

**Partial Agreement
in the Social and Public Health Field
Accord Partiel
dans le domaine social et de la santé publique**



PUBLIC HEALTH COMMITTEE

**COMMITTEE OF EXPERTS ON MATERIALS COMING INTO CONTACT
WITH FOOD**

**POLICY STATEMENT
CONCERNING**

**ION EXCHANGE AND ADSORBANT RESINS IN THE
PROCESSING OF FOODSTUFFS**

Version 1 – 10.06.2004

NOTE TO THE READER

The following documents are part of the Policy statement concerning ion exchange and adsorbent resins used in the processing of foodstuffs:

- Resolution ResAP (2004) 3 on ion exchange and adsorbent resins used in the processing of foodstuffs
- Technical document No. 1 – List of substances to be used in the manufacture of ion exchange and adsorbent resins used in the processing of foodstuffs (Version N° 1)

The documents are available on the Internet website of the Partial Agreement Division in the Social and Public Health Field:

www.coe.int/soc-sp

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**RESOLUTION RESAP (2004) 3 ON
ION EXCHANGE AND ADSORBENT RESINS
USED IN THE PROCESSING OF FOODSTUFFS**

**RESOLUTION RESAP (2004) 3 ON
ION EXCHANGE AND ADSORBENT RESINS
USED IN THE PROCESSING OF FOODSTUFFS**

*(adopted by the Committee of Ministers
on 1st December 2004 at the 907th meeting of the Ministers' Deputies)
(superseding Resolution AP (97) 1)*

The Committee of Ministers, in its composition restricted to the Representatives of Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, The Netherlands, Norway, Portugal, Slovenia, Spain, Sweden, Switzerland and the United Kingdom, member states of the Partial Agreement in the Social and Public Health Field,

Recalling Resolution (59) 23 of 16 November 1959, concerning the extension of the activities of the Council of Europe in the social and cultural fields;

Having regard to Resolution (96) 35 of 2 October 1996, whereby it revised the structures of the Partial Agreement and resolved to continue, on the basis of revised rules replacing those set out in Resolution (59) 23, the activities hitherto carried out and developed by virtue of that resolution; these being aimed in particular at:

a. raising the level of health protection of consumers in its widest sense, including constant contribution to harmonising – in the field of products having a direct or indirect impact on the human food chain as well as in the field of pesticides, pharmaceuticals and cosmetics – legislation, regulations and practices governing, on the one hand, quality, efficiency and safety controls for products and, on the other hand, the safe use of toxic or noxious products;

b. integrating people with disabilities into the community; defining – and contributing to its implementation at European level – a model of coherent policy for people with disabilities, which takes account simultaneously of the principles of full citizenship and independent living; contributing to the elimination of barriers to integration, whatever their nature, whether psychological, educational, family-related, cultural, social, professional, financial or architectural;

Having regard to the action carried out for several years for the purposes of harmonising legislation in the public health field and, in particular, with regard to materials and articles intended to come into contact with foodstuffs;

Considering that ion exchange and adsorbent resins used in the processing of foodstuffs may, by reason of the migration of their components to the foodstuffs, pose in certain conditions a risk to human health;

Taking the view that each member state, faced with the need to introduce regulations governing this matter, would find it beneficial to harmonise such regulations at European level,

Recommends to the governments of the member states of the Partial Agreement in the social and public health field to take into account in their national laws and regulations on ion exchange and adsorbent resins used in the processing of foodstuffs the principles set out hereafter.

APPENDIX TO RESOLUTION RESAP (2004) 3

1. Definition

Ion exchange and adsorbent resins, hereafter called resins, are synthetic organic macromolecular compounds which can be used in the processing of foodstuffs to bring about exchange of ions or adsorption of foodstuffs constituents. They do not include, however, cellulosic ion exchangers.

