

COEI-1-MEMELE Electrodialysis membranes

1. Objective, Origin and Scope of Application

An electrodialysis membrane is a thin, dense, insoluble wall composed of a polymer material that is permeable to ions. When placed between two solutions, it allows the selective transfer of ions from one solution to the other when acted upon by an electric field.

The membrane pair consists of a cationic membrane and an anionic membrane.

The cationic membrane is a polymer which allows the preferred flow of cations, in particular the K^+ and Ca^{++} cations.

The anionic membrane is a polymer which allows the preferred flow of anions, in particular tartrate anions.

Electrodialysis membranes are used to stabilize wine in the event of tartaric precipitation.

2. Composition

The cation-exchange membrane that can be used is a styrene-divinylbenzene copolymer which carries sulfonic functional groups.

The anion-exchange membrane that can be used is either:

A styrene-divinylbenzene copolymer which carries quaternary ammonium functional groups, or A quaternary ammonium-divinylbenzene copolymer.

Electrodialysis membranes used for tartaric stabilization in wine should meet the following requirements:

- 2.1. They should be manufactured in accordance with the good manufacturing practices for the substances enumerated in :
 - 2.1.1. Annex 1 pertaining to materials placed in contact with foodstuffs
 - 2.1.2. Annex 2 and Annex 3 pertaining to ion-exchange resins used in processing foodstuffs
- 2.2. They should be prepared to serve their intended function, in accordance with the instructions of the manufacturer or supplier.
- 2.3. They should not release any substance in a quantity which poses a human health threat or which alters the taste or odor of foodstuffs.
- 2.4. In use, there should be no interaction between the constituents of the membrane and those of the wine that could form new compounds in the product that could produce toxicological consequences.

INTERNATIONAL OENOLOGICAL CODEX

Electrodialysis membranes

The stability of new electrodialysis membranes shall be established using a simulator which reproduces the physicochemical properties of wine, in order to study the migration of certain substances given off by the electrodialysis membrane.

The proposed experimental method is as follows:

Composition of the simulator:

This is an hydro-alcoholic solution with the pH and conductivity of wine. It is composed of

the following:

| | |
|-----------------------------|------------------------------------|
| Absolute ethanol | 11 liters |
| Potassium hydrogen tartrate | 380 g |
| Potassium chloride | 60 g |
| Concentrated sulfuric acid | 5 ml |
| Distilled water | quantity sufficient for 100 liters |

This solution is used to test migration in a closed circuit on a live electrodialysis stack (1 volt/cell) in a proportion of 50 liters/m² of anionic and cationic membranes until the solution is 50% demineralized. The effluent circuit is activated by a 5 g/l potassium chloride solution.

The migrating substances tested for in the simulator and in the electrodialysis effluent.

The organic molecules forming a constituent of membrane and which can migrate into the treated solution will be quantitatively analyzed.

A specific determination for each of these constituents will be carried out an approved laboratory. The content in the simulator must be less than the total, for all compounds analyzed at 50 µg/l.

Generally, the rules governing materials used in contact with foodstuffs shall also apply to these membranes.

3. Limits on use

The membrane pair used for tartaric wine-stabilizationprocessing using electrodialysis is specified in such a way that:

- the pH reduction in the wine is no greater than 0.3 pH units;

INTERNATIONAL OENOLOGICAL CODEX

Electrodialysis membranes

- volatile acid reduction is less than 0.12 g/l (2 meq. expressed in acetic acid);
- electro dialysis-based processing does not affect the non-ionic constituents of the wine, in particular the polyphenols and polysaccharides;
- the diffusion of small molecules such as ethanol is reduced and does not lead to a reduction of alcoholometric content greater than 0.1%.

4. Conditions of use

These membranes should be stored and cleaned using accepted techniques and substances whose use is authorized for the preparation of foodstuffs.

Annex 1

List of monomers and other starting substances that can be used in the manufacture of plastic materials and devices designed to be placed in contact with foodstuffs, products, and beverages.

| List of approved monomers and other starting substances | | | |
|---------------------------------------------------------|-------------|--------------------------------------------|----------------------------|
| PM/REF No. | Case No. | Name | Restrictions |
| (1) | (2) | (3) | (4) |
| 10030 | 000514-10-3 | Abietic acid | |
| 10060 | 000075-07-0 | Acetaldehyde | |
| 10090 | 000064-19-7 | Acetic acid | |
| 10120 | 000108-05-4 | Vinyl acetate | SML = 12 mg/kg |
| 10150 | 000108-24-7 | Acetic anhydride | |
| 10210 | 000074-86-2 | Acetylene | |
| 10630 | 000079-06-1 | Acrylamide | SML = ND (DL = 0.01 mg/kg) |
| 10660 | 015214-89-8 | 2-acrylamido-2-methylpropane-sulfonic acid | SML = 0/05 mg/kg |

