

European Eco-label application pack for lubricants



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Purpose of this User Manual

This manual consists of **two parts**. The first one (PART 1) includes the general information concerning the European Eco-label. The second (PART 2) is intended to be a reference guide for applicants on how to apply for the European Eco-label lubricants and under what conditions products can be certified.

These criteria have been established in terms of the Commission Decision of 26 April 2005 (2005/360/EC) and were published in the Official Journal of 5 May 2005 (hereinafter to be referred as “the Decision”).

The criteria cover hydraulic oils, greases, chainsaw oils, two stroke oils, concrete release agents and total loss lubricants for use by private consumers and professional users¹.

To apply for the European Eco-label the products have to meet requirements for performance, show limited toxicity to aquatic organisms, have high biodegradability and low potential for bioaccumulation and contain a certain percentage of renewable sources.

Aerobic biodegradation data are mandatory for all substances present in the candidate product in concentrations higher than 0,1% by weight. Bioaccumulation data are required for only those substances that are non-biodegradable. Moreover, aquatic toxicity data are mandatory for all main components (any individual substance accounting for more than 5% by weight of the candidate product). The applicant must finally provide data on the aquatic toxicity of the preparation or the aquatic toxicity of each of the individual substances being present in the candidate product at concentrations between 0,1% and 5% by weight.

The ecological criteria for lubricants aim in particular at promoting those products that:

- are of reduced harm to water and soil during use, and
- lead to reduced CO₂ emissions.

The criteria for this product category and background information are available at:
http://europa.eu.int/comm/environment/ecolabel/product/pg_lubricants_en.htm

¹ article 1 of the Decision

PART 1. General information concerning the European Eco-label

1. The European Union Eco-label (referred to as the European Eco-label in this user manual) is Europe's official environmental label. The EU eco-label scheme is now part of a wider approach on Integrated Product Policy (IPP). "The Flower" was first established in 1992 and revised by Regulation (EC) No 1980/2000, which extended the scheme to cover services. In this manual, "product" refers to both goods and services.
2. At <http://europa.eu.int/ecolabel> which is the European Commission's official website for the European Eco-label you find all background information. All key documents are available and you can easily download the texts.
3. Participation in the scheme is voluntary. It is administered by officially appointed Competent Bodies in each EU member state. Competent Bodies are independent and have no vested interest. You find a list of Competent Bodies at:
http://europa.eu.int/comm/environment/ecolabel/tools/competentbodies_en.htm
4. Businesses whose products comply with the published product group definition and the criteria for the product can apply for the European Eco-label. The criteria for specific product groups are agreed by EU member states after consultation with relevant interests, including other departments within the European Commission and European representatives of industry, consumers, environmental organizations, retailers and public authorities.
5. A manufacturer, retailer or service provider who meets the criteria for a product group and who applies for the award of the European Eco-label, can market his eco-labelled product in all Member States of the European Union. The Flower is also recognised and present in those countries, which are signatories to the EEA Agreement (Norway, Iceland and Liechtenstein).
6. So far, criteria have been agreed for 28 product categories. You find an actual list of established product-groups and details on eco-labelled products and on manufacturers at <http://europa.eu.int/ecolabel/>
7. Manufacturers, importers, retailers or service providers should make their applications to the Competent Body in the Member State in which their product or service is manufactured, first marketed, or imported from a third country. If the product is manufactured in several Member States, the applicant is free to choose a Competent Body in one of those Member States.
8. Applicants should seek guidance from the Competent Bodies on the information needed in each case. The European Eco-label for each product group has its own environmental criteria (published in the Official Journal of the European Communities) and the information required to demonstrate compliance will depend on the relevant criteria.
9. The applicant either tests whether the product complies with the criteria for the relevant product group, or asks a laboratory to do the tests independently. The test costs are met by the applicant. The applicant compiles a dossier of relevant documents to show compliance, and submits this with the application form.