2. Specifications

Resins used in processing of foodstuffs should meet the following requirements:

2.1. they should not transfer their constituents to foodstuffs in quantities which could endanger human health or bring about an unacceptable change in the composition of the foodstuffs or deterioration in the organoleptic characteristics thereof;

2.2. they should be manufactured in accordance with a certified Quality Assurance System (e.g. ISO 9002 or CEN 29-004) and should use the substances listed and under the conditions specified in "*Technical document No. 1 – List of substances to be used in the manufacture of ion exchange and adsorbent resins used in the processing of foodstuffs*" and according to the conditions specified;

2.3. the listing of a substance in a particular category (monomers, chemical modifiers or polymerisation aids) does not preclude its use at some other stage of the manufacturing process;

2.4. the user should be instructed that mechanical attrition of the resin is possible, and steps should be taken to filter the treated liquor to ensure that any fine particles are removed;

2.5. they should be made ready for use in accordance with the instructions of the manufacturer;

2.6. regeneration of resins should be performed in such a manner that they are not contaminated with substances detrimental to health;

2.7. resins should be subjected to AFNOR test T 90-601.¹ All five bed-volumes prepared should be tested for total organic carbon (TOC) in order to demonstrate a decreasing release of organic carbon from the first through to the last bed-volume. Total organic carbon in the fifth bed-volume should not exceed 1 mg/l;

2.8. where appropriate, migration of specific resin constituents should be determined as well, using water, 3% (w/v) acetic acid or 15% (v/v) ethanol as the food simulant, whichever is relevant. Migration of specific resin constituents to the fifth bed-volume, obtained as in the AFNOR test, should not exceed the limits set out in "*Technical document No. 1 – List of substances to be used in the manufacture of ion exchange and adsorbent resins used in the processing of foodstuffs*". Specific migration should be determined by a method of analysis validated at the specific migration limit level;

2.9. verification of compliance with specific migration limits is not compulsory if it can be demonstrated, for example by calculation, that by assuming complete migration of the residual quantity of a substance, the specific limit of migration of that substance will not be exceeded;

2.10. where appropriate, residual quantity of specific resin constituents should be determined in the resin. The residual quantity should not exceed the limits set out in "*Technical document No. 1 – List of substances to be used in the manufacture of ion exchange and adsorbent resins used in the processing of foodstuffs*".

¹ Water treatment. Ion exchange resins. Release test of total organic carbon. December 1988.

TECHNICAL DOCUMENT No. 1

**LIST OF SUBSTANCES TO BE USED IN THE MANUFACTURE
OF ION EXCHANGE AND ADSORBENT RESINS
USED IN THE PROCESSING OF FOODSTUFFS
Version 1 – 10.06.2004**

1. CLASSIFICATION SYSTEM OF SUBSTANCES TO BE USED FOR MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

General specifications

List 1 - Substances approved for the use of materials and articles intended to come into contact with food

1. Substances evaluated by SCF, classified in list 0-4, and used in compliance with specific migration limits or other restrictions, if any.
2. Substances evaluated and approved by the Committee of expert on materials coming into contact with food.
3. Substances approved in Partial Agreement member states or by FDA, based on an evaluation of a toxicological dossier, which meets the present SCF criteria;
4. Substances authorised as direct food additives in compliance with specific migration limits or other restrictions;
5. The substances which have been approved by Partial Agreement member states or by FDA applying scientific evaluation criteria of the time of their approval will be listed in a Temporary Appendix to List 1.

List 2 – Substances not approved for the use of materials and articles intended to come into contact with food

Substances which do not meet the criteria set for List 1 substances.

Complementary specifications

1. The substances of the Temporary Appendix should be integrated in List 1 or List 2 not later than five years after adoption of the List of substances.
2. List 1 and List 2 will be updated in principle once a year in order to take into account newly evaluated substances, new submissions by industry or substances to be deleted.

2. INTRODUCTION

2.1. The lists contain monomers, chemical modifiers and polymerisation aids to be used in the manufacture of ion exchange and adsorbent resins to be used for food processing.

