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

RUBBER PRODUCTS INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

Version 1 – 10.06.2004

NOTE TO THE READER

The following documents are part of the Policy statement for rubber products intended to come into contact with foodstuffs:

- Resolution ResAP (2004) 4 on rubber products intended to come into contact with foodstuffs

- Technical document No. 1 - List of substances to be used in the manufacture of rubber products intended to come into contact with foodstuffs (to be prepared)

- Technical document No. 2 - Practical guide for users of Resolution ResAP (2004) 4 on rubber products intended to come into contact with foodstuffs

- Appendix 1 - Inventory list of substances used for the manufacture of rubber products intended to come into contact with foodstuffs

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

www.coe.int/soc-sp

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RESOLUTION RESAP (2004) 4 ON RUBBER PRODUCTS INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

(Adopted by the Committee of Ministers on 1st December 2004 at the 907th meeting of the Ministers' Deputies)

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

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

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

a. raising the level of health protection of consumers in its widest 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 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 rubber products intended to come into contact with foodstuffs may, by reason of migration of rubber constituents to the foodstuffs, pose under certain conditions a risk to human health;

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

Recommends to the governments of the member states of the Partial Agreement in the Social and Public Health field to take into account in their national laws and regulations on rubber products intended to come into contact with foodstuffs the principles set out hereafter.

APPENDIX TO RESOLUTION RESAP (2004) 4 on rubber product included to come into contact with foodstuffs

1. Field of application

1.1. The resolution applies to finished materials and articles constituted of rubber including thermoplastic rubber as well as blends of rubber with plastics and other materials, which are intended to come into contact with or are placed in contact with foodstuffs, hereafter called “rubber products”.

1.2. It also applies to rubber products which are in contact with water intended for human consumption.

1.3. It does not apply to fixed public or private supply equipment [1].

1.4. It does not affect the national regulations concerning the quality of drinking water, and therefore the limits laid down in the national regulations for drinking water should be met.

1.5. It does not apply to soothers which are primarily not considered as food contact materials.

1.6. A non-exhaustive list of common application of rubber products is:

- food transportation (conveyer belts, hoses and tubing)
- handling food (gloves)
- food netting
- pipe-work components (seals, gaskets, flexible connectors and diaphragm/butterfly valves)
- pumping systems (progressive cavity pumps stators, diaphragm pumps)
- plate heat exchangers (gaskets)
- general seals and gaskets (used in machinery and storage vessels)
- can sealants
- bottle seals and closures
- feeding teats and breast caps (nipple shields)

2. Definitions

Within the resolution:

2.1. rubber designates a family of materials showing property of high elasticity. In an unaged state, rubber can be substantially deformed under stress, but recovers nearly to its original stage when the stress is removed. Rubber is usually made from a mixture of (solid and/or liquid) materials and can be subjected to a curing process, which changes its nature.

2.2. thermoplastic rubber is a polymer or blend of polymers that does not require vulcanisation or cross-linking during processing, yet has properties, at its service temperature, similar to those of vulcanised rubber. These properties disappear at processing temperature, so that further processing is possible, but return when the material is returned to its service temperature.

3. Specifications

Rubber products used for food contact application should, under normal or foreseeable conditions of use, meet the following conditions:

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

3.2. they should be manufactured in accordance with the following requirements:

3.2.1. they should comply with guidelines on good manufacturing practice for food contact rubber;

3.2.2. they should be manufactured using the substances of "T*echnical document No. 1 List of substances to be used in the manufacture of rubber products intended to come into contact with foodstuffs*" and according to the conditions therein specified for each of the categories as set out in Article 5 of the resolution. However they can contain other decomposition and reaction products as well as impurities originating from authorised substances provided their migration complies with Article 3.1. of the resolution;

3.2.3. rubber products of Categories I and II should not transfer their constituents to foodstuffs or food simulants in total quantities > 60 mg/kg of food or food simulant (overall migration limit).

3.2.4. rubber products of Categories I and II should comply with the restrictions laid down in "*Technical document No. 1 - List of substances to be used in the manufacture of rubber products intended to come into contact with foodstuffs"*. In addition these rubber products should comply with the requirements set out in Table 1 of the resolution, excepting rubber teats which should comply with Directive 93/11/EEC.

Table 1: Restriction for N-nitrosamines, N-nitrosatable substances, aromatic amines

Substance/substance group	Restrictions
- N-nitrosamines	ND[1] (DL[2] = 0.01 mg/kg food or food stimulant)
- N-nitrosatable substances	ND (DL = 0.1 mg/kg food or food simulant)
Aromatic amines	ND unless an SML is set in Technical document N° 1

[1] ND = not detectable [2] DL = the required detection limit of the analytical method at the indicated value

3.3. Substances should be used only in amounts strictly needed for the manufacturing and performance of the rubber product.

3.4. Where rubber is blended with plastics and/or other materials, the composition of these materials used in the blends should comply with relevant Council of Europe resolutions or EU directives, or, in their absence, with relevant national regulations. In addition the rubber products should comply with the overall migration limit as well as with the relevant specific migration limits.

3.5. Rubber teats should also comply with Directive 93/11/EEC.

4. Compliance testing

4.1. Verification of compliance with the quantitative restrictions should be carried out according to the requirements laid down in "*Technical document No. 2 - Practical guide for users of Resolution ResAP (2004) 4 on rubber products intended to come into contact with foodstuffs"*.

4.2. The verification of compliance with the specific migration limits provided for in Article 3.2. of the resolution does not apply, if it can be established that compliance with the overall migration limit laid down in Article 3.2.3. of the resolution implies that the specific migration limits are not exceeded.

4.3. The verification of compliance with the specific migration limits provided for in Article 3.2. of the resolution does not apply, if it can be established that, by assuming complete migration of the residual substance in the rubber product, it cannot exceed the specific limit of migration.

4.4. The verification of compliance with the specific migration limits provided for in Article 3.2.3. of the resolution may be ensured by the determination of the quantity of a substance in the finished rubber product provided that a relationship between that quantity and the value of the specific migration of the substance has been established either by an adequate experimentation or by the application of generally recognised diffusion models based on scientific evidence. To demonstrate the non-compliance of a rubber product, confirmation of the estimated migration value by experimental testing is obligatory.

4.5. Rubber products intended for repeated use should be subjected to tests according to Directive 2002/72/EC, Annex I.

4.6. The overall migration and specific limits per feeding teats are one-fifth of the values[2] set out in "*Technical document No. 1 - List of substances to be used in the manufacture of rubber products intended to come into contact with foodstuffs"*.

4.7. Rubber products belonging to Category III do not require migration testing, unless otherwise specified.

5. Classification and migration requirements for rubber products

Rubber products are classified in three categories[3]:

5.1. Category I comprising the following rubber products for which migration testing is required:

- feeding teats
- rubber products to come in contact with baby food, for which the R-total is equal or greater than 0.001.

5.2. Category II comprising rubber products for which R-total is equal or greater than 0.001 and for which migration testing is required.

5.3. Category III comprising rubber products for which R-total is smaller than 0.001 and for which migration testing is not required, except for rubber products containing substances listed in Table 1 and Category III substances with an SML in "*Technical document No. 1 - List of substances to be used in the manufacture of rubber products intended to come into contact with foodstuffs".*

Notes

1) see Directive 89/109/EEC, Article 1

2) Concerning single-use teats, for practical reasons it is assumed that five bottle teats are used per child per day.

3) Taking into account the wide variety of the applications of rubber products the migration may vary with the application. Therefore rubber products are classified in different categories. The level of migration for rubber products may be estimated by taking into account four factors, R_1, R_2, R_3 and R_4 referring respectively to the relative contact area, contact temperature, contact time and number of times that the article is used. Categories are based on the intended use or on the result of the multiplication of the four factors (R_1x R_2,x R_3 x R_4 = R_{total}).

The factors R_1, R_2, R_3 and R_4 are defined and determined as follows:

R_1 refers to the relative contact area (A_R) between rubber products and food or beverage, expressed in cm² of rubber surface per kg of food or beverage. For a relative area smaller than or equal to 100 cm²/kg foodstuffs, R_1 has a value calculated according to the formula: $R_1 = A_R : 100$. For a relative surface larger than 100 cm²/kg, R_1 always has the value 1.00.

R_2 refers to the temperature during the contact period of the rubber product with the food or beverage. At a temperature lower than or equal to 130°C, R_2 has a value calculated according to the formula: $R_2 = 0.05\ e^{0.023T}$. Where "e" is the base of the natural or Napierian logarithms and T is the contact temperature, expressed in ^{o}C. For temperatures higher than 130 ^{0}C, R_2 always has the value 1.00.

R_3 refers to the time t, expressed in hours, during which a rubber product is in contact with the food or beverage. For a contact time shorter than or equal to 10 hours, R_3 has a value calculated according to the formula: $R_3 = t : 10$. For a contact time of more than 10 hours, R_3 has the value 1.00.

R_4 refers to the number of times N that one and the same rubber product, or part of that rubber product comes into recurrent contact with a quantity of food or beverage. If the number of contact times is greater than 1000, then R_4 is calculated according to the formula: $^{10}\log R_4 = 6 - 2\ ^{10}\log N$. If the number of contact times is smaller than or equal to 1000, then R_4 always has the value 1.00.

(For detailed information see "*Technical document No. 2 - Practical guide for users of Resolution ResAP (2004) 4 on rubber products intended to come into contact with foodstuffs"*).

References:

Council Directive of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs (89/109/EEC).
Official Journal of the European Communities L40 11.2.89.

Commission Directive of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs (82/711/EEC).
Official Journal of the European Communities L297 23.10.82.

Commission Directive of 29 July 1997 amending for the second time Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs (97/48/EC).
Official Journal of the European Communities L222 18.2.97.

Commission Directive of 15 March 1993 concerning the release of N-nitrosamines and N-nitrosatable substances from elastomers or rubber teats and soothers 93/11/EEC).
Official Journal of the European Communities L93 17.04.93.

Methods for determining the release of N-nitrosamines and N-nitrosatable substances from elastomers or rubber teats and soothers of the European Committee for Standardisation (CEN).
EN 12868 September 1999.

Council of Europe Resolution AP (89) 1 on the use of colourants in plastic materials.

Council of Europe Resolution AP (99) 3 on the use of Silicones for food contact applications.

TECHNICAL DOCUMENT No. 2

PRACTICAL GUIDE FOR USERS OF RESOLUTION RESAP (2004) 4 ON RUBBER PRODUCTS INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

Version 1 - 00.00.2004

1. INTRODUCTION

The Practical Guide is intended to provide guidelines for bodies and persons concerned with the application of *Resolution ResAP (2004) 4 on rubber products intended to come into contact with foodstuffs* and the related technical documents.

The Practical Guide has no legally binding value.

Materials coming into contact with foodstuffs are regulated in EU by the framework Directive 89/109/EEC on the approximation of the laws of the member states relating to materials and articles intended to come into contact with foodstuffs.

It stipulates that all kinds of materials and articles intended to come into contact with foodstuffs "should be manufactured in compliance with good manufacturing practice so that, under their normal or foreseeable conditions of use, they do not transfer their constituents to foodstuffs in quantities which could endanger human health, bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof".

Resolution ResAP (2004) 4 and the related technical documents are based on the same principles.

Resolution ResAP (2004) 4 has the following intended purpose:

- provide adequate assurance of the safety of human health;
- establish special measures to protect babies and very young children adequately;
- restrict the number of allowed substances in rubber articles intended for contact with baby food and their migration into baby food to an acceptable and unavoidable level;
- elaborate a harmonised list of substances for rubber products intended to be used for food contact applications;
- divide rubber food contact materials into categories based on condition of contact and thus related to the potential migration of rubber components;
- exclude some rubber product applications from migration testing because of the very restricted potential migration;

In order to achieve these aims a division into three categories is made taking into account the potential exposure and the more vulnerable groups (e.g. babies).

2. GLOSSARY

In *Resolution ResAP (2004) 4* a definition of rubber and thermoplastic rubbers is given. It is known that ISO1382 2002 has formulated more technical definitions for rubber and thermoplastic rubber. However, for the purpose of this resolution, the ISO definition was not considered as appropriate.

Accelerator: Compounding ingredients used in small amounts with a vulcanisation agent to increase the speed of vulcanisation and/or enhance the physical properties of the vulcanisate.

Activator: Compounding ingredient used in small proportions to increase the effectiveness of an accelerator.

Additive: A substance compounded into a resin to enhance certain characteristics such as plasticisers, light stabilisers, flame retardants, etc.

Aids to polymerisation: Substance which directly influence the formation of polymers and constitute a separate class of substances planned to be regulated by specific rules. They include for example:

Accelerators
Catalysts
Catalyst deactivators
Catalyst supports
Catalyst modifiers
Chain scission reagents
Chain transfer or extending gents
Chain stop reagents
Cross-linking agents
Initiators and promoters
Molecular weight regulators
Polymerisation inhibitors
Redox agents

Blend: A physical mixtures of rubber with other polymeric substances in the same physical state, each of which can be used as such for the manufacture of materials and articles.

Catalyst: Substance that causes or accelerates a chemical reaction when added to the reactants in a minor amount, and that is not consumed in the reaction.

Coagulation: Irreversible agglomeration of particles originally dispersed in a rubber latex, to form a continuous phase of the polymer and a dispersed phase of the serum.

Colourants/pigments: substances used to achieve a colour to the final product.

Compound: Intimate mixture of an elastomer or elastomers or other forming materials, as well as liquid systems, with all the ingredients necessary for the finished product.

Cross-linking agent: Substance added to obtain a chemically bond or atom joining of two rubber chains or parts of the same rubber chain as a result of vulcanisation.

Curing: Synonym for vulcanisation (the preferred term). However it is the common term for the chain extension/cross linking type reaction which produce rubber articles from for example polyurethane and other similar liquid systems.

Degradation product: Substances occurring from compounds intentionally added to the final product. The occurrence of degradation products is considered unavoidable due to the production process or conditions of use.

Elasticity: The rapid recovery of a material to its approximate shape and dimensions after substantial deformation by a force and subsequent release of that force.

Elastomer: A macromolecular material which returns rapidly to approximately its initial dimensions and shape after substantial deformation by a weak stress and release of the stress.

Emulsifier/emulsion stabiliser: A substance used to facilitate the formation of an emulsion, w.s. from two or more immiscible liquids, and/or to promote the stability of the emulsion.

Filler: A relative inert substance added to a rubber compound to reduce its costs per unit volume and/or to improve such mechanical properties as hardness, modulus and impact strength.

Initiator: Agent that causes a chemical reaction to commence and that enters into the reaction to become part of the resultant compound.

Monomers and starting substances: Any starting substance (regardless of its chemical nature (compound, mixture, monomer, oligomer, prepolymer natural or synthetic macromolecules etc.) used in any type of polymerisation process (e.g. polycondensation, polyaddition, curing) including the modification of natural or synthetic substances.

Natural rubber: Obtained from natural rubber latex after removal of the water.

Natural rubber latex: An amorphous polymer consisting essentially of cis 1,4-polyisoprene obtained from the sap (latex), in general, of the botanical source *Hevea brasiliensis*.

Plastic polymers: Organic macromolecular compounds obtained by polymerisation, polycondensation, polyaddition or any other similar process from molecules with a lower molecular weight or by chemical alteration of natural macromolecules.

Plasticiser/softener: Compounding ingredient used in small proportions to reduce the stiffness of a rubber mix or the hardness of the vulcanisate.

Polymerisation production aids: Any substance used to provide a suitable medium in which polymerisation occurs (e.g. emulsifiers, surfactants, buffering agents, etc.).

Protective agent: Compounding ingredient used to retard deterioration by aging.

Retarder: Compounding ingredient used to reduce the tendency of a rubber compound to vulcanize prematurely.

Rubber: Family of materials showing property of high elasticity. In an unaged state, rubber can be substantially deformed under stress, but recovers nearly to its original stage when the stress is removed. Rubber is usually made from a mixture of (solid and/or liquid) materials and can be subjected to a curing process, which changes its nature.

Rubberise: Impregnate and/or coat a substrate with rubber compound.

Rubber product: Finished material and article constituted of rubber including thermoplastic rubber as well as blends of rubber with plastics and other materials, which are intended to come into contact with or are placed in contact with foodstuffs. A rubber product may be made almost entirely of rubber, as for example a glove, or it may contain components and reinforcement other than rubber, as for example in a rubber-coated fabric, a tyre, a steel laminated bridge bearing and a rubber hose fitted with a metallic coupling.

Synthetic polymer: Rubber produced by polymerisation of one or more monomers.

Synthetic rubber latex: Colloidal aqueous dispersion of rubber particles.

Thermoplastic elastomers (TPE): Polymer or blend of polymers that has properties at its service temperature similar to those of vulcanised rubber but can be processed and reprocessed at elevated temperature like a thermoplastic.

Thermoplastic rubber is a polymer or blend of polymers that may or may not require vulcanisation or cross linking during processing, yet has properties, at its service temperature, similar to those of vulcanised rubber; these properties disappear at processing temperature, so that further processing is possible, but return when the material is returned to its service temperature.
Note: Thermoplastic rubber is a commonly used term for thermoplastic elastomer.

Vulcanisation: Process (usually involving heat) in which rubber, through a change in its chemical structure (for example cross-linking), is converted to a condition in which the elastic properties are conferred or re-established or improves or extended over a great range of temperatures. In some cases, the process is carried to a point where the substance becomes rigid.

Vulcanising agents: Compounding ingredients that produces cross-linking in rubber.

Vulcanised rubber: Product of the vulcanisation of a compound or mixture.

3. FIELD OF APPLICATION

Resolution ResAP (2004) 4 "applies to materials and articles constituted of rubber including thermoplastic rubber as well as blends of rubber with plastics and other materials, which are intended to come into contact with or are placed in contact with foodstuffs, hereafter called 'rubber products' " (Article 1.1.).

Blends of rubber with plastics and other materials are considered rubber products as long as the final article shows rubber properties at its service temperature as defined in the resolution.