10. The Competent Body will conclude a contract covering the terms of use of the label with each successful applicant. A standard contract has been prepared for this purpose and Competent Bodies can provide copies to potential applicants.
11. The Competent Body can request the necessary documentation from the license holder in order to monitor the compliance with the product's criteria and the terms of use set out in the contract. The Competent Body can also visit the holder's premises without prior notice.
12. The following table gives the indicative fees to be charged by Competent Bodies according to the Decision:

| | Minimum | Maximum | Reductions (1) |
|---|---|--|---|
| Application fee covers the costs of processing the application. | EUR 300 | EUR 1300 | 25% for SMEs and applicants from developing countries |
| | Minimum | Maximum | Reductions (2) |
| Annual fee for the use of the label = 0.15% of annual volume of sales of the product within the Community | EUR 500 per product group per applicant | EUR 25000 per product group per applicant. | 25% for SMEs and applicants from developing countries 15% for companies registered under EMAS or certified under ISO 14001 Other reductions possible, please contact your Competent Body for further details. |

(1) These reductions are cumulative.

(2) These reductions are cumulative, but shall not exceed in total 50%

These fees do not include the costs of testing and verification, which applicants have to meet themselves.

13. Product group criteria are usually valid for a period of 3-5 years according to the Commission Decision on the relevant product group. Ecological criteria are reviewed before they expire and may be revised. If criteria have been revised you will have to renew your contract. If criteria have been prolonged your contract is automatically renewed, as long as the criteria remain valid. You may use the eco-label from the date it is awarded until the end of the period of the validity of the criteria.
14. Retailers can ask for an eco-label, although only for products put on the market under their own brand name. As a retailer you can also request, or even insist that your suppliers apply for the European Eco-label. In this way you will also contribute to providing environmentally friendly products to your clients.
15. It is possible to have an European Eco-label for "own brand" products. If a product is sold under two brand names, you only need to submit one application.
16. If some of the characteristics of an eco-labelled product have changed you will not need to submit a new application if only characteristics that do not affect compliance with the criteria have changed. However, the Competent Body should be notified of significant modifications.
17. More information about the scheme can be found at the website <http://europa.eu.int/ecolabel/>. You can also contact your national Competent Body to know more about the Scheme at the national level, to submit your application, etc.

PART 2. User Manual

PART 2 provides guidelines to help you apply for the European Eco-label for lubricants.

It describes how the European Eco-label application should be assembled, and the process of assessment to ensure that the candidate product complies with the criteria. Compliance is shown by a mixture of laboratory test reports or data from peer reviewed studies and applicant's declarations.

Definitions and descriptions of terms used in this manual

- 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 the reduction of contaminant suspension.
- f) **'Grease'** means a solid to semi-solid preparation consisting of a thickening agent in a liquid lubricant.
- g) **'Ultimately aerobically biodegradable'** is a substance which...

... is listed in annex II of this user manual. This list is established by Council Regulation (EEC) 793/93 on the Control and Evaluation of the Risks of Existing Substances. The list includes substances, which, on the basis of their intrinsic properties, involve risks recognized as minimal by the European Commission.

... differs by only one functional group from a reference substance (with a chemical structure closely related to that of the substance in question) on which data do exist showing ultimate biodegradation. The functional groups for which this rule applies are: aliphatic and aromatic alcohol [-OH], aliphatic and aromatic acid [-C(=O)-OH], aldehyde [-CHO], ester [-C(=O)-O-C], amide [-C(=O)-N or -C(=S)-N].

... achieves at least 70% degradation within 28 days according to OECD 301 A or E test².

... achieves at least 60% degradation within 28 days according to one of the OECD 301 B,C, D or F tests³

...has a BOD5/COD or BOD5/ThOD ratio > 0,5

² Or equivalent tests methods

Note that it is not necessary to keep the “10 days window” for assessing the ultimate biodegradability of substances in lubricants according to OECD 301.

h) **‘Inherently aerobically biodegradable’** is a substance which...

.....achieves more than 70% degradation according to OECD 302 C test³. Note that for thickeners this condition is less stringent. A thickener is considered ‘inherently aerobic biodegradable’ if it achieves more than 20% degradation according to OECD 302 C test³.

