

# COUNCIL OF EUROPE

## COMMITTEE OF MINISTERS

(PARTIAL AGREEMENT IN THE SOCIAL AND PUBLIC HEALTH FIELD)

---

### RESOLUTION AP (89) 2

#### ON ION EXCHANGE RESINS USED IN FOOD PROCESSING

*(Adopted by the Committee of Ministers on 13 September 1989  
at the 428th meeting of the Ministers' Deputies)*

The Representatives on the Committee of Ministers of Belgium, France, the Federal Republic of Germany, Italy, Luxembourg, the Netherlands and the United Kingdom of Great Britain and Northern Ireland, these states being parties to the Partial Agreement in the social and public health field, and the Representatives of Austria, Denmark, Ireland, Norway, Spain, Sweden and Switzerland, states which have participated in the public health activities carried out within the above-mentioned Partial Agreement since 1 October 1974, 2 April 1968, 23 September 1969, 11 July 1979, 21 April 1988, 10 June 1975 and 5 May 1964 respectively,

Considering that the aim of the Council of Europe is to achieve a greater unity between its members and that this aim may be pursued by common action in the social and public health field;

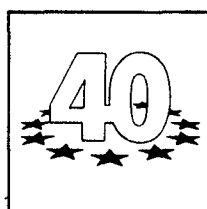
Having regard to the provisions of the Brussels Treaty, signed on 17 March 1948, by virtue of which Belgium, France, Luxembourg, the Netherlands and the United Kingdom of Great Britain and Northern Ireland declared themselves resolved to strengthen the social ties by which they were already united;

Having regard to the protocol modifying and completing the Brussels Treaty, signed on 23 October 1954 by the signatory states of the Brussels Treaty, on the one hand, and the Federal Republic of Germany and Italy, on the other hand;

Observing that the seven states parties to the Partial Agreement which have continued within the Council of Europe the social work hitherto undertaken by the Brussels Treaty Organisation and then by Western European Union, which derived from the Brussels Treaty as modified by the protocol mentioned in the fourth paragraph above, as well as Austria, Denmark, Ireland, Norway, Spain, Sweden and Switzerland, which participate in Partial Agreement activities in the field of public health, have always endeavoured to be in the forefront of progress in social matters and also in the associated field of public health, and have for many years undertaken action towards harmonisation of their legislation;

Having regard to the fact that ion exchange resins are used to process food;

Considering that ion exchange resins used to process food may, by reason of the migration of their components, pose under certain conditions a risk to human health;



Forty years  
Council of Europe

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,

Recommend that the governments of the states parties to the Partial Agreement as well as the governments of Austria, Denmark, Ireland, Norway, Spain, Sweden and Switzerland take into account in their national laws and regulations the principles set out in this resolution and the procedures for approving components in ion exchange resins used in food processing as well as the positive lists on ion exchange resin substances set out in the appendices to this resolution.

## Appendices to Resolution AP (89) 2

### Definition

Ion exchange resins are macromolecular compounds which can be used in the processing of food to bring about the exchange of either cations or anions. They do not include cellulosic ion exchangers or inorganic materials.

### Principles

#### 1. *Specifications*

Ion exchange resins used in food processing should meet the following conditions:

- 1.1. They should be manufactured in accordance with good manufacturing practice using substances listed in Appendix 2 or provisionally in Appendix 3 according to the conditions specified; the listing of a substance in a particular category does not preclude its use at another stage of the manufacturing process.
- 1.2. They should be made ready for use in accordance with the instructions of the manufacturer or the supplier.
- 1.3. They should not release any substance in quantities that pose a risk to human health or adversely affect the taste or odour of the food.
- 1.4. During use, interaction between the components of the resin and the foodstuffs should not lead to the formation in the processed food of new compounds which might be of toxicological concern (for example nitrosamines).
- 1.5. They should not release to any of the simulants referred to in item 1.9 below more than 1 mg/l of organic substances, calculated as total organic carbon (TOC), when subjected to the tests described in Appendix 4, item 1.
- 1.6. When the free base form of the resin is subjected to the test described in Appendix 4, item 2, and using the simulants referred to in item 1.9 below, they should not yield more than 7mg/l nitrogenous extract (calculated as N).
- 1.7. They should be of sufficient mechanical stability, such that no resin particles are released to the processed food.
- 1.8. They should be regenerated with substances permitted for use in the preparation of foodstuffs.
- 1.9. Where appropriate, migration tests should be conducted using distilled water (AFNOR method), 15% (v/v) aqueous ethanol and 5% (w/w) aqueous acetic acid (EEC method) as food simulants according to the procedure specified in Appendix 4, item 3.
- 1.10. The migration limits set out in the appendices should be met.
- 1.11. Using currently available methods of analysis, migrants can generally be detected at a level of 0.01 mg/l, and this should be taken as the limit of detection (n.d. = non-detectable). If more sensitive methods become available, the limit of detection (n.d.) should be reconsidered.
- 1.12. When applying for approval to use ion exchange resins, information should be provided on the practical use of the resin, for example ratio of the weight of resin to the weight of the processed food, use of disinfectants, mode of regeneration of the resin and technical efficacy of the regenerated resin. Tests that have been performed to check the regeneration of the resins should be specified.

