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COMMISSION OF THE EUROPEAN COMMUNITIES
Directorate-General
INDUSTRY
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pages

"FIRST SUPPLEMENT TO SYNOPTIC 6"

1. This document updates the document "Synoptic 6".

2 It contains all the substances evaluated by the SCF after the issue of the Synoptic 6. Therefore it contains all the monomers (see Annex 1) and additives (see Annex 2) examined by the working group "Food Contact Materials" of the SCF ("SCF-WG") during the 53rd and 54th meetings. These substances have also been confirmed by the SCF during its September meeting.

3. It does not contain the substances examined during the 55th meeting of the SCF-WG, because they have not yet been confirmed by the SCF.

4. The second supplement of the Synoptic 6 will be available to the European professional association and to the national authorities not before 31 March 1993. The mailing list appearing on pages 6 and 7 of the Synoptic 6 will receive the supplement automatically, when it is available. *Therefore, please avoid sending faxes or letters or calling the Commission services on the availability of the supplement, because this may cause a delay in its preparation..*

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ANNEX 1

LIST OF MONOMERS

LIST OF MONOMERS AND OTHER STARTING SUBSTANCES UPDATED TO 21 OCTOBER 1993

Rec n	U	PM/REF N.	COUNTRY	CAS N.	NAME	SCF L	EEC L.	SCF M/R	AGE NDA	CS/PM	R	OPINION SCF	RESTRICTIONS	REMARKS	MAT PL	MAT C
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	16	17
21	+	10660	B.I.UK	15214-89-8	*2-ACRYLAMIDO-2-METHYLPROPANESULPHONIC ACID	3	B0/ B1/ B2/ A3+	M54/M49 /M44/M4 0/M23/R 19	54	1826+/2013,2 055,2083//	R:0.05 mg/kg	R: 0.05 mg/kg of food. Available: Migration data and mutagenicity tests. Considered non-genotoxic based on the available studies (CS/PM/2083).	SML = 0.05 mg/kg		+	+
74	+	12190	B.E.I.	00105-97-5	*ADIPIC ACID, DI-n-DECYL ESTER	6B	B0/ B1/ B2/ B3+	M54/M46 /M40/R1 7	P	790*/2117//	R(T)=0. 05 mg/kg bw	Group R: 0.025 mg/kg b.w. See references for same substance(32320)in additive list.	SML(Tp)= 3 mg/kg	UP/Same 32320/To be del.in 3rd amendm	+	+
75	+	12220	B.E.I.	27178-16-1	*ADIPIC ACID, DIISODECYL ESTER	6B	B0/ B1/ B2/ B3+	M54/M46 /M40/R1 7	54	698*/2117//	R(T)=0. 05 mg/kg bw	Group R: 0.05 mg/kg b.w. Needed: in first instance specifications and then on the specified substances toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation studies too.	SML(Tp) = 3 mg/kg	UP/Same 32560/To be del.in 3rd amendm	+	+
1172	+	12235		00627-93-0	*ADIPIC ACID, DIMETHYL ESTER	6B	Dx	M54/M46 /M43	54	537/2117//	R(T)= 0.05 mg/kg bw	Group R : 0.025 mg/kg b.w. Needed: toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation study too.	SML(Tp)= 3 mg/kg	S2(10240)		+
76	+	12250	B.E.I.	00123-79-5	*ADIPIC ACID, DI-n-OCTYL ESTER	6B	B0/ B1/ B2/ B3+	M54/M46 /M40/R1 7	54	731*,2117//	R(T)= 0.05 mg/kg bw	Group R: 0.025 mg/kg b.w. Needed: toxicological data depending on migration level (see SCFguidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation study too.	SML(Tp)= 3 mg/kg	UP/to be del.in 3rd amendm	+	+
926	+	12761	D.N.UK	00693-57-2	*12-AMINODODECANOIC ACID	7	Bx	M55/M54 /M43	55, 56	1829+,2084// 2155,2162(RI VM-HP)	0.05 mg/kg	R: 0.05 mg/kg of food. Mutagenicity tests are negative and migration is low (less than 50 ppb). (RIVM/TNO doc. CS/PM/2162).	SML= 0.05 mg/kg	Cov.by 12760		+

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Rec n	U	PM/REF N.	COUNTRY	CAS N.	NAME	SCF L	EEC L.	SCF M/R	AGE NDA	CS/PM	R	OPINION SCF	RESTRICTIONS	REMARKS	MAT PL	MAT C
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	16	17
822		17040	-	00149-57-5	*2-ETHYLHEXANOIC ACID	6B	B1S /B2	M53/M42	56	1815+ (Rossi)		Needed: toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.05 mg/kg, peroxisome proliferation studies too. (N.B. To be confirmed)		S1(10480)/Same 54120	+	+
294		18220	F.	68564-88-5	N-HEPTYLAMINOUNDECANOIC ACID	3	B0/ B1/ B2/ A3	M53/M30	56	1880+,2011// 2172 (Rivm-HP)	R:0.05 mg/kg	R: 0.05 mg/kg of food and not for use with fatty foods. Available: migration into non-fat simulants, 5 negative mutagenicity studies, incomplete 90-day oral rat study.	SML= 0.05 MG/KG and not for use with fatty foods.	PA	+	
300	+	18400	B.E.N.UK.	00592-42-7	*1,5-HEXADIENE	7	B0/ B1/ B2	M54/M50 /R17	54	509/592,625* /2086		Available: 4-week rat study by inhalation and mutagenicity tests. Needed: migration data and gene mutation in mammalian cells in vitro. If migration exceeds 0.05 mg/kg of food, additional study according to SCF guidelines should be supplied.		PO	+	+
367		20380	B.D.E.I.N. UK.	01189-08-8	*METHACRYLIC ACID, DIESTER WITH 1,3-BUTANEDIOL	8	B0/ B1/ B2	M53/M45 /R17	53	1819+//		Available: hydrolysis study shows incomplete hydrolysis.			+	+
1093		23505	UK	00110-85-0	PIPERAZINE	3	Ax	M53/M43	53	503/1362*//		Migration negligible. Only for use as a constituent of composite nanofiltration membrane.	Only for use as a constituent of composite nanofiltration membrane.			+
482	+	23770	B.D.E.I.N. UK	00504-63-2	*1,3-PROPANEDIOL	7	B0/ B1/ B2	M54/M50 /R17	54	1840+,2057// 2108//		Available: oral teratogenicity study in rats, migration low. Needed : mutagenicity studies according SCF guidelines. Presentation of analytical data should be according to "Practical Guide N.1"		PUR	+	+