.....achieves more than 20% but less than 60% degradation within 28 days according to one of the OECD 301 B, C en F tests³

..... at least 60 % degradation according to ISO 14593³

... differs by only one functional group from a reference substance (with a chemical structure closely related to that of the substance in question) on which data do exist showing inherent biodegradation. The functional groups for which this rule applies 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].

i) **‘Not bioaccumulating’** is a substance which...

.....has a Molecular Mass > 800 Dalton

.....has a Molecular Diameter > 1.5nm (15 Å)

.....has an experimental Bio-Concentration Factor (BCF) ≤ 100 according to OECD 305³

..... has a logK_{ow} < 3 or > 7 according to OECD 107, 117 or the draft 123⁴

j) **‘Not toxic to aquatic organisms’** is a substance which.....

.....is listed in annex II of this user manual.

....has a Molecular Mass > 800 Dalton

....has a Molecular Diameter > 1.5nm (15 Å)

....is highly insoluble in water (solubility < 10µg/l) according to OECD 105⁴

.....has a NOEC > 10 mg / l according to OECD 210 and 211 (chronic toxicity tests)⁴

.... has a EC50/LC50/IC50 > 100 mg/l according to OECD 201 and 202 (acute toxicity tests)⁴

k) **‘Harmful’** is a substance which....

.....has a NOEC between 1-10 mg / l according to OECD 210 and 211 (chronic toxicity tests)⁴

³ Or equivalent test methods

... has a EC50/LC50/IC50 between 10-100 mg/l according to OECD 201 and 202 (acute toxicity tests)⁴

l) **'Toxic'** is a substance which...

...has a NOEC between 0,1-1 mg / l according to OECD 210 and 211 (chronic toxicity tests)⁴

... has a EC50/LC50/IC50 between 1-10 mg/l according to OECD 201 and 202 (acute toxicity tests)⁴

m) **'Very toxic'** is a substance which...

....has a NOEC \leq 0,1 mg / l according to OECD 210 and 211 (chronic toxicity tests)⁴

... has a EC50/LC50/IC50 \leq 1 mg/l according to OECD 201 and 202 (acute toxicity tests)⁴

n) **'Highly insoluble'** is a substance which...

... has a water solubility $<$ 10 μ g/l according to OECD 105⁴

o) **'Slightly soluble'** is a substance which...

... has a water solubility $<$ 10mg/l according to OECD 105⁴

p) **"Bioconcentration factor"** (BCF) means the ratio of chemical concentration in an organism to that in surrounding water.

q) **"EC50"** is median effective concentration. It is the concentration that is estimated to cause some defined toxic effect to 50% of the test organisms; (e.g., death, immobilization, or serious incapacitation).

r) **"IC50"** means the inhibiting concentration for a 50% effect on the test organisms. It represents a point estimate of the concentration of test materials that can cause a 50% impairment in a quantitative biological function (e.g. reduced growth, impairment of the reproductive). These potential impacts do not kill the organism but may reduce the total population over time thereby decreasing aquatic productivity.

s) **"LC50"** means median lethal concentration. It is the concentration of material that is estimated to be lethal to 50% of the test organisms.

t) **"Octanol/water partition coefficient"** (K_{ow}) means the ratio of a chemical's solubility in n-octanol and water at equilibrium.

u) **"NOEC"** means 'no observed effect concentration'. It is the highest concentration at which no effect on test organisms is observed over a relatively long period in a chronic aquatic toxicity test.

v) **"Biochemical Oxygen Demand"** (BOD) means the quantity of oxygen utilized by micro-organisms growing under aerobic (oxygenated) conditions for the biochemical oxidation of organic substances under standard laboratory procedures which is usually 5 days (hence BOD₅) but can be longer for specific purposes. BOD is usually expressed as a concentration (e.g., mg/l).

- w) **“Chemical Oxygen Demand”** (COD) means the quantity of oxygen utilized in the chemical oxidation of an organic substance in water, as determined using a strong oxidant, under standard laboratory procedure, usually expressed in milligrams per litre (e.g., mg/l).

