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



### **CONSUMER HEALTH PROTECTION 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 3 - 28.01.2009

### 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 3)

The documents are available on the Internet website of the Partial Agreement 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 1<sup>st</sup> December 2004 at the 907<sup>th</sup> 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. 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".

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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 3 – 28.01.2009

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

### **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/EFSA, 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 experts 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/EFSA 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 used in the manufacture of ion exchange and adsorbent resins used in food processing.
- 2.2. The lists include:
- List 1 of substances used in the manufacture of ion exchange and adsorbent resins: list of substances assessed and approved by Partial Agreement member states
- List 2 of substances used in the manufacture of ion exchange and adsorbent resins: list of substances not yet assessed and not yet approved by Partial Agreement member states
- 2.3. The following substances are not included even if they are intentionally used and are authorised:
- (a) salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium and sodium of authorised acids, phenols or alcohols. However, names containing "... acid(s), salts" appear in the lists, if the corresponding free acid(s) is (are) not mentioned;
- (b) salts (including double salts and acid salts) of zinc of authorised acids, phenols or alcohols. For these salts a Group SML = 25 mg/kg (expressed as Zn) apply. The same restriction for Zn applies to substances whose name contains "... acid(s), salts" which appear in the lists, if the corresponding free acid(s) is (are) not mentioned.
- 2.4. The lists also do not include the following substances, although they may be present:
- (a) Substances which could be present in the finished product as:
  - impurities in the substances used;
  - reaction intermediates:
  - decomposition products.
- (b) Oligomers and natural or synthetic macromolecular substances as well as their mixtures, if the monomers or starting substances required to synthesise them are included in the lists.
- (c) Mixtures of the authorised substances
- 2.5. Monomers, chemical modifiers and polymerisation aids shall 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 SCF/ 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

FP finished product

FCC Food Chemicals Codex

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

QM maximum permitted quantity of the residual substance in the material

QM(T) maximum permitted quantity of the residual substance in the material expressed

as total of moiety or substance(s) indicated

### 4. NOTES RELATED TO THE COLUMN "RESTRICTIONS AND/OR SPECIFICATIONS"

| (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, 20110, 20890, 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: 40320, 87040                      |
| (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: 47680, 53650                      |
| (6)  | 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: 18640, 25240                      |
| (7)  | 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: 86960, 87120                      |
| (8)  | Polydimethylsiloxane (Mw > 6 800)<br>Minimum viscosity 100 x 10 <sup>-6</sup> m <sup>2</sup> /s (= 100 centistokes) at 25°C  |
| (9)  | Polyvinylpyrrolidone The substance shall meet the purity criteria established in Directive 96/77/EC  |
| (10) | Triallylamine 40 mg/kg hydrogel at a ration of 1 kg food to a maximum of 1.5 gram of hydrogel. For use only in hydrogels intended for non-direct food contact use.                               |
| (11) | Polyvinyl alcohol Weight average molecular weight should not be less than 25000 Da.  |

