

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



**PUBLIC HEALTH COMMITTEE**

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

**POLICY STATEMENT CONCERNING PACKAGING INKS  
APPLIED TO THE NON-FOOD CONTACT SURFACE OF  
FOOD PACKAGING**

**21 December 2006**



### NOTE TO THE READER

The following documents are part of the Council of Europe's policy statement concerning packaging inks applied to the non-food contact surface of food packaging:

- Resolution ResAP (2005)2 on packaging inks applied to the non-food contact surface of food packaging
- Technical document N° 1 : Requirements for the selection of packaging ink raw materials applied to the non-food contact surface of food packaging articles intended to come into contact with foodstuffs
- Technical document N° 2: Guidelines on test conditions and methods of analysis (under preparation)
- Technical document N° 3: Guidelines on test conditions for packaging inks applied to the non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs

It is underlined that the resolution and the technical documents form a whole and should be read in conjunction with each other.

Resolution ResAP (2005) 2 was adopted by the Committee of Ministers on 14 September 2005 at the 937<sup>th</sup> meeting of the Ministers' Deputies.

The present document includes a Mission Statement and the available Technical Documents N° 1 and 3 concerning the role of the Council of Europe's Committee of Experts on materials coming into contact with food.

Documents may be consulted on the Internet website of the Partial Agreement Division in the Social and Public Health Field.

[www.coe.int/soc-sp](http://www.coe.int/soc-sp)

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## MISSION STATEMENT

### COUNCIL OF EUROPE AND FOOD CONTACT MATERIALS

#### 1. Council of Europe

The Council of Europe is a political organisation which was founded on 5 May 1949 by ten European countries in order to promote greater unity between its members. It now numbers 46 member states<sup>1</sup>.

The main aims of the Organisation are to reinforce democracy, human rights and the rule of law and to develop common responses to political, social, cultural and legal challenges in its member states. Since 1989 the Council of Europe has integrated most of the countries of central and eastern Europe into its structures and supported them in their efforts to implement and consolidate their political, legal and administrative reforms.

The work of the Council of Europe has led, to date, to the adoption of about 200 European conventions and agreements, which create the basis for a common legal space in Europe. They include the European Convention on Human Rights (1950), the European Cultural Convention (1954), the European Social Charter (1961), the European Convention on the Prevention of Torture (1987) and the Convention on Human Rights and Bioethics (1997). Numerous recommendations and resolutions of the Committee of Ministers propose policy guidelines for national governments.

The Council of Europe has its permanent headquarters in Strasbourg (France). By statute, it has two constituent organs: the Committee of Ministers composed of the Ministers of Foreign Affairs of the 46 member states, and the Parliamentary Assembly, comprising delegations from the 46 national parliaments. The Congress of Local and Regional Authorities of Europe represents the entities of local and regional self-government within the member states. A multinational European Secretariat serves these bodies and the intergovernmental committees.

#### 2. The Partial Agreement in the social and public health field

Where a lesser number of member states of the Council of Europe wish to engage in some action in which not all their European partners desire to join, they can conclude a 'Partial Agreement' which is binding on themselves alone.

The Partial Agreement in the social and public health field was concluded on this basis in 1959.

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<sup>1</sup> Albania, Andorra, Armenia, Austria, Azerbaijan, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Moldova, Monaco, The Netherlands, Norway, Poland, Portugal, Romania, Russian Federation, San Marino, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey, Ukraine, United Kingdom of Great Britain and Northern Ireland.

The areas of activity of the Partial Agreement in the social and public health field include two sectors:

- Protection of public health
- Rehabilitation and integration of people with disabilities.

At present, the Partial Agreement in the public health field has 18 member states<sup>1</sup>.

The activities are entrusted to committees of experts, which are responsible to a steering committee for each area.

The work of the Partial Agreement committees occasionally results in the elaboration of conventions or agreements. The more usual outcome is the drawing-up of resolutions of member states, adopted by the Committee of Ministers. The resolutions should be considered as statements of policy for national policy makers. Governments have actively participated in their formulation. The delegates to the Partial Agreement committees are both experts in the field in question and responsible for the implementation of government policy in their national ministries.

The procedure provides for considerable flexibility in that any state may reserve its position on a given point without thereby preventing the others from going ahead with what they consider appropriate. Another advantage is that the resolutions are readily susceptible to amendment should the need arise. Governments are furthermore called upon periodically to report on the implementation of the recommended measures.

A less formal procedure is the elaboration of guidelines intended to serve as requirements or models for member states and industry.

Bodies of the Partial Agreement in the social and public health field enjoy close co-operation with equivalent bodies in other international institutions, in particular the Commission of the European Union. Contact is also maintained with international non-governmental organisations (NGOs) and industry, working in similar or related fields.

### **3. Council of Europe committees in the public health field**

- Public Health Committee (Steering Committee)
- Committee of experts on materials coming into contact with food

Ad hoc Groups of the Committee of experts:

- Ad hoc Group on safety evaluation of food contact substances

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<sup>1</sup> Austria, Belgium, Bulgaria, Cyprus, Finland, France, Germany, Ireland, Italy, Luxembourg, The Netherlands, Norway, Portugal, Slovenia, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland.

- Ad hoc Group on recycled fibres
  - Ad hoc Group on test conditions for paper and board
  - Ad hoc Group on tissue papers
  - Ad hoc Group on packaging inks
  - Ad hoc Group on coatings
  - Ad hoc Group on cork
  - Ad hoc Group on rubber
  - Ad hoc Group on lead leaching from glass
- Committee of experts on nutrition, food and consumer health, and Ad hoc Groups
  - Committee of experts on flavouring substances
  - Committee of experts on cosmetic products, and Ad hoc Groups
  - Committee of experts on pharmaceutical questions, and Ad hoc Groups
  - Committee of experts on the legal classification of medicines as regards their supply, and Ad hoc Groups

#### **4. Terms of reference of the Committee of experts on materials coming into contact with food**

The overall aim of the Council of Europe Partial Agreement public health activities is to raise the level of health protection of consumers in its widest sense.

The terms of reference of the Committee of experts on materials coming into contact with food (hereafter called 'Committee of experts') are part of the overall aim of these activities and are related to precise problems concerning food contact materials and articles.

The representatives of the Partial Agreement member states and delegates of the Committee of experts are both experts in the field of food contact materials and responsible for the implementation of government policies in their national ministries.

The Commission of the European Union has a particular status of participation within the Committee of experts.

European industry branch associations may be represented at the level of the Ad hoc Groups, which are advisory bodies to the Committee of experts. Ad hoc Groups are not entitled to take formal decisions.

Hearings are regularly organised between the Committee of experts and the European industry branch associations on specific questions related to the work programme.

## **5. Main tasks of the Committee of experts on materials coming into contact with food**

### **▪ Elaboration of resolutions**

Resolutions elaborated by the Committee of experts are approved by the Public Health Committee and adopted by the Committee of Ministers<sup>1</sup>;

They have to be considered as statements of policy or statements for national policy makers of the Partial Agreement member states to be taken into account in the national laws and regulations on food contact materials and articles, with the view of harmonising regulations at European level.

Resolutions lay down the field of application, the specifications and the restrictions concerning the manufacture of food contact materials and articles.

If necessary, they are amended in order to update their content.

### **▪ Elaboration of guidelines**

Guidelines, set out in Technical documents, are approved by the Committee of experts and adopted by the Public Health Committee. They are not submitted to the Committee of Ministers.

They have to be considered as requirements to be taken into account in the context of resolutions or as models for the implementation of national policies.

They provide practical guidance for the application of resolutions and/or lay down technical and/or scientific specifications for the manufacture of food contact materials and articles.

If necessary, guidelines are amended in the light of technical or scientific developments of manufacturing processes and techniques of food contact materials and articles.

Typical examples of guidelines are:

- List of substances to be used for the manufacture of food contact materials
- Test conditions and methods of analysis
- Good manufacturing practices (GMP)

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<sup>1</sup> The Committee of Ministers is the Council of Europe's political decision-making body. It comprises the Ministers for Foreign Affairs of the forty-six member states, or their permanent diplomatic representatives in Strasbourg. It monitors member states' compliance with their undertakings. Resolutions of the Partial Agreement in the social and public health field are adopted by the Committee of Ministers restricted to Representatives of the member states of the Partial Agreement.

- **Safety evaluations of substances to be used in food contact materials and articles**

Safety evaluations of substances to be used in food contact materials and articles are carried out by the ad hoc Group on safety evaluation of food contact substances and submitted for approval to the Committee of experts and adoption to the Public Health Committee. They are not forwarded to the Committee of Ministers.

- **Elaboration of opinions**

On request by the Committee of Ministers and/or the Public Health Committee, the Committee of experts elaborates opinions on specific questions related to food contact materials and articles.



**COUNCIL OF EUROPE  
COMMITTEE OF MINISTERS**

**RESOLUTION ResAP(2005)2  
ON PACKAGING INKS APPLIED TO THE NON-FOOD CONTACT SURFACE  
OF FOOD PACKAGING MATERIALS AND ARTICLES INTENDED TO COME INTO  
CONTACT WITH FOODSTUFFS**

*(Adopted by the Committee of Ministers on 14 September 2005  
at the 937th meeting of the Ministers' Deputies)*

The Committee of Ministers, in its composition restricted to the Representatives of the states of the Council of Europe which are members of the Partial Agreement in the Social and Public Health Field,<sup>1</sup>

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 application: 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 packaging inks applied to the non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs may, through migration of constituents to the foodstuffs, under certain conditions, pose a risk to human health;

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<sup>1</sup> Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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 states members of the Partial Agreement in the Social and Public Health Field to take into account in their national laws and regulations on packaging inks applied to the non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs the principles set out hereafter.

## **APPENDIX TO RESOLUTION RESAP(2005)2**

### **1. SCOPE**

1.1. This resolution applies to printing inks and varnishes (hereafter called “packaging inks”) and any layer of printing inks or varnishes, coloured or uncoloured, applied by an appropriate process to the non-food contact surface of any material or article intended to come into contact with foodstuffs.

1.2. Layers of packaging inks in direct contact with foodstuffs are excluded from the field of application of the present resolution.

1.3. When there is evidence that a substrate renders the migration of any substance in packaging inks substance impossible, and that the set-off or transfer via a gas phase can be excluded, the present resolution does not apply.

### **2. DEFINITIONS**

In this resolution:

2.1. packaging inks are printing inks and varnishes intended to be printed on the non-food contact surface of materials and articles intended to come into contact with foodstuffs;

2.2. packaging inks means any mixture manufactured from colourants, binders, plasticisers, solvents, driers and other additives. They are solvent-based, water-borne, oleo-resinous or energy-curing (UV or electron beam) formulas. They are applied by a printing or varnishing process, such as flexography, gravure, letterpress, offset, screen printing (ink or varnish) and roller coating;

2.3. packaging inks, in their finished state, are thin films of dried or hardened printing ink or varnish on the non-food contact surface of substrates;

2.4. a substrate is any material or article intended to come into contact with food such as glass, metal, paper, board, plastic, textiles and laminates of these materials.

### **3. REQUIREMENTS**

3.1. Printed materials and articles intended to come into contact with foodstuffs, should not, in their finished state and under normal and foreseeable conditions of use, 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 a deterioration in the organoleptic characteristics thereof, in accordance with Article 3 of Regulation (EC) No. 1935/2004.

3.2. In order to achieve this aim, the following requirements should be met:

3.2.1. the substances in packaging inks should be selected in conformity with the requirements for the selection of packaging ink substances as set out in Technical Document No.1:

3.2.1.1 only substances which are listed in the inventory list can be used in the manufacture of packaging inks covered by this resolution;

3.2.1.2 substances which are listed in the inventory list but not evaluated can be used subject to the condition that it can be demonstrated that they will not migrate into the food.<sup>1</sup> The demonstration can be carried out by “worse case calculation” or by a practical test as set out in Technical Document No. 3;<sup>2</sup>

3.2.2. the packaging inks should be manufactured in accordance with the guides for good manufacturing practice set out in Technical Document No. 2, Part 1;

3.2.3. the packaging inks should be applied in accordance with converters’ good manufacturing practices as set out in Technical Document No. 2, Part 2;

3.2.4. the finished printed material or article intended to come into contact with foodstuffs should meet the following requirements:

3.2.4.1 the printed or overprinted varnished layer of finished printed material or article should not come into direct contact with food;

3.2.4.2 global and specific migration from the finished printed material or article should not exceed the relevant limits;

3.2.4.3 there should be no, or only negligible, visible set-off or migration from the printed or varnished non-food contact layer to the food contact surface.