The flexibility of rubber makes it suitable for specific applications. The important types of rubber materials used in contact with food and some typical (but not exhaustive) applications are detailed in the following table:

Polymer	Typical Applications
Polyisoprene (natural or synthetic rubber) and a range of blends with other polymers	Gloves, can sealants, feeding teats, conveyer beltings, seals, hosing products and meat netting
Nitrile rubber (butadiene acrylonitrile copolymer) and blends for example with styrene butadiene rubber, PVC etc.	Seals gaskets, hosing, dairy equipments, milk liners and gloves
Ethylene propylene copolymer and terpolymer	Heat exchanger gasket (maximum use temperature 150°C)
Fluorocarbon elastomers or fluoroelastomers	High temperature seals and gaskets (<200°C)
Thermoplastic elastomers (can be mixed and compounded), styrene block copolymers, olefinic blends with rubber (cured or uncured), polyurethanes, polyesters	Seals, gaskets, diaphragms, tubing, lidding materials, conveyer belting, lining material, soft touch utensils and synthetic corks

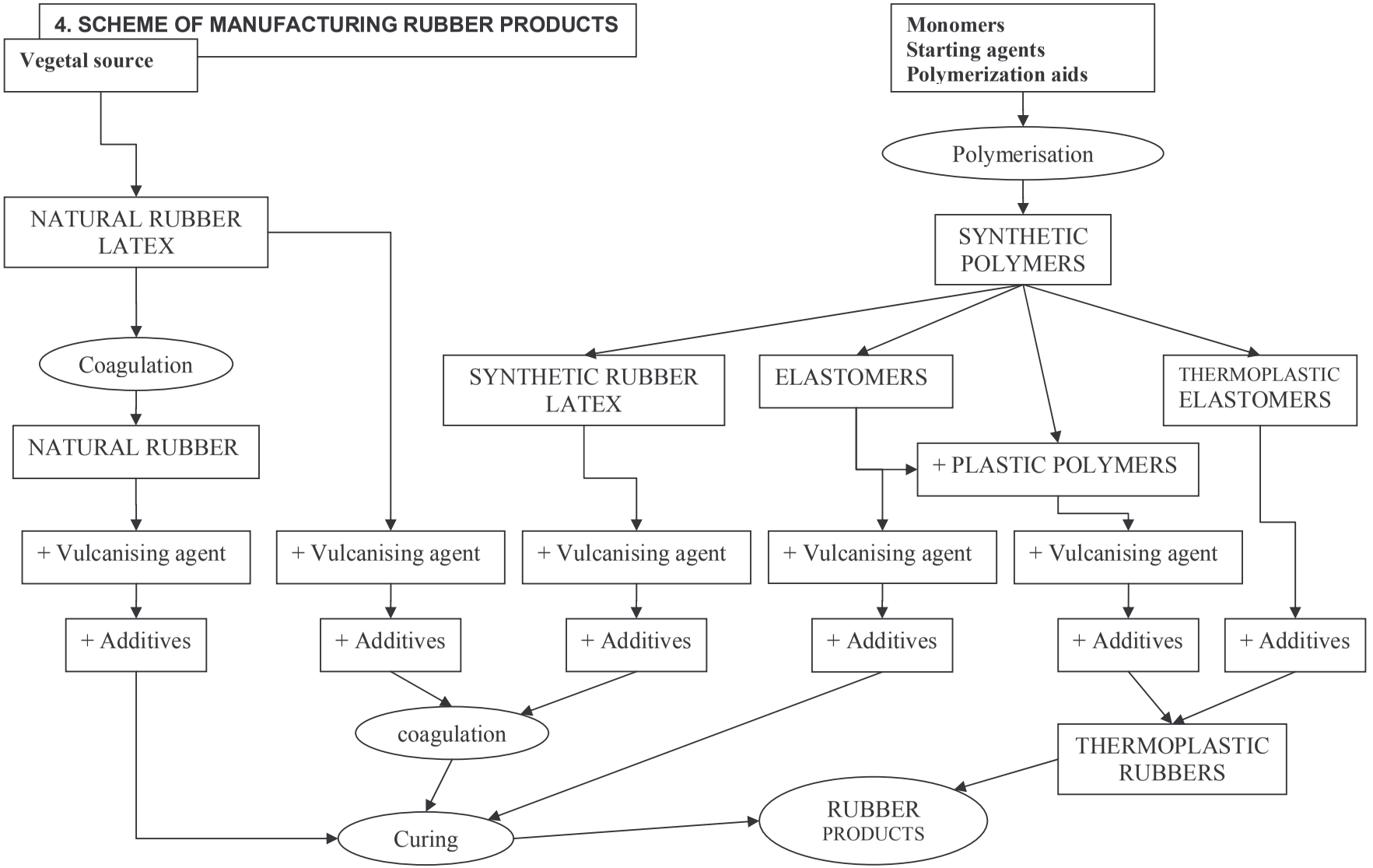
The following are excluded from *Resolution ResAP (2004) 4* :

a) Baby soothers and other articles that may be taken into the mouth are excluded since they are primarily not considered as food contact articles, they are mouth and sucking articles and primarily in contact with the mucous membrane and therefore the test methods would be different from food contact articles. These articles may be subject to other requirements.

b) Silicone elastomers, which are used to manufacture e.g. tubes, seals, conveyor belts, sweet moulds and teats, as well as silicone oils are subject to *Resolution ResAP (2004) 5 on silicones used for food contact applications*. Blends of rubber with silicone products are not regulated in *Resolution ResAP (2004) 4*, but are allowed, provided that the composition of the silicone part is in compliance with *Resolution ResAP (2004) 5 on silicones used for food contact applications*, and composition of the rubber part is in compliance with *Resolution ResAP (2004) 4*. Migration behaviour should comply with the restrictions laid down in *Resolution ResAP (2004) 5 on silicones used for food contact applications* or in *Resolution AP (2004) 4*. If different restrictions for a component are established then the more severe restriction should be applied.

c) Colourants are not regulated by *Resolution ResAP (2004) 4* but are allowed, provided that they are in compliance with *Resolution AP (89) 1 on the use of colourants in plastic materials coming into contact with food*.

4. SCHEME OF MANUFACTURING RUBBER PRODUCTS



5. FUNCTION CODES

In "*Technical document No. 1 - List of substances to be used in the manufacture of rubber products intended to come into contact with foodstuffs lists of substances*" (to be prepared) a column with the intended function of the substance is included. This column was added to provide information on the intended use and the possible actual concentration in the final article. This may be relevant for enforcement laboratories and to establish potential migration from a material, e.g. a substance used as a monomer will hardly be present in the final article, but if the same substance is used as an additive then the initial concentration will be comparable to the actual concentration in that article. Priority for evaluation and restrictions may be set based on exposure assessment and not only on toxicological hazard evaluation. In that case the allowance and restriction of the substance may be connected to its requested use. In principle the use of a substance should be restricted to its listed function, taking into account GMP and the requirement that "substances should be used only in amounts strictly needed for manufacturing and performance of the finished product".

For the substance list, the following function codes have been assigned:

1. Monomers / Starting agents
2. Activators
3. Accelorators
4. Colourants / pigments
5. Cross-linkers
6. Emulsifiers / emulsion stabilisers
7. Fillers
8. Initiators
9. Plasticisers
10. Protective agents
11. Retarders
12. Vulcanising agents
13. Degradation products
14. Other

6. CLASSIFICATION INTO CATEGORIES

6.1. Justification of classification in categories

In principle the rubber products could follow the approach set out in EU plastics directives or in the "*Resolution AP (2002) 1 on paper and board materials intended to come into contact with foodstuffs"* as they also are mainly composed by organic materials and substances. However there is a fundamental technological difference between rubber products and the other organic materials from the previous mentioned materials. The rubber products are not or rarely used as food packaging and they are mainly used in applications such as conveyor belts, tubing, gloves, gaskets, seals etc. where the contact is often dynamic and very short and the ratio of surface/volume or weight of foodstuffs is so low that expected migration should be very low or negligible and the risk for the consumer should be in significant.

In addition a survey of the national laws or recommendations shows that the majority of the existing regulations (e.g. in The Netherlands, in Germany and in France) do not follow the approach of plastic rules. They are based on a classification of rubber products in various categories in accordance to the expected migration or to destination of use (e.g. for baby food).

Finally it was also considered that at present there is insufficient data available to validate a mathematical model based on the diffusion properties.

Taking into account all these elements i.e. very low exposure, the national laws and the lack of mathematical models, a specific and pragmatic approach for rubber products was established based on their allocation into 3 categories in accordance with the expected migration and destination of use. This approach will not prevent the future use of mathematical models as the factors set out in this approach (see later) can be inserted easily in the equation of mathematical models.

The classification is based on four factors relevant for migration behaviour of a rubber product. One category is made for rubber materials coming into contact with baby and infant food. The factors (R-factors) are conventionally established based on practical experience and conditions of use.

6.2. Factors (R_1, R_2 ,R_3 and R_4) to classify the rubber material into a category

Rubber is often used in food applications, but, contrarily to plastic articles, it is seldom used as food-packaging material (bottles, wrapping films, container etc.). Therefore the conventional ratio of 6 dm²/ kg food, used for plastics, is not appropriate for main applications of which have the following main characteristics:

a) The ratio of surface area over quantity of food may be very small, e.g. a rubber ring in a tubing connector or a washer in a tap.

b) The contact temperature may vary from deep freeze conditions up to a temperature as high as 200°C in case of cooking and frying.

c) The contact times may vary over a very broad range from a few seconds up to one year or even longer.

d) Due to the specific properties of rubber products, these materials are frequently used in recurrent use applications. In this way the first contact occasions may cause significant migration but on the other hand after many thousand times of re-use the migration will be negligible, if any.

The four above-mentioned characteristics above-mentioned (area, time, temperature, number of recurrent uses) are relevant to estimate the potential migration from rubber products into the food. The parameters are part of the representative parameters used in mathematic predictive migration models. Unfortunately such models do not yet exist for rubber materials. In the future such models may be developed but then a large amount of data would have to be generated in order to develop and validate models suitable for reliable prediction of migration.

To avoid migration experiments with materials for which the migration is often expected to be insignificant, the four factors (R_1, R_2, R_3 and R_4) have been conventionally quantified and used to classify rubber products into three categories in accordance to their intended use (cat I) or in accordance with their potential migration (cat II and III). To each factor a conventional numerical value proportional (R_1, R_2 and R_3) or inversely proportional to the contribution of the parameters to the expected potential migration was attributed. The multiplication of the four R factors gives a factor called total factor or R_{total}, directly proportional to the expected migration. The greater the R_{total}, the greater the potential migration. The value of the R factors are chosen in such way that if the R_{total} is equal or greater than 0.001 (cat. II) a migration is expected and therefore a migration test should be carried out. If the R_{total} is smaller than 0.001(cat III) the migration is negligible and the

migration testing is not required. An exception is made for carcinogenic substances or highly toxic substances, classified by the SCF/EFSA into SCF-list 4A and which should not be detectable in foodstuffs or food simulants. This could be determined from migration experiments or applying the rules mentioned in Item 4.3 and 4.4 of Resolution ResAP (2004) 4 on rubber products.

6.3. Categories

Conventionally rubber products have been divided into three categories:

Category I, for feeding teats and rubber products for contact with baby food, for which the R_{total} is equal or greater than 0.001.

Children up to three years are vulnerable consumers due to the relative large food consumption per kg body weight. Therefore the substances allowed for the manufacture of rubber products intended for contact with baby food is very restrictive. In addition the migration of substances is generally set at 1/10 of the limits considered acceptable for adults. Migration experiments are usually required. Materials classified in category III are excluded from this rule.

Category II, for products where the R_{total} is greater than 0.001.

Products in this category have conditions of contact with food which may cause significant migration of its constituents. The products should comply with a restricted positive list. Migration should be measured at worst case representative conditions in food or food simulants. Migration values should be in conformity with the restrictions specified. Migration experiments are usually required.

Category III, for products where the R_{total} is less than 0.001.

Rubber products in this category by definition have very limited contact with food. As a consequence migration will be very limited and of no significance. The limited contact is the consequence of -at least- one of the parameters of time, temperature, surface area or number of recurrent uses. Any substance from the more extensive positive list can be taken for the manufacture of the rubber products. In addition the migration will be very limited and therefore no migration experiments are required.

6.4. Calculation of the R-factors and the calculated continued product: (R-total)

The system of classification of categories II and III is a cut-off principle and is used to establish the need for migration experiments and the relevant positive list. The system should not be seen as a predictive model for the calculation of the migration, although the parameters which are used in mathematic models are used to calculate the R_{total}. The system was actually designed for those cases where an expert using common sense would conclude that migration should be considered negligible. The intention is that such conclusion can be confirmed by a simple objective calculation taking into account relevant parameters. The cut-off value of 0.001 is a conventional value but giving sufficient security on the potential migration, particularly when the frequency of use of rubber food contact materials is taken into account. When the R_{total} is borderline and open for different interpretation of one of the parameters then always the worst case conditions should be taken into account. Based on this precautionary principle a rubber article classified in category II may finally appear to belong in category III. Such results could be used to demonstrate the correct category in similar applications.

6.5. Determination of the data required for the calculation of the R-factors

Before the R-factors and the R_{total} can be calculated the relevant parameters have to be determined. In many cases this is straightforward but in some cases it will appear a matter of interpretation of the conditions of contact occurring in real use.

Factor R_1 - Determination of relative contact area

Factor R_1 is a measure for the contact area related to the amount of food in contact with the product. The relative contact area is expressed in cm²/kg food by dividing the actual contact area by the actual amount of food coming in contact with that area. Only the area coming into contact with the food should be calculated. This means that if only a part of the object is in contact with the food then only that part should be considered.

For products completely in contact with food, the area can be measured (usually) simple. Then the amount of food in contact with the product should be established, and the ratio "area/weight food" be calculated. In many cases the amount of food in contact with the rubber product may vary. In those cases the worst-case amount of food, which is the smallest amount, should be taken for calculation of the R_1 factor.

6.6. Determination of contact area

Measure the total area in contact with the food in cm². Determination of the contact area of products not completely in contact with the food may be more problematic. For example, a closing ring for a beer bottle is only partly in contact with the beer. Usually the area can be determined by observation of the imprint of the glass ring.

The contact area of an O-ring in a tube connector may be even more difficult to determine. If it is impractical to determine the area through a visual imprint on the product then a rough estimate should be made. If there is a serious doubt about the real contact area then it is allowed to take the whole area of the product.

In case of e.g. conveyor belts the rubber product is usually significant larger than the food area. In such cases the area of the food in contact with the belt should be considered.

6.7. Determination of the amount of food

Determine the total quantity of food, in kg, in contact with the rubber product. For products used only once, this is usually no problem. Taking the example of the beer bottle (example 7.2.1.2.) the content of the bottle is the amount of food in contact with the rubber ring. Also in case of the examples 7.2.1.1. and 7.2.1.3. the calculation of the amount of food is straightforward. Also the example of the conveyor belt is relatively simple (example 7.2.2.3) concerning the use of a conveyor belt in a bakery. The belt is used for cakes with a contact area of 78 cm² and a weight of 90 g., than the ratio A/W =78/0.09 or 867.

Factor R_2 - Determination of the temperature

The temperature at which the product is in contact with the food shall be taken for the calculation of the Factor R_2. In all cases the worst-case temperature shall be taken. In some cases there may be two different contact temperatures. A food first sterilised and then stored at room temperature has two significantly different contact temperatures, but connected to that also two different contact times (Factor R_3) are relevant. The classification systems have no clear solution for this. To make a proper classification the R_{total} can be calculated for the two individual time – temperature conditions. If both

conditions conclude a classification in category III then the sum of the individual conditions shall be taken and the classification shall be established on the result of this calculation. In example 7.2.1.3 a typical example is given. Another typical example is the case where the food follows a temperature gradient during contact with the food. This gradient may be increasing or decreasing temperature. Depending on the actual conditions the highest temperature could be taken, but it may be allowed to use an average temperature. (see 7.2.2.3.). In case the classification is boarder line than the worst case shall be taken for drawing final conclusions.

Factor R_3 - Determination of contact time

The contact time is the time that a rubber product is in contact with the food. In static applications the contact time is the total time that the product is in contact with the food at one given temperature. For dynamic conditions of contact it may be confusing to establish the real contact time. By convention, it is assumed that a human being eats during its life-time, daily, 1 kg of food that has been in contact with the subject material. For plastics this is known to be an exaggeration or an additional safety margin. For rubber material this safety margin is even higher because of the frequency of use of rubber materials in contact with food. Based on this assumption the contact time in dynamic application should be established for 1 kg of food. This means e.g. the time (h) required to pass 1 kg of food through a specified length of tubing, examples 7.2.2.). This type of application should be seen as repeated use application. Each time 1 kg of food passes through the tube a new period of exposure is initiated.

It may be more appropriate to apply a batch approach. This approach should only be applied for liquid foodstuffs where the food is mixed in a batch after the contact with the rubber article. The time that a certain amount of food is in contact with the rubber products is then used in the calculation of R_3. Using this approach has an influence on the factors R_1 and R_4 as well. In general both approaches will result into the same classification.

Factor R_4 - Determination of number of times of recurrent use

In static conditions of use the number of recurrent uses is easy to establish. Each time a batch or fixed amount of food is brought into contact with the same product then a recurrent use is assumed. Under dynamic conditions of use the number of uses may be more difficult to establish. Usually a lot of information is required, e.g. flow rate, life time of the product, daily hours of use, total amount of food passing the product. Based on these parameters the number of recurrent uses can be established. For all these parameters the worst-case conditions should be considered.

Typical examples are given in 7.2.2.

6.8. R-factors and R-total

The calculation consists in assessing four numbers (the R-factors), relating to the various possible contact circumstances between the rubber object in question and the food.

These circumstances refer, as set forth in the regulation, to the following:

- R_1= the contact surface

- R_2= the contact temperature

• R_3= the contact time interval

• R_4= the number of times the contact is effect ad.

Each factor reaches conventionally a maximum value of 1, but may assume a lower value if the migration probability decreases. By multiplication of the four factors, resulting in R_{total}, any significant decrease of the risk results in a lower value of the final product.

The maximum value of 1 for each of the R-factors is conventionally established based on practical experience and conditions of use. It is not likely that for instance the area will be higher than 100 cm²/kg food. whereas the combination of time and temperature may be compensating each other. The R factor for the number of repeated uses which is set at 1000 times before it starts to decrease is certainly on the safe side as migration will start to decrease after a couple of repeated contact times. Connected to the maximum value of 1 assigned for the R factors the cut-off value of 0.001 was established. Changing the maximum value would implicate a change of the cut-off value of 0.001. As this is not desirable the arbitrary maximum value should be maintained.

The conditions connected to a maximum value of 1 should not be confused with conditions to be applied in migration testing. In migration testing of materials in category II the actual condition of contact should be used.

For the final R_{total} a value of 0,001 (one thousandth) has been arbitrarily established as a criterion.

If this final R_{total} is lower than this value this risk is assumed to be very low indeed; as a result a rather extended list of starting materials is available for the rubber composition.

If this result of the calculation is between 1 and 0,001 then the risk is assumed to be not negligible, and the list of starting materials is drastically restricted; additionally migration tests are obligatory.

