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Commission of the European Communities

# **food — science and techniques**

## **Reports of the Scientific Committee for Food**

(Seventeenth series)



**Report**

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Directorate-General  
Internal Market and Industrial Affairs

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REPORT OF THE SCIENTIFIC COMMITTEE FOR FOOD ON CERTAIN MONOMERS AND OTHER STARTING  
SUBSTANCES TO BE USED IN THE MANUFACTURE OF PLASTIC MATERIALS AND ARTICLES INTENDED TO  
COME INTO CONTACT WITH FOODSTUFFS

(Opinion expressed 14th December 1984)

TERMS OF REFERENCE

To advise on the toxicological assessment of certain monomers and other starting substances migrating into food from plastic materials and articles intended to come into contact with foodstuffs.

BACKGROUND

1. The outline Directive on Materials and Articles intended to come into Contact with Foodstuffs (76/983/EEC) (1) provides in Article 3 that:
  - the Council shall adopt by means of Directives special provisions applicable to certain groups of materials and articles (specific Directives);
  - such specific Directives may include among other provisions a list of the substances the use of which is authorized to the exclusion of all others (positive list).
2. Monomers and other starting substances (hereinafter referred to as "monomers") were selected for toxicological assessment as a first group of chemical substances used in the manufacture of plastic materials and articles intended to come into contact with foodstuffs (hereinafter referred to as "plastic materials and articles"), because
  - a number of monomers used in the manufacture of such plastic materials and articles might constitute a danger to human health if they migrate into food in toxicologically significant amounts,
  - in certain Member States of the Community differing legislation or recommendations exist which constitute a technical barrier to intercommunity trade in these plastic materials and articles or in the foodstuffs in contact with these products.

Initially the Committee was requested by the Commission to express an opinion on the toxicological assessment of the first list of monomers, in which were included many substances already examined and, where appropriate, evaluated by the Council of Europe (2). The Committee was informed that, meanwhile, other lists of monomers had been prepared by the Commission at the request of the government authorities and other organisations. For practical reasons the Commission asked the Committee to finalise the examination of the monomers listed in the Annexes I and II.

The Committee evaluated the data available to it before the end 1984 and the Commission made its views known to governments and interested organizations, since then other information has become available and the present opinion takes account of the new data.



## CURRENT REVIEW

1. The Committee was informed by the Commission that it is intended to regulate plastic materials and articles coming into contact with food by directives based on the principle of positive lists.

In elaborating its advice the Committee has taken into consideration its guidelines on the "Toxicological evaluation of a substance for materials and articles intended to come into contact with foodstuffs" (3). Each substance examined in this report was evaluated on the basis of information on its properties, on its use in plastic materials and articles and toxicity submitted to the Committee. Unpublished data available to the Committee are listed among the references. (See Annex III).

2. In some cases the evaluation of the Committee differs from that of the Council of Europe, because new toxicological data have become available for some of the listed substances subsequent to the publication of the Council of Europe Report and because new scientific developments in toxicology, e.g. concerning genotoxicity, have been taken into consideration.
3. For the purposes of this Report the Committee endorsed the ADIs (Acceptable Daily Intake) for food additives established by JECFA (4) without necessarily reviewing the data base for the JECFA-decision because of the low level of intake likely to arise from the migration of monomers into food. In other cases the Committee referred to the ADIs it had established in previous reviews as published in its reports. ADIs relate to the total intake from food.
4. The Committee considered that many of the monomers which could migrate potentially from plastic materials and articles might also migrate from other materials, when present therein, into the same or other foods or might be ingested from other sources. The Committee established Tolerable Daily Intakes (TDI) where the data sufficed for this purpose. In selecting this approach the Committee was aware that the available toxicological data were less extensive than in the case of food additives. Therefore, in establishing these TDIs a particularly cautious approach was chosen involving the choice of a larger safety factor than usual. The Committee emphasises however, that the procedure adopted for establishing TDIs for these migrants differs from the well known classical procedures for establishing ADIs. The TDIs need not be restricted in their applicability to substances used in plastic materials and articles. The TDIs are valid equally if these substances are used as components in the manufacture of any other groups of materials and articles for food packaging. If individual TDIs have been set for closely related substances these must be reduced proportionately when mixtures of these substances are used.
5. The Committee emphasises that, for toxicological reasons as well as for food hygiene, migration of such substances into foods from plastic materials and articles should be limited. The Committee therefore recommended that the finished plastic materials and articles contain the lowest possible level of residual free monomer. (This may also avoid a situation in which most of a TDI is taken up by a substance approved for use in plastic materials and articles and thus blocking its use in other packaging materials and articles, where it might also be technologically required).
6. During its consideration of the available toxicological information the Committee noted that practically no relevant information existed in many instances on the effects of individual substances concerning reproduction or on teratogenicity. Data on mutagenic



potential were incomplete in several cases. These aspects could therefore not be considered in the present evaluation of such substances but may well be in future re-evaluations.

7. List 4 contains some substances for which sensitive methods of analysis have been developed and for which very low migration limits have been set. For the other substances on List 4 similar sensitive methods should be developed so that appropriate low migration limits could be defined. The Committee recognises that these substances are known to be toxic. They are, however, essential for polymer technology generally at present. The Committee recommends that appropriate sensitive methods of analysis should be developed within three years of publication of this report.
8. Conclusions on the toxicological assessment - with selected references - were prepared for those substances for which the Committee was able to express an opinion. These are listed in Annex III.
9. The Committee considered that the substances in list 6 for which data are lacking or are insufficient were suspected of being toxic. The Committee recommends that information be supplied or that appropriate toxicological tests be made as soon as possible.

Lists 7 and 8 also contain substances of concern due respectively to the incompleteness or absence of the available data.

10. The Committee recognises that priorities will have to be set because of the large number of substances contained in lists 6, 7 and 8 and the volume of experimental work that would be necessary to provide a basis for toxicological assessment of each substance mentioned. The criteria for setting these priorities should include, for example, data on exposure (e.g. usage, extent of migration), availability of analytical methods, the toxicological and biochemical profile, and consideration of chemical structure in relation to toxicity (this last approach was used in preparing list 6). In setting priorities, the Committee recommends that the Commission obtain within 3 years the relevant data mentioned above and should invite industry and governments to provide information and assistance to enable the Committee to conclude its evaluation.
11. The Committee draws attention to the need for ensuring that in the manufacture of plastic materials and articles the requirements in the "guidelines"<sup>(3)</sup> concerning quality and specifications are followed. The Committee recommends the development of procedures to permit examination of plastic materials and articles with respect to compliance with the conclusions of this report.
12. Whenever an acid has been evaluated, the assessment also includes aluminium, ammonium, calcium, magnesium, potassium, sodium and zinc salts.
13. Substances for which the Committee was able to express an opinion are reported in Annex I. Substances for which there was insufficient toxicological or technological data to enable the Committee to express an opinion are reported in Annex II. Where CAS numbers are available these are specified to the left of the chemical name (some CAS numbers have an asterisk).
14. Where the required data are not specified in the lists and for new substances the information needed in general for assessment has been set out elsewhere by the Committee in its Guidelines (3), but will also depend on the migration data.

15. Annex I consists of the following 6 lists

List 0

Substances which may be used in the production of plastic materials and articles, e.g. food ingredients and certain substances known from the intermediate metabolism in man and for which an ADI need not be established.

List 1

Substances for which an ADI has been established by JECFA or this Committee.

List 2

Substances for which a TDI has been established by this Committee.

List 3

Substances for which an ADI or TDI could not be established, but where the continued use could be accepted.

List 4

Section A

Substances for which an ADI or TDI could not be established, but which could be used if the substance migrating into food is not detectable by an agreed sensitive method (see also para 7).

Section B

Substances for which an ADI or TDI could not be established, but which could be used if the levels of monomer residues in materials and articles intended to come into contact with foodstuffs are reduced, as much as possible.

List 5

Reserved for substances which should not be used.

16. Annex II consists of the following 4 lists

List 6

Substances suspected of being toxic for which data are lacking or are insufficient. The Committee recommends that information be supplied or that appropriate toxicological tests be made as soon as possible.

List 7

Substances for which some toxicological data exist, but for which an ADI or TDI could not be established. The additional specified information should be furnished. The list will be reevaluated.

List 8

Substances for which no or only scanty and inadequate data were available.