### LIST 1 OF SUBSTANCES USED IN THE MANUFACTURE OF ION EXCHANGE AND ADSORBENT RESINS

| PM/REF No | CAS No      | NAME   | SCF-L | RESTRICTIONS AND/OR<br>SPECIFICATIONS   | ADI/TDI<br>mg/kg bw         |
|-----------|-------------|--|-------|---|-----------------------------|
|           |             | Monomers and other starting substances                     |       |   |                             |
| 10120     | 000108-05-4 | Acetic acid, vinyl ester                                   | 2     | SML = 12 mg/kg  | 0.2                         |
| 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)<br>(as acrylic acid)   | 0.1 (as<br>acrylic<br>acid) |
| 11710     | 000096-33-3 | Acrylic acid, methyl ester                                 | 2     | SML(T) = 6 mg/kg (1)<br>(as acrylic acid)   | 0.1 (as acrylic acid)       |
| 12100     | 000107-13-1 | Acrylonitrile  | 4A    | SML = ND (DL = 0.02 mg/kg, analytical tolerance included)   |                             |
| 14508     | 009004-36-8 | Cellulose acetate butyrate                                 | 3     |   |                             |
| -         | 000107-06-2 | 1,2-Dichloroethane   | -     | In compliance with the FCC specifications   |                             |
| 16690     | 001321-74-0 | Divinylbenzene (containing up to 45% of ethylvinylbenzene) | 4A    | SML = ND (DL = 0.02 mg/kg, analytical tolerance included, for the sum of divinylbenzene and ethylvinylbenzene |                             |
| 16750     | 000106-89-8 | Epichlorohydrin  | 4A    | QM = 1 mg/kg in FP  |                             |
| 16950     | 000074-85-1 | Ethylene   | 3     |   |                             |
| 17260     | 000050-00-0 | Formaldehyde   | 3     | SML(T) = 15  mg/kg  (3)   |                             |
| 18640     | 000822-06-0 | Hexamethylene diisocyanate                                 | 4A    | QM(T) = 1 mg/kg (6)<br>(as NCO)   |                             |
| 19990     | 000079-39-0 | Methacrylamide   | 4A    | SML = ND (DL = 0.02 mg/kg, analytical tolerance included)   |                             |
| 20020     | 000079-41-4 | Methacrylic acid   | 2     | SML(T) = 6 mg/kg (2)  | 0.1                         |
| 20110     | 000097-88-1 | Methacryclic acid, butyl ester                             | 2     | SML(T) = 6 mg/kg (2) (as methacrylic acid)  | 0.1 (as<br>m. acid)         |
| 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    | QM = 1 mg/kg in FP  |                             |

| PM/REF No | CAS No      | NAME  | SCF-L | RESTRICTIONS AND/OR<br>SPECIFICATIONS   | ADI/TDI<br>mg/kg<br>bw |
|-----------|-------------|---|-------|---|------------------------|
| 20890     | 000097-63-2 | Methacrylic acid, ethyl ester                   | 2     | SML(T) = 6 mg/kg (2) (as methacrylic acid)  | 0.1 (as<br>m. acid)    |
| 21130     | 000080-62-6 | Methacrylic acid, methyl ester                  | 2     | SML(T) = 6 mg/kg (2)<br>(as methacrylic acid)   | 0.1 (as<br>m. acid)    |
| 21190     | 000868-77-9 | Methacrylic acid, monoester with ethyleneglycol | 2     | SML(T) = 6 mg/kg (2)<br>(as methacrylic acid)   | 0.1 (as<br>m. acid)    |
| 21550     | 000067-56-1 | Methanol  | 3     |   |                        |
| 21640     | 000078-79-5 | 2-Methyl-1,3-butadiene                          | 4A    | QM = 1 mg/kg in FP or<br>SML = ND (DL = 0.02 mg/kg,<br>analytical tolerance included) |                        |
| 22333     | 000079-11-8 | Monochloroacetic acid                           | 3     | SML = 0.05 mg/kg  |                        |
| 22555     | 000112-92-5 | 1-Octadecanol                                   | 3     |   |                        |
| 22960     | 000108-95-2 | Phenol  | 2     |   | 1.5                    |
| 87120     | 007772-98-7 | Sodium thiosulphate                             | 1     | SML(T) = 10 mg/kg (7)<br>(as SO2)   | 0.7<br>(SO2)           |
| 24610     | 000100-42-5 | Styrene   | 4B    |   |                        |
| 25120     | 000116-14-3 | Tetrafluoroethylene                             | 3     | SML = 0.05 mg/kg  |                        |
| 25240     | 000091-08-7 | 2,6-Toluene diisocyanate                        | 4A    | QM(T) = 1 mg/kg (6)<br>(as NCO)   |                        |
| 25840     | 003290-92-4 | 1,1,1-Trimethylolpropane 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                     |
| 12763     | 000141-43-5 | 2-Aminoethanol                                  | 3     | SML = 0.05 mg/kg  |                        |
| 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                    |
| -         | 000107-06-2 | 1,2-Dichloroethane                              | -     | In compliance with the FCC specifications   |                        |
| 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                    |

