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(Thirty-third series)



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**food science  
and  
techniques**

**Reports of  
the Scientific Committee for Food**

**(33rd series)**

**First report of the Scientific Committee for Food  
on certain additives used in the manufacture of plastic materials  
intended to come into contact with foodstuffs**

*(Opinions expressed until 3 May 1992)*

Directorate-General for Industry

1995

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# **First report of the Scientific Committee for Food on certain additives used in the manufacture of plastic materials intended to come into contact with foodstuffs**

*(Opinions expressed until 3 May 1992)*

## **Terms of reference**

To advise on the toxicological assessment of certain additives which could migrate into food from plastic materials and articles intended to come into contact with foodstuffs.

## **Background**

The Scientific Committee for Food ("the Committee") has already published various reports on toxicological assessment of certain monomers and other starting substances hereinafter referred to as "monomers" used in the manufacture of plastic materials and articles intended to come into contact with foodstuffs <sup>1,2,3,4</sup> which comply with the definition of plastic materials and articles reported in the **Directive 90/128/EEC** <sup>5</sup>.

Subsequently the Commission of the European Communities has requested the Committee to evaluate additives in order to establish a list of substances, the use of which is authorized to the exclusion of all others (positive list). The list included in the present report is a first list of additives submitted to the Committee by the Commission. It is only restricted to the substances classified into SCF lists 0-5. Other additives will be the subject of further reviews.

The Annex III lists in alphabetical and/or PM/REF ("EEC packaging material reference number") order all the substances examined in this report.

## **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 toxicological guidelines established in 1976<sup>6</sup> and revised in 1990<sup>7</sup>. 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 of toxicity data submitted to the Committee. Unpublished data available to the Committee are listed among the references. Only the main sources of information on which it has based its assessment have been indicated.

2. In some cases the evaluation of the Committee differs from that of the Council of Europe<sup>8</sup>, 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 has endorsed acceptable daily intakes (ADI) already established by this Committee or by JECFA. When JECFA ADIs were used the Committee did not necessarily review the data base for the JECFA decision. Intake from packaging materials should be included within the quantity ingested from food additive use. The Committee stresses that the acceptance of an ADI figure, in the context of this evaluation of additives used in the manufacture of plastic materials does not necessarily mean the endorsement of the figure for food additive use.

The Committee also endorsed provisional maximum tolerable daily intakes (PMTDI) or provisional tolerable weekly intakes (PTWI) set by JECFA for contaminants. In former times JECFA used the terminology "not limited". At the 18th JECFA meeting this classification was changed to "not specified" as this was found more appropriate. In line with the background for the latter decision SCF has for reasons of consistency used the classification "not specified" throughout. Some substances which have not been found acceptable for direct food uses may still be considered acceptable for inclusion in plastic materials since concentrations in food from migration would be so low as to be toxicologically acceptable.

4. The Committee established tolerable daily intakes (TDI) where the data sufficed for this purpose and temporary TDIs (t-TDI) where additional data are required. In selecting this approach the Committee was aware that the available toxicological data were less extensive than in the case of food additives (eg. reproduction, teratogenicity or mutagenicity data sometimes were incomplete or lacking.) Therefore, in establishing these TDIs a particularly cautious approach was chosen involving the choice of a larger safety factor than usual. The Committee considered that many of the additives 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 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 group of materials and articles for food packaging.

5. The Committee emphasises that, even when a additive is toxicologically acceptable, for reasons of food quality, migration of such a substance into foods from plastic materials and articles should be as low as possible and therefore recommended that the finished plastic materials and articles contain the lowest possible level of additives to achieve the technological effect. 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. Conclusions on the toxicological assessment – with selected references – were prepared for those substances for which the Committee was able to express an opinion. The Committee considered that the assessment of substances in lists 6-9 posed a number of difficulties due to incompleteness or absence of data or because the data indicated that the substance might have toxic properties.
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 other substances on List 4 similar sensitive methods should be developed so that appropriate low migration limits could be defined. The Committee recommends that appropriate sensitive methods of analysis should be developed within three years of publication of this report.
8. The Committee considered that substances in List 6 for which data are lacking or are insufficient were suspected of having toxic properties. Those in List 6A are suspected of having carcinogenic properties, those in List 6B are suspected of having other toxic properties. Each substance listed in List 6A should in principle not be detectable in foods or in food simulants by an appropriate sensitive method for that substance. The Committee recommends that the information be supplied or that the appropriate toxicological tests be carried out as soon as possible.

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

9. The Committee recommends that for the substances in Lists 6-9 the requested data should be supplied in accordance with the timetable set out in the Appendix of this report.

When additional studies are needed for the final evaluation this is indicated beside the substance by the word "Needed" together with a brief note of the studies required as follows:



### 9.1 *Hydrolysis data*

In some cases results of hydrolysis studies may justify a reduction in toxicological testing. This may arise when the chemical structure of monoesters suggests ready hydrolysis into substances which are toxicologically acceptable and already in Lists 0, 1, 2, or 3. Demonstration of hydrolysis may be carried out in foods or food simulants, representing the range of foods with which the substance may come into contact. Alternatively, or in cases where hydrolysis in food does not occur, hydrolysis can be evaluated in simulated saliva and/or gastrointestinal fluids.

### 9.2 *Mutagenicity studies*

In principle, the following three tests should be provided.

- i) a test for gene-mutations in bacteria;
- ii) a test for chromosomal aberrations in cultured mammalian cells;
- iii) a test for gene-mutations in cultured mammalian cells; under special circumstances another validated eukaryotic test detecting gene-mutations may be acceptable.

For detection of chromosomal aberrations the Committee has chosen an *in vitro* test with cultured mammalian cells only, despite the fact that for many chemicals the *in vivo* micronucleus test will already have been performed. The reason is that the micronucleus test may be relatively insensitive in comparison with the *in vitro* test with cultured mammalian cells.

### 9.3 *Peroxisome proliferation study*

A number of esters possess the potential of inducing proliferation of hepatic peroxisomes and increased enzyme activity when administered at high dietary levels to rodents. The rodents have also reacted with an increase in hepatic adenomas and/or hepatic carcinomas.

It is not known whether tumour development is casually related to peroxisome proliferation. However, peroxisome proliferation is one of the sensitive toxic responses to these compounds and is a marker for their hepatotoxicity.

### 9.4 *Neurotoxicity studies*

Neurotoxicity has been induced by numerous toxins of natural origin, solvents and organosphosphorus compounds. When compounds from the latter group have to be assessed, a study on neurotoxicity is essential. In this instance the hen is the animal model of choice. Other methods are more appropriate for other groups of substances.

10. Whenever acids, phenols or alcohols have been evaluated, the assessment also includes aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc salts.
11. Substances for which the Committee was able to express an opinion are reported in Annex I. Substances for which there was insufficient toxicological 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.
12. 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 in guidelines by this Committee <sup>7</sup>. The extent to which substances migrate into foods or in food simulants will determine the amount and type of toxicity data which may be required.
13. **Annex I: Substances for which the Committee was able to express an opinion**

**Annex I consists of the following 6 lists:**

(See abbreviations in paragraph 14)

**List 0**

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

**List 1**

Substances for which an ADI, a temporary ADI (t-ADI), a MTDI, a PMTDI, a PTWI or the classification "acceptable" has been established by this Committee or by JECFA.

**List 2**

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

**List 3**

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

### **List 3**

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

Some of these substances are self-limiting because of their organoleptic properties or are volatile and therefore unlikely to be present in the finished product. For other substances with very low migration, a TDI has not been set but the maximum level to be used in any packaging material or a specific limit of migration is stated. This is because the available toxicological data would give a TDI which allows that a specific limit of migration or a composition limit could be fixed at levels very much higher than the maximum likely intakes arising from present uses of the additive.

### **List 4**

**Section 4A:** Substances for which an ADI or a TDI could not be established, but which could be used if the substance migrating into foods or in food simulants is not detectable by an agreed sensitive method (see also paragraph 7).

**Section 4B:** Substances for which an ADI or a 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**

Substances which should not be used.

## 14. Abbreviations

### First part:

ADI	=	Acceptable Daily Intake
MTDI	=	Maximum Tolerable Daily Intake
NS	=	Not Specified
PMTDI	=	Provisional Maximum Tolerable Daily Intake
PTWI	=	Provisional Tolerable Weekly Intake
R	=	Restriction indicated. If not otherwise indicated R: x mg/kg means mg/kg of food or food stimulant
TDI	=	Tolerable Daily Intake
t-ADI	=	Temporary ADI
t-TDI	=	Temporary TDI

### Second part

BIBRA	=	British Industrial Biological Research Association (UK)
CAS No	=	Chemical Abstract Service Registry Number (USA)
CIVO-TNO	=	Central Institute for Nutrition and Food Research (NL)
EM	=	electron microscopy
FAO	=	Food and Agriculture Organization (UN)
HRC	=	Huntingdon Research Centre (UK)
IARC	=	International Agency for Research on Cancer (F)
JECFA	=	Joint FAO/WHO Expert Committee on Food Additives (UN)
NTP	=	National Toxicology Program (USA)
RIVM	=	National Institute for Public Health and Environmental Protection (NL)
SCC	=	Scientific Committee for Cosmetology (EEC)
SCF	=	Scientific Committee for Food (EEC)
WHO	=	World Health Organisation (UN)

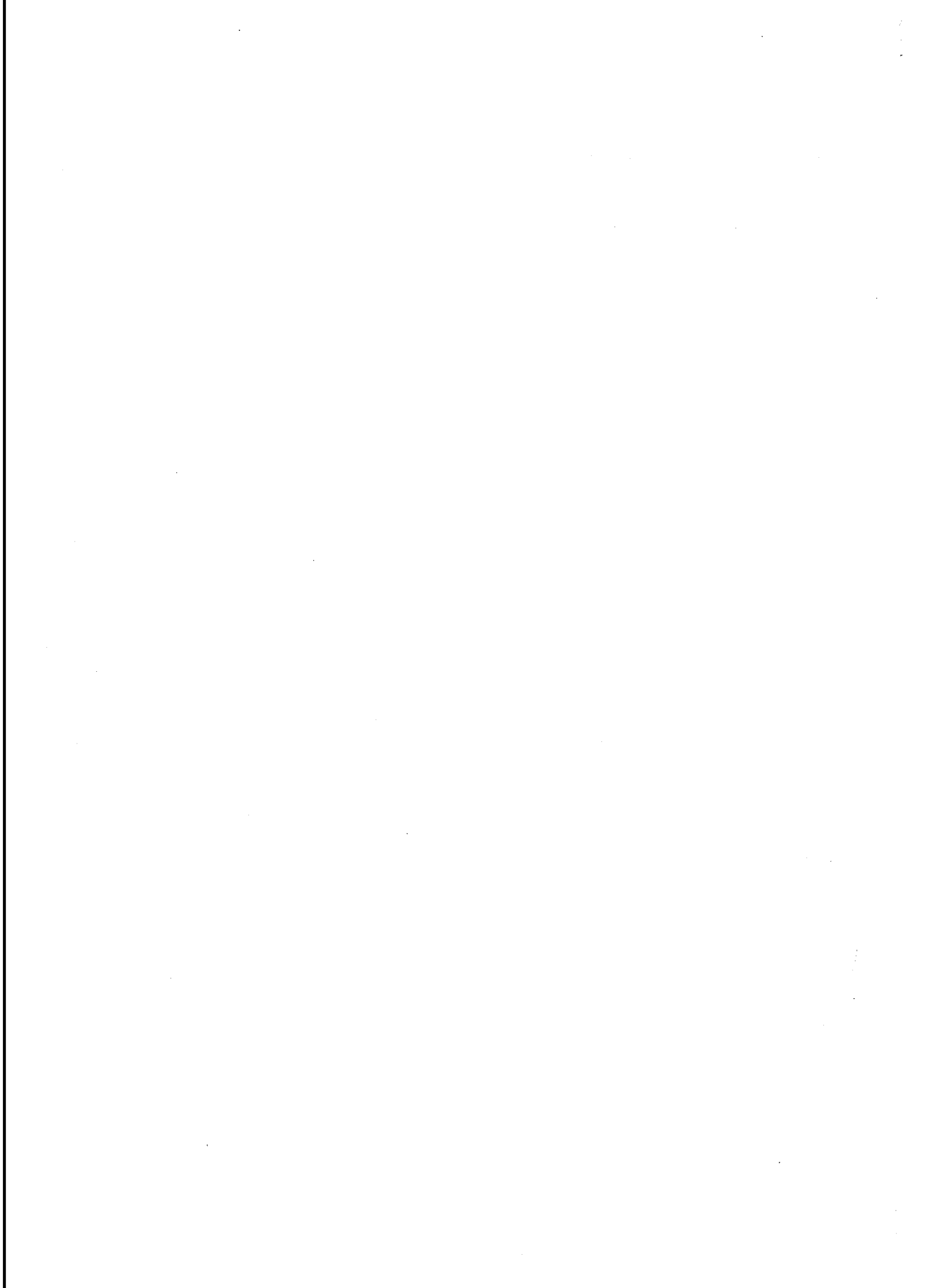
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- |                       |   |
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## **ANNEX I**

**SUBSTANCES FOR WHICH THE COMMITTEE WAS ABLE TO EXPRESS AN OPINION.**



## 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 for this purpose.

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>
30370	-	Acetylacetic acid, salts
30380	000623-58-5	Acetylacetic acid, sodium salt
35840	000506-30-9	Arachidic acid
35845	007771-44-0	Arachidonic acid
36880	008012-89-3	Beeswax
37040	000112-85-6	Behenic acid
41040	005743-36-2	Calcium butyrate
41960	000124-07-2	Caprylic acid
42800	009000-71-9	Casein
45940	000334-48-5	n-Decanoic acid
46070	010016-20-3	alpha-Dextrin
46080	007585-39-9	beta-Dextrin
55190	029204-02-2	Gadoleic acid
55440	009000-70-8	Gelatin
55630	000050-99-7	Glucose
55680	000110-94-1	Glutaric acid
56040	?	Glycerol dibutyrate
56160	026402-29-9	Glycerol dipropionate
56240	027902-24-5	Glycerol diricinoleate
56640	026999-06-4	Glycerol monobutyrate
56720	026402-22-2	Glycerol monohexanoate
56880	026402-26-6	Glycerol monooctanoate
57360	026894-50-8	Glycerol monopropionate
57440	001323-38-2	Glycerol monoricinoleate

**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 for this purpose.

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>
57840	000060-01-5	Glycerol tributyrat
57920	000620-67-7	Glycerol triheptanoate
58080	000139-45-7	Glycerol tripropionate
58160	000139-44-6	Glycerol tris(12-hydroxystearate)
58240	000555-43-1	Glycerol tristearate
59360	000142-62-1	n-Hexanoic acid
61840	000106-14-9	12-Hydroxystearic acid
62040	000139-44-6	12-Hydroxystearic acid, triester with glycerol
63280	000143-07-7	Lauric acid
63840	000123-76-2	Levulinic acid
63920	000557-59-5	Lignoceric acid
64015	000060-33-3	Linoleic acid
64130	-	Linoleic acid, salts
64150	028290-79-1	Linolenic acid
64500	-	Lysine, salts
71020	000373-49-9	Palmitoleic acid
88800	009005-25-8	Starch, edible
88880	068412-29-3	Starch, hydrolysed
91185	000057-50-1	Sucrose
92100/ 0	061789-97-7	Tallow
92195	-	Taurine, salts
95870	-	Wheat protein
95990	009010-66-6	Zein

## LIST 1

Substances for which an ADI, a t-ADI, a MTDI, a PMTDI, a PTWI or the classification "acceptable" has been established by this Committee or by JECFA.

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
30000	000064-19-7	Acetic acid	Group ADI : not specified. (SCF, 25th Series, 1991)
30045	000123-86-4	Acetic acid, n-butyl ester	t-ADI : 6 mg/kg b.w. (SCF, 25th Series, 1991)
30080	004180-12-5	Acetic acid, copper salt	PMTDI : 0.5 mg/kg b.w. (expressed as Cu). (JECFA, 26th meeting, 1982)
30140	000141-78-6	Acetic acid, ethyl ester	ADI : not specified. (SCF, 11th Series, 1981)
30180	000638-38-0	Acetic acid, manganese(II) salt	L1 for acetic acid. Group ADI : not specified. (SCF, 25th Series, 1991). L2 for Mn. Group TDI : 0.01 mg/kg b.w. (expressed as Mn). Recommended daily allowance : 2-3 mg/day. Average daily intake : 10 mg. (Manganese. Environmental Health Criteria 17, WHO, Geneva, 1981)
30400	-	Acetylated glycerides	ADI : not specified. (SCF, 7th Series, 1978)
30960	-	Acids, aliphatic, monocarboxylic (C6-C22), esters with polyglycerol	Group ADI : 25 mg/kg b.w. (SCF, 7th Series, 1978)
31730	000124-04-9	Adipic acid	ADI : 5 mg/kg b.w. (SCF, 25th Series, 1991)
33070	009002-18-0	Agar-agar	ADI : not specified. (SCF, 21st Series, 1989)
33350	009005-32-7	Alginate acid	ADI : not specified. (JECFA, 1992)
33360	-	Alginate acid, salts	ADI : 50 mg/kg b.w. (JECFA, 17th meeting, 1973)
35320	007664-41-7	Ammonia	ADI : not specified. (SCF, 25th Series, 1991)
35440	012124-97-9	Ammonium bromide	Group ADI : 1 mg/kg b.w. (expressed as Br) as pesticide residue. (JMPR "Pesticide residues in food", 1988, paper 93/2)
35520	012125-02-9	Ammonium chloride	ADI : not specified. (SCF, Rx)

## LIST 1

Substances for which an ADI, a t-ADI, a MTDI, a PMTDI, a PTWI or the classification "acceptable" has been established by this Committee or by JECFA.

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
35600	001336-21-6	Ammonium hydroxide	ADI : not specified. (SCF, Rx)
36000	000050-81-7	Ascorbic acid	Acceptable. (SCF, 22nd Series, 1989)
36080	000137-66-6	Ascorbyl palmitate	Acceptable. (SCF, 22nd Series, 1989)
36160	010605-09-1	Ascorbyl stearate	Acceptable. Covered by the assessment for ascorbyl palmitate.
37360	000100-52-7	Benzaldehyde	Group ADI : 5 mg/kg b.w. expressed as benzoic acid. (JECFA, 11th meeting, 1967)
37600	000065-85-0	Benzoic acid	Group ADI : 5 mg/kg b.w. (JECFA, 27th meeting, 1983)
38400	000100-51-6	Benzyl alcohol	Group ADI : 5 mg/kg b.w. expressed as benzoic acid. (SCF, 11th Series, 1981)
40720	025013-16-5	tert-Butyl-4-hydroxyanisole (= BHA)	t-ADI : 0.5 mg/kg b.w. (SCF, 22nd Series, 1989)
41120	010043-52-4	Calcium chloride	ADI : not specified. (SCF, Rx)
41280	001305-62-0	Calcium hydroxide	ADI : not specified. (SCF, Rx)
41520	001305-78-8	Calcium oxide	ADI : not specified. (SCF, Rx)
42160	000124-38-9	Carbon dioxide	ADI : not specified. (JECFA, 23rd meeting, 1980)
42320	007492-68-4	Carbonic acid, copper salt	PMTDI : 0.5 mg/kg b.w. (expressed as Cu). (JECFA, 26th meeting, 1982)
42500	-	Carbonic acid, salts	ADI : not specified for carbonate. (SCF, Rx)
44160	000077-92-9	Citric acid	Group ADI : not specified for citric acid and its salts. (SCF, 25th Series, 1991)
44640	000077-93-0	Citric acid, triethyl ester	ADI : 20 mg/kg b.w. (JECFA, 28th meeting, 1984)

## LIST 1

Substances for which an ADI, a t-ADI, a MTDI, a PMTDI, a PTWI or the classification "acceptable" has been established by this Committee or by JECFA.