ANNEX 2

LIST OF ADDITIVES

LIST OF ADDITIVES UPDATED TO 21 OCTOBER 1993

Rec n	U	PM/REF N.	COUNTRY	CAS N.	NAME	SCF L	EEC L.	SCF M/R	AGE NDA	CS/PM	R	OPINION SCF	RESTRICTIONS	REMARKS	MAT PL	MAT C
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	16	17
1424	+	30200		00110-49-6	*ACETIC ACID, 2-METHOXYETHYL ESTER	6B-P	Bx	M54/M47	56?	672//2114 (RIVM)	R= 0.05 mg/kg	R: 0.05 mg/kg of food.	SML = 0.05 mg/kg			+
2146		30385		00123-54-6	*ACETYLACETONE	8	Bx	M53	53	1287*//					+	
2100	+	30725		68603-38-3	*ACIDS, ALIPH., MONOCARB. (C16-C18), COMPOUNDS WITH DIETHANOLAMINE	7	Bx	M54/M51	54	1665,2109//		Available: 90 day oral rat and dog studies with different diethanolamides of fatty acids; inadequate migration and mutagenicity data. Needed: migration data and remaining data according to SCF guidelines on a compound representative of the diethanolamides group (30725/39140/39280/39480/39520 /45040/63560). (RIVM doc. CS/PM/2089). N.B. When the diethanolamides wil be re-evaluated restrictions on diethanolamine impurities are needed.		S1(30720)	+	
2167		31530		123968-25-2	*ACRYLIC ACID, 2,4-DI-tert.PENTYL-6-[1(3,5-DI-tert.PENTYL-2-HYDROXYPHENYL)ETHYL]PHENYL ESTER	W7	Dx	M53	53	1726,2028//		Available: 3 negative mutagenicity studies, 90-day oral rat study, inadequate migration data (CS/PM/1726,2028).		New subst.	+	
26	+	31760	B.E.N.UK	-	*ADIPIC ACID, ALKYL, PRIMARY (C4-C13) ESTERS	9	Bx	M54/M46 /Rx	46	956,2117//	R(T)=0.05 mg/kg	Group R= 0.05 mg/kg b.w.	SML(Tp)= 3.0 mg/kg	PVC	+	
29	+	32000	B.E.	00105-96-4	*ADIPIC ACID, BIS(6-METHYLHEPTYL) ESTER	6B	Bx	M54/M46 /Rx	46	2217//	R= 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w. Needed : toxicological data depending on migration level (see SCF guidelines) and if migration exceeds 0.050 mg/kg peroxisome proliferation studies too.	SML(Tp) = 3 mg/kg	PVC	+	
30	+	32080	UK.	00110-29-2	*ADIPIC ACID, n-DECYL n-OCTYL ESTER	6B	Bx	M54/M46 /Rx	46	2217//	R= 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w. Needed: toxicological data depending on migration level (see SCF guidelines) and if	SML(Tp) = 3 mg/kg	PVC	+	

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Rec n	U	PM/REF N.	COUNTRY	CAS N.	NAME	SCF L	EEC L.	SCF M/R	AGE NDA	CS/PM	R	OPINION SCF	RESTRICTIONS	REMARKS	MAT PL	MAT C
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	16	17
												toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation studies too.				
37	+	32640	E.UK	33703-08-1	*ADIPIC ACID, DIISONONYL ESTER	6B	Bx	M54/M46 /Rx	46	1856+/2117//	R= 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w. Available: 90-day oral rat and dog studies and two mutagenicity studies. Needed: in first instance specifications, test for chromosome aberrations in mammalian cells in vitro and then the remaining toxicological tests depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation study too.	SML(Tp) = 3.0 mg/kg	PVC	+	
38	+	32720	B.N.UK	01330-86-5	*ADIPIC ACID, DIISOOCTYL ESTER	6B	Bx	M54/M46 /Rx	46	956,1287,2117//	R= 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w. Needed: in first instance specifications and then on the specified substances provide toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation study too.	SML(Tp) = 3.0 mg/kg	PVC	+	
1437	+	32760		00627-93-0	*ADIPIC ACID, DIMETHYL ESTER	6B	Bx	M54/M46	46	672,2217//	R= 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w. Needed: toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation study too.	SML(Tp) = 3.0 mg/kg	Same 12235		+
39	+	32800	B.E.UK	00151-32-6	*ADIPIC ACID, DI-n-NONYL ESTER	6B	Bx	M54/M46 /Rx	46	956,2217//	R: 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w. Needed: toxicological data depending on migration level	SML(Tp) = 3.0 mg/kg	PVC	+	

Rec n	U	PM/REF N.	COUNTRY	CAS N.	NAME	SCF L	EEC L.	SCF M/R	AGE NDA	CS/PM	R	OPINION SCF	RESTRICTIONS	REMARKS	MAT PL	MAT C
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	16	17
												method.				
88	+	36240	B.N.UK	-	*AZELAIC ACID, ALKYL, PRIMARY(C1-C12) ESTERS	9	Bx	M54/M46 /Rx	46	956/2117//	R(Tp)=0 .05 mg/kg bw	Group R: 0.05 mg/kg b.w.	SML(Tp)= 3.0 mg/kg	PVC	+	
89	+	36320	B.E.I.UK	00103-24-2	*AZELAIC ACID, BIS(2-ETHYLHEXYL) ESTER	6B	Bx	M54/M46 /Rx	46	956,2217//	R: 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w. Available: inadequate 90-day study. Needed: toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation study too.	SML(Tp) = 3.0 mg/kg		+	
90	+	36400	B.E	00106-03-6	*AZELAIC ACID, BIS(6-METHYLHEPTYL) ESTER	6B	Bx	M54/M46 /Rx	46	956,2117//	R: 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w. Needed: toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation study too.	SML(Tp) = 3.0 mg/kg		+	
91	+	36480	B.D.E.F.I. N.UK	00109-31-9	*AZELAIC ACID, DI-n-HEXYL ESTER	6B	Bx	M54/M46 /Rx	46	956,2117//	R: 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w. Available: 90-day and 2-year oral rat, 1-year oral dog studies. Needed: toxicological data depending on migration level (see SCF guidelines) and if migration exceeds 0.050 mg/kg peroxisome proliferation study too.	SML(Tp) = 3.0 mg/kg		+	+
1474	+	36520		26544-17-2	*AZELAIC ACID, DIISOOCTYL ESTER	6B	Bx	M54/M46	46	672/956,2217 //	R: 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w. Needed:in first instance specifications and on the specified susbtances provide toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation study too.	SML(Tp) = 3.0 mg/kg			+