### List 9

Groups of substances which could not be evaluated due to lack of specificity. These groups should be replaced by individual substances actually in use.

17. Annex III contains selected references for substances, for which the Committee was able to express an opinion

### REFERENCES

- (1) OJ No L 340, 9.12.1976.
- (2) Council of Europe Publication "Substances used in plastic materials coming into contact with food" 2nd Edition, Strasbourg 1982.
- (3) Commission of the European Communities, Report of the Scientific Committee for Food (3rd Series, 1977).
- (4) JECFA = Joint FAO/WHO Expert Committee on Food Additives.

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SUBSTANCES FOR WHICH THE COMMITTEE WAS ABLE TO EXPRESS AN OPINIONLIST 0

Substances which can be used in the production of plastic materials and articles, e.g. food ingredients and certain substances known from the intermediate metabolism in man

-	Acids, aliphatic linear saturated and unsaturated C <sub>6</sub> -C <sub>22</sub> with an even number of carbon atoms.
107-92-6	Butyric acid
124-07-20	Caprylic acid
8001-79-4	Castor oil (food grade quality only)
9004-34-6	Cellulose
68442-85-3	Cellulose regenerated
64-17-5	Ethanol
61788-47-4 *	Fatty acids coco
68308-53-2 *	Fatty acids soya
50-99-7	Glucose
57-10-3	Palmitic acid
68425-13-8 *	Rubber natural
8001-22-7 *	Soybean oil
57-11-4	Stearic acid
110-15-6	Succinic acid
57-50-1	Sucrose
57-13-6	Urea

LIST 1

Substances for which an ADI has been established by JECFA or this Committee

64-19-7	Acetic acid	Group ADI: not specified in the ADI for acetic acid (JECFA 17. M.)
108-24-7	Acetic anhydride	" " "
124-04-9	Adipic acid	ADI: 5 mg/kg b.w. (JECFA 21. M)
100-51-6	Benzyl alcohol	Group ADI: 5 mg/kg b.w. in the ADI for benzoic acid (SCF 11th Series)
107-88-0	1,3-Butanediol	ADI: 4 mg/kg b.w. (JECFA 23. M)
77-92-9	Citric acid	ADI: not specified (JECFA 25. M)
110-17-8	Fumaric acid	ADI: 6 mg/kg b.w. (JECFA 18. M)
56-81-5	Glycerol	ADI: not specified (JECFA 20. M)
7664-38-2	Phosphoric acid	MTDI <sup>1</sup> : 70 mg/kg b.w. (JECFA 26. M)
57-55-6	1,2-Propanediol	
	/=1,2-Propyleneglycol/	ADI: 25 mg/kg b.w. (JECFA 17. M)
67-63-0	2-Propanol	ADI: 1.5 mg/kg b.w., Temporary (SCF 11th Series)
79-09-4	Propionic acid	ADI: not specified (JECFA 17. M)
50-70-4	Sorbitol	ADI: not specified (JECFA 25. M)
112-60-7	Tetraethyleneglycol	ADI: 10 mg/kg b.w. (JECFA 23. M)

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<sup>1</sup> Maximum tolerable daily intake. It is not an ADI.

LIST 2

Substances for which a TDI has been established by this Committee

75-07-0	Acetaldehyde	TDI : 0.1 mg/kg b.w.
79-10-7	Acrylic acid	Group TDI : 0.1 mg/kg b.w. Temporary
141-32-2	Acrylic acid, n-butyl ester	" " "
818-61-1	Acrylic acid, ethyleneglycol monoester	" " "
140-88-5	Acrylic acid, ethyl ester	" " "
106-63-8	Acrylic acid, isobutyl ester	" " "
689-12-3	Acrylic acid, isopropyl ester	" " "
96-33-3	Acrylic acid, methyl ester	" " "
925-60-0	Acrylic acid, n-propyl ester	" " "
- . -	Alcohols aliphatic monohydric saturated (C9-C15)	TDI : 1 mg/kg b.w.
123-99-9	Azelaic acid	Group TDI : 3 mg/kg b.w.
111-20-6	Sebacic acid	" " "
111-46-6	Bis(2-hydroxyethyl)ether /=diethylene glycol/	Group TDI : 0.5 mg/kg b.w.
107-21-1	1,2-Ethandiol /=ethylene glycol/	" " "
77-99-6	2,2-Bis(hydroxymethyl)-1-butanol /=1,1,1-trimethylolpropane/	TDI : 0.1 mg/kg b.w.
80-05-7	2,2-Bis(4-hydroxyphenyl)propane /=bisphenol A/	TDI : 0.05 mg/kg b.w.
47465-97-4	3,3-Bis(3-methyl-4-hydroxyphenyl) -2-indolinone	TDI : 0.03 mg/kg b.w.
105-60-2	Caprolactam	Group TDI: 0.25 mg/kg b.w.
2123-24-2	Caprolactam sodium salt	" " "
- . -	Cardura /=glycidyl ester of versatic acid/	TDI : 0.1 mg/kg b.w.
107-15-3	1,2-Diaminoethane /=ethylene-diamine/	TDI : 0.2 mg/kg b.w.
124-09-4	1,6-Diaminohexane /=hexamethylene-diamine/	TDI : 0.04 mg/kg b.w.
106-46-7	p-Dichlorobenzene	TDI : 0.1 mg/kg b.w.
120-80-9	1,2-Dihydroxybenzene/=pyrocatechol/	TDI : 0.1 mg/kg b.w.
108-46-3	1,3-Dihydroxybenzene /=resorcinol/	TDI : 0.04 mg/kg b.w.
123-31-9	1,4-Dihydroxybenzene /=hydro-quinone/	TDI : 0.01 mg/kg b.w.
108-01-0	Dimethylaminoethanol	TDI : 0.3 mg/kg b.w.
126-58-9	Dipentaerythritol	Group TDI : 1 mg/kg b.w.
115-77-6	Pentaerythritol	" " "



25265-71-8 and 110-98-5	Dipropylene glycol/=bis(hydroxy- propyl) ether/	Group TDI : 1.5 mg/kg b.w. (with 1,2 polypropylene glycol)
25322-69-4	1,2-Polypropylene oxide	" " "
111-27-3	1-Hexanol	TDI : 2 mg/kg b.w.
110-16-7	Maleic acid	Group TDI : 0.5 mg/kg b.w. expressed as maleic acid
108-31-6	Maleic anhydride	" " "
108-78-1	Melamine	TDI : 0.5 mg/kg b.w.
79-41-4	Methacrylic acid	Group TDI : 0.1 mg/kg b.w.
760-93-0	Methacrylic acid anhydride	" " "
97-88-1	Methacrylic acid, butyl ester	" " "
97-63-2	Methacrylic acid, ethyl ester	" " "
97-86-9	Methacrylic acid, isobutyl ester	" " "
80-62-6	Methacrylic acid, methylester	" " "
2210-28-8	Methacrylic acid, propylester	" " "
143-08-8	1-Nonanol	TDI : 1 mg/kg b.w.
71-41-0	1-Pentanol	TDI : 2 mg/kg b.w.
108-95-2	Phenol	TDI : 1.5 mg/kg b.w.
25322-68-3	Polyethylene oxide	Group TDI : 5 mg/kg b.w.
112-27-6	Triethylene glycol	" " "
85-44-9	Phthalic anhydride	TDI : 1 mg/kg b.w.
- . -	Resin acids	Group TDI : 1 mg/kg b.w.
61790-12-3 *	Fatty acids tall oil	" " "
8050-09-7 *	Rosin /=colophony/	" " "
8050-07-7	Rosin gum	" " "
8052-10-6	Rosin tall oil	" " "
9014-63-5	Rosin wood	" " "
514-10-3	Abietic acid	" " "
100-21-0	Terephthalic acid	tTDI: 0.125 mg/Kg b.w.
120-61-6	Terephthalic acid, dimethyl ester	TDI : 1 mg/kg b.w.
109-99-6	Tetrahydrofuran	TDI : 0.05 mg/kg b.w.
102-60-3	N,N,N',N'-Tetrakis(2-hydroxy- propyl)ethylenediamine	TDI : 1 mg/kg b.w.
108-05-4	Vinyl acetate	TDI : 0.2 mg/kg b.w.