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
45195	007787-70-4	Copper(I) bromide	PMTDI : 0.5 mg/kg b.w. (expressed as Cu). (JECFA, 26th meeting, 1982). ADI : 1 mg/kg b.w. (expressed as Br). It occurs also as a pesticide residue. (JMPR, "Pesticide residues in food", 1988, paper 93/2)
45200	007681-65-4	Copper(I) iodide	PMTDI : 0.5 mg/kg b.w. (expressed as Cu). (JECFA, 26th meeting, 1982) PMTDI : 0.017 mg/kg b.w. (expressed as I). (JECFA, 33rd meeting, 1988)
46640	000128-37-0	2,6-Di-tert-butyl-p-cresol (= BHT)	ADI : 0.05 mg/kg b.w. (SCF, 22nd Series, 1989)
49525	-	Dimethylpolysiloxane	ADI : 1.5 mg/kg b.w. (JECFA, 18th report, 1971)
52800	000064-17-5	Ethanol	Acceptable. (SCF, 11th Series, 1981)
54420	000121-32-4	Ethylvanillin	ADI : 5 mg/kg b.w. (JECFA, 35th meeting, 1990)
55040	000064-18-6	Formic acid	Group ADI : 3 mg/kg b.w. for formic acid and ethyl formate. (JECFA, 17th meeting, 1973)
55120	000110-17-8	Fumaric acid	ADI : 6 mg/kg b.w. (SCF, 25th Series, 1991)
55200	001166-52-5	Gallic acid, dodecyl ester	Group ADI : 0.5 mg/kg b.w. for dodecyl, octyl and propyl esters. (SCF, 22nd Series, 1989)
55280	001034-01-1	Gallic acid, octyl ester	Group ADI : 0.5 mg/kg b.w. for dodecyl, octyl and propyl esters. (SCF, 22nd Series, 1989)
55360	000121-79-9	Gallic acid, propyl ester	Group ADI : 0.5 mg/kg b.w. for dodecyl, octyl and propyl esters. (SCF, 22nd Series, 1989)
55920	000056-81-5	Glycerol	Group ADI : not specified for glycerol, glycerol diacetate, glycerol triacetate and glycerol monoacetate. (SCF, 11th Series, 1981)
56000	025395-31-7	Glycerol diacetate	Group ADI : not specified for glycerol, glycerol diacetate, glycerol triacetate and glycerol

## LIST 1

Substances for which an ADI, a t-ADI, a MTDI, a PMTDI, a PTWI or the classification "acceptable" has been established by this Committee or by JECFA.

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
			monoacetate. (SCF, 11th Series, 1981)
56080	025637-84-7	Glycerol dioleate	ADI : not specified. (JECFA, 17th meeting, 1973)
56320	001323-83-7	Glycerol distearate	ADI : not specified. (JECFA, 17th meeting, 1973)
56600	026446-35-5	Glycerol monoacetate	Group ADI : not specified for glycerol, glycerol diacetate, glycerol triacetate and glycerol monoacetate. (SCF, 11th Series, 1981)
56960	025496-72-4	Glycerol monooleate	ADI : not specified. (JECFA, 17th meeting, 1973)
57120	?	Glycerol monooleate, ester with citric acid	ADI : not specified for citric acid and fatty acid esters of glycerol. (SCF, 7th Series, 1978)
57280	?	Glycerol monopalmitate, ester with citric acid	ADI : not specified for citric acid and fatty acid esters of glycerol. (SCF, 7th Series, 1978)
57520	031566-31-1	Glycerol monostearate	ADI : not specified. (JECFA, 17th meeting, 1973)
57680	?	Glycerol monostearate, ester with citric acid	ADI : not specified for citric acid and fatty acid esters of glycerol. (SCF, 7th Series, 1978)
57760	000102-76-1	Glycerol triacetate	Group ADI : not specified for glycerol, glycerol diacetate, glycerol triacetate and glycerol monoacetate. (SCF, 11th Series, 1981)
58300	-	Glycine, salts	ADI : acceptable. (SCF, 25th Series, 1991)
58360	009000-29-7	Guaiac gum	ADI : 2.5 mg/kg b.w. (JECFA, 17th meeting, 1973)
58400	009000-30-0	Guar gum	ADI : not specified. (SCF, 7th Series, 1978)
58480	009000-01-5	Gum arabic	ADI : not specified. (JECFA, 35th meeting, 1989)
59990	007647-01-0	Hydrochloric acid	ADI : not specified.

## LIST 1

Substances for which an ADI, a t-ADI, a MTDI, a PMTDI, a PTWI or the classification "acceptable" has been established by this Committee or by JECFA.

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
			(SCF, Rx)
60160	000120-47-8	4-Hydroxybenzoic acid, ethyl ester	Group ADI : 10 mg/kg b.w. for ethyl, methyl and propyl esters. (SCF, 1st Series, 1975)
60200	000099-76-3	4-Hydroxybenzoic acid, methyl ester	Group ADI : 10 mg/kg b.w. for ethyl, methyl and propyl esters. (SCF, 1st Series, 1975)
60240	000094-13-3	4-Hydroxybenzoic acid, propyl ester	Group ADI : 10 mg/kg b.w. for ethyl, methyl and propyl esters. (SCF, 1st Series, 1975)
61800	009049-76-7	Hydroxypropyl starch	ADI : not specified. (SCF, 13th Series, 1982)
62720	001332-58-7	Kaolin	ADI : not specified. (SCF, 25th Series, 1991)
62830	009000-36-6	Karaya gum	ADI : 12.5 mg/kg b.w. (SCF, 21st Series, 1989)
62960	000050-21-5	Lactic acid	ADI : not specified. (SCF, 25th Series, 1991)
63200	051877-53-3	Lactic acid, manganese salt	L1 for lactic acid. ADI : not specified. (SCF, 25th Series, 1991) L2 for Mn. See references for acetic acid, manganese(II) salt in L2.
63760	008002-43-5	Lecithin	ADI : not specified. (JECFA, 17th meeting, 1973)
64560	007786-30-3	Magnesium chloride	ADI : not specified. (SCF, Rx)
64640	001309-42-8	Magnesium hydroxide	ADI : not specified. (SCF, Rx)
64720	001309-48-4	Magnesium oxide	ADI : not specified. (SCF, Rx)
65020	006915-15-7	Malic acid	ADI : not specified. (SCF, 25th Series, 1991)
65520	000087-78-5	Mannitol	ADI : acceptable. (SCF, 16th Series, 1985)

## LIST 1

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
67891	000544-63-8	Myristic acid	ADI : not specified. (SCF, 25th Series, 1991)
69040	000112-80-1	Oleic acid	ADI : not specified. (SCF, 25th Series, 1991)
69455	007384-22-7	Oleic acid, lithium salt	L1 (= not specified) for oleic acid. L2 for Li. Group TDI : 0.01 mg/kg b.w. (expressed as Li). See references for 38000 in L2 in this report.
69465	019153-79-8	Oleic acid, manganese salt	L1 (= not specified) for oleic acid. L2 for Mn. Group TDI : 0.01 mg/kg b.w. (expressed as Mn). See references for 30180 in L2 in this report.
70400	000057-10-3	Palmitic acid	ADI : not specified. (SCF, 25th Series, 1991)
70820	020466-33-5	Palmitic acid, lithium salt	L1 (= not specified) for palmitic acid. L2 for Li. Group TDI : 0.01 mg/kg b.w. (expressed as Li). See references for 38000 in L2 in this report.
70840	031678-63-4	Palmitic acid, manganese salt	L1 (= not specified) for palmitic acid. L2 for Mn. Group TDI : 0.01 mg/kg b.w. (expressed as Mn). See references for 30180 in L2 in this report.
71440	009000-69-5	Pectin	ADI : not specified. (SCF, 7th Series, 1978)
72640	007664-38-2	Phosphoric acid	MTDI : 70 mg/kg b.w. (expressed as P). (SCF, 25th Series, 1991)
73040	013763-32-1	Phosphoric acid, lithium salt	L1 for phosphoric acid. MTDI : 70 mg/kg b.w. (expressed as P). (SCF, 25th Series, 1991) L2 for Li. Group TDI : 0.01 mg/kg b.w. (expressed as Li). See references for benzoic acid, lithium salt.
73120	010124-54-6	Phosphoric acid, manganese salt	L1 for phosphoric acid. MTDI : 70 mg/kg b.w. (expressed as P). (SCF, 25th Series, 1991) L2 for Mn. Group TDI : 0.01 mg/kg b.w. (expressed as Mn). See references for acetic acid, manganese(II) salt.
79040	009005-64-5	Polyethyleneglycol sorbitan monolaurate	Group ADI : 10 mg/kg b.w. for



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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
			polyethyleneglycol sorbitan monolaurate, polyethyleneglycol sorbitan monooleate, polyethyleneglycol sorbitan monopalmitate, polyethyleneglycol sorbitan monostearate and polyethyleneglycol sorbitan tristearate. (SCF, 15th Series, 1985)
79200	009005-66-7	Polyethyleneglycol sorbitan monopalmitate	Group ADI : 10 mg/kg b.w. for polyethyleneglycol sorbitan monolaurate, polyethyleneglycol sorbitan monooleate, polyethyleneglycol sorbitan monopalmitate, polyethyleneglycol sorbitan monostearate and polyethyleneglycol sorbitan tristearate. (SCF, 15th Series, 1985)
79280	009005-67-8	Polyethyleneglycol sorbitan monostearate	Group ADI : 10 mg/kg b.w. for polyethyleneglycol sorbitan monolaurate, polyethyleneglycol sorbitan monooleate, polyethyleneglycol sorbitan monopalmitate, polyethyleneglycol sorbitan monostearate and polyethyleneglycol sorbitan tristearate. (SCF, 15th Series, 1985)
79440	009005-71-4	Polyethyleneglycol sorbitan tristearate	Group ADI : 10 mg/kg b.w. for polyethyleneglycol sorbitan monolaurate, polyethyleneglycol sorbitan monooleate, polyethyleneglycol sorbitan monopalmitate, polyethyleneglycol sorbitan monostearate and polyethyleneglycol sorbitan tristearate. (SCF, 15th Series, 1985)
80160	037349-34-1	Polyglycerol monostearate	ADI : 25 mg/kg b.w. (SCF, 7th Series, 1978)
80240	029894-35-7	Polyglycerol ricinoleate	ADI : 7.5 mg/kg b.w. (SCF, 7th Series, 1978)
80320	009009-32-9	Polyglycerol stearate	ADI : 25 mg/kg b.w. (JECFA, 26th meeting, 1982)
80720	008017-16-1	Polyphosphoric acids	MTDI : 70 mg/kg b.w. (expressed as P). (JECFA, 26th meeting, 1982)
81520	007758-02-3	Potassium bromide	Group ADI : 1 mg/kg b.w. (expressed as Br) as pesticide residue. See references for ammonium bromide.
81600	001310-58-3	Potassium hydroxide	ADI : not specified. (SCF, Rx)

## LIST 1

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
81680	007681-11-0	Potassium iodide	PMTDI : 0.017 mg/kg b.w. (expressed as I). (JECFA, 33rd meeting, 1988)
81840	000057-55-6	1,2-Propanediol	ADI : 25 mg/kg b.w. (JECFA, 17th meeting, 1973)
81882	000067-63-0	2-Propanol	t-ADI : 1.5 mg/kg b.w. (SCF, 11th Series, 1981)
82000	000079-09-4	Propionic acid	Group ADI : not specified. (SCF, 1st Series, 1975)
82080	009005-37-2	1,2-Propyleneglycol alginate	Group ADI : 25 mg/kg b.w. (JECFA, 17th meeting, 1973)
82240	022788-19-8	1,2-Propyleneglycol dilaurate	Group ADI : 25 mg/kg b.w. (expressed as propyleneglycol) for 1,2-propyleneglycol esters of fatty acids. (JECFA, 17th meeting, 1973)
82400	000105-62-4	1,2-Propyleneglycol dioleate	Group ADI : 25 mg/kg b.w. (expressed as propyleneglycol) for 1,2-propyleneglycol esters of fatty acids. (JECFA, 17th meeting, 1973)
82560	033587-20-1	1,2-Propyleneglycol dipalmitate	Group ADI : 25 mg/kg b.w. (expressed as propyleneglycol) for 1,2-propyleneglycol esters of fatty acids. (JECFA, 17th meeting, 1973)
82720	006182-11-2	1,2-Propyleneglycol distearate	Group ADI : 25 mg/kg b.w. (expressed as propyleneglycol) for 1,2-propyleneglycol esters of fatty acids. (JECFA, 17th meeting, 1973)
82800	027194-74-7	1,2-Propyleneglycol monolaurate	Group ADI : 25 mg/kg b.w. (expressed as propyleneglycol) for 1,2-propyleneglycol esters of fatty acids. (JECFA, 17th meeting, 1973)
82960	001330-80-9	1,2-Propyleneglycol monooleate	Group ADI : 25 mg/kg b.w. (expressed as propyleneglycol) for 1,2-propyleneglycol esters of fatty acids. (JECFA, 17th meeting, 1973)
83120	029013-28-3	1,2-Propyleneglycol monopalmitate	Group ADI : 25 mg/kg b.w. (expressed as propyleneglycol) for 1,2-propyleneglycol esters of fatty acids. (JECFA, 17th meeting, 1973)

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
83300	001323-39-3	1,2-Propyleneglycol monostearate	Group ADI : 25 mg/kg b.w. (expressed as propyleneglycol) for 1,2-propyleneglycol esters of fatty acids. (JECFA, 17th meeting, 1973)
83440	002466-09-3	Pyrophosphoric acid	MTDI : 70 mg/kg b.w. (expressed as P). (JECFA, 26th meeting, 1982)
84000	008050-31-5	Rosin, ester with glycerol	ADI : 12.5 mg/kg b.w. (SCF in press, see CS/PM/1623)
84880	000119-36-8	Salicylic acid, methyl ester	ADI : 0.5 mg/kg b.w. (JECFA, 11th meeting, 1967)
85550	009000-59-3	Shellac	ADI : acceptable. (SCF, 26th Series, 1992)
86240	007631-86-9	Silicon dioxide	ADI : not specified. (SCF, Rx)
86480	007631-90-5	Sodium bisulphite	Group ADI : 0.7 mg/kg b.w. (JECFA, 27th meeting, 1983)
86560	007647-15-6	Sodium bromide	Group ADI : 1 mg/kg b.w. (expressed as Br) as pesticide residue. See references for ammonium bromide.
86720	001310-73-2	Sodium hydroxide	ADI : not specified. (SCF, Rx)
86800	007681-82-5	Sodium iodide	PMTDI : 0.017 mg/kg b.w. (expressed as I). (JECFA, 33rd meeting, 1988)
86960	007757-83-7	Sodium sulphite	Group ADI : 0.7 mg/kg b.w. (JECFA, 27th meeting, 1983)
87120	007772-98-7	Sodium thiosulphate	Group ADI : 0.7 mg/kg b.w. (expressed as SO <sub>2</sub> ). Included in the group ADI for sulphites. (JECFA, 27th meeting, 1983)
87200	000110-44-1	Sorbic acid	ADI : 25 mg/kg b.w. (SCF, 6th Series, 1978)
87600	001338-39-2	Sorbitan monolaurate	Group ADI : 5 mg/kg b.w. for sorbitan monolaurate and sorbitan monooleate. (SCF, 7th Series, 1978)
87680	001338-43-8	Sorbitan monooleate	Group ADI : 5 mg/kg b.w. for sorbitan monolaurate and sorbitan monooleate. (SCF, 7th Series, 1978)

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
87760	026266-57-9	Sorbitan monopalmitate	Group ADI : 25 mg/kg b.w. for sorbitan monostearate, sorbitan monopalmitate and sorbitan tristearate. (SCF, 7th Series, 1978)
87840	001338-41-6	Sorbitan monostearate	Group ADI : 25 mg/kg b.w. for sorbitan monostearate, sorbitan monopalmitate and sorbitan tristearate. (SCF, 7th Series, 1978)
88240	026658-19-5	Sorbitan tristearate	Group ADI : 25 mg/kg b.w. for sorbitan monostearate, sorbitan monopalmitate and sorbitan tristearate. (SCF, 7th Series, 1978)
88320	000050-70-4	Sorbitol	Acceptable. (SCF, 16th Series, 1985)
89040	000057-11-4	Stearic acid	ADI : not specified. (SCF, 25th Series, 1991)
89200	000660-60-6	Stearic acid, copper(II) salt	PMTDI : 0.5 mg/kg b.w. (expressed as Cu). (JECFA, 26th meeting, 1982)
90260	004485-12-5	Stearic acid, lithium salt	L1 for stearic acid. ADI : not specified. See references for stearic acid. L2 for Li. Group TDI : 0.01 mg/kg b.w. (expressed as Li). See references for 38000 in L2 in this report.
90290	010476-84-3	Stearic acid, manganese salt	L1 for stearic acid. ADI : not specified. See references for stearic acid. L2 for Mn. Group TDI : 0.01 mg/kg b.w. (expressed as Mn). See references for 30180 in L2 in this report.
90600	006994-59-8	Stearic acid, tin(II) salt	L1 for stearic acid. ADI : not specified. See references for stearic acid. L1 for Sn. PTWI : 14 mg/kg b.w. (expressed as Sn). (JECFA, 33rd meeting, 1989)
90800	005793-94-2	Stearoyl-2-lactylic acid, calcium salt	ADI : 20 mg/kg b.w. (SCF, 7th Series, 1978)
90960	000110-15-6	Succinic acid	ADI : not specified. (SCF, 25th Series, 1991)

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
91200	000126-13-6	Sucrose acetate isobutyrate	ADI : 10 mg/kg b.w. (SCF in press, see CS/PM/1561)
91920	007664-93-9	Sulphuric acid	ADI : not specified. (SCF, Rx)
92060	007488-55-3	Sulphuric acid, tin(II) salt	L1 for sulphuric acid. ADI : not specified. See references for sulphuric acid. L1 for Sn. PTWI : 14 mg/kg b.w. (expressed as Sn). (JECFA, 33rd meeting, 1989)
92080	014807-96-6	Talc	ADI : not specified. (SCF, Rx)
92160	000087-69-4	Tartaric acid	ADI : 30 mg/kg b.w. (SCF, Rx)
92350	000112-60-7	Tetraethyleneglycol	ADI : 10 mg/kg b.w. (SCF, 17th Series, 1986)
93415	007772-99-8	Tin(II) chloride	PTWI : 14 mg/kg b.w. (JECFA, 1989)
93420	007646-78-8	Tin(IV) chloride	PTWI : 14 mg/kg b.w. (JECFA, 33rd report, 1989)
93440	013463-67-7	Titanium dioxide	Acceptable. (SCF, 1st Series, 1975)
93520	000059-02-9 010191-41-0	alpha-Tocopherol	Acceptable. (SCF, 22nd Series, 1989)
93680	009000-65-1	Tragacanth gum	ADI : not specified. (SCF, 21st Series, 1989)
95680	000121-33-5	Vanillin	ADI : 10 mg/kg b.w. (JECFA, 11th meeting, 1967)
95935	011138-66-2	Xanthan gum	ADI : not specified. (JECFA, 30th meeting, 1986)
96180		Zinc dust	ADI : 1 mg/kg b.w. (JECFA, 26th meeting, 1982)
96190	020427-58-1	Zinc hydroxide	ADI : 1 mg/kg b.w. (JECFA, 26th meeting, 1982)