INTERNATIONAL OENOLOGICAL CODEX

Electrodialysis membranes

| 10690 | 000079-10-7 | Acrylic acid | |
|-----------|-------------|---------------------------------------------------------------------------------|------------------------------------------------------------|
| 10750 | 002495-35-4 | Benzyl acrylate | |
| 10780 | 000141-32-2 | n-butyl acrylate | |
| 10810 | 002998-08-5 | Sec-butyl acrylate | |
| 10840 | 001663-39-4 | Tert-butyl acrylate | |
| 11470 | 000140-88-5 | Ethyl acrylate | |
| | 000818-61-1 | Hydroxyethyl acrylate | See « Ethylene glycol monoacrylate » |
| 11590 | 00106-63-8 | Isobutyl acrylate | |
| 11680 | 00689-12-3 | Isopropyl acrylate | |
| 11710 | 000096-33-3 | Methyl acrylate | |
| 11830 | 000818-61-1 | Ethylene glycol monoacrylate | |
| 11890 | 002499-59-4 | n-octyl acrylate | |
| 11980 | 000925-60-0 | Propyl acrylate | |
| PM/REF N° | Case N° | Name | Restrictions |
| 12100 | 000107-13-1 | Acrylonitrile | LMS = ND (LD = 0,020 mg/kg) (including analytic tolerance) |
| 12310 | | Albumin | |
| 12340 | | Albumin coagulated by formaldehyde | |
| 12375 | | Saturate, linear, primary monhydric alcohols (C ₄ -C ₂₂) | |
| 12670 | 002855-13-2 | 1-amino-3-aminomethyl-3,5,5-trimethylcyclohexane | SML = 6 mg/kg |
| 12788 | 002432-99-7 | 11-aminoundecanoic acid | SML = 5 mg/kg |

INTERNATIONAL OENOLOGICAL CODEX

Electrodialysis membranes

| 12789 | 007664-41-7 | Ammonia | |
|-----------|-------------|----------------------------------------------------------------|------------------------------------------------------------------------------------------|
| 12820 | 00123-99-9 | Azelaic acid | |
| 12970 | 004196-95-6 | Azelaic anhydride | |
| 13000 | 001477-55-0 | 1,3-benzene dimethanamine | SML = 0.05 mg/kg |
| 13090 | 000065-85-0 | Benzoic acid | |
| 13150 | 000100-51-6 | Benzylic acid | |
| | 000111-46-6 | Bis(2-hydroxyethyl)ether | See Diethylene glycol |
| | 000077-99-6 | 2,2-bis(hydroxymethyl)-1-butanol | See 1,1,1-trimethylolpropane |
| 13390 | 000105-08-8 | 1,4-bis(hydroxymethyl) cyclohexane) | |
| 13480 | 000080-05-7 | 2,2-bis(4-hydroxyphenyl) propane | SML = 3 mg/kg |
| 13510 | 001675-54-3 | Bis(2,3-epoxypropylic) ether of 2,2-bis(hydroxyphenyl) propane | MQ = 1 mg/kg PF or SML = non-detectable (DL = 0.020 mg/kg, including analytic tolerance) |
| | 000110-98-5 | Bis(hydroxypropylic) ether | See Dipropylene glycol |
| | 005124-30-1 | Bis(4-isocyanato-cyclohexyl) methane | See 4,4-Diisocyanate dedicyclohexylmethane |
| 13530 | 038103-06-9 | Bis(phthalic anhydride) of 2,2 bis(4-hydroxyphenyl) propane | SML = 0.05 mg/kg |
| 13600 | 047465-97-4 | 3,3-bis(3-methyl-4-hydroxyphenyl)-2-indolinone | SML = 1.8 mg/kg |
| | 000080-05-7 | Bisphenol A | See 2,2-bis(4-hydroxyphenyl) propane |
| | 001675-54-3 | Bis(2,3-epoxypropylic)ether of bisphenol A | See Bis(2,3-epoxypropylic)ether of 2,2-bis(4-hydroxyphenyl) propane |
| 13614 | 038103-06-9 | Bis (phthalic anyhydride)of bisphenol | See 13530 |
| PM/REF N° | Case N° | Name | Restrictions |