- x) **“Theoretical Oxygen Demand”** (ThOD) is the calculated amount of oxygen required to oxidise an organic substance to its final oxidation products. However, there are some differences between standard methods that can influence the results obtained: for example, some calculations assume that nitrogen released from organics is generated as ammonia, whereas others allow for ammonia oxidation to nitrate. Therefore in expressing results, the calculation assumptions should always be stated.

Checklist of tests and methods

It is not possible to provide a specific checklist of tests for diverse candidate products, since the testing strategy will depend in part on the availability of existing data. A decision tree (annex V) has been made to allow a logical decision on the nature and extent of testing necessary for different types of lubricant preparations.

The following list provides an overview of all possible tests that may be used when applying for the European Eco-label lubricants. The applicant reserves the right to provide equivalent test data for the test methods referred to in this manual.

Ready Biodegradability tests

1. OECD 301 A : DOC-Die-Away
2. OECD 301 B : CO₂ Evolution
3. OECD 301 C : MITI (Ministry of International Trade and Industry, Japan)
4. OECD 301 D : Closed Bottle Test
5. OECD 301 E : Modified OECD Screening
6. OECD 301 F : Manometric Respirometry

Inherent Biodegradability tests

1. OECD 302 C : MITI-II Test (with modified inoculum)
2. ISO 14593 : Closed Bottle CO₂ evolution

BOD₅ and COD determination

Test guidelines as described in C.5 and C.6 of Dir 92/69/EEC

Bioaccumulation

1. OECD 305 : Bioaccumulation in fish: measurement of the Bio-concentration factor (BCF)
2. OECD 107 : Octanol/water partition coefficient (log K_{ow}): Shake test / non dissociating substance
3. OECD 117 : Octanol/water partition coefficient (log K_{ow}): HPLC Screen / non dissociating substance
4. Draft OECD 123 : Octanol/water partition coefficient (log K_{ow}): Slow-Stirring Method
5. Calculations of the Octanol/water partition coefficient (log K_{ow}) by using the latest update version of the CLOGP method (for a log K_{ow} between 0 and 9), the KOWWIN method (for a log K_{ow} between -4 and 8) and the AUTOLOGP method (for a log K_{ow} greater than 5). The calculated log K_{ow} is the highest value of the three calculations.

Acute aquatic toxicity

1. OECD 201 : Alga growth inhibition test
2. OECD 202 : Acute toxicity to Daphnia magna test
3. OECD 203 : Acute toxicity to fish test

Chronic aquatic toxicity

1. OECD 210 : Fish, Early-life Satge Chronic Toxicity Test
2. OECD 211 : Daphnia magna reproduction Chronic Toxicity Test (semi-static)

Water solubility

OECD 105

Preparation of the Water accommodated Fraction

In case of slightly soluble substances (aquatic solubility < 10 mg/L) the applicant may apply the aquatic toxicity tests (OECD 201, 202, 203, 210 and 211 tests) on the water accommodated fraction (WAF). The WAF should in this case have been prepared according to one of the following four possibilities:

1. ECETOC Technical Report No. 20 (1986)
2. Annex III of OECD 1992 301
3. ISO 10634
4. ASTM D6081-98

Read-across for estimating the biodegradability of a substance

Estimation method for the determination of the biodegradability of a substance for which no data are available.

According to this approach the biodegradability of a substance can be estimated using data from a reference substance (with a chemical structure closely related to that of the substance in question) on which there is data. If the chemically similar substance is ultimately or inherently aerobically biodegradable and differs only one functional group from the substance in question then the substance in question may also be regarded as ultimately or inherently biodegradable if the functional group has a positive effect on the biodegradation. Functional groups 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 or -C(=S)-N].

How to apply

To apply for the European Eco-label please:

- a) complete the Application Form in annex I.
- b) send a hardcopy of the completed form together with the supporting documents to the Competent Body.