2.2. The lists include:

- Substances undergoing polymerisation, which includes polycondensation, polyaddition or any other similar process, to manufacture macromolecules;
- Natural or synthetic macromolecular substances to be used in the manufacture of modified macromolecules, if the monomers or the other starting substances required to synthesise them are not included in the lists;
- Substances to be used to provide a suitable medium in which polymerisation occurs;
- Substances to be used to modify existing natural or synthetic macromolecular substances;
- Substances which are incorporated into ion exchange and adsorbent resins in order to achieve a technical effect in the finished product.

2.3. The lists do not include the salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc of the listed acids, phenols or alcohols. These salts can, however, be used as well. Chemical names containing '... acid(s), salts' appear in the lists if the free acid(s) is (are) not listed separately. In such cases the meaning of the term 'salts' is 'salts of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc'.

2.4. Neither of the lists include the following substances although they may be present:

- Substances which could be present in the finished product as:
 - impurities of the substances used;
 - reaction intermediates;
 - decomposition products;
- Oligomers and natural or synthetic macromolecular substances as well as their mixtures, if the monomers or other starting substances required to synthesise them are included in the lists.

2.5. Monomers, chemical modifiers and polymerisation aids should be of good technical quality as regards the purity criteria.

3. ABBREVIATIONS

PM/REF No	:	the EU packaging material reference number of the substance
CAS No	:	the Chemical Abstracts Service Registry Number of the substance
NAME	:	the chemical name of the substance
SCF-L	:	the number of the list in which the substance is classified by the Scientific Committee for food / EFSA
RESTRICTIONS AND/OR SPECIFICATIONS	:	restrictions and/or specifications related to the substance
ADI/TDI	:	acceptable daily intake or tolerable daily intake as defined in the reports of the Scientific Committee for food / EFSA.

A number of abbreviations are used under RESTRICTIONS AND/OR SPECIFICATIONS and ADI/TDI, the meanings of which are as follows:

ACC	acceptable
DL	detection limit of the method of analysis
ND	not detectable
NS	not specified
SML	specific migration limit in food or in food simulants
SML(T)	specific migration limit in food or in food simulants expressed as total of moiety/substance(s) indicated

- (1) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 10690, 10780, 11470, 11710
- (2) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 20020, 21130, 21190
- (3) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 17260, 54880, 59280
- (4) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 13780, 20590
- (5) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 40320, 87040

LIST 1 - Substances approved for the use of materials and articles intended to come into contact with foodstuffs					
PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS	ADI/TDI mg/kg bw
		Monomers and other starting substances			
10780	000141-32-2	Acrylic acid, n-butyl ester	2	SML(T) = 6 mg/kg (1) (as acrylic acid)	0.1 (as acrylic acid)
11470	000140-88-5	Acrylic acid, ethyl ester	2	SML(T) = 6 mg/kg (1) (as acrylic acid)	0.1 (as acrylic acid)
11710	000096-33-3	Acrylic acid, methyl ester	2	SML(T) = 6 mg/kg (1) (as acrylic acid)	0.1 (as acrylic acid)
12100	000107-13-1	Acrylonitrile	4A	SML = ND (DL = 0.01 mg/kg)	
16690	001321-74-0	Divinylbenzene (containing up to 40% of ethylvinylbenzene)	4A	SML = ND (DL = 0.01 mg/kg) for the sum of divinylbenzene and ethylvinylbenzene	
16750	000106-89-8	Epichlorohydrin	4A	SML = ND (DL = 0.01 mg/kg)	
16950	000074-85-1	Ethylene	3		
17260	000050-00-0	Formaldehyde	3	SML(T) = 15 mg/kg (3)	
20020	000079-41-4	Methacrylic acid	2	SML(T) = 6 mg/kg (2)	0.1
20440	000097-90-5	Methacrylic acid, diester with ethyleneglycol	3	SML = 0.05 mg/kg	
20590	000106-91-2	Methacrylic acid, 2,3-epoxypropyl ester	4B	SML(T) = ND (DL = 0.01 mg/kg, expressed as epoxy group, Mw = 43) (4)	
21130	000080-62-6	Methacrylic acid, methyl ester	2	SML(T) = 6 mg/kg (2) (as methacrylic acid)	0.1 (as m. acid)
21190	000868-77-9	Methacrylic acid, monoester with ethyleneglycol	2	SML(T) = 6 mg/kg (2) (as methacrylic acid)	0.1 (as m. acid)
21550	000067-56-1	Methanol	3		
21640	000078-79-5	2-Methyl-1,3-butadiene	4A	SML = ND (DL = 0.01 mg/kg)	
24610	000100-42-5	Styrene	4B		
25120	000116-14-3	Tetrafluoroethylene	3	SML = 0.05 mg/kg	
25840	003290-92-4	1,1,1-Trimethylpropane trimethacrylate	3	SML = 0.05 mg/kg	
26360	007732-18-5	Water (in compliance with 98/83/EC)	0		