INTERNATIONAL OENOLOGICAL CODEX

Electrodialysis membranes

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|-------|-------------|-------------------------------|--------------------------------------------------------------------------------------------------------|
| 13630 | 000106-99-0 | Butadiene | MQ = 1 mg/kg of PF or SML = non-detectable (DL = 0.02 mg/kg, including analytic tolerance) |
| 3690 | 000107-88-0 | 1,3-butanediol | |
| 13840 | 000071-36-3 | 1-butanol | |
| 13870 | 000106-98-9 | 1-butene | |
| 13900 | 000107-01-7 | 2-butene | |
| 14110 | 000123-72-8 | Butyraldehyde | |
| 14140 | 000107-92-6 | Butyric acid | |
| 14170 | 000106-31-0 | Butyric anhydride | |
| 14200 | 000105-60-2 | Caprolactam | SML(T) = 15 mg/kg |
| 14230 | 002123-24-2 | Caprolactam, sodium salt | SML(T) = 15 mg/kg (expressed in terms of caprolactam) |
| 14320 | 0001207-2 | Caprylic acid | |
| 14350 | 00630-08-0 | Carbon monoxide | |
| 14380 | 000075-44-5 | Carbonyl chloride | MQ = 1 mg/kg in FP |
| 14411 | 008001-79-4 | Castor oil | |
| 14500 | 009004-34-6 | Cellulose | |
| 14530 | 007782-50-5 | Chlorine | |
| | 000106-89-8 | 1-chloro-2,3-epoxy propane | See Epichlorhydrin |

INTERNATIONAL OENOLOGICAL CODEX

Electrodialysis membranes

| 14680 | 000077-92-9 | Citric acid | |
|--------------|--------------|-------------------------------------------|------------------------------------------------|
| 14710 | 000108-39-4 | <i>m</i> -cresol | |
| 14740 | 000095-48-7 | <i>o</i> -cresol | |
| 14770 | 00106-44-5 | <i>p</i> -cresol | |
| | 00105-08-8 | 1,4-cyclohexanedi- methanol | See 1,4- bis(hydroxymethyl) cyclohexane |
| 14950 | 003173-53-3 | Cyclohexyl isocyanate | MQ(T) = 1 mg/kg in FP (expressed as NCO) |
| 15070 | 001647-16-1 | 1,9-decadiene | SML = 0.05 mg/kg |
| 15095 | 000334-48-5 | Decanoic acid | |
| 15100 | 000112-30-1 | 1-decanol | |
| PM/REF N° | Case N° | Name | Restrictions |
| | 000107-15-3 | 1,2-diaminoethane | See Ethylenediamine |
| | 000124-09-4 | 1,6-diaminohexane | See Hexamethylene- diamine |
| 15250 | 000110-61-1 | 1,4-diaminobutane | |
| 15565 | 0000106-46-7 | 1,4-dichlorobenzene | SML == 12 mg/kg |
| 15700 | 005124-30-1 | 1-cyclohexylmethane-4,4'- diisocyanate | MQ(T) - 1 mg/kg in FP (expressed as NCO) |

INTERNATIONAL OENOLOGICAL CODEX

Electrodialysis membranes

| | | | |
|-------|-------------|-----------------------------------------|-------------------------------------------------------|
| 15760 | 000111-46-6 | Diethylene glycol | SML(T) = 30 mg/kl alone or with ethylene glycol |
| 15790 | 000111-46-6 | Diethylene triamine | SML = 5 mg/kg |
| 15820 | 000345-92-6 | 4,4'-difluorobenzo-phenone | SML = 0.05 mg/kg |
| 15880 | 000120-80-9 | 1,2-dihydroxybenzene | SML = 6 mg/kg |
| 15910 | 000108-46-3 | 1,3-dihydroxybenzene | SML = 2.4 mg/kg |
| 15940 | 000123-31-9 | 1,4-dihydroxybenzene | SML = 0.6 mg/kg |
| 15970 | 000611-99-4 | 4,4'-dihydroxybenzo-phenone | SML = 6 mg/kg |
| 16000 | 000092-88-6 | 4,4'-dihydroxydiphenyl | SML = 6 mg/kg |
| 16150 | 000108-01-0 | Dimethylaminoethanol | SML = 18 mg/kg |
| 16240 | 000091-97-4 | 3,3'-dimethylbiphenyl-4,4'-diisocyanate | MQ(T) = 1 mg/kg in FP (expressed as NCO) |
| 16480 | 000126-58-9 | Dipentaerythritol | |
| 16570 | 004128-73-8 | 4,4'-diisocyanate of diphenyl ether | MQ(T) = 1 mg/kg in FP (expressed as NCO) |
| 16600 | 005873-54-1 | Diphenylmethane-2,4'-diisocyanate | MQ(T) = 1 mg/kg in FP (expressed as NCO) |
| 16630 | 000101-68-8 | Diphenylmethane-4,4'-diisocyanate | MQ(T) = 1 mg/kg in FP (expressed as NCO) |
| 16660 | 000110-98-5 | Diproylene glycol | |