#### **4. CONFORMITY ASSESSMENT**

4.1. Verification of the compliance of the substances in packaging inks with the quantitative restrictions laid down by the resolution should be carried out in conformity with the rules set out in Technical Document No. 3.<sup>2</sup>

4.2. The finished printed and/or varnished food contact material or article should be tested in accordance with the intended conditions of use (one side migration test on the side intended for food contact) and according to the rules set out in Technical Document No. 3.<sup>2</sup>

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<sup>1</sup> For the purposes of control, this means that they shall not be detectable at the lowest concentration at which a substance can be measured with statistical certainty by a validated method of analysis. It is agreed that the detection limit would depend on the nature of the raw materials. However, this limit expressed as concentration shall not exceed 0.01 mg/kg of food or food simulant. It shall apply to the sum of migration of a group of compounds if they are structurally and toxicologically related (e.g. isomers).

<sup>2</sup> Technical Document No. 3 – Test conditions and methods of analysis for packaging inks: under preparation.

**5. RESPONSIBILITY**

The packaging ink suppliers are responsible for the composition of packaging inks in accordance with the requirements set out in this resolution. In line with Article 16 of Regulation (EC) No. 1935/2004, they should communicate without any unjustified delay to the concerned business operator, under appropriate confidentiality agreements, the relevant information necessary to manufacturing the finished materials or articles in compliance with the rules applicable to them.

**6. TRACEABILITY**

The packaging ink suppliers are responsible for the traceability of packaging inks. They should have in place systems and procedures to allow the identification of the businesses from which and to which the packaging inks are supplied.



**TECHNICAL DOCUMENT N° 1**

**REQUIREMENTS FOR THE SELECTION OF PACKAGING  
INK RAW MATERIALS APPLIED TO THE NON-FOOD CONTACT  
SURFACE OF FOOD PACKAGING ARTICLES INTENDED TO COME  
INTO CONTACT WITH FOODSTUFFS**

## **REQUIREMENTS FOR THE SELECTION OF PACKAGING INK RAW MATERIALS APPLIED TO THE NON-FOOD CONTACT SURFACE OF FOOD PACKAGING ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS**

### **Introduction**

The safety of food contact materials and articles is governed by the European Regulation EC 1935/2004. This stipulates that materials and articles in contact with food, whether printed or not, must not transfer to the foodstuffs any of their components which could endanger human health or bring about any unacceptable change in the composition of the foodstuffs or a deterioration in their organoleptic properties.

Council of Europe committees in the public health field are elaborating resolutions and guidelines for the manufacture of materials and articles intended to come into contact with foodstuffs, which are not yet covered by specific EC Directives.

This document gives guidance on the selection process of substances used in the manufacture of printing inks applied to the non-food contact surface of food packaging. For the preparations used in the manufacture of packaging inks, the selection process should be applied for each substance composing the preparation. This technical document should be read in conjunction with the specifications laid down in the Resolution AP (2005) 2 on packaging inks applied to the non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs.

### **Definitions**

Substances and preparations used in the manufacture of packaging inks are defined according to the Directives 67/548/EEC and 1999/45/EC:

*“Substances”* means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the products and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

*“Preparations”* means mixtures or solutions composed of two or more substances.

## **Explanations and working principles**

### ***Exclusion criteria***

Substances and preparations which meet such a criterion or fall into one of these categories cannot be used in the manufacture of packaging inks. The exclusion criteria will be amended, if appropriate, in the light of new data on safety, health and environmental matters.

### ***Inventory list***

The Inventory List catalogues the individual substances currently used in the manufacture of packaging inks but not the preparations. The inventory list will be updated once a year by the Council of Europe Secretariat if necessary.

### ***Evaluation of migration***

The evaluation of a possible migration of any substances will be carried out by worst case calculation and/or practical extraction or migration tests. The conditions of testing and rules for worst case calculations are described in the Technical Document N° 3.

The evaluation results should be made available to the Council of Europe and to the control authorities.

### ***Limit of migration***

The substances which are not evaluated should not be detectable in a migration test at the lowest concentration at which a substance can be measured with statistical certainty by a validated method of analysis. It is agreed that the detection limit would depend on the nature of the substance. However, this limit expressed in concentration shall not exceed 0.01 mg/kg of food or food simulant (analytical tolerance included). It shall apply to the sum of a group of compounds if they are structurally and toxicologically related, e.g. isomers.

### ***Disclosure process***

A substance can be disclosed by the industry to the Council of Europe for its insertion in the *inventory list*. The request should include the necessary information on the substance in regard to its safe use.

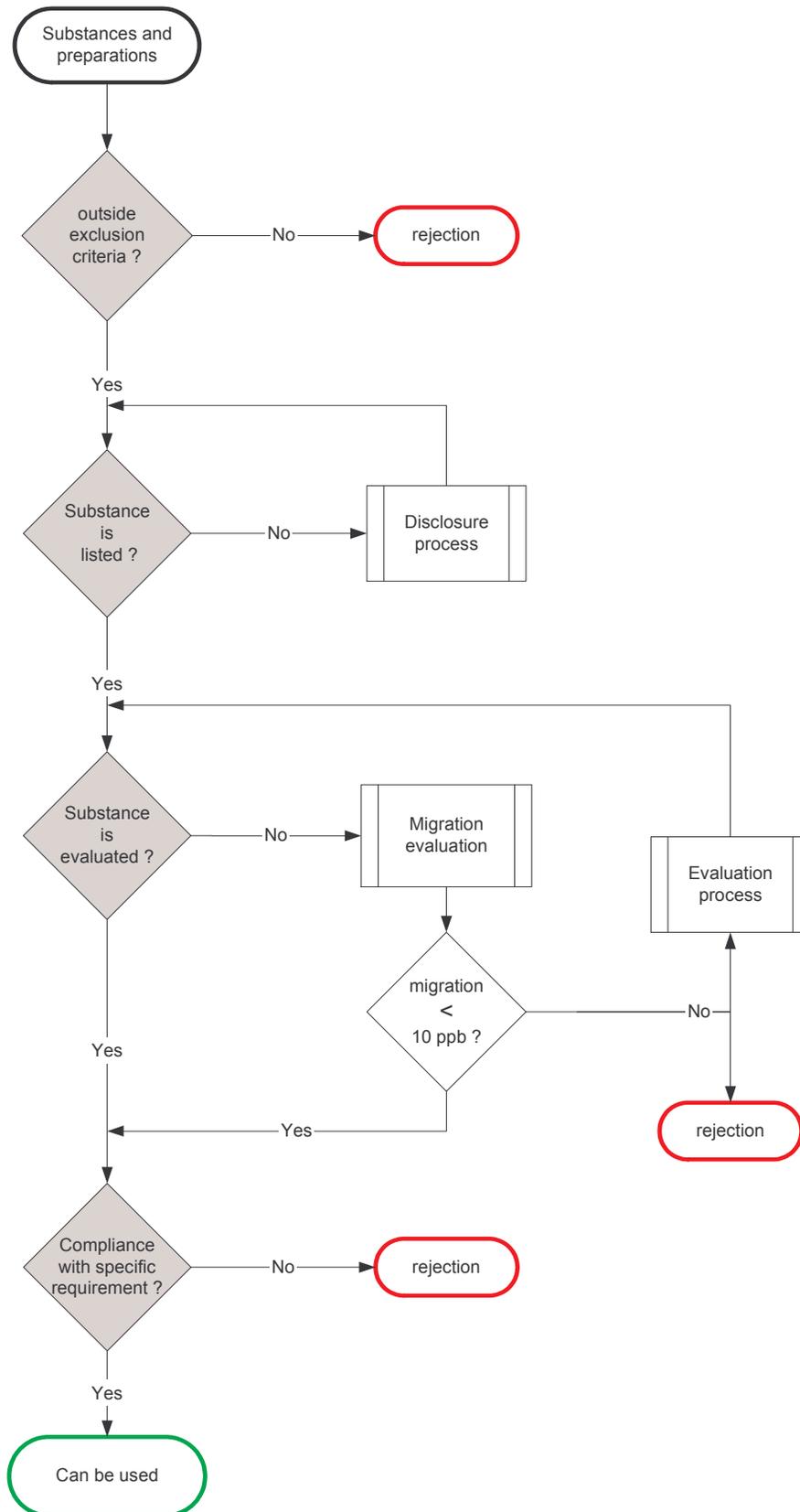
### ***Evaluation process***

To be registered in the list of evaluated substances (List 1), a substance should pass through an evaluation process based on the "Guidelines concerning the safety evaluation of substances to be used in food contact materials and articles" covered by Council of Europe resolutions. The Council of Europe accepts the safety evaluations of the European Food Safety Authority (EFSA) as well as the evaluations performed by other organisations recognised by EFSA.

### ***Specific requirements***

See part 4.

## 1. Selection Scheme for packaging ink substances



## 2. Exclusion criteria for Printing Inks and Related Products

Known substances and preparations which meet one of the following exclusion criteria are excluded as components for the manufacture of packaging inks:

- 2.1 Carcinogenic, mutagenic and toxic for reproduction substances classified as category 1 or category 2 or category 3 in Annex 1 of the Dangerous Substances Directive 67/548/EEC. Substances which, however, are classified as category 1, 2, or 3 but are evaluated by (a) Scientific Committees(s) and as a result can be used under the specified conditions, are admitted.
- 2.2 Substances classified under the self-responsibility criteria as carcinogenic, mutagenic or toxic for reproduction as category 1, 2 or 3 according to the rules of article 6 of Directive 67/548/EEC and its amendments.
- 2.3 Pigment colourants based on and compounds of antimony<sup>1</sup>, arsenic, cadmium, chromium (VI), lead, mercury, selenium.
- 2.4 Azo dyes which can decompose in the body to bio-available carcinogenic aromatic amines of category 1 and 2 according to Directive 67/548/EEC.
- 2.5 Azo dyes which can decompose during the manufacture process to carcinogenic aromatic amines of category 1 and 2 according to Directive 67/548/EEC.
- 2.6 Substances and preparations which are not permitted according to Directive 76/769/EC (relating to the restrictions on the marketing and use of certain dangerous substances and preparations) and its amendments.

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<sup>1</sup> With the exception of non-bio-available pigments in which antimony is a constituent of the crystal lattice and of organic derivatives not classified nor labelled as T or T+

### 3. List of substances used for the manufacture of packaging inks

The lists contain the following information:

- PM/REF No            the EU packaging material reference number of the substance;
- CAS No                the Chemical Abstracts Service Registry Number of the substance;
- C.I. No                the Colour Index Number of the colourant;
- C.I. Name             the Colour Index Name of the colourant;
- NAME                 the chemical name of the substance;
- SCF-L                the number of the list in which the substance is classified by the Scientific Committee for food/EFSA;
- RESTRICTION        restriction related to the substance;
- ADI/TDI              acceptable daily intake or tolerable daily intake as defined in the reports of the Scientific Committee of food/EFSA.

A number of abbreviations are used under RESTRICTION and ADI/TDI, the meanings of which are as follows:

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

#### NOTES

(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 : 15760, 16990, 47680, 53650
(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 : 48030, 48050, 53765
(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 : 64115, 68690, 90290
(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 : 68070, 68650
(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 : 10690, 10780, 11470, 11710
(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 : 16630, 19110, 25208

(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 : 19540, 19960, 64800
(8)	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
(9)	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 : 75100, 75105
(10)	The product (PM/REF 95859) should have the following specifications: <ul style="list-style-type: none"> <li>- Content of mineral hydrocarbons with carbon number less than 25, not more than 5% (w/w)</li> <li>- Viscosity not less than <math>8,5 \times 10^{-6} \text{ m}^2/\text{s}</math> (= 8,5 centistokes) at 100°C</li> <li>- Average molecular weight not less than 480</li> </ul>

### 3.1 Additives

Additives are substances used normally in small quantities, which essentially determine the technical properties of the printing ink, primer and/or overprint varnish in their manufacture or the printing process as well as in the printed product.

The different additive groups describing the principal technological functions are given in the table below for information.