		Chemical modifiers				
10150	000108-24-7	Acetic anhydride		2		NS
30295	000067-64-1	Acetone		3		
36720	017194-00-2	Barium hydroxide		3	SML = 1 mg/kg (as Ba)	
40590	000071-36-3	1-Butanol		3		
40720	025013-16-5	tert-Butyl-4-hydroxyanisole (= BHA)		1	SML = 30 mg/kg	0.5
42500	-	Carbonic acid, salts		1		NS
14530	007782-50-5	Chlorine		3		
15250	000110-60-1	1,4-Diaminobutane		2		0.6
15790	000111-40-0	Diethylenetriamine		3	SML = 5 mg/kg	
49225	000124-40-3	Dimethylamine		3	SML = 0.06 mg/kg	
49235	000108-01-0	Dimethylaminoethanol		2	SML = 18 mg/kg	0.3
53540	000107-15-3	Ethylenediamine		2	SML = 12 mg/kg	0.2
17020	000075-21-8	Ethylene oxide		4A	SML = ND (DL = 0.01 mg/kg)	
54880	000050-00-0	Formaldehyde		3	SML(T) = 15 mg/kg (3)	
18460	000124-09-4	Hexamethylenediamine		2	SML = 2.4 mg/kg	0.04
59280	000100-97-0	Hexamethylenetetramine		3	SML(T) = 15 mg/kg (3) (as formaldehyde)	
59990	007647-01-0	Hydrochloric acid		1		NS
64300	001310-65-2	Lithium hydroxide		2	SML = 0.6 mg/kg (as Li)	0.01 (Li)
22333	000079-11-8	Monochloroacetic acid		3	SML = 0.05 mg/kg	
68140	007697-37-2	Nitric acid		2		3
72640	007664-38-2	Phosphoric acid		1		70
81600	001310-58-3	Potassium hydroxide		1		NS
81882	000067-63-0	2-Propanol		1		1.5
85980	-	Silicic acid, salts		2		NS
86240	007631-86-9	Silicon dioxide		1		NS
86720	001310-73-2	Sodium hydroxide		1		NS
86920	007632-00-0	Sodium nitrite		3	SML = 0.6 mg/kg	0.01
91920	007664-93-9	Sulphuric acid		1		NS