Follow the 8 steps below to verify whether your product is eligible for the European Eco-label:

| 8 steps to the flower | | Reference to the text of the Decision |
|------------------------------|---|--|
| Step 1 | Check whether the candidate product falls within the product group definition | Article 1 |
| Step 2 | Confirm that the candidate product does not carry any R-phrases indicating environmental or human health hazards. | Criterion 1 |
| Step 3 | Check whether the candidate product meets the technical performance specifications | Criterion 6 |
| Step 4 | Check whether the candidate product contains substances appearing in the Community list of priority substances in the field of water policy (2000/60/EC) and the OSPAR List. These substances are not allowed in an eco-labelled product. Similarly organic halogens, nitrite compounds and metals or metallic compounds are not allowed in an eco-labelled product with the exception of sodium, potassium, magnesium and calcium. In the case of thickeners, also lithium and/or aluminium compounds may be used. | Criterion 4 |
| Step 5 | Check whether the candidate product meets the criteria concerning the use of renewable raw materials content | Criterion 5 |
| Step 6 | Check whether the candidate product meets the biodegradation and bioaccumulation requirements | Criterion 3 |
| Step 7 | Check whether the candidate product meets the aquatic toxicity requirements | Criterion 2 |
| Step 8 | Confirm that once the European Eco-label has been awarded to the product, its label contains the text: <ul style="list-style-type: none"> - Reduced harm for water and soil during use - Reduced CO2 emissions | Criterion 7 |

Note that the steps are not organized in the sequence of the actual criteria listed in Commission Decision of 23 March 2005. This is done for efficiency reasons. The first 5 steps guide you through the requirements that are relatively uncomplicated to check, the ones that can be verified at a glance. Steps 6 to 7 are more sophisticated and complex to verify. They involve the verification of the criteria on aquatic toxicity, biodegradability and bioaccumulation and may entail the generation and compilation of data. It only makes sense to go through 6 to 7 if you have first checked for steps 1 to 5. Step 8 is to be undertaken after the candidate product has passed all other requirements.

Step 1 - Product group definition / Article 1

The candidate product must fall within the product group definition. The European Eco-label can be awarded to hydraulic fluids, greases, chainsaw oils, two stroke oils, concrete release agents, and other total loss lubricants. The product group covers products for both private and professional use.

Data and documents to be submitted

The applicant completes step 1 of the application form in annex I whether his/her product is a hydraulic fluid, grease, chainsaw oil, two stroke oil, concrete release agent, or an other total loss lubricant and optionally submits the corresponding and most recent technical data sheet to the Competent Body.

Step 2 - R-phrases / Criterion 1

To be eligible for the Eco-label the candidate product should not carry any of the following R-phrases indicating environmental or human health hazards: R20, 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, R39, R 40, R 41, R 42, R 43, R 45, R 46, R 48, R 49, R 50, R 51, R52, 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.

Data and documents to be submitted

The signed declaration included in step 2 of the application form in annex I should be returned to the Competent Body. The declaration states that the candidate product does not carry any of the above R-phrases. Additionally, he or she declares that sufficient data are available for the evaluation of the environmental hazards of the candidate product.

The Material Safety Data Sheet (MSDS) of the candidate product and main components should be provided to the Competent Body. In case that the product is non-hazardous en thus has no MSDS the declaration is sufficient⁴.

Step 3 - Technical performance / Criterion 6

The candidate product must meet technical performance criteria to qualify for the European Eco-label. Compliance with the technical performance criteria will be evaluated by an appropriate standard test in the case of hydraulic fluids, chain saw oils and two stroke oils. For greases, concrete release agents and other total loss lubricants the applicant has to provide documents to show that the performance level is 'fit for purpose'.

Data and documents to be submitted

The signed declaration in step 3 of the application form in annex I should be submitted to the Competent Body. Additionally, the applicant submits documentation demonstrating compliance with the technical performance criteria laid down in ISO 15380 for hydraulic fluids, in RAL-UZ 48 of the Blue Angel for

⁴ Please note that manufacturers are under no obligation to produce MSDS's for non-hazardous materials. However, some manufacturers/suppliers do produce MSDS also for non-hazardous products. These MSDS can be provided as relevant documents.

chain saw oils and in “NMMA Certification for two-stroke cycle gasoline engine lubricants’ of NMMA TC-W3 for two stroke oils.