Rec n	U	PM/REF N.	COUNTRY	CAS N.	NAME	SCF L	EEC I	SCF M/R	AGE NDA	CS/PM	R	OPINION SCF	RESTRICTIONS	REMARKS	MAT PL	MAT C
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	16	17
												questionable. Needed: migration data and toxicity tests according to SCF guidelines for one of the following substances: 38860/38862/38864/38870/39800/39930.				
1543	+	38870	N		*4,4'-BIS[[4-DIETHYLAMINO-6-(2,5-DISULPHOANILINO)-s-TRIAZIN-2-YL]AMINO]-2,2'-STILBENEDISULPHONIC ACID	7	Bx	M54	54+	1083,2088//		Available: data on structurally related substance. Reports questionable. Needed: migration data and toxicity tests according to SCF guideline for one of the following substances: 38860/38862/38864/38870/39800/39930.				+
2106	+	39140		00136-26-5	*N,N-BIS(2-HYDROXYETHYL)DECANAMIDE	7	Bx	M54/M52	52, 54	1665//2089,2109//		Same references as 30725.		S1(30720)	+	
135	+	39280	B.D.E.UK.	00120-40-1	*N,N-BIS(2-HYDROXYETHYL)LAURAMIDE	7	Bx	M54/Rx	-	1372*,1449*, 2089,2109//		Same references as 30725.			+	+
2107	+	39480		00093-83-4	*N,N-BIS(2-HYDROXYETHYL)OLEAMIDE	7	Bx	M54/M52	54	1665//2089,2109//		Same references as 30725.		S1(30720)	+	
444	+	39520	B.D.UK.	00093-82-3	*N,N-BIS(2-HYDROXYETHYL)STEARAMIDE	7	Bx	M54/Rx	54	2109//		Same references as 30725.			+	
1546	+	39800	N.	07342-13-4	*4,4'-BIS[[4-METHOXY-6-ANILINO-s-TRIAZIN-2-YL]AMINO]-2,2'-STILBENEDISULPHONIC ACID	7	Bx	M54	54+	1083,2088//		Available: data on structurally related substance. Reports questionable. Needed: migration data and toxicity tests according to SCF guideline on a compound representative of the group: 38860/38862/38864/38870/39800/39930. (RIVM doc. CS/PM/2088).				+
1547	+	39930	N.		*4,4'-BIS[[4-MONO- AND DIETHANOLAMINO-6-ANILINO-s-TRIAZIN-2-YL]AMINO]-2,2'-STILBENEDISULPHONIC ACID	7	Bx	M54	54+	1083,2088//		Available: data on structurally related substance. Reports questionable.				+

Rec n	U	PM/REF N.	COUNTRY	CAS N.	NAME	SCF L	EEC L.	SCF M/R	AGE NDA	CS/PM	R	OPINION SCF	RESTRICTIONS	REMARKS	MAT PL	MAT C
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	16	17
												Cerium (CS/PM/2090)).				
210	+	44240	B.D.E.N.	-	*CITRIC ACID, ALKYL, PRIMARY (C2-C12), ESTERS	9	Bx	M54/M46 /Rx	46	956,1083/2117//	R(Tp)=0.05 mg/kg bw	Group R: 0.05 mg/kg b.w.	SML(Tp) = 3.0 mg/kg		+	+
2187	+	44280	UK,EP	29589-99-9	*CITRIC ACID, DIOCTADECYL ESTER	6B	Bx	M54/M49	54	1083/	R: 0.050 mg/kg bw	Group R: 0.05 mg/kg b.w. Needed: specification on identity and toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation studies too.	SML(Tp) = 3 mg/kg			+
214	+	44560	B.E.I.N.UK	00077-94-1	*CITRIC ACID, TRIBUTYL ESTER	6B	Bx	M54/M46 /Rx	46	956,2217//	R: 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w. Needed: toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation study too.	SML(Tp) = 3.0 mg/kg	CA,PVAC	+	+
216	+	44720	B.E.UK	07775-50-0	*CITRIC ACID, TRI-n-OCTADECYL ESTER	6B	Bx	M54/M46 /Rx	46	956,2217//	R: 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w. Needed: toxicological data depending on migration level (see SCF guidelines) and if migration exceeds 0.050 mg/kg peroxisome proliferation study too.	SML(Tp) = 3.0 mg/kg	PS	+	+
217	+	44800	B.I	07147-34-4	*CITRIC ACID, TRIS(2-ETHYLHEXYL) ESTER	6B	Bx	M54/M46 /Rx	46	956,2217//	R: 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w. Needed: toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation study too.	SML(Tp) = 3.0 mg/kg		+	
220	+	45040	B.UK.	61790-63-4 68603-42-9 and	*COCONUT OIL FATTY ACIDS DIETHANOLAMIDE	7	Bx	M54/R1	54	1902+//2089, 2109//		Same references as 30725.		PO,PS/Add CAS_N= 68440-04-0	+	
229		45560		-	CRISTOBALITE	3	Ax	M53	53			Inert material.			+	+