If, in some cases, it is not clear which tests should be carried out, the applicants should contact the competent national authorities with a view to drawing up an appropriate research programme to evaluate the toxicity of the substance or material proposed for use in food processing.

The results should be presented so that an evaluation can be made ; if studies are mentioned that are already published, these should be submitted with the application. If some of the required information is not supplied, the reasons should be mentioned.

*6. Official authorisation for use*

Indicate the country(ies) where this authorisation is given and the references to regulations in those countries.

Appendix 1 to Resolution AP (89) 2

**Procedure for approving components  
in ion exchange resins used in food processing**

1. *Identity*

1.1. For a chemically defined compound, indicate :

1. the chemical name (and/or synonym, abbreviation, commercial name, etc.);
2. the molecular and structural formulae;
3. the composition, that is, degree of purity, qualitative and quantitative data concerning the principal impurities.

1.2. For the mixture containing at least two compounds, each one should be dealt with separately, as shown above in item 1.1. Their proportion in the mixture shall also be mentioned.

1.3. For a substance or material which cannot clearly be defined, indicate :

1. the compounds used to produce the substance or material ;
2. the production procedure, its controls and reproducibility ;
3. the method used to purify the substance or material ;
4. all the chemical products which might be formed during the preparation of the substance or material.

2. *Properties*

Indicate :

1. the physical properties (for example, physical state, melting-point, boiling-point, decomposition temperature, density and solubility in different solvents, particularly in the food simulants specified in item 1.9 of the principles set out above) ;
2. the chemical properties ;
3. information on every decomposition or transformation product of the substance or material liable to occur during manufacture of the resin, as well as the principal decomposition or transformation products which might be present in the resin.

3. *Use*

Indicate :

1. the type of resin in which the substance or material is going to be used ;
2. the role that the substance or material is to play in the resin ;
3. justification (technical, economic, etc.) for the use of the substance or material ;
4. the maximum percentage of the substance or material to be incorporated in the resin ;
5. the foodstuffs to be processed by the resin in which the substance or material has been incorporated ;
6. the mode of action of the resin.

4. *Data on migration*

Supply :

1. a description of any method(s) used to determine the migration of specific components of the resin and, if necessary, of its decomposition or transformation products that differ from those specified in Appendix 4. The reproducibility and the detection limits of any such method(s) should be indicated ;
2. all results obtained in the tests referred to in Appendix 4 and, if appropriate, on the determination of the decomposition or transformation products.

5. *Toxicological data*

When applying for authorisation to use a component in the manufacture of an ion exchange resin, toxicological data should be supplied as indicated in Chapter 3 of the Council of Europe's publication *Substances used in plastics materials coming into contact with food* (2nd edition, Strasbourg, 1982, p. 69 onwards). If the substance is already listed in section I or II of that publication and it has already been evaluated, data need not be provided again, except if new additional toxicological data have become available.

If, in some cases, it is not clear which tests should be carried out, the applicants should contact the competent national authorities with a view to drawing up an appropriate research programme to evaluate the toxicity of the substance or material proposed for use in food processing.

The results should be presented so that an evaluation can be made ; if studies are mentioned that are already published, these should be submitted with the application. If some of the required information is not supplied, the reasons should be mentioned.

6. *Official authorisation for use*

Indicate the country(ies) where this authorisation is given and the references to regulations in those countries.