6.9. Shape of the curves between the start and ultimate values

R_1. For the effect of the relative contact surface on the migration risk a linear relation has been assumed. In view of the established upper limit this means that contact surfaces have to be divided by 100.
($R1 = A_r /100$) where A_R is the relative contact area of rubber product per kg food expressed in cm²/kg)

R_2. The effect of the contact temperature on the migration risk has been assumed to be more than proportional. This model has been approximated by formulating an exponential function. The parameters 0,05 resp. 0,023 cause the function to yield a value of R_2 = 1 in the vicinity of 130 °C, and to yield a relatively low value (R_2 approximately 0,005) at 0 °C.
($R_2 = 0.05\ e^{0.023T}$)

R_3. For the effect of the contact time on the migration risk a simple linear relation has been assumed during contact times up to 10 h. This is considered a worst case, as it is known that migration will decrease rapidly as a function of time. In view of the established upper limit this means that contact times (h) have to be divided by 10.
(R3 = t/10)

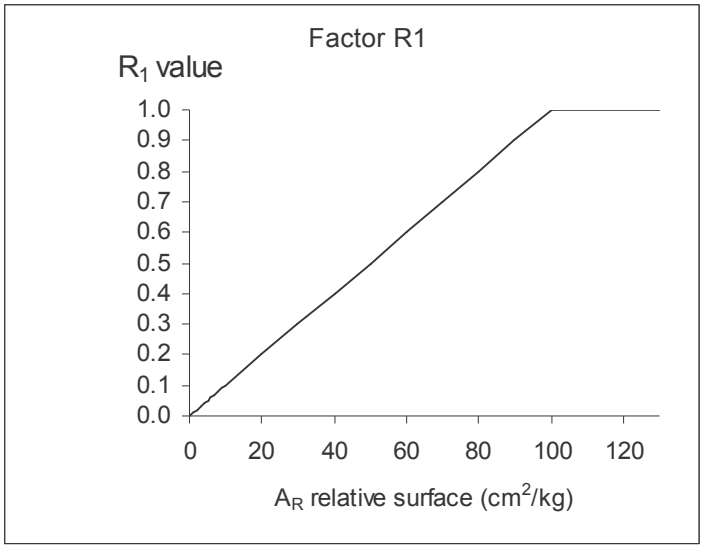
R_4 In view of the large numbers involved in the number of contact times a logarithmic relation has been selected for the effect on the migration risk. The parameters 6 reps. 2 cause the function to yield a value of 1 at contact frequency 1000; the outcome at frequency one million is one millionth (0,000,001).
($^{10}logR4 = 6 – 2\ ^{10}log\ N$)

In the figures below the curves of the R factors are graphically presented:

With the tables that can be used for the calculation of the factors R_1, R_2, R_3 and R_4. Intermediate values should be calculated using the proper formulas

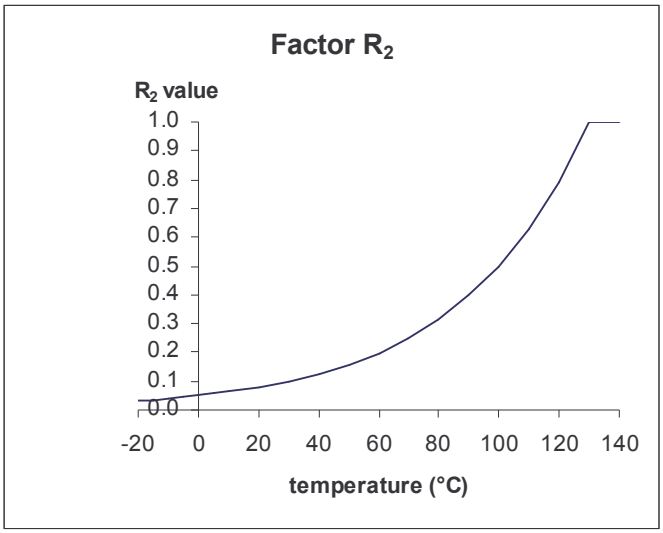
Factor R_1

Relative contact area	
cm²/kg	R_1
1	0.01
2	0.02
3	0.03
4	0.04
5	0.05
6	0.06
7	0.07
8	0.08
9	0.09
10	0.1
20	0.2
30	0.3
40	0.4
50	0.5
60	0.6
70	0.7
80	0.8
90	0.9
100	1
>100	1



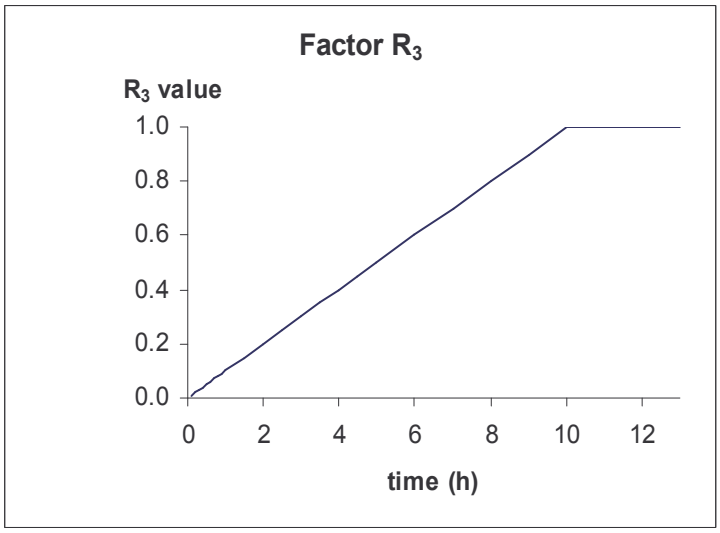
Factor R_2

Temperature of food contact	
°C	R_2
-20	0.032
-15	0.035
-10	0.04
-5	0.045
0	0.05
5	0.056
10	0.063
20	0.079
30	0.1
40	0.125
50	0.158
60	0.199
70	0.25
80	0.315
90	0.396
100	0.499
110	0.628
120	0.79
130	1
>130	1



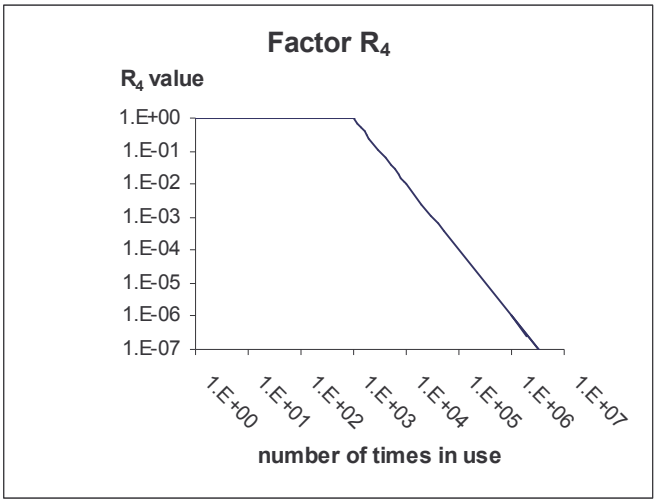
Factor R_3

Contact time	
Hours	R_3
0.1	0.01
0.2	0.02
0.3	0.03
0.4	0.04
0.5	0.05
0.6	0.06
0.7	0.07
0.8	0.08
0.9	0.09
1	0.1
1.5	0.15
2	0.2
2.5	0.25
3	0.3
3.5	0.35
4	0.4
4.5	0.45
5	0.5
6	0.6
7	0.7
8	0.8
9	0.9
10	1
>10	1



Factor R_4

Numbers of repeated use	
No	R_4
100	1.00E+00
1000	1.00E+00
1200	6.94E-01
1400	5.10E-01
1600	3.91E-01
1800	3.09E-01
2000	2.50E-01
3000	1.11E-01
4000	6.25E-02
5000	4.00E-02
6000	2.78E-02
7000	2.04E-02
8000	1.56E-02
9000	1.24E-02
10000	1.00E-02
20000	2.50E-03
30000	1.11E-03
40000	6.25E-04
50000	4.00E-04
1000000	1.00E-06
5000000	4.00E-08
1000000	1.00E-06
2000000	2.50E-07



6.10. Subdivision in the substance lists set out in Technical document N° 1 - List of substances to be used in the manufacture of rubber products intended to come into contact with foodstuffs

The substance lists set out in *Technical document No. 1* (to be prepared) contain a subdivision in categories in accordance with the expected exposure /migration.

In nutshell:

Category I comprises rubber products requiring special attention because of their intended use:

- particularly baby feeding teats;
- products which can be classified in Category II and which are intended to come in contact with baby food.

Category II comprises rubber products for which the R_{total} of the R_1 ,R_2, R_3 and R_4 is greater than 0.001.

Category III comprises rubber products for which the R-total of the R_1,R_2,R_3 and R_4 is smaller than 0.001 and for which the migration of constituents can be neglected.

7. EXAMPLES OF CALCULATIONS

7.1. Introduction

The intention of this section is to guide users of *Resolution ResAP (2004) 4* how to establish the factors R_1 – R_4. The examples should give some insight how conditions of contact occurring in real life can be transferred into those parameters that can be used for the calculation of the R factors. However each practical problem may need interpretation by the user of the system. In general it is easy to arrive to the correct parameters but in some cases common sense and knowledge of the practical uses of the product may be indispensable. In other cases one could arrive at a different conclusion depending on the approach followed. In such cases the worst case (but realistic) situation should be taken into account.

Attention is given on the calculation of the surface area in contact with the food and on the different approaches in respect to contact time and number of recurrent uses when considering flowing contact or static contact.

Depending on the result of the calculation of R_{total} the product is classified in one of the following categories, each category having its specific requirements:

- Category II: if the $R_{total} > 0.001$
- Category III: if the $R_{total} < 0.001$
- Category I is only for teats and material that will come into contact with baby-food and very young children.

The factors to calculate the continued product are:

- R_1= the relative contact area (=A_R expressed in cm²/kg food)
  If this area $\geq$ 100 cm^2, than R1 = 1.00 or otherwise use the formula: R1 = RO/100
- R_2= this contact temperature (= T in °C)
  If the temperature $\geq$ 130 °C, than R_2=1.00 or otherwise use the formula: $R_2=0.05^{e0.023T}$

- R_3= the contact time (= t expressed in hours)
  If this time $\geq$ 10 hour, than R_3 = 1.00 or otherwise use the formula R_3 = t/10
- R_4= the number of use of the same rubber product (= N)
  If this number $\leq$ 1000, than R_4 = 1.00 or otherwise use the formula:
  $^{10}\log R_4 = 6\text{-}2^{10}\log N$

7.2. Examples of rubber products and the classification in categories

Rubber products can be in contact with the food under static conditions. This means that a quantity of food is in contact with the specified area of the rubber product. Determination of the relevant parameters for the calculation of the R-factors is relatively simple and will lead to consistent conclusions.

In many applications the food is in contact with the rubber under continuous flowing or dynamic conditions. This makes estimation of the relevant parameter difficult. In flowing contact one could consider the area of the rubber in repeated contact with a specified amount of food. In that case the specified amount of food should be established at 1 kg, which is the conventional accepted amount of food in contact with the subject food contact material and that may be consumed by one person. As another approach one could consider the total amount of food that is in contact during the life time of the rubber product. In the first case the surface area/volume may be high but as a counter weight the number of recurrent uses may be high. In the second case the area/volume will be very low and the number of recurrent uses is set at 1. In the first case an impression is obtained on the potential migration in a specified volume of food and in the second situation the average potential migration is estimated. The different approaches in some cases may lead to different classifications. In case of doubt always the worst case situation should be taken into account.

Below a number of examples is given for both static and dynamic contact conditions.

7.2.1. Static conditions

7.2.1.1. Rubber band for binding chicken during frying

Rubber bands are used for binding chicken during frying. For that purpose a length of 50 cm rubber band is used. The average weight of the chicken is 800g. The rubber band has a diameter of 2 mm. Taking into account the small diameter and the preparation process of the chicken, the band is consider to have full contact with the food. Frying takes place at temperatures varying from 200°C to 120°C during a period of 2 hours. These parameters are taken for the calculation of the R-factors and the R-total:

Contact area: 31 cm^2/0.8 kg	R_1 = 0.39
Contact temperature: >130 °C	R_2 = 1.00
Contact time: 2 h	R_3 = 0.2
Number of times of exposure: 1	R_4 = 1.00
R_{total} = 0.078	Category II

7.2.1.2. Rubber closure ring (washer) in beer bottles

The washer has an outside diameter of 18 mm and a thickness of 2 mm. In the middle the washer has a hole of 10 mm diameter. The imprint of the bottle neck shows that the diameter of contact is 16 mm. The content of the bottle is 500 ml. The rings are rejected after use. The beer is stored at room temperature and has a shelf-life of 6 months.

From these parameters the R-factors and the R-total are calculated:

Contact area: 1.22 cm^2/0.5 l	R_1 = 0.024
Contact temperature: 20 °C	R_2 = 0.079
Contact time: 6 month	R_3 = 1.00
Number of times of exposure: 1	R_4 = 1.00
R_{total} = 0.0019	Category II

7.2.1.3. Ring for preserving jar

Glass jars used for preserving food are provided with a rubber ring for gas tight sealing. The jar is designed in such way that the rubber ring has very limited contact, if any at all. The rubber ring has an outside diameter of 10.2 cm, whereas the thickness is 4 x 4 mm. The capacity of the jar may vary from 0.25 to 2 l. The food is preserved for 1 hour at 100°C and subsequently stored at room temperature for maximum 1 year. The rubber ring will be re-used once a year over a period of 5 years.

Contact area: As a worst case, one side of the ring is assumed to contact the food, resulting in a total contact area of 15.5 cm^2/jar:

For a jar of 0.25 l	R_1 = 0.62
For a jar of 2 l	R_1' = 0.078
Contact temperature: 100 °C	R_2 = 0.5
Contact temperature : 20°C	R_2' = 0.079
Contact time: 1 h	R_3 = 0.1
Contact time: 360 days	R_3' = 1
Number of times of exposure: 5 times	R_4 = 1.00

R_{Total}

R_{Total} depends on the capacity of the jar, temperature and time conditions. In this example all these parameters may vary. Therefore the R_{total} is calculated for the different situations

R_{Total} for a 0.25 l jar at 100°C = (0.62 x 0.5 x 0.1 x 1) = 0.032	Category II
R_{Total} for a 2 l jar at 100°C = (0.078 x 0.5 x 0.1 x 1) = 0.0039	Category II
R_{Total} for a 0.25 l jar at 20°C = (0.62 x 0.079 x 1 x 1) = 0.049	Category II
R_{Total} for a 2 l jar at 20°C = (0.078 x 0.079x 1 x 1) = 0.0061	Category II

Conclusions: In the example the R_{total} is always >0.001, which means it is always a category II product and the relevant positive list should be respected and migration experiments should be performed. The migration occurring during the consecutive time and temperature periods of 1 h at 100°C and 1 year at 20°C have not been considered, because the individual R-total values result in a category II product. However, conditions may occur that the individual exposure conditions result into a category III product, while the combined contact conditions result in a category II product. In the above example this situation would occur if the jar has a capacity of 14 l. In that case the sum of R_{Total} of the individual exposure conditions could be taken as the worst case.

R_{Total} for a 14 l jar at 100°C = (0.0113 x 0.5 x 0.1 x 1) = 0.00056 Category III
R_{Total} for a 14 l jar at 20°C = (0.0113 x 0.079 x1 x 1) = 0.00089 Category III
Sum of R_{Total} 0.00145 Category II

Only if the jar has a content of 20 l would the R_{Total} result in a Category III product.

7.2.2. Dynamic contact

7.2.2.1. Tubing in milk machine

The rubber tubing is part of a unit of a milk machine and has a inside diameter of 15 mm and a wall thickness of 1.5 mm. Length may vary from 1 – 2.5 m. The temperature of the milk in the tubing is 30°C. Each cow is connected to the machine for 15 minutes and delivers 10 l of milk on each occasion, twice a day. Life time of the tubing is guaranteed for 1 year, but will only be replaced after two years. The unit has a maximum capacity of 10 cows/milking session. Tubing is cleaned with hot water before first use and in between two milking sessions.

Based on these data the R-total can be calculated as follows using the equations given for the R 1 – 4 factors:

R1
Area is calculated for the worst-case situation assuming a length of 2.5 m tubing with a diameter of 15 mm. The inside surface area is 1178 cm²:

Determination of the amount of milk following two different approaches:

1. assuming 1 cow delivering 10 l of milk in 15 minutes. So the minimum flow or contact time is 1 l/1.5 min.

2. assuming 10 cows delivering 365 x 200 l = 73000 l milk in 1 year with an actual contact time of 365 x (20 x 0.25h) = 1825 h

The above assumption not only effect the value of R_1 but also R_3 (contact time) A decrease of R_1 will result in an increase of R3. Both assumptions are taken in the calculation of the R_{total}.

RA_1= 1178 cm² / 1 l R_1 = 11.8, but maximum value is set at 1. $R1_1$ = 1
RA_2 = 1178 cm² / 73000 l/ =0.016 $R1_2$ = 0.00016

R_2
Contact temperature is 30°C R2 = 0.100

R_3
Contact time; depends on the calculation of R1 and the two different approache are considered

$R_{time\ 1}$ = 1.5 minutes contact time $R3_1$ = 0.0025

$R_{time\ 2}$ = 1825 h contact time R3 = 182.5 but, maximum value is set at 1 $R3_2$ = 1

R_4
Number of recurrent uses; is also connected to the different approaches as given for the calculation of R1.

If the approach for the contact period per litre milk is taken (assumption 1) than the number of recurrent uses should be considered as the total amount (l) of milk passing the tubing during its period of use . This means for 10 cows delivering 10 l/ session and *two* sessions a day and a life time of the tubing of, at least, one year that the total number of recurrent uses is 20 x 10 times a day or 73,000 for one year.

Assumption 2 results in 1 exposure per year

As a consequence the following R4 factors may be calculated

$R4_1$ = Number of recurrent uses 73000	$R4_1$ = 0.0188
$R4_2$ = Number of recurrent uses 1 minimum value set at 1	$R4_2$ = 1.0

Calculation of R_{total} for the four different approaches

$R\text{-total}_1$ = 1 x 0.1 x 0.0025 x 0.000188 =	0.000000047	Category III
$R\text{-total}_2$ = 0.000161 x 0.1 x 1 x 1 =	0.000016	Category III

Discussion: Both methods of calculation result in the same conclusions. One could object against fixing the factors R1 and R3 at 1 in the first and second method respectively. However taking the extrapolated values would not change the conclusions. For R2 in the second method the contact time which was calculated at 1825 hours is disputable. It should be considered that the tubing is in contact with milk for that time, but not the whole batch of milk is in contact with the tubing during this whole period. This is corrected by the R1 factor which represents the area/amount of food.

The large differences between the two methods of calculation are mainly caused by the effect of the number of recurrent uses. In the first method the migration is assumed to decrease according to a conventional worst-case curve. Only after 1000 exposures the migration is considered to decrease slowly. This is a conventional general applicable approach. Such a curve, in reality, will depend on the properties of the irritable substance and the foodstuff. For example different curves will be obtained when plotting the migration of substances with high or low molecular weight. As the calculation of the R-factors is rather conservative and only meant as a cut-off value these differences will not likely effect risk to human health.

In the second calculation method the migration in the whole batch of food is considered a first contact period. No correction is made for the fact that the migration will decrease in time.

Both methods of calculation were made to demonstrate the differences between the different approaches. In cases of flowing contact the first approach should be the preferred one. In conclusion this means:

- assume 1 kg of food
- calculate the relative contact area of 1 kg food (cm^2/kg)
- calculate the contact time of 1 kg food with the relative contact area (h)
- calculate the number of times that 1 kg of food is in contact with the relative contact area during the lifetime of the product. (N)
- establish the relevant contact temperature
- calculate the factors R1, R2, R3 and R4
- calculate R_{total} as R1 x R2 x R3 x R4
- determine the relevant category
- prepare a programme of requirements for compliance with the resolution.