(1)	<b>Acid catalyst</b>
(2)	<b>Adhesion promoter</b>
(3)	<b>Amine solubiliser</b>
(4)	<b>Antifoam agent</b>
(5)	<b>Antimist</b>
(6)	<b>Antistatic</b>
(7)	<b>Biocide</b>
(8)	<b>Chelating agent</b>
(9)	<b>Dispersing agent</b>
(10)	<b>Drier</b>
(11)	<b>Flow agent</b>

(12)	<b>Gellant</b>
(13)	<b>Ink stabiliser</b>
(14)	<b>Optical brightener</b>
(15)	<b>Photoinitiator</b>
(16)	<b>Plasticizer</b>
(17)	<b>Slip agent</b>
(18)	<b>Solvent</b>
(19)	<b>Suspension agent</b>
(20)	<b>Thickener</b>
(21)	<b>UV stabiliser</b>
(22)	<b>Wetting agent</b>

List 1 - Substances evaluated by SCF/EFSA

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION	ADI/TDI mg/kg bw
30045	000123-86-4	Acetic acid, butyl ester	1		6
30140	000141-78-6	Acetic acid, ethyl ester	1		NS
30295	000067-64-1	Acetone	3		
31920	000103-23-1	Adipic acid, bis(2-ethylhexyl) ester	2	SML = 18 mg/kg	0.3
34230	-	Alkyl(C8-C22)sulphonic acid	2	SML = 6 mg/kg	0.1
34560	021645-51-2	Aluminium hydroxide	2		1 (as Al)
35320	007664-41-7	Ammonia	1		NS
37600	000065-85-0	Benzoic acid	1		5
37680	000136-60-7	Benzoic acid, butyl ester	2		5
38400	000100-51-6	Benzyl alcohol	1		5
(13210)	001761-71-3	Bis(4-aminocyclohexyl)methane	3	SML = 0.05 mg/kg	
38560	007128-64-5	2,5-Bis(5-tert-butyl-2-benzoxazolyl)thiophene	2	SML = 0.6 mg/kg	0.01
40590	000071-36-3	1-Butanol	3		
41280	001305-62-0	Calcium hydroxide	1		NS
41960	000124-07-2	Caprylic acid	0		
42500	000471-34-1	Carbonic acid, calcium salt	1		NS
42640	009004-32-4	Carboxymethylcellulose, sodium salt	2		NS
42880	008001-79-4	Castor oil	3		
43300	009004-36-8	Cellulose acetate butyrate	3		
44160	000077-92-9	Citric acid	1		NS
44640	000077-93-0	Citric acid, triethyl ester	1		20
46070-46080	009004-53-9	Dextrin	0		
46640	000128-37-0	2,6-Di-tert-butyl-p-cresol (= BHT)	1	SML = 3 mg/kg	0.05
47680	000111-46-6	Diethyleneglycol	2	SML(T) = 30 mg/kg (1)	0.5
48030	000112-34-5	Diethyleneglycol monobutyl ether	2	SML(T) = 3 mg/kg (2)	0.05
48050	000111-90-0	Diethyleneglycol monoethyl ether	2	SML(T) = 3 mg/kg (2)	0.05
49235	000108-01-0	Dimethylaminoethanol	2	SML = 18 mg/kg	0.3
50320	015571-58-1	Di-n-octyltin bis(2-ethylhexyl mercaptoacetate)	2	SML = 0.04 mg/kg (as Sn)	0.0006(Sn)

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION	ADI/TDI mg/kg bw
51760	025265-71-8	Dipropyleneglycol	2		1.5
52000	027176-87-0	Dodecylbenzenesulphonic acid	2	SML = 30 mg/kg	0.5
52720	000112-84-5	Erucamide	3		
52800	000064-17-5	Ethanol	1		ACC
53280	009004-57-3	Ethylcellulose	2		NS
53600	000060-00-4	Ethylenediaminetetraacetic acid	2		2.5
53650	000107-21-1	Ethyleneglycol	2	SML(T) = 30 mg/kg (1)	0.5
53765	000111-76-2	Ethyleneglycol monobutyl ether	2	SML(T) = 3 mg/kg (2)	0.05
55920	000056-81-5	Glycerol	1		NS
56000	025395-31-7	Glycerol diacetate	1		NS
56080	025637-84-7	Glycerol dioleate	1		NS
56960	025496-72-4	Glycerol monooleate	1		NS
57440	001323-38-2	Glycerol monoricinoleate	3		
57760	000102-76-1	Glycerol triacetate	1		NS
57840	000060-01-5	Glycerol tributyrate	3		
56540	000122-32-7	Glycerol trioleate	3		
58160	000139-44-6	Glycerol tris(12-hydroxystearate)	3		
58790	036653-82-4	Hexadecanol	3		
60560	009004-62-0	Hydroxyethylcellulose	2		NS
60880	009032-42-2	Hydroxyethylmethylcellulose	2		NS
61440	002440-22-4	2-(2'-Hydroxy-5'-methylphenyl)benzotriazole	2	SML = 30 mg/kg	0.5
61840	000106-14-9	12-Hydroxystearic acid	3/0		
62720	001332-58-7	Kaolin	1		NS
63040	000138-22-7	Lactic acid, butyl ester	2		NS
63940	008062-15-5	Lignosulphonic acid	3	SML = 0.24 mg/kg	
64115	006904-78-5	Linoleic acid, manganese salt	2	SML(T) = 0.6 mg/kg (as Mn) (3)	0.01 (Mn)
64160	008001-26-1	Linseed oil	3		
64720	001309-48-4	Magnesium oxide	1		NS
64800	000110-16-7	Maleic acid	2	SML(T) = 30 mg/kg (7)	0.5
66240	009004-67-5	Methylcellulose	2		NS
66655	000078-93-3	Methyl ethyl ketone	3	SML = 5 mg/kg	

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION	ADI/TDI mg/kg bw
66700	009004-65-3	Methylhydroxypropylcellulose	2		NS
66725	000108-10-1	Methyl isobutyl ketone	3	SML = 5 mg/kg	
66755	002682-20-4	2-Methyl-4-isothiazolin-3-one	4A	SML = ND (DL = 0.01 mg/kg)	
67420	000141-43-5	Monoethanolamine	3	SML = 0.05 mg/kg	
67680	027107-89-7	Mono-n-octyltin tris(2-ethylhexyl mercaptoacetate)	2	SML = 1.2 mg/kg (as Sn)	0.02 (Sn)
68070	052270-44-7	Neodecanoic acid, cobalt(II) salt	3	SML(T) = 0.05 mg/kg (as Co) (4) SML = 0.05 mg/kg (as neodecanoic acid)	
(22450)	009004-70-0	Nitrocellulose	3		
68225	000112-92-5	1-Octadecanol	3		
68650	006700-85-2	n-Octanoic acid, cobalt salt	3	SML(T) = 0.05 mg/kg (as Co) (4)	
68690	006535-19-9	n-Octanoic acid, manganese salt	2	SML(T) = 0.6 mg/kg (as Mn) (3)	0.01 (Mn)
68960	000301-02-0	Oleamide	3		
69040	000112-80-1	Oleic acid	1		NS
70400	000057-10-3	Palmitic acid	1		NS
71680	006683-19-8	Pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]	2		3
72800	001241-94-7	Phosphoric acid, diphenyl 2-ethylhexyl ester	2	SML = 2.4 mg/kg	0.04
74880	000084-74-2	Phthalic acid, dibutyl ester	2	SML = 6 mg/kg	0.1
75100	-	Phthalic acid, diesters with primary, saturated C8-C10 branched alcohols containing more than 60% C9	2	SML(T) = 9 mg/kg (9)	0.15
75105	-	Phthalic acid, diesters with primary, saturated C9-C11 branched alcohols containing more than 90% C10	2	SML(T) = 9 mg/kg (9)	0.15
76720	009016-00-6 063148-62-9	Polydimethylsiloxane	2		1.5
76960	025322-68-3	Polyethyleneglycol	2		5
77360	009005-07-6	Polyethyleneglycol dioleate	2		10
77895	068439-49-6	Polyethyleneglycol monoalkyl(C16-C18) ether	3	SML = 0.05 mg/kg	
79360	009005-70-3	Polyethyleneglycol sorbitan trioleate	2		10

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION	ADI/TDI mg/kg bw
80000	009002-88-4	Polyethylene wax	3		
80800	025322-69-4	Polypropyleneglycol	3		
81840	000057-55-6	1,2-Propanediol	1		25
81880	000071-23-8	1-Propanol	3		
81882	000067-63-0	2-Propanol	1		1.5
83610	073138-82-6	Resin acids and rosin acids	2		1
83840	008050-09-7	Rosin	2		1
84210	065997-06-0	Rosin, hydrogenated	2		1
84240	065997-13-9	Rosin, hydrogenated, ester with glycerol	3		
84320	008050-15-5	Rosin, hydrogenated, ester with methanol	2		1
(24160)	008052-10-6	Rosin tall oil	3		
85360	000109-43-3	Sebacic acid, dibutyl ester	3		
85980	001335-30-4	Silicic acid, aluminium salt	2		NS
85980	001344-00-9	Silicic acid, aluminium sodium salt	2		NS
86240	007631-86-9	Silicon dioxide	1		NS
86440	001302-42-7	Sodium aluminate	2		1 (as Al)
87680	001338-43-8	Sorbitan monooleate	1		5
87760	026266-57-9	Sorbitan monopalmitate	1		25
88630/1	008001-22-7	Soybean oil	3		
88640	008013-07-8	Soybean oil, epoxidized	2		1
89040	000057-11-4	Stearic acid	1		NS
90290	003353-05-7	Stearic acid, manganese salt	2	SML(T) = 0.6 mg/kg (as Mn) (3)	0.01 (Mn)
91200	000126-13-6	Sucrose acetate isobutyrate	1		10
91920	007664-93-9	Sulphuric acid	1		NS
92000	007727-43-7	Sulphuric acid, barium salt	3	SML = 1 mg/kg (as Ba)	
92080	014807-96-6	Talc	1		NS
92430	000109-99-9	Tetrahydrofuran	2	SML = 0.6 mg/kg	0.01
93120	000123-28-4	Thiodipropionic acid, didodecyl ester	3	SML = 5 mg/kg	
93440	013463-67-7	Titanium dioxide	1		
93980	000112-70-9	1-Tridecanol	3		
94320	000112-27-6	Triethyleneglycol	2		5

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION	ADI/TDI mg/kg bw
(25910)	024800-44-0	Tripropyleneglycol	2		1.5
95630	000057-13-6	Urea	0		
95859	-	Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks	2	See Note 10	20