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Rec n	U	PM/REF N.	COUNTRY	CAS N.	NAME	SCF L	EEC L.	SCF M/R	AGE NDA	CS/PM	R	OPINION SCF	RESTRICTIONS	REMARKS	MAT PL	MAT C
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	16	17
318		51985		09002-92-0	*alpha-n-DODECANOL-omega-HYDROXYPOLY(OXYETHYLENE)	9/D	D	M53	53					Same 77480	+	
329		52720	B.D.F.I.N. UK.	00112-84-5	*ERUCAMIDE	7	Bx	M53/M47 /M44/M4 2/Rx	53	1775+//2101		Available: Ames test negative and migration data. (Rivm doc. 1990-09-12). Hydrolysis < 95% (doc. CS/PM/1023). Needed: 90-day oral study, gene mutation and chromosome aberration in mammalian cells, bioaccumulation; to be performed with erucamide, oleamide or stearamide or demonstrate full hydrolysis by method suggested by applicant (CS/PM/1550).			+	+
2184		52780			*ESTERS OF 12-HYDROXYSTEARIC AND STEARIC ACID WITH C20-GUERBET ALCOHOLS	W9	Dx	M53	53	2059//				New subst.	+	
1122		53255	B.D	00100-41-4	ETHYLBENZENE	3	Ax	M53	53	394/1524,203 5//	R=0.6 mg/kg	R: 0.6 mg/kg of food. Available: 6-month rat inhalation study, mutagenicity studies, TDI=0.1 mg/kg bw. Based on allowing 1/10 of TDI for packaging.	SML = 0.6 MG/KG	PS	+	+
345 +		53670	B.D.E.F.N. UK.	32509-66-3	ETHYLENEGLYCOL BIS (3,3-BIS(3-tert-BUTYL-4-HYDRO XYPHENYL)BUTYRATE)	2	Ax	M53/M52 /R1	56?	255,964,1048 //(Rivm)	0.1* mg/kg bw	t-TDI: 0.1 mg/kg b.w pending mutagenicity data. 90-day oral dog and 16 weeks oral rat (after in utero exposure) and a 2-year oral dog study. (RIVM, report 300/197, December 1980, CS/PM/1048).	SML= 6 mg/kg		+	+
1123 +		53860	B	00109-86-4	*ETHYLENEGLYCOL MONOMETHYL ETHER	6B-p	Bx	M54/M47 /M44	56?	2114 (RIVM)		Suspected of embriotoxicity/teratogenicity. Available : some studies, but inadequate. R: 0.05 mg/kg of food.	SML = 0.05 mg/kg	Same as 17002.	+	+
353		54120	B.D.I.N.UK	00149-57-5	*2-ETHYLHEXANOIC ACID	6B	Bx	M53/R1	56	1776+//(Ross i)		Same reference for the same substance (17040) in monomer		Same 17040	+	

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Rec n	U	PM/REF N.	COUNTRY	CAS N.	NAME	SCF L	EEC L.	SCF M/R	AGE NDA	CS/PM	R	OPINION SCF	RESTRICTIONS	REMARKS	MAT PL	MAT C
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	16	17
1608	+	54750	UK		*FATTY ACIDS, TALL OIL, ZIRCONIUM SALTS	7	Bx	M54/M52	54	1083/2091//		L3 for fatty acids tall oil. L7 for zirconium. See references for 54220.				+
2169	+	57880			*GLYCEROL, TRIESTERS WITH ACIDS, ALIPH., MONOCARB. (MORE THAN C6)	9	Bx	M53/M52	52, 54	1732//				Derived by 56400	+	+
1624	+	59885	N.		*HYDROCARBONS, ALIPHATIC (BOILING POINT 230-330°C), WITH A MAXIMUM AROMATICS CONTENT OF 25%	9	Bx	M53	53	1083//		Specifications on identity.				+
1626		59900	D		*HYDROCARBONS, ALIPHATIC AND CYCLOALIPHATIC, OBTAINED BY HYDROGENATION OF MINERAL OIL FRACTION (M.W.: 440-550)	9	Bx	M53	53	1083//		Specifications on identity.				+
1628		60180	N.	04191-73-5	4-HYDROXYBENZOIC ACID, ISOPROPYL ESTER	2	Ax	M53	53	1083//	10 mg/kg bw	Group-TDI: 10 mg/kg bw based on group ADI = 10 mg/kg bw for ethyl, methyl and propyl esters.				+
2154	+	61055		00122-99-6	*2-HYDROXYETHYL PHENYL ETHER	8	Bx	M54	54	1287,2092//				Same as 53880	+	
2155	+	62110		07681-52-9	*HYPOCHLOROUS ACID, SODIUM SALT	6A	Bx	M54	54	1287,2093//		Positive in several mutagenicity studies. (RIVM doc. CS/PM/2093).	SML = 0.05 mg/kg		+	
2156		62140		06303-21-5	HYPOPHOSPHOROUS ACID	3	Ax	M53	53	1287//		Easily oxidized to phosphoric acid.			+	
2157	+	62175		10025-82-8	*INDIUM TRICHLORIDE	8	Bx	M54	54	1287,2038//					+	
1634	+	62340	UK		*ISODECANOIC ACID, CERIUM SALT	9	Bx	M54	54*	1083,2090//		L9 for isodecanoic acid. L8 for cerium.				+
1636	+	62390	UK		*ISODECANOIC ACID, ZIRCONIUM SALT	7-9	Bx	M54/M52	54?	1083/2091//		L9 for isodecanoic acid. L7 for zirconium. See references for 54220.				+
474	+	63200	B.D.E.N.	51877-53-3	LACTIC ACID, MANGANESE SALT	1-2	Ax	M53/M52 /M37	52		0.01 as Mn	L1 for lactic acid. ADI: not specified. (SCF, 25th Series, 1991).	SML(T)= 0.6 mg/kg (expressed as Mn)	A	+	

Rec n	U	PM/REF N.	COUNTRY	CAS N.	NAME	SCF L	EEC L.	SCF M/R	AGE NDA	CS/PM	R	OPINION SCF	RESTRICTIONS	REMARKS	MAT PL	MAT C
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	16	17
					SODIUM SALT (MW>70000)							methyl vinyl ether (PM/REF. 22270).				
2190		65280	B,E,N	10043-84-2	MANGANESE(II)HYPOPHOSPHITE	2-3	Ax	M53/M37	53		0.01T as Mn	Group TDI: 0.01 mg/kg b.w. (as Mn). See references for acetic acid, manganese(II) salt in list 2. L3 for hypophosphite. Hypophosphite easily oxidised tp phosphoric acid.	SML(T)= 0.6 mg/kg (as Mn)	PA	+	
2158	+	65910		02530-85-0	*[3-(METHACRYLOXY)PROPYL] TRIMETHOXYSILANE	8	Bx	M53	53	1287//					+	
1173	+	66620	D	00075-09-2	METHYLENE CHLORIDE	3	Ax	M54	54	391,1287/1468//	R=0.05 mg/kg	R: 0.05 mg/kg of foods. (SCF, 29th Series, 1992).	SML = 0.05 mg/kg	PC	+	+
1177	+	66655	B	00078-93-3	METHYL ETHYL KETONE	3	Ax	M54	54	2098//	R=5 mg/kg	R: 5 mg/kg of food. Available: 3 and 6 month inhalation studies in rats, teratogenicity studies by inhalation in mice and rats, mutagenicity tests. (RIVM doc. CS/PM/2098).	SML = 5 mg/kg		+	+
1179	+	66725	B	00108-10-1	METHYL ISOBUTYL KETONE	3	Ax	M54	54	2096//	R=5 mg/kg	R: 5 mg/kg of food. Available: 3 month oral rat study and 3 month inhalation studies mice, rats, dogs and monkeys, teratogenicity studies by inhalation in mice and rats , mutagenicity tests. (WHO Env. Health Crit. n. 117 (1990) Geneva).	SML = 5 mg/kg		+	+
536		67360	D.UK.	67649-65-4	MONO-n-DODECYLTIN TRIS(ISOOCTYL MERCAPTOACETATE)	2	Ax	M55/M53 /M40	55	2167+//	0.4*	t-TDI: 0.4 mg/kg b.w. pending results of in-vivo test for unscheduled DNA synthesis. Available: 10- and 90-day oral rat studies, mutagenicity tests negative except human lymphocytes. (RIVM report 02-04-1990).	SML= 24 mg/kg	PVC	+	+