LIST 3

Substances for which an ADI or TDI could not be established but where the continued use could be accepted

74-86-2	Acetylene
105-08-8	1,4-Bis(hydroxymethyl)cyclohexane /1,4-cyclohexanedimethanol/
71-36-3	1-Butanol
106-98-9	1-Butene
107-01-7	2-Butene
123-72-8	Butyraldehyde
- . -	Cellulose nitrate
7782-50-5	Chlorine
108-39-4	m-Cresol
95-48-7	o-Cresol
106-44-5	p-Cresol
74-85-1	Ethylene
50-00-0	Formaldehyde
100-97-0	Hexamine/=hexamethylenetetramine/
115-11-7	Isobutene
67-56-1	Methanol
80-56-8	alpha-Pinene
127-91-3	beta-Pinene
71-23-8	1-Propanol
123-38-6	Propionaldehyde
115-17-1	Propylene
1313-82-2	Sodium sulfide

LIST 4

SECTION A

Substances for which an ADI or TDI could not be established but which could be used if the substance migrating into food is not detectable by an agreed sensitive method

107-13-1	Acrylonitrile (1)
106-99-0	1,3-Butadiene
3173-53-3	Cyclohexyl isocyanate
5124-30-1	Dicyclohexylmethane-4,4'-diisocyanate
91-97-4	3,3'-Dimethyl-4,4'-diisocyanatobiphenyl
5873-54-1	2,4'-Diphenylmethane-diisocyanate
4128-73-8	Diphenylether-4,4'-Diisocyanate
101-68-8	4,4'-Diphenylmethane-diisocyanate
106-89-8	Epichlorhydrin
151-56-4	Ethyleneimine
75-21-8	Ethylene oxide
822-06-0	Hexamethylene diisocyanate
126-98-7	Methacrylonitrile
3173-72-6	1,5-Naphthylene diisocyanate
75-44-5	Phosgene
75-56-9	Propylene oxide
112-96-9	Stearyl isocyanate
584-84-9	2,4-Toluene-diisocyanate
26747-90-0	2,4-Toluene diisocyanate dimer
91-08-7	2,6-Toluene-diisocyanate
75-01-4	Vinyl chloride (2)

SECTION B

Substances for which an ADI or TDI could not be established but which could be used if the levels of monomer residues in materials and articles intended to come into contact with foodstuffs are reduced as much as possible

100-42-5	Styrene (1)
75-35-4	Vinylidene chloride (1)

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(1) See the individual opinion given in the Report of the Scientific Committee for Food (13rd series, 1982)

(2) See the individual opinion given in the Report of the Scientific Committee for Food (1st series, 1975)

LIST 5

Reserved for substances which should not be used

SUBSTANCES WITH INSUFFICIENT TOXICOLOGICAL OR TECHNOLOGICAL DATA FOR THE COMMITTEE TO EXPRESS AN OPINION

LIST 6

Substances suspected of being toxic for which data are lacking or are insufficient. The Committee recommends that information be supplied or that appropriate toxicological tests be made as soon as possible.

106-90-1	Acrylic acid, 2,3-epoxypropyl ester /glycidyl acrylate/
107-05-1	Allyl glycidyl ether
- . -	Allylstyrenes
1204-28-0	Benzoylchloride-3,4-dicarboxylic anhydride
1675-54-3	2,2-Bis(4-hydroxyphenyl)propane diglycidyl ether /bisphenol A diglycidyl ether/
2425-79-8	1,4-Butanediol diglycidyl ether
115-28-6	Chlorendic acid /hexachloroendomethylenetetrahydrophthalic acid/
79-38-9	Chlorotrifluoroethylene
1631-25-0	N-Cyclohexylmaleimide
7748-43-8	Itaconic acid, 2,3-epoxypropyl monoester
- . -	Itaconic acid, 2,3-epoxypropyl diester
116-15-4	Hexafluoropropylene
106-91-2	Methacrylic acid, 2,3-epoxypropyl ester /glycidylmethacrylate/
561-92-8	Methallylsulfonate /2-methyl-2-propen-1-sodiumsulfonate/
122-60-1	Phenyl glycidyl ether
116-14-3	Tetrafluoroethylene
528-44-9	Trimellitic acid /1,2,4-benzentricarboxylic acid/
552-30-7	Trimellitic anhydride
689-97-4	Vinylacetylene
3195-78-6	N-Vinyl-N-methylacetamide
100-69-6	2-Vinylpyridine
100-43-6	4-Vinylpyridine
2768-02-7	Vinyltrimethoxysilane
1067-53-4	Vinyltris(2-methoxyethoxy)silane

LIST 7

Substances for which some toxicological data exist, but for which an ADI or TDI could not be established. The additional specified information should be furnished.

79-06-1	<u>Acrylamide</u> Is cumulatively neurotoxic in all species examined including man. An appropriate 90-day oral study showed neurological effects at 1 mg/kg b.w./day with NEL at 0.2 mg/kg b.w. (J. Env. Pathol. of Toxicol. 4, 1980, 155-182). Evaluation postponed until results of ongoing carcinogenicity and mutagenicity studies are available.  Needed: migration data and a sensitive analytical method.
999-55-3	<u>Acrylic acid, allyl ester</u> Needed: hydrolysis data.
2495-35-4	<u>Acrylic acid, benzyl ester</u> Needed: hydrolysis data.
19485-03-1	<u>Acrylic acid, 1,3-butanediol diester</u> Needed: hydrolysis data.
- . -	<u>Acrylic acid, 1,3-butanediol monoester</u> Needed: hydrolysis data.
1070-70-8	<u>Acrylic acid, 1,4-butanediol diester</u> Needed: hydrolysis data.
2478-10-6	<u>Acrylic acid, 1,4-butanediol monoester</u> Needed: hydrolysis data.
2206-89-5	<u>Acrylic acid, 2-chloroethyl ester</u> Needed : hydrolysis and migration data of chlorhydrin.
3066-71-5	<u>Acrylic acid, cyclohexyl ester</u> Needed : hydrolysis data.
16868-13-6	<u>Acrylic acid, cyclopentyl ester</u> Needed : hydrolysis data.
2426-54-2	<u>Acrylic acid, diethylaminoethyl ester</u> Needed :90-day oral study.
4074-88-8	<u>Acrylic acid, diethyleneglycol diester</u> Needed : hydrolysis data.
13533-05-6	<u>Acrylic acid, diethyleneglycol monoester</u> Needed : hydrolysis data

2274-11-5	<u>Acrylic acid, ethyleneglycol diester</u> Needed : hydrolysis data.
103-11-7	<u>Acrylic acid, 2-ethylhexyl ester</u> Needed : hydrolysis data.
13048-33-4	<u>Acrylic acid, 1,6-hexanediol diester</u> Needed : hydrolysis data.
25584-83-2	<u>Acrylic acid, hydroxypropyl ester</u> Needed : hydrolysis data.
999-61-1	<u>Acrylic acid, 2-hydroxypropyl ester</u> Needed : hydrolysis data.
5888-33-5	Acrylic acid, isobornyl ester Needed : hydrolysis data
1330-61-6	<u>Acrylic acid, isodecyl ester</u> Needed : hydrolysis data
5048-81-8	<u>Acrylic acid, phenylaminoethyl ester</u> Needed : hydrolysis data.
76570-48-9	<u>Acrylic acid, polyethyleneglycol diester</u> Needed : hydrolysis data.
39121-78-3	<u>Acrylic acid, sulfopropyl ester</u> Needed : hydrolysis data.
2177-18-6	<u>Acrylic acid, vinyl ester</u> Needed : hydrolysis data.
2035-75-8	<u>Adipic anhydride</u> Needed: hydrolysis data.
105-97-5	<u>Adipic acid, didecyl ester</u> Needed : migration and hydrolysis data.
27128-16-1	<u>Adipic acid, diisodecyl ester</u> Needed : hydrolysis data.
123-79-5	<u>Adipic acid, octyl ester</u> Needed : migration and hydrolysis data.
- . -	<u>Alcohols, aliphatic, saturated, monovalent C<sub>4</sub>-C<sub>18</sub></u> 1-Alcohols (except 1-butanol, 1-pentanol, 1-hexanol, 1-nonanol which are included in other Lists): 1-heptanol 1-octanol 1-decanol 1-undecanol 1-dodecanol .



1-tetradecanol  
1-hexadecanol  
1-octadecanol

Needed: information on actual use. One or two of these alcohols should be tested in a 28-day oral study to enable the evaluation of the whole group of 1-alcohols.