## LIST 2

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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
30180	000638-38-0	Acetic acid, manganese(II) salt	L1 for acetic acid. Group ADI : not specified. (SCF, 25th Series, 1991). L2 for Mn. Group TDI : 0.01 mg/kg b.w. (expressed as Mn). Recommended daily allowance : 2-3 mg/day. Average daily intake : 10 mg. (Manganese. Environmental Health Criteria 17, WHO, Geneva, 1981)
30280	000108-24-7	Acetic anhydride	Group TDI : included in the ADI not specified for acetic acid. (SCF, 25th Series, 1991)
31520	061167-58-6	Acrylic acid, 2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methylbenzyl)-4-methylphenyl ester	3-Month oral rat study. Mutagenicity studies. Migration data. No bioaccumulation in fish. (RIVM 90/678608/007; CS/PM/926)
31540	000096-33-3	Acrylic acid, methyl ester	See references for same substance in monomer report.
31920	000103-23-1	Adipic acid, bis(2-ethylhexyl) ester	TDI : 0.3 mg/kg b.w. Several oral short-term studies in mice, rats and dogs, oral carcinogenicity studies in mice and rats, oral teratogenicity and fertility studies in rats and several mutagenicity studies. (RIVM report 1990-05-02, ICI reports CT 4/P/2119, July 1988 and CTL/P/2119, August 1988)
34230	-	Alkyl(C8-C22)sulphonic acid	TDI : 0.1 mg/kg b.w. 1- and 2-Year oral rat studies. (Bayer report, 1960)
34240	-	Alkyl(C10-C20)sulphonic acid, esters with phenols	t-TDI : 0.1 mg/kg b.w. Available : 90-day oral rat study and Ames test. Needed : additional mutagenicity studies according to guidelines. (RIVM doc. 1990-05-08)
34560	021645-51-2	Aluminium hydroxide	TDI : 1 mg/kg b.w. (expressed as Al), based on PTWI : 7 mg/kg b.w. (expressed as Al). (SCF, 25th Series, 1991)
34660	001327-41-9	Aluminium hydroxychloride	TDI : 1 mg/kg b.w. (expressed as Al), based on PTWI : 7 mg/kg b.w. (expressed as Al). (SCF, 25th Series, 1991)
34720	001344-28-1	Aluminium oxide	TDI : 1 mg/kg b.w. (expressed as Al), based on PTWI : 7 mg/kg b.w. (expressed as Al). (SCF, 25th Series, 1991)

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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
35120	013560-49-1	3-Aminocrotonic acid, diester with thiobis(2-hydroxyethyl) ether	t-TDI : 5 mg/kg b.w. pending results of mutagenicity studies. Available : 28-day and 90-day oral rat studies, metabolism, very low migration.
35630	010196-04-0	Ammonium sulphite	Group TDI : 0.7 mg/kg b.w. Based on ADI for SO <sub>2</sub> . (JECFA, 30th meeting, 1986)
36800	010022-31-8	Barium nitrate	TDI : 3 mg/kg b.w. (expressed as nitrate), based on ADI (= 5 mg/kg b.w.) for sodium nitrate. (SCF, 26th Series, 1992) L3 for Ba. R : 1 mg/kg (expressed as Ba). (RIVM doc., May 1992 (CS/PM/1584))
36840	?	Barium tetraborate	L3 for Ba. R : 1 mg/kg (expressed as Ba). (RIVM doc., May 1992 (CS/PM/1584)). L2 for borate. TDI : 0.2 mg/kg b.w. (expressed as B). See references for boric acid (L2) in this report.
37520	002634-33-5	1,2-Benzisothiazolin-3-one	t-TDI : 0.02 mg/kg b.w. Available : several oral dog studies and a 90-day oral rat study. (RIVM, June 1980) Needed : mutagenicity studies.
37680	000136-60-7	Benzoic acid, butyl ester	Group TDI : 5 mg/kg b.w. (expressed as benzoic acid) for butyl, ethyl, methyl and propyl benzoate on the basis of the group ADI for benzoic acid. (JECFA, 27th meeting, 1983)
37840	000093-89-0	Benzoic acid, ethyl ester	Group TDI : 5 mg/kg b.w. (expressed as benzoic acid) for butyl, ethyl, methyl and propyl benzoate on the basis of the group ADI for benzoic acid. (JECFA, 27th meeting, 1983)
38000	000553-54-8	Benzoic acid, lithium salt	Group TDI : 0.01 mg/kg b.w. (expressed as Li). Available : 90-day oral rat studies, mutagenicity data, therapeutic use of Li salts. (RIVM summary, Sept. 1991)
38080	000093-58-3	Benzoic acid, methyl ester	Group TDI : 5 mg/kg b.w. (expressed as benzoic acid) for butyl, ethyl, methyl and propyl benzoate on the basis of the group ADI for benzoic acid. (JECFA, 27th meeting, 1983)
38160	002315-68-6	Benzoic acid, propyl ester	Group TDI : 5 mg/kg b.w. (expressed as benzoic acid) for butyl, ethyl, methyl and propyl benzoate on the basis of the group ADI for benzoic acid.

## LIST 2

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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
			(JECFA, 27th meeting, 1983)
38240	000119-61-9	Benzophenone	Group TDI : 0.01 mg/kg b.w. 90-Day oral rat study and metabolism study. (CIVO report R 3301, 1970)
38560	007128-64-5	2,5-Bis(5-tert-butyl-2-benzoxazolyl)thio- phene	TDI : 0.01 mg/kg b.w. 90-Day oral dog and rat studies, 1-year (+ 0.5-year recovery) study in mice showed accumulation in tissues by fluorescence. (RIVM doc. tox. 300/277, June 1981)
38700	063397-60-4	Bis(2-carbobutoxyethyl)tin bis(isooctyl mercaptoacetate)	t-TDI : 0.3 mg/kg b.w. pending additional mutagenicity studies. Available : 28-day (young rats) and 90-day oral rat studies, and Ames test. (RIVM report 89/678608/003, 1989-04-04)
38800	032687-78-8	N,N'-Bis[3-(3,5-di-tert-butyl-4-hydroxy- phenyl)propionyl]hydrazide	TDI : 0.25 mg/kg b.w. 3-Month oral rat study, mutagenicity studies, migration data. (RIVM, September 1990)
38820	026741-53-7	Bis(2,4-di-tert-butylphenyl)pentaerythritol diphosphite	TDI : 0.01 mg/kg b.w. 90-Day oral rat and 4-month oral dog studies and Ames test. (RIVM doc. tox. 300/335, June 1982)
38950	079072-96-1	Bis(4-ethylbenzylidene)sorbitol	Group TDI : 1 mg/kg b.w. [bis(4-ethylbenzylidene) sorbitol, bis(methylbenzylidene)sorbitol and dibenzylidenesorbitol]. Several 90-day oral mouse and rat studies, several mutagenicity studies negative. (RIVM doc. 88/678608/008, 1.11.1988; RIVM doc. tox. 300/425, May 1983; RIVM, 15.11.1989)
39090	-	N,N-Bis(2-hydroxyethyl)alkyl(C8-C18)- amine	Group t-TDI : 0.02 mg/kg b.w. (expressed as free amine), with N,N-bis(2-hydroxyethyl)- alkyl(C8-C18)amine hydrochloride. See references for N,N-bis(2-hydroxyethyl)- alkyl(C8-C18)amine hydrochloride.
39120	-	N,N-Bis(2-hydroxyethyl)alkyl(C8-C18)amine hydrochloride	Group t-TDI : 0.02 mg/kg b.w. (expressed as free amine) with N,N-bis(2-hydroxyethyl)- alkyl(C8-C18)amine. Available : 90-day oral rat and dog studies. (RIVM report, November 1971) Needed : adequate 28-day oral study.
39200	006200-40-4	Bis(2-hydroxyethyl)-2-hydroxypropyl-3- (dodecyloxy)methylammonium chloride	TDI : 0.03 mg/kg b.w. 90-Day oral rat study.



## LIST 2

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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
			(CIVO report R 2491, September 1967, and 2628, February 1968)
39600	000077-62-3	Bis[2-hydroxy-3-(1-methylcyclohexyl)-5-methylphenyl]methane	TDI : 0.1 mg/kg b.w. Several oral rat and dog short term studies, a 90-day oral dog and 2-year oral rat and dog studies. (Report from H.C. Hodge, 20 March 1961)
39680	000080-05-7	2,2-Bis(4-hydroxyphenyl)propane	TDI : 0.05 mg/kg b.w. (SCF, 17th Series, 1986)
39890	087826-41-3 069158-41-4	Bis(methylbenzylidene)sorbitol	Group TDI : 1 mg/kg b.w. [bis(4-ethylbenzylidene)sorbitol, bis(methylbenzylidene)sorbitol and dibenzylidenesorbitol]. 28- And 90-day oral rat studies, one in-vitro mutagenicity study. See references for bis(4-ethylbenzylidene)sorbitol.
40000	000991-84-4	2,4-Bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	TDI : 0.5 mg/kg b.w. 90-Day oral rat and dog studies. (RIVM monograph 300/211, December 1980)
40020	110553-27-0	2,4-Bis(octylthiomethyl)-6-methylphenol	TDI : 0.1 mg/kg b.w. Available : 1- and 3-month oral rat studies and teratogenicity studies in rats. Bioaccumulation and mutagenicity studies and migration data. (RIVM 90/678608/008)
40160	061269-61-2	N,N'-Bis(2,2,6,6-tetramethyl-4-piperidyl)-hexamethylenediamine-1,2-dibromoethane, copolymer	t-TDI : 0.04 mg/kg b.w. pending results of mutagenicity study in eukaryotic cells. Available : 90-day oral rat study, rat teratogenicity study and mutagenicity study. (HRC reports MTI 135/85733/ST, 24 September 1985 and MTI 133/85540, 14 August 1985 plus Farmitalia report, 6 March 1985)
40240	-	Bis(triethyleneglycol) hydroxymethylphosphonate	t-TDI : 0.01 mg/kg b.w. Available : 90-day oral rat study and migration < 0.1 mg/kg. (RIVM doc., October 1970). Needed : mutagenicity studies.
40320	010043-35-3	Boric acid	Group TDI : 0.2 mg/kg b.w. (expressed as B). Several short-term, 90-day and 2-year oral rat studies, 38-week and 2-year oral dog studies and a 3-generation oral rat study. A 2-year oral mouse carcinogenicity study. (Toxicol. Appl. Pharmacol. 1972, 23, 351-364, NTP report TR 324, 26 March 1986)
40800	013003-12-8	4,4'-Butylidenebis(6-tert-butyl-3-methyl-	TDI : 0.1 mg/kg b.w.

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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
		phenyl-ditridecyl phosphite)	90-Day oral rat study. (CIVO report 5254, February 1977)
40880	015666-29-2	Butylthiostannoic acid	t-TDI : 25 mg/kg b.w. Available : 70- and 90-day and 2-year oral rat studies, observations in man and migration data. Needed : mutagenicity studies.
40980	?	Butyric acid, manganese salt	L0 for butyric acid. L2 for Mn. TDI : 0.01 mg/kg b.w. (expressed as Mn). See references for 30180 in L2 in this report.
41600	012004-14-7 037293-22-4	Calcium sulphoaluminate	TDI : 1 mg/kg b.w. (expressed as Al), based on PTWI : 7 mg/kg b.w. (expressed as Al). (SCF, 25th Series, 1991)
41840	000105-60-2	Caprolactam	Group TDI : 0.25 mg/kg b.w. (SCF, 17th Series, 1986)
42000	063438-80-2	(2-Carbobutoxyethyl)tin tris(isooctyl mercaptoacetate)	t-TDI : 0.5 mg/kg b.w. pending additional mutagenicity studies. Available : 35-day (young rats) and 90-day oral rat studies, and Ames test. (RIVM report 89/678608/002, 1989-04-04)
42400	010377-37-4	Carbonic acid, lithium salt	Group TDI : 0.01 mg/kg b.w. (expressed as Li). See references for benzoic acid, lithium salt.
42480	000584-09-8	Carbonic acid, rubidium salt	TDI : 0.2 mg/kg b.w. 90-Day oral rat study on diet low in K+. Normal food may contain up to 140 mg/kg. Average daily intake for man : 1-4 mg. (RIVM 617601002, 1981)
42640	009000-11-7	Carboxymethylcellulose	Group TDI : not specified based on group ADI (= not specified) for certain modified cellulose. (JECFA, 35th meeting, 1989)
43360	068442-85-3	Cellulose, regenerated	Group TDI : not specified based on group ADI (= not specified) for certain modified cellulose. (JECFA, 35th meeting, 1989)
43600	004080-31-3	1-(3-Chloroallyl)-3,5,7-triaza-1-azonia-adamantane chloride	TDI : 0.005 mg/kg b.w. Two 90-day oral rat and a dog studies and teratogenicity studies in rats and rabbits, and negative mutagenicity studies. (RIVM doc., December 1983)
43600	000075-45-6	Chlorodifluoromethane	TDI : 0.1 mg/kg b.w. (based on teratogenicity study). Specifications : free from carcinogenic

## LIST 2

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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
			substances.
			One-year oral rat study. Several inhalation studies in several animal species, including teratogenicity in rabbits. Mutagenicity tests in vitro and in vivo. N.B. The Committee has not considered the environmental implications of the use of the solvent in food technology, but recognises that environmental considerations should take precedence over its own evaluation on this occasion.
45520	-	p-Cresol, styrenated	t-TDI : 0.2 mg/kg b.w. Available : 3-month oral rat and 2-year oral rat and dog studies, rat reproduction study. (Food Drug Research Lab., 1964). Needed : specifications and mutagenicity studies.
45760	000108-91-8	Cyclohexylamine	TDI : 1 mg/kg b.w. calculated with reference to the ADI for cyclamic acid (11 mg/kg b.w.) (JECFA, 26th meeting, 1982)
45970	020336-95-2	n-Decanoic acid, lithium salt	L0 for n-decanoic acid. L2 for Li. Group TDI : 0.01 mg/kg b.w. (expressed as Li). See references for 38000 in L2 in this report.
45980	010139-57-8	n-Decanoic acid, manganese salt	L0 for n-decanoic acid. L2 for Mn. Group TDI : 0.01 mg/kg b.w. (expressed as Mn). See references for 30180 in L2 in this report.
46480	032647-67-9	Dibenzylidene sorbitol	Group TDI : 1 mg/kg b.w. [bis(4-ethylbenzylidene)sorbitol, bis(methylbenzylidene)sorbitol and dibenzylidenesorbitol]. Several 90-day oral mouse and rat studies, several mutagenicity studies negative. See references for bis(4-ethylbenzylidene)sorbitol.
46800	067845-93-6	3,5-Di-tert-butyl-4-hydroxybenzoic acid, hexadecyl ester	TDI : 2.5 mg/kg b.w. 90-Day oral rat and dog studies, reproduction study in rats, mutagenicity studies. (RIVM doc. 88/678608/001, 1 November 1988)
46880	065140-91-2	3,5-Di-tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	TDI : 0.1 mg/kg b.w. A 4+4-week, a 13+4-week and a 2-year oral rat study. (Ciba-Geigy reports CBG 174/78110 (10.7.1978), CBG 192/781233 (22.3.1979), CBG 261/821163 (4.4.1984))
47200	004221-80-1	2,4-Di-tert-butylphenyl 3,5-di-tert-butyl-4-hydroxybenzoate	TDI : 2 mg/kg b.w. 90-Day oral rat study.

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
			(RIVM report, May 1973)
47440	000461-58-5	Dicyanodiamide	TDI : 1 mg/kg b.w. 2-Year oral rat and dog studies and Ames tests. (American Cyanamide report, 1969)
47600	084030-61-5	Di-n-dodecyltin bis(isooctyl mercaptoacetate)	TDI : 0.2 mg/kg b.w. 10- and 90-day oral rat studies, mutagenicity tests. (RIVM report 2.4.1990)
47680	000111-46-6	Diethyleneglycol	Group TDI : 0.5 mg/kg b.w. (with ethyleneglycol). (SCF, 17th Series, 1986)
48030	000112-34-5	Diethyleneglycol monobutyl ether	Group t-TDI : 0.05 mg/kg b.w. See references for 16996.
48050	000111-90-0	Diethyleneglycol monoethyl ether	t-TDI : 0.05 mg/kg b.w. See references for same substance in monomer report.
48620	000123-31-9	1,4-Dihydroxybenzene	TDI : 0.01 mg/kg b.w. (SCF, 17th Series, 1986)
48640	000131-56-6	2,4-Dihydroxybenzophenone	Group TDI : 0.1 mg/kg b.w. (with 4,4'-dihydroxybenzophenone; 2,2'-dihydroxy-4-methoxybenzophenone; 2-hydroxy-4-n-hexyloxybenzophenone; 2-hydroxy-4-n-octyloxybenzophenone). 90-Day oral rat studies (2,2'-dihydroxy-4-methoxybenzophenone; 2-hydroxy-4-methoxybenzophenone; 2-hydroxy-4-n-octyloxybenzophenone), a 18-week oral dog study (2-hydroxy-4-n-octyloxybenzophenone) and 2-year rat and dog studies (2-hydroxy-4-n-octyloxybenzophenone), a reproduction study (2-hydroxy-4-n-octyloxybenzophenone) plus metabolism. (J. Occup. Med. 1969, 11, 703, Food Cosm. Tox. 1972, 10, 41-50, RIVM report, October 1972)
48720	000611-99-4	4,4'-Dihydroxybenzophenone	Group TDI : 0.1 mg/kg b.w. See references for 2,4-dihydroxybenzophenone.
48760	000092-88-6	4,4'-Dihydroxybiphenyl	TDI : 0.1 mg/kg b.w. See references for same substance in monomer report.
48800	000097-23-4	2,2'-Dihydroxy-5,5'-dichlorodiphenylmethane	TDI : 0.2 mg/kg b.w. 2-Week and 13-week oral rat studies and observations in man from its therapeutic use. (J. Am. Leather. Chemists Assoc., 1944, 39,

