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COMMISSION DECISION

of 26 April 2005

establishing ecological criteria and the related assessment and verification requirements for the award of the Community eco-label to lubricants

(notified under document number C(2005) 1372)

(Text with EEA relevance)

(2005/360/EC)

(OJ L 118, 5.5.2005, p. 26)

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(2005/360/EC)

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 [1], and in particular the second subparagraph of Article 6(1) thereof,

After consulting the European Union Eco-Labelling 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-Labelling Board, are to be established according to product groups.

(3) Since the use of lubricants may be hazardous for the environment, due to, for example, their aquatic toxicity or their bioaccumulation, appropriate ecological criteria should be laid down.

(4) The environmental impact may be considered negligible in the case of substances contained in lubricants which, when applied, change their chemical nature and no longer need to be classified according to Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations [2]. The criteria for eco labels should therefore not apply to those substances where less than 0,1 % of the substance in the treated part remains in the form as observed before application.

(5) The ecological criteria and the related assessment and verification requirements should be valid for a period of four years.

(6) 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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[1] OJ L 237, 21.9.2000, p. 1.

[2] OJ L 200, 30.7.1999, p. 1. Directive as last amended by Council Directive 2004/66/EC (OJ L 168, 1.5.2004, p. 35).

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HAS ADOPTED THIS DECISION:

Article 1

The product group ‘lubricants’ shall comprise hydraulic oils, greases, chainsaw oils, two stroke oils, concrete release agents and other total loss lubricants, for use by consumers and professional users.

Article 2

1. For the purpose of this Decision, the following definitions shall apply:

(a) ‘lubricant’ means a preparation consisting of base fluids and additives;

(b) ‘base fluid’ means a lubricating fluid whose flow, ageing, lubricity and anti-wear properties, as well as its properties regarding contaminant suspension, have not been improved by the inclusion of additives;

(c) ‘thickener’ means a substance in the base fluid used to thicken or modify the rheology of a lubricating fluid or grease;

(d) ‘main component’ means any substance accounting for more than 5 % by weight of the lubricant;

(e) ‘additive’ means a substance whose primary functions are the improvement of the flow, ageing, lubricity, anti-wear properties or of contaminant suspension;

(f) ‘grease’ means a solid to semi-solid preparation which consists of a thickening agent in a liquid lubricant.

2. In the case of greases, other ingredients imparting special properties may be included.

Article 3

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

The criteria shall apply to the freshly manufactured product at the time of delivery.

Where criteria are formulated in terms of constituent substances, those criteria shall apply to any substance which has been deliberately added and which constitutes more than 0,1 % of the product’s content, as measured both before and after any chemical reaction has taken place between the substances mixed to provide the lubricant preparation.

The criteria shall not, however, apply to a substance which, on application, changes its chemical nature so as no longer to warrant classification according to Directive 1999/45/EC, and of which less than 0,1 % in the treated part remains in its pre-application form.

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Article 4

The ecological criteria for the product group ‘lubricants’, and the related assessment and verification requirements, shall be valid until 31 July 2010.

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Article 5

For administrative purposes, the code number assigned to the product group ‘lubricants’ shall be ‘27’.

Article 6

This Decision is addressed to the Member States.

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ANNEX

FRAMEWORK

The aims of the criteria

These criteria aim in particular at promoting those products that:

— are of reduced harm to the water and soil during use, and

— lead to reduced CO_2 emissions.

Assessment and verification requirements

The specific assessment and verification requirements are indicated within each criterion.

Where the applicant is required to provide declarations, documentation, analyses, test reports, or other evidence to show compliance with the criteria to the competent body, it is understood that these may originate from the applicant and/or his supplier(s) and/or their supplier(s), etc., as appropriate. The supplier of the additive, additive package or base fluid may provide the relevant information directly to the competent body.

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 appropriate, competent bodies may require supporting documentation and may carry out independent verifications.

The competent bodies are recommended to take into account the implementation of recognised environmental management schemes, such as EMAS or EN ISO 14001, when assessing applications and monitoring compliance with the criteria

(NB: it is not required to implement such management schemes.)