In the cases of greases, concrete release agents and other total loss lubricants documentation demonstrating that the product is ‘fit for purpose’ should be provided. Such documentation may include, but is not limited to, case studies accompanied by statements of applicant’s clients that the product has met their expectations regarding technical performance or copy of published data.

| |
|---|
| Step 4 - Exclusion of specific substances / Criterion 4 |
|---|

The lubricant should not contain substances appearing in the Community list of priority substances in the field of water policy (2000/60/EC) and the OSPAR List, Organic halogens, Nitrite compounds, Metals or metallic compounds with the exception of sodium, potassium, magnesium and calcium. In the case of thickeners, also lithium and/or aluminium compounds may be used.

The OSPAR list and the list of priority substances in the field of water policy (2000/60/EC) can be found in annex III (OSPAR list) and IV (Directive 2000/60/EC).

Data and documents to be submitted

The applicant fills in the DATA TABLE 4 and signs the declaration included in step 4 of the application form in annex I.

| |
|---|
| Step 5 - Renewability content / Criterion 5 |
|---|

The candidate product must meet the criteria concerning the use of renewable raw materials content.

The European Eco-label demands a high content of renewable raw materials in the lubricant formulation. Since the base fluid constitutes up to 98% of a lubricant formulation this requirement very strongly favours the use of oleochemical derived base fluids that is, natural esters or synthetic esters from vegetable or animal fats.

The lubricant shall have a carbon content derived from renewable materials of

- ≥ 50 % for hydraulic oils
- ≥ 45 % for greases
- ≥ 70 % for chain saw oils, concrete release agents and other total loss lubricants
- ≥ 50 % for two-stroke oils

Data and documents to be submitted

The applicant should sign the declaration included in step 5 of the application form in annex I and calculates the renewable materials content by using the formula:

$$\text{Renewable carbon content} = \sum \left(x \frac{C_{renewable}^X}{C_{total}^X} + y \frac{C_{renewable}^Y}{C_{total}^Y} + z \frac{C_{renewable}^Z}{C_{total}^Z} + etc. \right)$$

Where:

x, y, z etc stand for the mass percentage (w/w%) of all substances X, Y, Z etc. constituting > 0,1% (w/w) of the candidate product

$C_{renewable}$ is the number of C atoms from vegetable and animal oils and fats

C_{total} is the total number of C atoms (C atoms from vegetable and animal oils and fats AND C atoms from petrochemical origin)

Additionally the applicant indicates in the same form (DATA TABLE 5, step 5 in annex I) for all substances

- Chemical name
- EINECS or Cas nr
- Mass percentage
- Number of renewable atoms
- Total number of C atoms

Step 6 - Biodegradation and bioaccumulation requirements / Criterion 3

The lubricant may contain one or more substances that are non-biodegradable - but which do not accumulate - and inherently aerobically biodegradable as long as they don't exceed certain cumulative concentrations. Ultimately aerobically biodegradable substances should make up the biggest part of the product.

Data and documents to be submitted

Data are required that allow for the evaluation of the biodegradation potential of all substances present in the product. For non-biodegradable substance the applicant should also evaluate their bioaccumulation potential.

As proof of compliance with the requirements on biodegradability and bioaccumulation potential the applicant fills in the data table(s), submits supporting documentation and signs the declaration(s) included in step 6 of the Application Form in annex I.

More specifically, the applicant indicates for each substance whether it is to be classified as:

A = Ultimately aerobically biodegradable

B = Inherently aerobically biodegradable

C = Non-biodegradable and non-bioaccumulative

X = Non-biodegradable and bioaccumulative

The definition of a substance as “Ultimately aerobically biodegradable”, “Inherently aerobically biodegradable”, “Non-biodegradable” and bioaccumulative is given in the criteria document and cited in this manual under the heading “Definitions and description of terms used in this manual”.