| PM/REF No | CAS No      | NAME                     | SCF-L | RESTRICTIONS AND/OR<br>SPECIFICATIONS                       | ADI/TDI<br>mg/kg<br>bw |
|-----------|-------------|--------------------------|-------|---|------------------------|
| 53255     | 000100-41-1 | Ethylbenzene             | 3     | SML = 0.6 mg/kg   | 0.1                    |
| 53540     | 000107-15-3 | Ethylenediamine          | 2     | SML = 12 mg/kg  | 0.2                    |
| 17020     | 000075-21-8 | Ethylene oxide           | 4A    | QM = 1 mg/kg in FP  |                        |
| 54880     | 000050-00-0 | Formaldehyde             | 3     | SML(T) = 15 mg/kg (3)                                       |                        |
| 55630     | 000526-95-4 | Gluconic acid            | W     | In compliance with the specifications of food additive E574 |                        |
| 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)<br>(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)              |
| 65040     | 000141-82-2 | Malonic acid             | 3     |   |                        |
| 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                     |
| -         | 007758-09-0 | Potassium nitrite        | -     | In compliance with the FCC specifications                   |                        |
| 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                     |
| 25385     | 000102-70-5 | Triallylamine            | 3     | (10)  |                        |
|           |             | Polymerisation aids      |       |   |                        |
| 30000     | 000064-19-7 | Acetic acid              | 1     |   | NS                     |
| 30045     | 000123-86-4 | Acetic acid, butyl ester | 1     |   | 6                      |
| 30140     | 000141-78-6 | Acetic acid, ethyl ester | 1     |   | NS                     |

| PM/REF No | CAS No      | NAME   | SCF-L | RESTRICTIONS AND/OR SPECIFICATIONS                           | ADI/TDI<br>mg/kg<br>bw |
|-----------|-------------|--|-------|--|------------------------|
| 30610     | -           | Acids, C2-C24, aliphatic, linear, monocarboxylic, from natural oils and fats, and their mono-, di- and triglycerol esters (branched fatty acids at naturally occuring levels are included) | 3     |  |                        |
| 30612     | -           | Acids, C2-C24, aliphatic, linear, monocarboxylic, synthetic, and their mono-, di-<br>and triglycerol esters  | 3     |  |                        |
| 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) (4)                                 | 0.1 (B)                |
| 13780     | 002425-79-8 | 1,4-Butanediol bis(2,3-epoxypropyl) ether  | 4A    | QM = 1 mg/kg in FP<br>(expressed as epoxy group,<br>Mw = 43) |                        |
| 41120     | 010043-52-4 | Calcium chloride   | 1     | ,  | NS                     |
| 41280     | 001305-62-0 | Calcium hydroxide  | 1     |  | NS                     |
| 42500     | -           | Carbonic acid, salts   | 1     |  | NS                     |
| 42640     | 009000-11-7 | Carboxymethylcellulose   | 2     |  | NS                     |
| -         | 009000-07-1 | Carrageenan  | -     | In compliance with the specifications of E407                |                        |
| 46440     | 000094-36-0 | Dibenzoyl peroxide   | 8     | In compliance with the FCC specifications                    |                        |
| 47680     | 000111-46-6 | Diethyleneglycol   | 2     | SML(T) = 30 mg/kg (5)  | 0.5                    |
| 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                    |
| 53280     | 009004-57-3 | Ethylcellulose   | 2     |  | NS                     |
| 53520     | 000110-30-5 | N,N'-Ethylenebisstearamide   | 3     |  |                        |
| 53600     | 000060-00-4 | Ethylenediaminetetraacetic acid  | 2     |  | 2.5                    |
| 53650     | 000107-21-1 | Ethyleneglycol   | 2     | SML(T) = 30 mg/kg (5)  | 0.5                    |
| 55040     | 000064-18-6 | Formic acid  | 1     |  | 3                      |