LIST OF ADDITIVES UPDATED TO 21 OCTOBER 1993

Rec n	U	PM/REF N.	COUNTRY	CAS N.	NAME	SCF L	EEC L.	SCF M/R	AGE NDA	CS/PM	R	OPINION SCF	RESTRICTIONS	REMARKS	MAT PL	MAT C
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	16	17
												L0 for n-octanoic acid.				
1846		68680	I,N,UK	16577-52-9	n-OCTANOIC ACID, LITHIUM SALT	0-2	Ax	M53/M52 /M49	53	1040,1083//	0.01T (as Li)	L2 for the Lithium. Group TDI : 0.01 mg/kg b.w. (as Li). See references for 38000 in L2 in this report.	SML(T) = 0.6 mg/kg (expressed as Li)	Cov.by 31120		+
												L0 for n-octanoic acid.				
1193	+	68690	I,N,UK	06535-19-9	n-OCTANOIC ACID, MANGANESE SALT	2	Ax	M53/M52 /M49	48, 53	1083//	0.01T (as Mn)	L2 for the Mn. Group TDI: 0.01 mg/kg b.w. (as Mn). See references for 30180 in L2 in this report.	SML(T) = 0.6 mg/kg (as Mn)	UP/Cov.by 31120		+
												L0 for n-octanoic acid.				
1195	+	68730	N,UK	18312-04-4	OCTANOIC ACID, ZIRCONIUM SALT	9	Bx	M54	54?	1083/2091//		L9 for octanoic acid.		UP		+
												L7 for zirconium. See references for 54220.				
559		68960	B.D.E.F.I. UK	00301-02-0	*OLEAMIDE	7	Bx	M53/M47 /M44/M4 2/R29	53	1781+//2101		Available: Ames test negative and migration data. (Rivm doc. 1990-09-12). Hydrolysis<95% (doc.CS/PM/1023). Needed: 90-day oral rat study, gene mutation and chromosome aberration in mammalian cells, bioaccumulation to be performed with erucamide, oleamide or stearamide or demonstrate full hydrolysis by method suggested by applicant (CS/PM/1550).			+	+
1668	+	69140	UK	07492-61-7	*OLEIC ACID, CERIUM SALT	8	Bx	M54/M52	54*	1083,2090//		L1 (=not specified) for oleic acid. L8 for cerium.				+
2122		69560		03687-45-4	*OLEIC ACID, OLEYL ESTER	7	Bx	M53	53	1665//		Needed: hydrolysis data.		S1(30640)	+	
1672	+	69650	UK		*OLEIC ACID, ZIRCONIUM SALT	7	Bx	M54/M52	54	1083/2091//		L1 (=not specified) for oleic				+

Rec n	U	PM/REF N.	COUNTRY	CAS N.	NAME	SCF L	EEC L.	SCF M/R	AGE NDA	CS/PM	R	OPINION SCF	RESTRICTIONS	REMARKS	MAT PL	MAT C
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	16	17
								/M34		7//	mg/kg bw	Needed: toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation studies and neurotoxicity studies too.				
1230	+	72760	D	03138-43-0	*PHOSPHORIC ACID, DI-n-NONYL ESTER	6B	Bx	M54/M46	46	956,2117//	R: 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w. Needed: toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferations studies and neurotoxicity studies too.	SML(Tp) = 3.0 mg/kg	PAM	+	+
618	+	72800	B.D.E.I.N. UK	01241-94-7	*PHOSPHORIC ACID, DIPHENYL 2-ETHYLHEXYL ESTER	6B-P	Bx	M54/M46 /Rx	56?	23,52,956,1519*,2060,2117(Rivm)	R: 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w. Available: neurotoxicity, 2 teratogenicity and 3 mutagenicity studies. Inadequate 2-year oral rat study also. Needed: remaining toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation study too. A new technical dossier is available (CS/PM/2060) and has to be yet evaluated.	SML(Tp) = 3.0 mg/kg	PVC,PVDC-To be re-evaluated	+	+
1405	+	72840		00078-31-9	*PHOSPHORIC ACID, DIPHENYL-p-TOLYL ESTER	6B	Bx	M54/M46	46	672/956/2117 //		Needed: toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, neurotoxicity studies too.				+
619	+	72880	D.UK.	97489-40-2	*PHOSPHORIC ACID, ETHANOLAMINE HEXYL BRANCHED AND LINEAR ESTER	9	Bx	M54/M46 /Rx	46	956,2117//	R(Tp)=0.05 mg/kg bw	Group R: 0.05 mg/kg b.w.	SML(Tp) = 3.0 mg/kg		+	
623	+	73040	B.D.	13763-32-1	PHOSPHORIC ACID, LITHIUM SALTS	1-2	Ax	M53/M52	52,	1040//	0.01T(a	L2 for lithium.	SML(T)= 0.6 mg/kg	PUR	+	