Alcohols, aliphatic, saturated, monovalent C<sub>4</sub>-C<sub>18</sub>  
2-, 3-, and 4-alcohols

2-hexanol  
3-hexanol  
2-heptanol  
3-heptanol  
4-heptanol  
2-octanol  
3-octanol  
2-nonanol  
2-undecanol  
2-dodecanol

Needed: information on actual use. One alcohol from this group should be tested in a 90-day oral study and in addition two other alcohols from this group should be tested in a 28-day oral study to enable the evaluation of the whole group of 2-, 3-, and 4-alcohols.

107-18-6

Allyl alcohol

Needed : new long-term oral studies.

2855-13-2

1-Amino-3-aminomethyl-3,5,5-trimethylcyclohexane

Needed : 90-day oral study and mutagenicity studies.

80-46-6

p-tert-Amylphenol

Needed : migration, 90-day oral study

4196-95-6

Azelaic acid anhydride

Needed : hydrolysis data

123-98-8

Azelaic acid chloride

Needed : migration and hydrolysis data. Pending these results necessity for further studies to be considered.

1732-10-1

Azelaic acid, dimethyl ester

Needed : migration and hydrolysis data. Pending decision on further studies.

1620-68-4

2,6-Bis(2-hydroxy-5-methylbenzyl)-4-methylphenol

Needed : migration, 90-day oral study.

584-03-2

1,2-Butanediol

Needed : 28-day oral study.



- 110-63-4      1,4-Butanediol (=tetramethyleneglycol /  
 Needed : 90-day oral study (an unconventional 6-month  
 oral rat study indicates high toxicity).
- 513-85-9      2,3-Butanediol  
 Needed : metabolic studies and/or a 28-day oral study.
- 98-54-4      p-tert-Butylphenol  
 Needed : 28-day oral study.
- 126-99-8      2-Chloro-1,3-butadiene (=chloroprene/  
 All data considered show that chloroprene is hepatotoxic,  
 teratogenic, mutagenic and causes chromosomal abnormalities  
 in exposed workers. It affects testicular function in man  
 and animals.  
 Needed: migration data and an adequately performed 90-day oral  
 study.
- 3274-65-0      Crotonic acid  
 Needed : migration, mutagenicity tests, 90-day oral study.
- 623-68-7      Crotonic anhydride  
 Needed: information on crotonic acid.
- 109-76-2      1,3-Diaminopropane  
 Needed : migration, 90-day oral study.
- 1653-19-6      2,3-Dichloro-1,3-butadiene  
 Needed : metabolism, mutagenicity studies, reproduction/terato-  
 genicity studies, 90-day oral study, long-term oral study.
- 80-07-9      4,4'-Dichlorodiphenyl sulfone  
 Needed: 90-day oral study.
- 80-09-1      4,4'-Dihydroxy-diphenyl sulfone(=bisphenol S/  
 Needed: 90-day oral study and mutagenicity studies.
- 576-26-1      2,6-Dimethylphenol  
 Needed : migration data, 90-day oral study.
- 104-76-7      2-Ethyl-1-hexanol  
 Needed : migration data, mutagenicity studies and  
 90-day oral study.
- 1321-74-0      Divinylbenzene (mixed isomers)  
 Needed : migration data and on that basis decide on  
 indication for a 28/90 day oral study.
- 16219-75-3      5-Ethylidenebicyclo[2.2.1]hept-2-ene  
 Needed: 90-day oral study and mutagenicity studies.

98-01-1	<u>Furfural</u> Needed: 90-day oral study and mutagenicity studies.
2807-54-7	<u>Fumaric acid, diallyl ester</u> Needed : hydrolysis data.
105-75-9	<u>Fumaric acid, dibutyl ester</u> Needed : hydrolysis data.
623-91-6	<u>Fumaric acid, diethyl ester</u> Needed : hydrolysis data.
	Glucosides obtained from :
- . -	<u>Glucose and bis(2-hydroxyethyl) ether</u> Needed : hydrolysis data.
- . -	<u>Glucose and 1,3-butanediol</u> Needed : hydrolysis data.
- . -	<u>Glucose and 1,4-butanediol</u> Needed : hydrolysis data.
- . -	<u>Glucose and 2,2-dimethyl-1,3-propanediol</u> Needed : hydrolysis data.
- . -	<u>Glucose and ethanediol</u> Needed : hydrolysis data.
- . -	<u>Glucose and glycerol</u> Needed : hydrolysis data.
- . -	<u>Glucose and 1,6-hexanediol</u> Needed : hydrolysis data.
- . -	<u>Glucose and 1,2,6-hexanetriol</u> Needed : hydrolysis data.
- . -	<u>Glucose and pentaerythritol</u> Needed : hydrolysis data.
- . -	<u>Glucose and polyethylene oxide (M.W.more than 200)</u> Needed : hydrolysis data.
- . -	<u>Glucose and polypropylene oxide (M.W.more than 400)</u> Needed : hydrolysis data.
- . -	<u>Glucose and propanediol</u> Needed : hydrolysis data.
- . -	<u>Glucose and sorbitol</u> Needed : hydrolysis data.

- . -	<u>Glucose and sucrose</u> Needed : hydrolysis data.
- . -	<u>Glucose and 1,1,1-trimethylolpropane</u> Needed : hydrolysis data.
3634-94-4	<u>Glutaric acid, decyl ester</u> Needed : hydrolysis data.
29773-18-4	<u>Glutaric acid, diisodecyl ester</u> Needed : hydrolysis data.
5137-27-9	<u>Glutaric acid, nonyl ester</u> Needed : hydrolysis data.
33814-34-5	<u>Glutaric acid, octyl ester</u> Need : hydrolysis data.
107-41-5	<u>Hexyleneglycol / =2-methyl-2,4-pentanediol/</u> Needed: purity, physicochemical state, migration data.
78-83-1	<u>Isobutanol</u> Needed : migration, 28-day oral study and mutagenicity studies.
78-84-2	<u>Isobutyraldehyde</u> Needed : migration, 28-day oral study.
78-79-5	<u>Isoprene</u> Needed: purity, physicochemical state, migration data, 90-day oral study.
-.-	<u>Maleic acid, 1,3-butanediol ester</u> Needed : hydrolysis data.
999-21-3	<u>Maleic acid, diallyl ester</u> Needed : hydrolysis data.
105-76-0	<u>Maleic acid, dibutyl ester</u> Needed : hydrolysis data.
141-05-9	<u>Maleic acid, diethyl ester</u> Needed : hydrolysis data.
14234-82-3	<u>Maleic acid, diisobutylester</u> Needed : hydrolysis data.
1330-76-3	<u>Maleic acid, diisooctylester</u> Needed : hydrolysis data.
624-48-6	<u>Maleic acid, dimethyl ester</u> Needed : hydrolysis data.
2915-53-9	<u>Maleic acid, dioctyl ester</u> Needed : hydrolysis data.

71550-61-3	<u>Maleic acid,1,2-propanediol diester</u> Needed : hydrolysis data.
2424-58-0	<u>Maleic acid, monoallyl ester</u> Needed : hydrolysis data.
79-39-0	<u>Methacrylamide</u> Needed: migration data, an adequate 90-day oral study combined with a one generation, reproduction study (cf acrylamide).
96-05-9	<u>Methacrylic acid, allyl ester</u> Needed : 90-day oral study and mutagenicity studies.
2495-37-6	<u>Methacrylic acid, benzyl ester</u> Needed : hydrolysis data.
1189-08-8	<u>Methacrylic acid, 1,3-butanediol diester</u> Needed : hydrolysis data.
2082-81-7	<u>Methacrylic acid, 1,4-butanediol diester</u> Needed : hydrolysis data.
1888-94-4	<u>Methacrylic acid, beta-chloroethyl ester</u> Needed : hydrolysis data.
101-43-9	<u>Methacrylic acid, cyclohexyl ester</u> Needed : hydrolysis data.
16868-14-7	<u>Methacrylic acid, cyclopentyl ester</u> Needed : hydrolysis data.
105-16-8	<u>Methacrylic acid, diethylaminoethyl ester</u> Needed : hydrolysis data.
39670-09-2	<u>Methacrylic acid, ethoxytriethyleneglycol ester</u> Needed : hydrolysis data.
688-84-6	<u>Methacrylic acid, 2-ethylhexyl ester</u> Needed : hydrolysis data.
7534-94-3	<u>Methacrylic acid, isobornyl ester</u> Needed : hydrolysis data.
29964-84-5	<u>Methacrylic acid, isodecylester</u> Needed : hydrolysis data
868-77-9	<u>Methacrylic acid, 2-hydroxyethyl ester</u> Needed : 4 week oral study and mutagenicity studies.
923-26-2	<u>Methacrylic acid, 2-hydroxypropyl ester</u> Needed : 4 week oral study and mutagenicity studies.
142-90-5	<u>Methacrylic acid, lauryl ester</u> Needed : hydrolysis data.