7.2.2.2. Closure ring for beer tap

A beer tap is provided with a washer in the tap. The washer has the following dimensions:

Outside diameter: 20 mm, thickness 3 mm.

The average temperature of the beer is 6 °C but may occasionally increase to 10 °C. Contact time with the washer with beer during tapping 0.5 l beer is 15 seconds. The life time of the tap is 0.5 year. The amount of beer passing the tap is 20000 l per year.

Calculation of R factors
R_1 area of the washer is 3.14 cm². So the relative area is 3.14 cm²/l and R_1 = 0.0314
R_2 is set at worst case of 10°C and is found R_2 = 0.063
R_3 0.5 l has 15 seconds contact time. So 1 litre has contact for 30 seconds and R_3 = 0.00083
R_4 in half a year 10000 l passes the tap. So N is 10000, resulting in R_4 = 0.01

$R_{total} = 1.6^{-8}$

Conclusion: Category III

No migration experiments required, but positive list should be respected.

7.2.2.3. Conveyor belt for bakery products

A new conveyor belt was installed in a bakery. The belt has a length of 60m with a width of 0.6 m. The belt has a life time of 3 years. The belt is intended to be used to transport cakes from the oven to the packing department. Belt is running at 0.36 km/h. At the start the cakes will have a temperature of 70°C and at the end they will be cooled down to 20°C. The cakes have a size of 8 cm diameter and a weight of 100 g each. The average production is 10,000 cakes an hour. Bakery is producing for 8 h a day during 220 days a year. According to good hygiene practice the belt is cleaned at least at the end of the day.

Which category should this belt be classified?

Determination of R_1

Contact area of one cake is 50.2 cm². The relative contact area (A_R) is 50.2 x 100/1000 = 502 cm²/kg cake. $R_1 = A_R/100$ = 5.02, but maximum value is set at 1.

Determination of R_2

A temperature decrease from 70 – 20 °C is given, however no profile is given. One could assume that the temperature gradient is linear (although this is not likely) and calculate the temperature after 5 minutes at the belt. This will be 45°C. Alternatively the worst case could be considered and the maximum temperature can be taken for calculation of R2.

$R2_{45°C}$ = 0.140
$R2_{70°C}$ = 0.250

Determination of R_3

Belt speed is 360 m/h or 6 m/minutes. This means that one cake is on the belt for 10 minutes (0.167 h) R3 = 0.0167

Determination of R_4

To calculate R4 the number of recurrent contact periods have to be calculated. It is necessary to calculate the number of recurrent contacts of a cake with one and the same place of the belt. The effective length of the belt is 60 m, but the total length (up and down) is 120 m. This means that only after 20 min the same spot on the belt can accept a new cake. This is 3 cakes an hour and 24 cakes a day. After 3 years at 220 working days the total number of recurrent contact is 15840. Using this number R4 is calculated to be 0.0040.

Calculation of R-total

$R\text{-total}_{45°C} = 1 \times 0.14 \times 0.0167 \times 0.0040 = 9.4^{-6}$
$R\text{-total}_{70°C} = 1 \times 0.25 \times 0.0167 \times 0.0040 = 1.7^{-5}$

The conveyor belt is classified in category III.

Discussion

In this example the relative area of the belt over the food is more than the conventional maximum value of 1. However even if a correction was made this would not effect the conclusion. The high number of repeated uses are the crucial parameter for a final classification in category III.

7.2.3. Application of given examples

The examples given above may be replaced by any other conditions of contact. It is important to take into consideration the contact area, the amount of food in contact with the product and the number of repeated contact as these parameters are closely connected to each other. Although guidance is given to arrive to a conclusion, common sense is indispensable to arrive at a justified conclusion. The temperature is a more independent parameter and needs only considerations when different temperatures are applied in tandem.

8. MIGRATION TESTS

8.1. Need for migration testing

The R-factors determine whether there is a need for migration testing or not. Based on worst-case migration it can be calculated whether there is any need for carrying out migration tests. This calculation also gives a justification for the use of the categories II and III. The migration potential for a rubber ring in contact with food under three different conditions are given below. In the three cases the weight and size of the ring is assume to be the same. Other parameter which influence the migration differ. Assume the following cases:

- Example 1 (category II product)
  Rubber ring, weight 0.5 g *in contact with 0.5 l food*
  Assume the migration is 10% of total weight (=50 mg)
  Calculated migration is 50 mg/0.5 L or 100 mg/l
  Based on this calculation all the relevant migration experiments have to be carried out.

- Example 2 (Category III product)

  Rubber ring, weight 0.5 g, *in contact with 6000 l food*

  a. Assume the migration is 10% of total weight (=50mg)
     Calculated migration is 0.8 μg/l
  b. Assume the migration is 100% of total weight (=500mg)
     Worst case migration is 8μg/l

     The calculated migration is very low, no migration tests are required.

- Example 3 (Category III product)

  Rubber ring, weight 0.5 g, *in contact with 1.920.000 l food*
  Assume the migration is 100% of total weight (=500mg)
  Migration is 0.026μg/l
  The worst migration is very low, no migration tests are required.

8.2. Testing protocols for repeated use application

Assuming that a rubber product has been classified in category II, then suitability for food contact should be demonstrated by migration testing. In many cases it may be difficult to establish the right testing protocol. In many cases there will be more then one approach for compliance testing. The way and type of contact should be considered carefully. Below two possible approaches have been explained for the use of latex gloves.

Assume:

Latex gloves used in the chocolate industry.
Contact area of gloves with chocolate is 1 dm^2
Contact condition: 0.5 min to take 10 chocolates with a weight of 100 g
Use period: 2 h then gloves are changed

8.2.1. Repeated use approach

Ratio food/contact area = 0.1 kg/dm^2

Migration test: to be performed: 3 consecutive tests for 0.5h at 40°C.

Migration is expressed in mg/kg chocolate taking into account the actual ratio of surface area/amount of food.

The value obtained shall not exceed the migration limit (as mentioned in the column “restrictions”)

8.2.2. Batch approach

Total amount of food in contact with the glove during a period of two hours is 120 min / 0.5 min x 0.1 kg chocolate = 24 kg of chocolate

Ratio food/contact area = 1 dm^2/24kg
Migration test to be performed is one test for 2h at 40°C.
Migration is expressed in mg/kg chocolate taking into account the actual ratio of surface area/amount of food
The value obtained shall not exceed the migration limit (as mentioned in the column “restrictions”)

Both approaches may results in deviating conclusions. The repeated use approach is a more general one whereas the batch approach is more related to one example occurring in practice. Which of the two is the most realistic depends on the situation and information available.

9. RESTRICTIONS

9.1. SML and QMA

For some substances in the positive list, restrictions have been applied. In the positive list restrictions on the specific migration (SML) or the maximum quantity per area of material (QMA) of a substance may be inserted.

The restrictions may be derived from EU Directives relating to plastics materials and articles and they are based on toxicological assessments carried out by the EU Scientific Committee for Food and/or European Food Safety Authority (SCF and/or EFSA) or as a result of the evaluation by a group of Experts of Evaluation.

It is recognised that the toxicological assessments carried out by the SCF and/or EFSA were based on data supplied for evaluation of the use of substances in the manufacture of plastics materials and articles, for which it is assumed that the consumer is exposed to 1 kg of food packed in 6 dm^2 of plastic material. Therefore the SML or QMA may be expressed in mg/kg food or mg/6 dm^2 of material. However this approach may not be applicable to rubber products due to the different ratio of rubber product surface to food. Therefore SML's should always be expressed in mg/kg food taking into account the actual ratio of contact surface to food quantity. QMA's should also be determined using the actual rubber product surface related to the amount of food in contact with that surface. Values should be express in mg/area in contact with 1 kg food.

9.2. Other restrictions

Additional restrictions are inserted in Table 1 of *Resolution ResAP (2004) 4*, as the substances mentioned therein have been found in many applications.

Other dangerous substances may be present as a result of a reaction or decomposition of an individual or combination of substance(s), e.g. benzothiazole which may be generated from mercaptobenzthiazoles (MBT, MBTS, ZMBT) or sulphenamide and mercaptanes. The restrictions for such dangerous substances appear alongside the related mother substance in the column of restrictions in the positive list

10. COMPLIANCE WITH THE RESTRICTIONS

1. Migration shall only be measured in mg/kg food in case of examination of:

- products which can be filled and for which it is impractical to estimate the surface area in contact with foodstuffs
- caps, gaskets, stoppers tubing or similar devices, exclusive bottle teats.

2. Migration tests should be conducted according to Directives 82/711/EEC, 97/48/EEC and their future amendments, as appropriate, unless technically impracticable due to the nature of the material and the migration tests. Labelling should mention the limit conditions of use of the finished product.

3. Migration tests for N-nitrosamines and N-nitrosable substances from the rubber manufactured parts of rubber of feeding teats should be conducted according to EN 12868 and the results should be expressed in mg/kg rubber product.

   Migration testing of rubber products intended for repeated use, e.g. feeding teats, tubing, shall be carried out on a single sample in accordance with the conditions laid down in Directive 2002/72/EC Annex I using a fresh amount of the food or simulant on each occasion. The migration value, expressed in mg/kg food, should comply with the restrictions as given in the positive list in **"***Technical document No. 1 - List of substances to be used in the manufacture of rubber products intended to come into contact with foodstuffs"*.

4. If more severe methods of analyses prove that the demands of *Resolution ResAP (2004) 4* are fulfilled then no migration tests will be required.

5. If a calculation of the continued product shows that the continued product of the four R-factors is smaller than 0.001, no migration tests are necessary. Therefore the substances to manufacture the rubber products of category III need no specific migration limits, unless a special reason, such as carcinogenic substances, is identified.

11. EXPLANATION OF EXPRESSIONS USED IN TECHNICAL DOCUMENT No. 1 - LIST OF SUBSTANCES TO BE USED IN THE MANUFACTURE OF RUBBER PRODUCTS INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

11.1. Information of tables/lists of Technical document No. 1

column 1: **PM/REF nr**, the EU food contact material reference number of the substance;

column 2: **CAS nr**, the Chemical Abstracts Service registry number of the substance;

column 3: **Name**, the chemical name of the substance;

column 4: **List A**, the definitive list of permitted substances.

Categories I, II and III: '**x**', indicates the allowed use to manufacture the type of rubber product;

column 5: **Restrictions**, the restrictions of the evaluated substances (if applicable);

column 6: **Transfer list B**, the interest declared for use in the type of rubber product;

column 7: **Index list C**, substances which are approved at national level in the following countries (e.g. AU=Austria, D=Germany, F=France, I=Italy,
NL= The Netherlands, UK= United Kingdom, USA=United States of America);

column 8: **SCF Status**, the evaluation by SCF: the list, the restrictions (for Plastics)
Definition of the SCF Lists (briefly):

List 0: Substances which may be used and for which an ADI need not be established.
List 1: Substances, for which an ADI, a t-ADI, a MTDI, a PMTDI, a PTWI or classification "acceptable" has been established.

List 2: Substances for which a TDI or a t-TDI has been established.
List 3: Substances for which an ADI or a TDI could not be established, but where the present use could be accepted.
List 4A (for monomers): Substances for which an ADI or a TDI could not be established but which could be used if the substances migrating are not detectable.
List 4B (for monomers): Substances for which an ADI or a TDI could not be established but which could be used if the levels of monomer residues are reduced as much as possible.
List 4 (for additives): Substances for which an ADI or a TDI could not be established, but which could be used if the substance migrating is not detectable.
List 5: Substances which should not be used.
List 6: Substances for which there exist suspicions about their toxicity and for which data is lacking or is insufficient.
List 6A: Substances suspected to have carcinogenic properties. These substances should not be detectable.
List 6B: Substances suspected to have toxic properties (other than carcinogenic). Restrictions may be indicated.
List 7: Substances for which some toxicological data exist, but for which an ADI or a TDI could not be established. The required additional information should be furnished.
List 8: Substances for which no or only scanty and inadequate data were available.
List 9: Substances and groups of substances which could not be evaluated due to the lack of specifications (substances) or to lack of adequate descriptions (group of substances).
List W: Waiting List. Substances not yet included in the Community Lists. New substances, i.e. substances never approved at national level.
List W7: Substances for which some toxicological data exist, but for which an ADI or a TDI could not be established. The required additional information should be furnished.
List W8: Substances for which no or only scanty and inadequate data were available.
List W9: Substances and group of substances which could not be evaluated due to lack of specifications (substances) or to lack of an adequate description (group of substances).

ADI=Acceptable Daily Intake
t-ADI=temporary ADI
MTDI= Maximum Tolerable Daily Intake
PMTDI=Provisional MTDI
PTWI=Provisional Tolerable Weekly Intake
(see also the EU Synoptic Document);
D=Deleted;
DL=limit of detection;
fp=final product;
NCO=isocyanated moiety;
n.d=not detectable;
QM=maximum permitted quantity of the 'residual' substance in the material or product;
QMA=maximum quantity per area;
QM(T)=maximum permitted quantity of the 'residual' substance in the material or product expressed as total of moiety/substance(s) indicated;
SML=specific migration limit in foods or food simulant ;
SML(T)=specific migration limit in foods or food simulant expressed as total of moiety/substance(s) indicated;
W=SCF waiting list (new substance);

11.2. Salts

Salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc of authorised acid, alcohol or phenol shall be automatically authorised. Salts of acids and bases that have been evaluated separately and are assigned to any of SCF lists 1 to 4 are also authorised. The restrictions should be the same as those of the individual acid and/or base.

11.3. Procedure to transfer substances to List A

11.3.1. General

In *Technical document No. 1* a list with substances, further referred to as List C, is presented. List C is a temporary list of all substances that can be found on a European, national or US FDA list of substances allowed for rubber production. The list (Step 0) is published on the internet by the Council of Europe. It is the intention to reduce the list of substances to those that are actually in use, as the compilation of national lists is expected to contain many substances that are no longer used. Industry should declare interest in the substances actually in use. From the moment industry has declared interest in a substance and indicated the intended category of use, then that substance will be transferred to list B with a mark in the appropriate categories. In case the substance has been evaluated by the SCF/EFSA then the substances will automatically be transferred to List A. Restrictions corresponding to the evaluation of the SCF/EFSA will be inserted taking into account the various categories. Substances not yet evaluated will remain in list B until the substance has been evaluated by a recognised body.

List C will be deleted after a three year period.

Substances, for any reason not included in List C, but authorised at national level will be added directly to List B by submitting a declaration of interest. List A becomes a positive list of substances authorised in rubber products, the moment the time frame of List B has expired. Deadline for List B has been set at 7 years after the deadline of List C.

A declaration of interest should be send to the secretariat of the Council of Europe using the model letter N° 1 and the information required in section 11.

Substances not authorised in any regulation (“new substances”) should be petitioned for inclusion into List A by sending a petition to EFSA or the Committee of Evaluation.

11.3.2. Overview of rules

A more detailed lay out and time frame of the procedure is given below:

1. The Committee of experts decided in Dec 2003 to establish a positive list of substances to be used in the manufacture of rubber products intended to come into contact with foodstuffs.

2. To establish this list, the Secretariat of the CoE on the request of the Committee of experts published in *Technical document No. 1* an incomplete list of substances notified to an ad hoc working group of the Council of Europe. In principle this initial list containing all substances appearing in the national lists as well as substances currently used by industry. However because omissions can occur in the

preparation of this List C, a period of three years is given to the interested parties, to transfer substances from List C into List B or A by sending a declaration of interest (See item 11). Substances not listed in List C but authorised at the national level will be submitted to the same procedure.

3. During the three years each substance for which a declaration of interest has been received by the secretariat of the CoE is transferred into List B ("provisional list") or directly into List A if they have been classified in the SCF list 0-4.

4. After three years List C will be withdrawn and only the substances mentioned in List B or List A may be used in the manufacture of rubber products for food contact applications.

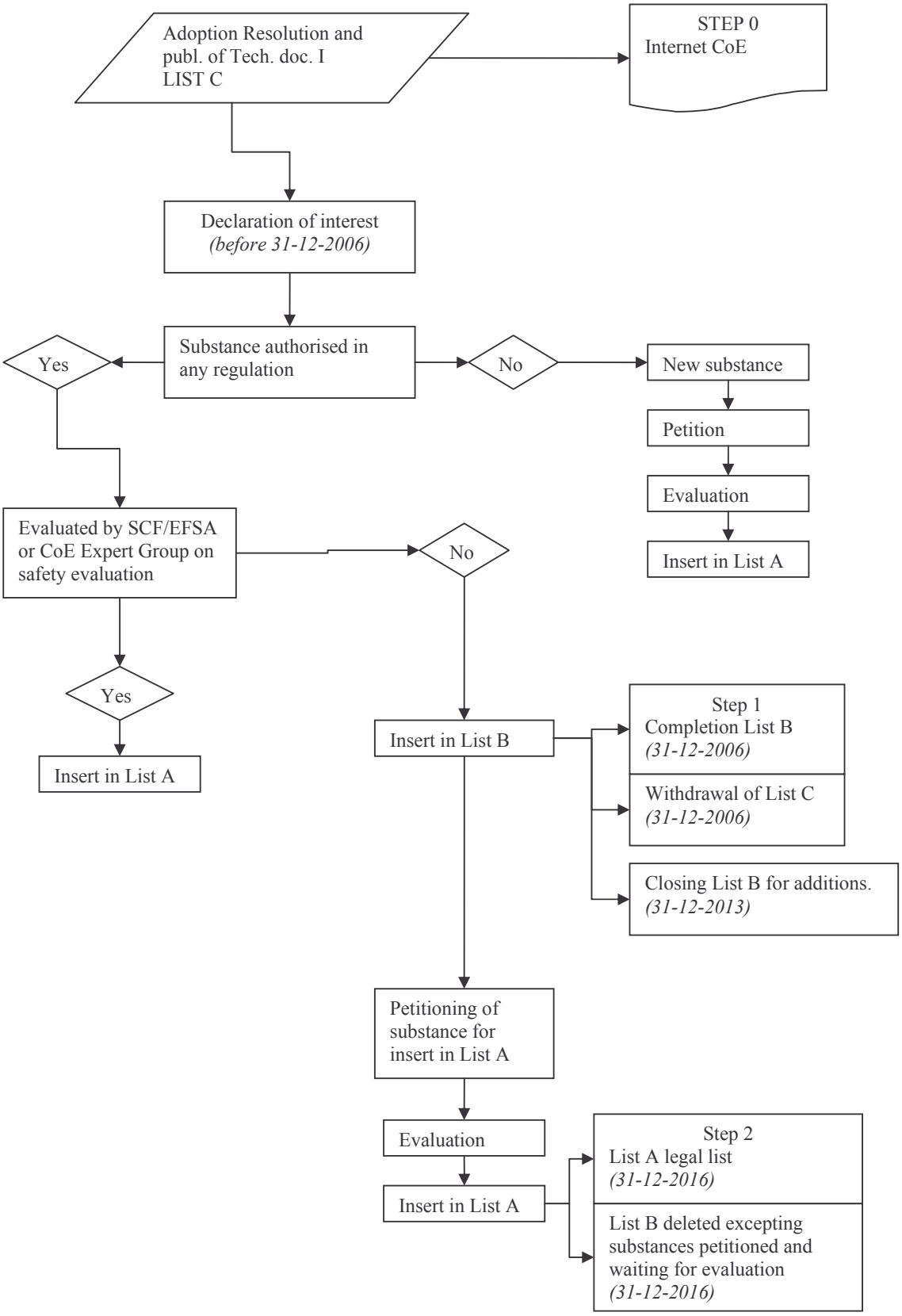
5. After three years substances not appearing in the Lists B or A are considered new substances and they cannot be used unless they are authorised by the Committee of Experts. These substances will then be inserted into List A.