Temporary appendix to list 1: substances evaluated by other agencies than EFSA

NONE

List 2 - Substances not evaluated

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
-	071328-93-3	Abietic acid, 2-hydroxy-3-sulphopropyl ester, sodium salt	-	To be fixed
-	068214-33-5	Abietic acid, fumaric acid adduct, polymer with glycerol	-	To be fixed
-	068214-32-4	Abietic acid, fumaric acid adduct, polymer with pentaerythritol	-	To be fixed
-	068214-35-7	Abietic acid, maleic anhydride adduct, polymer with glycerol	-	To be fixed
-	068214-18-6	Abietic acid, maleic anhydride adduct, polymer with pentaerythritol	-	To be fixed
-	000127-25-3	Abietic acid, methyl ester	-	To be fixed
-	054839-24-6	Acetic acid, ethoxyisopropyl ester	-	To be fixed
-	000110-19-0	Acetic acid, isobutyl ester	-	To be fixed
30165	000108-21-4	Acetic acid, isopropyl ester	7	To be fixed
30210	000108-65-6	Acetic acid, 2-methoxyisopropyl ester	6B	To be fixed
30245	000109-60-4	Acetic acid, propyl ester	7	To be fixed
30480	000140-04-5	Acetylricinoleic acid, butyl ester	7	To be fixed
-	000140-03-4	Acetylricinoleic acid, methyl ester	-	To be fixed
-	068409-81-4	Acids, fatty, C6-C19, branched, cobalt(II) salts	-	To be fixed
-	067701-02-4	Acids, fatty, C14-C18	-	To be fixed
-	067701-06-8	Acids, fatty, C14-C18 and C16-C18 unsaturated	-	To be fixed
-	085736-49-8	Acids, fatty, C14-C18 and C16-C18 unsaturated, esters with ethyleneglycol	-	To be fixed
-	085186-88-5	Acids, fatty, C16-C18 and C18 unsaturated, esters with sorbitol	-	To be fixed
-	068154-28-9	Acids, fatty, C18, butyl esters	-	To be fixed
-	063117-82-8	Acrylamide - acrylic acid - ammonium acrylate, copolymer	-	To be fixed
-	029300-12-7	Acrylamide - acrylonitrile - ethyl acrylate, copolymer	-	To be fixed
-	025135-39-1	Acrylic acid - ethyl acrylate - methyl methacrylate, copolymer	-	To be fixed
31560	025085-34-1	Acrylic acid - styrene, copolymer	D	To be fixed
-	029383-53-7	Acrylonitrile - butadiene - itaconic acid - styrene, copolymer	-	To be fixed
-	058394-64-2	Adipic acid, benzyl 2-ethylhexyl ester	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
-	003089-55-2	Adipic acid, benzyl octyl ester	-	To be fixed
-	068526-86-3	Alcohols, C11-C14-iso, C13-rich	-	To be fixed
-	067774-74-7	Alkyl(C10-C13)benzene	-	To be fixed
-	068989-00-4	Alkyl(CI 0-Cl 6)benzylidimethylammonium chloride	-	To be fixed
-	066455-29-6	Alkyl(C12-C14)dimethylbetaines	-	To be fixed
-	068955-19-1	Alkyl(C12-C18)sulphuric acid, sodium salt	-	To be fixed
-	068649-05-8	3-Aminobutyric acid, N-coco alkyl derivatives	-	To be fixed
(12775)	000124-68-5	2-Amino-2-methyl-1-propanol	8	To be fixed
37520	002634-33-5	1,2-Benzisothiazolin-3-one	7	To be fixed
-	104133-71-3	Benzoic acid - ethylene oxide - formaldehyde - 4-nonylphenol - disodium sulphosuccinate, copolymer	-	To be fixed
-	007209-38-3	1,4-Bis(3-aminopropyl)piperazine	-	To be fixed
-	078952-69-9	4,4'-Bis[[1-[(2,4-dimethylphenyl)amino]carbonyl]-2-oxopropyl]azo]-1,1'-biphenyl-2,2'-disulphonic acid	-	To be fixed
-	062174-79-2	1, 3-Bis[(2-ethylhexyl)oxy]propane-2-sodium sulphate	-	To be fixed
-	083721-45-3	2,3-Bis[(2-ethylhexyl)oxy]propane-1-sodium sulphate	-	To be fixed
-	061789-80-8	Bis(hydrogenated tallow alkyl)dimethylammonium chloride	-	To be fixed
-	061791-31-9	N,N-Bis(2-hydroxyethyl)(cocoalkyl)amine	-	To be fixed
39480	000093-83-4	N, N -Bis(2-hydroxyethyl)oleamide	7	To be fixed
-	061791-44-4	N,N-Bis(2-hydroxyethyl)(tallow alkyl)amine	-	To be fixed
-	016324-24-6	Bis(isopropoxy)aluminium mono(acetylacetonate)	-	To be fixed
-	017927-72-9	Bis(isopropoxy)titanium bis(acetylacetonate)	-	To be fixed
40080	013879-32-8	Bis(phenoxyethyl)formal	8	To be fixed
-	026635-93-8	N,N-Bis(polyoxyethylene)oleylamine	-	To be fixed
40592	000078-92-2	2-Butanol	8	To be fixed
40618	005131-66-8	1-Butoxy-2-propanol	8	To be fixed
-	003622-84-2	N-Butylbenzenesulphonamide	-	To be fixed
-	001907-65-9	N-Butyl-p-toluenesulphonamide	-	To be fixed
(14002)	000098-73-7	p-tert-Butylbenzoic acid	7	To be fixed
-	004197-69-7	2-Butylhydroquinone	-	To be fixed
-	068648-78-2	Butyraldehyde - vinyl acetate - vinyl alcohol, copolymer	-	To be fixed
41000	000096-48-0	gamma-Butyrolactone	8	To be fixed
(14330)	000592-35-8	Carbamic acid, butyl ester	8	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
43230	008002-33-3	Castor oil, sulphated	9	To be fixed
-	068187-77-9	Castor oil, sulphated, ammonium salt	-	To be fixed
-	068187-76-8	Castor oil, sulphated, sodium salt	-	To be fixed
-	068604-22-8	Castor oil, sulphurized	-	To be fixed
43760	026172-55-4	5-Chloro-2-methyl-4-isothiazolin-3-one	7	To be fixed
-	004132-10-9	Citric acid, tricyclohexyl ester	-	To be fixed
-	001793-10-8	Citric acid, triisopentyl ester	-	To be fixed
-	061788-46-3	Coco alkyl amines	-	To be fixed
-	061788-93-0	(Coco alkyl)dimethyl amines	-	To be fixed
-	061788-90-7	(Coco alkyl)dimethyl amines, N-oxides	-	To be fixed
-	061789-18-2	(Coco alkyl)trimethylammonium chloride	-	To be fixed
-	061789-19-3	Coconut oil fatty acid amide	-	To be fixed
-	068140-01-2	Coconut oil fatty acid N-[3-(dimethylamino)propionamide]	-	To be fixed
-	068140-00-1	Coconut oil fatty acid monoethanolamide	-	To be fixed
-	068425-44-5	Coconut oil fatty acid monoethanolamide, ethoxylated	-	To be fixed
-	042739-64-0	Copper (phthalimidomethyl)phthalocyanine	-	To be fixed
-	068037-36-5	Copper phthalocyanine, sulphonated	-	To be fixed
-	073455-75-1	Copper phthalocyanine, sulphonated, compound with dodecylamine	-	To be fixed
45610	025609-89-6	Crotonic acid - vinyl acetate, copolymer	9	To be fixed
-	070693-20-8	Cyanamide, reaction products with carbon dioxide, ethylene oxide and octadecylamine	-	To be fixed
45700	000110-28-7	Cyclohexane	8	To be fixed
-	000080-30-8	N-Cyclohexyl-p-toluenesulphonamide	-	To be fixed
-	046911-70-0	2-Decyl-1-hydroxyethyl-2-imidazole	-	To be fixed
-	001446-61-3	Dehydroabietylamine	-	To be fixed
-	025417-20-3	Dibutylphthalenesulphonic acid, sodium salt	-	To be fixed
-	000085-98-3	Diethyldiphenylurea	-	To be fixed
47720	000120-55-8	Diethyleneglycol dibenzoate	W	To be fixed
-	000106-01-4	Diethyleneglycol dipelargonate	-	To be fixed
-	000112-59-4	Diethyleneglycol monoethyl ether	-	To be fixed
-	000111-77-3	Diethyleneglycol monomethyl ether	-	To be fixed
-	067893-02-1	Dihydroabietic acid, methyl ester	-	To be fixed
59810	026266-77-3	Dihydroabietyl alcohol	8	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
-	024650-42-8	2,2-Dimethoxy-2-phenylacetophenone	-	To be fixed
-	010287-53-3	4-Dimethylaminobenzoic acid, ethyl ester	-	To be fixed
49340	061789-71-7	Dimethyl(cocooalkyl)benzylammonium chloride	9	To be fixed
-	000107-64-2	Dimethyldioctadecylammonium chloride	-	To be fixed
-	000107-54-0	3,5-Dimethylhexyn-3-ol	-	To be fixed
-	082199-01-7	1,6-Dimethylnaphthalenesulphonic acid, sodium salt - formaldehyde, copolymer	-	To be fixed
-	004196-89-8	2,2-Dimethyl-1,3-propanediol dibenzoate	-	To be fixed
-	003332-27-2	N,N-Dimethyltetradecylamine N-oxide	-	To be fixed
51870	034590-94-8	Dipropylene glycol monomethyl ether	8	To be fixed
-	064742-13-8	Distillates (petroleum), acid-treated middle	-	To be fixed
-	064742-52-5	Distillates (petroleum), hydrotreated heavy naphthenic	-	To be fixed
-	064742-54-7	Distillates (petroleum), hydrotreated heavy paraffinic	-	To be fixed
-	064742-47-8	Distillates (petroleum), hydrotreated light	-	To be fixed
-	064742-55-8	Distillates (petroleum), hydrotreated light paraffinic	-	To be fixed
-	064742-56-9	Distillates (petroleum), solvent-dewaxed light paraffinic	-	To be fixed
-	064741-96-4	Distillates (petroleum), solvent-refined heavy naphthenic	-	To be fixed
-	064741-88-4	Distillates (petroleum), solvent-refined heavy paraffinic	-	To be fixed
-	064741-91-9	Distillates (petroleum), solvent-refined middle	-	To be fixed
-	109037-68-5	N,N'-Ditalow alkyl[1,2-ethanediybis(imino-3,1-propanediyl)]diamines, ethoxylated propoxylated	-	To be fixed
-	000124-22-1	n-Dodecylamine	-	To be fixed
53215	001569-02-4	1-Ethoxy-2-propanol	8	To be fixed
-	000763-69-9	3-Ethoxypropionic acid, ethyl ester	-	To be fixed
-	052503-47-6	Ethylenediamine - ethylene oxide - propylene oxide, copolymer	-	To be fixed
-	055845-06-2	Ethylene oxide - formaldehyde - nonylphenol, copolymer	-	To be fixed
54120	000149-57-5	2-Ethylhexanoic acid	6B	To be fixed
54205	000136-51-6	2-Ethylhexanoic acid, calcium salt	6B	To be fixed
54130	024593-34-8	2-Ethylhexanoic acid, cerium salt	6B	To be fixed
54150	000136-52-7	2-Ethylhexanoic acid, cobalt(II) salt	6B	To be fixed
54190	015956-58-8	2-Ethylhexanoic acid, manganese salt	6B	To be fixed
-	061788-37-2	2-Ethylhexanoic acid, rare earth salts	-	To be fixed
54220	022464-99-9	2-Ethylhexanoic acid, zirconium salt	6B	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
-	029759-19-1	2-Ethylhexyl epoxysearate	-	To be fixed
-	001077-56-1	N-Ethyl-o-toluenesulphonamide	-	To be fixed
-	000080-39-7	N-Ethyl-p-toluenesulphonamide	-	To be fixed
54380	008047-99-2	N-Ethyltoluenesulphonamide	8	To be fixed
54900	009084-06-4	Formaldehyde - naphthalenesulphonic acid, copolymer, sodium salt	9	To be fixed
-	036290-04-7	Formaldehyde - 2-naphthalenesulphonic acid, copolymer, sodium salt	-	To be fixed
-	104376-68-3	Formaldehyde, reaction products with branched nonylphenol and cyclohexylamine, ethoxylated	-	To be fixed
54960	001338-51-8	Formaldehyde - toluenesulphonamide, copolymer	9	To be fixed
(17350)	000105-75-9	Fumaric acid, dibutyl ester	7	To be fixed
55160	000098-00-0	Furfural	8	To be fixed
55880	001119-40-0	Glutaric acid, dimethyl ester	7	To be fixed
-	061215-87-0	Glycerol - pentaerythritol - phthalic anhydride, copolymer	-	To be fixed
-	000614-33-5	Glycerol tribenzoate	-	To be fixed
-	002540-54-7	Glycerol tricinoleate	-	To be fixed
-	000095-38-5	2-(8-Heptadecenyl)-2-imidazoline-1-ethanol	-	To be fixed
-	000112-02-7	Hexadecyltrimethylammonium chloride	-	To be fixed
-	092045-32-4	Heptane, branched and linear	-	To be fixed
(18449)	003089-11-0	N,N,N',N',N"-Hexakis(methoxymethyl)-2,4,6-triamino-1,3,5-triazine	8	To be fixed
59600	000107-41-5	Hexyleneglycol	7	To be fixed
-	005153-25-3	4-Hydroxybenzoic acid, 2-ethylhexyl ester	-	To be fixed
-	002809-21-4	1 -Hydroxyethane-1, 1 -diphosphonic acid	-	To be fixed
-	034375-28-5	N-Hydroxy-N-methylethanolamine	-	To be fixed
61415	000123-42-2	4-Hydroxy-4-methyl-2-pentanone	8	To be fixed
62270	000078-83-1	Isobutanol	8	To be fixed
-	025154-85-2	Isobutyl vinyl ether - vinyl chloride, copolymer	-	To be fixed
-	006846-50-0	Isobutyric acid, diester with 2,2,4-trimethyl-1,3-pentanediol	-	To be fixed
-	025265-77-4	Isobutyric acid, monoester with 2,2,4-trimethyl-1,3-pentanediol	-	To be fixed
-	053988-05-9	Isononanoic acid, calcium salt	-	To be fixed
-	084777-61-7	Isooctanoic acid, calcium salt	-	To be fixed
-	000078-59-1	Isophorone	-	To be fixed
-	003944-37-4	2-Isopropoxy-1-propanol	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
-	005495-84-1	2-Isopropylthioxanthone	-	To be fixed
-	027458-92-0	Isotridecanol	-	To be fixed
-	064742-81-0	Kerosine (petroleum), hydrodesulphurized	-	To be fixed
-	000097-64-3	Lactic acid, ethyl ester	-	To be fixed
-	063697-00-7	Lactic acid, isopropyl ester	-	To be fixed
-	068512-34-5	Lignosulphonic acid, sodium salt, sulphomethylated	-	To be fixed
64240	008016-11-3	Linseed oil, epoxidized	7	To be fixed
-	091722-72-4	Linseed oil, maleated, monoethyl ester, ammonium salt	-	To be fixed
-	067746-08-1	Linseed oil, polymerized	-	To be fixed
-	068458-91 3	Linseed oil, polymer with adipic acid, isophthalic acid and trimethylolpropane	-	To be fixed
(19600)	000105-76-0	Maleic acid, dibutyl ester	7	To be fixed
(19690)	014234-82-3	Maleic acid, diisobutyl ester	7	To be fixed
(19720)	001330-76-3	Maleic acid, diisooctyl ester	7	To be fixed
(19780)	002915-53-9	Maleic acid, dioctyl ester	7	To be fixed
-	038638-76-5	Maleic anhydride - pentaerythritol - phthalic anhydride, copolymer	-	To be fixed
-	068440-42-6	Menhaden oil, polymerized, oxidized	-	To be fixed
-	002517-43-3	3-Methoxy-1-butanol	-	To be fixed
-	000107-70-0	4-Methoxy-4-methyl-2-pentanone	-	To be fixed
66050	000107-98-2	1-Methoxy-2-propanol	8	To be fixed
(21749)	000583-60-8	2-Methylcyclohexanone	8	To be fixed
-	000137-20-2	N-Methyl-N-oleoyltaurine, sodium salt	-	To be fixed
66905	000872-50-4	N-Methylpyrrolidone	8	To be fixed
-	061791-42-2	N-Methyl-N-(2-sulphoethyl)cocoacylamines, sodium salt	-	To be fixed
-	064741-65-7	Naphtha (petroleum), heavy alkylate	-	To be fixed
-	064742-82-1	Naphtha (petroleum), hydrodesulphurized heavy	-	To be fixed
-	064742-48-9	Naphtha (petroleum), hydrotreated heavy	-	To be fixed
-	064742-49-0	Naphtha (petroleum), hydrotreated light	-	To be fixed
67950	061789-36-4	Naphthenic acids, calcium salts	9	To be fixed
67930	061789-51-3	Naphthenic acids, cobalt salts	9	To be fixed
67946	001336-93-2	Naphthenic acid, manganese salts	9	To be fixed
68115	039049-04-2	Neodecanoic acid, zirconium salt	8	To be fixed
-	005064-31-3	Nitrioltriacetic acid, trisodium salt	-	To be fixed
-	002687-94-7	N-Octyl-2-pyrrolidinone	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
-	000112-90-3	Oleamine	-	To be fixed
69120	000142-77-8	Oleic acid, butyl ester	7	To be fixed
-	010402-16-1	Oleic acid, copper salt	-	To be fixed
69360	042254-63-7	Oleic acid, heptyl ester	7	To be fixed
-	000142-15-4	Oleic acid, 2-sulphoethyl ester, sodium salt	-	To be fixed
-	005420-17-7	Oleic acid, tetrahydrofurfuryl ester	-	To be fixed
-	010460-00-1	Oleyl ammonium acetate	-	To be fixed
-	007173-62-8	N-Oleyl-1,3-diaminopropane	-	To be fixed
70720	000540-10-3	Palmitic acid, hexadecyl ester	7	To be fixed
71120	008012-95-1	Paraffin oil	9	To be fixed
-	064771-72-8	Paraffins (petroleum), n-C5-C20	-	To be fixed
-	000078-22-8	Pentaerythritol monoricinoleate	-	To be fixed
-	004196-86-5	Pentaerythritol tetrabenzoate	-	To be fixed
72080	064742-16-1	Petroleum hydrocarbon resins	9	To be fixed
72135	000092-84-2	Phenothiazine	8	To be fixed
-	029761-21-5	Phosphoric acid, diphenyl isodecyl ester	-	To be fixed
-	000078-40-0	Phosphoric acid, triethyl ester	-	To be fixed
73840	000126-71-6	Phosphoric acid, triisobutyl ester	6B	To be fixed
74000	000078-42-2	Phosphoric acid, tris(2-ethylhexyl) ester	6B	To be fixed
(23178)	000101-02-0	Phosphorous acid, triphenyl ester	8	To be fixed
-	000085-71-2	Phthalic acid, mixed esters with ethyl glycolate and methanol	-	To be fixed
76460	009003-01-4	Polyacrylic acid	7	To be fixed
76460	009003-03-6	Polyacrylic acid, ammonium salt	7	To be fixed
76460	009003-04-7	Polyacrylic acid, sodium salt	7	To be fixed
-	063148-69-6	Polyesters of polyhydric alcohols	-	To be fixed
77030	068891-38-3	Polyethyleneglycol alkyl(C12-C14) ether, sodium sulphate	9	To be fixed
-	009086-52-6	Polyethyleneglycol bis(1-phenylethyl)phenyl ether	-	To be fixed
77200	061791-14-8	Polyethyleneglycol cocoamine	9	To be fixed
-	009014-93-1	Polyethyleneglycol dinonylphenyl ether	-	To be fixed
77711	068439-50-9	Polyethyleneglycol ethers of C12-C14 alcohols	D	To be fixed
-	068920-66-1	Polyethyleneglycol ethers of alcohols, C16-C18 and C18 unsaturated	-	To be fixed
-	068511-37-5	Polyethyleneglycol ethers of C12-C14 alcohols, phosphates	-	To be fixed
-	068585-34-2	Polyethyleneglycol ethers of C10-C16 alcohols, sodium sulphates	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
-	?	Polyethyleneglycol ether of 2,2-bis(4-hydroxyphenyl)propane	-	To be fixed
-	061790-85-0	Polyethyleneglycol ethers of N-(tallow alkyl)trimethylenediamines	-	To be fixed
77760	061791-28-4	Polyethyleneglycol ether of tallow fatty alcohol	D	To be fixed
77790	009004-95-9	Polyethyleneglycol hexadecyl ether	9	To be fixed
77880	009043-30-5	Polyethyleneglycol isotridecyl ether	8	To be fixed
78400	009016-45-9	Polyethyleneglycol nonylphenyl ether	P	To be fixed
78440	026027-38-3	Polyethyleneglycol 4-nonylphenyl ether	W7	To be fixed
-	009051-57-4	Polyethyleneglycol nonylphenyl ether, ammonium salt	-	To be fixed
-	068412-54-4	Polyethyleneglycol nonylphenyl ether, branched	-	To be fixed
78480	051811-79-1	Polyethyleneglycol nonylphenyl phosphate	9	To be fixed
78560	009002-93-1 009036-19-5	Polyethyleneglycol octylphenyl ether	9	To be fixed
-	026636-37-3	Polyethyleneglycol 2,4,6-tri-tert-butylphenyl ether	-	To be fixed
-	109909-39-9	Polyethyleneglycol 2,4,6-tris(isobutyl)phenyl ether sodium sulphate	-	To be fixed
-	073297-33-3	Polyethyleneglycol tris[1-(methylphenyl)ethyl]phenyl ether	-	To be fixed
-	070559-25-0	Polyethyleneglycol 2,4,6-tris(1-phenylethyl)phenyl ether	-	To be fixed
79680	009002-98-6	Polyethyleneimine	W9-D	To be fixed
-	068130-97-2	Polyethyleneimine, reaction products with 1,2-dichloroethane	-	To be fixed
79920	009003-11-6	Poly(ethylene propylene)glycol	7/9	To be fixed
-	068551-13-3	Poly(ethylene propylene)glycol ethers of C12-C15 alcohols	-	To be fixed
-	011111-34-5	Poly(ethylene propylene)glycol ether of ethylenediaminetetrapropanol	-	To be fixed
-	009038-95-3	Poly(ethylene propylene)glycol monobutyl ether	-	To be fixed
80077	068441-17-8	Polyethylene, oxidized	7	To be fixed
80340	027924-99-8	Poly(12-hydroxystearic acid)	7	To be fixed
80340	?	Poly(12-hydroxystearic acid), calcium salt	7	To be fixed
-	068071-29-4	Poly(2-methyl-1,3-butadiene), phenol-modified	-	To be fixed
-	009057-91-4	Polypropyleneglycol - toluene diisocyanate, copolymer	-	To be fixed
81230	-	Polyurethanes	9	To be fixed
81245	009003-20-7	Polyvinyl acetate	D	To be fixed
(23710)	063148-65-2	Polyvinylbutyrals	9	To be fixed
81390	025104-37-4	Poly(vinyl ethyl ether)	9	To be fixed
82050	000108-32-7	Propylene carbonate	8	To be fixed
-	029387-86-8	Propyleneglycol monobutyl ether	-	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
83280	026402-31-3	1,2-Propyleneglycol monoricinoleate	7	To be fixed
-	068188-14-7	Resin acids and rosin acids, barium salts	-	To be fixed
-	068554-12-1	Resin acids and rosin acids, hydrogenated, calcium salts	-	To be fixed
-	068475-37-6	Resin acids and rosin acids, polymerised, glycerol esters	-	To be fixed
-	068152-78-3	Resin acids and rosin acids, strontium salts	-	To be fixed
-	000151-13-3	Ricinoleic acid, butyl ester	-	To be fixed
-	000106-17-2	Ricinoleic acid, 2-hydroxyethyl ester	-	To be fixed
-	000141-24-2	Ricinoleic acid, methyl ester	-	To be fixed
-	061790-47-4	Rosin amines	-	To be fixed
-	068648-50-0	Rosin, dimerized, calcium salt	-	To be fixed
-	008050-09-7	Rosin, disproportionated	-	To be fixed
-	?	Rosin, ethoxylated, ammonium salt	-	To be fixed
-	065997-04-8	Rosin, fumarated	-	To be fixed
-	068201-58-1	Rosin, fumarated, polymer with formaldehyde	-	To be fixed
-	065997-11-7	Rosin, fumarated, polymer with pentaerythritol	-	To be fixed
-	068333-69-7	Rosin, maleated, polymer with pentaerythritol	-	To be fixed
-	008050-28-0	Rosin, maleic acid-modified	-	To be fixed
(24150)	065997-05-9	Rosin, polymerized	9	To be fixed
-	068152-68-1	Rosin, polymer with 2,2-bis(4-hydroxyphenyl)propane and formaldehyde	-	To be fixed
-	065997-07-1	Rosin, polymer with formaldehyde	-	To be fixed
-	083137-13-7	Rosin, reaction products with acrylic acid	-	To be fixed
85120	000122-62-3	Sebacic acid, bis(2-ethylhexyl) ester	6B	To be fixed
-	064742-96-7	Solvent naphtha (petroleurn), heavy aliphatic	-	To be fixed
-	064742-89-8	Solvent naphtha (petroleurn), light aliphatic	-	To be fixed
-	064742-88-7	Solvent naphtha (petroleurn), medium aliphatic	-	To be fixed
-	052551-46-9	Sorbitol tetraoleate	-	To be fixed
-	001333-71-7	Sorbitol trioleate	-	To be fixed
-	066071-86-1	Soybean oil, polymer with isophthalic acid and pentaerythritol	-	To be fixed
-	067700-65-6	Soybean oil, polymer with isophthalic acid and trimethylolpropane	-	To be fixed
-	066070-60-8	Soybean oil, polymer with pentaerythritol and phthalic anhydride	-	To be fixed
89120	000123-95-5	Stearic acid, butyl ester	7	To be fixed
89150	010119-53-6	Stearic acid, cerium salt	8	To be fixed
90000	000646-13-9	Stearic acid, isobutyl ester	7	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
-	090459-62-4	Stearic acid, reaction products with diethylenetriamine, dimethyl sulphate-quaternized	-	To be fixed
91135	000160-65-0	Succinic acid, dimethyl ester	7	To be fixed
-	012738-64-6	Sucrose benzoate	-	To be fixed
-	068608-26-4	Sulphonic acids, petroleum, sodium salts	-	To be fixed
91572	000577-11-7	Sulphosuccinic acid, bis(2-ethylhexyl) ester, sodium salt	6B	To be fixed
-	091845-13-5	Tall oil fatty acids, compounds with N-oleyl-1,3-diaminopropane	-	To be fixed
-	061789-01-3	Tall oil fatty acids, epoxidized, 2-ethylhexyl esters	-	To be fixed
-	061788-72-5	Tall oil fatty acids, epoxidized, octyl esters	-	To be fixed
-	068334-13-4	Tall oil fatty acids, 2-ethylhexyl esters	-	To be fixed
-	068333-78-8	Tall oil fatty acids, isoocetyl esters	-	To be fixed
-	068410-37-7	Tall oil fatty acids, polymers with isophthalic acid, pentaerythritol and tall oil	-	To be fixed
-	061790-31-6	Tallow alkyl amides, hydrogenated	-	To be fixed
-	061790-33-8	Tallow alkyl amines	-	To be fixed
-	061788-45-2	Tallow alkyl amines, hydrogenated	-	To be fixed
-	061791-55-7	N-(Tallow alkyl)trimethylenediamine	-	To be fixed
-	067875-36-9	Terephthalic acid, polymer with 2,2-dimethyl-1,3-propanediol, dodecanedioic acid, 1,6-hexanediol and trimethylolpropane	-	To be fixed
-	069029-24-9	1-Tetradecanol phosphate	-	To be fixed
-	018268-70-7	Tetraethyleneglycol bis(2-ethylhexanoate)	-	To be fixed
-	070729-68-9	Tetraethyleneglycol diheptanoate	-	To be fixed
92685	000126-86-3	2,4,7,9-Tetramethyl-5-decylne-4,7-diol	8	To be fixed
-	068227-33-8	2,5,8,11-Tetramethyl-6-dodecylne-5,8-diol	-	To be fixed
(25300)	000088-19-7	o-Toluenesulphonamide	8	To be fixed
(25330)	000070-55-3	p-Toluenesulphonamide	7	To be fixed
-	001333-07-9	Toluenesulphonamide	-	To be fixed
93585	000104-15-4	p-Toluenesulphonic acid	8	To be fixed
-	000080-40-0	p-Toluenesulphonic acid, ethyl ester	-	To be fixed
93760	000077-90-7	Tributyl acetylacrylate	?	To be fixed
94000	000102-71-6	Triethanolamine	8	To be fixed
-	010277-04-0	Triethanolamine monooleate	-	To be fixed
94240	000077-89-4	Triethyl acetylacrylate	8	To be fixed