INTERNATIONAL OENOLOGICAL CODEX

Electrodialysis membranes

| 16750 | 000106-89-8 | Epichlorhydrin | MQ = 1 mg/kg in FP |
|-----------|-------------|---------------------------------------------------|---------------------------------------------------|
| 16780 | 000064-17-5 | Ethanol | |
| 16950 | 000074-85-1 | Ethylene | |
| 16960 | 000107-15-3 | Ethylenediamine | SML = 12 mg/kg |
| 16990 | 000107-21-1 | Ethylenje glycol | SML(T) = 30 mg/kg alone or with diethylene glycol |
| PM/REF N° | Case N° | Name | Restrictions |
| 17005 | 000151-56-4 | Ethyleneimine | SML = ND (DL = 01 mg/kg) |
| 17020 | 000075-21-8 | Ethylene oxide | MQ = 1 mg/kg in FP |
| 17050 | 000104-76-7 | 2-ethyl-1-hexanol | SML = 30 mg/kg |
| 17160 | 000097-53-0 | Eugenol | SML= 0.1 mg/kg |
| 17170 | 061788-47-4 | Coconut fatty acids | |
| 17200 | 068308-53-2 | Fatty acids of soybean oil | |
| 17230 | 061790-12-3 | Fatty acids of tall oil | |
| 17260 | 000050-00-0 | Formaldehyde | SML = 15 mg/kg |
| 17290 | 000110-17-8 | Fumaric acid | |
| 17530 | 000050-99-7 | Glucose | |
| 18010 | 000110-94-1 | Glutaric acid | |
| 18070 | 000108-55-4 | Glutaric anhydride | |
| 18100 | 000056-81-5 | Glycerol | |
| 18250 | 000115-28-6 | Hexachloroendo-methyl-Enetetrahy-drophthalic acid | SML = ND (DL = 0.01 mg/kg) |

INTERNATIONAL OENOLOGICAL CODEX

Electrodialysis membranes

| 18280 | 00115-27-5 | Hexachloroendome-thyl Enetetrahydro-phthalic anhydride | SML = ND (DL = 0.01 mg/kg) |
|-----------|-------------|--------------------------------------------------------|-----------------------------------------------|
| 18310 | 036653-82-4 | 1-hexadecanol | |
| 18430 | 00116-15-4 | Hexafluoropropylene | SML = ND (DL = 0.01 mg/kg) |
| 18460 | 000124-09-4 | Hexamethylenediamine | SML = 2.4 mg/kg |
| 18640 | 000822-06-0 | Hexamethylene diisocyanate | MQ(T) = 1 mg/kg in FP (expressed as NCO) |
| 18670 | 000100-97-0 | Hexamehtylene tetramine | SML(T) = 15 mg/kg (expressed as formaldehyde) |
| | 00123-31-9 | Hydroquinone | See 1,4-dihydroxybenzene |
| 18880 | 000099-96-7 | p-hydroxybenzoic acid | |
| 19000 | 000115-11-7 | Isobutene | |
| 19210 | 001459-93-4 | Dimethyl isophthalate | SML = 0.05 mg/kg |
| 19270 | 000097-65-4 | Itaconic acid | |
| 19460 | 000050-21-5 | Lactic acid | |
| PM/REF N° | Case N° | Name | Restrictions |
| 19470 | 000143-07-7 | Lauric acid | |
| 19480 | 002146-71-6 | Vinyl laurate | |
| 19510 | 011132-73-3 | Lignocellulose | |
| 19540 | 000110-16-7 | Maleic acid | SML(T) 30 mg/kg |
| 19960 | 00108-31-6 | Maleic anhydride | SML(T) = 30 mg/kg (expressed as maleic acid) |

INTERNATIONAL OENOLOGICAL CODEX

Electrodialysis membranes

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|-------|-------------|----------------------------------|-----------------------------------------------------------------------|
| | 000108-31-6 | Melamine | See 2,4,6-triamino-1,3,5-triazine |
| 20020 | 000079-41-4 | Methacrylic acid | |
| 20080 | 002495-37-6 | Benzyl methacrylate | |
| 20110 | 000097-88-1 | Butyl methacrylate | |
| 20140 | 002998-18-7 | sec-butyl methacrylate | |
| 20890 | 000097-63-2 | Ethyl methacrylate | |
| 21010 | 000097-86-9 | Isobutyl methacrylate | |
| 21100 | 004655-34-9 | Isopropyl methacrylate | |
| 21130 | 000080-62-6 | Methyl methacrylate | |
| 21190 | 000868-77-9 | Ethylene glycol monomethacrylate | |
| 21280 | 002177-70-0 | Phenyl methacrylate | |
| 21340 | 000760-93-0 | Propyl methacrylate | |
| 21460 | 000760-93-0 | Methacrylic anhydride | |
| 21490 | 000126-98-7 | Methacrylonitrile | SML = not detectable (DL = 0.020 mg/kg, including analytic tolerance) |
| 21550 | 000067-56-1 | Methanol | |
| 21940 | 000924-42-5 | N-methylolacrylamide | SML = ND (DL = 0.0 mg/kg) |
| 22150 | 000691-37-2 | 4-methyl-pentene | SML = 0.02 mg/kg |
| 22350 | 000544-63-8 | Myristic acid | |