6. Within seven years of the completion of List B, interested parties should submit a request for the transfer of a substance from List B into List A. The petition transmitted to the Secretariat of the Council of Europe should contain the data requested in the Council of Europe guidelines concerning safety evaluation of food contact materials. The substances, for which a petition is transmitted in compliance with the Council of Europe guidelines, will be maintained in List B pending their evaluation. Substances for which no petition has been received will be deleted from List B and will no longer be authorised.

7. Ten years after the completion of List B (31 December 2016), it will be withdrawn and only the substances which are included in the positive list i.e. in List A may be used.

8. A substance in List B may be transposed into List A if the transfer is authorised by the Committee of experts.

SCHEMATIC PROCEDURE TO ESTABLISH A LIST OF SUBSTANCES THAT MAY BE USED IN RUBBER PRODUCTS INTENDED FOR FOOD CONTACT



12. DECLARATION OF INTEREST

12.1. MODEL LETTER N° 1

REQUEST FOR THE TRANSFER OF A SUBSTANCE FROM “INDEX LIST C” TO “TRANSFER LIST B”

Council of Europe
Committee of Experts on Materials coming into contact with Food
(For the attention of ……)

Our reference:..... Date:.....

The
undersigned.....(3)…….....
.....
.....
requests the transfer to the “List B” of the following substance:
.....(4).....
.....
.....

The person responsible for answering any question on the substance is:
.....(5).....
.....

Enclosed are the following:

1. Brief information on substance

Yours sincerely,

.....

Enclosure. Data for expression of interest

12.1.1. LEGENDA TO MODEL LETTERS

The numbers between brackets in model letters n.1 and 2 have the following meaning:

(1) submit a separate request for each substance (except when a group of substances is being considered for a group evaluation and group restriction)

(2) put X in the appropriate box

(3) specify name, address, telephone, fax and E-mail of petitioner

(4) specify the chemical name, main chemical synonyms (e.g. IUPAC name) and trade names, CAS number

(5) specify name, address, telephone, fax and E-mail of the person responsible for the technical dossier

12.2. MODEL LETTER N° 2:

RECEIPT OF AN EXPRESSION OF INTEREST BY THE COUNCIL OF EUROPE

Dear Mr/Ms ..... Date:

Ref. : Your petition dated ....., concerning the substance REF.N. .....

On behalf of the Committee of experts, I acknowledge receipt of the documentation referred to above which you have sent for insert of the substance in List B of the Technical document No. 1 to the Resolution ResAP (2004) 4.

Your documentation has been classified under document reference number .....
The substance reference number..... has been attributed to the substance // has been already attributed to the substance. The name of the substance is unchanged/changed to.....In all future correspondence referring to this documentation, please quote both these reference numbers as well the old and the new names.

Yours sincerely
…….....
CoE responsible
Mr/Ms.....
.....

Any person interested in the insertion of a substance into List B of Technical document No. 1 is asked to fill in the form below. Based on the information provided transfer to List B will be considered.

Information requested	Guidance for providing the data requested
1. IDENTITY OF SUBSTANCE	
1.1 individual substance:	Answer 'yes' or 'no'
1.2 mixture	Answer 'yes' or 'no'
1.3 polymeric substance	Answer 'yes' or 'no'
1.4 chemical name:	Give chemical name of substance.
1.5 synonym(s):	Set out synonyms, if any.
1.6 trade name(s):	Set out trade name(s), if any.
1.7 CAS No.	Set out CAS number, if any.
1.8 molecular formula:	Give molecular formula.
1.9 structural formula	Give structural formula
1.10 molecular weight:	Give molecular weight.
1.11 purity (%):	Set out percentage purity.
1.12 major impurities (%):	Set out major impurities, individual impurity levels
1.13 specifications:	Where appropriate, give a proposal for a specification to be included in the Resolution
1.14 other information	Give any other relevant information.

2. INTENDED USE	
2.1 technological function:	Set out function of substance in the production process or in the finished product. For example monomer, co-monomer in the production of rubber x, antioxidant, catalyst, initiator, vulcanisation agent etc. Provide any relevant information to demonstrate the functionality of the substance in the final product. If relevant, provide information on the production process.
2.2 maximum percentage in formulation:	Set out maximum percentage in formulation. The maximum percentage to achieve a technological property, as well as the foreseeable level used in practice should be given, if relevant.
2.3 conditions of contact in practice	Set out in which category (I, II or III) the final product is expected to be used.

3. AUTHORISATION OF SUBSTANCE	
3.1 EU countries	Set out Member State(s), give relevant regulation(s), SCF listing with PM/Ref No or other and give further details like restrictions and conditions
3.2 non-EU countries	Set out country, give relevant regulation(s) or other and give further details like restrictions and conditions.
3.3 new substance, not regulated in any country	Answer 'yes' or 'no'.

4. MIGRATION DATA	
4.1 Available migration data	Indicate availability of migration data and analytical method. Do not yet provide detailed information or data
5. TOXICOLOGICAL DATA	
5.1 Available toxicity data	Indicate the availability of toxicity data., E.g. mutagenicity tests, oral studies, $LD_{50,}$ carcinogenicity study , etc. Do not yet provide detailed information or data.

APPENDIX 1

INVENTORY LIST OF SUBSTANCES USED FOR THE MANUFACTURE OF RUBBER PRODUCTS INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

Document elaborated by the Netherlands delegation
for the 4th meeting of the Ad hoc Group on rubber
The Hague, 18 – 19 June 2003

1. Explanation of the abbreviations used in the columns in the tables of Appendix 1

The tables / lists of Appendix 1 contain the following information:

- column 1: **PM/REF nr**, the EU food contact material reference number of the substance;
- column 2: **CAS nr**, the Chemical Abstracts Service registry number of the substance;
- column 3: **Name**, the chemical name of the substance;
- column 4: **List A**, the definitive list of permitted / evaluated substances

Categories I, II and III: 'x', indicates the use to manufacture the type of rubber product;
- column 5: **Restrictions**, the restrictions of the evaluated substances (if necessary);
- column 6: **Transfer list B**, the interest declared for use in the type of rubber product;
- column 7: **Legislation/national approval**, substances which are approved at national level in the following countries (e.g. AU=Austria, D=Germany, F=France, I=Italy, NL= The Netherlands, UK= United Kingdom, USA=United States of America);
- column 8: **SCF Status**, the evaluation by SCF: the list, the restrictions (for Plastics)

Definition of the SCF Lists (briefly):

- List 0: Substances which may be used and for which an ADI need not be established.
- List 1: Substances, for which an ADI, a t-ADI, a MTDI, a PMTDI, a PTWI or classification "acceptable" has been established.
- List 2: Substances for which a TDI or a t-TDI has been established.
- List 3: Substances for which an ADI or a TDI could not be established, but where the present use could be accepted.
- List 4A (for monomers): Substances for which an ADI or a TDI could not be established but which could be used if the substances migrating is not detectable.
- List 4B (for monomers): Substances for which an ADI or a TDI could not be established, but which could be used if the levels of monomer residues are reduced as much as possible.
- List 4 (for additives): Substances for which an ADI or a TDI could not be established, but which could be used if the substance migrating is not detectable.
- List 5: Substances which should not be used.
- List 6: Substances for which there exist suspicions about their toxicity and for which data are lacking or are insufficient.
- List 6A: Substances suspected to have carcinogenic properties. These substances should be not detectable.
- List 6B: Substances suspected to have toxic properties (other than carcinogenic). Restrictions may be indicated.
- List 7: Substances for which some toxicological data exist, but for which an ADI or a TDI could not be established. The required additional information should be furnished.
- List 8: Substances for which no or only scanty and inadequate data were available.
- List 9: Substances and groups of substances which could not be evaluated due the lack of specifications (substances) or to lack of adequate descriptions (group of substances).
- List W: Waiting List. Substances not yet included in the Community Lists. New substances, i.e. substances never approved at national level.
- List W7: Substances for which some toxicological data exists, but for which an ADI or a TDI could not be established. The required additional information should be furnished.
- List W8: Substances for which no or only scanty and inadequate data were available.

- List W9: Substances and group of substances which could not be evaluated due to lack of specifications (substances) or to lack of an adequate description (group of substances).

  ADI=Acceptable Daily Intake
  t-ADI=temporary ADI
  MTDI= Maximum Tolerable Daily Intake
  PMTDI=Provisional MTDI
  PTWI=Provisional Tolerable Weekly Intake
  (see also the EU Synoptic Document);

  D=Deleted;
  DL=limit of detection;
  fp=final product;
  NCO=isocyanated moiety;
  n.d=not detectable;
  QM=maximum permitted quantity of the 'residual' substance in the material or article;
  QMA=maximum quantity per area;
  QM(T)=maximum permitted quantity of the 'residual' substance in the material or article expressed as total of moiety/substance(s) indicated;
  SML=specific migration limit in foods or food simulant ;
  SML(T)=specific migration limit in foods or food simulant expressed as total of moiety/substance(s) indicated;

  W=SCF waiting list (new substance);

2. Function codes:

1. Monomers / Starting Agents
2. Accelerators
3. Activators
4. Catalysts
5. Colourants / pigments
6. Cross-linking agents
7. Emulsifiers / emulsion stabilisers
8. Initiators
9. Fillers
10. Plasticisers
11. Protective agents
12. Retarders
13. Vulcanising agents

3. Salts:

Salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc of authorised acid, alcohol or phenol shall be automatically authorised. Salts of acids and bases that have been evaluated separately and are assigned to any of SCF lists 1 to 4 are also authorised. The restrictions should be the same as those of the individual acid and/or.

Index list of Monomers and other Starting Agents for Rubber Products

PM /REF	CAS Nr	Name	Function	List A			Restrictions		Transfer List B			Index List C	SCF Status (for Plastics)
				Category			Category	Category	Declaration of interest for the continuation of the substance in category:			Legislation / approval of the substance for manufacture of rubber in country:	List/Restriction
			No	I	II	III	I	II	I	II	III		
10120	108-05-4	Acetic acid, vinyl ester										D,F,I,NL	2 SML=12 mg/kg
-	-	Acids, aliphatic, monocarboxylic, saturated (C2-C18), vinyl esters										D	-
-	-	Acids, aliphatic, mono- and dicarboxylic, unsaturated (C3-C8)										D	-
-	-	Acids, aliphatic, mono- and dicarboxylic, unsaturated (C3-C8), esters with alcohols, aliphatic, monohydric, saturated (C2-C12)										D	-
-	-	Acids, fatty (C8-C24), hydroxylated or not										I	-
10630	79-06 –1	Acrylamide										F,I	4A SML=n.d (DL=0.01 mg/kg)
10690	79-10-7	Acrylic acid										D,F,I	2
10780	141-32-2	Acrylic acid, n-butyl ester										D,I,NL	6A
10810	2998-08-5	Acrylic acid, sec-butyl ester										D	2
10840	1663-39-4	Acrylic acid, tert-butyl ester										D	2
11260	106-90-1	Acrylic acid, 2,3-epoxypropyl ester										I,NL	6A QM(T)=5 mg/kg in FP (expressed as epoxy m.w. to 43)
	-	Acrylic acid, esters with alcohols, aliphatic, monohydric, saturated (C5-C8)										D	-
11470	140-88-5	Acrylic acid, ethyl ester										D,I,NL	2
11680	689-12-3	Acrylic acid, isopropyl ester										D	2
11710	96-33-3	Acrylic acid, methyl ester										D,I	2

Index list of Monomers and other Starting Agents for Rubber Products

PM /REF	CAS Nr	Name	Function	List A			Restrictions		Transfer List B			Index List C	SCF Status (for Plastics)
				Category			Category	Category	Declaration of interest for the continuation of the substance in category:			Legislation / approval of the substance for manufacture of rubber in country:	List/Restriction
			No	I	II	III	I	II	I	II	III		
11980	925-60-0	Acrylic acid, n-propyl ester										D	2
12100	107-13-1	Acrylonitrile										D,F,I,NL,USA	4A SML=n.d. (DL=0.01 mg/kg)
12130	124-04-9	Adipic acid										I,USA	1
-	-	Alkenylbicyclo[2.2.1]hept-2-ene										D	-
12610	107-18-6	Allyl alcohol										I	6A
12820	123-99-9	Azelaic acid										I	2
13480	80-05-7	2,2-Bis(4-hydroxyphenyl)propane										I	2 SML=3 mg/kg
-	7726-95-6	Bromine										F,USA	-
13630	106-99-0	Butadiene										D,F,I,NL.USA	4A QM=1mg/kg in FP or SML=n.d. (DL=0.02mg/kg)
13690	00107-88-0	1,3-Butanediol										**which country?**	1
13720	110-63-4	1,4-Butanediol										I,USA	7
13750	513-85-9	2,3-Butanediol										I	8
13870	106-98-9	1-Butene										D,I	3
14530	7782-50-5	Chlorine										F	3
13900	107-01-7	2-Butene										I	3
14560	126-99-8	2-Chloro-1,3-butadiene										D,F,I,NL,USA	6A
14585	110-75-8	Chloroethyl vinyl ether										I,NL	6A
		Chloroprene see '2-Chloro-1,3-butadiene'											
14650	79-38-9	Chlorotrifluorethylene										F,NL.USA	3 QMA= 0.05mg/ $6dm^2$
		p-Cresol-dicyclopentadiene										**to discuss?**	

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PM /REF	CAS Nr	Name	Function	List A			Restrictions		Transfer List B			Index List C	SCF Status (for Plastics)
				Category			Category	Category	Declaration of interest for the continuation of the substance in category:			Legislation / approval of the substance for manufacture of rubber in country:	List/Restriction
			No	I	II	III	I	II	I	II	III		
14800	3724-65-0	Crotonic acid										I	6A
-	-	Cyclooctadiene										D,I,UK	-
	110-82-7	Cyclohexane										**which country?**	
15040	542-92-7	1,3-Cyclopentadiene										I	8
15580	1653-19-6	2,3-Dichloro-1,3-butadiene										D,F,I	6A
15730	77-73-6	Dicyclopentadiene										D,F,I,NL, USA	8
15760	111-46-6	Diethyleneglycol										I	2 SML(T)=30mg/kg alone or with ethyleneglycol
-	-	1,3-Dimethylpropanediol										I	-
16390	126-30-7	2,2-Dimethyl-1,3-propanediol										I	8
16600	5873-54-1	Diphenylmethane-2,4'-diisocyanate										I,USA	4A Qm(T)=1mg/kg in fp(as NCO)
16630	00101-68-8	Diphenylmethane-4,4'-diisocyanate										I,USA	4A Qm(T)=1mg/kg in fp(as NCO)
-	-	Diphenylmethane-2,6'-diisocyanate										I,USA	-
16690	1321-74-0	Divinylbenzene										D,F,I,NL	6A
16750	106-89-8	Epichlorohydrin										I,UK	4A Qm=1mg/kg in fp
16950	74-85-1	Ethylene										D,F,I,NL	3
16960	107-15-3	Ethylenediamine										I	2 SML=12mg/kg
16990	107-21-1	Ethyleneglycol										I	2 SML=30mg/kg alone or with diethyleneglycol
17020	75-21-8	Ethylene oxide										D,I	4A Qm=1mg/kg

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			No	I	II	III	I	II	I	II	III		
													in fp
17110	16219-75-3	5-Ethylidenebicyclo[2.2.1]hept-2-ene										F,I,NL,USA	8
17290	110-17-8	Fumaric acid										F,I	1
-	-	Fumaric acid, esters with alcohols, aliphatic, monohydric, saturated (C1-C8)										D	-
18100	56-81-5	Glycerol										I	1
18370	592-45-0	1,4-Hexadiene										D,F,I,NL	6A
18400	592-42-7	1,5-Hexadiene										F	7
18430	116-15-4	Hexafluorpropylene										F,I,NL,USA	4A SML= 0.01mg/kg
18460	124-09-4	Hexamethylenediamine										I	2 SML=2.4mg/kg
18640	822-06-0	Hexamethylene diisocyanate										I	4A Qm(T)=1mg/kg in fp (as NCO)
	110-54-3	n-Hexane										UK	
18700	629-11-8	1,6-Hexanediol										I	7
-	1333-74-0	Hydrogen										NL **to discuss!**	-
19000	115-11-7	Isobutene										D,F,I,NL,USA	3
19060	109-53-5	Isobuytyl vinyl ether										D	3 SML=0.05mg/kg
	78-78-4	Isopentane										UK	
19150	121-91-5	Isophthalic acid										I	3 SML=5mg/kg
		2-methyl-1,3-butadiene see '2-Methyl-1,3-butadiene'											
19270	97-65-4	Itaconic acid										F,I	0
19490	947-04-6	Laurolactam										USA	7

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			No	I	II	III	I	II	I	II	III		
19518	60-33-3	Linoleic acid										I	0
19540	110-16-7	Maleic acid										I	2 SML(T)=30mg/kg (with maleic anhydride)
-	-	Maleic acid, esters with alcohols, aliphatic, monhydric, saturated (C1-C8)										D	-
19960	108-31-6	Maleic anhydride										D,F	2 SML(T)=30mg/kg (expressed as maleic acid)
-	-	Maleic resins modified with rosin and abietic acid										I	-
19990	79-39-0	Metharcylamide										I	4A SML=n.d. (DL=0.02mg/kg)
20020	79-41-4	Methacrylic acid										D,F,I,NL.USA	2
20110	97-88-1	Methacrylic acid, n-butyl ester										D,I	2
20140	2998-18-7	Methacrylic acid, sec-butyl ester										D	2
20170	585-07-9	Methacrylic acid, tert-butyl ester										D	2
20380	1189-08-8	Methacrylic acid, diester with 1,3-butanediol										D	8
20440	97-90-5	Methacrylic acid, diester with ethyleneglycol										I,NL,USA	7
20560	142-90-5	Methacrylic acid, dodecyl ester										D	7
-	-	Methacryl acid, esters with alcohols, aliphatic, monohydric, saturated (C5-C8)										D	-