CRITERIA

1. **R-phrases indicating environmental and human health hazards**

The product shall not have been assigned any R-phrase at the time of applying for the eco label, indicating environmental and human health hazards according to Directive 1999/45/EC. The following R-phrases are considered relevant for this product group:

R 20, R 21, R 22, R 23, R 24, R 25, R 26, R 27, R 28, R 33, R 34, R 35, R 36, R 37, R 38, R 39, R 40, R 41, R 42, R 43, R 45, R 46, R 48, R 49, R 50, R 51, R 52, R 53, R 59, R 60, R 61, R 62, R 63, R 64, R 65, R 66, R 67, R 68, and combinations thereof.

Assessment and verification of criterion 1

Conformity with criterion 1 shall be stated in writing and signed by the applicant company.

All main components included in the product shall be unambiguously stated, giving their names and where applicable, their Einecs or Elincs number and the concentrations in which they are used.

The producer of the product shall provide the competent body with:

— a product safety data sheet (meeting the requirements of Commission Directive 91/155/EEC ([1])).

— safety data sheets of applicant suppliers (meeting the requirements of Directive 91/155/EEC and Council Directive 67/548/EEC ([2])) for each main component.

Sufficient data shall be available to allow for the evaluation of the environmental hazards (indicated by the R-phrases: R 50, R 50/53, R 51/53, R 52, R 52/53, R 53), of the product in accordance with Directives 91/155/EEC and 1999/45/EC.

([1]) OJ L 76, 22.3.1991, p. 35.
([2]) OJ L 196, 16.8.1967, p. 1.

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The evaluation of a product for hazards to the environment shall be performed by the conventional method as indicated in Annex III to Directive 1999/45/EC. However, as defined by part C of Annex III to that Directive, the results of testing the preparation (either the product preparation or the additive package) as such can be used to modify the classification concerning the aquatic toxicity that would have been obtained using the conventional method.

2. **Additional aquatic toxicity requirements**

The applicant shall demonstrate compliance by meeting the requirements of either criterion 2.1 or criterion 2.2.

Criterion 2.1. Requirements for the preparation and main components

Data are required on the aquatic toxicity of:

— the preparation, and

— the main components.

The critical concentration for the aquatic toxicity of each main component shall be at least 100 mg/l. The test shall be carried out on algae and daphnia (OECD 201 and 202).

For hydraulic oils the critical concentration for the aquatic toxicity shall be at least 100 mg/l.

For greases, chainsaw oils, concrete release agents and other total loss lubricants the critical concentration for the aquatic toxicity shall be at least 1 000 mg/l.

Greases may be evaluated by providing data for the preparation and the main components only if the thickener shows ultimate biodegradation (see criterion 3) or inherent biodegradation according to:

— a biodegradation > 70 % in the OECD 302 C test for inherent biodegradation or equivalent test methods, or

— a biodegradation > 20 % but < 60 % after 28 days in the OECD 301 tests based on oxygen depletion or carbon dioxide generation, or

— biodegradation > 60 % in ISO 14593 (CO_2 headspace test).

The test on the preparation shall be carried out on all three groups of species (OECD 201, 202, and 203).

Table 1 summarises the requirements for the different product subgroups according to criterion 2.1.

Table 1

Aquatic toxicity requirements for the different product subgroups — Data requirements for the preparation and main components

Criterion 2.1	Hydraulic fluids	Greases (*)	Chainsaw oils, concrete release agents and other total loss lubricants	Two-stroke oils
Aquatic toxicity for the fully formulated product in all three of the acute toxicity tests OECD 201, 202 and 203	≥ 100 mg/l	≥ 1 000 mg/l	≥ 1 000 mg/l	≥ 1 000 mg/l
Aquatic toxicity for each individual main component in OECD 201 and 202	≥ 100 mg/l	≥ 100 mg/l	≥ 100 mg/l	≥ 100 mg/l

(*) Greases can be evaluated in this way only if the thickener shows a biodegradation > 70 % in the OECD 302 C or equivalent test methods or biodegradation > 20 % but < 60 % after 28 days in OECD tests based on oxygen depletion or carbon dioxide generation.