INTERNATIONAL OENOLOGICAL CODEX

Electrodialysis membranes

| 22390 | 000840-65-3 | 2,6-dimethyl naphthalene-dicarboxylate | SML = 0.05 mg/kg |
|-----------|-------------|----------------------------------------|------------------------------------------|
| 22420 | 003173-72-6 | 1,5-naphthalene diisocyanate | MQ(T) 1 mg/kg in FP (expressed as NCO) |
| PM/REF N° | Case N° | Name | Restrictions |
| 22450 | 009004-70-0 | Nitrocellulose | |
| 22480 | 000143-08-8 | 1-nonanol | |
| 22570 | 000112-96-9 | Octadecyl isocyanate | MQ(T) = 1 mg/kg in FP (expressed as NCO) |
| 22600 | 000111-87-5 | 1-octanol | |
| 22660 | 000111-66-0 | 1-octene | SML = 15 mg/kg |
| 22763 | 000112-80-1 | Oleic acid | |
| 22780 | 000057-10-3 | Palmitic acid | |
| 22840 | 000115-77-5 | Pentaerythritol | |
| 22870 | 000071-41-0 | 1-pentanol | |
| 22960 | 000108-95-2 | Phenol | |
| 23050 | 000108-45-2 | 1,3-phenylenediamine | MQ = 1 mg/kg in FP |
| | 000075-44-5 | Phosgene | See Carbonyl chloride |
| 23170 | 007664-38-2 | Phosphoric acid | |
| | | Phthalic acid | See Terephthalic acid |
| 23200 | 000088-99-3 | <i>o</i> -phthalic acid | |

INTERNATIONAL OENOLOGICAL CODEX

Electrodialysis membranes

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|--------------|-------------|------------------------|---------------------------------------------------|
| 23230 | 000131-17-9 | Diallyl phthalate | SML = ND (DL = 0.01 mg/kg) |
| 23380 | 000085-44-9 | Phthalic anhydride | |
| 23470 | 000080-56-8 | alpha-pinene | |
| 23500 | 000127-91-3 | beta-pinene | |
| 23590 | 025322-68-3 | Polyethylene glycol | |
| 23651 | 025322-69-4 | Polypropylene glycol | |
| 23740 | 000057-55-6 | 1,2-propanediol | |
| 23800 | 000071-23-8 | 1-propanol | |
| 23830 | 000067-63-0 | 2-propanol | |
| 23860 | 000123-38-6 | Propionaldehyde | |
| 23890 | 000079-09-4 | Propionic acid | |
| PM/REF N° | Case N° | Name | Restrictions |
| 23950 | 000123-62-6 | Propionic anhydride | |
| 23980 | 000115-07-1 | Propylene | |
| 24010 | 000075-56-9 | Propylene oxide | MQ = 1 mg/kg in FP |
| | 000120-80-9 | Pyrocatechol | See 1,2-dihydroxybenzene |
| 24057 | 000089-32-7 | Pyromellitic anhydride | SML = 0.05 mg/kg (expressed as pyromellitic acid) |
| 24070 | 073138-82-6 | Resin acids | |

INTERNATIONAL OENOLOGICAL CODEX

Electrodialysis membranes

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|-------|-------------|------------------------------------------|--------------------------|
| | 000108-46-3 | Resorcinol | See 1,2-dihydroxybenzene |
| 24100 | 008050-09-7 | Rosin | |
| 24130 | 008050-09-7 | Rosin gum | See Rosin |
| 24160 | 008052-10-6 | Tall oil resin | |
| 24190 | 009014-63-5 | Wood resin | |
| 24250 | 009006-04-6 | Natural rubber | |
| 24270 | 000069-72-7 | Salicylic acid | |
| 24280 | 000111-20-6 | Sebacic acid | |
| 24430 | 002561-88-8 | Sebacic anhydride | |
| 24475 | 001313-82-2 | Sodium sulfide | |
| 24490 | 000050-70-4 | Sorbitol | |
| 24520 | 008001-22-7 | Soybean oil | |
| 24540 | 009005-25-8 | Food starch | |
| 24550 | 000057-11-4 | Stearic acid | |
| 24610 | 000100-42-5 | Styrene | |
| 24820 | 000110-15-6 | Succinic acid | |
| 24850 | 000108-30-5 | Succinic anhydride | |
| 24880 | 000057-50-1 | Saccharose | |
| 24887 | 006362-79-4 | 5-sulfoisophthalic acid, monosodium salt | SML = 5 mg/kg |