		Polymerisation aids			
10690	000079-10-7	Acrylic acid	2	SML(T) = 6 mg/kg (1)	0.1
34230	-	Alkyl(C8-C22)sulphonic acids	2	SML = 6 mg/kg	0.1
34281	-	Alkyl(C8-C22)sulphuric acids, linear, primary, with an even number of carbon atoms	3		
35600	001336-21-6	Ammonium hydroxide	1		NS
40320	010043-35-3	Boric acid	2	SML(T) = 6 mg/kg (as B) (5)	0.1 (B)
13780	002425-79-8	1,4-Butanediol bis(2,3-epoxypropyl) ether	4A	SML(T) = ND (DL = 0.01 mg/kg, expressed as epoxy group, Mw = 43) (4)	
41120	010043-52-4	Calcium chloride	1		NS
41280	001305-62-0	Calcium hydroxide	1		NS
42640	009000-11-7	Carboxymethylcellulose	2		NS
15910	000108-46-3	1,3-Dihydroxybenzene	2	SML = 2.4 mg/kg	0.04
48620	000123-31-9	1,4-Dihydroxybenzene	2	SML = 0.6 mg/kg	0.01
52800	000064-17-5	Ethanol	1		ACC
53600	000060-00-4	Ethylenediaminetetraacetic acid	2		2.5
55040	000064-18-6	Formic acid	1		3
55440	009000-70-8	Gelatin	0		
60560	009004-62-0	Hydroxyethylcellulose	2		NS
60880	009032-42-2	Hydroxyethylmethylcellulose	2		NS
63940	008062-15-5	Lignosulphonic acid	3	SML = 0.24 mg/kg	
64640	001309-42-8	Magnesium hydroxide	1		NS
19960	000108-31-6	Maleic anhydride	2	SML = 30 mg/kg (as maleic acid)	0.5 (as maleic acid)
65960	000067-56-1	Methanol	3		
66200	037206-01-2	Methylcarboxymethylcellulose	2		NS
66620	000075-09-2	Methylene chloride	3	SML = 0.05 mg/kg	
66655	000078-93-3	Methyl ethyl ketone	3	SML = 5 mg/kg	
66725	000108-10-1	Methyl isobutyl ketone	3	SML = 5 mg/kg	
78160	009004-96-0	Polyethyleneglycol monooleate	2		10
86960	007757-83-7	Sodium sulphite	1	SML = 10 mg/kg (as SO2)	0.7 (SO2)
87040	001330-43-4	Sodium tetraborate	2	SML(T) = 6 mg/kg (as B) (5)	0.1 (B)
91170	000108-30-5	Succinic anhydride	2		NS
93420	007646-78-8	Tin(IV) chloride	1		2
93540	000108-88-3	Toluene	3	SML = 1.2 mg/kg	

LIST 2 – Substances not approved for the use of materials intended to come into contact with food

PM/REF No	CAS No	NAME	SCF-L	RESTRICTIONS AND/OR SPECIFICATIONS	ADI/TDI mg/kg bw
		Monomers and other starting substances			
-	083729-54-8	4-Bromobutylstyrene	-	To be fixed	
-	030030-25-2	Chloromethylstyrene	-	To be fixed	
-	000764-99-8	Diethyleneglycol divinyl ether	-	To be fixed	
-	000109-87-5	Dimethoxymethane	-	To be fixed	
22585	003710-30-3	1,7-Octadiene	8	To be fixed	
25645	000682-09-7	1,1,1-Trimethylolpropane diallyl ether	6A	To be fixed	
-	002855-27-8	1,2,4-Trivinylcyclohexane	-	To be fixed	
26217	000100-43-6	4-Vinylpyridine	6A	To be fixed	
		Chemical modifiers			
-	055295-98-2	Ammonium chloride - dicyanodiamide - formaldehyde, copolymer	-	To be fixed	
-	000100-44-7	Benzyl chloride	-	To be fixed	
-	007726-95-6	Bromine	-	To be fixed	
-	000107-07-3	2-Chloroethanol	-	To be fixed	
-	000107-30-2	Chloromethyl methyl ether	-	To be fixed	
-	007790-94-5	Chlorosulphonic acid	-	To be fixed	
15295	000373-44-4	1,8-Diaminooctane	8	To be fixed	
15340	000109-76-2	1,3-Diaminopropane	8	To be fixed	
-	000107-06-2	1,2-Dichloroethane	-	To be fixed	
-	000078-87-5	1,2-Dichloropropane	-	To be fixed	
-	000109-89-7	Diethylamine	-	To be fixed	
-	003710-84-7	N,N-Diethylhydroxylamine	-	To be fixed	
-	006406-74-2	4-(Dimethylaminomethyl)aniline	-	To be fixed	
49380	000109-55-7	N,N-Dimethyl-1,3-diaminopropane	8	To be fixed	
-	000099-98-9	N,N-Dimethyl-1,4-phenylenediamine	-	To be fixed	
-	000074-87-3	Methyl chloride	-	To be fixed	
-	006284-40-8	N-Methylglucamine	-	To be fixed	