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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
			203-209; J. Pharmacol. Exper. Therap., 1949, 96, 238-249)
48880	000131-53-3	2,2'-Dihydroxy-4-methoxybenzophenone	Group TDI : 0.1 mg/kg b.w. See references for 2,4-dihydroxybenzophenone.
49235	000108-01-0	Dimethylaminoethanol	See references for same substance in monomer report.
49425	000137-30-4	Dimethyldithiocarbamic acid, zinc salt	ADI : 0.02 mg/kg b.w. (JECFA, 24th meeting, 1980)
49600	026636-01-1	Dimethyltin bis(isooctyl mercaptoacetate)	Group TDI : 0.003 mg/kg b.w. (expressed as Sn) with monomethyltin tris(isooctyl mercaptoacetate). Available : 28-day and two 3-month oral rat studies. Mutagenicity tests to be re-evaluated. (RIVM doc., 2.2.1988 and April 1991)
49760	003135-18-0	Di-n-octadecyl 3,5-di-tert-butyl-4-hydroxybenzylphosphonate	TDI : 1 mg/kg b.w. A 90-day oral rat study. (Ciba-Geigy report, 14.2.1970)
49840	002500-88-1	Di-octadecyl disulphide	TDI : 0.05 mg/kg b.w. A 90-day oral rat study. (Hoechst report, 1967)
50160	-	Di-n-octyltin bis[n-alkyl(C10-C16) mercaptoacetate]	Group t-TDI : 0.0003 mg/kg b.w. (expressed as Sn) for all di-n-octyltin derivatives. See references for 50480.
50240	010039-33-5	Di-n-octyltin bis(2-ethylhexyl maleate)	Group t-TDI : 0.0003 mg/kg b.w. (expressed as Sn) for all di-n-octyltin derivatives. See references for 50480.
50320	015571-58-1	Di-n-octyltin bis(2-ethylhexyl mercaptoacetate)	Group t-TDI : 0.0003 mg/kg b.w. (expressed as Sn) for all di-n-octyltin derivatives. See references for 50480.
50360	-	Di-n-octyltin bis(ethyl maleate)	Group t-TDI : 0.0003 mg/kg b.w. (expressed as Sn) for all di-n-octyltin derivatives. See references for 50480.
50400	033568-99-9	Di-n-octyltin bis(isooctyl maleate)	Group t-TDI : 0.0003 mg/kg b.w. (expressed as Sn) for all di-n-octyltin derivatives. See references for 50480.
50480	026401-97-8	Di-n-octyltin bis(isooctyl mercaptoacetate)	Group t-TDI : 0.0003 mg/kg b.w. (expressed as Sn). Available : several oral short-term and semichronic studies in rats and dogs and 2-year

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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
			rat studies, several mutagenicity studies in vitro and in vivo, insufficient reproduction and teratogenicity studies. (RIVM report, May 1989) Needed : reproduction and teratogenicity studies.
50560	?	Di-n-octyltin 1,4-butanediol bis(mercaptoacetate)	Group t-TDI : 0.0003 mg/kg b.w. (expressed as Sn) for all di-n-octyltin derivatives. See references for 50480.
50640	003648-18-8	Di-n-octyltin dilaurate	Group t-TDI : 0.0003 mg/kg b.w. (expressed as Sn) for all di-n-octyltin derivatives. See references for 50480.
50720	015571-60-5	Di-n-octyltin dimaleate	Group t-TDI : 0.0003 mg/kg b.w. (expressed as Sn) for all di-n-octyltin derivatives. See references for 50480.
50800	-	Di-n-octyltin dimaleate, esterified	Group t-TDI : 0.0003 mg/kg b.w. (expressed as Sn) for all di-n-octyltin derivatives. See references for 50480.
50880	-	Di-n-octyltin dimaleate, polymers (n = 2-4)	Group t-TDI : 0.0003 mg/kg b.w. (expressed as Sn) for all di-n-octyltin derivatives. See references for 50480.
50960	069226-44-4	Di-n-octyltin ethyleneglycol bis(mercaptoacetate)	Group t-TDI : 0.0003 mg/kg b.w. (expressed as Sn) for all di-n-octyltin derivatives. See references for 50480.
51040	015535-79-2	Di-n-octyltin mercaptoacetate	Group t-TDI : 0.0003 mg/kg b.w. (expressed as Sn) for all di-n-octyltin derivatives. See references for 50480.
51120	?	Di-n-octyltin thiobenzoate (2-ethylhexyl mercaptoacetate)	Group t-TDI : 0.0003 mg/kg b.w. (expressed as Sn) for all di-n-octyltin derivatives. See references for 50480.
51200	000126-58-9	Dipentaerythritol	Group TDI : 1 mg/kg b.w. (with pentaerythritol). (SCF, 17th Series, 1986)
51680	000102-08-9	N,N'Diphenylthiourea	TDI : 0.05 mg/kg b.w. 28-Day, 1-year and 2-year oral rat studies, (RIVM, January 1967 and May 1973)
51760	000110-98-5	Dipropylene glycol	Group TDI : 1.5 mg/kg b.w. (SCF, 17th Series, 1986)
52000	027176-87-0	Dodecylbenzenesulphonic acid	TDI : 0.5 mg/kg b.w. Two 2-year oral rat studies, mutagenicity studies. (RIVM Summary report, March 1965)

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
52320	052047-59-3	2-(4-Dodecylphenyl)indole	TDI : 0.001 mg/kg b.w. A 90-day oral rat study. (Inst. f. Biol. Forsch. Köln, report 1976)
52880	023676-09-7	4-Ethoxybenzoic acid, ethyl ester	t-TDI : 0.06 mg/kg b.w. Available : 28-day oral rat study and 3 mutagenicity tests. (RIVM, 17 March 1987). Needed : 90-day oral study.
53200	023949-66-8	2-Ethoxy-2'-ethyloxanilide	TDI : 0.5 mg/kg b.w. 90-Day and 2-year oral rat studies. (Sandoz reports 1973 and 1975)
53270	037205-99-5	Ethylcarboxymethylcellulose	Group TDI : not specified based on group ADI (= not specified) for certain modified cellulose. (JECFA, 35th meeting, 1989)
53280	009004-57-3	Ethylcellulose	Group TDI : not specified based on group ADI (= not specified) for certain modified cellulose. (JECFA, 35th meeting, 1989)
53540	000107-15-3	Ethylenediamine	TDI : 0.2 mg/kg b.w. Two 90-day oral rat studies. (ICI report, April 1975)
53600	000060-00-4	Ethylenediaminetetraacetic acid	TDI : 2.5 mg/kg b.w. expressed as calcium disodium salt on the basis of JECFA ADI for calcium disodium EDTA. (JECFA, 17th meeting, 1973; SCF, 4th Series, 1977)
53610	054453-03-1	Ethylenediaminetetraacetic acid, copper salt	Group TDI : 0.5 mg/kg b.w. (expressed as Cu) on the basis of JECFA ADI for calcium disodium EDTA (2.5) and PMTDI for Cu (0.5). (JECFA, 26th meeting, 1982 for Cu; SCF, 4th Series, 1977, for calcium disodium EDTA)
53650	000107-21-1	Ethyleneglycol	Group TDI : 0.5 mg/kg b.w. (with diethyleneglycol). (SCF, 17th Series, 1986)
53670	032509-66-3	Ethyleneglycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]	TDI : 0.005 mg/kg b.w. 90-Day oral dog and 16-week oral rat (after in utero exposure) and a 2-year oral dog study. (RIVM report 300/197, December 1980)
53765	000111-76-2	Ethyleneglycol monobutyl ether	Group t-TDI : 0.05 mg/kg b.w. See references for 16996.
53820	000110-80-5	Ethyleneglycol monoethyl ether	Group t-TDI : 0.05 mg/kg b.w. See references for 16996.

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
54180	015590-62-2	2-Ethylhexanoic acid, lithium salt	Postponed for 2-ethylhexanoic acid. Group TDI : 0.01 mg/kg b.w. (expressed as Li). For Li, see references for 38000 in L2 in this report.
54260	009004-58-4	Ethylhydroxyethylcellulose	Group TDI : not specified based on group ADI (= not specified) for certain modified celluloses. (JECFA, 35th meeting, 1989)
54270	?	Ethylhydroxymethylcellulose	Group TDI : not specified based on group ADI (= not specified) for certain modified celluloses. (JECFA, 35th meeting, 1989)
54280	?	Ethylhydroxypropylcellulose	Group TDI : not specified based on group ADI (= not specified) for certain modified celluloses. (JECFA, 35th meeting, 1989)
54300	?	2,2'-Ethylidenebis(4,6-di-tert-butylphenyl) fluorophosphonite	TDI : 0.1 mg/kg b.w. 3-Month oral dog and 3-month combined oral fertility study in rats. Mutagenicity tests negative. (Doc. CS/PM/841)
54680/ 1	?	Fatty acids, soya, lithium salts	L3 for fatty acids, soya. Constituents of natural fats. L2 for Li. Group TDI : 0.01 mg/kg b.w. (as Li). See references for 38000 in L2 in this report.
54685/ 1	?	Fatty acids, soya, manganese salts	L3 for fatty acids, soya. Constituents of natural fats. L2 for Mn. Group TDI : 0.01 mg/kg b.w. (as Mn). See references for 30180 in L2 in this report.
54735/ 1	?	Fatty acids, tall oil, lithium salts	L3 for fatty acids, tall oil. Constituents of natural fats. L2 for Li. Group TDI : 0.01 mg/kg b.w. (as Li). See references for 38000 in L2 in this report.
54740/ 1	008030-70-4	Fatty acids, tall oil, manganese salts	L3 for fatty acids, tall oil. Constituents of natural fats. L2 for Mn. Group TDI : 0.01 mg/kg b.w. (as Mn). See references for 30180 in L2 in this report.
57040	?	Glycerol monooleate, ester with ascorbic acid	Group TDI : not specified. Similarity with the citric acid esters. (JECFA, 17th meeting, 1973)
57200	?	Glycerol monopalmitate, ester with ascorbic acid	Group TDI : not specified. Similarity with the citric acid esters.



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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
			(JECFA, 17th meeting, 1973)
57600	?	Glycerol monostearate, ester with ascorbic acid	Group TDI : not specified. Similarity with the citric acid esters. (JECFA, 17th meeting, 1973)
58740	016761-13-0	Heptanoic acid, lithium salt	L3 for heptanoic acid. L2 for Li. TDI : 0.01 mg/kg b.w. (expressed as Li). See references for 38000 in L2 in this report.
58760	?	Heptanoic acid, manganese salt	L3 for heptanoic acid. L2 for Mn. TDI : 0.01 mg/kg b.w. (expressed as Mn). See references for 30180 in L2 in this report.
58960	000057-09-0	Hexadecyltrimethylammonium bromide	TDI : 0.1 mg/kg b.w. 400-Day oral rat study. (RIVM report, September 1978)
59120	023128-74-7	1,6-Hexamethylenebis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide]	TDI : 0.75 mg/kg b.w. 2-Year and 90-day oral rat studies, teratogenicity studies in mice, rats, rabbits. (RIVM report 88/678608/010, 1989-01-24)
59200	035074-77-2	1,6-Hexamethylenebis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]	TDI : 0.1 mg/kg b.w. 90-Day oral rat and dog (+ 4-week recovery period) studies and a 2-year oral study. (RIVM, July 1975, report CBG 182/80928, 5 April 1982)
59240	000124-09-4	Hexamethylenediamine	See references for same substance in monomer report.
60320	070321-86-7	2-[2-Hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl]benzotriazole	TDI : 0.025 mg/kg b.w. 90-Day oral rat study, 3 mutagenicity studies. (RIVM doc., 27 October 1987)
60400	003896-11-5	2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-5-chlorobenzotriazole	Group TDI : 0.5 mg/kg b.w. for 2-(2-hydroxy-3-tert-butyl-5-methylphenyl)-5-chlorobenzotriazole, 2-(2-hydroxy-3,5-di-tert-butylphenyl)-5-chlorobenzotriazole and 2-(2-hydroxy-5-methylphenyl)-benzotriazole.
60480	003864-99-1	2-(2-Hydroxy-3,5-di-tert-butylphenyl)-5-chlorobenzotriazole	Group TDI : 0.5 mg/kg b.w. for 2-(2-hydroxy-3-tert-butyl-5-methylphenyl)-5-chlorobenzotriazole, 2-(2-hydroxy-3,5-di-tert-butylphenyl)-5-chlorobenzotriazole and 2-(2-hydroxy-5-methylphenyl)-benzotriazole.
60560	009004-62-0	Hydroxyethylcellulose	Group TDI : not specified based on group ADI (= not specified) for certain modified celluloses.

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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
			(JECFA, 35th meeting, 1989)
60800	065447-77-0	1-(2-Hydroxyethyl)-4-hydroxy-2,2,6,6-tetramethylpiperidine - succinic acid, dimethyl ester, copolymer (M.W. 1500-5000)	TDI : 0.5 mg/kg b.w. 90-Day oral rat and dog studies, 2-year oral rat study. (HRC report CBG 237/92271, 10 May 1983)
60880	009032-42-2	Hydroxyethylmethylcellulose	Group TDI : not specified based on group ADI (= not specified) for certain modified celluloses. (JECFA, 35th meeting, 1989)
61120	009005-27-0	Hydroxyethyl starch	Group TDI : not specified. (JECFA, 26th meeting, 1982)
61280	003293-97-8	2-Hydroxy-4-n-hexyloxybenzophenone	Group TDI : 0.1 mg/kg b.w. See references for 2,4-dihydroxybenzophenone.
61360	000131-57-7	2-Hydroxy-4-methoxybenzophenone	Group TDI : 0.1 mg/kg b.w. See references for 2,4-dihydroxybenzophenone.
61390	037353-59-6	Hydroxymethylcellulose	Group TDI : not specified based on group ADI (= not specified) for certain modified celluloses. (JECFA, 35th meeting, 1989)
61440	002440-22-4	2-(2-Hydroxy-5-methylphenyl)benzotriazole	Group TDI : 0.5 mg/kg b.w. for 2-(2-hydroxy-3-tert-butyl-5-methylphenyl)-5-chlorobenzotriazole, 2-(2-hydroxy-3,5-di-tert-butylphenyl)-5-chlorobenzotriazole and 2-(2-hydroxy-5-methylphenyl)-benzotriazole. Several 90-day oral rat and dog studies and a 2-year oral rat study and 3-4 month oral dosing of man. (HRC report CBG 161/78164)
61600	001843-05-6	2-Hydroxy-4-n-octyloxybenzophenone	Group TDI : 0.1 mg/kg b.w. See references for 2,4-dihydroxybenzophenone.
61680	009004-64-2	Hydroxypropylcellulose	Group TDI : not specified based on group ADI (= not specified) for certain modified celluloses. (JECFA, 35th meeting, 1989)
61760	009004-65-3	Hydroxypropylmethylcellulose	Group TDI : not specified based on group ADI (= not specified) for certain modified celluloses. (JECFA, 35th meeting, 1989)
62240	001332-37-2	Iron oxide	ADI : not specified. (SCF, 1st Series, 1975)
63040	000138-22-7	Lactic acid, butyl ester	Group TDI : not specified. Similarity with lactic acid, ethyl ester for which an ADI not specified was established by JECFA, 26th meeting, 1982.

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
63200	051877-53-3	Lactic acid, manganese salt	L1 for lactic acid. ADI : not specified. (SCF, 25th Series, 1991) L2 for Mn. See references for acetic acid, manganese(II) salt in L2.
64100	074488-09-8	Linoleic acid, lithium salt	L0 for linoleic acid. L2 for Li. Group TDI : 0.01 mg/kg b.w. (expressed as Li). See references for 38000 in L2 in this report.
64115	006904-78-5	Linoleic acid, manganese salt	L0 for linoleic acid. L2 for Mn. Group TDI : 0.01 mg/kg b.w. (expressed as Mn). See references for 30180 in L2 in this report.
64270	007447-41-8	Lithium chloride	Group TDI : 0.01 mg/kg b.w. (expressed as Li). See references for 38000 in L2 in this report.
64300	001310-65-2	Lithium hydroxide	Group TDI : 0.01 mg/kg b.w. (expressed as Li). See references for 38000 in L2 in this report.
64320	010377-51-2	Lithium iodide	Group TDI based on PMTDI : 0.017 mg/kg b.w. (expressed as I). (JECFA, 33rd meeting, 1988). 90-Day oral rat studies and metabolism and therapeutic use of Li salts. (RIVM tox. 105/76, July 1976, tox. 204/78, November 1978, tox. 126/79, October 1979). For Li, see references for benzoic acid, lithium salt.
64350	012057-24-8	Lithium oxide	Group TDI : 0.01 mg/kg b.w. (expressed as Li). See references for 38000 in L2 in this report.
64800	000110-16-7	Maleic acid	Group TDI : 0.5 mg/kg b.w. (expressed as maleic acid). (SCF, 17th Series, 1986)
65120	007773-01-5	Manganese(II) chloride	Group TDI : 0.01 mg/kg b.w. (expressed as Mn). See Environmental Health Criteria 17, WHO, 1981.
65200	012626-88-9	Manganese hydroxide	Group TDI : 0.01 mg/kg b.w. (expressed as Mn). See references for acetic acid, manganese(II) salt.
65280	010043-84-2	Manganese(II) hypophosphite	Group TDI : 0.01 mg/kg b.w. (expressed as Mn). See references for acetic acid, manganese(II) salt.
65360	011129-60-5	Manganese oxide	Group TDI : 0.01 mg/kg b.w. (expressed as Mn). See references for acetic acid, manganese(II) salt.