## Appendix 2 to Resolution AP (89) 2

### Substances which can be used in the manufacture of ion exchange resins used for food processing\*

#### I. Monomers and other starting substances

<i>Name</i>	<i>CAS No.</i>	<i>Limit</i>
acetone	67-64-1	
acrylic acid	79-10-7	
acrylic acid, alkyl (C1-C4) esters	—	
acrylonitrile	107-13-1	n.d.
divinylbenzene	1321-74-0	n.d.
divinylether of diethyleneglycol	764-99-8	
epichlorohydrin	106-89-8	n.d.
formaldehyde	50-00-0	5
maleic acid	110-16-7	
maleic anhydride	108-31-6	
methacrylic acid	79-41-4	
methacrylic acid, alkyl (C1-C4) esters	—	
paraformaldehyde	30525-89-4	5 (as formaldehyde)
phenol	108-95-2	
styrene	100-42-5	
trimethylolpropane trimethacrylate	3290-92-4	

#### II. Chemical modifiers

acetic acid	64-19-7	
acetic anhydride	108-24-7	
chloromethyl methyl ether	107-30-2	n.d.
chlorosulphonic acid	7790-94-5	
dimethylamine	124-40-3	n.d.
2-dimethylaminoethanol (N,N-dimethylethanolamine)	108-01-0	n.d.
dimethylaminopropylamine (N,N-dimethyl-1,3-propanediamine)	109-55-7	n.d.
ethylenediamine	107-15-3	n.d.
hexamethylenetetramine	100-97-0	5 (as formaldehyde)
methyl chloride	74-87-3	n.d.
methylene chloride	75-09-2	n.d.
methyl iodide	74-88-4	n.d.
monochloroacetic acid	79-11-8	n.d.
phosphoric acid	7664-38-2	
phosphorous acid	13598-36-2	
phosphorous trichloride	7719-12-2	
phthalic anhydride	85-44-9	
polyoxymethylene	—	5 (as formaldehyde)
sulphur monochloride	10025-67-9	n.d.

\* Polymers, copolymers and condensation products prepared from monomers and other starting substances included in the Council of Europe list of monomers and other starting substances for ion exchange resins do not appear in the Council of Europe list of chemical modifiers and polymerisation aids for ion exchange resins. However, these polymers, copolymers and condensation products are automatically authorised as chemical modifiers or polymerisation aids for ion exchange resins. All restrictions specified for the monomers and other starting substances shall apply.

<i>Name</i>	<i>CAS No.</i>	<i>Limit</i>
sulphur trioxide	7446-11-9	
sulphuric acid	7664-93-9	
thionyl chloride	7719-09-7	
triethylamine	121-44-8	n.d.
trimethylamine	75-50-3	n.d.
 <i>III. Polymerisation aids</i>		
alkaline salts ; the following :		
(sodium, potassium, ammonium)		
borates		
carbonates and bicarbonates		
chlorides		
nitrites		
persulphates		
phosphates		
silicates		
sulphates		
sulphites		
aluminium chloride	7446-70-0	
ammonium hydroxide	1336-21-6	
amyl alcohol	71-41-0	
arabic gum	9000-01-5	
azobisisobutyronitrile	78-67-1	n.d.
barium sulphate (soluble barium free)	7727-43-7	
bentonite	1302-78-9	
di-(4-tert.butyl-cyclohexyl) peroxydicarbonate	15520-11-3	n.d.
boric acid	10043-35-3	
butanols		
calcium chloride	10043-52-4	
calcium hydroxide	1305-62-0	
calcium phosphate	12167-74-7	
camphor	21368-68-3	
carbon dioxide	124-38-9	
carboxymethylcellulose	9004-32-4	
cobalt naphthenate	—	
cyclohexanol	108-93-0	
dibenzoyl peroxide	94-36-0	n.d.
dibutyl peroxydicarbonate	16215-49-9	n.d.
dicetyl peroxydicarbonate	26322-14-5	n.d.
1,2-dichloroethane	107-06-2	n.d.
1,2-dichloropropane	78-87-5	n.d.
dicyclohexyl peroxydicarbonate	1561-49-5	n.d.
di(2-ethylhexyl) peroxydicarbonate	16111-62-9	n.d.
di-isobutyl ketone	108-83-8	
di-isononanoyl peroxide	58499-37-9	n.d.
dilauroyl peroxide	105-74-8	n.d.
dimethoxymethane	109-87-5	
ethanol	64-17-5	
ethylenediaminetetraacetic acid, sodium salt	139-33-3	
formic acid	64-18-6	
gelatin	9000-70-8	
heptane	142-82-5	
hexane	110-54-3	
hydrochloric acid	7647-01-0	