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
-	000094-28-0	Triethyleneglycol bis(2-ethylhexanoate)	-	To be fixed
-	000111-21-7	Triethyleneglycol diacetate	-	To be fixed
-	000120-56-9	Triethyleneglycol dibenzoate	-	To be fixed
-	025176-75-4	Triethyleneglycol dihexanoate	-	To be fixed
-	000106-10-5	Triethyleneglycol dioctanoate	-	To be fixed
-	000106-06-9	Triethyleneglycol dipelargonate	-	To be fixed
-	068583-52-8	Triethyleneglycol, mixed diesters with decanoic acid and octanoic acid	-	To be fixed
-	001528-48-9	Trimellitic acid, triheptyl ester	-	To be fixed
-	036631-30-8	Trimellitic acid, trisodecyl ester	-	To be fixed
-	053894-23-8	Trimellitic acid, trisononyl ester	-	To be fixed
-	000089-04-3	Trimellitic acid, trioctyl ester	-	To be fixed
-	025498-49-1	Tripropyleneglycol monomethyl ether	-	To be fixed
95730	009003-22-9	Vinyl acetate - vinyl chloride, copolymer	D	To be fixed
-	-	Waxes (paraffinic), refined, derived from petroleum based or synthetic hydrocarbon feedstocks	-	To be fixed
95880	008042-47-5	White mineral oil	9	To be fixed
96400	001314-23-4	Zirconium oxide	7	To be fixed

### 3.2 Binders (monomers)

Binders are the film-forming components of inks and coatings in which the colouring material is finely dispersed or dissolved. Binders are important for the transfer of the ink from the press to the substrate. After the drying of the print, binders serve to adhere the ink film to the printed surface and contribute to functional properties.