INTERNATIONAL OENOLOGICAL CODEX

Electrodialysis membranes

| PM/REF N° | Case N° | Name | Restrictions |
|--------------|-------------|--------------------------------------------------------------|--------------------------------------------------------------|
| 24888 | 003965-55-7 | 5-dimethylsulfo- isophthalate, monosodium salt | SML = 0.05 mg/kg |
| 24910 | 000100-21-0 | Terephthalic acid | SML = 7.5 mg/kg |
| 24940 | 000100-20-9 | Terephthalic acid dichloride | SML(T) = 7.5 mg/kg (expressed as terephthalic acid) |
| 24970 | 000120-61-6 | Dimethyl terephthalatae | |
| 25090 | 000112-60-7 | Tetraethylene glycol | |
| 25120 | 000116-14-3 | Tetrafluoroethylene | SML = 0.05 mg/kg |
| 25150 | 000109-99-9 | Tetrahydrofuran | SML = 0.6 mg/kg |
| 25180 | 000102-60-3 | N,N,N',N'-tetrakis(2-hydroxypropyl)-ethylene-diamine | |
| 25210 | 000584-84-9 | Toluene-2,4-diisocyanate | MQ(T) = 1 mg/kg in FP (expressed as nCO) |
| 25240 | 000091-08-7 | Toluene-2,6-diisocyanate | MQ(T) = 1 mg/kg in FP (expressed as nCO) |
| 25270 | 026747-90-0 | Toluene-2,4-diisocyanate, dimer | MQ(T) = 1 mg/kg in FP (expressed as nCO) |
| 25360 | | 2,3-epoxy trialkyl(C ₅ -C ₁₅) acetate | SML = 6 mg/kg |
| 25420 | 000108-78-1 | 2,4,6-triamino-1,3,5-triazine | SML = 30 mg/kg |
| 25510 | 000112-27-6 | Triethylene glycol | |
| 25600 | 000077-99-6 | 1,1,1-trimethylolpropane | SML = 6 mg/kg |
| 25910 | 024800-44-0 | Tripropylene glycol | |
| 25960 | 000057-13-6 | Urea | |
| 26050 | 000075-01-4 | Vinyl chloride | See Council Directive 78/142/EEC |

INTERNATIONAL OENOLOGICAL CODEX

Electrodialysis membranes

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|-------|-------------|---------------------|--------------------------------------------------------|
| 26110 | 000075-35-4 | Vinylidene chloride | MQ = 5 mg/kg in FP or SML = ND (DL = 0.05 mg/kg) |
| 26140 | 000075-38-7 | Vinylidene fluoride | SML = 5 mg/kg |

A number of abbreviations or notations are given in Column 4. Their meaning is listed below:

- DL = Detection limit of the analytical method.
- FP = Finished material or product
- NCO = isocyanate group
- ND = not detectable.

For the purposes of the present directive, the expression «not detectable» means that the substance will not be detected by the approved analytical method, which is sensitive enough to detect it at the specified detection limit. If, however, a method of this kind does not currently exist, an analytical technique possessing performance characteristics suited to the specified limit may be used, while awaiting the development of an approved method.

- MQ = maximum permitted quantity of the «residual» substance in the material or article.
- MQ(T) = maximum permitted quantity of residual substance in the material or article, expressed as the total group or of the indicated substances(s).

For the purposes of this directive, «MQ(T)» means that the maximum permitted quantity of the «residual» substance in the material or article should be determined using an analytical method approved for the specified limit. If, however, a method of this kind does not currently exist, an analytical technique possessing performance characteristics suitable for determining the specified limit may be used, while awaiting the development of an approved method.

- SML = specific migration limit in the food product or the simulated food, unless otherwise specified.

For the purposes of this directive, «SML» means that the specific migration of the substance should be determined using an analytical method approved for the specified limit. If, however, a method of this kind does not currently exist, an analytical technique possessing performance characteristics suitable for determining the specified limit may be used, while awaiting the development of an approved

INTERNATIONAL OENOLOGICAL CODEX

Electrodialysis membranes

method.

- SML(T) = specific migration limit in the food product or simulated food, expressed as the total

of the group or of the indicated substance(s).

For the purposes of this directive, «SML(T)» means that the specific migration of the substance should be determined using an analytical method approved for the specified limit. If, however, a method of this kind does not currently exist, an analytical technique possessing performance characteristics suitable for determining the specified limit may be used, while awaiting the development of an approved method.

Annex 2: List of substances used in the manufacture of adsorbant ion-exchange resins used to condition foodstuffs. (Resolution AP (97)1 EC)

| List 1: Substances assessed by an international organization | | | |
|--------------------------------------------------------------|--------|------------|-------------------|
| Name | PM/REF | Case | Restrictions |
| Monomers and other Starting substances | | | |
| n-butyl acrylate | 10780 | 00141-32-2 | - |
| Ethyl acrylate | 11470 | 00140-88-5 | - |
| Methyl acrylate | 11710 | 00096-33-3 | - |
| Acrylonitrile | 12100 | 00107-13-1 | SML = ND |
| | | | (DL = 0.02 mg/kg) |
| | | | SML = 15 mg/kg |
| Formaldehyde | 17260 | 00050-00-0 | |
| Methyl methacrylate | 21130 | 00080-62-6 | - |
| Methanol | 21550 | 00067-56-1 | - |