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Rec n	U	PM/REF N.	COUNTRY	CAS N.	NAME	SCF L	EEC L.	SCF M/R	AGE NDA	CS/PM	R	OPINION SCF	RESTRICTIONS	REMARKS	MAT PL	MAT C
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	16	17
											bw					
629	+	73600	E.UK.	00078-51-3	*PHOSPHORIC ACID, TRIBUTOXYETHYL ESTER	6B	Bx	M54/M46 /Rx	46	956/2117//	R: 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w. Available: Ames test, 14-day and 18-week oral rat studies. Needed: remaining toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, neurotoxicity studies too.	SML(Tp) = 3.0 mg/kg		+	
630	+	73680	B.E.UK.	00126-73-8	*PHOSPHORIC ACID, TRIBUTYL ESTER	6B	Bx	M54/M46 /Rx	46	956/2117//	R: 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w. Available: Ames test and several subchronic oral rat studies. Needed: remaining toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation studies and neurotoxicity studies too.	SML(Tp) = 3.0 mg/kg		+	+
1232	+	73720	UK	00115-96-8	PHOSPHORIC ACID, TRICHLOROETHYL ESTER	4	Ax	M54/M46	54	956//		Carcinogenic to rats. (NTP Tech. Rep. Ser. N. 391, May 1991).	SML = ND (DL = 0.01 mg/kg)	UP	+	
964	+	73760	N.	-	*PHOSPHORIC ACID, TRIETHANOL ESTER	9	Bx	M54/M46 /M37	46	956/2117//	R(Tp)= 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w.	SML(Tp) = 3.0 mg/kg	PTFE/give formula	+	+
631	+	73840	B.UK.	00126-71-6	*PHOSPHORIC ACID, TRIISOBUTYL ESTER	6B	Bx	M54/M46 /Rx	46	956/2117//	R: 0.05 mg/kg bw	Group R: 0.05 mg/kg bw. Needed: toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg peroxisome proliferation studies and neurotoxicity studies too.	SML(Tp) = 3.0 mg/kg		+	+
632	+	73920	UK.	00115-86-6	*PHOSPHORIC ACID, TRIPHENYL ESTER	6B	Bx	M54/M46 /Rx	46	956/1287,1462,2117//		Needed: toxicological data depending on migration level (see SCF guidelines) and, if		CA,PES,PET	+	

LIST OF ADDITIVES UPDATED TO 21 OCTOBER 1993

Rec n	U	PM/REF N.	COUNTRY	CAS N.	NAME	SCF L	EEC L.	SCF M/R	AGE NDA	CS/PM	R	OPINION SCF	RESTRICTIONS	REMARKS	MAT PL	MAT C
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	16	17
614	+	74160	B.D.E.	13423-78-4	*PHOSPHOROUS ACID, TRIS-2-(CYCLOHEXYLPHENYL) ESTER	6B	Bx	M54/M46 /Rx	46	956,2117//		Needed: toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, neurotoxicity studies too.		PC	+	+
636	+	74320	D.E.	39865-35-5	*PHOSPHOROUS ACID, TRIS((3-ETHYL-3-OXETANYL)-METHYL) ESTER	6B	Bx	M54/M46 /Rx	46	956/2117//		Needed: toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, neurotoxicity studies too.		PC	+	+
640	+	74560	B.D.E.F.N. UK.	00085-68-7	PHTHALIC ACID, BENZYL BUTYL ESTER	2	Ax	M54/Rx	54	17,30,38,105 ,2117//	0.1*	t-TDI: 0.1 mg/kg b.w. Available: 6-month oral rat study, carcinogenicity and peroxisome proliferation studies in vitro. (RIVM 1987, September). Needed: reproduction, teratogenicity and peroxisome proliferation studies.	SML= 6 mg/kg	PVC,PVDC	+	+
1691	+	74600	N		*PHTHALIC ACID, BIS(ALKOXYALKYL C3-C18) ESTER	9	Bx	M54/M49	48	1083,2117//	R(Tp)= 0.05 mg/kg bw	Group R: 0.05 mg/kg bw.	SML(Tp) = 3 mg/kg			+
641	+	74640	B.D.E.F.I. N.UK.	00117-81-7	PHTHALIC ACID, BIS(2-ETHYLHEXYL) ESTER	2	Ax	M54/M42 /R1	55, 56	1791+,2066// 2161 (Rivm)	0.05 mg/kg	TDI: 0.05 mg/kg b.w. Postponed to 55M the individual opinion on the substance.	SML= 3.0 mg/kg		+	+
642		74720	B.E.I.	00117-82-8	*PHTHALIC ACID, BIS(2-METHOXYETHYL) ESTER	6B	Bx	M53/M49 /M46	53	956/1051//	R: 0.05 mg/kg	R: 0.05 mg/kg of food (by analogy with 53860). Suspected of embriotoxicity/teratogenicity. Available: some studies, but inadequate.	SML = 0.05 mg/kg (as ethyleneglycol monoethyl ether)	CA,PVC	+	+
1692	+	74760	I	27987-25-3	*PHTHALIC ACID, BIS(METHYLCYCLOHEXYL) ESTER	9	Bx	M54/M49	48	10,1083,2117 //	R(Tp)= 0.05 mg/kg bw	Group R: 0.05 mg/kg bw.	SML(Tp) = 3 mg/kg			+
643	+	74800	B.D.E.F.N.	68515-41-3	*PHTHALIC ACID, DIALKYL (C7-C11) ESTERS	6B	Bx	M54/M49	54	1792+,2217//	R: 0.05	Group R: 0.05 mg/kg b.w.	SML(Tp)= 3.0 mg/kg	Similar to	+	+

Rec n	U	PM/REF N.	COUNTRY	CAS N.	NAME	SCF L	EEC L.	SCF M/R	AGE NDA	CS/PM	R	OPINION SCF	RESTRICTIONS	REMARKS	MAT PL	MAT C
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	16	17
											bw	depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation studies too.				
650	+	75360	B.D.E.I.N. UK.	?	PHTHALIC ACID, DIISODECYL ESTER	2-P	Ax	M54/M45 /Rx	56	1793+ (Feigenbaum)	0.05*	t-TDI: 0.05 mg/kg bw. Available: 90-day oral rat and dog studies, mutagenicity studies. (RIVM report, 1 September 1987). Needed: specifications on identity, establishment of NOEL for peroxisome proliferation, reproduction and teratogenicity studies. To be re-examined.	SML= 3 mg/kg	Mixt	+	+
651	+	75440	B.D.E.I.UK	?	PHTHALIC ACID, DIISONONYL ESTER	2-P	Ax	M54/M43 /Rx	56	1794+ (Feigenbaum)	0.03*	t-TDI: 0.03 mg/kg b.w. Available: a 2-year oral rat study, teratogenicity, mutagenicity and peroxisome proliferation studies. (Exxon project n. 326075, January 13, 1986). Needed: specifications on identity, reproduction and teratogenicity studies. To be re-examined (cs/pm/568).	SML= 1.8 mg/kg	CAS N. to be added (CS/PM/568)/Mix t	+	+
652	+	75520	B.D.E.I.UK	27554-26-3	*PHTHALIC ACID, DIISOOCTYL ESTER	9	Bx	M54/M46 /Rx	46	1859+/2117//	R(Tp)= 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w.	SML(Tp)= 3.0 mg/kg		+	+
653	+	75600	B.D.E.N.UK	00131-11-3	*PHTHALIC ACID, DIMETHYL ESTER	6B-P	Bx	M54	56	1287,2044,2117//2157 (Rivm)	R: 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w. Needed: (to be fixed at 55M).	SML(Tp) = 3.0 mg/kg		+	
1693	+	75640	D	00084-77-5	*PHTHALIC ACID, DI-n-DECYL ESTER	6B	Bx	M54/M49	53	828,1083,2044,2117//	R: 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w. Needed: toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation	SML(Tp) = 3.0 mg/kg			+