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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
65440	?	Manganese(II) pyrophosphate	Group TDI : 0.01 mg/kg b.w. (expressed as Mn). See references for acetic acid, manganese(II) salt.
65860	000080-62-6	Methacrylic acid, methyl ester	Group t-TDI : 0.1 mg/kg b.w. See references for same substance in monomer report.
65920	066822-60-4	N-Methacryloylethyl-N,N-dimethylammonium-alpha-N-methylcarboxylate - octadecyl methacrylate - ethyl methacrylate - cyclohexyl methacrylate - N-vinyl-2-pyrrolidone, copolymers	TDI : 1 mg/kg b.w. 90-Day oral rat study. Mutagenicity data not needed for this polymer. (RIVM doc. tox. 300/482, March 1984)
66120	010605-21-7	Methyl benzimidazolecarbamate	TDI : 0.01 mg/kg b.w. Based on ADI (= 0.01 mg/kg b.w.) for carbendazim. (JMPR, 5-14 December 1983)
66200	037206-01-2	Methylcarboxymethylcellulose	Group TDI : not specified based on group ADI (= not specified) for certain modified celluloses. (JECFA, 35th meeting, 1989)
66240	009004-67-5	Methylcellulose	Group TDI : not specified based on group ADI (= not specified) for certain modified celluloses. (JECFA, 35th meeting, 1989)
66400	000088-24-4	2,2'-Methylenebis(4-ethyl-6-tert-butylphenol)	Group t-TDI : 0.025 mg/kg b.w. with 2,2'-methylenebis(4-methyl-6-tert-butylphenol). Available : two 90-day oral rat studies, 4-month oral dog study. (RIVM Doc/Tox 300/418, April 1983). Needed : mutagenicity studies.
66480	000119-47-1	2,2'-Methylenebis(4-methyl-6-tert-butylphenol)	Group t-TDI : 0.025 mg/kg b.w. with 2,2'-methylenebis(4-ethyl-6-tert-butylphenol). Available : two 90-day oral rat studies, 4-month oral dog study. (RIVM Doc/Tox 300/418, April 1983). Needed : mutagenicity studies.
66560	004066-02-8	2,2'-Methylenebis(4-methyl-6-cyclohexylphenol)	TDI : 0.05 mg/kg b.w. 2-Year oral rat and dog studies. (RIVM, October 1969)
66640	009004-59-5	Methylethylcellulose	Group TDI : not specified based on group ADI (= not specified) for certain modified celluloses. (JECFA, 35th meeting, 1989)
66695	?	Methylhydroxymethylcellulose	Group TDI : not specified based on group ADI (= not specified) for certain modified celluloses. (JECFA, 35th meeting, 1989)

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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
66700	009004-65-3	Methylhydroxypropylcellulose	Group TDI : not specified based on group ADI (= not specified) for certain modified celluloses. (JECFA, 35th meeting, 1989)
67280	000108-90-7	Monochlorobenzene	TDI : 0.6 mg/kg b.w. 90-Day oral rat study, 2-year oral mouse and rat studies, Ames test negative, in vitro mutagenicity test positive. (Appendix to RIVM report 758701004, March 1990)
67360	067649-65-4	Mono-n-dodecyltin tris(isooctyl mercaptoacetate)	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)
67520	054849-38-6	Monomethyltin tris(isooctyl mercaptoacetate)	Group TDI : 0.003 mg/kg b.w. (expressed as Sn), with dimethyltin bis(isooctyl mercaptoacetate). See 49600.
67600	-	Mono-n-octyltin tris[alkyl(C10-C16)-mercaptoacetate]	Group t-TDI : 0.02 mg/kg b.w. (expressed as Sn). See references for mono-n-octyltin tris(isooctyl mercaptoacetate).
67680	027107-89-7	Mono-n-octyltin tris(2-ethylhexyl mercaptoacetate)	Group t-TDI : 0.02 mg/kg b.w. (expressed as Sn) with mono-n-octyltin tris(isooctyl mercaptoacetate).
67760	026401-86-5	Mono-n-octyltin tris(isooctyl mercaptoacetate)	Group t-TDI : 0.02 mg/kg b.w. (expressed as Sn). Needed : mutagenicity studies for chromosome aberrations in human lymphocytes, reproduction and teratogenicity studies, and migration data on the non-tin part of the molecule. Several oral short-term and semichronic studies in rats and dogs, oral chronic study in rats with mixture of mono- and dioctyltin chloride. Several mutagenicity studies in vitro and in vivo. (RIVM doc., May 1989)
68040	003333-62-8	7-[2-H-Naphtho-(1,2-D)triazol-2-yl]-3-phenylcoumarin	TDI : 1 mg/kg b.w. 90-Day oral rat and dog studies, 2 mutagenicity tests (RIVM 300/234 Tox/75, July 1981)
68140	007697-37-2	Nitric acid	TDI : 3 mg/kg b.w. (expressed as nitrate), based on ADI (= 5 mg/kg b.w.) for sodium nitrate. (SCF, in press)

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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
68320	002082-79-3	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxy-phenyl)propionate	TDI : 0.05 mg/kg b.w. Several oral rat studies (3 weeks to 3 months), 2-year oral studies in mice and rats, 2-generation and teratogenicity studies, mutagenicity tests. (RIVM doc., 31.03.92)
68680	016577-52-9	n-Octanoic acid, lithium salt	L0 for n-octanoic acid. L2 for Li. Group TDI : 0.01 mg/kg b.w. (expressed as Li). See references for 38000 in L2 in this report.
68690	006535-19-9	n-Octanoic acid, manganese salt	L0 for n-octanoic acid. L2 for Mn. Group TDI : 0.01 mg/kg b.w. (expressed as Mn). See references for 30180 in L2 in this report.
69455	007384-22-7	Oleic acid, lithium salt	L1 (= not specified) for oleic acid. L2 for Li. Group TDI = 0.01 mg/kg b.w. (expressed as Li). See references for 38000 in L2 in this report.
69465	019153-79-8	Oleic acid, manganese salt	L1 (= not specified) for oleic acid. L2 for Mn. Group TDI = 0.01 mg/kg b.w. (expressed as Mn). See references for 30180 in L2 in this report.
69920	000144-62-7	Oxalic acid	TDI : 0.1 mg/kg b.w. 2-Year oral rat study, observations in man. (J. Am. Pharm. Ass., 1947, 36, 217-219, Patty)
70000	070331-94-1	2,2'-Oxamidobis[ethyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]	TDI : 10 mg/kg b.w. 90-Day oral rat and dog studies, 2-generation rat study, 2 mutagenicity tests. (RIVM 85/627915/128, November 1985)
70820	020466-33-5	Palmitic acid, lithium salt	L1 (= not specified) for palmitic acid. L2 for Li. Group TDI = 0.01 mg/kg b.w. (expressed as Li). See references for 38000 in L2 in this report.
70840	031678-63-4	Palmitic acid, manganese salt	L1 (= not specified) for palmitic acid. L2 for Mn. Group TDI = 0.01 mg/kg b.w. (expressed as Mn). See references for 30180 in L2 in this report.
71600	000115-77-5	Pentaerythritol	Group TDI : 1 mg/kg b.w. (with dipentaerythritol). (SCF, 17th Series, 1986)
71680	006683-19-8	Pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]	TDI : 3 mg/kg b.w.

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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
		tyl-4-hydroxyphenyl]propionate]	Oral studies for 3 months and 2 years in rats, 3 and 4 months in dogs, lifetime in mice, reproduction and teratogenicity studies in mice and rats, and mutagenicity studies. (RIVM report 89/678608/013, 13.6.1989)
72160	000948-65-2	2-Phenylindole	TDI : 0.25 mg/kg b.w. 1- and 2-Year oral rat studies, migration data. (Arch. Toxicol., 1964, 20, 220-225)
73040	013763-32-1	Phosphoric acid, lithium salt	L1 for phosphoric acid. MTDI : 70 mg/kg b.w. (expressed as P). (SCF, 25th Series, 1991) L2 for Li. Group TDI : 0.01 mg/kg b.w. (expressed as Li). See references for benzoic acid, lithium salt.
73120	010124-54-6	Phosphoric acid, manganese salt	L1 for phosphoric acid. MTDI : 70 mg/kg b.w. (expressed as P). (SCF, 25th Series, 1991) L2 for Mn. Group TDI : 0.01 mg/kg b.w. (expressed as Mn). See references for acetic acid, manganese(II) salt.
74240	031570-04-4	Phosphorous acid, tris(2,4-di-tert-butyl-phenyl) ester	TDI : 1 mg/kg b.w. 90-Day and 2-year oral rat studies, 2-generation study in rats and mutagenicity studies. (HRC report CBG 167/76339, 18 August 1976, LSR 80/CIA 015/111, 21 October 1980, Ciba-Geigy 82 0873, February 1985)
74400	026523-78-4 001333-21-7	Phosphorous acid, tris(nonyl- and/or dinonylphenyl) ester	TDI : 0.5 mg/kg b.w. 90-Day oral rat and 2-year oral rat and dog studies, 3-generation oral rat reproduction study, 3 negative mutagenicity studies. (RIVM, 8-1-1990)
74480	000088-99-3	o-Phthalic acid	Group TDI : 1 mg/kg b.w. Included in the group TDI for phthalic anhydride.
74560	000085-68-7	Phthalic acid, benzyl butyl ester	t-TDI : 0.1 mg/kg b.w. Available : 6-month oral rat study, carcinogenicity and peroxisome proliferation studies in vitro. (RIVM, September 1987). Needed : reproduction, teratogenicity and peroxisome proliferation studies in rats (EM).
74640	000117-81-7	Phthalic acid, bis(2-ethylhexyl) ester	TDI : 0.025 mg/kg b.w. Oral carcinogenicity studies in mice and rats, 9-month oral rat study, oral fertility and teratogenicity studies in mice, special studies on

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
			testicular effects, mutagenicity tests and tests for peroxisome proliferation. (RIVM, June 1986)
74880	000084-74-2	Phthalic acid, dibutyl ester	t-TDI : 0.05 mg/kg b.w. Available : limited 90-day and 1-year oral rat studies, oral reproduction and teratogenicity studies, limited mutagenicity studies. (RIVM report, May 1988) Needed : 28-day oral study, peroxisome proliferation study, tests for gene mutation and chromosome aberration in mammalian cells in vitro.
74960	000084-61-7	Phthalic acid, dicyclohexyl ester	t-TDI : 0.1 mg/kg b.w. Available : three 90-day oral rat studies, limited in vitro mutagenicity studies. (RIVM, 1988) Needed : reproduction and teratogenicity studies, tests for gene mutation and chromosome aberration in mammalian cells in vitro.
75040	-	Phthalic acid, diesters with hexadecanol and/or octadecanol	t-TDI : 0.15 mg/kg b.w. Available : 3-month oral rat study, teratogenicity study and Ames test negative. (RIVM doc. 1990-09-11, CS/PM/529) Needed : reproduction study, gene mutation and chromosome aberration in mammalian cells in vitro.
75120	000084-66-2	Phthalic acid, diethyl ester	t-TDI : 0.2 mg/kg b.w. Available : a 3-month oral rat study, in vitro mutagenicity studies, i.p. teratogenicity studies and peroxisome proliferation studies. (Fd. Cosm. Toxicol., 1978, 16, 415-422, RIVM, June 1986)
75360	?	Phthalic acid, diisodecyl ester	t-TDI : 0.05 mg/kg b.w. pending establishment of NOEL for peroxisome proliferation in rats by EM and adequate reproduction and teratogenicity studies. Available : 90-day oral rat and dog studies, mutagenicity studies. (RIVM report, 1 September 1987). TO BE RE-EXAMINED, DOUBT IN THE IDENTITY OF THE SUBSTANCE (CS/PM/568)
75440	?	Phthalic acid, diisononyl ester	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 : reproduction and teratogenicity studies.



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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
			TO BE RE-EXAMINED, DOUBT IN THE IDENTITY OF THE SUBSTANCE.
76320	000085-44-9	Phthalic anhydride	TDI : 1 mg/kg b.w. (SCF, 17th Series, 1986)
76720	009016-00-6 063148-62-9	Polydimethylsiloxane (M.W. 13500-90000)	TDI : 1.5 mg/kg b.w., based on ADI = 1.5 mg/kg b.w. (JECFA, 34th meeting, M.W. 13500-30000)
76730	-	Polydimethylsiloxane, gamma-hydroxypropylated	TDI : 0.1 mg/kg b.w. 90-Day oral rat study, mutagenicity tests in vitro and in vivo. (RIVM report, 1990-04-26)
76960	025322-68-3	Polyethyleneglycol	Group TDI : 5 mg/kg b.w. (with triethyleneglycol). See references for triethyleneglycol. (SCF, 6th Series, 1978)
77280	009005-02-1	Polyethyleneglycol dilaurate	Group TDI : 10 mg/kg b.w. for all polyethyleneglycol esters of food fatty acids. (CS/PM/1656)
77320	?	Polyethyleneglycol dimyristate	Group TDI : 10 mg/kg b.w. for all polyethyleneglycol esters of food fatty acids. (CS/PM/1656)
77360	009005-07-6	Polyethyleneglycol dioleate	Group TDI : 10 mg/kg b.w. for all polyethyleneglycol esters of food fatty acids. (CS/PM/1656)
77440	?	Polyethyleneglycol diricinoleate	TDI : 0.7 mg/kg b.w. based on TDI for castor oil. (SCF, 7th Series, 1978) (CS/PM/1656)
77520	061791-12-6	Polyethyleneglycol ester of castor oil	TDI : 0.7 mg/kg b.w. based on TDI for castor oil. (SCF, 7th Series, 1978) (CS/PM/1656)
77550	-	Polyethyleneglycol ester of coconut oil fatty acids	Group TDI : 10 mg/kg b.w. for all polyethyleneglycol esters of food fatty acids. (CS/PM/1656)
77640	-	Polyethyleneglycol esters of acids, linear, with an even number of carbon atoms (C8-C22)	Group TDI : 10 mg/kg b.w. for all polyethyleneglycol esters of food fatty acids. (CS/PM/1656)
77660	-	Polyethyleneglycol esters of natural fatty acids	Group TDI : 10 mg/kg b.w. for all polyethyleneglycol esters of food fatty acids. (CS/PM/1656)

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
77702	-	Polyethyleneglycol esters of aliphatic monocarboxylic acids (C6-C22), and their ammonium and sodium sulphates	Group TDI : 10 mg/kg b.w. for all polyethyleneglycol esters of food fatty acids. (CS/PM/1656)
78080	009004-81-3	Polyethyleneglycol monolaurate	Group TDI : 10 mg/kg b.w. for all polyethyleneglycol esters of food fatty acids. (CS/PM/1656)
78120	?	Polyethyleneglycol monomyristate	Group TDI : 10 mg/kg b.w. for all polyethyleneglycol esters of food fatty acids. (CS/PM/1656)
78160	009004-96-0	Polyethyleneglycol monooleate	Group TDI : 10 mg/kg b.w. for all polyethyleneglycol esters of food fatty acids. (CS/PM/1656)
78240	009004-94-8	Polyethyleneglycol monopalmitate	Group TDI : 10 mg/kg b.w. for all polyethyleneglycol esters of food fatty acids. (CS/PM/1656)
78320	009004-97-1	Polyethyleneglycol monoricinoleate	TDI : 0.7 mg/kg b.w. based on TDI for castor oil. (SCF, 7th Series, 1978) (CS/PM/1656)
79120	009005-65-6	Polyethyleneglycol sorbitan monooleate	Group TDI : 10 mg/kg b.w. for polyethyleneglycol sorbitan monolaurate, polyethyleneglycol sorbitan monooleate, polyethyleneglycol sorbitan monostearate, polyethyleneglycol sorbitan tristearate. (SCF, 15th Series, 1985)
79360	009005-70-3	Polyethyleneglycol sorbitan trioleate	Group TDI : 10 mg/kg b.w. based on the group ADI (10 mg/kg b.w.) for polyethyleneglycol sorbitan monolaurate and other polyethyleneglycol sorbitan esters. (SCF, 15th Series, 1985)
79520	?	Polyethyleneglycol stearate	Group TDI : 10 mg/kg b.w. for all polyethyleneglycol esters of food fatty acids. (CS/PM/1656)
79760	-	Polyethyleneimine, butylated	TDI : 0.1 mg/kg b.w. Specifications for ethyleneimine (R = 0.01 mg/kg). 90-Day oral rat study, mutagenicity studies negative. (RIVM report 90/678608/002, February 1990)
80480	082451-48-7	Poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino]-hexamethylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino]	t-TDI : 0.03 mg/kg b.w. Available : 3-month oral rat and dog studies. (Reports Ciba-Geigy provided, April 1989). Needed : mutagenicity studies, chemical and

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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
			physical data, and migration data.
80800	025322-69-4	Polypropyleneglycol (1,3-propyleneglycol content not to exceed 1%)	Group TDI : 1.5 mg/kg b.w. (with dipropyleneglycol). See references for dipropyleneglycol.
81200	071878-19-8	Poly[6-[(1,1,3,3-tetramethylbutyl)amino]-1,3,5-triazine-2,4-diyl]-[(2,2,6,6-tetramethyl-4-piperidyl)imino]-hexamethylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino]	TDI : 0.05 mg/kg b.w. 3-Month oral dog and 3- and 6-month oral rat studies, mutagenicity studies. (RIVM rep. 89/678608/006, 1989-04-11)
81720	010117-38-1	Potassium sulphite	Group TDI : 0.7 mg/kg b.w. Based on ADI for SO <sub>2</sub> . (JECFA, 30th meeting, 1986)
83320	?	Propylhydroxyethylcellulose	Group TDI : not specified based on group ADI (= not specified) for certain modified celluloses. (JECFA, 35th meeting, 1989)
83325	?	Propylhydroxymethylcellulose	Group TDI : not specified based on group ADI (= not specified) for certain modified celluloses. (JECFA, 35th meeting, 1989)
83330	?	Propylhydroxypropylcellulose	Group TDI : not specified based on group ADI (= not specified) for certain modified celluloses. (JECFA, 35th meeting, 1989)
83390	016210-51-8	Pyroantimonic acid, potassium salt	R : 0.01 mg/kg.
83595	119345-01-6	Reaction product of di-tert-butyl phosphonite with biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with Friedel Craft reaction product of phosphorus trichloride and biphenyl	TDI : 0.3 mg/kg b.w. 90-Day oral rat study and mutagenicity studies. (Sandoz report, 1979)
83610	073138-82-6	Resin acids and rosin acids	Group TDI : 1 mg/kg b.w. (SCF, 17th Series, 1986)
83640	?	Resin acids and rosin acids, lithium salts	L2 (= 1 mg/kg b.w.) for resin acids. L2 for Li. Group TDI : 0.01 mg/kg b.w. (expressed as Li). See references for 38000 in L2 in this report.
83650	009008-34-8	Resin acids and rosin acids, manganese salts	L2 (= 1 mg/kg b.w.) for resin acids. L2 for Mn. Group TDI : 0.01 mg/kg b.w. (expressed as Mn). See references for 30180 in L2 in this report.
83700	000141-22-0	Ricinoleic acid	TDI : 0.7 mg/kg b.w. based on TDI for castor oil. (SCF, 7th Series, 1978)

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
83790	015467-06-8	Ricinoleic acid, lithium salt	L2 (= 0.7 mg/kg b.w.) for ricinoleic acid. L2 for Li. Group TDI : 0.01 mg/kg b.w. (expressed as Li). See references for 38000 in L2 in this report.
83805	?	Ricinoleic acid, manganese salt	L2 (= 0.7 mg/kg b.w.) for ricinoleic acid. L2 for Mn. Group TDI : 0.01 mg/kg b.w. (expressed as Mn). See references for 30180 in L2 in this report.
83840	008050-09-7	Rosin	Group TDI : 1 mg/kg b.w. (SCF, 17th Series, 1986)
84080	008050-26-8	Rosin, ester with pentaerythritol	Group TDI : 1 mg/kg b.w. Included in the group TDI (1 mg/kg b.w.) for colophony. (SCF, 6th Series, 1978) also including rosins (SCF, 17th Series, 1986)
84240	065997-13-9	Rosin, hydrogenated, ester with glycerol	Group TDI : 1 mg/kg b.w. Included in the group TDI (1 mg/kg b.w.) for colophony. (SCF, 6th Series, 1978) also including rosins (SCF, 17th Series, 1986)
84320	008050-15-5	Rosin, hydrogenated, ester with methanol	Group TDI : 1 mg/kg b.w. Included in the group TDI (1 mg/kg b.w.) for colophony. (SCF, 6th Series, 1978) also including rosins (SCF, 17th Series, 1986)
84400	064365-17-9	Rosin, hydrogenated, ester with pentaerythritol	Group TDI : 1 mg/kg b.w. Included in the group TDI (1 mg/kg b.w.) for colophony. (SCF, 6th Series, 1978) also including rosins (SCF, 17th Series, 1986)
84800	000087-18-3	Salicylic acid, 4-tert-butylphenyl ester	TDI : 0.2 mg/kg b.w. 2-Year oral rat study. (RIVM, March 1972)
85760	012068-40-5	Silicic acid, lithium aluminium salt	L2 for Li. Group TDI : 0.01 mg/kg b.w. (expressed as Li). See references for 38000 in L2 in this report. L2 for Al. TDI : 1 mg/kg b.w. (expressed as Al), based on PTWI : 7 mg/kg b.w. (expressed as Al). (SCF, 25th Series, 1991)
85840	053320-86-8	Silicic acid, lithium magnesium sodium salt	Group TDI : 0.01 mg/kg b.w. (expressed as Li). See references for benzoic acid, lithium salt.