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				Category			Category	Category	Declaration of interest for the continuation of the substance in category:			Legislation / approval of the substance for manufacture of rubber in country:	List/Restriction
			No	I	II	III	I	II	I	II	III		
20890	97-63-2	Methacrylic acid, ethyl ester										D,I	2
21100	4655-34-9	Methacrylic acid, isopropyl ester										D	2
21130	80-62-6	Methacrylic acid, methyl ester										D,I	2
21340	2210-28-8	Methacrylic acid, n-propyl ester										D	2
21415	2549-53-3	Methacryl acid, tetradecyl ester										D	7
21640	78-79-5	2-Methyl-1,3-butadiene										D,F,I,NL, USA	6A
21730	563-45-1	3-Methyl-1-butene										D	4B QMA=0.006 mg/6dm^2
21760	694-91-7	5-Methylenebicyclo[2.2.1]hept-2-ene										I,NL.USA	8
-	101-14-4	4,4'-Methylenebis(2-chloroaniline)										I	-
21940	924-42-5	Methylolacrylamide										I	4A SML=n.d (DL=0.01mg/kg expressed as acrylamide)
-	-	Methylpentadiene										I	-
22150	691-37-2	4-Methyl-1-pentene										D	3 SML=0.05mg/kg
22210	98-83-9	alpha-Methylstyrene										D,I	7
22270	107-25-5	Methyl vinyl ether										D	7
22335	28693-00-7	Monochloroacetic acid, ester with 5-(hydroxymethyl)bicyclo-[2.2.1]-hept-2-ene										NL	6A
22420	3173-72-6	1,5-Naphthalene diisocyanate										I	4A Qm(T)=1mg/kg in fp (as NCO)
22660	111-66-0	1-Octene										D	2 SML=15mg/kg
		alpha Olefines C_3-C_4										D **to discuss!**	
-	-	Organopolysiloxanes containing methyl, vinyl, phenyl, and fluorine										I,USA	-

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				Category			Category	Category	Declaration of interest for the continuation of the substance in category:			Legislation / approval of the substance for manufacture of rubber in country:	List/Restriction
			No	I	II	III	I	II	I	II	III		
		groups											
22810	504-60-9	1,3-Pentadiene										I	8
22840	115-77-5	Pentaerythritol										I	2
	109-66-0	Pentane										UK	
22900	109-67-2	1-Pentene										I,UK	2
22901	109-68-2	2-pentene										I,UK	8
23200	88-99-3	o-Phtathalic acid										I	2
76320	85-44-9	Phthalic anhydride										D,F,I,NL,USA	2
23530	25190-06-1	Poly(1,4-butyleenglycol)										USA	7
-	68037-39-8	Polyethylene, chlorosulphonated										D,F,I,AU	-
81280	9002-89-5	Polyvinyl alcohol										I	7
81500	9003-39-8	Polyvinylpyrrolidone										I	9
23740	57-55-6	1,2-Propanediol										I	1
23770	504-63-2	1,3-Propanediol										I	3 SML=0.05mg/kg
23980	115-07-1	Propylene										D,F,I,NL, USA	3
24010	75-56-9	Propylene oxide										I	4A Qm=1mg/kg in fp
-	-	Rosin, condensation products with citric and maleic acids, and their esters with C3-C6 polyols										I	-
24220	9006-03-5	Rubber, chlorinated										I	9
-	-	Rubber, cyclized										I	-
24250	9006-04-6	Rubber, natural										D,I,USA,AU **to discuss !**	3
-	-	Rubber, natural, light colored, non smoked grade										D	-
-	-	Rubber, natural, pre-vulcanized										D	-

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			No	I	II	III	I	II	I	II	III		
-	-	Rubber, naturated, grafted with acrylic acid esters and/or methacrylic acid esters of monovalent alcohols C_1-C_4										D	-
24280	111-20-6	Sebacic acid										I	2
24445	-	Silanols containing at least one hydroxyl group and one or more methyl groups on each silicon atom										NL	9
-	-	Siloxanes containing one hydrogen atom and one methyl group on each silicon atom										NL	-
-	-	Siloxanes containing two methyl groups on each silicon atom and one vinyl group on the terminating silicon atoms										NL	-
24490	50-70-4	Sorbitol										I	1
24610	100-42-5	Styrene										D,F,I,NL,UK, USA	4B
24910	100-21-0	Terephthalic acid										I	2 SML=7.5mg/kg
24970	120-61-6	Terephthalic, dimethyl ester										USA	2
-	-	Terpene resins made of dipentene, alpha-pinene, and beta-pinene										I	-
25120	116-14-3	Tetrafluorethylene										F,I,NL, USA	3 SML= 0.05mg/kg
25210	584-84-9	2,4-Toluene diisocyanate										I	4A Qm(T)=1mg/kg in fp (as NCO)

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				Category			Category	Category	Declaration of interest for the continuation of the substance in category:			Legislation / approval of the substance for manufacture of rubber in country:	List/Restriction
			No	I	II	III	I	II	I	II	III		
25240	91-08-7	2,6-Toluene diisocyanate										I	4A Qm(T)=1mg/kg in fp (as NCO)
25435	-	Trichlorobutadiene										D	6A
25510	112-27-6	Triethyleneglycol										I	2
25600	77-99-6	1,1,1-Trimethylolpropane										I	2 SML=6mg/kg
-	-	Triphenylmethanediisocyanate										I	-
26000	3048-64-4	5-Vinylbicyclo[2.2.1]hept-2-ene										NL	6A
26050	75-01-4	Vinyl chloride										D,F,I	4A Qm=1mg/kg in fp and SML=0.01mg/kg
26110	75-35-4	Vinylidene chloride										D,I,AU	4B Qm=5mg/kg in fp or SML=n.d. (DL=0.05mg/kg)
26140	75-38-7	Vinylidene fluoride										1 F,I,NI,USA	3 SML= 5mg/kg
26215	100-69-6	2-Vinylpyridine										F	6A
26260	1184-84-5	Vinylsulphonic acid										I	6A
26290	25013-15-4	Vinyltoluene										D	7

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PM/REF	CAS Nr	Name	Function	List A			Restrictions		Transfer List B			Index List C	SCF Status (for Plastics)
				Category			Category	Category	Declaration of interest for the continuation of the substance in category:			Legislation / approval of the substance for manufacture of rubber in country:	List
			No	I	II	III	I	II	I	II	III		
30000	64-19-7	Acetic acid										D,F,I	1
-	7346-79-4	Acetic acid, cyclohexylamine salt										D	-
-	-	Acetone - aromatic amine - phenyl-2-naphthylamine, copolymer										USA	-
	68412-48-6	Acetone-diphenylamine, copolymer										F,USA	-
-	-	Acetone-diphenylamine-formaldehyde, copolymer										USA	-
30480	140-04-5	Acetylricinoleic acid, butyl ester										NL,USA	7
-	-	Acids, fatty										USA	-
	-	Acids, fatty, hydrogenated										USA	-
-	-	Acids, fatty, salts (sodium or potassium)										USA,AU	-
-	-	Acids, fatty, C12-C20										D	-
-	-	Acids, fatty, C12-C20, with an even number of carbon atoms										D,F	-
-	-	Acids, fatty, C12-C20, even numbered, saturated and unsaturated, zinc salt										F	
-	-	Acids, fatty, C14-C20, ammonium, potassium, sodium and zinc salts										D,USA	-
-	-	Acids, fatty, mainly C16-C18, n-butyl ester										D	-
31390		Acids, fatty, lineair, with an even number of carbon atoms (C8-C22)										NL	9
-	-	Acids, fatty, linear, with an even number of carbon atoms C8-C22), esters with glycerol										NL	-

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				Category			Category	Category	Declaration of interest for the continuation of the substance in category:			Legislation / approval of the substance for manufacture of rubber in country:	List
			No	I	II	III	I	II	I	II	III		
-	-	Acids, fatty, linear, with an even number of carbon atoms (C8-C22), esters with pentaerythritol										NL	-
31520	61167-58-6	Acrylic acid, 2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methyl-benzyl)-4-methylphenyl ester										D	2 SML=6mg/kg
31530	123968-25-2	Acrylic acid, 2,4-di-tert-pentyl-6-[1-(3,5-di-tert-pentyl-2-hydro-xyphenyl) ethylphenyl ester										D,AU	3 SML=5mg/kg
31660	9003-54-7	Acrylonitrile-styrene, copolymer										USA	D
-	141-17-3	Adipic acid, bis[2-(2-butoxy-ethoxy)-ethyl) ester										NL,USA	-
31920	103-23-1	Adipic acid, bis(2-ethylhexyl) ester										D,F,I	2 SML=18mg/kg
32080	110-29-2	Adipic acid, n-decyl n-octyl ester										NL,USA	6B
-	2451-84-5	Adipic acid, dibenzyl ester										NL,USA	-
32320	105-97-5	Adipic acid, di-n-decyl ester										NL,USA	6B
	141-28-6	Adipic acid, diethyl ester										UK	
32480	141-04-8	Adipic acid, diisobutyl ester										F,I	6B
32560	27178-16-1	Adipic acid, diisodecyl ester										NL,USA	6B
32720	1330-86-5	Adipic acid, diisooctyl ester										NL,USA	6B
32880	123-79-5	Adipic acid, di-n-octyl ester										USA	6B
33350	9005-32-7	Alginic acid										D,F	1

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			No	I	II	III	I	II	I	II	III		
-	-	n-Alkenyl(C10-C16)benzene-sulphonic acid, ammonium, calcium, magnesium, potassium and sodium salts										USA	-
-	-	1-n-Alkenyl(C12-C20)sulphonic acid, sodium salt										F	-
-	-	Alkyl(C8-C20)arylphosphonic acid, calcium or sodium salt										F	-
-	-	Alkylarylsulphonic acid										D	
33680	-	Alkyl(C8-C20)arylsulphonic acid, calcium or sodium salt										F,NL	9
33760	-	Alkyl(C8-C20)arylsulphuric acid, calcium or sodium salt										F,NL	9
34030	-	N-n-Alkyl(C14-C18, even)-N'(carboxymethyl)-N,N'-tri-methylenediglycine										USA	9
34230	-	Alkyl(C8-C20)sulphonic acids										D,F,NL	2 SML= 6mg/kg
34240	-	Alkyl(C10-C20)sulphomic acid, esters with phenols										D,F,AU	2 SML=6mg/kg
-	-	Alkyl(C8-C18)sulphuric acids, sodium salts										NL	-
-	-	N-Alkyl(C14-C18)-N,N'-tri-acetoyl-1,3-diaminopropane										NL	-
-	-	Alkylxanthogenic acid, sodium salt										D	-
-	-	Alkylxanthogenic acid, zinc salt										D	-
34560	21645-51-2	Aluminium hydroxide										D,F,USA,UK	2
34720	1344-28-1	Aluminium oxide										D,F,I,NL	2
34480	-	Aluminium powder										D	2

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			No	I	II	III	I	II	I	II	III		
85980	1344-00-9	Alumium sodium silicate										D,F	2
-	-	Amides of acids, fatty, linear, with an even number of carbon atoms (C8-C22)										NL	-
-	-	Amines of fatty acids										USA	-
12775	124-68-5	2-Amino-2-methyl-1-propanol										F	8
35320	7664-41-7	Ammonia										D,F,UK	1
USA		Aniline-butyraldehyde, copolymer											-
-	9003-50-3	Aniline-heptaldehyde, copolymer										USA	-
-	-	Animal glue										F,NL,USA	-
-	-	Animal oils										I	-
-	131-08-8	2-Anthraquinonesulphonic acid, sodium salt										USA	-
35960	1332-21-4 12001-29-5 12001-28-4	Asbestos fiber, chrysolite or crocidolite										USA	5
36480	109-31-9	Azelaic acid, di-n-hexyl ester										NL	6B
36640	123-77-3	Azodicarbonamide										D,F,I,NL,USA,AU	3
37280	1302-78-9	Bentonite										D,I	3
37440	80-17-1	Benzenesulphonic acid hydrazide										D,NL	6A
37520	2634-33-5	1,2-Benzisothiazolin-3-one										D,F,USA	2 SML=1.2mg/kg
37600	65-85-0	Benzoic acid										D,F,I,NL,AU	1
38240	119-61-9	Benzophenone										USA	2 SML=0.6mg/kg
-	105-11-3	1,4-Benzoquinone dioxime										USA	-
-	95-30-7	2-Benzothiazyl-N,N-diethylthio-carbamyl sulphide										NL,USA	-

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			No	I	II	III	I	II	I	II	III		
-	15484-34-1	Bis(4-aminocyclohexyl)methane carbamate										NL,USA	-
13250	101-77-9	Bis(4-aminophenyl)methane										USA	4A SML=ND (DL=0.01mg/kg)
-	95-35-2	1,3-Bis(2-benzothiazolylmercapto-methyl)urea										NL,USA	-
-	-	2,2-Bis(3-tert.butyl-4-hydroxy-phenyl)propane esterified with p-nonylphenyl phosphite										NL	-
-	26511-61	3,3-Bis(tert.butylperoxy)butanoic acid, n-butyl ester										NL	
-	3006-86-8	1,1-Bis(tert.butylperoxy)cyclo-hexaan										NL	-
38600	78-63-7	2,5-Bis(tert.butylperoxy)-2,5-dimethylhexane										D,F,UK,USA	9
38615	2212-81-9	1,3-Bis(tert.butylperoxyiso-propyl)-benzene										F,USA,AU	9
38625	2781-00-2	1,4-Bis(tert-butylperoxyiso-propyl)-benzene										D,AU	9
-	995-33-5	4,4-Bis(tert-butylperoxy)-pentanoic acid , butyl ester										NL	-
-	6731-36-8	1,1-Bis(tert-butylperoxy)-3,5,5-trimethylcyclohexane										NL	-
-	94-17-7	Bis(4-chlorobenzoyl) peroxide										F	-
38800	32687-78-8	N,N'-Bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl)-hydrazide										USA	2 SML=15mg/kg
-	33145-10-7	Bis(3,5-dimethyl-2-hydroxy-phenyl)-isobutane										D,AU	-

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				Category			Category	Category	Declaration of interest for the continuation of the substance in category:			Legislation / approval of the substance for manufacture of rubber in country:	List
			No	I	II	III	I	II	I	II	III		
-	-	2,6-Bis(2-hydroxy-3-nonyl-5-methylbenzyl) -p-cresol										D,USA	-
-	-	2,2-Bis(4-hydroxyphenyl) propane, polybutylated										USA	-
-	-	Bis(isopropyl xanthogen) poly-sulphide consisting of a 1:2:1 mixture of bis(isopropyl xantho-gen) trisulphide, bis(isopropyl xanthogen) tetrasulphide, and bis(isopropyl xanthogen) pentasulphide										USA	-
-	-	Bis(isopropyl xanthogen) tetra-sulphide										F	-
-	895-85-2	Bis(4-methylbenzoyl) peroxide										USA	-
39920	85-60-9	1,1-Bis(2-methyl-4-hydroxy-5-tert-butylphenyl) butane										F,I,USA	7
40000	991-84-4	2,4-Bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butyl-anilino)-1,3,5-triazine										D,F,I,NL,UK,USA	2 SML= 30mg/kg
40020	110553-27-0	2,4-Bis(octylthiomethyl)-6-methylphenol										D,I,USA,NL,AU	2 SML= 6mg/kg
-	97-39-2	Bis(o-tolyl)guanidine										I,NL,USA	-
13690	107-88-0	1,3-Butanediol										USA	1
-	95-31-8	N-tert-Butyl-2-benzothiazole-sulphenamide										F,NL,USA	-
40640	98-29-3	4-tert-Butylcatechol										USA	8
-	3457-61-2	tert-Butyl cumyl peroxide										NL	-
40720	25013-16-5	tert-Butyl-4-hydroxyanisole										I	1 SML=30mg/kg
-	109-72-8	n-Butyllithium										USA	-
-	15570-10-2	4-tert-Butyl-2-methylthiophenol										NL,USA	-

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				Category			Category	Category	Declaration of interest for the continuation of the substance in category:			Legislation / approval of the substance for manufacture of rubber in country:	List
			No	I	II	III	I	II	I	II	III		
-	4545-30-6	4-tert-Butylthiophenol, zinc salt										NL,USA	-
-	141-33-3	Butylxanthogenic acid, sodium salt										D,I	-
-	150-88-9	Butylxanthogenic acid, zinc salt										D,I,NL,USA	-
42180	1305-62-0	Calcium hydroxide										D,F	1
41520	1305-78-8	Calcium oxide										D,F,I,NL	1
41600	12004-14-7 37293-22-4	Calcium sulphoaluminate										D	2
-	23847-08-7	Caprolactam disulphide (=N,N'-dithio-bis(hexahydro-2H-azepinone-2)								x	x	D,AU	-
-	15484-34-1	Carbamic acid, bis(4-amino-cyclohexyl)methyl ester										F	-
42080	1333-86-4	Carbon black										D,F,I,NL,USA,UK	3 Max. Toluene extractable fraction= 0.15%
42160	124-38-9	Carbon dioxide										D	1
-	68133-93-7	Carbon disulphide - 1,1-methyl-enebispiperdine, copolymer										USA	-
42240	-	Carbon fibers										D	9
		Carboxymethylated anionic alcohol polyglycol ether										**to discuss! to delete?**	
42500	-	Carbonic acid, salts										D,F,I,NL,UK,USA	1
42640	9000-11-7	Carboxymethylcellulose										D,F	2
42720	8015-86-9	Carnauba wax										F	3
42800	9000-71-9	Casein										D,F	0
42880	8001-79-4	Castor oil										NL.USA	3

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			No	I	II	III	I	II	I	II	III		
43280	9004-34-6	Cellulose										D,NL	0
-	-	Cinnamaldehyde-hexa-methylenediamine, copolymer										I	-
44160	77-92-9	Citric acid										D,F	1
	70131-50-9	Clay										D,NL	3
-	-	Condensation products of ethylene oxide with alkyl-, dialkyl-,and trialkylamines (C12-C18)										F	-
-	-	Copolymers of acrylic acid, methacrylic acid, and maleic acid with styrene, methyl vinyl ether, vinyl versatate and butadiene, and their ammonium, potassium and sodium salts (MW > 1000)										D,F	-
53985	9010-79-1	Copolymer of ethyleneoxide vinylpyrrolidone										UK	
54060	24937-78-8	Copolymer of ethylene vinylacetate										UK	
-	61789-98-8	Cork										NL,USA	-
45280	-	Cotton fibers										D,NL,USA	3
-	-	Coumarone-indene, copolymer										NL,USA	-
45450	68610-51-5	p-Cresol-dicyclopentadiene-iso-butylene, copolymer										D,F,I,USA	3 SML=0.05mg/kg
45440	-	Cresols, butylated, styrenated										D,USA	2 SML=12mg/kg
45470	-	Cresols, styrenated										USA	9
45760	108-91-8	Cyclohexylamine										D	
-	95-33-0	N-Cyclohexyl-2-benzothiazole-sulphenamide										D,F,I,NL	-
-	5459-93-8	N-Cyclohexylethylamine										D,F,I,NL	-

