

Draft October 7 2005

## COMMISSION DECISION

of [...]

**establishing ecological criteria for the award of the Community eco-label to soaps and shampoos.**

**(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1980/2000 of the European Parliament and of the Council of 17 July 2000 on a revised Community eco-label award scheme<sup>1</sup>, and in particular the second subparagraph of article 6(1) thereof,

After consulting the European Union Eco-Labeling Board,

Whereas:

1. Under Regulation (EC) No 1980/2000 the Community eco-label may be awarded to a product possessing characteristics which enable it to contribute significantly to improvements in relation to key environmental aspects.
2. Regulation (EC) No 1980/2000 provides that specific eco-label criteria, drawn up on the basis of the criteria drafted by the European Union Eco-Labeling Board, are to be established according to product groups.
3. Since the use of soaps and shampoos may be hazardous for the environment due to, for example, their aquatic toxicity or their bio-accumulation, appropriate ecological criteria should be laid down
4. The ecological criteria, as well as the related assessment and verification requirements, should be valid for a period of 3 years
5. The measures provided for in this Decision are in accordance with the opinion of the Committee instituted by Article 17 of Regulation (EC) No 1980/2000,

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<sup>1</sup> OJ L 237, 21.9.2000, p. 1.

HAS ADOPTED THIS DECISION:

*Article 1*

The product group “soaps and shampoos” shall comprise all cosmetic products (as defined under Cosmetic Directive 76/768/EEC and its amendments and adaptations) that are primarily used for cleaning and washing the skin and hair of the body and which are removed by water after use.

It shall also comprise all products for hair conditioning that is removed by water after use.

The product group shall not cover products that are specifically marketed for disinfecting and/or anti-bacterial use.

The product group shall cover products for both private and professional use.

*Article 2*

In order to be awarded the Community eco-label under Regulation (EC) No 1980/2000, soaps and shampoos must fall within the product group ‘soaps and shampoos’ and must comply with the ecological criteria set out in the Annex to this Decision.

*Article 3*

For administrative purposes the product group code number assigned to this product group shall be “ ”.

*Article 4*

The ecological criteria for the product group ‘soaps and shampoos’ as well as the related assessment and verification requirements shall be valid until [?].

This Decision is addressed to the Member States.

Done at Brussels, [...]

*For the Commission*  
**Stavros DIMAS**  
*Member of the Commission*

## ANNEX

### FRAMEWORK

#### **The aims of the criteria**

These criteria aim in particular at promoting:

- the reduction of water pollution both by limiting the quantity of potentially harmful ingredients and the total toxic impact of the product.
- the minimisation of waste production by reducing the amount of packaging.
- the reduction or prevention of potential risks for the environment and for human health related to the use of hazardous substances.

Additionally, the criteria enhance the consumers' environmental awareness. The criteria are set at levels that promote the labelling of soaps and shampoos that have a lower environmental impact than the market average.

#### **Assessment and verification requirements**

The specific assessment and verification requirements are indicated within each of the ecological criteria later in this Annex.

Where appropriate, test methods other than those indicated for each criterion may be used if the Competent Body assessing the application accepts their equivalence.

Where possible, the testing should be performed by laboratories that meet the general requirements of EN ISO 17025 or equivalent.

Where no tests are mentioned, or are mentioned as being for use in verification or monitoring, Competent Bodies should rely as appropriate on declarations and documentation provided by the applicant and/or independent verification.

Where appropriate, Competent Bodies may require supporting documentation and may carry out independent verification.

Where the applicant is required to provide declarations, documentation, test reports, or other evidence to show compliance with the criteria, it is understood that these may originate from the applicant and/or his supplier(s) and/or their supplier(s), et cetera, as appropriate.

Where ingredients are referred to, this includes substances and preparations.