<i>Name</i>	<i>CAS No.</i>	<i>Limit</i>
hydrogen peroxide	7722-84-1	n.d.
hydroxyethylcellulose	9004-62-0	
hydroxyethylmethylcellulose	9032-42-2	
hydroxypropylmethylcellulose	9004-65-3	
iron (III) chloride	7705-08-0	
isooctane	540-84-1	
isopropanol	67-63-0	
lignosulfonic acid, sodium salt	8061-51-6	
limonene	138-86-3	
magnesium hydroxide	1309-42-8	
methanol	67-56-1	
methylamyl alcohol	543-49-7	
methylcarboxymethylcellulose	9088-05-5	
methylcellulose	9004-67-5	
methylisobutyl ketone	108-10-1	
mineral oil	8012-95-1	
(food grade: free of polycyclic aromatic hydrocarbons)		
n-octane	111-65-9	
p-tert.octylphenoxy-(ethoxy) n ethanol (n between 3 and 10) may contain nonylated derivative	—	
polyacrylamide	9003-05-8	n.d. (as acrylamide)
polydimethylsiloxane	9016-00-6	
poly(ethylene-propylene)oxide	9003-11-6	
polyoxyethylene	25322-68-3	
polyvinylacetate (partially hydrolysed)	9003-20-7	
polyvinyl alcohol	9002-89-5	
polyvinylpyrrolidone	9003-39-8	
potassium bromide	7758-02-3	10 (Br)
potassium hydroxide	1310-58-3	
propanol	71-23-8	
phthalic anhydride	85-44-9	
silicates (natural)	—	
sodium bromide	7647-15-6	10 (Br)
sodium hydroxide	1310-73-2	
sodium hypochlorite	7681-52-9	
sodium lauryl sulphate	151-21-3	
sulphur	7704-34-9	
terpinolene	586-62-9	
tin (IV) chloride	7646-78-8	
toluene	108-88-3	
xanthan gum	11138-66-2	
xylenes	1330-20-7	
zinc chloride	7646-85-7	



Appendix 3 to Resolution AP (89) 2

Part 1

Substances which can provisionally be used in the manufacture  
of ion exchange resins used for food processing  
for a period of three years  
during which complementary studies should be carried out

I. Monomers and other starting substances

<i>Name</i>	<i>CAS No.</i>	<i>Limit</i>
bicyclo(2.2.1)-hept-2-ene*	498-66-8	
p-(chloromethyl)styrene**	1592-20-7	
cyclododecatriene**	27070-59-3	
cyclododecene**	1501-82-2	
cyclohexadiene**	29797-09-9	
cyclooctadiene**	111-78-4	
decadiene**	1647-16-1	
dicyclopentadiene*	77-73-6	
ethyleneglycol dimethacrylate*	97-90-5	
ethylvinyl benzene**	28106-30-1	
glycidyl methacrylate*	106-91-2	n.d.
methacrylamide*	79-39-0	n.d.
methacrylic acid, 2-(dimethylamino)ethyl ester*	2867-47-2	
2-methyl-1,3-butadiene*	78-79-5	
methylcyclopentadiene**	26519-91-5	
$\alpha$ -methylstyrene*	98-83-9	
pentaerythritol tetraacrylate**	4986-89-4	
pentaerythritol tetramethacrylate**	3253-41-6	
phenylacetylene**	536-74-3	
trimethylolpropane diallyl ether**	682-09-7	
trivinylcyclohexane**	2855-27-8	
vinylpyrrolidone*	88-12-0	
vinylquinoline**	772-03-2	
vinyltoluene*	25013-15-4	
p-vinyltoluene*	622-97-9	

II. Chemical modifiers

diethylaminoethylamine**	100-36-7	n.d.
diethylaminopropylamine**	104-78-9	n.d.
diethylenetriamine*	111-40-0	n.d.
dimethylaminoethylamine**	108-00-9	n.d.
1-hydroxy-2-chloro-ethane**	107-07-3	
hydroxylamine**	7803-49-8	n.d.
monomethylaminoethanol**	109-83-1	
phthalic acid*	88-99-0	
phthalimide**	85-41-6	

\* In the first instance, evidence that this substance is used in the manufacture of ion exchange resins and accompanying migration data (item 3.4) are required. In the light of these data, the committee of experts will decide whether the toxicological data requested by the EEC Scientific Committee for Food (17th series of reports, 1987) need to be provided before this substance can be recommended for use in the manufacture of ion exchange resins.

\*\* In the first instance, evidence that this substance is used in the manufacture of ion exchange resins and accompanying migration data (item 3.4) are required. In the light of these data, the committee of experts will decide on the need for toxicity studies.