**List 1 - Substances evaluated by SCF/EFSA**

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION	ADI/TDI mg/kg bw
10120	000108-05-4	Acetic acid, vinyl ester	2	SML = 12 mg/kg	0.2
10690	000079-10-7	Acrylic acid	2	SML(T) = 6 mg/kg (5)	0.1
10780	000141-32-2	Acrylic acid, n-butyl ester	2	SML(T) = 6 mg/kg (as acrylic acid) (5)	0.1 (as acrylic acid)
11470	000140-88-5	Acrylic acid, ethyl ester	2	SML(T) = 6 mg/kg (as acrylic acid) (5)	0.1 (as acrylic acid)
11710	000096-33-3	Acrylic acid, methyl ester	2	SML(T) = 6 mg/kg (as acrylic acid) (5)	0.1 (as acrylic acid)
12130	000124-04-9	Adipic acid	1		5
12670	002855-13-2	1-Amino-3-aminomethyl-3,5,5-trimethylcyclohexane	2	SML = 6 mg/kg	0.1
12820	000123-99-9	Azelaic acid	2		3
13090	000065-85-0	Benzoic acid	1		5
13480	000080-05-7	2,2-Bis(4-hydroxyphenyl)propane	2	SML = 0.6 mg/kg	0.01
13720	000110-63-4	1,4-Butanediol	3	SML = 5 mg/kg	
13840	000071-36-3	1-Butanol	3		
14020	000098-54-4	4-tert-Butylphenol	3	SML = 0.05 mg/kg	
14110	000123-72-8	Butyraldehyde	3		
14200	000105-60-2	Caprolactam	2	SML = 15 mg/kg	0.25
14508	009004-36-8	Cellulose acetate butyrate	3		
14512	009004-39-1	Cellulose acetate propionate	3		

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION	ADI/TDI mg/kg bw
14710	000108-39-4	m-Cresol	3		
14740	000095-48-7	o-Cresol	3		
14770	000106-44-5	p-Cresol	3		
15310	000091-76-9	2,4-Diamino-6-phenyl-1,3,5-triazine	3	SML = 5 mg/kg	0.5
15760	000111-46-6	Diethyleneglycol	2	SML(T) = 30 mg/kg (1)	
16390	000126-30-7	2,2-Dimethyl-1,3-propanediol	3	SML = 0.05 mg/kg	
16630	000101-68-8	Diphenylmethane 4,4'-diisocyanate	4A	SML(T) = ND (DL = 0,01 mg/kg (as NCO) (6)	
16750	000106-89-8	Epichlorohydrin	4A	SML = ND (DL = 0.01 mg/kg)	
16925	009004-57-3	Ethylcellulose	2		NS
16960	000107-15-3	Ethylenediamine	2	SML = 12 mg/kg	0.2
16990	000107-21-1	Ethyleneglycol	2	SML(T) = 30 mg/kg (1)	0.5
17260	000050-00-0	Formaldehyde	3	SML = 15 mg/kg	
17290	000110-17-8	Fumaric acid	1		6
18100	000056-81-5	Glycerol	1		NS
18460	000124-09-4	Hexamethylenediamine	2	SML = 2.4 mg/kg	0.04
18700	000629-11-8	1,6-Hexanediol	3	SML = 0.05 mg/kg	
19060	000109-53-5	Isobutyl vinyl ether	3	SML = 0.05 mg/kg	
19110	004098-71-9	1-Isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	4A	SML(T) = ND (DL = 0,01 mg/kg (as NCO) (6)	
19150	000121-91-5	Isophthalic acid	3	SML = 5 mg/kg	
19532	008001-26-1	Linseed oil	3		
19540	000110-16-7	Maleic acid	2	SML(T) = 30 mg/kg (7)	0.5
19960	000108-31-6	Maleic anhydride	2	SML(T) = 30 mg/kg (as maleic acid) (7)	0.5
20020	000079-41-4	Methacrylic acid	2	SML(T) = 6 mg/kg (8)	0.1
20110	000097-88-1	Methacrylic acid, butyl ester	2	SML(T) = 6 mg/kg (as methacrylic acid) (8)	0.1 (as m. acid)
20890	000097-63-2	Methacrylic acid, ethyl ester	2	SML(T) = 6 mg/kg (as methacrylic acid) (8)	0.1 (as m. acid)

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION	ADI/TDI mg/kg bw
21130	000080-62-6	Methacrylic acid, methyl ester	2	SML(T) = 6 mg/kg (as methacrylic acid) (8)	0.1 (as m. acid)
21550	000067-56-1	Methanol	3		
22210	000098-83-9	alpha-Methylstyrene	3	SML = 0.05 mg/kg	
22450	009004-70-0	Nitrocellulose	3		
22780	000057-10-3	Palmitic acid	1		NS
22840	000115-77-5	Pentaerythritol	2		1
22960	000108-95-2	Phenol	2		1.5
23380	000085-44-9	Phthalic anhydride	2		1
23590	025322-68-3	Polyethyleneglycol	2		5
23651	025322-69-4	Polypropyleneglycol	3		
23740	000057-55-6	1,2-Propanediol	1		25
24100	008050-09-7	Rosin	2		1
24115	008050-31-5	Rosin, ester with glycerol	1		12.5
(84080)	008050-26-8	Rosin, ester with pentaerythritol	2		1
24520	008001-22-7	Soybean oil	3		
24610	000100-42-5	Styrene	4B		
24895	008001-21-6	Sunflower oil	3		
24910	000100-21-0	Terephthalic acid	2	SML = 7.5 mg/kg	0.125
25208	026471-62-5	Toluene diisocyanate	4A	SML(T) = ND (DL = 0.01 mg/kg (as NCO) (6)	
25420	000108-78-1	2,4,6-Triamino-1,3,5-triazine	2	SML = 30 mg/kg	0.5
25600	000077-99-6	1,1,1-Trimethylolpropane	2	SML = 6 mg/kg	0.1
25960	000057-13-6	Urea	0		
26050	000075-01-4	Vinyl chloride	4A	SML = ND (DL = 0.01 mg/kg)	

Temporary appendix to list 1: substances evaluated by other agencies than EFSA

NONE

List 2 - Substances not evaluated

PM/REF No	CAS No	NAME	SCF-L	RESTRICTION
10157	000098-86-2	Acetophenone	8	To be fixed
11100	057472-68-1	Acrylic acid, diester with dipropylene glycol	8	To be fixed
11170	026570-48-9	Acrylic acid, diester with polyethyleneglycol	8	To be fixed
11195	068901-05-3 042978-66-5	Acrylic acid, diester with tripropylene glycol	8	To be fixed
13510	001675-54-3	2,2-Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (= BADGE)	7	To be fixed
- (45520)	053814-24-7	2,2-Bis(4-hydroxyphenyl)propane-epichlorohydrin copolymer diacrylate	-	To be fixed
14910	-	p-Cresol, styrenated	9	To be fixed
15040	000108-94-1	Cyclohexanone	6A	To be fixed
15730	000542-92-7	1,3-Cyclopentadiene	8	To be fixed
16713	000077-73-6	Dicyclopentadiene	8	To be fixed
-	-	Drying oils	9	To be fixed
-	-	Drying oil acids	-	To be fixed
-	-	Epoxides, cycloaliphatic	-	To be fixed
17140	000109-92-2	Ethyl vinyl ether	7	To be fixed
18436	001687-30-5	Hexahydrophthalic acid	8	To be fixed
18441	000085-42-7	Hexahydrophthalic anhydride	8	To be fixed
20920	000688-84-6	Methacrylic acid, 2-ethylhexyl ester	8	To be fixed
22270	000107-25-5	Methyl vinyl ether	7	To be fixed
-	051728-26-8	Pentaerythritol ethoxylate tetraacrylate	-	To be fixed
25810	015625-89-5	1,1,1-Trimethylolpropane triacrylate	8	To be fixed
25975	-	Vegetable oil acids, dimers	8	To be fixed

### 3.3 Dyes

#### List 1 - Substances evaluated by SCF/EFSA

NONE

#### Temporary appendix to list 1: substances evaluated by other agencies than EFSA

CAS No	C.I. No	C.I. Name	Restriction
007576-65-0	47020	C.I. Disperse Yellow 54	To be fixed
000128-80-3	61565	C.I. Solvent Green 3	To be fixed
000082-38-2	60505	C.I. Solvent Red 111	To be fixed
020749-68-2	564120	C.I. Solvent Red 135	To be fixed
000081-48-1	60725	C.I. Solvent Violet 13	To be fixed
004702-90-3	48160	C.I. Solvent Yellow 93	To be fixed

#### List 2 - Substances not evaluated

CAS No	C.I. No	C.I. Name	Restriction
000129-17-9	42045	C.I. Acid Blue 1	To be fixed
003536-49-0	42051	C.I. Acid Blue 3	To be fixed
004368-56-3	62045	C.I. Acid Blue 62	To be fixed
071872-19-0	-	C.I. Acid Blue 317	To be fixed
004129-84-4	42650	C.I. Acid Violet 17	To be fixed
001934-21-0	19140	C.I. Acid Yellow 23	To be fixed
000587-98-4	13065	C.I. Acid Yellow 36	To be fixed
005601-29-6	-	C.I. Acid Yellow 129	To be fixed
003521-06-0	42025	C.I. Basic Blue 1	To be fixed
002787-91-9	51004	C.I. Basic Blue 3	To be fixed
003943-82-6	42140	C.I. Basic Blue 5	To be fixed
003251-84-1	44044	C.I. Basic Blue 55	To be fixed
000989-38-8	45160	C.I. Basic Red 1	To be fixed
000081-88-9	45170	C.I. Basic Violet 10	To be fixed
002390-63-8	45175	C.I. Basic Violet 11	To be fixed
006359-45-1	48013	C.I. Basic Violet 16	To be fixed
006358-36-7	41001	C.I. Basic Yellow 37	To be fixed
006428-31-5	35255	C.I. Direct Black 19	To be fixed
006473-13-8	35435	C.I. Direct Black 22	To be fixed
001330-38-7	74180	C.I. Direct Blue 86	To be fixed
012222-04-7	74190	C.I. Direct Blue 199	To be fixed
028407-37-6	24401	C.I. Direct Blue 218	To be fixed
203210-48-4	-	C.I. Direct Blue 301	To be fixed
001325-35-5	40002/40003	C.I. Direct Orange 15	To be fixed
006598-63-6	29156	C.I. Direct Orange 102	To be fixed
006227-02-7	27680	C.I. Direct Red 16	To be fixed
003441-14-3	29160	C.I. Direct Red 23	To be fixed
002610-11-9	28160	C.I. Direct Red 81	To be fixed