Appendix I presents the new revised Detergent Ingredient Database (DID list), version 30 June 2004, which contain many of the most widely used ingredients in soap and shampoo formulations. Part A of DID list shall be used for deriving the data for the calculations of CDV and for the assessment of the biodegradability of surfactants. Applicants may only present their own data if the list do not give a value, except for perfume (including biological additives) and dyes.

For ingredients that are not included in the part A of DID list, the applicant shall, under his own responsibility, apply the procedure as described in part B of Appendix I.

For ingredients, which are not listed in the DID-list, the applicant may use an approach to provide the necessary documentation of anaerobic degradability described in Appendix IV.

The Competent Bodies are recommended to take into account the implementation of recognised environmental management schemes, such as EMAS or ISO 14001, when assessing applications and monitoring compliance with the criteria in this Annex (Note: It is not required to implement such management schemes.)

### **FUNCTIONAL UNIT**

The Functional unit is 1 gram of "Active Content (AC)". AC is defined as the weight of organic ingredients in the product. It must be calculated on the basis of the complete formulation of the product. Rubbing/abrasive agents in hand cleaning agents are not included in the calculation of AC.

*Assessment and verification:*

- *Technical description of the contents of the product (complete formulation), including known pollutants. The description must include a specification of quantities, CAS-No. and INCI designations.*
- *A specification of the function of each individual ingredient in the product, stating the purpose for which the component is added.*
- *Safety data sheet/Product data sheet with the name of the supplier of all ingredients.*

### **ECOLOGICAL CRITERIA**

#### **1. TOXICITY TO AQUATIC ORGANISMS**

The critical dilution volume toxicity (CDV) is calculated for each ingredient (i) and for the whole product using the following equation:

$$\text{CDV}(\text{ingredient } i) = \text{weight } (i) \times \text{DF}(i) \times 1000 / \text{TF}_{\text{chronic}}(i)$$

$$\text{CDV} = \sum \text{CDV}(\text{ingredient } i)$$

where weight (i) is the weight of the ingredient (in gram) per functional unit.. DF (i) is the degradation factor and TF chronic (i) is the toxicity factor of the ingredient (in milligram/litre).

The values of DF and TF chronic shall be as given in the Detergent Ingredient Database list-part A (DID list-part A) (Appendix I). If the ingredient in question is not included in the DID list-part A, the applicant shall estimate the values following the approach described in the DID list-part B (Appendix 1). The CDV<sub>tox</sub> is summed for each ingredient, making the CDV for the product.

The total CDV of the product must not exceed the following values:

Shampoo, shower products and liquid soaps: 16 000 l/g AC  
Solid soaps: 3 500 l/g AC  
Conditioner: 20 000 l/g AC

*Assessment and verification:*

*The exact formulation of the product must be given. Furthermore the exact chemical description of ingredients (e.g. identification according to IUPAC, CAS-no, INCI-name, purity, type and percentage of impurities, additives; for mixtures e.g. surfactants: DID-number, composition and spectrum of homologue distribution, isomers and trade names).*

*Copies of the Material Safety Data Sheet of all ingredients must be given.*

*The calculation of CDV and the related score shall be provided in detail. For all ingredients included in the DID-list the appropriate ingredient number must be given. For ingredients not included in the DID-list, test results and test methods for ecotoxicity (long-term effects (NOEC data) on fish, Daphnia magna, and algae), biodegradation and bioaccumulation shall be submitted. The reference for the relevant tests shall be the appropriate Annexes of Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances<sup>2</sup>, and its subsequent amendments.*

## **2. ENVIRONMENTALLY HARMFUL PRODUCTS**

The product must not fulfil the requirements for classification for any of the following risk phrases according to The Directive of Dangerous Preparations:

N, R50/53:  $(W_{R50/53}/25 \%) \geq 1$

N, R51/53:  $((W_{R50/53}/2,5 \%) + (W_{R51/53}/25 \%) \geq 1$

R52/53:  $((W_{R50/53}/0,25 \%) + W_{R51/53}/2,5 \%) + W_{R52/53}/25 \%) \geq 1$

$W_{R50/53}$  = Weight percent of ingredients that may be classified as R50/53.