Rec n	U	PM/REF N.	COUNTRY	CAS N.	NAME	SCF L	EEC L.	SCF M/R	AGE NDA	CS/PM	R	OPINION SCF	RESTRICTIONS	REMARKS	MAT PL	MAT C
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	16	17
												migration exceeds 0.050 mg/kg peroxisome proliferation too.				
659	+	76080	B.E.I.UK.	-	*PHTHALIC ACID, MIXED ESTERS WITH ETHYL GLYCOLATE AND ALCOHOLS, ALIPH.,MONOH., (C1-C4)	9	Bx	M54/M46 /Rx	46	956/2117//	R(Tp)= 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w.	SML(Tp)= 3.0 mg/kg		+	
977	+	76085	B.E.I.N.UK	00084-72-0	*PHTHALIC ACID, MIXED ESTERS WITH ETHYL GLYCOLATE AND ETHANOL	6B	Bx	M54/M46 /Rx	46	956,2117//	R: 0.025 mg/kg bw	Group R: 0.05 mg/kg b.w. Available: 4-month and 2-year rat and 1-year dog studies all inadequate. Needed: toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation studies too.	SML(Tp) = 3.0 mg/kg		+	+
1857	+	76120	D	68442-70-6	PHTHALIC ACID, n-HEXADECYL n-OCTADECYL ESTER	2	Ax	M54/M51 /M49	54	1083,2044,2117//	R:0.15T *	Group t-TDI = 0.15 mg/kg bw (with 75040). Covered by Group t-TDI for 75040.	SML = 9 mg/kg (with 75040)	Cov. by 75040		+
660	+	76160	B.	01240-18-2	*o-PHTHALIC ACID, n-PENTYL BENZYL ESTER	6B	Bx	M54/M46 /Rx	46	956,2117//	R: 0.025 mg/kg	Group R: 0.05 mg/kg b.w. Needed: toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation studies too.	SML(Tp) = 3.0 mg/kg	PVC,PVDC	+	
665		76480	N.	-	*POLYAMIDES (MW>6000)	9	Bx	M53/Rx	53			In first instance, specify the nature of starting substances and provide the MW distribution curve.		POM	+	
2089		77035		68891-38-3	*POLYETHYLENEGLYCOL (EO=2-3) ALKYL(C12-C14)ETHER SODIUM SULPHATE	8	Bx	M53	53	1653//				S1(78720)	+	
683		77600	E.UK.	61788-85-0	POLYETHYLENEGLYCOL ESTER OF HYDROGENATED CASTOR OIL	3	Ax	M53/Rx	53	136,1665,1762//		L3. Based on TDI for 77520 and L3 for 14470.			+	
2124	+	77602		61788-85-0	*POLYETHYLENEGLYCOL (EO = 40) ESTER OF HYDROGENATED CASTOR OIL	D	D	M53	53	1665//				S1(77600)	+	

Rec n	U	PM/REF N.	COUNTRY	CAS N.	NAME	SCF L	EEC L.	SCF M/R	AGE NDA	CS/PM	R	OPINION SCF	RESTRICTIONS	REMARKS	MAT PL	MAT C
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	16	17
1753	+	83630	UK	68956-82-1	RESIN ACIDS AND ROSIN ACIDS, COBALT SALTS	2-3	Ax	M53/M52	52, 54	1083,1707//	R(T)=0.05(as Co)/1T	L3 for Cobalt. R: 0.05 mg/kg of food (as Co). (RIVM, summary data, October 1992)(CS/PM/1707). L2 for resin and rosins acids. TDI: 1 mg/kg bw.	SML(T) = 0.05 mg/kg (as Co)			+
1756	+	83660	UK		*RESIN ACIDS AND ROSIN ACIDS, ZIRCONIUM SALTS	7	Bx	M54/M52	54	1083/2091//		L2(= 1 mg/kg bw) for resin acids. L7 for zirconium. See references for 54220.				+
1757	+	83720	UK	07492-63-9	*RICINOLEIC ACID, CERIUM SALT	8	Bx	M54/M52	54	1083/2090//		L2 (=0.7 mg/kg bw) for ricinoleic acid. L8 for cerium.				+
1760	+	83820	UK		*RICINOLEIC ACID, ZIRCONIUM SALT	7	Bx	M54/M52	54	1083/2091//		L2 (=0.7 mg/kg bw) for ricinoleic acid. L7 for zirconium. See references for 54220.				+
791	+	85040	N.UK.	-	*SEBACIC ACID, ALKYL (C6-C12) ESTERS	9	Bx	M54/M46 /Rx	46	956/2117//	R(Tp)= 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w.	SML(Tp)= 3.0 mg/kg	PVC	+	
792	+	85120	B.E.F.I.N. UK.	00122-62-3	*SEBACIC ACID, BIS(2-ETHYLHEXYL) ESTER	6B	Bx	M54/M46 /Rx	46	956/2117//	R: 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w. Available: Ames test and 3-week oral rat study. Needed: remaining toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation studies too.	SML(Tp) = 3.0 mg/kg	PVC	+	+
793	+	85200	B.E.N.	27214-90-0	*SEBACIC ACID, BIS(6-METHYLHEPTYL) ESTER	6B	Bx	M54/M46 /Rx	46	956,2117//	R: 0.025 mg/kg bw	Group R: 0.05 mg/kg b.w. Needed: toxicological data depending on migration level (see SCF guidelines) and, if	SML(Tp) = 3.0 mg/kg	PVC	+	

