I, F, A		
BPA derivatives	943-503-9		F, I																		F, I, P
BPAF derivatives	947-368-7		I,F, A																I,F, A		

Table 9b: No hypothesis yet – data generation ongoing

sub-group	EC/List number	acronyms	(Intermediate in) the manufacture of polymers, polymer resins, epoxy resins	Inks and toners	Flame retardant polymer articles	Thermal paper	Polycarbonate articles	Paints, coatings and fillers	Adhesives and sealants	Electrical/electronic engineering ceramic boards	Carbon fibre articles	Dental products	Pharmaceutical	Fuel Additive	Rubber products
BPA derivatives	204-137-9	BPA 2 PO	F, I	F											
BPA derivatives	212-985-6	BPA 2 EO	F, I												
Other aliphatic aryl bridged bisphenols	217-420-7		F, A						F, I, P , C , A	F, I, P, C, A					
Bisphenol Z (BPZ) derivatives	219-110-7									<u>^</u>					
BPF derivatives	226-378-9		F, I												
BPA derivatives	253-781-7	BPA-DA	I	Patent											
Other aliphatic aryl bridged bisphenols	405-800-7		P, A												
BPA derivatives	425-220-8	BPADP			F, I, P, A										

BPA derivatives	701-404-6	BADGE-DETA			F, I, P					
BPA derivatives	500-082-2	BPA-EO	F, I, P ,	F, I, P , C			F, I, P , A			
BPA derivatives	701-407-2		F, I		F, I, P	F, I, P				
BPA derivatives	701-406-7	BADGE-TETA	F, I		F, I, P	F, I, P				
BPA derivatives	500-130-2	DGEBADA	Ι	F, I	F, I, P	F, I, P				
BPA derivatives	500-240-0	BADGE-TETA adduct		F, I, P	F, I, P					
BPA derivatives	701-405-1	BADGE_EDA			F, I, P	F, I, P				
BPA derivatives	609-946-4		F, I, P			F, C		F, P		
Other aliphatic aryl bridged bisphenols	610-104-3									
BPA derivatives	701-373-9			F, I						
BPA derivatives	701-308-4		F, I, P		I, P	P	I, P	Ρ		
BPA derivatives	701-359-2			F, I, P						
Bisphenol AP (BPAP) derivatives	811-683-7									
BPA derivatives	947-794-3		F, I							

sub-group	EC/List number	acronyms	(Intermediate in) the manufacture of polymers, polymer resins, epoxy resins	Inks and toners	Flame retardant polymer articles	Polycarbonate articles	Paints, coatings and fillers	Adhesives and sealants	Electrical/electronic engineering ceramic boards	Carbon fibre articles	Dental products	Pharmaceutical	Fuel Additive	Rubber products
BPA derivatives	214-590-4	BADCy	F, I											
BPA derivatives	216-823-5	BADGE	F, I				F, I, P , C , A	F, I, P, C, A						
BPA derivatives	235-985-8	BAPP												F, I
Other aliphatic aryl bridged bisphenols	255-002-6													
Other aliphatic aryl bridged bisphenols	255-003-1													
BPF derivatives	405-790-4													
Bisphenol M (BPM) derivative	428-970-4	BPM	I, P , A											
BPF derivatives	439-910-1	YSLV-80XY							I, A					
BPA derivatives	460-230-6	EP-4000S	F, I					1	F, I					

sub-group	EC/List number	acronyms	(Intermediate in) the manufacture of polymers, polymer resins, epoxy resins	Inks and toners	Flame retardant polymer articles	Polycarbonate articles	Paints, coatings and fillers	Adhesives and sealants	Electrical/electronic engineering ceramic boards	Carbon fibre articles	Dental products	Pharmaceutical	Fuel Additive	Rubber products
BPA derivatives	500-090-6		F, I											
BPA derivatives	500-097-4	BPA-PO	F, I	F, P , C , A										
BPA derivatives	500-180-5		I				F, I, P	F, I, P						
BPA derivatives	500-181-0		I				F, I, P							
BPA derivatives	500-268-3						F, I, P	F, I, P						
BPA derivatives	614-657-1						F, I, P , C	F, I, P , C						
Other aliphatic aryl bridged bisphenols	680-046-1			F, A			F, A							
BPF derivatives	701-263-0		F, I, P , C , A				F, I, P , C , A	F, I, P, C, A	I, P					
Bisphenol Z (BPZ) derivatives	810-464-3						I, P , C , A	I, P , C						

sub-group	EC/List number	acronyms	(Intermediate in) the manufacture of polymers, polymer resins, epoxy resins	Inks and toners	Flame retardant polymer articles	Polycarbonate articles	Paints, coatings and fillers	Adhesives and sealants	Electrical/electronic engineering ceramic boards	Carbon fibre articles	Dental products	Pharmaceutical	Fuel Additive	Rubber products
BPA derivatives	941-183-5		F, I				F,I	F, I						
BPF derivatives	941-357-0													
Bisphenol M (BPM) derivative	944-616-6		F, I, A				F, I, A							
BPA derivatives	945-830-2	DD80					F, I							
Bisphenol C2 (BPC2) derivatives	945-909-1		F, I, A											
BPA derivatives	947-250-5													
BPA derivatives	947-984-6						F, I, P							
BPA derivatives	948-520-5					1	F, I, P							