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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
85920	012627-14-4	Silicic acid, lithium salt	Group TDI : 0.01 mg/kg b.w. (expressed as Li). See references for benzoic acid, lithium salt.
86440	?	Sodium aluminate	TDI : 1 mg/kg b.w. (expressed as Al), based on PTWI : 7 mg/kg b.w. (expressed as Al). (SCF, 25th Series, 1991)
86880	-	Sodium monoalkyl dialkylphenoxybenzene- disulphonate	t-TDI : 0.15 mg/kg b.w. pending reproduction and teratogenicity studies. Available : 2-year oral rat and dog studies.
87040	001330-43-4	Sodium tetraborate	Group TDI : 0.2 mg/kg b.w. (expressed as B). See references for boric acid.
87280	029116-98-1	Sorbitan dioleate	Group TDI : 5 mg/kg b.w. based on the group ADI (5 mg/kg b.w.) for sorbitan esters of lauric and oleic acids. (SCF, 7th Series, 1978)
87520	062568-11-0	Sorbitan monobehenate	Group TDI : 5 mg/kg b.w. based on the group ADI (5 mg/kg b.w.) for sorbitan esters of lauric and oleic acids. (SCF, 7th Series, 1978)
87920	061752-68-9	Sorbitan tetrastearate	Group TDI : 5 mg/kg b.w. based on the group ADI (5 mg/kg b.w.) for sorbitan esters of lauric and oleic acids. (SCF, 7th Series, 1978)
88080	026266-58-0	Sorbitan trioleate	Group TDI : 5 mg/kg b.w. based on the group ADI (5 mg/kg b.w.) for sorbitan esters of lauric and oleic acids. (SCF, 7th Series, 1978)
88160	054140-20-4	Sorbitan tripalmitate	Group TDI : 5 mg/kg b.w. based on the group ADI (5 mg/kg b.w.) for sorbitan esters of lauric and oleic acids. (SCF, 7th Series, 1978)
88600	026836-47-5	Sorbitol monostearate	TDI : not specified, based on ADI for sorbitol. (SCF, 17th Series, 1986)
88640	008013-07-8	Soybean oil, epoxidized (oxirane < 8%, iodine number < 6)	t-TDI : 1 mg/kg b.w. Available : 15-week and 2-year oral rat studies and 1-year oral dog study. (BIBRA report n. 515/86; summary report prepared by UK, January 1988) Needed : reproduction and teratogenicity studies.
89440	-	Stearic acid, esters with ethyleneglycol	TDI : 0.5 mg/kg b.w. (SCF, 6th Series, 1978)

## LIST 2

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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
90260	004485-12-5	Stearic acid, lithium salt	L1 (= not specified) for stearic acid. L2 for Li. Group TDI = 0.01 mg/kg b.w. (expressed as Li). See references for 38000 in L2 in this report.
90290	010476-84-3	Stearic acid, manganese salt	L1 (= not specified) for stearic acid. L2 for Mn. Group TDI = 0.01 mg/kg b.w. (expressed as Mn). See references for 30180 in L2 in this report.
90720	058446-52-9	Stearoylbenzoylmethane	TDI : 1.5 mg/kg b.w. 30-Day oral rat, 90-day oral dog, 2-generation oral rat studies, mutagenicity and migration data. (RIVM report, June 1979)
91170	000108-30-5	Succinic anhydride	TDI : not specified, based on ADI (= not specified) for succinic acid.
92205	057569-40-1	Terephthalic acid, diester with 2,2'-methylenebis(4-methyl-6-tert-butylphenol)	TDI : 1 mg/kg b.w. A 90-day oral rat study. (CIVO report 5569, December 1977)
92320	-	Tetradecyl-polyethylene oxide(3-8) ether of glycolic acid	t-TDI : 0.25 mg/kg b.w. Available : 28- and 90-day oral rat studies. (CIVO/TNO 3108, October 1970, 3287, October 1970). Needed : mutagenicity studies and specify monomer content.
92430	000109-99-9	Tetrahydrofuran	See references for same substance in monomer report.
92560	038613-77-3	Tetrakis(2,4-di-tert-butylphenyl)-4,4'-biphenylene diphosphonite	TDI : 0.3 mg/kg b.w. 90-Day oral rat study and mutagenicity studies. (Sandoz report, 1979)
92640	000102-60-3	N,N,N',N'-Tetrakis(2-hydroxypropyl)ethylenediamine	TDI : 1 mg/kg b.w. (SCF, 17th Series, 1986)
92800	000096-69-5	4,4'-Thiobis(6-tert-butyl-3-methylphenol)	t-TDI : 0.008 mg/kg b.w. pending results of ongoing 2-year and reproduction studies. Available : 28- and 90-day oral rat studies, one in vitro mutagenic test. (RIVM doc. 88/678608/007, 1 November 1988)
92880	041484-35-9	Thiodiethanol bis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]	TDI : 0.04 mg/kg b.w. 90-Day oral rat study, mutagenicity studies. Needed : migration data. (RIVM report 88/678608/009, 1989-01-24)
92930	120218-34-0	Thiodiethylenebis(5-methoxycarbonyl-2,6-	TDI : 0.1 mg/kg b.w.

## LIST 2

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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
		dimethyl-1,4-dihydropyridine-3-carboxylate)	90-Day oral rat study, mutagenicity tests negative, absence of bioaccumulation. (CS/PM/305, 336, 358, 460).
93720	000108-78-1	2,4,6-Triamino-1,3,5-triazine	TDI : 0.5 mg/kg b.w. (SCF, 17th Series, 1986)
94320	000112-27-6	Triethyleneglycol	Group TDI : 5 mg/kg b.w. (with polyethyleneglycol). (SCF, 17th Series, 1986)
94400	036443-68-2	Triethyleneglycol bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propionate]	TDI : 0.05 mg/kg b.w. 90-Day and 2-year oral rat and 90-day oral dog studies, teratogenicity and mutagenicity studies. (RIVM report 89/678608/001, 1989-09-01)
94960	000077-99-6	1,1,1-Trimethylolpropane	TDI : 0.1 mg/kg b.w. (SCF, 17th Series, 1986)
95200	001709-70-2	1,3,5-Trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene	t-TDI : 1 mg/kg b.w. pending check of the reports. 2-Year oral studies in rats and dogs and oral carcinogenicity studies in mice and rats. (Shell reports n. TLGR 0023.68, March 1969, TLGR 0024.68, September 1968, TLGR 0019.69, March 1969)
95280	040601-76-1	1,3,5-Tris(4-tert-butyl-3-hydroxy-2,6-dimethylbenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	t-TDI : 0.1 mg/kg b.w. Available : 90-day oral rat and dog studies. (RIVM document, June 1989). Needed : mutagenicity and migration data, impurities to be specified.
96200	055799-16-1	Zinc hydroxyphosphate	TDI : 1 mg/kg b.w. (expressed as Zn). (JECFA, 26th meeting, 1982). TDI : 70 mg/kg b.w. based on ADI (= 70 mg/kg b.w.) for phosphate. (JECFA, 26th meeting, 1982)

## LIST 3

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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
30295	000067-64-1	Acetone	Residue in food less than 5 mg/kg. (SCF, 11th Series, 1981)
33120	-	Alcohols, aliphatic, monohydric, saturated, linear, primary (C4-C22)	90-Day oral studies, metabolic and/or mutagenicity studies with some substances out of the group. (SCF, 17th Series, 1986)
36640	000123-77-3	Azodicarbonamide	Evaluated in the context of its use as blowing agent which on heating will break down. Decision postponed until UK presents results of technological improvements (end 1990).
36720	017194-00-2	Barium hydroxide	R : 1 mg/kg of food or food simulant. (RIVM doc., May 1992 (CS/PM/1584))
36800	010022-31-8	Barium nitrate	TDI : 3 mg/kg b.w. (expressed as nitrate), based on ADI (= 5 mg/kg b.w.) for sodium nitrate. (SCF, 26th Series, 1992) L3 for Ba. R : 1 mg/kg (expressed as Ba). (RIVM doc., May 1992 (CS/PM/1584))
36840	?	Barium tetraborate	L3 for Ba. R : 1 mg/kg (expressed as Ba). (RIVM doc., May 1992 (CS/PM/1584)). L2 for borate. TDI : 0.2 mg/kg b.w. (expressed as B). See references for boric acid (L2) in this report.
36960	003061-75-4	Behenamide	Metabolized to ammonia and behenic acid.
37280	001302-78-9	Bentonite	Inert material.
38320	005242-49-9	4-(2-Benzoxazolyl)-4'-(5-methyl-2-benzo- zazolyl)stilbene	Maximum amount to be used : 0.05 % (w/w)
39060	035958-30-6	1,1-Bis(2-hydroxy-3,5-di-tert-butylphenyl)- ethane	R : 5 mg/kg of food or food simulant. Available : 3-month oral rat and dog studies, reproduction study and tests for mutagenicity negative. (RIVM doc., February 1992)
40400	010043-11-5	Boron nitride	Inert, insoluble material.
40570	000106-97-8	Butane	Volatile compound.
40590	000071-36-3	1-Butanol	See references for same substance in monomer report.
40594	000075-65-0	tert-Butanol	Residue in food less than 10 mg/kg.



## LIST 3

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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
			(SCF, 11th Series, 1981; EHC 65)
41680	000076-22-2	Camphor	Natural compound with strong flavour.
41760	008006-44-8	Candelilla wax	Natural wax. Purity to be specified.
42720	008015-86-9	Carnauba wax	Natural wax. Purity to be specified.
43300	009004-36-8	Cellulose acetate butyrate	Inert material, modified natural cellulose.
43440	008001-75-0	Ceresin, refined	Refined, natural, crystalline wax. Purity to be specified.
45280	-	Cotton fibers	Inert, insoluble material.
45920	009000-16-2	Dammar	Natural wax. Purity to be specified.
46050	000112-30-1	1-Decanol	See references for "Alcohols, aliphatic, monohydric, saturated, linear, primary (C4-C22)" in monomer report.
46375	?	Diatomaceous earth	Inert material.
49225	000124-40-3	Dimethylamine	Occurs naturally in foods up to 45 mg/kg in herring and up to 10 mg/kg in other foods. (Health-based recommended occupational exposure limits for dimethylamine. Dutch Expert Committee for Occupational Standards, RA 10/90, October 1990)
49540	000067-68-5	Dimethyl sulphoxide	DMSO is used as a carrier of drugs to facilitate skin penetration.
51975	000112-53-8	1-Dodecanol	See references for same substance in monomer report.
52640	016389-88-1	Dolomite	Inert material. Purity to be specified.
52730	000112-86-7	Erucic acid	Occurs in small amounts in some vegetable oils.
53360	000110-31-6	N,N'-Ethylenebisoleamide	Chemically similar to N,N'-ethylene-bisstearamide.
53440	005518-18-3	N,N'-Ethylenebispalmitamide	90-Day oral monkey study. Chemically similar to N,N'-ethylenebisstearamide.
53520	000110-30-5	N,N'-Ethylenebisstearamide	Two inadequate 2-year oral rat studies and low migration. (Hoechst report 13/05, 1963)
54005	005136-44-7	Ethylene-N-palmitamide-N'-stearamide	Chemically similar to N,N'-ethylene-

## LIST 3

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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
			bisstearamide.
54680/ 1	?	Fatty acids, soya, lithium salts	L3 for fatty acids, soya. Constituents of natural fats. L2 for Li. Group TDI : 0.01 mg/kg b.w. (as Li). See references for 38000 in L2 in this report.
54685/ 1	?	Fatty acids, soya, manganese salts	L3 for fatty acids, soya. Constituents of natural fats. L2 for Mn. Group TDI : 0.01 mg/kg b.w. (as Mn). See references for 30180 in L2 in this report.
54735/ 1	?	Fatty acids, tall oil, lithium salts	L3 for fatty acids, tall oil. Constituents of natural fats. L2 for Li. Group TDI : 0.01 mg/kg b.w. (as Li). See references for 38000 in L2 in this report.
54740/ 1	008030-70-4	Fatty acids, tall oil, manganese salts	L3 for fatty acids, tall oil. Constituents of natural fats. L2 for Mn. Group TDI : 0.01 mg/kg b.w. (as Mn). See references for 30180 in L2 in this report.
54880	000050-00-0	Formaldehyde	See references for same substance in monomer report. (SCF, 17th Series, 1986)
55520	-	Glass fibers (d = 0.5-30 $\mu$ m)	Inert material.
55600	-	Glass microballs (d = 0.5-500 $\mu$ m), hollow or solid	Inert material.
56800	030899-62-8	Glycerol monolaurate diacetate	Chemically similar to natural fats.
58320	007782-42-5	Graphite	Inert material.
58720	000111-14-8	Heptanoic acid	Fatty acid from food.
58740	016761-13-0	Heptanoic acid, lithium salt	L3 for heptanoic acid. L2 for Li. TDI : 0.01 mg/kg b.w. (expressed as Li). See references for 38000 in L2 in this report.
58760	?	Heptanoic acid, manganese salt	L3 for heptanoic acid. L2 for Mn. TDI : 0.01 mg/kg b.w. (expressed as Mn). See references for 30180 in L2 in this report.

## LIST 3

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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
58790	036653-82-4	1-Hexadecanol	See references for "Alcohols, aliphatic, monohydric, saturated, linear, primary (C4-C22)" in monomer report.
59280	000100-97-0	Hexamethylenetetramine	See references for same substance in monomer report.
59680	?	Hydromagnesite (natural basic magnesium carbonate)	Inert material. Purity to be specified.
59760	019569-21-2	Huntite (natural calcium magnesium carbonate)	Inert, insoluble material.
60080	012304-65-3	Hydrotalcite (Mg/Al carbonate complex)	Inert, insoluble material.
62160	007681-53-0	Hypophosphorous acid, sodium salt	Easily oxidized to phosphorous acid.
62220	010045-89-3	Iron(II) diammonium bisulphate	PMTDI (Iron) : 0.8 mg/kg b.w. (JECFA, 27th meeting, 1983)
62255	000075-28-5	Isobutane	Volatile compound.
62450	000078-78-4	Isopentane	Volatile compound.
62640	008001-39-6	Japan wax	Refined, natural wax. Purity to be specified.
62800	066402-68-4	Kaolin, calcined	Inert material.
62880	061790-53-2	Kieselguhr	Inert material.
64400	001345-05-7	Lithopone (C.I. Pigment White 5)	Free from water soluble barium. Insoluble, inert material.
65040	000141-82-2	Malonic acid	Occurs in plants.
65960	000067-56-1	Methanol	See references for same substance in monomer report.
66360	085209-91-2	2,2'-Methylenebis(4,6-di-tert-butylphenyl)-sodium phosphate	R : 5 mg/kg of food or food simulant. Available : 3-month oral rat study, mutagenicity tests negative, migration data. (RIVM doc., 15 October 1991)
67120	012001-26-2	Mica	Inert silicate.
67200	001317-33-5	Molybdenum disulphide	Inert, insoluble material.
67840	-	Montanic acids (purified) and/or their esters with ethyleneglycol and/or with 1,3-butanediol and/or glycerol	3 Products : Hoechst Wax E, Hoechst Wax OP, Hoechst Wax WE4. 3-4-Month oral dog, 3-month rat and 2-year rat studies, plus negative Ames test.

## LIST 3

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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
			(RIVM report, 05-03-1990)
67850	008002-53-7	Montan wax	Inert compound, specifications needed.
68125	068187-64-4	Nepheline syenite	Inert material.
68225	000112-92-5	1-Octadecanol	See references for same substance in monomer report.
68750	000111-87-5	1-Octanol	See references for "Alcohols, aliphatic, monohydric, saturated, linear, primary (C4-C22)" in monomer report.
69760	000143-28-2	Oleyl alcohol	Precursor of oleic acid.
69840	016260-09-6	Oleylpalmitamide	R : 5 mg/kg of food or food simulant. Available : 3-month oral rat study, mutagenicity studies negative, migration data. (RIVM doc., 17.03.1992)
70240	?	Ozokerite	Mineral wax. Purity to be specified.
71720	000109-66-0	Pentane	Volatile compound.
80640	-	Polyoxyalkyl(C2-C4)dimethylpolysiloxane	...
84560	009006-04-6	Rubber, natural	Migration unlikely.
84640	000069-72-7	Salicylic acid	Naturally occurred in food in low concentration.
85600	-	Silicates, natural	Free from asbestos. Inert, insoluble material. Some specific silicates have been allocated an ADI not specified. (SCF, 1988, in press)
85680	001343-98-2	Silicic acid	Inert, insoluble material.
85700	012650-28-1	Silicic acid, barium salt	L3 for silicic acid. L3 for Ba. R : 1 mg/kg in food or food simulant. (RIVM doc., May 1992 (CS/PM/1584))
86000	-	Silicic acid, silylated	Inert material.
86160	000409-21-2	Silicon carbide	Inert material.
91360	000126-14-7	Sucrose octaacetate	Bitter taste.
91840	007704-34-9	Sulphur	Inert material.
92000	007727-43-7	Sulphuric acid, barium salt (soluble Ba free)	L3 for Ba.

## LIST 3

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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
			R : 1 mg/kg (expressed as Ba) in food or food simulant. (RIVM doc., May 1992 (CS/PM/1584)) L3 for the compound. Insoluble material.
92300	000112-72-1	1-Tetradecanol	Included in 33120. (SCF, R...)
93980	000112-70-9	1-Tridecanol	See references for "Alcohols, aliphatic, monohydric, saturated, linear, primary (C4-C22)" in monomer report.
95360	027676-62-6	1,3,5-Tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	R : 5 mg/kg of food or food simulant. Available : 3-month oral rat study, mutagenicity studies negative, migration data. (RIVM doc., February 1992)
95905	013983-17-0	Wollastonite (= natural calcium silicate, free from asbestos)	Free from asbestos. Inert, insoluble material.
95920	-	Wood flour and fibers	Inert material.
96240	001314-13-2	Zinc oxide	Inert material.
96320	001314-98-3	Zinc sulphide	Inert material.

**LIST 4**

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

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
43760	026172-55-4	5-Chloro-2-methyl-4-isothiazolin-3-one	90-Day oral rat and dog studies. Reproduction and teratogenicity studies in rabbits. Three mutagenicity studies. (RIVM doc. tox. 300/430, May 1979, September 1983, June 1984) Very potent sensitizer.
44000	001333-82-0	Chromium trioxide	Cr(VI) is a genotoxic carcinogen. (IARC monograph 1980, vol. 23)
51540	000101-68-8	Diphenylmethane 4,4'-diisocyanate	See references for same substance in monomer report.
53950	000151-56-4	Ethyleneimine	See references for same substance in monomer report.
66755	002682-20-4	2-Methyl-4-isothiazolin-3-one	See references for 5-chloro-2-methyl-4-isothiazolin-3-one. Carcinogen.
71500	000087-86-5	Pentachlorophenol	Carcinogen.
74840	000131-17-9	Phthalic acid, diallyl ester	Genotoxic carcinogen (mouse and rat). (RIVM doc. 91/679112/001)

**LIST 5**

Substances which should not be used.