CAS No	C.I. No	C.I. Name	Restriction
?	-	C.I. Direct Red 262	To be fixed
006227-14-1	27885	C.I. Direct Violet 9	To be fixed
005489-77-0	27905	C.I. Direct Violet 51	To be fixed
003051-11-4	24890	C.I. Direct Yellow 4	To be fixed
001325-37-7	40000	C.I. Direct Yellow 11	To be fixed
008005-52-5	29000	C.I. Direct Yellow 44	To be fixed
003214-47-9	29025	C.I. Direct Yellow 50	To be fixed
067969-87-3	29042	C.I. Direct Yellow 118	To be fixed
072705-26-1	13965	C.I. Direct Yellow 157	To be fixed
?	-	C.I. Disperse Blue 355	To be fixed
213328-78-0	-	C.I. Disperse Blue 359	To be fixed
031482-56-1	11227	C.I. Disperse Orange 25	To be fixed
017418-58-5	60756	C.I. Disperse Red 60	To be fixed
000522-75-8	73300	C.I. Disperse Red 364	To be fixed
000128-95-0	61100	C.I. Disperse Violet 1	To be fixed
002832-40-8	11855	C.I. Disperse Yellow 3	To be fixed
027425-55-4	-	C.I. Disperse Yellow 82	To be fixed
003844-45-9	42090	C.I. Food Blue 2	To be fixed
003536-49-0	42051	C.I. Food Blue 5	To be fixed
004553-89-3	20285	C.I. Food Brown 3	To be fixed
003567-69-9	14720	C.I. Food Red 3	To be fixed
002611-82-7	16255	C.I. Food Red 7	To be fixed
000915-67-3	16185	C.I. Food Red 9	To be fixed
002783-94-0	15985	C.I. Food Yellow 3	To be fixed
001934-21-0	19140	C.I. Food Yellow 4	To be fixed
016823-51-1	61205:1	C.I. Reactive Blue 5	To be fixed
012238-09-4	74460	C.I. Reactive Blue 7	To be fixed
149315-83-3	-	C.I. Reactive Blue 238	To be fixed
070210-21-8	18279	C.I. Reactive Orange 5	To be fixed
070161-14-7	-	C.I. Reactive Orange 12	To be fixed
070616-89-6	18270	C.I. Reactive Orange 13	To be fixed
070210-20-7	18208	C.I. Reactive Red 24	To be fixed
064181-81-3	-	C.I. Reactive Red 43	To be fixed
070210-46-7	18209	C.I. Reactive Red 45	To be fixed
061951-82-4	25810	C.I. Reactive Red 120	To be fixed
171172-56-8	-	C.I. Reactive Red 220	To be fixed
140876-11-5	-	C.I. Reactive Red 228	To be fixed
132579-39-6	-	C.I. Reactive Red 235	To be fixed
050662-99-2	18972	C.I. Reactive Yellow 2	To be fixed
006539-67-9	13245	C.I. Reactive Yellow 3	To be fixed
004197-25-5	26150	C.I. Solvent Black 3	To be fixed
012237-22-8	-	C.I. Solvent Black 27	To be fixed
012237-23-9	-	C.I. Solvent Black 28	To be fixed
061901-87-9	-	C.I. Solvent Black 29	To be fixed
032517-36-5	-	C.I. Solvent Black 34	To be fixed
061931-53-1	12195 + 12197	C.I. Solvent Black 35	To be fixed
094765-62-5	-	C.I. Solvent Black 45	To be fixed
006786-83-0	44045:1	C.I. Solvent Blue 4	To be fixed
001328-54-7	74350	C.I. Solvent Blue 25	To be fixed
017354-14-2	61554	C.I. Solvent Blue 35	To be fixed
003861-73-2	13390	C.I. Solvent Blue 37	To be fixed
061725-69-7	-	C.I. Solvent Blue 44	To be fixed
037229-23-5	-	C.I. Solvent Blue 45	To be fixed

CAS No	C.I. No	C.I. Name	Restriction
012226-78-7	-	C.I. Solvent Blue 67	To be fixed
012237-24-0	-	C.I. Solvent Blue 70	To be fixed
061725-72-2	-	C.I. Solvent Brown 28	To be fixed
061901-89-1	-	C.I. Solvent Brown 35	To be fixed
061725-74-4	-	C.I. Solvent Brown 37	To be fixed
061725-75-5	-	C.I. Solvent Brown 42	To be fixed
061116-28-7	-	C.I. Solvent Brown 43	To be fixed
061969-45-7	-	C.I. Solvent Brown 44	To be fixed
071872-85-0	-	C.I. Solvent Brown 58	To be fixed
013463-42-8	18745:1	C.I. Solvent Orange 5	To be fixed
010127-28-3	18736:1	C.I. Solvent Orange 6	To be fixed
061725-76-6	-	C.I. Solvent Orange 11	To be fixed
061813-62-5	-	C.I. Solvent Orange 25	To be fixed
061901-91-5	-	C.I. Solvent Orange 41	To be fixed
013011-62-6	-	C.I. Solvent Orange 45	To be fixed
012237-30-8	-	C.I. Solvent Orange 54	To be fixed
013463-42-8	18745:1	C.I. Solvent Orange 56	To be fixed
061969-46-8	-	C.I. Solvent Orange 59	To be fixed
052256-37-8	12714	C.I. Solvent Orange 62	To be fixed
016294-75-0	68550	C.I. Solvent Orange 63	To be fixed
006925-69-5	564100	C.I. Solvent Orange 78	To be fixed
110342-29-5	-	C.I. Solvent Orange 99	To be fixed
050926-68-6	-	C.I. Solvent Red 7	To be fixed
033270-70-1	12715	C.I. Solvent Red 8	To be fixed
000085-83-6	26105	C.I. Solvent Red 24	To be fixed
003176-79-2	26110	C.I. Solvent Red 25	To be fixed
061725-78-8	16260 + 45170:1	C.I. Solvent Red 35	To be fixed
000509-34-2	-	C.I. Solvent Red 49	To be fixed
061725-81-3	-	C.I. Solvent Red 89	To be fixed
061901-92-6	-	C.I. Solvent Red 91	To be fixed
061901-93-7	-	C.I. Solvent Red 92	To be fixed
053802-03-2	-	C.I. Solvent Red 109	To be fixed
012237-26-2	-	C.I. Solvent Red 118	To be fixed
012237-27-3	-	C.I. Solvent Red 119	To be fixed
012227-55-3	-	C.I. Solvent Red 122	To be fixed
012239-74-6	-	C.I. Solvent Red 124	To be fixed
012271-00-0	-	C.I. Solvent Red 125	To be fixed
061969-48-0	-	C.I. Solvent Red 127	To be fixed
061725-84-6	-	C.I. Solvent Red 130	To be fixed
061725-85-7	-	C.I. Solvent Red 132	To be fixed
069899-68-9	-	C.I. Solvent Red 160	To be fixed
164251-88-1	-	C.I. Solvent Red 195	To be fixed
?	77301	C.I. Solvent Red 233	To be fixed
061725-86-8	16055 + 45170	C.I. Solvent Violet 2	To be fixed
052080-58-7	42535:1	C.I. Solvent Violet 8	To be fixed
061725-87-9	-	C.I. Solvent Violet 24	To be fixed
004314-14-1	12700	C.I. Solvent Yellow 16	To be fixed
006407-78-9	12740	C.I. Solvent Yellow 18	To be fixed
010343-55-2	13900:1	C.I. Solvent Yellow 19	To be fixed
005601-29-6	-	C.I. Solvent Yellow 21	To be fixed
037219-73-1	-	C.I. Solvent Yellow 25	To be fixed
006706-82-7	21230	C.I. Solvent Yellow 29	To be fixed

<b>CAS No</b>	<b>C.I. No</b>	<b>C.I. Name</b>	<b>Restriction</b>
061931-84-8	48045	C.I. Solvent Yellow 32	To be fixed
019125-99-6	561930	C.I. Solvent Yellow 43	To be fixed
002478-20-8	56200	C.I. Solvent Yellow 44	To be fixed
061725-88-0	-	C.I. Solvent Yellow 48	To be fixed
002481-94-9	11021	C.I. Solvent Yellow 56	To be fixed
061901-95-9	-	C.I. Solvent Yellow 62	To be fixed
012237-31-9	-	C.I. Solvent Yellow 79	To be fixed
012227-56-4	-	C.I. Solvent Yellow 81	To be fixed
012227-67-7	-	C.I. Solvent Yellow 82	To be fixed
012239-75-7	-	C.I. Solvent Yellow 83	To be fixed
061116-27-6	-	C.I. Solvent Yellow 83:1	To be fixed
061931-55-3	-	C.I. Solvent Yellow 88	To be fixed
061969-51-5	-	C.I. Solvent Yellow 89	To be fixed
144246-02-6	-	C.I. Solvent Yellow 135	To be fixed
109945-04-2	-	C.I. Solvent Yellow 146	To be fixed
104244-10-2	-	C.I. Solvent Yellow 162	To be fixed

### 3.4 Pigments

#### List 1 - Substances evaluated by SCF/EFSA

NONE

#### Temporary appendix to list 1: substances evaluated by other agencies than EFSA

CAS No	C.I. No	C.I. Name	Restriction
001333-86-4	77266	C.I. Pigment Black 7	To be fixed
012227-89-3	77499	C.I. Pigment Black 11	To be fixed
000147-14-8	74160	C.I. Pigment Blue 15	To be fixed
000147-14-8	74160	C.I. Pigment Blue 15:1	To be fixed
000147-14-8	74160	C.I. Pigment Blue 15:2	To be fixed
000147-14-8	74160	C.I. Pigment Blue 15:3	To be fixed
000147-14-8	74160	C.I. Pigment Blue 15:4	To be fixed
000147-14-8	74160	C.I. Pigment Blue 15:6	To be fixed
000574-93-6	74100	C.I. Pigment Blue 16	To be fixed
014038-43-8	77510	C.I. Pigment Blue 27	To be fixed
057455-37-5	77007	C.I. Pigment Blue 29	To be fixed
000081-77-6	69800	C.I. Pigment Blue 60	To be fixed
035869-64-8	20060	C.I. Pigment Brown 23	To be fixed
001328-53-6	74260	C.I. Pigment Green 7	To be fixed
001330-37-6	74255	C.I. Pigment Green 37	To be fixed
007429-90-5	77000	C.I. Pigment Metal 1	To be fixed
007440-50-8	77400	C.I. Pigment Metal 2	To be fixed
003468-63-1	12075	C.I. Pigment Orange 5	To be fixed
012236-62-3	11780	C.I. Pigment Orange 36	To be fixed
004424-06-0	71105	C.I. Pigment Orange 43	To be fixed
072102-84-2	12760	C.I. Pigment Orange 64	To be fixed
084632-50-8	561200	C.I. Pigment Orange 71	To be fixed
006041-94-7	12310	C.I. Pigment Red 2	To be fixed
002425-85-6	12120	C.I. Pigment Red 3	To be fixed
002814-77-9	12085	C.I. Pigment Red 4	To be fixed
006410-41-9	12490	C.I. Pigment Red 5	To be fixed
006410-32-8	12385	C.I. Pigment Red 12	To be fixed
007023-61-2	15865:2	C.I. Pigment Red 48:2	To be fixed
015782-05-5	15865:3	C.I. Pigment Red 48:3	To be fixed
001103-39-5	15630:2	C.I. Pigment Red 49:2	To be fixed
017852-99-2	15860:1	C.I. Pigment Red 52:1	To be fixed
005281-04-9	15850:1	C.I. Pigment Red 57:1	To be fixed
001309-37-1	77491	C.I. Pigment Red 101	To be fixed
006535-46-2	12370	C.I. Pigment Red 112	To be fixed
016043-40-6	73915	C.I. Pigment Red 122	To be fixed
005280-78-4	20735	C.I. Pigment Red 144	To be fixed
005280-68-2	12485	C.I. Pigment Red 146	To be fixed
004948-15-6	71137	C.I. Pigment Red 149	To be fixed
003905-19-9	20730	C.I. Pigment Red 166	To be fixed
002786-76-7	12475	C.I. Pigment Red 170	To be fixed
002379-74-0	73360	C.I. Pigment Red 181	To be fixed

<b>CAS No</b>	<b>C.I. No</b>	<b>C.I. Name</b>	<b>Restriction</b>
003089-17-6	73907	C.I. Pigment Red 202	To be fixed
031778-10-6	12514	C.I. Pigment Red 208	To be fixed
082643-43-4	-	C.I. Pigment Red 214	To be fixed
052238-92-3	20067	C.I. Pigment Red 242	To be fixed
088949-33-1	561300	C.I. Pigment Red 264	To be fixed
001047-16-1	73900	C.I. Pigment Violet 19	To be fixed
006358-30-1	51319	C.I. Pigment Violet 23	To be fixed
012225-08-0	12517	C.I. Pigment Violet 32	To be fixed
057971-98-9	51345	C.I. Pigment Violet 37	To be fixed
002379-75-1	73395	C.I. Pigment Violet 38	To be fixed
001345-05-7	77115	C.I. Pigment White 5	To be fixed
013463-67-7	77891	C.I. Pigment White 6	To be fixed
007727-43-7	77120	C.I. Pigment White 21	To be fixed
001332-73-6	77002	C.I. Pigment White 24	To be fixed
010101-41-4	77231	C.I. Pigment White 25	To be fixed
002512-29-0	11680	C.I. Pigment Yellow 1	To be fixed
006486-23-3	11710	C.I. Pigment Yellow 3	To be fixed
005979-28-2	20040	C.I. Pigment Yellow 16	To be fixed
051274-00-1	77492	C.I. Pigment Yellow 42	To be fixed
008007-18-9	77788	C.I. Pigment Yellow 53	To be fixed
012286-66-7	13940	C.I. Pigment Yellow 62	To be fixed
005580-57-4	20710	C.I. Pigment Yellow 93	To be fixed
005280-80-8	20034	C.I. Pigment Yellow 95	To be fixed
005590-18-1	56280	C.I. Pigment Yellow 110	To be fixed
079953-85-8	20037	C.I. Pigment Yellow 128	To be fixed
030125-47-4	56300	C.I. Pigment Yellow 138	To be fixed
036888-99-0	56298	C.I. Pigment Yellow 139	To be fixed
077465-46-4	-	C.I. Pigment Yellow 155	To be fixed
077804-81-0	21290	C.I. Pigment Yellow 180	To be fixed