Table 9d: Bisphenols for which the need for further EU RRM cannot be established- no data generation possible to clarify hazard

sub-group	EC/List number	acronyms	(Intermediate in) the manufacture of polymers, polymer resins, epoxy resins	Inks and toners	Chermal paper	Polycarbonate articles	Electrical/electronic engineering ceramic boards	Textile, Leather Paper and board	Photo lithography	Pharmaceuticals
Other aliphatic aryl bridged bisphenols	210-039-7									F, I
Bisphenol Z (BPZ) derivatives	212-677-1	BPZ								
BPA derivatives	216-367-7									
BPF derivatives	218-257-4									
BPA derivatives	223-123-3									
BPA derivatives	225-144-3									
BPS derivatives	235-986-3									
Bisphenol C2 (BPC2) derivatives	238-940-0	BPC2 (BPCI2)								
BPA derivatives	246-263-7									
BPS derivatives	263-920-3	BPS-MPE								
Bisphenol TMC (BP-TMC) derivatives	404-140-7	BP-TMC				I				
Bisphenol FL (BPFL) derivatives	404-470-1									

sub-group	EC/List number	acronyms	(Intermediate in) the manufacture of polymers, polymer resins, epoxy resins	Inks and toners	Thermal paper	Polycarbonate articles	Electrical/electronic engineering ceramic boards	Textile, Leather Paper and board	Photo lithography	Pharmaceuticals
Bisphenol E (BPE) derivatives	405-740-1									
Bisphenol FL (BPFL) derivatives	406-950-6	BPFL							I(?)	
BPS derivatives	427-620-8	(D90)			I, A					
BPA derivatives	432-380-2	HBPX-1							I, P	
BPF derivatives	432-740-9						Ι			
Bisphenol AP (BPAP) derivatives	433-130-5	BPAP		I, P				I, P	I, P	
Other aliphatic aryl bridged bisphenols	433-980-7									
BPA derivatives	434-000-0								I, P	
BPA derivatives	434-010-5								I	
BPS derivatives	479-880-7	BPS-MAE			I, P , A					
BPA derivatives	500-072-8									
BPA derivatives	500-089-0									
BPA derivatives	500-103-5									

sub-group	EC/List number	acronyms	(Intermediate in) the manufacture of polymers, polymer resins, epoxy resins	Inks and toners	Thermal paper	Polycarbonate articles	Electrical/electronic engineering ceramic boards	Textile, Leather Paper and board	Photo lithography	Pharmaceuticals
BPA derivatives	500-104-0									
BPA derivatives	500-253-1									
BPA derivatives	500-655-7			F, C ,						
BPF derivatives	500-770-2									
BPA derivatives	605-281-9									
BPA derivatives	605-913-3									
Bisphenol BPPP derivative	606-820-0	BPP								
BPA derivatives	607-500-3									
BPA derivatives	607-501-9									
BPA derivatives	607-535-4									
BPA derivatives	607-537-5									
BPF derivatives	608-164-0									
BPA derivatives	609-402-6									

sub-group	EC/List number	acronyms	(Intermediate in) the manufacture of polymers, polymer resins, epoxy resins	Inks and toners	Thermal paper	Polycarbonate articles	Electrical/electronic engineering ceramic boards	Textile, Leather Paper and board	Photo lithography	Pharmaceuticals
BPA derivatives	609-663-6									
BPA derivatives	614-177-2									
BPA derivatives	613-584-2									
BPA derivatives	614-207-4									
BPA derivatives	614-255-6									
BPA derivatives	620-316-8									
Bisphenol E (BPE) derivatives	627-637-2	BPE								
BPF derivatives	632-557-6									
BPA derivatives	641-007-4									
BPA derivatives	678-196-8	BPG								
BPA derivatives	678-197-3									
Bisphenol BP (BPBP) derivatives	679-999-6	BPBP								
BPF derivatives	680-136-0									

sub-group	EC/List number	acronyms	(Intermediate in) the manufacture of polymers, polymer resins, epoxy resins	Inks and toners	Thermal paper	Polycarbonate articles	Electrical/electronic engineering ceramic boards	Textile, Leather Paper and board	Photo lithography	Pharmaceuticals
BPA derivatives	680-511-9									
BPS derivatives	680-791-2									
BPA derivatives	686-711-2									
BPS derivatives	EC/List no 4				I, A					
BPF derivatives	700-487-6									
BPA derivatives	800-098-2									
BPA derivatives	806-676-0									
BPA derivatives	EC/List no 1									
BPF derivatives	941-435-4									
BPF derivatives	946-144-6							F, I		
BPA derivatives	946-322-3		F, I							
BPA derivatives	EC/List no 2									
BPA derivatives	EC/List no 3									

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

(28/11/2021)

		BPA and BPA derivatives	BPS and BPS derivatives	BPF and BPF derivatives	Miscellaneous Bisphenols	BPAF and its salts	Other aliphatic or aryl bridged bisphenols
RMOA		201-245-8 (BPA)	201-250-5 (BPS)	210-658-2; 226-378-9	201-025-1 (BPB)		401-720-1
Authorisation	Candidate List	201-245-8 (BPA)			201-025-1 (BPB)		401-720-1
	Annex XIV	201-245-8 (BPA, recommended for prioritisation for inclusion in Annex XIV)					
Restriction	Annex XVII	201-245-8 (BPA)					
CLH	Annex VI (CLP)	201-245-8 (BPA)	201-250-5 (BPS)	204-279-1 (TBMD)		216-036-7; 278-305-5; 479-100-5; 943-265-6; 947-368-7	
Actions not under REACH/CLP		201-245-8 (BPA)*+	201-250-5 (BPS)**				

*https://www.efsa.europa.eu/en/topics/topic/bisphenol

⁺ https://www.efsa.europa.eu/en/news/bisphenol-efsa-draft-opinion-proposes-lowering-tolerable-daily-intake

**https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2020.EN-1844