Assessment and verification of criterion 2.1

Reports shall be submitted to the competent body including the data on the aquatic toxicity of the preparation and all main components by making use of

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either existing material from registrations or new tests, allowing compliance to be demonstrated with the requirements set out in table 1.

The aquatic toxicity of the preparation shall be determined according to the OECD 201, 202 and 203 or equivalent methods.

The aquatic toxicity of each individual main component shall be determined according to the OECD 201 and 202 or equivalent methods.

Criterion 2.2. Requirements for each constituent substance

Aquatic toxicity data shall be provided for each constituent substance intentionally added in the product. One or more substances exhibiting a certain degree of aquatic toxicity are allowed in the lubricant for a cumulative mass concentration as indicated in Table 2.

Table 2

Aquatic toxicity requirements for the different product subgroups — Data requirements for each constituent substance

Criterion 2.2	Cumulative mass concentration of substances present in			
Aquatic toxicity	Hydraulic fluids	Greases	Chainsaw oils, concrete release agents and other total loss lubricants	Two-stroke oils
10 mg/l < Acute toxicity (*) ≤ 100 mg/l or 1 mg/l < NOEC ≤ 10 mg/l	≤ 20	≤ 25	≤ 5	≤ 25
1 mg/l < Acute toxicity (*) ≤ 10 mg/l or 0,1 mg/l < NOEC ≤ 1 mg/l	≤ 5	≤ 1	≤ 0,5	≤ 1
Acute toxicity (*) < 1 mg/l or NOEC ≤ 0,1 mg/l	≤ 1	≤ 0,1	≤ 0,1	≤ 0,1

(*) EC50/LC50/IC50.

Assessment and verification of criterion 2.2

Reports shall be submitted to the competent body including the data on the aquatic toxicity of each constituent substance by making use of either existing material from registrations or new tests, demonstrating compliance with the requirements set out in Table 2.

The aquatic toxicity of each constituent substance shall be determined according to the OECD 201 and 202 or equivalent methods.

Assessment and verification of both criteria 2.1 and 2.2

In the case of slightly soluble components (< 10 mg/l) the method of the water accommodated fraction (WAF) can be used in the aquatic toxicity determination. The established loading level, sometimes referred to as LL50 and related to the lethal loading, may be used directly in the classification criteria. The preparation of a water accommodated fraction shall follow the recommendations set out according to one of the following guidelines; ECETOC Technical Report No 20 (1986), Annex III to OECD 1992 301 or the ISO Guidance document ISO 10634, or ASTM D6081-98 (Standard practice for Aquatic Toxicity Testing for Lubricants: Sample Preparation and Results Interpretation or equivalent methods).

The acute aquatic toxicity study on algae and daphnia (OECD 201 and 202) does not need to be conducted when:

— the substance is unlikely to cross biological membranes MM > 800 or molecular diameter > 1,5 nm (> 15 Å),

— or the substance is highly insoluble in water (water solubility < 10 μg/l),

as such substances are not regarded as toxic for algae and daphnia in the aquatic system.

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Similarly, the acute aquatic toxicity study on daphnia (OECD 202) does not need to be considered when a long-term toxicity study on Daphnia's according to OECD 211 or equivalent one is available.

The water solubility of substances shall be determined where appropriate according to OECD 105 (or equivalent tests).

If chronic toxicity data are available (results of OECD 210 and 211 tests or equivalent methods), these may be used instead of acute aquatic toxicity data. Absence of chronic toxicity data shall be stated in writing and signed by the applicant.

3. **Biodegradability and bioaccumulative potential**

The product shall not contain substances that are both:

— non-biodegradable,

and

— (potentially) bioaccumulative.

However, the product may contain one or more substances with a certain degree of degradability and potential or actual bioaccumulation up to a cumulative mass concentration as indicated in Table 3.