-	000098-95-3	Nitrobenzene		-	To be fixed
-	030525-89-4	Paraformaldehyde		-	To be fixed
74005	013598-36-2	Phosphorous acid		D	To be fixed
-	000085-41-6	Phthalimide		-	To be fixed
79680	026913-06-4 009002-98-6	Polyethyleneimine		W9	To be fixed
-	007758-09-0	Potassium nitrite		-	To be fixed
-	007446-11-9	Sulphur trioxide		-	To be fixed
-	053369-71-4	N,N,2,2-Tetramethyl-1,3-diaminopropane		-	To be fixed
93790	000102-82-9	Tributylamine		8	To be fixed
94270	000121-44-8	Triethylamine		8	To be fixed
25520	000112-24-3	Triethylenetetramine		8	To be fixed
-	000075-50-3	Trimethylamine		-	To be fixed
		Polymerisation aids			
-	009003-06-9	Acrylamide - acrylic acid, copolymer		-	To be fixed
-	068603-58-7	tert-Alkyl(C12-C14)amines, ethoxylated, propoxylated		-	To be fixed
-	000078-67-1	Azobisisobutyronitrile		-	To be fixed
38280	000106-51-4	Benzoquinone		8	To be fixed
40640	000098-29-3	4-tert-Butylcatechol		8	To be fixed
46440	000094-36-0	Dibenzoyl peroxide		8	To be fixed
49050	000108-83-8	Diisobutyl ketone		8	To be fixed
-	000105-74-8	Dilauroyl peroxide		-	To be fixed
-	001122-58-3	4-(Dimethylamino)pyridine		-	To be fixed
-	003016-19-1	2,6-Dimethyl-2,4,6-octatriene		-	To be fixed
-	000112-55-0	Dodecyl mercaptan		-	To be fixed
-	068441-63-4	Glyoxal - hydroxyethylmethylcellulose, reaction product		-	To be fixed
-	000111-31-9	Hexyl mercaptan		-	To be fixed
-	007722-84-1	Hydrogen peroxide		-	To be fixed
62110	007681-52-9	Hypochlorous acid, sodium salt		6A	To be fixed
-	000142-73-4	Iminobis(acetic acid)		-	To be fixed
62270	000078-83-1	Isobutanol		8	To be fixed
62405	031807-55-3	Isododecane		9	To be fixed
-	026635-64-3	Isooctane		-	To be fixed

66030	000150-76-5	4-Methoxyphenol		8	To be fixed
66600	026545-58-4	Methylenebis(naphthalenesulphonic acid), disodium salt		8	To be fixed
-	000061-73-4	Methylene Blue		-	To be fixed
66860	000108-11-2	4-Methyl-2-pentanol		8	To be fixed
-	007761-88-8	Nitric acid, silver salt		-	To be fixed
-	000079-21-0	Peracetic acid		-	To be fixed
-	000614-45-9	Perbenzoic acid, tert-butyl ester		-	To be fixed
-	015520-11-3	Percarbonic acid, bis(4-tert-butylcyclohexyl) ester		-	To be fixed
-	003006-82-4	Per(2-ethylhexanoic acid), tert-butyl ester		-	To be fixed
-	013467-82-8	Peroctanoic acid, tert-butyl ester		-	To be fixed
75600	000131-11-3	Phthalic acid, dimethyl ester		6B	To be fixed
-	026062-79-3	Poly(diallyldimethylammonium chloride)		-	To be fixed
78560	009002-93-1	Polyethyleneglycol octylphenyl ether		9	To be fixed
-	052624-57-4	Poly(ethylene propylene)glycol ether of 1,1,1-trimethylolpropane		-	To be fixed
-	009038-95-3	Poly(ethylene propylene)glycol monobutyl ether		-	To be fixed
81260	-	Polyvinyl acetate, partially hydrolysed		7	To be fixed
81280	009002-89-5	Polyvinyl alcohols		7	To be fixed
81500	009003-39-8	Polyvinylpyrrolidone		9	To be fixed
93585	000104-15-4	p-Toluenesulphonic acid		8	To be fixed
-	000540-84-1	2,2,4-Trimethylpentane		-	To be fixed