INTERNATIONAL OENOLOGICAL CODEX

Electrodialysis membranes

| | | | |
|-----------------------------------|-------|------------|------------------|
| Styrene | 24610 | 00100-42-5 | - |
| Chemical Modifiers | | | |
| Carbonic acid, salts | 42500 | - | - |
| Hydrochloric acid | 72640 | 07664-38-2 | - |
| Silicic acid, salts | 85980 | - | - |
| Sulfuric acid | 91920 | 07664-93-9 | - |
| Acetic anhydride | 10150 | 00108-24-7 | - |
| tert-butyl-4-hydroxyanisole (BHA) | 40720 | 25013-16-5 | SML=30 mg/kg |
| Diethylene triamine | 15790 | 00111-40-0 | SML= 5 mg/kg |
| Dimethylamine | 49225 | 00124-40-3 | SML=0.06 mg/kg |
| 2-(dimethylamino)ethanol | 49235 | 00108-01-0 | SML=18 mg/kg |
| Formaldehyde | 54880 | 00050-00-0 | SML=15 mg/kg |
| Hexamethylenediamine | 18460 | 00124-09-4 | SML=2.4 mg/kg |
| Potassium hydroxide | 81600 | 01310-58-3 | - |
| Sodium hydroxide | 86720 | 01310-73-2 | - |
| Sodium nitrite | 86920 | 07632-00-0 | SML=0.6 mg/kg |
| Ethylene oxide | 17020 | 00075-21-8 | MQ=1 mg/kg in FP |
| 2-propanol | 81882 | 00067-63-0 | - |
| Polymerization Additives | | | |

INTERNATIONAL OENOLOGICAL CODEX

Electrodialysis membranes

| | | | |
|--------------------------------------------------------------------------------|-------|------------|----------------|
| Akylsulfonic acids (C ₈ -C ₂₂) | 34230 | - | SML=6 mg/kg |
| Linear, primary alkylsulfuric | 34281 | - | - |
| acids (C ₈ -C ₂₂) having an even number of carbon atoms | | | |
| Formic acid | 55040 | 00064-18-6 | - |
| Carboxymethylcellulose | 42640 | 09000-11-7 | - |
| Stannic chloride(IV) | 93420 | 07646-78-8 | - |
| Methylene chloride | 66620 | 00075-09-2 | SML=0.05 mg/kg |
| 1,4-dihydroxybenzene | 48620 | 00123-31-9 | SML=0.6 mg/kg |
| Gelatin | 55440 | 09000-70-8 | - |
| Ammonium hydroxide | 35600 | 01336-21-6 | - |
| Magnesium hydroxide | 64640 | 01309-42-8 | - |
| Hydroxyethylcellulose | 60560 | 09004-62-0 | - |
| Hydroxethylmethylcellulose | 60880 | 09032-42-4 | - |
| Methanol | 65960 | 00067-56-1 | - |
| Methylcarboxymethylcellulose | 66200 | 37206-01-2 | - |
| Methyl isobutyl ketone | 66725 | 00108-10-1 | SML=5 mg/kg |
| Toluene | 93540 | 00108-88-3 | SML=1.2 mg/kg |

Annex 3 Substances that may be used provisionally to manufacture ion-exchange resins.

List 2 Substances not fully evaluated by an international organization

INTERNATIONAL OENOLOGICAL CODEX

Electrodialysis membranes

| Name | PM/REF | Case | Restrictions |
|-----------------------------------------------|--------|------------|--------------|
| Monomers and other starting substances | | | |
| Ethylene glycol dimethacrylate | 20440 | 00097-90-5 | - |
| Divinylbenzene | 16690 | 01321-74-0 | - |
| Diallyl ether of 1,1,1-trimethylolpropane | 25645 | 00682-09-7 | - |
| 2,3-epoxypropyl methacrylate | 20590 | 00106-91-2 | - |
| 2-methyl-1,3-butadiene | 21640 | 00078-79-5 | - |
| 1,7-octadiene | 22585 | 03710-30-3 | - |
| 1,1,1-trimethylolpropane trimethacrylate | 25840 | 03290-92-4 | - |
| Chemical Modifiers | | | |
| N,N-dimethyl-1,3-diaminopropane | 49380 | 00109-55-7 | - |
| Triethylamine | 95270 | 00121-44-8 | - |
| Triethylene tetramine | 25520 | 00112-24-3 | - |
| Polymerization Additives | | | |
| Polyvinyl alcohols | 81280 | 09002-89-5 | - |
| 4-tert-butylcatechol | 40640 | 00098-29-3 | - |
| Diisobutyl ketone | 49050 | 00108-83-8 | - |
| Sodium hypochlorite | 62110 | 07681-52-9 | - |