Table 3

Requirements for biodegradability and bioaccumulative potential

	Cumulative mass concentration of substances is			
Biodegradation	Hydraulic fluids	Greases	Chainsaw oils, concrete release agents and other total loss lubricants	Two-stroke oils
Non-biodegradable (*)	≤ 5	≤ 10	≤ 5	≤ 10
Inherently aerobically biodegradable	≤ 5	≤ 20	≤ 5	≤ 20
Ultimately aerobically biodegradable	≥ 90	≥ 75	≥ 90	≥ 75

(*) NB: substances that are both non-biodegradable and bioaccumulative substances are not permitted.

Assessment and verification of criterion 3

Conformity shall be demonstrated by providing the following information:

— reports including the data on the biodegradability of each constituent substance if this is not adequately shown on the safety data sheets provided for each substance,

— reports including the data on the bioaccumulative potential of each constituent substance:

  — for non-biodegradable substances, and

  — for toxic and very toxic substances that are readily biodegradable (for classification purposes).

The biodegradability shall be determined for each constituent substance in the product separately by test methods specified below (or equivalent tests).

A substance is considered **ultimately biodegradable** (aerobic) if:

1. In a 28-day biodegradation study according to OECD 301 A-F or equivalent tests the following levels of biodegradation are achieved:

   — in OECD 301 tests based upon dissolved organic carbon ≥ 70 %,

   — in OECD 301 tests based upon oxygen depletion or carbonic dioxide generation ≥ 60 % of the theoretical maxima.

2. The BOD_5/ThOD or BOD5/COD ratio is larger than 0,5.

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In the OECD test the 10-day window principle will not necessarily apply. If the substance reaches the biodegradation pass level within 28 days but not within the 10-day time-window, a slower degradation rate is assumed.

A substance is considered **inherently biodegradable** if it shows:

— a biodegradation > 70 % in the OECD 302 C test for inherent biodegradation or equivalent test method, or

— a biodegradation > 20 % but < 60 % after 28 days in the OECD 301 tests based on oxygen depletion or carbon dioxide generation, or

— biodegradation ≥ 60 % in ISO 14593 (CO_2 headspace test).

A substance whose primary function is thickening shall be considered inherently aerobically biodegradable if it shows a biodegradation higher than 20 % in the OECD 302 C for inherent biodegradation or equivalent test methods. All of the aquatic toxicity requirements shall then apply also to the degradation products, which have been scientifically proven to be derivates of the thickener, after exposure to the aquatic environment.

A substance is non-biodegradable if it fails the criteria for ultimate and inherent biodegradability.

A substance does not bioaccumulate if its MM > 800 or has a molecular diameter > 1,5 nm (> 15 Å).

A substance with MM < 800 or molecular diameter < 1,5 nm (< 15 Å) does not bioaccumulate if:

— the octanol-water partition coefficient log K_{ow} < 3 or > 7, or

— the measured BCF is ≤ 100. Since most substances used in lubricants are quite hydrophobic the BCF-value should be based on the lipid weight content and care must be shown to ensure a sufficient exposure time.

Test methods

The tests to be applied for the determination of ready biodegradability are the OECD 301 A-F series, or ISO and ASTM equivalents or the BOD_5/(ThOD or COD) ratio. The BOD_5/(ThOD or COD) ratio can only be used if no data based on the OECD 301 or any other equivalent test methods are available. The BOD_5 shall be assessed according to C.5 (Commission Directive 92/69/EEC ([1])) or equivalent methods while the COD according to C.6 (Directive 92/69/EEC) or equivalent methods. For the determination of the inherent biodegradability the OECD 302 C or equivalent test methods are to be applied.

The applicant may also use read-across data to estimate the biodegradability of a substance. 'Read-across' for the assessment of the biodegradability of a substance shall be acceptable if the reference substance differs by only one functional group or fragment from the substance applied in the product. If the reference substance is readily or inherently biodegradable and the functional group has a positive effect on the aerobic biodegradation then the applied substance may also be regarded as readily or inherently biodegradable. Functional groups or fragments with a positive effect on the biodegradation are: aliphatic and aromatic alcohol [-OH], aliphatic and aromatic acid [-C(=O)-OH], aldehyde [-CHO], Ester [-C(=O)-O-C], amide [-C(=O)–N of -C(=S)–N]. Adequate and reliable documentation of the study on the reference substance should be provided. In case of a comparison with a fragment, not included here above, adequate and reliable documentation of the studies should be provided on the positive effect of the functional group on the biodegradation of structurally similar substances.