$W_{R51/53}$  = Weight percent of ingredients that may be classified as R51/53.

$W_{R52/53}$  = Weight percent of ingredients that may be classified as R52/53.

Rubbing/abrasive agents in hand cleaning agents are not included.

*Assessment and verification:*

*Test results for aquatic toxicity and biodegradation must be given. Toxicity results from the DID-list may not be used since these are median values, not lowest values. If the lowest toxicity is  $\leq 10$  mg/l test results for potential bioaccumulation (Bioconcentration factor (BCF) or logKow) must also be given. If no results are available the ingredient will be regarded as R 50/53. The following exceptions apply:*

*Fragrances and dyes: R 51/53.*

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<sup>2</sup> OJ No 196, 16.8.1967, p.1.

*Plant extracts and other ingredients isolated from plants or animals and with little or no chemical alteration: R 51/53.*

*All ingredients (substances or preparations) that exceed 0.010 % by weight of the final product shall be considered. This includes also each ingredient of any preparation used in the formulation that exceeds 0.010 % by weight of the final product.*

### **3. AEROBIC BIODEGRADABILITY**

#### **a) Aerobic degradability of surfactants**

Each surfactant used in the product shall be readily biodegradable.

***Assessment and verification:** the exact formulation of the product as well as a description of the function of each ingredient shall be provided to the Competent Body. Surfactant is defined in the same way as in the Detergents Directive. The DID list-part A (Appendix I) indicates whether a specific surfactant is aerobically biodegradable or not (the surfactants with an entry of 'R' in the column on aerobic biodegradability are readily biodegradable). For surfactants which are not included in the DID list-part A, the relevant information from literature or other sources, or appropriate test results, showing that they are aerobically biodegradable shall be provided. The tests for ready biodegradability shall be as referred to in Regulation (EC) No. 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents 3 . Surfactants shall be considered as readily biodegradable if the level of biodegradability (mineralisation) measured according to one of the five following tests is at least 60% within 28 days: CO<sub>2</sub> headspace test (OECD 310), Carbon dioxide (CO<sub>2</sub>) Evolution Modified Sturm test (OECD 301B; Directive 67/548/EEC Annex V.C.4-C), Closed Bottle test (OECD 301D; Directive 67/548/EEC Annex V.C.4-E), Manometric Respirometry (OECD 301F; Directive 67/548/EEC Annex V.C.4-D), or MITI (I) test (OECD 301C; Directive 67/548/EEC Annex V.C.4-D), or their equivalent ISO tests. Depending on the physical characteristics of the surfactant, one of the following tests might be used to confirm ready biodegradability, if the level of biodegradability is at least 70% within 28 days: Dissolved Organic Carbon DOC Die-Away (OECD 301A; Directive 67/548/EEC Annex V.C.4-A) or Modified OECD Screening DOC Die-Away (OECD 301E; Directive 67/548/EEC Annex V.C.4-B), or their equivalent ISO tests. The applicability of test methods based on measurement of dissolved organic carbon needs to be appropriately justified as 3 OJ L 104, 8.4.2004, p.13.*

*All ingredients (substances or preparations) that exceeds 0.010 % by weight of the final product shall be considered. This includes also each ingredient of any preparation used in the formulation that exceeds 0.010 % by weight of the final product.*

#### **b) Aerobic degradability of non-surfactants (aNBDOnon-surf)**

The content of ingredients that are not readily biodegradable (or have not been tested for aerobic degradability) must not exceed the following levels:

Shampoo, shower products and liquid soaps:	25 mg/g AC
Solid soaps:	15 mg/g AC

Conditioner: 50 mg/g AC

Rubbing/abrasive agents in hand cleaning agents are not included.

All ingredients (substances or preparations) exceeding 0,010 % by weight of the final product shall be considered. This includes also each ingredient of any preparation used in the formulation exceeding 0,010 % by weight of the final product.