| PM/REF No | CAS No                     | NAME   | SCF-L | RESTRICTIONS AND/OR<br>SPECIFICATIONS     | ADI/TDI<br>mg/kg<br>bw     |
|-----------|----------------------------|--|-------|---|----------------------------|
| 55440     | 009000-70-8                | Gelatin  | 0     |   |                            |
| -         | 007722-84-1                | Hydrogen peroxide  | -     | In compliance with the FCC specifications |                            |
| 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                         |
| 64720     | 001309-48-4                | Magnesium oxide  | 1     |   | NS                         |
| 19960     | 000108-31-6                | Maleic anhydride   | 2     | SML = 30 mg/kg<br>(as maleic acid)        | 0.5 (as<br>maleic<br>acid) |
| 65960     | 000067-56-1                | Methanol   | 3     |   |                            |
| 66200     | 037206-01-2                | Methylcarboxymethylcellulose   | 2     |   | NS                         |
| 66240     | 009004-67-5                | Methylcellulose  | 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                             |                            |
| 66700     | 009004-65-3                | Methylhydroxypropylcellulose   | 2     |   | NS                         |
| 66725     | 000108-10-1                | Methyl isobutyl ketone   | 3     | SML = 5 mg/kg                             |                            |
| 69040     | 000112-80-1                | Oleic acid   | 1     |   | NS                         |
| 72060     | 008009-03-8                | Petrolatum   | D     | In compliance with the FCC specifications |                            |
| 72640     | 007664-38-2                | Phosphoric acid  | 1     |   | 70                         |
| 23470     | 000080-56-8                | alpha-Pinene   | 3     |   |                            |
| 76721     | 009016-00-6<br>063148-62-9 | Polydimethylsiloxane (MW > 6800)   | 2     | (8)                                       | 1.5                        |
| 77708     | -                          | Polyethyleneglycol (EO = 1-50) ethers of linear and branched primary C8-C22 alcohols | 2     | SML = 1.8 mg/kg                           | 0.03                       |
| 78160     | 009004-96-0                | Polyethyleneglycol monooleate  | 2     |   | 10                         |
| 79920     | 009003-11-6<br>106392-12-5 | Poly(ethylene propylene)glycol   | 3     |   |                            |
| 80720     | 008017-16-1                | Polyphosphoric acids   | 1     |   | 70 (P)                     |
| 81280     | 009002-89-5                | Polyvinyl alcohol  | 3     | (11)                                      | ` ′                        |
| 81500     | 009003-39-8                | Polyvinylpyrrolidone   | 3     | (9)                                       |                            |
| 81680     | 007681-11-0                | Potassium iodide   | 1     | SML = 1 mg/kg (as I)                      | 0.017 (I)                  |
| 81840     | 000057-55-6                | 1,2-Propanediol  | 1     |   | 25                         |
| 81882     | 000067-63-0                | 2-Propanol   | 1     |   | 1.5                        |

| 83580/1 | 008002-13-9 | Rapeseed oil       | 3 |                                   |              |
|---------|-------------|--------------------|---|-----------------------------------|--------------|
| 86240   | 007631-86-9 | Silicon dioxide    | 1 |                                   | NS           |
| 86960   | 007757-83-7 | Sodium sulphite    | 1 | SML(T) = 10 mg/kg (7)<br>(as SO2) | 0.7<br>(SO2) |
| 87040   | 001330-43-4 | Sodium tetraborate | 2 | SML(T) = 6  mg/kg (as B) (4)      | 0.1 (B)      |
| 91170   | 000108-30-5 | Succinic anhydride | 2 |                                   | NS           |
| 24880   | 000057-50-1 | Sucrose            | 0 |                                   |              |
| 93420   | 007646-78-8 | Tin(IV) chloride   | 1 |                                   | 2            |
| 93540   | 000108-88-3 | Toluene            | 3 | SML = 1.2 mg/kg                   |              |