Rec n	U	PM/REF N.	COUNTRY	CAS N.	NAME	SCF L	EEC L.	SCF M/R	AGE NDA	CS/PM	R	OPINION SCF	RESTRICTIONS	REMARKS	MAT PL	MAT C
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	16	17
												Hydrolysis<95% (doc. CS/PM/1023). Needed: 90-day oral study, gene mutation and chromosome aberration in mammalian cells, bioaccumulation to be performed with erucamide, oleamide, or stearamide or demonstrate full hydrolysis by method suggested by applicant (CS/PM/1550).				
1770	+	89150	UK	10119-53-6	*STEARIC ACID, CERIUM SALT	8	Bx	M54/M52	54	1083/2090//		L1(= not specified) for stearic acid. L8 for cerium.				+
1772	+	90680	UK	15844-92-5	*STEARIC ACID, ZIRCONIUM SALT	7	Bx	M54/M52	54	1083,2081//		L1(=not specified) for stearic acid. L7 for zirconium. See references for 54220.				+
880	+	91540	B.D.E.N.UK	-	*SULPHOSUCCINIC ACID, ALKYL(C4-C20) ESTERS, SALTS	9	Bx	M54/Rx	54	1803+,2117//	R(Tp)= 0.05 mg/kg bw	Group R: 0.05 mg/kg bw.	SML(Tp) = 3 mg/kg		+	+
1924	+	91560		02373-38-8	*SULPHOSUCCINIC ACID, BIS(1,3-DIMETHYLBUTYL) ESTER, SODIUM SALT	6B	Bx	M54/M49	48	1871+2117//		Group R: 0.05 mg/kg b.w. Needed: toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation studies.	SML(Tp) = 3.0 mg/kg	S1(91600)	+	
2072	+	91570		10041-19-7	*SULPHOSUCCINIC ACID, BIS(2-ETHYLHEXYL)ESTER	6B	Bx	M54	54	1872+,2044,2117//		Group R: 0.05 mg/kg b.w. Needed: toxicological data depending on migration level (see SCF guidelines) and if migration exceeds 0.050 mg/kg peroxisome proliferation study too.	SML(Tp) = 3.0 mg/kg	S1(91600)	+	+
1926	+	91630		03006-15-3	*SULPHOSUCCINIC ACID, DIHEXYL ESTER, SODIUM SALT	6B	Bx	M54/M49	48	829,1287,1466*,2117//		Group R: 0.05 mg/kg b.w. Needed: toxicological data	SML(Tp) = 3.0 mg/kg	S1(9600)	+	

Rec n	U	PM/REF N.	COUNTRY	CAS N.	NAME	SCF L	EEC L.	SCF M/R	AGE NDA	CS/PM	R	OPINION SCF	RESTRICTIONS	REMARKS	MAT PL	MAT C
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	16	17
					SALT					117//		Needed: toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation studies too.				
1929	+	91800		37294-49-8	*SULPHOSUCCINIC ACID, ISODECYL ESTER, DISODIUM SALT	6B	Bx	M54/M49	48	825,1250*,2117//		Group R: 0.05 mg/kg bw. Needed: toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.05 mg/kg peroxisome proliferation studies too.	SML(Tp) = 3 mg/kg	S1(9160O)	+	
1779	+	93000	D	10526-15-5	*THIODIPROPIONIC ACID, BIS(2-ETHYLHEXYL) ESTER	6B-P	Bx	M54/M49	53	1083,2044,2117//		Group R: 0.05 mg/kg bw. Needed: toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation studies too.	SML(Tp) = 3.0 mg/kg			+
905	+	93040	B.UK.	-	*THIODIPROPIONIC ACID, DIBEHENYL ESTER	6B	Bx	M54/Rx	-	2117//		Group R: 0.05 mg/kg bw. Needed: toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation studies too.	SML(Tp) = 3 mg/kg	Not in EINECS/To be del	+	
906		93120	B.D.E.F.I. N.UK.	00123-28-4	*THIODIPROPIONIC ACID, DIDODECYL ESTER	6B	Bx	M54/M50 /M46/R1	54-P	1804+,2044,2103,2117	R: 0.05 mg/kg bw	Group R: 0.05 mg/kg b.w. Needed: toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation too.	SML(Tp) = 3 mg/kg		+	+
907	+	93200	B.E.I.UK.	03287-12-5	*THIODIPROPIONIC ACID, DIHEXADECYL ESTER	6B	Bx	M54/Rx	-	1368*,2117//		Group R: 0.05 mg/kg bw. Needed: toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.05O mg/kg, peroxisome proliferation studies too.	SML(Tp) = 3 MG/KG		+	+

LIST OF ADDITIVES UPDATED TO 21 OCTOBER 1993

Rec n	U	PM/REF N.	COUNTRY	CAS N.	NAME	SCF L	EEC L.	SCF M/R	AGE NDA	CS/PM	R	OPINION SCF	RESTRICTIONS	REMARKS	MAT PL	MAT C
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	16	17
935	+	95440	B.D.E.I.N	00144-15-0	*TRIS(2-ETHYLHEXYL) ACETYLCITRATE	6B	Bx	M54/M46 /Rx	46	956,2117//	R: 0.025 mg/kg bw	Group R: 0.05 mg/kg b.w. Needed: toxicological data depending on migration level (see SCF guidelines) and, if migration exceeds 0.050 mg/kg, peroxisome proliferation studies too.	SML(Tp) = 3.0 mg/kg		+	+
1002	+	95882	B.D.E.UK	08042-47-5	WHITE MINERAL OIL (CONVENTIONAL)	2	Ax	M53/M39 /M37	54	195,213,219, 239,256,331/ /	0.005*T	Group t-TDI: 0.005 mg/kg b.w. See references for 59950 in list 2.	SML(T)= 0.3 mg/kg for all conventional products (see introduction of the annex)		+	
1281	+	95945	B.UK	01330-20-7	XYLENE	3	Ax	M53/M52	53	1712//	R=1.2 mg/kg	R: 1.2 mg/kg food. See references for the same compound (PM/REF.N. 26370) in monomer list.	SML = 1.2 mg/kg	PVC/Same 26370/odor threshold 25 ppb.	+	+
1792	+	96400	D.N	53801-45-9	*ZIRCONIUM OXIDE	7	Bx	M54	54	1083/2091//		L7 for zirconium. See references for 54220.				+
1793	+	96480	N	32535-84-5	*ZIRCONYL AMMONIUM CARBONATE	7	Bx	M54	54	1083//		See references for 54220.				+

*** Total ***
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