*Assessment and verification: Identical to requirement 4 a).*

#### **4. ANAEROBIC BIODEGRADABILITY (anNBDO<sub>tox</sub>)**

The content of ingredients that are not anaerobically degradable (or have not been tested for anaerobic degradability) and have a lowest acute toxicity LC<sub>50</sub> or EC<sub>50</sub> < 100 mg/l (similar to the classification limit for R52 in the Dangerous Substances Directive) must not exceed the following levels:

Shampoo, shower products and liquid soaps:	25 mg/g AC
Solid soaps:	15 mg/g AC
Conditioner:	50 mg/g AC

Rubbing/abrasive agents in hand cleaning agents are not included.

#### **Assessment and verification:**

*The DID list-part A (Appendix I) indicates whether a specific ingredient is anaerobically biodegradable or not (the surfactants with an entry of 'Y' in the column on anaerobic biodegradability are biodegradable under anaerobic conditions). For ingredients which are not included in the DID list-part A or which are included with an entry "0" the relevant information from literature or other sources, or appropriate test results, showing that they are anaerobically biodegradable shall be provided. The reference test for anaerobic degradability shall be OECD 311, ISO 11734, ECETOC No. 28 (June 1988) or an equivalent test method, with the requirement of a minimum of 60% ultimate degradability under anaerobic conditions. Test methods simulating the conditions in a relevant anaerobic environment may also be used to document that 60% ultimate degradability has been attained under anaerobic conditions (see Appendix IV).*

*If several toxicity results are available the lowest validated value shall be used. The toxicity values on the DID-list are median values that cannot be used for this purpose.*

*All ingredients (substances or preparations) exceeding 0,010 % by weight of the final product shall be considered. This includes also each ingredient of any preparation used in the formulation exceeding 0,010 % by weight of the final product.*

#### **5. FRAGRANCES**

a)IFRA Guidelines.

Any ingredient added to the product as a fragrance must have been manufactured handled and applied in accordance with the code of practice of the International Fragrance Association.

*Assessment and verification: A declaration of compliance with each part of this criterion shall be provided to the Competent Body by the fragrance manufacturer.*

b) Fragrances in products for babies/infants

The maximum content of fragrance in products marketed specifically at babies/infants of age less than 3 years is 0,10 % (1000 ppm) of the total product. The product must not contain any of the fragrance substances specified in Appendix II. All fragrance compounds above the cut-off level of 0,0001 % (1 ppm) of the whole product must be considered.

*Assessment and verification: A completed and signed declaration of compliance with the requirement of absence of the fragrance substances specified in Appendix II must be given by the fragrance manufacturer.*

c) Quantities of fragrance substances

All other products (i.e. products marketed at persons above three years old) shall not contain the fragrance substances specified in Appendix II in quantities exceeding 0.010 % (100 ppm).

*Assessment and verification:*

*A completed and signed declaration by the fragrance manufacturer.*

*An account for the content of fragrance compound mentioned in appendix II given as percentage of the product.*

d) Nitromusks and polycyclic musks shall not be included in the product, either as part of the formulation or as part of any preparation included in the formulation. This concerns, amongst others, the following:

Musk xylene: 5-tert-butyl-2,4,6-trinitro-m-xylene

Musk ambrette: 4-tert-butyl-3-methoxy-2,6-dinitrotoluene

Moskene: 1,1,3,3,5-pentamethyl-4,6-dinitroindan

Musk tibetine: 1-tert-butyl-3,4,5-trimethyl-2,6-dinitrobenzene

Musk ketone: 4'-tert-butyl-2',6'-dimethyl-3',5'-dinitroacetaphenone

HHCB (1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta(g)-2-benzopyran)

AHTN (6-Acetyl-1,1,2,4,4,7-hexamethyltetralin)

*Assessment and verification: The applicant shall provide a declaration supported by declarations from manufacturers of ingredients, as appropriate, confirming that the listed substances have not been included in the product.*