24493-59-2      Methacrylic acid, methoxytriethyleneglycol ester  
 Needed : hydrolysis data.

2177-70-0      Methacrylic acid, phenyl ester  
 Needed : hydrolysis data.

27813-02-1      Methacrylic acid, 1,2-propanediol ester  
 Needed : hydrolysis data.

3683-12-3      Methacrylic acid, phenyl ethyl ester  
 Needed : hydrolysis data.

54276-35-6      Methacrylic acid, sulfopropyl ester  
 Needed : hydrolysis data.

4245-37-8      Methacrylic acid, vinyl ester  
 Needed : hydrolysis data.

694-91-7      5-Methylenebicyclo/2.2.1/hept-2-ene  
 Needed : 90-day oral study and mutagenicity studies.

98-83-9      alpha-Methylstyrene  
 Needed : purity, physicochemical state, migration data, 90-day oral study.

109-67-1      1-Pentene  
 Needed : migration data and on that basis decide on indication for a 28/90 day oral study.

92-69-3      p-Phenylphenol  
 Needed : migration data and 28-day oral study.

88-99-3      o-Phthalic acid  
 Needed : 90-day oral study.

88-95-9      Phthalic acid chloride  
 Needed : hydrolysis data.

25852-47-5      Polyoxyethylene dimethacrylate  
 Needed : hydrolysis data.

504-63-2      1,3-Propanediol  
 Needed : migration data and teratogenicity studies.

111-19-3      Sebacic acid dichloride  
 Needed : migration and hydrolysis. Pending these results necessity for a 28-day oral study and further studies to be considered.

2432-89-5      Sebacic acid, didecyl ester  
 Needed : hydrolysis data.

106-79-6      Sebacic acid, dimethyl ester  
 Needed : migration and hydrolysis data. Pending decision on further studies.

2561-88-8	<u>Sebacic anhydride</u> Needed : hydrolysis data.
32360-05-7	<u>Stearyl methacrylate</u> Needed : hydrolysis data.
108-30-5	<u>Succinic anhydride</u> Needed : hydrolysis data.
88-19-7	<u>o-Toluenesulfonamide</u> Needed: mutagenicity and reproduction studies on the commercial mixture to be specified.
70-55-3	<u>p-Toluenesulfonamide</u> Needed : mutagenicity and reproduction studies on the commercial mixture to be specified.
37275-47-1	<u>Trimethylolpropane diacrylate</u> Needed : hydrolysis data.
19727-16-3	<u>1,1,1-Trimethylolpropane dimethacrylate</u> Needed : hydrolysis data
- . -	<u>1,1,1-Trimethylolpropane monoacrylate</u> Needed : hydrolysis data
7024-09-1	<u>1,1,1-Trimethylolpropane monomethacrylate</u> Needed : hydrolysis data
15625-89-5	<u>Trimethylolpropane triacrylate</u> Needed : hydrolysis data.
3290-92-4	<u>Trimethylolpropane trimethacrylate</u> Needed : hydrolysis data and 28-day oral study.
110-88-3	<u>Trioxymethylene /=trioxane/</u> Needed : 28-day oral study and mutagenicity studies.
102-71-6	<u>Tris(2-hydroxyethyl)amine /=triethanolamine/</u> Needed : long term oral rat study.
75-38-7	<u>Vinylidene fluoride</u> Needed : 90-day oral study and mutagenicity studies.
88-12-0	<u>Vinyl pyrrolidone</u> Needed : migration data, mutagenicity studies, 90-day oral study.
1184-84-5	<u>Vinylsulfonic acid</u> Needed : migration data and on that basis decide on indication for a 28/90 day oral study.
25013-15-4	<u>Vinyltoluene</u> Needed : migration data and on that basis decide on indication for a 28/90 day oral study.



Vinyl versatate (vinyl esters of aliphatic monocarboxylic acids  
acids (C9-C11))

Needed : migration data and on that basis decide on indication for  
a 28/90 day oral study.

LIST 8

Substances for which no or only scanty and inadequate data were available

60-32-2	6-Aminocaproic acid
29602-44-6	Azelaic acid, bis(2-hydroxyethyl) ester
4080-88-0	Azelaic acid, diphenyl ester
91-76-9	Benzoguanamine /=2,4-Diamino-6-phenyl-s-triazine/
1761-71-3	Bis(4-aminocyclohexyl)methane
3377-24-0	2,2-Bis(4-aminocyclohexyl)propane
38050-97-4	1,4-Bis(4',4''-dihydroxytriphenyl-methyl)benzene
901-44-0	2,2-Bis(4-(2-hydroxyethoxy)phenyl)propane
843-55-0	1,1-Bis(4-hydroxyphenyl)cyclohexane /= 4,4'- Dihydroxydiphenyl-1-1-cyclohexane/
6117-91-5	2-Buten-1-ol
1852-16-0	Butoxymethylacrylamide
5153-77-5	Butoxymethylmethacrylamide
111-34-2	Butyl vinyl ether
926-02-3	tert-Butyl vinyl ether
602-44-3	Caprolactone
102-09-0	Carbonic acid, diphenyl ester
822-28-6	Cetyl vinyl ether
2842-38-8	2-(Cyclohexylamino)ethanol
1131-60-8	p-Cyclohexylphenol
542-02-7	1,3-Cyclopentadiene
1647-16-1	1,9-Decadiene
872-05-9	1-Decene
765-05-9	Decyl vinyl ether
110-60-1	1,4-Diaminobutane
542-02-9	2,4-Diamino-6-methyl-s-triazine /=Acetoguanamine/
3236-53-1	1,6-Diamino-2,2,4-trimethylhexane
3236-54-1	1,6-Diamino-2,4,4-trimethylhexane
156-60-5	trans-Dichloroethylene
498-66-8	Dicyclo/2.2.1/hept-2-ene /=Norbornene/
77-73-6	Dicyclopentadiene
80-09-1	4,4'-Dihydroxydiphenyl sulfone /=Bisphenol S/
110-97-4	Diisopropanolamine
141-07-1	1,3-Dimethoxymethylurea /=1,3 bis(methoxymethyl)urea/
5205-93-6	N-(Dimethylaminopropyl)methacrylamide
6864-37-5	3,3'-Dimethyl-4,4'-diaminodicyclohexylmethane
526-75-0	2,3-Dimethylphenol
105-67-9	2,4-Dimethylphenol
95-87-4	2,5-Dimethylphenol
126-30-7	2,2-Dimethyl-1,3-propanediol /= neopentylglycol/
123-91-1	1,3-Dioxane
125-13-3	4,4'-Dioxi-diphenyl-3,3'-oxindole /=3,3-Bis(4-hydroxyphenyl)oxindole
646-06-6	1,3-Dioxolane
138-86-3	Dipentene
826-62-0	Endomethylenetetrahydrophthalic anhydride
13036-41-4	N-(Ethoxymethyl)acrylamide