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF OPINION</u>
35960	001332-21-4	Asbestos	
44080	000104-55-2	Cinnamaldehyde	
46560	000106-93-4	1,2-Dibromoethane	
58770	025637-99-4	Hexabromocyclododecane	
60920	000622-40-2	N-(2-Hydroxyethyl)morpholine	
66785	000109-02-4	N-Methylmorpholine	
67870	000110-91-8	Morpholine	
67878	-	Morpholine, its salts of acids, aliphatic, monocarboxylic, saturated, above C7	
67882	-	Morpholine, its salts of acids, aliphatic, monocarboxylic, unsaturated, above C7	
68210	032536-52-0	Octabromodiphenyl ether	
71100	063449-39-8	Paraffins, chlorinated	
71470	032534-81-9	Pentabromodiphenyl ether	
93610	013732-62-2	p-Toluenesulphonic acid, morpholine salt	

## ANNEX II

## LIST OF SUBSTANCES EVALUATED IN THIS REPORT AND THEIR CLASSIFICATION.

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF</u>
30000	000064-19-7	Acetic acid	1
30045	000123-86-4	Acetic acid, n-butyl ester	1
30080	004180-12-5	Acetic acid, copper salt	1
30140	000141-78-6	Acetic acid, ethyl ester	1
30180	000638-38-0	Acetic acid, manganese(II) salt	1-2
30280	000108-24-7	Acetic anhydride	2
30295	000067-64-1	Acetone	3
30370	-	Acetylacetic acid, salts	0
30380	000623-58-5	Acetylacetic acid, sodium salt	0
30400	-	Acetylated glycerides	1
30960	-	Acids, aliphatic, monocarboxylic (C6-C22), esters with polyglycerol	1
31520	061167-58-6	Acrylic acid, 2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methylbenzyl)-4-methylphenyl ester	2
31540	000096-33-3	Acrylic acid, methyl ester	2
31730	000124-04-9	Adipic acid	1
31920	000103-23-1	Adipic acid, bis(2-ethylhexyl ester)	2
33070	009002-18-0	Agar-agar	1
33120	-	Alcohols, aliphatic, monohydric, saturated, linear, primary (C4-C22)	3
33350	009005-32-7	Alginic acid	1
33360	-	Alginic acid, salts	1
34230	-	Alkyl(C8-C22)sulphonic acid	2
34240	-	Alkyl(C10-C20)sulphonic acid, esters with phenols	2
34560	021645-51-2	Aluminium hydroxide	2
34660	001327-41-9	Aluminium hydroxychloride	2
34720	001344-28-1	Aluminium oxide	2
35120	013560-49-1	3-Aminocrotonic acid, diester with thiobis(2-hydroxyethyl) ether	2
35320	007664-41-7	Ammonia	1



## ANNEX II

## LIST OF SUBSTANCES EVALUATED IN THIS REPORT AND THEIR CLASSIFICATION.

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF</u>
35440	012124-97-9	Ammonium bromide	1
35520	012125-02-9	Ammonium chloride	1
35600	001336-21-6	Ammonium hydroxide	1
35630	010196-04-0	Ammonium sulphite	2
35840	000506-30-9	Arachidic acid	0
35845	007771-44-0	Arachidonic acid	0
35960	001332-21-4	Asbestos	5
36000	000050-81-7	Ascorbic acid	1
36080	000137-66-6	Ascorbyl palmitate	1
36160	010605-09-1	Ascorbyl stearate	1
36640	000123-77-3	Azodicarbonamide	3
36720	017194-00-2	Barium hydroxide	3
36800	010022-31-8	Barium nitrate	2-3
36840	?	Barium tetraborate	2-3
36880	008012-89-3	Beeswax	0
36960	003061-75-4	Behenamide	3
37040	000112-85-6	Behenic acid	0
37280	001302-78-9	Bentonite	3
37360	000100-52-7	Benzaldehyde	1
37520	002634-33-5	1,2-Benzisothiazolin-3-one	2
37600	000065-85-0	Benzoic acid	1
37680	000136-60-7	Benzoic acid, butyl ester	2
37840	000093-89-0	Benzoic acid, ethyl ester	2
38000	000553-54-8	Benzoic acid, lithium salt	2
38080	000093-58-3	Benzoic acid, methyl ester	2
38160	002315-68-6	Benzoic acid, propyl ester	2

## ANNEX II

## LIST OF SUBSTANCES EVALUATED IN THIS REPORT AND THEIR CLASSIFICATION.

<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF</u>
38240	000119-61-9	Benzophenone	2
38320	005242-49-9	4-(2-Benzoxazolyl)-4'-(5-methyl-2-benzoxazolyl)stilbene	3
38400	000100-51-6	Benzyl alcohol	1
38560	007128-64-5	2,5-Bis(5-tert-butyl-2-benzoxazolyl)thiophene	2
38700	063397-60-4	Bis(2-carbobutoxyethyl)tin bis(isooctyl mercaptoacetate)	2
38800	032687-78-8	N,N'-Bis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl]hydrazide	2
38820	026741-53-7	Bis(2,4-di-tert-butylphenyl)pentaerythritol diphosphite	2
38950	079072-96-1	Bis(4-ethylbenzylidene)sorbitol	2
39060	035958-30-6	1,1-Bis(2-hydroxy-3,5-di-tert-butylphenyl)ethane	3
39090	-	N,N-Bis(2-hydroxyethyl)alkyl(C8-C18)amine	2
39120	-	N,N-Bis(2-hydroxyethyl)alkyl(C8-C18)amine hydrochloride	2
39200	006200-40-4	Bis(2-hydroxyethyl)-2-hydroxypropyl-3-(dodecyloxy)methylammonium chloride	2
39600	000077-62-3	Bis[2-hydroxy-3-(1-methylcyclohexyl)-5-methylphenyl]methane	2
39680	000080-05-7	2,2-Bis(4-hydroxyphenyl)propane	2
39890	087826-41-3 069158-41-4	Bis(methylbenzylidene)sorbitol	2
40000	000991-84-4	2,4-Bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	2
40020	110553-27-0	2,4-Bis(octylthiomethyl)-6-methylphenol	2
40160	061269-61-2	N,N'-Bis(2,2,6,6-tetramethyl-4-piperidyl)hexamethylenediamine - 1,2-dibromoethane, copolymer	2
40240	-	Bis(triethyleneglycol) hydroxymethylphosphonate	2
40320	010043-35-3	Boric acid	2
40400	010043-11-5	Boron nitride	3
40570	000106-97-8	Butane	3
40590	000071-36-3	1-Butanol	3
40594	000075-65-0	tert-Butanol	3
40720	025013-16-5	tert-Butyl-4-hydroxyanisole (= BHA)	1

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF</u>
40800	013003-12-8	4,4'-Butylidenebis(6-tert-butyl-3-methylphenyl-ditridecyl phosphite)	2
40880	015666-29-2	Butylthiostannoic acid	2
40980	?	Butyric acid, manganese salt	2
41040	005743-36-2	Calcium butyrate	0
41120	010043-52-4	Calcium chloride	1
41280	001305-62-0	Calcium hydroxide	1
41520	001305-78-8	Calcium oxide	1
41600	012004-14-7 037293-22-4	Calcium sulphoaluminate	2
41680	000076-22-2	Camphor	3
41760	008006-44-8	Candelilla wax	3
41840	000105-60-2	Caprolactam	2
41960	000124-07-2	Caprylic acid	0
42000	063438-80-2	(2-Carbobutoxyethyl)tin tris(isooctyl mercaptoacetate)	2
42160	000124-38-9	Carbon dioxide	1
42320	007492-68-4	Carbonic acid, copper salt	1
42400	010377-37-4	Carbonic acid, lithium salt	2
42480	000584-09-8	Carbonic acid, rubidium salt	2
42500	-	Carbonic acid, salts	1
42640	009000-11-7	Carboxymethylcellulose	2
42720	008015-86-9	Carnauba wax	3
42800	009000-71-9	Casein	0
43300	009004-36-8	Cellulose acetate butyrate	3
43360	068442-85-3	Cellulose, regenerated	2
43440	008001-75-0	Ceresin, refined	3
43600	004080-31-3	1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	2
43680	000075-45-6	Chlorodifluoromethane	2

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF</u>
43760	026172-55-4	5-Chloro-2-methyl-4-isothiazolin-3-one	4
44000	001333-82-0	Chromium trioxide	4
44080	000104-55-2	Cinnamaldehyde	5
44160	000077-92-9	Citric acid	1
44640	000077-93-0	Citric acid, triethyl ester	1
45195	007787-70-4	Copper(I) bromide	1
45200	007681-65-4	Copper(I) iodide	1
45280	-	Cotton fibers	3
45520	-	p-Cresol, styrenated	2
45760	000108-91-8	Cyclohexylamine	2
45920	009000-16-2	Dammar	3
45940	000334-48-5	n-Decanoic acid	0
45970	020336-95-2	n-Decanoic acid, lithium salt	2
45980	010139-57-8	n-Decanoic acid, manganese salt	2
46050	000112-30-1	1-Decanol	3
46070	010016-20-3	alpha-Dextrin	0
46080	007585-39-9	beta-Dextrin	0
46375	?	Diatomaceous earth	3
46480	032647-67-9	Dibenzylidene sorbitol	2
46560	000106-93-4	1,2-Dibromoethane	5
46640	000128-37-0	2,6-Di-tert-butyl-p-cresol (= BHT)	1
46800	067845-93-6	3,5-Di-tert-butyl-4-hydroxybenzoic acid, hexadecyl ester	2
46880	065140-91-2	3,5-Di-tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	2
47200	004221-80-1	2,4-Di-tert-butylphenyl 3,5-di-tert-butyl-4-hydroxybenzoate	2
47440	000461-58-5	Dicyanodiamide	2
47600	084030-61-5	Di-n-dodecyltin bis(isooctyl mercaptoacetate)	2

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF</u>
47680	000111-46-6	Diethyleneglycol	2
48030	000112-34-5	Diethyleneglycol monobutyl ether	2
48050	000111-90-0	Diethyleneglycol monoethyl ether	2
48620	000123-31-9	1,4-Dihydroxybenzene	2
48640	000131-56-6	2,4-Dihydroxybenzophenone	2
48720	000611-99-4	4,4'-Dihydroxybenzophenone	2
48760	000092-88-6	4,4'-Dihydroxybiphenyl	2
48800	000097-23-4	2,2'-Dihydroxy-5,5'-dichlorodiphenylmethane	2
48880	000131-53-3	2,2'-Dihydroxy-4-methoxybenzophenone	2
49225	000124-40-3	Dimethylamine	3
49235	000108-01-0	Dimethylaminoethanol	2
49425	000137-30-4	Dimethyldithiocarbamic acid, zinc salt	2
49525	-	Dimethylpolysiloxane	1
49540	000067-68-5	Dimethyl sulphoxide	3
49600	026636-01-1	Dimethyltin bis(isooctyl mercaptoacetate)	2
49760	003135-18-0	Di-n-octadecyl 3,5-di-tert-butyl-4-hydroxybenzylphosphonate	2
49840	002500-88-1	Di-octadecyl disulphide	2
50160	-	Di-n-octyltin bis[n-alkyl(C10-C16) mercaptoacetate]	2
50240	010039-33-5	Di-n-octyltin bis(2-ethylhexyl maleate)	2
50320	015571-58-1	Di-n-octyltin bis(2-ethylhexyl mercaptoacetate)	2
50360	-	Di-n-octyltin bis(ethyl maleate)	2
50400	033568-99-9	Di-n-octyltin bis(isooctyl maleate)	2
50480	026401-97-8	Di-n-octyltin bis(isooctyl mercaptoacetate)	2
50560	?	Di-n-octyltin 1,4-butanediol bis(mercaptoacetate)	2
50640	003648-18-8	Di-n-octyltin dilaurate	2
50720	015571-60-5	Di-n-octyltin dimaleate	2

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF</u>
50800	-	Di-n-octyltin dimaleate, esterified	2
50880	-	Di-n-octyltin dimaleate, polymers (n = 2-4)	2
50960	069226-44-4	Di-n-octyltin ethyleneglycol bis(mercaptoacetate)	2
51040	015535-79-2	Di-n-octyltin mercaptoacetate	2
51120	?	Di-n-octyltin thiobenzoate (2-ethylhexyl mercaptoacetate)	2
51200	000126-58-9	Dipentaerythritol	2
51540	000101-68-8	Diphenylmethane 4,4'-diisocyanate	4
51680	000102-08-9	N,N'Diphenylthiourea	2
51760	000110-98-5	Dipropylenglycol	2
51975	000112-53-8	1-Dodecanol	3
52000	027176-87-0	Dodecylbenzenesulphonic acid	2
52320	052047-59-3	2-(4-Dodecylphenyl)indole	2
52640	016389-88-1	Dolomite	3
52730	000112-86-7	Erucic acid	3
52800	000064-17-5	Ethanol	1
52880	023676-09-7	4-Ethoxybenzoic acid, ethyl ester	2
53200	023949-66-8	2-Ethoxy-2'-ethyloxanilide	2
53270	037205-99-5	Ethylcarboxymethylcellulose	2
53280	009004-57-3	Ethylcellulose	2
53360	000110-31-6	N,N'-Ethylenebisoleamide	3
53440	005518-18-3	N,N'-Ethylenebispalmitamide	3
53520	000110-30-5	N,N'-Ethylenebissstearamide	3
53540	000107-15-3	Ethylenediamine	2
53600	000060-00-4	Ethylenediaminetetraacetic acid	2
53610	054453-03-1	Ethylenediaminetetraacetic acid, copper salt	2
53650	000107-21-1	Ethyleneglycol	2

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF</u>
53670	032509-66-3	Ethyleneglycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]	2
53765	000111-76-2	Ethyleneglycol monobutyl ether	2
53820	000110-80-5	Ethyleneglycol monoethyl ether	2
53950	000151-56-4	Ethyleneimine	4
54005	005136-44-7	Ethylene-N-palmitamide-N'-stearamide	3
54180	015590-62-2	2-Ethylhexanoic acid, lithium salt	2
54260	009004-58-4	Ethyhydroxyethylcellulose	2
54270	?	Ethyhydroxymethylcellulose	2
54280	?	Ethyhydroxypropylcellulose	2
54300	?	2,2'-Ethylidenebis(4,6-di-tert-butylphenyl) fluorophosphonite	2
54420	000121-32-4	Ethylvanillin	1
54680/ 1	?	Fatty acids, soya, lithium salts	2-3
54685/ 1	?	Fatty acids, soya, manganese salts	2-3
54735/ 1	?	Fatty acids, tall oil, lithium salts	2-3
54740/ 1	008030-70-4	Fatty acids, tall oil, manganese salts	2-3
54880	000050-00-0	Formaldehyde	3
55040	000064-18-6	Formic acid	1
55120	000110-17-8	Fumaric acid	1
55190	029204-02-2	Gadoleic acid	0
55200	001166-52-5	Gallic acid, dodecyl ester	1
55280	001034-01-1	Gallic acid, octyl ester	1
55360	000121-79-9	Gallic acid, propyl ester	1
55440	009000-70-8	Gelatin	0
55520	-	Glass fibers (d = 0.5-30 µm)	3

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF</u>
55600	-	Glass microballs (d = 0.5-500 $\mu$ m), hollow or solid	3
55630	000050-99-7	Glucose	0
55680	000110-94-1	Glutaric acid	0
55920	000056-81-5	Glycerol	1
56000	025395-31-7	Glycerol diacetate	1
56040	?	Glycerol dibutyrate	0
56080	025637-84-7	Glycerol dioleate	1
56160	026402-29-9	Glycerol dipropionate	0
56240	027902-24-5	Glycerol diricinoleate	0
56320	001323-83-7	Glycerol distearate	1
56600	026446-35-5	Glycerol monoacetate	1
56640	026999-06-4	Glycerol monobutyrate	0
56720	026402-22-2	Glycerol monohexanoate	0
56800	030899-62-8	Glycerol monolaurate diacetate	3
56880	026402-26-6	Glycerol monooleate	0
56960	025496-72-4	Glycerol monooleate	1
57040	?	Glycerol monooleate, ester with ascorbic acid	2
57120	?	Glycerol monooleate, ester with citric acid	1
57200	?	Glycerol monopalmitate, ester with ascorbic acid	2
57280	?	Glycerol monopalmitate, ester with citric acid	1
57360	026894-50-8	Glycerol monopropionate	0
57440	001323-38-2	Glycerol monoricinoleate	0
57520	031566-31-1	Glycerol monostearate	1
57600	?	Glycerol monostearate, ester with ascorbic acid	2
57680	?	Glycerol monostearate, ester with citric acid	1
57760	000102-76-1	Glycerol triacetate	1



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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF</u>
57840	000060-01-5	Glycerol tributyrate	0
57920	000620-67-7	Glycerol triheptanoate	0
58080	000139-45-7	Glycerol tripropionate	0
58160	000139-44-6	Glycerol tris(12-hydroxystearate)	0
58240	000555-43-1	Glycerol tristearate	0
58300	-	Glycine, salts	1
58320	007782-42-5	Graphite	3
58360	009000-29-7	Guaiac gum	1
58400	009000-30-0	Guar gum	1
58480	009000-01-5	Gum arabic	1
58720	000111-14-8	Heptanoic acid	3
58740	016761-13-0	Heptanoic acid, lithium salt	2-3
58760	?	Heptanoic acid, manganese salt	2-3
58770	025637-99-4	Hexabromocyclododecane	5
58790	036653-82-4	1-Hexadecanol	3
58960	000057-09-0	Hexadecyltrimethylammonium bromide	2
59120	023128-74-7	1,6-Hexamethylenebis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide]	2
59200	035074-77-2	1,6-Hexamethylenebis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]	2
59240	000124-09-4	Hexamethylenediamine	2
59280	000100-97-0	Hexamethylenetetramine	3
59360	000142-62-1	n-Hexanoic acid	0
59680	?	Hydromagnesite (natural basic magnesium carbonate)	3
59760	019569-21-2	Huntite (natural calcium magnesium carbonate)	3
59990	007647-01-0	Hydrochloric acid	1
60080	012304-65-3	Hydrotalcite (Mg/Al carbonate complex)	3
60160	000120-47-8	4-Hydroxybenzoic acid, ethyl ester	1

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF</u>
60200	000099-76-3	4-Hydroxybenzoic acid, methyl ester	1
60240	000094-13-3	4-Hydroxybenzoic acid, propyl ester	1
60320	070321-86-7	2-[2-Hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl]benzotriazole	2
60400	003896-11-5	2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-5-chlorobenzotriazole	2
60480	003864-99-1	2-(2-Hydroxy-3,5-di-tert-butylphenyl)-5-chlorobenzotriazole	2
60560	009004-62-0	Hydroxyethylcellulose	2
60800	065447-77-0	1-(2-Hydroxyethyl)-4-hydroxy-2,2,6,6-tetramethylpiperidine - succinic acid, dimethyl ester, copolymer (M.W. 1500-5000)	2
60880	009032-42-2	Hydroxyethylmethylcellulose	2
60920	000622-40-2	N-(2-Hydroxyethyl)morpholine	5
61120	009005-27-0	Hydroxyethyl starch	2
61280	003293-97-8	2-Hydroxy-4-n-hexyloxybenzophenone	2
61360	000131-57-7	2-Hydroxy-4-methoxybenzophenone	2
61390	037353-59-6	Hydroxymethylcellulose	2
61440	002440-22-4	2-(2-Hydroxy-5-methylphenyl)benzotriazole	2
61600	001843-05-6	2-Hydroxy-4-n-octyloxybenzophenone	2
61680	009004-64-2	Hydroxypropylcellulose	2
61760	009004-65-3	Hydroxypropylmethylcellulose	2
61800	009049-76-7	Hydroxypropyl starch	1
61840	000106-14-9	12-Hydroxystearic acid	0
62040	000139-44-6	12-Hydroxystearic acid, triester with glycerol	0
62160	007681-53-0	Hypophosphorous acid, sodium salt	3
62220	010045-89-3	Iron(II) diammonium bisulphate	3
62240	001332-37-2	Iron oxide	2
62255	000075-28-5	Isobutane	3
62450	000078-78-4	Isopentane	3
62640	008001-39-6	Japan wax	3