### LIST 2 OF SUBSTANCES USED IN THE MANUFACTURE OF ION EXCHANGE AND ADSORBENT RESINS

| PM/REF No | CAS No      | NAME   | SCF-L | RESTRICTIONS AND/OR SPECIFICATIONS | ADI/TDI<br>mg/kg bw |
|-----------|-------------|--|-------|------------------------------------|---------------------|
|           |             | Monomers and other starting substances                       |       |                                    |                     |
| -         | 009012-36-6 | Agarose  | -     | To be fixed                        |                     |
| 12640     | 000106-92-3 | Allyl 2,3-epoxypropyl ether                                  | 6A    | To be fixed                        |                     |
| -         | 004419-11-8 | 2,2'-Azobis(2,4-dimethylpentanenitrile)                      | -     | To be fixed                        |                     |
| -         | 083729-54-8 | 4-Bromobutylstyrene  | -     | To be fixed                        |                     |
| -         | 003891-33-6 | 1,4-Butanediol divinyl ether                                 | -     | To be fixed                        |                     |
| _         | 030030-25-2 | Chloromethylstyrene  | -     | To be fixed                        |                     |
| 14905     | 000108-93-0 | Cyclohexanol   | 8     | To be fixed                        |                     |
| -         | 000764-99-8 | Diethyleneglycol divinyl ether                               | -     | To be fixed                        |                     |
| -         | 000109-87-5 | Dimethoxymethane   | -     | To be fixed                        |                     |
| 16420     | 000123-91-1 | Dioxane  | 6A    | To be fixed                        |                     |
| -         | 013159-52-9 | Methacrylic acid, 3-chloro-2-hydroxypropyl ester             | -     | To be fixed                        |                     |
| 20500     | 000105-16-8 | Methacrylic acid, 2-(diethylamino)ethyl ester                | 8     | To be fixed                        |                     |
| 20560     | 000142-90-5 | Methacrylic acid, dodecyl ester                              | 7     | To be fixed                        |                     |
| 21220     | 032360-05-7 | Methacrylic acid, octadecyl ester                            | 7     | To be fixed                        |                     |
| 21580     | 003644-11-9 | N-(Methoxymethyl)acrylamide                                  | 6A    | To be fixed                        |                     |
| 21610     | 003644-12-0 | N-(Methoxymethyl)methacrylamide                              | 6A    | To be fixed                        |                     |
| -         | 002359-15-1 | Methylenebismethacrylamide                                   | -     | To be fixed                        |                     |
| 22585     | 003710-30-3 | 1,7-Octadiene  | 8     | To be fixed                        |                     |
| 25405     | 001025-15-6 | Triallyl isocyanurate  | 6A    | 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   |       |                                    |                     |
| <u>-</u>  | 068609-96-1 | Alkyl(C8-C10) 2,3-epoxypropyl ether                          | -     | To be fixed                        |                     |
| 12772     | 000140-31-8 | N-Aminoethylpiperazine                                       | 8     | To be fixed                        |                     |
| -         | 000156-87-6 | 3-Aminopropanol  | -     | To be fixed                        |                     |
| -         | 000107-11-9 | 3-Aminopropene   | -     | To be fixed                        |                     |
| -         | 055295-98-2 | Ammonium chloride - dicyanodiamide - formaldehyde, copolymer | _     | To be fixed                        |                     |