## List 2 - Substances not evaluated

CAS No	C.I. No	C.I. Name	Restriction
001325-87-7	42595:2	C.I. Pigment Blue 1	To be fixed
058569-23-6	42750:1	C.I. Pigment Blue 19	To be fixed
006417-46-5	42800	C.I. Pigment Blue 56	To be fixed
001324-76-1	42765:1	C.I. Pigment Blue 61	To be fixed
082338-76-9	42595:4	C.I. Pigment Blue 62	To be fixed
014154-42-8	741300	C.I. Pigment Blue 79	To be fixed
006992-11-6	12510	C.I. Pigment Brown 25	To be fixed
211502-16-8	-	C.I. Pigment Brown 41	To be fixed
001325-75-3	42040:1	C.I. Pigment Green 1	To be fixed
014302-13-7	74265	C.I. Pigment Green 36	To be fixed
003520-72-7	21110	C.I. Pigment Orange 13	To be fixed
006505-28-8	21160	C.I. Pigment Orange 16	To be fixed
015793-73-4	21115	C.I. Pigment Orange 34	To be fixed
012236-64-5	12367	C.I. Pigment Orange 38	To be fixed
063467-26-5	15602	C.I. Pigment Orange 46	To be fixed
052846-56-7	11775	C.I. Pigment Orange 62	To be fixed
006448-95-9	12315	C.I. Pigment Red 22	To be fixed
006471-49-4	12355	C.I. Pigment Red 23	To be fixed
007585-41-3	15865:1	C.I. Pigment Red 48:1	To be fixed
005280-66-0	15865:4	C.I. Pigment Red 48:4	To be fixed
001103-38-4	15630:1	C.I. Pigment Red 49:1	To be fixed
002092-56-0	15585	C.I. Pigment Red 53	To be fixed
005160-02-1	15585:1	C.I. Pigment Red 53:1	To be fixed
012224-98-5	45160	C.I. Pigment Red 81	To be fixed
080083-40-5	45160:3	C.I. Pigment Red 81:1	To be fixed
075627-12-2	45161:1	C.I. Pigment Red 81:2	To be fixed
068310-07-6	45161:2	C.I. Pigment Red 81:3	To be fixed
085959-61-1	45161:5	C.I. Pigment Red 81:4	To be fixed
063022-06-0	45160:4	C.I. Pigment Red 81:5	To be fixed
001332-25-8	77015 77491 77538	C.I. Pigment Red 102	To be fixed
068227-78-1	12433	C.I. Pigment Red 147	To be fixed
012237-63-7	45160:2	C.I. Pigment Red 169	To be fixed
012225-06-8	12515	C.I. Pigment Red 176	To be fixed
099402-80-9	12487	C.I. Pigment Red 184	To be fixed
061951-98-2	12516	C.I. Pigment Red 185	To be fixed
061847-48-1	12467	C.I. Pigment Red 188	To be fixed
061932-63-6	12477	C.I. Pigment Red 210	To be fixed
107397-16-0	-	C.I. Pigment Red 211	To be fixed
084632-65-5	56110	C.I. Pigment Red 254	To be fixed
036968-27-1	12474	C.I. Pigment Red 266	To be fixed
067990-05-0	12466	C.I. Pigment Red 269	To be fixed
001326-03-0	45170:2	C.I. Pigment Violet 1	To be fixed
001326-04-1	45175:1	C.I. Pigment Violet 2	To be fixed
001325-82-2	42535:2	C.I. Pigment Violet 3	To be fixed
010101-66-3	77742	C.I. Pigment Violet 16	To be fixed
012237-62-6	42535:3	C.I. Pigment Violet 27	To be fixed
064070-98-0	42555:2	C.I. Pigment Violet 39	To be fixed
001314-13-2	77947	C.I. Pigment White 4	To be fixed
001314-98-3	77975	C.I. Pigment White 7	To be fixed

<b>CAS No</b>	<b>C.I. No</b>	<b>C.I. Name</b>	<b>Restriction</b>
000471-34-1	77220	C.I. Pigment White 18	To be fixed
001318-74-7	77005	C.I. Pigment White 19	To be fixed
012001-26-2	77019	C.I. Pigment White 20	To be fixed
014807-96-6	77718	C.I. Pigment White 26	To be fixed
007631-86-9	77811	C.I. Pigment White 27	To be fixed
001657-16-5	11665	C.I. Pigment Yellow 4	To be fixed
004106-67-6	11600	C.I. Pigment Yellow 5	To be fixed
006358-85-6	21090	C.I. Pigment Yellow 12	To be fixed
005102-83-0	21100	C.I. Pigment Yellow 13	To be fixed
005468-75-7	21095	C.I. Pigment Yellow 14	To be fixed
004531-49-1	21105	C.I. Pigment Yellow 17	To be fixed
006358-37-8	21096	C.I. Pigment Yellow 55	To be fixed
006358-31-2	11741	C.I. Pigment Yellow 74	To be fixed
022094-93-5	21127	C.I. Pigment Yellow 81	To be fixed
005567-15-7	21108	C.I. Pigment Yellow 83	To be fixed
012225-18-2	11767	C.I. Pigment Yellow 97	To be fixed
069771-45-5	11745	C.I. Pigment Yellow 111	To be fixed
090268-23-8	21101	C.I. Pigment Yellow 126	To be fixed
068610-86-6	21102	C.I. Pigment Yellow 127	To be fixed
025157-64-6	12764	C.I. Pigment Yellow 150	To be fixed
031837-42-0	13980	C.I. Pigment Yellow 151	To be fixed
078952-72-4	21098	C.I. Pigment Yellow 174	To be fixed
090268-24-9	21103	C.I. Pigment Yellow 176	To be fixed
076199-85-4	56290	C.I. Pigment Yellow 185	To be fixed
023792-68-9	21094	C.I. Pigment Yellow 188	To be fixed
082199-12-0	11785	C.I. Pigment Yellow 194	To be fixed

#### **4. Specific requirements for substances used in the manufacture of packaging inks**

##### **4.1 Purity requirements for colourants**

All colourants used in the manufacture of packaging inks have to comply to the specifications given in Council of Europe Resolution AP (89) 1 on the use of colourants in plastic materials intended to come into contact with food.

##### **4.2 Migration limits**

All restrictions e.g. specific migration limit (SML) of substances listed in the *Inventory list* or in existing European regulations, such as the Plastics Directive 2002/72/EC, the Regenerated Cellulose Film Directive 2004/14/EC as well as in other Council of Europe resolutions are to be observed.

**TECHNICAL DOCUMENT N° 3**

**GUIDELINES ON TEST CONDITIONS FOR PACKAGING INKS  
APPLIED TO THE NON-FOOD CONTACT SURFACE OF FOOD  
PACKAGING MATERIALS AND ARTICLES INTENDED TO COME  
INTO CONTACT WITH FOODSTUFFS**

## **GUIDELINES ON TEST CONDITIONS FOR PACKAGING INKS APPLIED TO THE NON-FOOD CONTACT SURFACE OF FOOD PACKAGING MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS**

### **1. Introduction**

This technical document gives guidance on the test conditions to be used for testing packaging inks applied to non-food contact surface of food packaging materials and articles intended to come into contact with food. It should be read in conjunction with the specifications laid down in Resolution ResAP (2005) 2 on packaging inks applied to non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs and the corresponding Technical Document N° 1 on requirements for the selection of packaging ink raw materials.

No specific methods of analysis are included in this document though some international standards for materials and articles in contact with foodstuffs are listed.

### **2. Sampling**

The ink to be tested should be printed on the same substrate and by the same procedure that is intended for the final product.

N.B. The ink should not be tested as such as its composition may change during the printing process. Also the substrate greatly influences the migration properties of the components in the ink.

Tests pieces from printed samples should be chosen so that all components of the ink are represented at the same percentage composition as in the original material or article.

### **3. Testing for compliance with SML restrictions**

#### **3.1 General rules**

In principle, testing for compliance with SML restrictions should be carried out by migration testing, using the conditions established in the EU Regulation on migration testing<sup>1)</sup>. Extraction tests can be used if, on the basis of scientific evidence, the results obtained using these tests are at least equal to those obtained by migration testing using the conventional EU test simulants or real foodstuffs.

Migration testing can be replaced by mathematical simulation or by calculation of the maximum possible migration. In both cases the amount of the actual substance must be either known or determined by exhaustive extraction. A formula and an example are given in the Appendix.

N.B. Transfer of a packaging substance from a packaging material or an article can take place either as diffusion through the substrate or as a result of so-called set-off. In migration or extraction tests the result will represent the sum of both transfer mechanisms, but when using mathematical modelling, the transfer by set-off should be estimated separately.

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1) EU Directive 97/48/EC

### **3.2 Migration tests**

When possible, testing should be carried out using the same kind of food that is to come into contact with the material or article. However, if this is not practical, a food simulant may be used.

The EU Regulation on migration testing should be used for guidance on the selection of appropriate simulants and exposure conditions (time and temperature). For those foodstuffs for which in the EU Regulation on migration testing no simulant is provided (“dry foodstuffs”), migration testing should be carried out using modified polyphenylene oxide (“MPPO”) as a test medium.

Testing should take into account the worst foreseeable conditions of use for the material. This includes the type of foodstuff with which the printed material or article comes into contact, and the time and temperature of contact.

### **3.3 Mathematical simulation**

Mathematical modelling can be used to predict the migration under real conditions of use and verify the compliance with the specific migration limits. For that purpose, recognised diffusion models based on scientific evidence should be applied. In order to apply modelling to a printing ink substance that contaminates the surface layer in contact with the foodstuff (set-off), the amount of this substance at the surface in contact with the foodstuff has to be known.

## **4. Special cases**

### **4.1 Packagings and articles for use at high temperature**

Migration testing should be carried out using only MPPO as a simulant regardless of the type of foodstuff, using the time and temperature of contact provided in EU Regulation on migration testing.

Testing should take into account possible degradation products formed at elevated temperatures. When carrying out extraction testing to determine compliance with the Resolution and the corresponding Technical Document N° 1, the sample should, in principle, be preheated in a closed container, according to the time and temperature conditions given in the EU Regulation on migration testing.

### **4.2 Contact with dry food**

As it is possible that migration occurs from a printed surface, either because of presence of volatile substances in the print or an intimate contact between substances in the print and the dry foodstuff (set-off), the print is subject to the limitations stated in the Resolution and in Technical Document N° 1, though the printed material or article is in contact with dry foodstuffs only. In these situations, a migration testing with the food itself under the worst foreseeable conditions or a simulant appropriate to that specific foodstuff shall be carried out.

## **5. Methods of analysis**

There are no specific international standards for packaging inks dealing with determination of ink substances. The progress in chemical analysis is so rapid that any method may be considered obsolete after a limited number of years. It is therefore recommended that the reader search the literature in order to find an appropriate method. Special attention should be paid to the performance characteristics (trueness and precision) at the specified limit.

As some guidance may be found in the standards dealing with substances in paper and board and in plastics, some references are given below.

## **6. References and Standards**

Note for Guidance to petitioners for authorisation of food contact substances and materials, EFSA document, update 21.02.2005.

CEN 14338. Paper and Board. Migration into modified polyphenylene oxide (MPPO)

EN 118613, parts 1 – 15. Materials and articles in contact with foodstuffs. Plastics

EN 13130, parts 1 – 28. Materials and articles in contact with foodstuffs. Plastic substances subjected to limitations.

## APPENDIX

### Calculation of maximum possible migration; formula and example

In this so-called “worst case calculation” it is assumed that migration of the actual substance into the foodstuff is one hundred percent. Also the amount of the actual substance in the print or in the package or article must be either known or determined by exhaustive extraction.

The maximum possible migration is calculated in accordance with the principle in the “Note for Guidance to petitioners for authorisation of food contact substances and materials” by the formula:

$$M = \frac{Q \times C \times A}{10}$$

where

M is the maximum concentration of the substance in the foodstuff, expressed in mg/kg foodstuff;

Q is the surface weight of print on the surface of the package or article, in gram per square meter;

C is the concentration of the substance in the print, in percentage;

A is the area of package or article being in contact with 1 kg foodstuff. This is normally 6 dm<sup>2</sup>.

**Example:** The quantity of print on a paper box is 1 g/m<sup>2</sup>. The concentration of the actual substance in the print is 0,5 %.

The area of the paper box in contact with food is 6 dm<sup>2</sup>.

$$M = \frac{1 \times 0,5 \times 6}{10} = 0,3$$

Consequently, the maximum possible migration, M is 0,3 mg/kg foodstuff.