103-44-6	2-Ethylhexyl vinyl ether
109-92-2	Ethyl vinyl ether
110-94-1	Glutaric acid
108-55-4	Glutaric anhydride
4371-64-6	1,1-Heptadecanedicarboxylic acid
592-76-7	1-Heptene
25339-56-4	Heptene
115-27-5	Hexachloroendomethylenetetrahydrophthalic anhydride
592-45-0	1,4-Hexadiene
592-42-7	1,5-Hexadiene
15511-81-6	Hexamethylenediamine adipate
- . -	Hexamethylenediamine dodecanedicarboxylate
- . -	Hexamethylenediamine heptadecanedicarboxylate
6422-99-7	Hexamethylene diamine sebacate
629-11-8	1,6-Hexanediol
2935-44-6	2,5-Hexanediol
106-69-4	1,2,6-Hexanetriol
592-41-6	1-Hexene
25264-93-1	Hexene
288-32-4	Imidazole
95-13-6	Indene
16669-59-5	N-(Isobutoxymethyl)acrylamide
109-53-5	Isobutyl vinyl ether
121-91-5	Isophthalic acid
1459-93-4	Isophthalic acid, dimethyl ester
744-45-6	Isophthalic acid, diphenyl ester
99-63-8	Isophthalic acid chloride
97-65-4	Itaconic acid
2155-60-4	Itaconic acid, dibutyl ester
3775-90-4	Methacrylic acid, di-tert-butylaminoethyl ester
2439-35-2	Methacrylic acid, dimethylaminoethyl ester
97-90-5	Methacrylic acid, ethanediol diester
3644-11-9	Methoxymethylacrylamide
3644-12-0	Methoxymethylmethacrylamide
563-46-2	2-Methyl-1-butene
563-45-1	3-Methyl-1-butene
110-26-9	Methylenebisacrylamide
13093-19-1	Methylenebiscaprolactam
505-65-7	1,4-Methylenedioxybutane/=Butanediol formal/
924-42-5	N-Methylolacrylamide
923-02-4	N-Methylolmethacrylamide
1118-58-7	2-Methyl-1,3-pentadiene
1115-08-8	3-Methyl-1,4-pentadiene
926-56-7	4-Methyl-1,3-pentadiene
763-29-1	2-Methyl-1-pentene
760-20-3	3-Methyl-1-pentene
691-37-2	4-Methyl-1-pentene
6144-04-3	alpha-Methylstyrene dimer
107-25-5	Methyl vinyl ether
1822-74-8	Methyl vinyl thioether
27215-95-8	Nonene
104-40-5	p-Nonylphenol

930-02-9	Octadecyl vinyl ether
111-66-0	1-Octene
25377-83-7	Octene
1806-26-4	p-Octylphenol
140-66-9	p-tert-Octylphenol
504-60-9	1,3-Pentadiene
28994-41-4	alpha-Phenyl-o-cresol
131-17-9	Phthalic acid, diallyl ester
111-16-0	Pimelic acid
764-47-6	Propyl vinyl ether
2918-18-5	Sebacic acid, diphenyl ester
505-48-6	Suberic acid
9080-79-9	Styrene sulfonic acid polymer sodium salt
100-20-9	Terephthalic acid chloride
1539-04-4	Terephthalic acid, diphenyl ester
632-58-6	Tetrachlorophthalic acid
98-59-9	Toluene sulfonic acid chloride
101-37-1	Triallyl cyanurate
26896-48-0	Tricyclodecanedimethanol
67-48-1	Trimethylethanolammonium chloride
107-39-1	2,4,4-Trimethyl-1-pentene
27309-95-1	Trimethylolpropane maleate
25723-16-4	Trimethylolpropane propoxylate
769-68-8	Vinyl benzoate
2146-71-6	Vinyl laurate

## LIST 9

Groups of substances which could not be evaluated due to lack of specificity. These groups should be replaced by individual substances actually in use

Acids aliphatic dicarboxylic saturated ( $C_4-C_{18}$ )  
Acids aliphatic dicarboxylic unsaturated ( $C_4-C_{12}$ )  
Acids aliphatic monocarboxylic saturated ( $C_2-C_{24}$ )  
Acids aliphatic monocarboxylic unsaturated ( $C_2-C_{24}$ )  
Acids monocarboxylic ( $C_3-C_{12}$ ), alcohols unsaturated ( $C_3-C_{18}$ ) esters  
Acids aliphatic monocarboxylic unsaturated ( $C_3-C_8$ ), alcohols aliphatic saturated monohydric ( $C_2-C_{12}$ ) esters  
Acids aliphatic ( $C_4-C_8$ ) dicarboxylic unsaturated, alcohols aliphatic saturated monohydric ( $C_2-C_{12}$ ) esters  
Acids aliphatic dicarboxylic unsaturated, polyethylene glycol esters  
Acids aliphatic dicarboxylic unsaturated, polypropylene glycol esters  
Acids aliphatic dicarboxylic unsaturated, propylene glycol esters  
Acrylic acid, alcohols aliphatic monohydric saturated ( $C_5-C_{21}$ ) esters  
Acrylic acid, alcohols aliphatic monohydric unsaturated ( $C_3-C_{18}$ ) monoesters  
Acrylic acid, alcohols aliphatic polyhydric saturated ( $C_2-C_{21}$ ) esters  
Alcohols aliphatic monohydric saturated (up to  $C_9$  and  $C_{16}-C_{18}$ )  
Alcohols aliphatic monohydric unsaturated (up to  $C_{18}$ )  
Alcohols aliphatic polyhydric (up to  $C_{18}$ )  
Alcohols cycloaliphatic monohydric and/or polyhydric substituted (up to  $C_{18}$ )  
Alkadienes  
n-Alkenes (up to  $C_{14}$ )  
p-Alkyl ( $C_4-C_9$ ) phenols  
omega-Aminocarboxylic aliphatic unbranched acids ( $C_7-C_{12}$ )  
Anhydrides of the acids aliphatic monocarboxylic saturated ( $C_2-C_{24}$ )  
Bisphenol A epoxyresins  
Crotonic acids, alcohols mono and polyhydric esters  
Cycloalkenes  
Diamines aliphatic linear ( $C_2-C_{12}$ )  
Dihydroxydiethylether of hydroquinone and its condensation products with propylene oxide  
Etheralcohols  
Fumaric acid, alcohols aliphatic monohydric saturated ( $C_1-C_{18}$ ) esters  
Fumaric acid, alcohols aliphatic monohydric unsaturated ( $C_3-C_{18}$ ) esters  
Halogenated phthalic derivatives acid  
Isodecanol (Cas N. 25339-17-7)  
Itaconic acid, alcohols aliphatic monohydric saturated ( $C_1-C_{18}$ ) esters  
Lactams of omega-aminocarboxylic acids aliphatic unbranched ( $C_7-C_{12}$ )  
Maleic acid, alcohols aliphatic polyhydric saturated esters  
Methacrylic acid, alcohols aliphatic monohydric saturated ( $C_5-C_{21}$ ) esters  
Methacrylic acid, alcohols aliphatic monohydric unsaturated ( $C_3-C_{18}$ ) monoesters  
Methacrylic acid, alcohols aliphatic polyhydric saturated ( $C_2-C_{21}$ ) esters  
Methacrylic acid, glycol ethers (from mono and/or diglycols) with alcohols aliphatic monohydric ( $C_1-C_{18}$ ) esters  
Phenols, divalent also alkoxylated or hydrogenated  
Phthalic anhydride hydrogenated and/or partially hydrogenated  
Phthalic acids, hydrogenated anhydride  
Polyethers based on ethylene oxide and propylene oxide and/or tetrahydrofuran and containing free hydroxyl groups

Polyhydric alcohols (C<sub>3</sub>-C<sub>6</sub>)  
Polyols deriving from phenols and bisphenols hydrogenated and/or condensed  
with epoxyalkanes and/or aryloxyalkanes, which may be halogenated,  
alkoxylated  
Polytetramethylene etherglycol /polybutene-1,2 oxide-3,4/ (M.W. about 1000)  
Polyvinylalcohols (Cas N. 9002-89-5)  
Polyvinylbutyrals (Cas N. 63148-65-2)  
Ricinus oil, hydrogenated  
Rubber, chlorinated (Cas N. 9006-03-5\*)  
Vinyl esters of acids aliphatic mono and dicarboxylic (C<sub>2</sub>-C<sub>20</sub>)  
Vinyl ethers of alcohols aliphatic monohydric saturated (C<sub>1</sub>-C<sub>18</sub>)

REFERENCES OF THE SUBSTANCES LISTED IN LIST 1

See the references reported in List 1.