<i>Name</i>	<i>CAS No.</i>	<i>Limit</i>
tetraethylenepentamine**	112-57-2	n.d.
thiourea**	62-56-6	n.d.
triethylenetetramine**	112-24-3	n.d.
 <i>III. Polymerisation aids</i>		
benzyl chloride**	100-44-7	
tert.butyl perbenzoate**	614-45-9	n.d.
tert.butyl perisobutyrate**	109-13-7	n.d.
tert.butyl permeodecanoate**	26748-41-4	n.d.
tert.butyl peroctoate**	13467-82-8	n.d.
tert.butyl perpivalate**	927-07-1	n.d.
di-tert.butyl peroxide**	110-05-4	n.d.
diester of polybutenyl succinic acid and N-(hydroxyethyl)-2-morpholinone**	—	
poly (diallyldimethyl) ammonium chloride**	26062-79-3	
polymethoxysiloxane**		
sodium dichromate**	10588-01-9	0.05 (as chromium VI)

## Part 2

Substances on which insufficient information is available  
and which are not recommended for use in ion exchange resins\*

### I. Monomers and other starting substances

<i>Name</i>	<i>CAS No.</i>	<i>Limit</i>
acrylic acid, alkylaminoethyl esters		
acrylic acid, alkyl (C9-C14) esters		
bromostyrene		
butyleneglycoldiacrylate		
butyleneglycoldimethacrylate		
chlorostyrene		
dimethylaminopropylacrylamide		
2,6-dimethyloctatriene		
divinylcyclohexane		
divinyltoluene		
hexadiene		
hydroxyalkylacrylamide		
hydroxyalkylmethacrylamide		
methacrylic acid, alkyl (C5-C6) esters		
methylene-bis(methacrylamide)		
mono-, di-, methyl- and ethylvinylpyridine		
octadiene		
pentaerythritol trimethacrylate		
terpene		

\* The CAS number or other means of specification and the exact function of the substances must be known as a first step to enable the committee of experts to decide what type of toxicological and/or technological information is required for their proper evaluation.

<i>Name</i>	<i>CAS No.</i>	<i>Limit</i>
trimethylolbutane trimethacrylate		
vinylbenzylchloride		
vinyl naphthalene		
 <i>II. Chemical modifiers</i>		
dimethylaminopropylmethylamine		
maleic acid amide		
monoethyldiethanolamine		
N,N-tetramethyldiethanolamine		
 <i>III. Polymerisation aids</i>		
aliphatic hydrocarbons (C10-C14)		
tert.alkyl (C12-C14) amine		
alkyl (C8-C10) benzylchloride		
N-[3-(hydroxyethyl)dimethylammonium]propyl- stearamide		
lauryldimethylbenzylammoniumbromide		
condensation product of naphthalene		
sulfonic acid with formaldehyde		
poly-di-(isobutylenemaleic anhydride)		

**Test methods**

*1. Determination of the loss of organic matter*

As specified in item 1.5 of the principles set out above, the total organic extract obtained with each of the simulants — distilled water (AFNOR method), 15% (v/v) aqueous ethanol and 5% (w/w) aqueous acetic acid (EEC method) — should not exceed 1 mg/l. If foods do not correspond to the above simulants, for example because of high acid or alcohol content, the simulants should be modified accordingly.

The ion exchange resin is tested as specified in the annex of EEC Commission Regulation No. 2394/84 of 20 August 1984 and/or in AFNOR Pr T 90601 (for water).

The tests on migration of non-volatile substances should be completed by tests on volatile substances when the latter are of interest in the industry concerned.

*2. Determination of the loss of nitrogenous matter*

As specified in item 1.6 of the resolution, the total nitrogenous extract obtained with each of the simulants (distilled water, 15% (v/v) aqueous ethanol and 5% (w/w) aqueous acetic acid) should not exceed 7 mg/l. If foods do not correspond to the above simulants, for example because of high acid or alcohol content, the simulants should be modified accordingly.

Add to each of three columns 100 ml of the ion exchange resin to be tested, having been washed and treated in accordance with the manufacturer's directions for preparing them for use with food.

Block the outlet of each column and fill with the three different simulants at ambient temperature, until the simulant level reaches the top of the column. Seal each column and leave in a vertical position at ambient temperature for ninety-six hours. Remove the simulants and assay each for nitrogen, against a blank, by the Kjeldahl method.

*3. Determination of specific migrants*

Determine specific migrants in each of the three simulants (distilled water, 15% (v/v) aqueous ethanol and 5% (w/w) aqueous acetic acid). Prepare two-litre samples of the eluant as described in EEC Commission Regulation No. 2394/84 and/or in AFNOR Pr T 90601 (for water).