INTERNATIONAL OENOLOGICAL CODEX

Electrodialysis membranes

| Isobutanol | 62270 | 00078-83-1 | - |
|------------------------------------------------------------------|--------|------------|--------------|
| 4-methoxyphenol | 66030 | 00150-76-5 | - |
| Methylene bis(sodium naphthalenesulfonate) | 66600 | 26545-58-4 | - |
| 2-methyl-2-pentanol | 66860 | 00108-11-2 | - |
| Dibenzoylperoxide | 46440 | 00094-36-0 | - |
| Partially hydrolyzed vinyl polyacetate | 81260 | - | - |
| <i>Substances not evaluated by an international organization</i> | | | |
| Name | PM/REF | Case | Restrictions |
| Monomers and other starting substances | | | |
| Dimethoxymethane | - | 00109-87-5 | - |
| Diethylene glycol divinyl ether | - | 00764-99-8 | - |
| Ethyl vinyl benzene | - | 28106-30-1 | - |
| 1,2,4-trivinyl cyclohexane | - | 02855-27-8 | - |
| Chemical Modifiers | | | |
| Chlorosulfonic acid | - | 07790-94-5 | - |
| Monochloroacetic acid | - | 00079-11-8 | - |
| Phosphoric acid | - | 13598-36-2 | - |
| Bromine | - | 07726-95-6 | - |
| 2-chloroethanol | - | 00107-07-3 | - |

INTERNATIONAL OENOLOGICAL CODEX

Electrodialysis membranes

| Methyl chloride | - | 00074-87-3 | - |
|--------------------------------------------------------------------------------|--------|------------|--------------|
| 1,2-dichloroethane | - | 00107-07-3 | - |
| 1,2-dichloropropane | - | 00078-87-5 | - |
| 3-(dimethylamino)propane | - | 03179-63-3 | - |
| Name | PM/REF | Case | Restrictions |
| Monomers and other starting substances | | | |
| Methylic chloromethyl ether | - | 00107-30-2 | - |
| Nitrobenzene | - | 00098-95-3 | - |
| Potassium nitrite | - | 07758-09-0 | - |
| Phthalimide | - | 0085-41-6 | - |
| Sulfur trioxide | - | 07446-11-9 | - |
| Trimethylamine | - | 00075-50-3 | - |
| Polymerization additives | | | |
| Lignosulfonic acid | 63940 | 08062-15-5 | - |
| Peracetic acid | - | 00079-21-0 | - |
| Polyacrylic acid | 76460 | 09003-01-4 | - |
| Poly(styrenesulfonic) acid | - | 09080-79-9 | - |
| Acrylamide/acrylic acid copolymer | - | 09003-06-9 | - |
| Ethoxylated, propoxylated tert-alkylamines (C ₁₂ -C ₁₄) | - | 68603-58-7 | - |

INTERNATIONAL OENOLOGICAL CODEX

Electrodialysis membranes

| | | | |
|--------------------------------------------------------------------|-------|------------|---|
| Maleic anhydride-styrene copolymer, ammonium salt | - | 26022-09-3 | - |
| Attapulgite | - | 12174-11-7 | - |
| Azobisisobutyronitrile | - | 00078-67-1 | - |
| 1,1-bis(tert-butylperoxy)-3,3,5-trimethylcyclohexane | - | 06731-36-8 | - |
| n-Dodecyl mercaptan | - | 25103-58-6 | - |
| Poly(ethylene/propylene)glycol monobutyl ester | - | 09038-95-3 | - |
| Polyethylene glycol octylphenyl ether | 78560 | 09002-93-1 | |
| Poly(ethylene-propylene/glycol ether with 1,1,1-trimethylolpropane | - | 52624-57-4 | - |
| tert-hexadecyl mercaptan | - | 25360-09-2 | - |
| Cumyl hydroperoxide | - | 00080-15-9 | - |
| Isododecane | 62405 | 31807-55-3 | - |
| Isooctane | - | 26635-64-3 | - |
| Mono- and dialkyl (C ₁₀ -C ₁₈) Sulfonamides | - | - | - |
| Silver nitrate | - | 07761-88-8 | - |
| n-Octane | - | 00111-65-9 | - |
| tert-Butyl peracetate | - | 00107-71-1 | - |
| tert-Butyl perbenzoate | - | 00614-45-9 | - |

INTERNATIONAL OENOLOGICAL CODEX

Electrodialysis membranes

| | | | |
|--------------------------------------------------|-------|------------|---|
| bis(4-tert-butylcyclohexyloxy)percarbonate tert- | - | 15520-11-3 | - |
| Butyl per(2-ethyl-hexanoate) | - | 03006-82-6 | - |
| tert-Butyl peroctanoate | - | 13467-82-8 | - |
| Dilauroyl peroxide | - | 00105-74-8 | - |
| Poly(diallyldimethylammonium chloride) | - | 26062-79-3 | - |
| Polyvinylpyrrolidone | 81500 | 09003-39-8 | - |