## **6. DYES OR COLOURING AGENTS**

a) Any dyes or colouring agent used in the product must be permitted by Council Directive 76/768/EEC relating to cosmetic products and its subsequent amendments

*Assessment and verification: A declaration of compliance with this criterion shall be provided to the Competent Body, together with a full list of all dyes or colouring agents used.*

b) Organic dyes or colouring agents must not be potentially bioaccumulating. In the case of colouring agents approved for use in foodstuffs it is not necessary to submit documentation of bioaccumulation potential. In this context, a colouring agent or dye is considered to be potentially bioaccumulating if the experimentally determined BCF > 100. If no BCF (Bioconcentration Factor) test result is available, bioaccumulation may be demonstrated by the log Pow (log octanol/water partition coefficient). If logPow is > 3.0 the colouring agent or dye is considered as potentially bioaccumulating.

**Assessment and verification:** *The manufacturer must submit a test report or a published test result together with a reference to the publication. If the dye or colouring agent has been approved for use in foodstuffs a declaration from the manufacturer stating this fact must be submitted.*

## 7. BIOCIDES

a) The product may only include biocides in order to preserve the product, and in the appropriate dosage for this purpose alone. This does not refer to surfactants, which may also have biocidal properties.

**Assessment and verification:** *Copies of the material safety data sheets of any preservatives added shall be provided, together with information on their exact concentration in the product. The manufacturer or supplier of the preservatives shall provide information on the dosage necessary to preserve the product.*

b) Biocides, either as part of the formulation or as part of any preparation included in the formulation, that are used to preserve the product and that fulfil the criteria for classification with R50-53 or R51-53 risk phrases, in accordance with Directive 67/548/EEC and its amendments or Directive 1999/45/EC, are only permitted if they are not potentially bioaccumulating. In this context, a biocide is considered to be potentially bioaccumulating if the bioconcentration factor (BCF) > 100 or, if no BCF-results are available, the log Pow (log octanol/water partition coefficient) > 3.0.

The concentration of biocides in the final product shall not exceed the maximum authorized concentration in Council Directive 76/768/EEC 6 of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products and its subsequent amendments.

**Assessment and verification:** *Test results for aquatic toxicity must be supplied. If the lowest toxicity is  $\leq 10$  mg/l a test result for ready biodegradability must be given. If the biocide is not readily biodegradable test results for bioaccumulation potential must be given. Test procedures are as specified in the Dangerous Substances Directive.*

c) Preservatives must not release substances that are classifiable in accordance with the requirements on Classified Ingredients (Requirement 8a) and endocrine disruption (Requirement 8b).

*Assessment and verification: A completed and signed declaration from the biocide manufacturer.*

## **8. HAZARDEOUS INGREDIENTS**

The requirements concern all ingredients (substances or preparations) exceeding 0,010 % by weight of the final product. This includes also each ingredient of any preparation used in the formulation exceeding 0,010 % by weight of the final product.

### **a) Classified ingredients**

No constituent substance must be classified as carcinogenic (Carc), mutagenic (Mut) or toxic to reproduction (Rep) including rules for self-classification class I, II and III. No constituent substance must be classified as sensitizing Xi with R42 and/or R43 including rules for self-classification. See also the special rules applicable to fragrances in Ch 5.

Specific requirements are prescribed for biocides, either as part of the formulation or as part of any preparation included in the formulation (see criterion on biocides).

*Assessment and verification: copies of the material safety data sheets shall be provided for all ingredients (whether substances or preparations). A declaration prepared by the manufacturer of ingredients and showing compliance with this criterion shall be provided by the applicant.*

### **b) Endocrine disrupters**

No ingredient must be on the EU list (from Commission Staff Working Document on implementation of the Community Strategy for Endocrine Disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM (1999) 706)) of 118 substances with evidence of endocrine disrupting effect or evidence of potential endocrine disrupting effect.