The log octanol/water partition coefficient (log K_{ow}) shall be assessed according to OECD 107, 117 or the draft 123 or any other equivalent test method. The bioconcentration factor (BCF) shall be assessed according to OECD 305.

Log K_{ow} values are applicable to organic chemicals only. To assess the bioaccumulation potential of non-organic compounds, some surfactants, and some organo-metallic compounds, BCF measurements shall be carried out.

If the test cannot be performed (e.g. the substance has a high surface activity or does not dissolve in water or in octanol), a calculated value for log K_{ow} as well as details of the calculation method shall be provided.

The following calculation methods are allowed for the log K_{ow}: CLOGP for a log K_{ow} between 0 and 9, LOGKOW (KOWWIN) for a log K_{ow} between – 4 and 8,

([1]) OJ L 383, 29.12.1992, p. 113.

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AUTOLOGP for a log K_{ow} greater than 5 as laid down in Commission Regulation (EC) No 1488/94 ([1]), which is supported by a technical guidance document (TGD).

4. **Exclusion of specific substances**

Substances appearing in the Community list of priority substances in the field of water policy and the OSPAR List of Chemicals for Priority Action, both referred to the version applicable in December 2004, shall not be intentionally added as an ingredient in a product eligible for the Community eco-label.

Organic halogen compounds and nitrite compounds shall not be intentionally added as an ingredient in a product eligible for the Community eco-label.

Metals or metallic compounds shall not be intentionally added as an ingredient in a product eligible for the Community eco-label with the exception of sodium, potassium, magnesium and calcium. In the case of thickeners, also lithium and/or aluminium compounds may be used up to concentrations limited by the other criteria included in this Annex.

Assessment and verification of criterion 4

Conformance with these requirements shall be stated in writing and signed by the applicant.

5. **Renewable raw materials**

The formulated product shall have a carbon content derived from renewable raw materials that shall be:

— ≥ 50 % (m/m) for hydraulic oils,

— ≥ 45 % (m/m) for greases,

— ≥ 70 % (m/m) for chainsaw oils, concrete release agents and other total loss lubricants,

— ≥ 50 % (m/m) for two-stroke oils.

Carbon content derived from renewable raw material means the mass percentage of component A × [number of C-atoms in component A, which are derived from (vegetable) oils or (animal) fats divided by the total number of C-atoms in component A] plus mass percentage of component B × [number of C-atoms in component B, which are derived from (vegetable) oils or (animal) fats divided by the total number of C-atoms in component B] plus the mass percentage of component C × [number of C-atoms in component C], and so on.

Assessment and verification of criterion 5

The applicant shall provide the competent body with a declaration of compliance with this criterion.

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6. **Technical performance**

Hydraulic fluids shall at least meet the technical performance criteria laid down in ISO 15380, Tables 2 to 5.

Greases shall be ‘fit for purpose’.

Chain-saw oils shall at least meet the technical performance criteria laid down in the RAL-UZ 48 of the Blue Angel.

Concrete release agents and other total loss lubricants shall be fit for purpose.

Two-stroke oils for marine applications shall at least meet the technical performance criteria laid down in ‘NMMA Certification for Two-Stroke Cycle Gasoline Engine Lubricants’ of NMMA TC-W3.

Two-stroke oils for terrestrial applications shall at least meet the EGD level of technical performance criteria laid down in ISO 13738:2000.

([1]) OJ L 161, 29.6.1994, p. 3.

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Assessment and verification of criterion 6

The applicant shall provide the competent body with a declaration of compliance with this criterion, together with related documentation.

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7. **Information appearing on the eco-label**

Box 2 of the eco-label shall contain the following text: ‘reduced harm for water and soil during use; reduced CO_2 emissions’.

Assessment and verification of criterion 7

The applicant shall provide the competent body with a sample of the product packaging showing the label, together with a declaration of compliance with this criterion.