REFERENCES OF THE SUBSTANCES LISTED IN LIST 2

75-07-0	Acetaldehyde	Toxicity profiles similar to methaldehyde. A two-year oral rat study and a three-generation oral rat study including teratogenicity with methaldehyde enabled the establishment of a TDI of 0.1 mg/kg b.w. (RIV report 1960, v. Esch; Toxicology <u>4</u> , 1975, 97-115).
79-10-7	Acrylic acid	A 90-day oral rat study, an oral reproduction study, 2-year oral rat and dog studies with acrylic acid and an oral teratogenicity study in rats with ethyl acrylate, 3-year oral rat and dog studies with acrylic acid, ethylene glycol monoester enabled the establishment of a group TDI of 0.1 mg/kg b.w. made temporary pending results of ongoing teratogenicity and long-term studies on acrylic acid (NTP; Union Carbide report No. 43-529 (26 August 1980) and No. 43-528 (22 August 1980); RIVM report 65116008 (June 1984); Report Dow, 1967 and 1967.
141-32-2	Acrylic acid, n-butyl ester	
818-61-1	Acrylic acid, ethyleneglycol monoester	
140-88-5	Acrylic acid, ethyl ester	
106-63-8	Acrylic acid, isobutyl ester	
689-12-3	Acrylic acid, isopropyl ester	
96-33-3	Acrylic acid, methyl ester	
925-60-0	Acrylic acid, n-propyl ester	
-.-	Alcohols aliphatic monohydric saturated	3 month oral rat study and mutagenicity studies enabled the establishment of a group TDI at 1 mg/kg b.w. (J.Med. Soc. Tokyo, Japan, <u>25</u> (1), 193-201, 1978).



123-99-9 111-20-6	Azelaic acid Sebacic acid	A subacute oral rat study and absence of mutagenicity in bacterial systems with azelaic acid and a subacute oral rat study with sebacic acid enabled the establishment of a group TDI of 3 mg/kg b.w. (Arch. f. Exp. Path. u. Pharmak., <u>197</u> , 1941, 587-610)
111-46-6 107-21-1	Bis(2-hydroxyethyl) ether /=diethylene glycol/ 1,2-Ethanediol /=ethylene glycol/	Several 90-day and long-term oral rat studies enabled the establishment of a group TDI of 0,5 mg/kg b.w. (Fd. Cosm. Tox. <u>3</u> , 1965, 229 Bibra Research Rep. no. 5/1976, Ind. Hyg. Tox. <u>28</u> , 1946, 40).
77-99-6	2,2-Bis(hydroxymethyl)-1-butanol /=1,1,1-trimethylol-propane/	A 90-day oral rat study enabled the establishment of a TDI of 0.1 mg/kg b.w. (Report Perstorp, Sweden).
80-05-7	2,2-Bis(4-hydroxyphenyl)propane /=bisphenol A/	90-day and long-term oral studies in mice and rats enabled the establishment of a TDI of 0.05 mg/kg b.w. (CIVO rep. No. R 6229, November 1979).
47465-97-4	3,3-Bis(3-methyl-4-hydroxyphenyl)-2-indolinone	A 90-day oral rat study enabled the establishment of a TDI of 0.03 mg/kg b.w. (Bayer Bericht Nr. 8086, January 3, 1979).
105-60-2 2123-24-2	Caprolactam Caprolactam sodium salt	Two 90-day oral rat studies and 90-day oral studies in mice and dogs enabled the establishment of a group TDI of 0.25 mg/kg b.w. (CIVO report 3489 June 1971 and NTP Tech. Rep. Ser. 214, NTP 80-26).
- . -	Cardura /= glycidyl ester of versatic acid/	A 5-week oral rat study and mutagenicity tests enabled the establishment of a TDI of 0.1 mg/kg b.w.
107-15-31	2-Diaminoethane /=ethylenediamine/	Two 90-day oral rat studies enabled the establishment of a TDI of 0.2 mg/kg b.w. (ICI report April 1975).

124-09-4	1,6-Diaminohexane /=hexanemethylene-diamine/	A 4-week oral rat study enabled the establishment of a TDI of 0.04 mg/kg b.w. (RIV report No. 48/80 March 1981).
106-46-7	p-Dichlorobenzene	A 200-day, 5 days a week oral rat study and negative mutagenicity tests enabled the establishment of a TDI of 0.1 mg/kg b.w.. Long-term oral mouse and studies in progress. Arch. Ind. Health <u>14</u> , 1956, 138-147; IARC Monograph <u>7</u> , 1974, 230).
120-80-9	1,2-Dihydroxybenzene /=pyrocatechol/	A 90-day oral rat study, negative in vitro and in vivo mutagenicity tests, promoting effect in mouse skin painting assay enabled the establishment of a TDI of 0.1 mg/kg b.w. (SCC 1983)
108-46-3	1,3-Dihydroxybenzene /=resorcinol/	A 90-day oral rat study 5 days a week, metabolism in rabbit and man, several negative in vitro mutagenicity tests and no immunosuppressive action enabled the allocation of a TDI of 0.04 mg/kg b.w. (Henkel report 29-01-1980).
123-31-9	1,4-Dihydroxybenzene /=hydroquinone/	6-months and 2-year oral rat studies dog studies, mutagenicity studies in vitro and in vivo enabled the establishment of a TDI of 0.01 mg/kg b.w. pending outcome of ongoing carcinogenicity study (IARC, <u>15</u> , 1977).
108-01-0	Dimethylaminoethanol	A 90-day oral rat study, studies in other species and observations in man enabled the establishment of a TDI of 0.3 mg/kg b.w. (Arch. Ind. Hyg. Occup. Med., <u>4</u> , 1951, 119-122).
120-61-6	Terephthalic acid, dimethyl ester	90 day oral mouse and rat studies and long-term studies in mice and rats not indicating tumour induction enabled the establishment of a TDI of 1 mg/kg b.w. (NCI tech. rep. ser. no. 121,1979).

126-58-9 115-77-6	Dipentaerythritol Pentaerythritol	A 90-day oral rat study and observations in man enabled the establishment of a group TDI of 1 mg/kg b.w. (Hercules Bulletin T-110).
25265-71-8 25322-69-4	Dipropylene glycol 1,2-Polypropylene oxide	Included as a group TDI in the TDI for 1,2 polypropylene glycol of 1.5 mg/kg b.w. (SCF 6th Series).
111-27-3	1-Hexanol	Two subacute oral rat studies and metabolic studies enabled the establishment of a TDI of 2 mg/kg b.w. (Tox. appl. Pharmacol., <u>45</u> , 1978, 497-504, Tox. appl. Pharmacol., <u>46</u> , 1978, 421, Fd. Cosmet. Toxicol., <u>13</u> , 1975, 695-696).
110-16-7 108-31-6	Maleic acid Maleic anhydride	Included as a group TDI in the TDI for maleic acid of 0.5 mg/kg b.w. expressed as maleic acid (SCF 6th Series).
108-78-1	Melamine	Several oral short and long-term studies in mice and rats showed bladder stone formation at high dose levels and corresponding bladder tumour formation. Teratogenicity studies and a series of in vitro mutagenicity tests were negative and enabled the establishment of a TDI of 0.5 mg/kg b.w. (NTP-81-086 NIH publ. no. 82.2501; Toxicologist <u>2</u> , 1981, No.1.)
79-41-4 760-93-0 97-88-1 97-63-2 97-86-9 80-62-6 2210-28-8	Methacrylic acid Methacrylic acid anhydride Methacrylic acid, butyl ester Methacrylic acid, ethyl ester Methacrylic acid, isobutyl ester Methacrylic acid, methyl ester Methacrylic acid, propyl ester	A 2-year oral rat study and several other studies in several animal species with methyl methacrylate enabled the establishment of a group TDI of 0.1 mg/kg b.w. made temporary pending results of an adequate oral long-term study. (Tox. appl. Pharmacol., <u>6</u> , 1984, 29-36; RIV Doc. Tox. 300730, February 1983).
143-08-8	1-Nonanol	A 90-day oral rat study and metabolic studies enabled the establishment of a TDI of 1 mg/kg b.w. (RIV Report No. FT/30/60, v. Esch, 27-07-1960).