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF</u>
62720	001332-58-7	Kaolin	1
62800	066402-68-4	Kaolin, calcined	3
62830	009000-36-6	Karaya gum	1
62880	061790-53-2	Kieselguhr	3
62960	000050-21-5	Lactic acid	1
63040	000138-22-7	Lactic acid, butyl ester	2
63200	051877-53-3	Lactic acid, manganese salt	1-2
63280	000143-07-7	Lauric acid	0
63760	008002-43-5	Lecithin	1
63840	000123-76-2	Levulinic acid	0
63920	000557-59-5	Lignoceric acid	0
64015	000060-33-3	Linoleic acid	0
64100	074488-09-8	Linoleic acid, lithium salt	2
64115	006904-78-5	Linoleic acid, manganese salt	2
64130	-	Linoleic acid, salts	0
64150	028290-79-1	Linolenic acid	0
64270	007447-41-8	Lithium chloride	2
64300	001310-65-2	Lithium hydroxide	2
64320	010377-51-2	Lithium iodide	2
64350	012057-24-8	Lithium oxide	2
64400	001345-05-7	Lithopone (C.I. Pigment White 5)	3
64500	-	Lysine, salts	0
64560	007786-30-3	Magnesium chloride	1
64640	001309-42-8	Magnesium hydroxide	1
64720	001309-48-4	Magnesium oxide	1
64800	000110-16-7	Maleic acid	2

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF</u>
65020	006915-15-7	Malic acid	1
65040	000141-82-2	Malonic acid	3
65120	007773-01-5	Manganese(II) chloride	2
65200	012626-88-9	Manganese hydroxide	2
65280	010043-84-2	Manganese(II) hypophosphite	2
65360	011129-60-5	Manganese oxide	2
65440	?	Manganese(II) pyrophosphite	2
65520	000087-78-5	Mannitol	1
65860	000080-62-6	Methacrylic acid, methyl ester	2
65920	066822-60-4	N-Methacryloylethyl-N,N-dimethylammonium-alpha-N-methylcarboxylate - octadecyl methacrylate - ethyl methacrylate - cyclohexyl methacrylate - N-vinyl-2-pyrrolidone, copolymers	2
65960	000067-56-1	Methanol	3
66120	010605-21-7	Methyl benzimidazolecarbamate	2
66200	037206-01-2	Methylcarboxymethylcellulose	2
66240	009004-67-5	Methylcellulose	2
66360	085209-91-2	2,2'-Methylenebis(4,6-di-tert-butylphenyl)sodium phosphate	3
66400	000088-24-4	2,2'-Methylenebis(4-ethyl-6-tert-butylphenol)	2
66480	000119-47-1	2,2'-Methylenebis(4-methyl-6-tert-butylphenol)	2
66560	004066-02-8	2,2'-Methylenebis(4-methyl-6-cyclohexylphenol)	2
66640	009004-59-5	Methylethylcellulose	2
66695	?	Methylhydroxymethylcellulose	2
66700	009004-65-3	Methylhydroxypropylcellulose	2
66755	002682-20-4	2-Methyl-4-isothiazolin-3-one	4
66785	000109-02-4	N-Methylmorpholine	5
67120	012001-26-2	Mica	3
67200	001317-33-5	Molybdenum disulphide	3

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF</u>
67280	000108-90-7	Monochlorobenzene	2
67360	067649-65-4	Mono-n-dodecyltin tris(isooctyl mercaptoacetate)	2
67520	054849-38-6	Monomethyltin tris(isooctyl mercaptoacetate)	2
67600	-	Mono-n-octyltin tris[alkyl(C10-C16)mercaptoacetate]	2
67680	027107-89-7	Mono-n-octyltin tris(2-ethylhexyl mercaptoacetate)	2
67760	026401-86-5	Mono-n-octyltin tris(isooctyl mercaptoacetate)	2
67840	-	Montanic acids (purified) and/or their esters with ethyleneglycol and/or with 1,3-butanediol and/or glycerol	3
67850	008002-53-7	Montan wax	3
67870	000110-91-8	Morpholine	5
67878	-	Morpholine, its salts of acids, aliphatic, monocarboxylic, saturated, above C7	5
67882	-	Morpholine, its salts of acids, aliphatic, monocarboxylic, unsaturated, above C7	5
67891	000544-63-8	Myristic acid	1
68040	003333-62-8	7-[2-H-Naphtho-(1,2-D)triazol-2-yl]-3-phenylcoumarin	2
68125	068187-64-4	Nepheline syenite	3
68140	007697-37-2	Nitric acid	2
68210	032536-52-0	Octabromodiphenyl ether	5
68225	000112-92-5	1-Octadecanol	3
68320	002082-79-3	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	2
68680	016577-52-9	n-Octanoic acid, lithium salt	2
68690	006535-19-9	n-Octanoic acid, manganese salt	2
68750	000111-87-5	1-Octanol	3
69040	000112-80-1	Oleic acid	1
69455	007384-22-7	Oleic acid, lithium salt	1-2
69465	019153-79-8	Oleic acid, manganese salt	1-2
69760	000143-28-2	Oleyl alcohol	3
69840	016260-09-6	Oleylpalmitamide	3

## ANNEX II

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF</u>
69920	000144-62-7	Oxalic acid	2
70000	070331-94-1	2,2'-Oxamidobis[ethyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]	2
70240	?	Ozokerite	3
70400	000057-10-3	Palmitic acid	1
70820	020466-33-5	Palmitic acid, lithium salt	1-2
70840	031678-63-4	Palmitic acid, manganese salt	1-2
71020	000373-49-9	Palmitoleic acid	0
71100	063449-39-8	Paraffins, chlorinated	5
71440	009000-69-5	Pectin	1
71470	032534-81-9	Pentabromodiphenyl ether	5
71500	000087-86-5	Pentachlorophenol	4
71600	000115-77-5	Pentaerythritol	2
71680	006683-19-8	Pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]	2
71720	000109-66-0	Pentane	3
72160	000948-65-2	2-Phenylindole	2
72640	007664-38-2	Phosphoric acid	1
73040	013763-32-1	Phosphoric acid, lithium salt	1-2
73120	010124-54-6	Phosphoric acid, manganese salt	1-2
74240	031570-04-4	Phosphorous acid, tris(2,4-di-tert-butylphenyl) ester	2
74400	026523-78-4 001333-21-7	Phosphorous acid, tris(nonyl- and/or dinonylphenyl) ester	2
74480	000088-99-3	o-Phthalic acid	2
74560	000085-68-7	Phthalic acid, benzyl butyl ester	2
74640	000117-81-7	Phthalic acid, bis(2-ethylhexyl) ester	2
74840	000131-17-9	Phthalic acid, diallyl ester	4
74880	000084-74-2	Phthalic acid, dibutyl ester	2
74960	000084-61-7	Phthalic acid, dicyclohexyl ester	2

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75040	-	Phthalic acid, diesters with hexadecanol and/or octadecanol	2
75120	000084-66-2	Phthalic acid, diethyl ester	2
75360	?	Phthalic acid, diisodecyl ester	2
75440	?	Phthalic acid, diisononyl ester	2
76320	000085-44-9	Phthalic anhydride	2
76720	009016-00-6 063148-62-9	Polydimethylsiloxane (M.W. 13500-90000)	2
76730	-	Polydimethylsiloxane, gamma-hydroxypropylated	2
76960	025322-68-3	Polyethyleneglycol	2
77280	009005-02-1	Polyethyleneglycol dilaurate	2
77320	?	Polyethyleneglycol dimyristate	2
77360	009005-07-6	Polyethyleneglycol dioleate	2
77440	?	Polyethyleneglycol diricinoleate	2
77520	061791-12-6	Polyethyleneglycol ester of castor oil	2
77550	-	Polyethyleneglycol ester of coconut oil fatty acids	2
77640	-	Polyethyleneglycol esters of acids, linear, with an even number of carbon atoms (C8-C22)	2
77660	-	Polyethyleneglycol esters of natural fatty acids	2
77702	-	Polyethyleneglycol esters of aliphatic monocarboxylic acids (C6-C22), and their ammonium and sodium sulphates	2
78080	009004-81-3	Polyethyleneglycol monolaurate	2
78120	?	Polyethyleneglycol monomyristate	2
78160	009004-96-0	Polyethyleneglycol monooleate	2
78240	009004-94-8	Polyethyleneglycol monopalmitate	2
78320	009004-97-1	Polyethyleneglycol monoricinoleate	2
79040	009005-64-5	Polyethyleneglycol sorbitan monolaurate	1
79120	009005-65-6	Polyethyleneglycol sorbitan monooleate	2
79200	009005-66-7	Polyethyleneglycol sorbitan monopalmitate	1

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF</u>
79280	009005-67-8	Polyethyleneglycol sorbitan monostearate	1
79360	009005-70-3	Polyethyleneglycol sorbitan trioleate	2
79440	009005-71-4	Polyethyleneglycol sorbitan tristearate	1
79520	?	Polyethyleneglycol stearate	2
79760	-	Polyethyleneimine, butylated	2
80160	037349-34-1	Polyglycerol monostearate	1
80240	029894-35-7	Polyglycerol ricinoleate	1
80320	009009-32-9	Polyglycerol stearate	1
80480	082451-48-7	Poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)-imino]-hexamethylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino]	2
80640	-	Polyoxyalkyl(C2-C4)dimethylpolysiloxane	3
80720	008017-16-1	Polyphosphoric acids	1
80800	025322-69-4	Polypropyleneglycol (1,3-Propyleneglycol content not to exceed 1%)	2
81200	071878-19-8	Poly[6-[(1,1,3,3-tetramethylbutyl)amino]-1,3,5-triazine-2,4-diyl]-[(2,2,6,6-tetramethyl-4-piperidyl)imino]-hexamethylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino]	2
81520	007758-02-3	Potassium bromide	1
81600	001310-58-3	Potassium hydroxide	1
81680	007681-11-0	Potassium iodide	1
81720	010117-38-1	Potassium sulphite	2
81840	000057-55-6	1,2-Propanediol	1
81882	000067-63-0	2-Propanol	1
82000	000079-09-4	Propionic acid	1
82080	009005-37-2	1,2-Propyleneglycol alginate	1
82240	022788-19-8	1,2-Propyleneglycol dilaurate	1
82400	000105-62-4	1,2-Propyleneglycol dioleate	1
82560	033587-20-1	1,2-Propyleneglycol dipalmitate	1
82720	006182-11-2	1,2-Propyleneglycol distearate	1



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82800	027194-74-7	1,2-Propyleneglycol monolaurate	1
82960	001330-80-9	1,2-Propyleneglycol monooleate	1
83120	029013-28-3	1,2-Propyleneglycol monopalmitate	1
83300	001323-39-3	1,2-Propyleneglycol monostearate	1
83320	?	Propylhydroxyethylcellulose	2
83325	?	Propylhydroxymethylcellulose	2
83330	?	Propylhydroxypropylcellulose	2
83390	016210-51-8	Pyroantimonic acid, potassium salt	2
83440	002466-09-3	Pyrophosphoric acid	1
83595	119345-01-6	Reaction product of di-tert-butyl phosphonite with biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with Friedel Craft reaction product of phosphorus trichloride and biphenyl	2
83610	073138-82-6	Resin acids and rosin acids	2
83640	?	Resin acids and rosin acids, lithium salts	2
83650	009008-34-8	Resin acids and rosin acids, manganese salts	2
83700	000141-22-0	Ricinoleic acid	2
83790	015467-06-8	Ricinoleic acid, lithium salt	2
83805	?	Ricinoleic acid, manganese salt	2
83840	008050-09-7	Rosin	2
84000	008050-31-5	Rosin, ester with glycerol	1
84080	008050-26-8	Rosin, ester with pentaerythritol	2
84240	065997-13-9	Rosin, hydrogenated, ester with glycerol	2
84320	008050-15-5	Rosin, hydrogenated, ester with methanol	2
84400	064365-17-9	Rosin, hydrogenated, ester with pentaerythritol	2
84560	009006-04-6	Rubber, natural	3
84640	000069-72-7	Salicylic acid	3
84800	000087-18-3	Salicylic acid, 4-tert-butylphenyl ester	2

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84880	000119-36-8	Salicylic acid, methyl ester	1
85550	009000-59-3	Shellac	1
85600	-	Silicates, natural	3
85680	001343-98-2	Silicic acid	3
85700	012650-28-1	Silicic acid, barium salt	3
85760	012068-40-5	Silicic acid, lithium aluminium salt	2
85840	053320-86-8	Silicic acid, lithium magnesium sodium salt	2
85920	012627-14-4	Silicic acid, lithium salt	2
86000	-	Silicic acid, silylated	3
86160	000409-21-2	Silicon carbide	3
86240	007631-86-9	Silicon dioxide	1
86440	?	Sodium aluminate	2
86480	007631-90-5	Sodium bisulphite	1
86560	007647-15-6	Sodium bromide	1
86720	001310-73-2	Sodium hydroxide	1
86800	007681-82-5	Sodium iodide	1
86880	-	Sodium monoalkyl dialkylphenoxybenzenedisulphonate	2
86960	007757-83-7	Sodium sulphite	1
87040	001330-43-4	Sodium tetraborate	2
87120	007772-98-7	Sodium thiosulphate	1
87200	000110-44-1	Sorbic acid	1
87280	029116-98-1	Sorbitan dioleate	2
87520	062568-11-0	Sorbitan monobehenate	2
87600	001338-39-2	Sorbitan monolaurate	1
87680	001338-43-8	Sorbitan monooleate	1
87760	026266-57-9	Sorbitan monopalmitate	1

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<u>PM/REF</u>	<u>CAS</u>	<u>NAME</u>	<u>SCF</u>
87840	001338-41-6	Sorbitan monostearate	1
87920	061752-68-9	Sorbitan tetrastearate	2
88080	026266-58-0	Sorbitan trioleate	2
88160	054140-20-4	Sorbitan tripalmitate	2
88240	026658-19-5	Sorbitan tristearate	1
88320	000050-70-4	Sorbitol	1
88600	026836-47-5	Sorbitol monostearate	2
88640	008013-07-8	Soybean oil, epoxidized (oxirane < 8%, iodine number < 6)	2
88800	009005-25-8	Starch, edible	0
88880	068412-29-3	Starch, hydrolysed	0
89040	000057-11-4	Stearic acid	1
89200	000660-60-6	Stearic acid, copper(II) salt	1
89440	-	Stearic acid, esters with ethyleneglycol	2
90260	004485-12-5	Stearic acid, lithium salt	1-2
90290	010476-84-3	Stearic acid, manganese salt	1-2
90600	006994-59-8	Stearic acid, tin(II) salt	1
90720	058446-52-9	Stearoylbenzoylmethane	2
90800	005793-94-2	Stearoyl-2-lactylic acid, calcium salt	1
90960	000110-15-6	Succinic acid	1
91170	000108-30-5	Succinic anhydride	2
91185	000057-50-1	Sucrose	0
91200	000126-13-6	Sucrose acetate isobutyrate	1
91360	000126-14-7	Sucrose octaacetate	3
91840	007704-34-9	Sulphur	3
91920	007664-93-9	Sulphuric acid	1
92000	007727-43-7	Sulphuric acid, barium salt (soluble Ba free)	3

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92060	007488-55-3	Sulphuric acid, tin(II) salt	1
92080	014807-96-6	Talc	1
92100/ 0	061789-97-7	Tallow	0
92160	000087-69-4	Tartaric acid	1
92195	-	Taurine, salts	0
92205	057569-40-1	Terephthalic acid, diester with 2,2'-methylenebis(4-methyl-6-tert-butylphenol)	2
92300	000112-72-1	1-Tetradecanol	3
92320	-	Tetradecyl-polyethylene oxide(3-8) ether of glycolic acid	2
92350	000112-60-7	Tetraethyleneglycol	1
92430	000109-99-9	Tetrahydrofuran	2
92560	038613-77-3	Tetrakis(2,4-di-tert-butylphenyl)-4,4'-biphenylene diphosponite	2
92640	000102-60-3	N,N,N',N'-Tetrakis(2-hydroxypropyl)ethylenediamine	2
92800	000096-69-5	4,4'-Thiobis(6-tert-butyl-3-methylphenol)	2
92880	041484-35-9	Thiodiethanol bis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]	2
92930	120218-34-0	Thiodiethylenebis(5-methoxycarbonyl-2,6-dimethyl-1,4-dihydropyridine-3-carboxylate)	2
93415	007772-99-8	Tin(II) chloride	1
93420	007646-78-8	Tin(IV) chloride	1
93440	013463-67-7	Titanium dioxide	1
93520	000059-02-9 010191-41-0	alpha-Tocopherol	1
93610	013732-62-2	p-Toluenesulphonic acid, morpholine salt	5
93680	009000-65-1	Tragacanth gum	1
93720	000108-78-1	2,4,6-Triamino-1,3,5-triazine	2
93980	000112-70-9	1-Tridecanol	3
94320	000112-27-6	Triethyleneglycol	2
94400	036443-68-2	Triethyleneglycol bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propionate]	2

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94960	000077-99-6	1,1,1-Trimethylolpropane	2
95200	001709-70-2	1,3,5-Trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene	2
95280	040601-76-1	1,3,5-Tris(4-tert-butyl-3-hydroxy-2,6-dimethylbenzyl)-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione	2
95360	027676-62-6	1,3,5-Tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	3
95680	000121-33-5	Vanillin	1
95870	-	Wheat protein	0
95905	013983-17-0	Wollastonite (= natural calcium silicate, free from asbestos)	3
95920	-	Wood flour and fibers	3
95935	011138-66-2	Xanthan gum	1
95990	009010-66-6	Zein	0
96180		Zinc dust	1
96190	020427-58-1	Zinc hydroxide	1
96200	055799-16-1	Zinc hydroxyphosphite	2
96240	001314-13-2	Zinc oxide	3
96320	001314-98-3	Zinc sulphide	3

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The Scientific Committee for Food was established by Commission Decision 74/234/EEC of 16 April 1974 (OJ L 136, 20.5.1974, p. 1) to advise the Commission on any problem relating to the protection of the health and safety of persons arising from the consumption of food, and in particular the composition of food, processes which are liable to modify food, the use of food additives and other processing aids as well as the presence of contaminants.

The members are independent persons, highly qualified in the fields associated with medicine, nutrition, toxicology, biology, chemistry, or other similar disciplines.

The secretariat of the Committee is provided by the Directorate-General for Industry of the Commission. Recent Council directives require the Commission to consult the Committee on provisions which may have an effect on public health falling within the scope of these directives.

The present report deals with the first report of the Scientific Committee for Food on certain additives used in the manufacture of plastic materials intended to come into contact with

for staff (provisions approved until 2 May 1992)