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			No	I	II	III	I	II	I	II	III		
-	-	N-Cyclohexyl-N'-phenyl-phenylenediamine										USA	-
-	-	Decylbenzenesulphonic acid, sadium salt										USA	-
-	-	Dialkyl(C8-C18)dimethylammonium-chloride										NL.USA	-
46240	-	Dialkyldithiocarbamic acid, sodium salt										D,F	9
96080	-	Dialkyldithiocarbamic acid, zinc salt										D,F,AU	9
-	95-80-7	2,4-Diaminotoluene										NL,USA	-
-	-	Diaryl-1,4-phenylenediamine (aryl = phenyl, tolyl or xylyl)										USA	-
46375	61790-53-2	Diatomaceous earth										NL	3
-	135-57-9	2,2'Dibenzamidodiphenyl disulphide										USA	-
46400	120-78-5	Dibenzothiazyl disulphide										D,F,I,NL,USA	8
-	120-52-5	Dibenzolyl-1,4-benzoquinone dioxime										USA	-
46440	94-36-0	Dibenzolyl peroxide										D,F,NL,USA	8
-	103-49-1	Dibenzylamine										USA	-
-	14726-36-4	Dibenzyldithiocarbamic acid, zinc salt										D,F,NL,USA	-
-	111-92-2	Dibutylamine										D,NL	-
46640	128-37-0	2,6-Di-tert-butyl-p-cresol (=BHT)										D,F,I,NL,UK,USA	1 SML= 3mg/kg
-	-	Dibutyldithiocarbamic acid, copper salt										I	-
-	149--82-6	Dibutyldithiocarbamic acid, N,N-dimethylcyclohexylamine salt										NL,USA	-
-	136-30-1	Dibutyldithiocarbamic acid, sodium salt										D,F,I,NL,USA	-
96160	136-23-2	Dibutyldithiocarbamic acid, zinc salt										D,F,I,NL,USA	8

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			No	I	II	III	I	II	I	II	III		
-	88-26-6	3,5-Di-tert-butyl-4-hydroxy-benzyl alcohol										USA	-
46880	65140-91-2	3,5-Di-tert-butyl-4-hydroxy-benzylphosphonic acid, monoethyl - ester, calcium salt										USA	2 SML=6mg/kg
47040	34137-09-2	3,5-Di-tert-butyl-4-hydroxy-hydrocinnamic acid, triester with 1,3,5-tris (2-hydroxy-ethyl)-1,3,5-triazine-2,4,6-(1H,3H,5H) trione										D,USA	8
-	87-97-8	2,6-Di-tert-butyl-4-(methoxy-methyl)phenol										NL	-
47080	110-05-4	Di-tert-butyl peroxide										F,NL,USA	8
-	2668-47-5	2,6-Di-tert-butyl-4-phenyl-phenol										NL.USA	-
-	105-77-1	Dibutylxanthogen disulphide										NL,USA	-
-	133-14-2	2,4-Dichlorobenzoyl peroxide										D,F,NL,USA	-
-	80-43-3	Dicumyl peroxide										D,F,NL,USA	-
47440	461-58-5	Dicyanodiamide										USA	2
47620	111-42-2	Diethanolamine										USA	W8
-	-	1,2-Diethoxypropane										D	-
-	148-18-5	Diethyldithiocarbamic acid, sodium salt										D	-
-	109-89-7	Diethylamine										NL,USA	-
96170	14324-55-1	Diethyldithiocarbamic acid, zinc salt										D,F,NL,I,USA	8
47680	111-46-6	Diethyleneglycol										NL	2 SML(T)= 30mg/kg with ethylene-glycol

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				Category			Category	Category	Declaration of interest for the continuation of the substance in category:			Legislation / approval of the substance for manufacture of rubber in country:	List
			No	I	II	III	I	II	I	II	III		
-	105-55-5	1,3-Diethylthiourea										NL	-
-	502-55-6	Diethylxanthogen disulphide										NL,USA	-
-	89-28-1	1,2-Dihydro-6-dodecyl-2,2,4-trimethylquinoline										USA	-
-	91-53-2	1,2-Dihydroxy-6-ethoxy-2,2,4-trimethylquinoline										USA	-
-	3562-69-4	1,2-Dihydro-6-phenyl-2,2,4-tri-methylquinoline										USA	-
15910	108-46-3	1,3-Dihydroxybenzene										I	2 SML=2.4mg/kg
		Diisononylthiocarbamic acid, Zinc salt										UK	
-	20018-09-1	4-(Dijodomethylsulphonyl)toluene										USA	-
	91-16-7	1,2-Dimethoxybenzene										UK	
-	101-70-2	4,4'-Dimethoxydiphenylamine										NL,USA	-
49235	108-01-0	Dimethylaminoethanol										F	2 SML=18mg/kg
-	7005-47-2	2-Dimethylamino-2-methyl-1-propanol										F	-
-	793-24-8	N-(1,3-Dimethylbutyl)-N'-phenyl-p-phenylenediamine										D,F	-
-	53880-86-7	Dimethyldiphenylthiuram disulphide										D,F,NL	-
-	137-29-1	Dimethyldithiocarbamic acid, copper salt										F,I,NL,USA	-
-	128-04-1	Dimethyldithiocarbamic acid, sodium salt										D,F,I,NL,USA	-
49425	137-30-4	Dimethyldithiocarbamic acid, zinc salt										D,F,I,NL,USA	1 SML=1.2mg/kg
49485	134701-20-5	2,4-Dimethyl-6-(1-methylpenta-decyl)phenol										USA	3 SML=1mg/kg

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				Category			Category	Category	Declaration of interest for the continuation of the substance in category:			Legislation / approval of the substance for manufacture of rubber in country:	List
			No	I	II	III	I	II	I	II	III		
-	102-78-3	2-(2,6-Dimethylmorpholino-thio)benzthiazole										NL,USA	-
-	-	Dimethylphenylthiouram										I	-
-	-	Dimethylsiloxane polyether-polyol										F	-
49680	93-46-9	N,N'-Di(2-naphthyl)-p-phenylene-diamine										USA	7
-	3011-61-8	4,6-Dinonyl-o-cresol										USA	-
	54771-30-1	(2,4-dinonylphenyl)di-4-monononyl-phenyl) phosphite										UK **to discuss! to delete!**	
-	-	N,N'-Dioctyl-1,4-phenylene-diamine										USA	-
-	971-15-3	Dipentamethylenethiuram hexa-sulphide										I,NL,USA	-
-	120-54-7	Dipentamethylenethiuram tetra-sulphide										D,F,I,NL	-
-	-	Dipentene resin										USA	-
51320	79-74-3	2,5-Di-tert-pentylhydroquinone										F,USA	8
-	101-76-7	Diphenylamine, octylated										F,USA	-
51360	68442-68-2	Diphenylamine, styrenated										D,F,NL,USA	9
-	150-61-8	N,N'-Diphenylethylenediamine										USA	-
51500	102-06-7	Diphenylguanidine										D,F,I,NL,USA	D
-	17573-13-6	Diphenylguanidine phthalate										USA	-
51680	102-08-9	N,N'-Diphenylthiourea										F,I,NL,USA	2 SML=3mg/kg
51760	25265-71-8 110-98-5	Dipropyleneglycol										D	2
-	120-70-7	N,N'-Disalicylalpropylene-diamine										USA	-
-	-	Dithiodiethylammoniumbisdibenzyl-dithiocarbamate										D **to discuss! structure?**	

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			No	I	II	III	I	II	I	II	III		
-	103-34-4	4,4'-Dithiodimorpholine										USA	-
-	94-92-8	N,N'-Di-o-tolylethylenediamine										USA	-
-	16971-82-7	Di-o-tolylguanidine salt of pyrocatechol borate										USA	-
-	7691-02-3	1,3-Divinyltetramethyldisilazane										NL	-
52000	25155-30-0	Dodecylbenzenesulphonic acid, sodium salt										USA	2 SML=30mg/kg
-	112-55-0	Dodecylmercaptan										NL	-
-	-	Dodecylmercaptan isomers, single or mixed										USA	-
34281	151-21-3	Dodecylsulphuric acid, sodium salt										USA **=52565 ? to delete !**	3
	7128-64-5	2,3-Epoxypropyl phenyl ether										UK	
52720	112-84-5	Erucamide										D,F	3
53280	9004-57-3	Ethylcellulose										F	2
53520	110-30-5	N,N'-Ethylenebisstearamide										D	3
-	109-58-0	Ethylenediamine carbamate										NL,USA	-
-	53600	Ethylenediaminetetraacetic acid, sodium salts										NL,USA	2
53650	107-21-1	Ethyleneglycol										NL	2 SML(T)= 30mg/kg with diethylene-glycol
-	123-81-9	Ethyleneglycol bis(mercapto-acetate)										NL	-
53820	110-80-5	Ethyleneglycol monoethyl ether										USA	2 SML=3mg/kg
	026221-73-8	Etthylene-1-octene copolymer										UK	
54020	9010-79-1	Ethylene-propylene, copolymer										D,UK	D
	149-57-5	Ethylhexanoic acid										**which country?**	

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			No	I	II	III	I	II	I	II	III		
54260	9004-58-4	Ethylhydroxyethylcellulose										F	2
54300	118337-09-0	2,2'-Ethylidenebis(4,6-di-tert-butylphenyl) fluorphosphonite										USA	2 SML=6mg/kg
-	-	Ethylphenyldithiocarbamic acid, copper salt										I	-
-	-	Ethylphenyldithiocarbamic acid, sodium salt										D,I	-
-	14634-93-6	Ethylphenyldithiocarbamic acid, zinc salt										D,F,I,NL	-
-	140-90-9	Ethylxanthogenic acid, sodium salt										D,I	-
-	13435-46-8	Ethylxanthogenic acid, zinc salt										D,I	-
-	78-27-3	1-Ethynylcyclohexanol										NL	-
	112-84-5	Erucamide										UK	
-	-	Factices										D,F,AU	-
54710/1	61790-12-3	Fatty acids, tall oil										USA	3
-	-	Fatty acids, tall oil, n-butyl ester										USA	-
-	-	Fatty acids, tall oil, isooctyl ester										USA	-
-	-	Fatty acids, tall oil, n-propyl ester										USA	-
54820	-	Fibers, natural or synthetic										F	D
54880	50-00-0	Formaldehyde										I	3 SML=15mg/kg
-	-	Formaldehyde-cresols, copolymers										I	-
54900	9017-33-8	Formaldehyde-naphthalene-sulphonic acid, copolymer										D,F,NL,USA	9
	908-40-64	Formaldehyde-naphthalene-sulphonic polycondensate, sodium salt										**which country?**	
54940	9003-35-4	Formaldehyde-phenol, copolymer										I,NL,USA	D
-	24969-11-7	Formaldehyde-resorcinol, copolymer										D,F,I,AU	-

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			No	I	II	III	I	II	I	II	III		
54970	9003-08-1	Formaldehyde-2,4,6-triamino-1,3,5-triazine, copolymer										D	D
-	-	Formaldehyde-2,4,6-triamino-1,3,5-triazine - resorcinol, copolymer										D	-
-	-	Formaldehyde-tris(nonylphenyl) phosphite, copolymer										USA	-
-	9006-24-0	Formaldehyde-xylene, copolymer										D,F,I,NL	-
55200	1166-52-5	Gallic acid, dodecyl ester										I	1 SML(T)= 30 mg/kg (expressed as gallic acid)
55280	1034-01-1	Gallic acid, octyl ester										I	1 SML(T)=30 mg/kg (expressed as gallic acid)
55360	121-79-9	Gallic acid, propyl ester										I	1 (SML(T)=30 mg/kg (expressed as gallic acid
55440	900-70-8	Gelatin										D,F	0
55520	-	Glass fibers										D,F,NL	3
55600	-	Glass microballs										D	3
55920	56-81-5	Glycerol										NL,USA	1
57520	31566-31-1	Glycerol monostearate										F	1
58300	-	Glycine, sodium salt										NL	1
58320	7782-42-5	Graphite										NL,D	3
-	16941-12-1	Hexachloroplatinic acid										NL	-
58790	36653-82-4	1-Hexadecanol										I	3
-	999-97-3	Hexamethyldisilazane							x	x		NL	-

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59120	23128-74-7	1,6-Hexamethylenebis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionamide]										USA	2 SML=45mg/kg
59200	35074-77-2	1,6-Hexamethylenebis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]										USA	2 SML=6mg/kg
-	1434-06-6	Hexamethylenediamine carbamate										F,I,NL,USA	-
59280	100-97-0	Hexamethylenetetramine										F,I,NL,USA	3 SML(T)= 15mg/kg (expressed as formaldehyde)
71280	8002-74-2 63231-60-7	Hydrocarbon waxes, paraffin and microcrystalline										F,I	9
59990	7647-01-0	Hydrochloric acid										D,F	1
-	103-16-2	Hydroquinone monobenzyl ether										USA	-
60160	120-47-8	4-Hydroxybenzoic acid, ethyl ester										D	1
60200	99-76-3	4-Hydroxybenzoic acid, methyl ester										D	1
60240	94-13-3	4-Hydroxybenzoic acid, propyl ester										D	1
-	-	4-Hydroxybenzoic acid, sodium salt										D	-
-	3568-26-1	N-(3-hydroxy-1-butylidene)-1-naphthylamine										USA	-
60400	3896-11-5	2-(2-Hydroxy-3-tert-butyl-5-methyl-phenyl)-5-chlorobenzo-triazole										F	2 SML=30mg/kg
60560	9004-62-0	Hydroxyethylcellulose										D,F,NL	2
60800	65447-77-0	1-(2-Hydroxethyl)-4-hydroxy-2,2,6,6-tetramethylpiperidine - succinic acid, dimethyl ester, copolymer										F	2 SML=30mg/kg
61120	9005-27-0	Hydroxyethyl starch										D	2
61340	149-44-0	Hydroxymethanesulphinic acid, sodium salt										NL,USA	8

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			No	I	II	III	I	II	I	II	III		
	111-42-2	2,2'-iminobis-ethanol phosphoric acid ester										UK =diethanolamine phosphate?	
-	75-47-8	Iodoform										USA	-
		2,2'-Isobutyliden-bis-(4,6-dimethylphenole)										I	
62295	-	Isobutylene-2-methyl-1,3-butadiene copolymer										D,F,USA	-
-	-	Isobutylene-2-methyl-1,3-butadiene copolymer, brominated										F,USA	
-	-	Isobutylene-2-methyl-1,3-butadiene copolymer, chlorinated										F	
-	-	N-Isohexyl-N'-phenyl-p-phenylene-diamine										NL	-
-	-	Isopropoxydiphenylamine										USA	-
-	101-72-4	N-Isopropyl-N'-phenyl-1,4-phenylenediamine										USA	-
-	140-93-2	Isopropylxanthogenic acid, sodium salt										D,I	-
-	1000-90-4	Isopropylxanthogenic acid, zinc salt										D,I,NL	-
62720	1332-58-7	Kaolin										D,NL,I	1
63280	143-07-7	Lauric acid										I	0
-	106-18-3	Lauric acid, butyl ester										NL,USA	-
63760	8002-43-5	Lecithin										D,F,I,NL	1
64160	8001-26-1	Linseed oil										F,NL	3
64640	1309-42-8	Magnesium hydroxide										D	1
64720	1309-48-4	Magnesium oxide										D,F,I,NL, USA	1

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				Category			Category	Category	Declaration of interest for the continuation of the substance in category:			Legislation / approval of the substance for manufacture of rubber in country:	List
			No	I	II	III	I	II	I	II	III		
64800	-	Maleic acid, zinc salt										I	2 SML(T)= 30 mg/kg expressed as maleic acid)
19960	108-31-6	Maleic anhydride										D,F,UK	2
64940	9011-13-6	Maleic anhydride-styrene, copolymer										F	9
-	26762-92-5	p-Menthane hydroperoxide										NL,USA	-
-	583-39-1	2-Mercaptobenzimidazole										I	-
-	3030-80-6	2-Mercaptobenzimidazole, zinc salt										I	-
65768	149-30-4	2-Mercaptobenzothiazole										D,F,NL,USA	SML=8mg/kg rubber (24 hours extraction)
65770	2492-26-4	2-Mercaptobenzothiazole, sodium salt										F	SML=8mg/kg rubber (24 hours extraction)
-	155-04-4	2-Mercaptobenzothiazole, zinc salt										D,F,I,NL,USA	
-	96-45-7	2-Mercaptoimidazoline										NL	-
-	96-53-7	2-Mercaptothiazoline										F,NL,USA	-
-	115-19-5	2-Methyl-3-butyn-2-ol										NL	-
66240	9004-67-5	Methylcellulose										D,F,NL,AU	2
-	77-61-2	2(1-Methylcyclohexyl)-4,6-dimethylphenol										D,AU	-
66320	118-82-1	4,4-Methylenebis(2,6-di-tert-butylphenol)										USA	8
66400	88-24-4	2,2'-Methylenebis(4-ethyl-6-tert-butylphenol)										D,F,I,NL	2 SML(T)= 1.5mg/kg (with 66480)

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			No	I	II	III	I	II	I	II	III		
66480	119-47-1	2,2'Methylenebis(4-methyl-6-tert-butylphenol)										D,F,I,NL, USA	2 SML(T)= 1.5mg/kg (with 66400)
66560	4066-02-8	2,2'Methylenebis(4-methyl-6-cyclohexylphenol)										D,F,NL,AU	2 SML(T)=3mg/kg (with 66580)
66580	77-62-3	2,2'Methylenebis[4-methyl-6-(1-methylcyclohexyl)- phenol]										D,F,NL	2 SML(T)= 3mg/kg (with 66560)
-	7786-17-6	2,2'-Methylenebis(4-methyl-6-nonylphenol)										D,F,NL,USA	-
-	14020-52-1	2,2'-Methylenebis(4-methyl-6-tert-octylphenol)										NL,USA	-
	9011-11-4	alpha-Methylstryrene, copolymer										UK	
-	9017-27-0	alpha-Methylstyrene-vinyl-toluene, copolymer										USA	-
		Methyltris(cyclohexylamino)silane										**which country?**	
		Methyltris(sec.butylamino)silane										D	
		Methyltrisacetoxysilane										D	
		Methyltris(methylethylketoxime)silane										D	
-	6370-03-2	Methylxanthogenic acid, sodium salt										D,I	-
-	16079-37-1	Methylxanthogenic acid, zinc salt										D,I	-
67120	12001-26-2	Mica										NL,USA	3
67840	-	Montanic acids and/or their esters with ethyleneglycol and/or 1,3-butanediol										NL	3
67850	8002-53-7	Montan wax										USA	3
-	102-77-2	2-(Morpholinothio)benzothiazole										NL,USA	-

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			No	I	II	III	I	II	I	II	III		
67891	544-63-8	Myristic acid										USA	1
68140	7697-37-2	Nitric acid										D,F	2
-	-	Nylon										USA	-
68225	112-92-5	1-Octadecanol										I	3
68320	2082-79-3	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate										D,F,I,NL USA,UK	2 SML=6 mg/kg
-	37625-75-5	1-(Octadecylthio)-3 (or 4) -[2-(octadecylthio)ethyl cyclo-hexane										USA	-
68880	992-55-2	2-n-Octylthio-4,6-bis(4-hydroxy-3,5-di-tert-butyl-phenoxy)-1,3,5-triazine										D,I	8
68960	301-02-0	Oleamide										F,UK	3
69040	112-80-1	Oleic acid										I	1
69120	142-77-8	Oleic acid, butyl ester										NL,USA	7
-	7620-75-9	Oleic acid, dibutylamine salt										NL,USA	-
-	1912-84-1	Oleic acid, tin(II) salt										NL,USA	-
69848	-	Organopolysiloxanes										D,F	9
69870	-	Organopolysiloxanes containing methyl groups, poly(ethylene and propylene)glycol ethers										D	9
69855	-	Organopolysiloxanes containing two methyl groups on each slicicon atom										NL	9
70080	80-51-3	4,4'-Oxybis(benzene sulphonyl - hydrazide)										F,USA	6A
70400	57-10-3	Palmitic acid										I,USA	1
	111-06-08	Palmitic acid, butyl ester										I	
	26718-83-2	Palmitic acid, heptyl ester										I	