*Assessment and verification: A completed and signed declaration from the manufacturer must be submitted. Additionally a completed and signed declaration from the fragrance manufacturer must be submitted.*

### **c) Specified excluded ingredients**

The following ingredients shall not be included in the product, either as part of the formulation or as part of any preparation included in the formulation:

- Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives
- NTA (nitrilo-tri-acetate)
- Boric acid, borates and perborates

*Assessment and verification: A completed and signed declaration from the manufacturer must be submitted.*

### **d) Specified limited ingredients**

Ethylenediaminetetraacetate (EDTA) and its salts and not readily biodegradable phosphonates may only be added in solid soaps and only in a maximum content of 0,6 mg/g AC.

*Assessment and verification: A completed and signed declaration from the manufacturer must be submitted.*

## **9. PACKAGING**

a) The Weight/Content Relationship (WCR) must be  $< 0,30$  g packaging/g product.

$$WCR = \frac{(W_i + N_i)}{(D_i \times r)}$$

$W_i$  = The weight (grams) of packaging-component  $i$  (primary or secondary packaging) including label.

$N_i$  = Weight (grams) of not-recycled material of packaging-component (primary or secondary packaging). If the packaging component does not contain recycled material then  $N_i = V_i$ .

$D_i$  = gram product the packaging-component contains.

$r$  = Return number, i.e. the number of times packaging-component  $i$  is used for the same purpose through a system of return or refill ( $r=1$  if no reuse occurs).

If the packaging is reused  $r$  is set to 20 for plastics and 10 for corrugated board unless the applicant can document a higher number.

*Assessment and verification: Calculation of WCR.*

b) Labelling of packaging

To allow for identification of different parts of the packaging for recycling, plastic parts in the primary packaging must be marked in accordance with DIN 6120, Part 2 or the equivalent. Caps and pumps are exempted from this requirement.

*Assessment and verification: Completed and signed declaration.*

*Sample of primary packaging.*

c) Dosage

The packaging must be designed to make correct dosage easy, e.g. by ensuring that the opening at the top is not too wide.

*Assessment and verification: Description of the dosage device.*

d) The packaging must not contain additives based on Cadmium or Mercury or compounds with these elements. Neither may the packaging contain endocrine disrupters (defined in requirement 8b) such as Bisphenol A.

*Assessment and verification: Declaration from the packaging producer.*

## **10. PERFORMANCE**

The cleaning or conditioning efficiency of the product must be demonstrated through a laboratory test or a consumer test. The efficiency of the product must be equal to, or better than a comparison product. The comparison product may be a market-leading

product for the same usage and in the same area as the product is being marketed. The market-leading product can be chosen among the 4 highest selling products in the area the product is being marketed. The comparison product may also be a generic product. The comparison product must be approved by the relevant Competent Body.

The test must be in conformity with the guidelines in Appendix III for testing of product efficiency.

*Assessment and verification: Report from a laboratory test or consumer test documenting satisfactory efficiency.*

## **11. INFORMATION APPEARING ON THE ECO-LABEL**

According to Annex III of the EU Eco-label Regulation 1980/2000, Box 2 of the eco-label shall contain the following text

- \* low impact on aquatic life
- \* fulfil strict requirements regarding health and the environment
- \* reduced packaging waste

*Assessment and verification: The applicant shall provide a sample of the product packaging showing the label, together with a declaration of compliance with this criterion.*

## APPENDIX I DID-LIST

## APPENDIX II. LIMITED FRAGRANCE COMPOUNDS

The following fragrance compounds are not allowed (in products marketed to persons above the age of three years old) in concentration exceeding 0,01% or not at all (to babies and small children below the age of three).