| PM/REF No | CAS No      | NAME   | SCF-L | RESTRICTIONS AND/OR SPECIFICATIONS | ADI/TDI<br>mg/kg bw |
|-----------|-------------|--|-------|------------------------------------|---------------------|
| -         | 000100-44-7 | Benzyl chloride  | -     | To be fixed                        |                     |
| -         | 083411-71-6 | Bis(2,4,4-trimethylpentyl)phosphinic acid                    | -     | To be fixed                        |                     |
| 40430     | 000109-63-7 | Boron trifluoride etherate                                   | 8     | 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                        |                     |
| -         | 006959-47-3 | 2-(Chloromethyl)pyridine hydrochloride                       | -     | To be fixed                        |                     |
| -         | 007790-94-5 | Chlorosulphonic acid   | -     | To be fixed                        |                     |
| -         | 000869-24-9 | 2-Chlorotriethylamine hydrochloride                          | -     | To be fixed                        |                     |
| -         | 000420-04-2 | Cyanamide  | -     | 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                        |                     |
| -         | 000629-03-8 | 1,6-Dibromohexane  | -     |                                    |                     |
| -         | 000088-27-7 | 2,6-Di-tert-butyl-4(dimethylaminomethyl)phenol               | -     | To be fixed                        |                     |
| -         | 144538-83-0 | N-(1,2-Dicarboxyethyl)aspartic acid, tetrasodium salt        | -     | To be fixed                        |                     |
| -         | 000078-87-5 | 1,2-Dichloropropane  | -     | To be fixed                        |                     |
| -         | 000109-89-7 | Diethylamine   | -     | To be fixed                        |                     |
| -         | 000100-36-7 | N,N-Diethylethylenediamine                                   | -     | To be fixed                        |                     |
| -         | 003710-84-7 | N,N-Diethylhydroxylamine                                     | -     | To be fixed                        |                     |
| _         | 006406-74-2 | 4-(Dimethylaminomethyl)aniline                               | -     | To be fixed                        |                     |
| -         | 025952-53-8 | N-(3-Dimethylaminopropyl)-N'-ethylcarbodiimide hydrochloride | -     | 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                        |                     |
| -         | 019351-18-9 | 2,2-Dimethylthiazolidine                                     | -     | To be fixed                        |                     |
| 16755     | 000556-52-5 | 2,3-Epoxypropanol  | 6A    | To be fixed                        |                     |
| -         | 015965-99-8 | 2,3-Epoxypropyl hexadecyl ether                              | -     | To be fixed                        |                     |
| -         | 001072-52-2 | 1-(2-Hydroxyethyl)ethyleneimine                              | -     | To be fixed                        |                     |
| -         | 001562-00-1 | 2-Hydroxyethylsulphonic acid, sodium salt                    | -     | To be fixed                        |                     |
| 18910     | 000288-32-4 | Imidazole  | 8     | To be fixed                        |                     |
| -         | 006290-05-7 | Iminobis(acetic acid), diethyl ester                         | -     | To be fixed                        |                     |
| -         | 001539-42-0 | 2,2'-(Iminodimethylene)dipyridine                            | -     | To be fixed                        |                     |
| -         | 000074-87-3 | Methyl chloride  | -     | To be fixed                        |                     |
| <u>-</u>  | 006284-40-8 | N-Methylglucamine  |       | To be fixed                        |                     |
|           | 000098-95-3 | Nitrobenzene   | _     | To be fixed                        |                     |
|           | 030525-89-4 | Paraformaldehyde   | _     | To be fixed                        |                     |
| 72048     | 007727-21-1 | Persulphuric acid, potassium salt                            | 8     | To be fixed                        |                     |

| PM/REF No | CAS No                     | NAME   | SCF-L | RESTRICTIONS AND/OR SPECIFICATIONS | ADI/TDI<br>mg/kg bw |
|-----------|----------------------------|--|-------|------------------------------------|---------------------|
| -         | 007775-27-1                | Persulphuric acid, sodium salt   | -     | To be fixed                        |                     |
| -         | 000868-85-9                | Phosphonic acid, dimethyl ester  | -     | To be fixed                        |                     |
| -         | 000298-07-7                | Phosphoric acid, bis(2-ethylhexyl) ester   | -     | To be fixed                        |                     |
| 74005     | 013598-36-2                | Phosphorous acid   | D     | To be fixed                        |                     |
| -         | 000085-41-6                | Phthalimide  | -     | To be fixed                        |                     |
| 76445     | 009003-05-8                | Polyacrylamide   | D     | To be fixed                        |                     |
| 79680     | 026913-06-4<br>009002-98-6 | Polyethyleneimine  | W9    | 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                        |                     |
| -         | 000540-84-1                | 2,2,4-Trimethylpentane   | -     | To be fixed                        |                     |
| -         | 000102-69-2                | Tri-n-propylamine  | -     | To be fixed                        |                     |
|           |                            | Polymerisation aids  |       |                                    |                     |
| 31330     | -                          | Acids, fatty, from animal or vegetable fats and oils, methyl esters                  | 9     | To be fixed                        |                     |
| -         | 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                        |                     |
| 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                        |                     |
| 49465     | 000068-12-2                | Dimethylformamide  | 6B    | To be fixed                        |                     |
| -         | 002764-13-8                | N,N-Dimethyl-N-(2-hydroxyethyl)-3-stearamidopropylammonium nitrate                   | -     | To be fixed                        |                     |
| -         | 000673-84-7                | 2,6-Dimethyl-2,4,6-octatriene  | -     | To be fixed                        |                     |
| 51300     | 000138-86-3                | Dipentene  | 8     | To be fixed                        |                     |
|           | 000112-55-0                | Dodecyl mercaptan  | -     | To be fixed                        |                     |
| 54900     | 009017-33-8                | Fromaldehyde-naphthalenesulphonic acid, copolymer                                    | 9     | To be fixed                        |                     |
|           | 068441-63-4                | Glyoxal - hydroxyethylmethylcellulose, reaction product                              | -     | To be fixed                        |                     |
| -         | 000111-31-9                | Hexyl mercaptan  | -     | To be fixed                        |                     |
| -         | 093685-81-5                | Hydrocarbons, C4, 1,3-butadiene-free, polymd., triisobutylene fraction, hydrogenated | -     | To be fixed                        |                     |