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			No	I	II	III	I	II	I	II	III		
	540-10-3	Palmitic acid, hexadecyl ester										I	
	16958-85-3	Palmitic acid, octyl ester										I	
	31148-31-39	Palmitic acid, pentyl ester										I	
-	-	Palm kernel oil										D,AU	-
-	-	Paraffin										D,I,NL	-
71120	8012-95-1	Paraffin oil										D,F,I,USA,NL,UK	9
71500	131-52-2	Pentachlorophenol, sodium salt										USA,AU	5
71520	117-97-5	Pentachlorothiophenol, zinc salt										D,NL	8
71680	6683-19-8	Pentaerythritol tetrakis [3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]										D,F,I,NL, USA	2
71710	98-77-1	Pentamethyleneammonium-pentamethylenedithiocarbamate										D,AU	8
-	-	Pentamethylenedithiocarbamic acid, copper salt										I	-
-	98-77-1	Pentamethylenedithiocarbamic acid, piperidine salt										F,NL,USA	-
-	-	Pentamethylenedithiocarbamic acid, potassium salt										NL,USA	-
-	873-57-4	Pentamethylenedithiocarbamic acid, sodium salt										I	-
-	13878-54-1	Pentamethylenedithiocarbamic acid, zinc salt										F,I,NL	-
-	-	Pentamethylenexanthogenic acid, sodium salt										I	-
-	10219-96-2	Pentaxanthogenic acid, zinc salt										I	-
-	107-71-1	Peracetic acid, tert-butyl ester										NL,USA	-

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			No	I	II	III	I	II	I	II	III		
-	-	Peroxides, hydroperoxides, peracids, persalts and perketals										I	-
-	614-45-9	Peroxybenzoic acid, tert-butyl ester										NL	-
72060	8009-03-8	Petrolatum										NL,USA	9
-	-	Petrolateum hydrocarbon resins (cyclopentadiene type), hydro-genated										USA	-
-	-	Petroleum hydrocarbon resins (produced by the homo- and copolymerization of dienes and olefins of the aliphatic, alicyclic, and monobenzenoid arylalkene types from distillates of cracked petroleum stocks)										USA	-
-	-	Petroleum hydrocarbon resins (produced by the catalytic polymerisation and subsequent hydrogenation of styrene, vinyltoluene, and indene types from distillates of cracked petroleum stocks)										USA	-
72081	-	Petroleum hydrocarbon resins, hydrogenated										F	7
-	-	Petroleum oil, sulphonated										USA	-
72095	-	Petroleum waxes										USA	9
-	-	Phenols, butylated, isobutylated, and/or octylated										F,USA	-
-	-	Phenols and/or cresols-styrene and/or alpha-methyl-styrene, copolymers										I	-

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			No	I	II	III	I	II	I	II	III		
72105	-	Phenols and/or cresol styrene and/or alpha-methyl-styrene and/or olefins(C3-C12), copolymers										D,NL	9
-	61788-44-1	Phenols, styrenated										D,F,NL,USA	-
72135	92-84-2	Phenothiazine										USA	8
-	-	Phenyl-1-naphthylamine										USA	-
-	-	Phenyl-2-naphthylamine										USA	-
72240	90-43-7	2-Phenylphenol										USA	D
72400	131-27-4	2-Phenylphenol, sodium salt										F	D
72320	92-69-3	4-Phenylphenol										USA	8
-	7774-80-3	N-Phenyl-N'-o-tolyl-1,4-phenylene-diamine										USA	-
73680	126-73-8	Phosphoric acid, tributyl ester										D,F	6B
74020	20227-53-6	Phosphorous acid, 2-tert-butyl-alpha-(3-tert-butyl-4-hydroxy-phenyl)-p-cumenyl bis(4-nonyl-phenyl) ester										USA	6B
74240	31570-04-4	Phosphorous acid, tris(2,4-di-tert-butylphenyl) ester										D,F,I,USA,NL	2
74400	26523-78-4 1333-21-7 8012-67-7	Phosphorous acid, tris(nonyl- and/or dinonylphenyl) ester										D,F,I,NL, USA	2 SML=30mg/kg
74560	85-68-7	Phthalic acid, benzylbutyl ester										F,I	2 SML=6mg/kg
74640	117-81-7	Phthalic acid, bis(2-ethylhexyl) ester										D,F,I,NL	2 SML= 3mg/kg
-	119-07-3	Phthalic acid, n-decyl n-octyl ester										USA	-
-	-	Phthalic acid, n-decyl n-pentyl ester										USA	-
74880	84-74-2	Phthalic acid, dibutyl ester										F,I,NL, USA	2 SML= 3mg/kg

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			No	I	II	III	I	II	I	II	III		
74960	84-61-7	Phthalic acid, dicyclohexyl ester										F	2 SML= 6mg/kg
-	-	Phthalic acid, didecyl ester										USA	-
75120	84-66-2	Phthalic acid, diethyl ester										I	2 SML=12mg/kg
75360	26761-40-0	Phthalic acid, diisodecyl ester										F,I,NL	D
75440	28553-12-0	Phthalic acid, diisononyl ester										F	D
75520	27554-26-3	Phthalic acid, diisooctyl ester										I	9
-	-	Phthalic acid, di(2-methylhexyl) ester										NL	-
75840	117-84-0	Phthalic acid, di-n-octyl ester										NL,USA	6B
76320	85-44-9	Phthalic anhydride										D,F,I,NL, USA	2
-	8011-48-1	Pine tar										USA	-
23505	110-85-0	Piperazine										I	3
76461	9003-01-4	Polyacrylic acid										F	7
-	-	Polyalkyleneglycol esters of fatty acids, C8-C20, with an even number of carbon atoms										F	-
-	-	Polybutadiene										D	
76520	9003-29-6	Polybutene										F,NL,USA,UK	D
-	-	Poly(2-chloro-1,3-butadiene)										D	-
-	-	Poly(2-chloro-1,3-butadiene) based on 2,3-dichlorobutadiene										D **to delete!**	-
-	-	Poly, 2-chloro-1,3-butadiene) based on trichlorobutadiene										D	-
76680	-	Polycyclopentadiene, hydrogenated										F,NL	3 SLM= 5mg/kg
76790	-	Polyesters of adipic acid with 1,3- and 1,4-butanediol										F	D
76805	-	Polyesters of adipic acid with 1,3-butanediol and 1,6-hexanediol										F	9

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			No	I	II	III	I	II	I	II	III		
-	-	Polyesters produced by reacting acetic acid, acrylic acid, adipic acid, azelaic acid, caprylic acid, crotonic acid, phthalic acid, fumaric acid, coco fatty acids, tall oil fatty acids, itaconic acid, maleic acid, palmitic acid, sebacic acid and stearic acid with 2,2-bis(4-hydroxyphenyl)-propane, butanediols, butanols, cyclohexanol, n-decanol, hexanediols, glycerol, mono-, di- and polyethyleneglycols, mon-, di- and polypropyleneglycols, isodecanol, 2,2-dimethyl-, 1,3-propanediol, pentaerythritol and sorbitol										I	-
76951	9002-88-4	Polyethylene										D,NL,UK,USA	7
76960	25322-68-3	Polyethyleneglycol										D,F,I,NL	2
77000	-	Polyethyleneglycol alkylaryl ethers and their sulphonated derivatives										D	D
-	-	Polyethyleneglycol alkyl ethers and their sulphated and phosphated derivatives										F	-
77050	-	Polyethyleneglycol alkyl ethers and their sulphonated derivatives										D,F	9
-	-	Polyethyleneglycol alkyl(C4-C9)-phenyl ethers and their sulphated, sulphonated, and phosphated derivatives										F	-

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			No	I	II	III	I	II	I	II	III		
77640	-	Polyethyleneglycol (EO=8-14) esters of lauric acid, oleic acid, ricinoleic acid and/or stearic acid										NL	2
77700	-	Polyethyleneglycol esters and their sulphonated derivatives										D	9
-	-	Polyethyleneglycol (EO=4-14) ethers of alcohols, aliphatic, monohydric, linear, saturated (C12-C18)										D,NL	-
	68130-72-3**?**	Polyethyleneglycol ether of biphenyl, benzylated										**which country?**	
	-	Polyethyleneglycol (EO=4-14) ethers of octylphenol and/or nonylphenol										NL	-
-	-	Polyethyleneglycol 4-nonylphenyl mixture of dihydrogen phosphate and monohydrogen phosphate esters, barium salt										USA	-
-	-	Poly(ethylene and/or propylene)glycol, copolymers with polyisocyanates and/or polyurethanes										F	-
76951	-	Polyethylene wax										F	7
-	-	Poly(2-methyl-1,3-butadiene)										D	-
-	-	Polymers of acrylic, methacrylic acid, crotonic acid, maleic acid, fumaric acid, itaconic acid, vinylsulphonic acid, amides and salts										D	-
80720	8017-16-1	Polyphosphoric acids										F	1
80765	9003-07-0	Polypropylene										D,NL	7

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			No	I	II	III	I	II	I	II	III		
80800	25322-69-4	Polypropyleneglycol										D,F,NL	3
80280	25101-03-5	Polypropyleneglycol adipate										NI = **76865?**	7-D
80840	-	Polypropyleneglycol alkyl(C8-C20) ethers										F	9
-	-	Polysaccharides										F	-
81080	9003-53-6	Polystyrene										D,NL,USA,UK	9
81120	-	Polyterpenes										F	9
81160	9002-84-0	Polytetrafluorethylene										D	D
81280	9002-89-5	Polyvinyl alcohols										D,F	7
81360	-	Polyvinyl ethers										D	D
-	-	Poly(vinyl methyl ethers)										D,F	7
81500	9003-39-8	Polyvinylpyrrolidone										D,F	9
81600	1310-58-3	Potassium hydroxide										D,F	1
-	7727-21-1	Potassium persulphate										NL,USA	-
81840	57-55-6	1,2-Propanediol										D,NL,USA	1
81882	67-63-0	2-Propanol										D,F	1
83470	14808-60-7	Quartz										D	D
83580/1	8002-13-9	Rapeseed oil										NL	3
-	68153-37-7	Rapeseed oli, vulcanized with sulphur										USA	-
83595	119345-01-6	Reaction product odf di-tert-butyl - phosphonite with biphenyl, obtained by conden-sation of 2,4-di-tert.butyl-phenol with Friedel-Crafts reaction product of phosphorus trichloride and biphenyl										USA	2 SML=18mg/kg
-	164907-73-7	Reaction product of formaldehyde with dodecylmercaptan and 4-nonylphenol										USA	-

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83610	73138-82-6	Resin acids										NL,D,F	2
83840	8050-09-7	Rosin (=Colophony)										D,F,I,NL,USA	2
83920	-	Rosin derivatives										USA	9
-	-	Rosin, dimerized, ester										F	-
-	8050-09-7	Rosin, diproportionated										I,NL	-
-	-	Rosin, esters										F	-
84000	8050-31-5	Rosin, esters with glycerol										D,F	1
-	-	Rosin, esters with glycerol and pentaerythritol										I	-
		Rosin, esters with maleic acid, citric acid and polyols (C3-C6)										I **monomer?, to discuss**	
84080	8050-26-8	Rosin, esters with pentaerythritol										D,F	2
84210	65997-06-0	Rosin, hydrogenated										I	2
-	-	Rosin, hydrogenated, esters										F	-
84240	65997-13-9	Rosin, hydrogenated, esters with glycerol										F	3
84320	8050-15-5	Rosin, hydrogenated, esters with methanol										I	2
84400	64365-17-9	Rosin, hydrogenated, esters with pentaerythritol										F	2
-	-	Rubber, regenerated										D,NL	D
84640	69-72-7	Salicylic acid										F,I,NL,USA	3
85120	122-62-3	Sebacic acid, bis(2-ethylhexyl) ester										F,I	6B
85360	109-43-3	Sebacic acid, dibutyl ester										F,I,NL,USA	3
-	27214-90-0	Sebacic acid, diisooctyl ester										NL,USA	-
85520	2432-87-3	Sebacic acid, di-n-octyl ester										NL,USA	6B
85680	1343-98-2	Silicic acid										D,F,I,NL,USA	2

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			No	I	II	III	I	II	I	II	III		
86000	-	Silicic acid, silanated										D,F	3
86080	10101-52-7	Silicic acid, zirconium salt										D	7
86240	7631-86-9 112945-52-5	Silicon dioxide										D,F,I,NL,USA,UK	1
86300	63148-62-9	Silicone oils										D,I,AU	9
86320	-	Silicones										D,I	9
86720	1310-73-2	Sodium hydroxide										D,F	1
86920	7632-00-0	Sodium nitrite										NL,USA	3
-	1344-08-7	Sodium polysulphide										NL,USA	-
-	1313-82-2	Sodium sulphide										NL,USA	-
82700	110-44-1	Sorbic acid										NL,D,F,I	1
88630/1	8001-22-7	Soybean oil										NL	3
88640	8013-07-8	Soybean oil, epoxidized										F,I,NL	2 Oxirane<8%, iodine number<6
-	-	Soybean oil, vulcanized with sulphur										NL,USA	-
88960	124-26-5	Stearamide										F	3
89040	57-11-4	Stearic acid										D,F,I,NL,UK, AU, USA	1
89120	123-95-5	Stearic acid, butyl ester										NL,USA	7
24610 M	100-42-5	Styrene										USA	4B
91540	-	Sulphosuccinic acid, alkyl-(C4-C16)esters, salts										F	9
91840	7704-34-9	Sulphur										D,F,I,NL,USA	3
91920	7664-93-9	Sulphuric acid										D,F,I	1
92000	7727-43-7	Sulphuric acid, barium salt										D,F,I,NL,USA	3
92080	14807-96-6	Talc										I,NL,UK	1
24905 M	8002-26-4	Tall oil										USA	3

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			No	I	II	III	I	II	I	II	III		
92160	87-69-4	Tartaric acid										D,F	1
92220	-	Terpene resins										USA	9
-	10591-85-2	Tetrabenzylthiuram disulphide										F	-
-	93-73-2	Tetrabutylthiuram monosulphide										NL,USA	-
-	118-75-2	Tetrachloro-1,4-benzoquinone										USA	-
92400	97-77-8	Tetraethylthiuram disulphide										D,F,I,NL,USA	8
92685	126-86-3	2,4,7,9-Tetramethyl-5-decyne-4,7-diol										F	8
92720	137-26-8	Tetramethylthiuram disulphide										D,F,I,NL,USA	8
-	97-74-5	Tetramethylthiuram monosulphide										D,F,I,NL,USA	-
92800	96-69-5	4,4'-Thiobis(6-tert-butyl-3-methyl-phenol)										D,F,NL,USA	2 SML= 0.5mg/kg
92880	41484-35-9	Thiodiethanol bis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate										USA	2 SML=2.4mg/kg
92960	111-17-1	Thiodipropionic acid										I,USA	8
93120	123-28-4	Thiodipropionic acid, didodecyl ester										D,F,I,UK	3 SML(T)= 5mg/kg (with 93280)
93200	3287-12-5	Thiodipropionic acid, dihexadecyl ester										I,USA	6B
93280	693-36-7	Thiodipropionic acid, dioctadecyl ester										I	3 (SML(T)= 5mg/kg with 93120)
93360	16545-54-3	Thiodipropionic acid, ditetradecyl ester										USA	6B
-	-	Thioxylenols										NL,USA	-
93415	7772-99-8	Tin (II) chloride										I,NL,USA	1
93440	13463-67-7	Titanium dioxide										F,I,NL,USA	1

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PM/REF	CAS Nr	Name	Function	List A			Restrictions		Transfer List B			Index List C	SCF Status (for Plastics)
				Category			Category	Category	Declaration of interest for the continuation of the substance in category:			Legislation / approval of the substance for manufacture of rubber in country:	List
			No	I	II	III	I	II	I	II	III		
93520	59-02-9 10191-41-0	alpha-Tocopherol										F,NL	1
-	93-69-6	o-Tolylbiguanidine										D,F,I,NL	-
-	-	p-(p-Tolylsulphanilamide)-diphenylamine										USA	-
93680	9000-65-1	Tragacanth gum										D	1
25390	101-37-1	Triallyl cyanurate										NL,USA	6A
93760	77-90-7	Tributyl acetylcitrate										NL	7
-	19484-26-5	Tridecylmercaptan										NL,USA	-
94000	102-71-6	Triethanolamine										F,I,NL,USA	8
-	10017-56-8	Tri(ethanol)amine phosphate										NL	-
-	10024-58-5	Triethyleneglycol didecanoate										USA	-
-	-	Triethyleneglycol dihexanoate										NL	-
-	-	Triethyleneglycol dioctanoate										F,NL,USA	-
-	-	Triethyleneglycol esters of phthalic acid and/or benzoic acid										NL	-
25520	112-24-3	Triethylenetetramine										USA	8
-	779-27-3	1,3,5-Triethylhexahydro-1,3,5-triazine										USA	-
-	69851-61-2	N,N'-1,3-trimethylenebis(3,5-di-tert-butyl-4-hydroxyhydrocinnan amide)										USA	-
95200	1709-70-2	1,3,5-Trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene										D,F,I,NL,USA, UK	2
-	101-01-9	Triphenylguanidine										USA	-
95600	1843-03-4	1,1,3-Tris(2-methyl-4-hydroxy-5-tert-butylphenyl)butane										USA	7
95630	57-13-6	Urea										D,I,NL	0
-	-	Vegetable oils										I	-

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				Category			Category	Category	Declaration of interest for the continuation of the substance in category:			Legislation / approval of the substance for manufacture of rubber in country:	List
			No	I	II	III	I	II	I	II	III		
59040	-	Vinylidene fluoride hexafluoro-propylene copolyners										F,USA	
-	-	Vinylidene fluoride hexafluoro-propylene tetrafluoroethylene copolyners										F,USA	-
	68610-49-6	Vitanox										**which country ? to delete ?**	
		White mineral oil Paraffine derived from petroleum based hydrocarbon feedstok										UK	
95920	-	Wood flour and fibers, untreated										D	3
	119462-56-5	**N,N'-m-Xylylenebis(citraconic - imide)**										I	
-	-	Xylenes (or toluene) alkylated with dicyclopentadiene										USA	-
-	25550-52-1	Xylenethiol										NL	-
-	-	Zinc 2-benzamidothiophenate										USA	-
96240	1314-13-2	Zinc oxide										D,F,I,NL	2
-	1314-22-3	Zinc peroxide										D,I,AU	-
96320	1314-98-3	Zinc sulphide										NL,USA	2