<b>Name</b>	<b>Cas-no.</b>
Amyl cinnamal	122-40-7
Benzyl alcohol	100-51-6
2 - pentyl - 3 - phenylprop - 2 - en - 1 - ol (Amylcinnamyl alcohol)	101-85-9
Coumarin	91-64-5
Geraniol	106-24-1
4 - (4 - hydroxy - 4 - methylpentyl) cyclohex - 3 - enecarboxaldehyde. (Methyl heptine carbonate)	31906-04-4
4 - methoxybenzyl alcohol (Anisyl alcohol)	105-13-5
Benzyl cinnamate	103-41-3
Farnesol	4602-84-0
Linalool	78-70-6
Benzyl benzoate	120-51-4
Citronellol	106-22-9
a-hexylcinnamaldehyde	101-86-0
methyl oct-2-ynoate (methyl heptine carbonate)	111-12-6
3-methyl-4- (2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one (γ-Methylione)	127-51-5
Oak moss Evernia prunastri, ext)	90028-68-5
Tree moss (Evernia furfuracea, ext)	90028-67-4

The following fragrance compounds are on the list of 26 allergenic fragrance but they are classified as irritating according to the risk phrase R42 or R43 and hence are not allowed to use in ecolabelled products.

<b>Name</b>	<b>Cas-no.</b>
Benzyl salicylate	118-58-1
Cinnamaldehyde	104-55-2
Cinnamyl alcohol	104-54-1
Citral	5392-40-5
7-hydroxycitronellal	107-75-5
Eugenol	97-53-0
Isoeugenol	97-54-1
2-(4-tert-butylbenzyl)-propionaldehyd (Lilial)	80-54-6
d-Limonene	5989-27-5

### **APPENDIX III - GUIDELINES FOR PERFORMANCE TEST**

The products efficiency performance can be demonstrated through a laboratory test or a consumer test. If a laboratory test is employed the producers own test method can be accepted. The applicant must, however, demonstrate that the test gives a measure of the products performance.

If a consumer test is employed the following guidelines must be followed:

A consumer test must include as a minimum 10 test persons. The consumers must be asked of the products efficiency as compared to a market leading product. The questions to the consumers must cover at least the following aspects:

1. How well does the product perform in comparison with the market leading product?
2. How easy is it to apply the desired dosage of the product in comparison with the market leading product?
3. How easy is it to apply the product to the hair and/or skin in comparison with the market leading product?

At least 80 % of the consumers must be at least as satisfied with the product as with the market leading product.

## **APPENDIX IV DOCUMENTATION OF ANAEROBIC BIODEGRADABILITY**

The following approach may be used to provide the necessary documentation of anaerobic biodegradability in the case of ingredients that are not listed in the DID list.

Apply reasonable extrapolation. Use test results obtained with one raw material to extrapolate the ultimate anaerobic degradability of structurally related surfactants. If anaerobic biodegradability has been confirmed for a surfactant (or a group of homologues) according to the DID list (Appendix I), it can be assumed that a similar type of surfactant is also anaerobically biodegradable (for example, C12-15 A 1-3 EO sulphate (DID No 8) is anaerobically biodegradable, and a similar anaerobic biodegradability may also be assumed for C12-15 A 6 EO sulphate). If anaerobic biodegradability has been confirmed for a surfactant by use of an appropriate test method, it can be assumed that a similar type of surfactant is also anaerobically biodegradable (for example, literature data confirming the anaerobic biodegradability of surfactants belonging to the group alkyl ester ammonium salts may be used as documentation for a similar anaerobic biodegradability of other quaternary ammonium salts containing ester-linkages in the alkyl chain(s)).

Perform screening test for anaerobic degradability. If new testing is necessary, perform a screening test by use of OECD 311, ISO 11734, ECETOC No. 28 (June 1988) or an equivalent method.

Perform low-dosage degradability test. If new testing is necessary, and in the case of experimental problems in the screening test (for example, inhibition due to toxicity of test substance), repeat testing by using a low dosage of surfactant and monitor degradation by <sup>14</sup>C measurements or chemical analyses. Testing at low dosages may be performed by use of OECD 308 (24 April 2002) or an equivalent method provided that strict anaerobic conditions are applied. The testing and the interpretation of the test results should be conducted by an independent expert.