| PM/REF No | CAS No      | NAME   | SCF-L | RESTRICTIONS AND/OR SPECIFICATIONS | ADI/TDI<br>mg/kg bw |
|-----------|-------------|--|-------|------------------------------------|---------------------|
| 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                        |                     |
| -         | 000108-87-2 | Methylcyclohexane  | -     | 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                        |                     |
| 69855     | -           | Organopolysiloxanes containing one or two methyl groups on each silicon atom (silicones)                   | 9     | To be fixed                        |                     |
| 69885     | -           | Organopolysiloxanes with methyl and/or phenyl groups (silicone oil)  | 9     | 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                        |                     |
| -         | 104376-72-9 | Polyethyleneglycol biphenylol ether, benzylated  | -     | To be fixed                        |                     |
| -         | 068954-84-7 | Polyethyleneglycol nonylphenyl ether, sodium phosphate   | -     | To be fixed                        |                     |
| -         | 068954-84-7 | Polyethyleneglycol nonylphenyl ether, sodium phosphate   | -     | To be fixed                        |                     |
| 78560     | 009002-93-1 | Polyethyleneglycol octylphenyl ether   | 9     | To be fixed                        |                     |
| -         | 052623-95-7 | Polyethyleneglycol octylphenyl ether phosphate   | -     | To be fixed                        |                     |
| -         | 134180-76-0 | Poly(ethylene propylene)glycol ether of 3-[1,3,3,3-tetramethyl-1-(trimethylsiloxy)-disiloxanyl]-1-propanol | -     | 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                        |                     |
| 80760     | 009003-07-0 | Polypropylene  | D     | To be fixed                        |                     |
| -         | 009080-79-9 | Poly(styrenesulphonic acid), sodium salt   | -     | To be fixed                        |                     |
| 81260     | -           | Polyvinyl acetate, partially hydrolysed  | 7     | To be fixed                        |                     |
| 86425     | 067762-90-7 | Siloxanes and silicones, dimethyl, reaction products with silica   | W     | To be fixed                        |                     |
| -         | 011138-47-9 | Sodium perborate   | -     | To be fixed                        |                     |
| -         | 002764-13-8 | Stearamidopropyl(dimethyl)(2-hydroxyethyl)ammonium nitrate   | -     | To be fixed                        |                     |

| PM/REF No | CAS No      | NAME                                   | SCF-L | RESTRICTIONS AND/OR SPECIFICATIONS | ADI/TDI<br>mg/kg bw |
|-----------|-------------|--|-------|------------------------------------|---------------------|
| 93585     | 000104-15-4 | p-Toluenesulphonic acid                | 8     | To be fixed                        |                     |
| -         | 000540-84-1 | 2,2,4-Trimethylpentane                 | -     | To be fixed                        |                     |
| 95726     | 025213-24-5 | Vinyl acetate-vinyl alcohol, copolymer | W     | To be fixed                        |                     |