71-41-0	1-Pentanol	A 90-day oral rat study enabled the establishment of a TDI of 2 mg/kg b.w. (Fd. Cosmet. Toxicol. <u>16</u> , 1978,203-207).
108-95-2	Phenol	90-day oral studies in mice and rats, multigeneration studies oral in rats and 2-year studies oral in mice and rats enabled the establishment of a TDI of 1.5 mg/kg b.w. (NTP 80-15, NIH Tech. Rep.203; J. Pharm. Exp. Ther. <u>184</u> ,1973,695).
25322-68-3 112-27-6	Polyethylene oxide Triethylene glycol	Included as a group TDI in the TDI for triethyleneglycol of 5 mg/kg b.w. (SCF 6th Series).
85-44-9	Phthalic anhydride	18 month and 2 year oral studies in mouse and rat respectively enabled the establishment of a TDI of 1 mg/kg b.w. (NCI bioassays January 1979)
- . - 61790-12-3* 8050-09-7* 8050-07-7 8052-10-6 9014-63-5 514-10-3	Resin acid Fatty acids tall oil Rosin /=Colophony/ Rosin gum Rosin talloil Rosin wood Abietic acid	Included as a group TDI in the TDI for colophony of 1 mg/kg b.w. (SCF 6th Series)
100-21-0	Terephthalic acid	A 90-day oral feeding study in rats (CIIT,1982) enabled the establishment of a temporary TDI of 0.125 mg/Kg b.w. (U.K. document "Terephthalic acid:proposed use in Animal Foodstuffs,1984)
109-99-6	Tetrahydrofuran	6-month oral studies in mice, rats and rabbits enabled the establishment of a TDI of 0.01 mg/kg b.w. (Gig. Sanit. <u>34</u> , 1969, 114, EPA 560/11-80-011, April 1980)
102-60-3	N,N,N',N'-Tetrakis(2-hydroxypropyl)-ethylenediamine	A 90-day oral rat study enabled the establishment of a TDI of 1 mg/kg b.w. (Hilltop Research Inst. Inc. January 3, 1956)

108-05-4 Vinyl acetate

90-day oral studies and metabolism studies in mice and rats teratogenicity studies in rats and several mutagenicity studies negative enabled the establishment of a TDI of 0.2 mg/kg b.w. (Hazelton: 2146-51/4 January 1980; 2511-51/11-14 and 2195-51/6 & 7)

REFERENCES OF THE SUBSTANCES LISTED IN LIST 3

74-86-2	Acetylene	Residues of this gas in plastics are very small. The gas has very low toxic potential. Migration into food will be toxicologically negligible. (Occupational Exposure to Acetylene. HEW Publ. No. (NIOSH) 76-195)
105-08-8	1,4-Bis(hydroxymethyl)-cyclohexane /1,4-cyclohexanedimethanol/	A limited 36-day oral rat study showed no adverse effects of 50 mg/kg b.w./day (Eastman Kodak report, April 1966)
71-36-3	1-Butanol	9-month oral rat study showed no adverse effects at 500 mg/kg b.w./day (Shell report, Dec. 1976)
106-98-9	1-Butene	Residues of this gas in plastics are very small. The gas has a very low toxic potential. Migration into food will be toxicologically negligible. (Patty's Industrial Hygiene and Toxicology, 3rd ed. 1981)
107-01-7	2-Butene	Residues of this gas in plastics are very small. The gas has a very low toxic potential. Migration into food will be toxicologically negligible. (Patty's Industrial Hygiene and Toxicology, 3rd ed. 1981)

123-72-8	Butyraldehyde	Occurs naturally in food. Used as a flavour in food at 0,1 - 10 mg/kg. Migration into food would be self-limiting because of its taste.
7782-50-5	Chlorine	Residues of this gas in plastics will be very small. Migration into food would be self-limiting because of odour.
108-39-4	m-Cresol	28-day oral rat study showed no adverse effects at 25 mg/kg b.w./day (Shell report, April 1978)
95-48-7	o-Cresol	28-day oral rat study showed no adverse effects at 12 mg/kg b.w./day. (Shell report, April 1978)
106-44-5	p-Cresol	28-day oral rat study showed no adverse effects at 25 mg/kg b.w./day. (Shell report, April 1978)
74-85-1	Ethylene	Residues of this gas in plastics are very small. The gas has a very low toxic potential. Migration into food will be toxicologically negligible. (Patty's Industrial Hygiene and Toxicology, 3rd ed. 1981)
50-00-0	Formaldehyde	Residues of this gas in plastics will be very small. Formaldehyde is a normal intermediate in human metabolism. Carcinogenic for rats by inhalation at concentrations irritant to the respiratory tract. (Final report on a chronic inhalation toxicology study in rats and mice exposed to formaldehyde. Battelle Columbus Labs. Columbus, Ohio, 1981)
100-97-0	Hexamine (=hexa-methylenetetramine/	Formaldehyde liberator. Evaluated by JECFA as a preservative for food. Amounts of formaldehyde likely to migrate into food are of no toxicological significance. (JECFA 17.M)

115-11-7	Isobutene	Residues of this gas in plastics are very small. The gas has a very low toxic potential. Migration into food will be toxicologically negligible. (Patty's Industrial Hygiene and Toxicology, 3rd ed. 1981)
67-56-1	Methanol	The toxicity profile well known also from intoxication of man. The potential migration into food will not be of toxicological significance.
80-56-8	alpha-Pinene	Occurs naturally in food. Used as a flavour. Migration into food would be self-limiting, because of its taste (Fd. Cosmetic Tox. <u>16</u> , 1978 suppl. 1, 853)
127-91-3	beta-Pinene	Occurs naturally in food. Used as a flavour up to 600 mg/kg food. Migration into food would be self-limiting because of its taste.
71-23-8	1-Propanol	(SCF 11th Report Series, JECFA 25 M)
123-38-6	Propionaldehyde	Occurs naturally in food. Used as a flavour up to 13 mg/kg food. Migration into food would be self-limiting because of its taste.
115-17-1	Propylene	Residues of this gas in plastics are very small. The gas has a very low toxic potential. Migration into food will be toxicologically negligible.
1313-82-2	Sodium sulfide	Is readily transformed into hydrogen sulphide which has a very strong unpleasant odour. Migration into food would therefore be self-limiting.



REFERENCES OF THE SUBSTANCES LISTED IN LIST 4 \*

Section A

107-13-1	Acrylonitrile	(SCF 13th Report Series, 1982)
106-99-0	1,3-Butadiene	Suspected of having carcinogenic potential (NTP report 83-071, NIH publ.n. 84-2544, 1983)
3173-53-3 5124-30-1	Cyclohexyl isocyanate Dicyclohexylmethane- 4,4'-diisocyanate	Iso- and diisocyanates have been dealt with as a group. Aromatic diisocyanates are not only very toxic but are also strong sensitizers. Although information concerning the sensitization potential of the isocyanates is lacking, these substances should also be considered as potent sensitizers similar to the aromatic diisocyanates. There is an urgent need for adequate diisocyanate toxicity data. (Occupational exposure to diisocyanates, DHEW (NIOSH) Publ. No. 78-215)
91-97-4	3,3'-Dimethyl-4,4'- diisocyanatobiphenyl	
5873-54-1	2,4'-Diphenylmethane diisocyanate	
101-68-8	4,4'-Diphenylmethane diisocyanate	
822-06-0	Hexamethylene diisocyanate	
3173-72-6	1,5-Naphthylene diisocyanate	
4128-73-8	Diphenylether-4,4'-Diisocyanate	
112-96-9	Stearyl isocyanate	
584-84-9	2,4-Toluene diisocyanate	
26747-90-0 91-08-7	2,4-Toluene diisocyanate dimer 2,6-Toluene diisocyanate	
106-89-8	Epichlorhydrin	Highly toxic. Induces forestomach tumours in rats after oral administration. (Report from Nat. Inst. of Publ. Health, Bilthoven 1982; International Program on Chemical Safety, Series Environmental Health Criteria, WHO, in press).
151-56-4	Ethyleneimine	Highly toxic by all exposure routes. Carcinogenic for mice orally. (IARC Monographs Vol. 9, p. 37, Lyon 1975)

75-21-8	Ethylene oxide	Strongly mutagenic in several studies. Induces forestomach tumours in rats after oral administration. (Brit. J. Cancer, 1982, <u>46</u> , 924; IARC Monographs Vol. 11 and Suppl. 4, Lyon 1976 and 1982; Toxicity of ethylene oxide and its relevance to man. ECETOC, Technical Report No. 5, 1982)
126-98-7	Methacrylonitrile	The chemical structure is similar to acrylonitrile. Methacrylonitrile should be treated in the same way as acrylonitrile.
75-44-5	Phosgene	Residues of this gas in plastics will be very small. It is readily hydrolysed to CO <sub>2</sub> and HCl. Has a strong odour. Migration into food would therefore be self-limiting.
75-56-9	Propylene oxide	Mutagenic in several studies. Induces forestomach tumours in rats after oral administration. (Brit. J. Cancer 1982, <u>46</u> , 924).
75-01-4	Vinyl chloride	(SCF 1st Report Series, 1975)
<u>Section B</u>		
100-42-5	Styrene	(SCF 13th Report Series, 1982)
75-35-4	Vinylidene chloride	(SCF 13th Report Series, 1982)





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