The applicant adds up all mass percentages of substances within the categories **A**, **B**, **C** and **X** to confirm that the next condition is met:

| | |
|--|---|
| Σ (A) \geq 90 % Σ (B) \leq 5 % Σ (C) \leq 5 % Σ (X) = 0 | Hydraulic fluids Chain saw oils Concrete release agents and other total loss lubricants |
| Σ (A) \geq 75 % Σ (B) \leq 20 % Σ (C) \leq 10 % Σ (X) = 0 | Greases Two-stroke oils |

If the candidate product is a grease containing a thickener, the thickener will be considered as inherently aerobic biodegradable if it shows a degradation > 20% (but lower than 70%) according to the OECD 302 C or equivalent tests. In this case the applicant should provide a signed statement stating the absence or formation of stable intermediate (see declaration step 6 annex I). This does not include the obligation to perform additional tests. Evidence should be based on knowledge from existing scientific literature.

For each stable intermediate the applicant should provide

- chemical name
- CAS No
- the theoretical mass percentage present in the lubricant assuming full conversion to the stable metabolite from its parent compound unless scientific evidence indicates otherwise.

Stable intermediates occurring during the biodegradation of thickeners are referred to as B_T. B_T intermediates need to be identified for the assessment of the aquatic toxicity of the candidate product according to step 7-I but do not play a role in the assessment of the biodegradability and bioaccumulation potential of the candidate product.

Annex V shows the sequence of operations needed and the type of data that can be used to classify each substance in one of the categories A, B, C, B_T or X.

QUALITY OF DATA AND REPORTING ON BIODEGRADATION AND BIOACCUMULATION POTENTIAL

DATA TABLE 6A

Fill in column “Biodegradation Potential Method” and for each substance with one of the following methods:

1. OECD 301 A, B, C-F or equivalent test methods
2. OECD 302 C, ISO 14593 or equivalent test methods
3. BOD₅/ThOD or BOD₅/COD ratio
4. read across
5. reference to the list of substances in annex II; substances on this list are considered as ultimately biodegradable

- If no data are available regarding the aerobic biodegradation of the substance, the applicant needs to provide measured data according to one of the OECD 301 C, D or F or equivalent tests.
- The BOD5/COD ratio can only be used if no data based on the OECD 301 or any other equivalent test methods are available.

Fill in column “Bioaccumulation Potential Method” with one of the following methods:

1. OECD 305 or equivalent test method
2. OECD 107, 117 or the draft 123 or equivalent methods
3. Calculated log octanol/water partition coefficient (log Kow)
4. evidence based on the Molecular Mass (MM) or Molecular Diameter (MD) of the substance; substances with MM > 800 dalton or MD > 15Å are considered non –bioaccumulative

Fill in column “Biodegradation Potential Result” with the corresponding results. The results are considered as valid only if they meet certain quality criteria.

OECD 301

Fill in the DATA TABLE 6A as method in the column ‘Biodegradation potential method’ ‘OECD 301’ and as result the mean percentage degradation after 28 days \pm standard deviation. The standard deviation should be smaller than 1/5th (20%) of the mean value. Submit the underlying report according to the outline stated under “Test Report” of the OECD guidelines 301 or an equivalent test.

BOD5/COD or BOD5/ThOD ratio

Fill in DATA TABLE 6A as method in the column ‘Biodegradation potential method’ ‘BOD5/COD or BOD5/ThOD’ and as result the ratio $(BOD5 \pm \text{standard deviation}) / (COD \pm \text{standard deviation})$ or $(BOD5 \pm \text{standard deviation}) / ThOD$

BOD5 being the mean value (grams of BOD per gram of tested substance) after 5 days. The standard deviation of BOD5 should be smaller than 1/5th (20%) of its mean value.

COD being the mean value (grams of COD per gram of tested substance). The standard deviation of COD should be smaller than 1/10th (10%) of the mean value.

ThOD is the Theoretical Oxygen Demand. The calculation of the ThOD can be based on e.g. Annex II.2 from C.4 (Biodegradation determination of the “Ready” biodegradability) (Dir 92/69/EEC in L 383 A 1992).

Submit the underlying reports for the determination of BOD5 and COD according to the outline stated in “Data and Reporting” according to C.5 and C.6 (Dir 92/69/EEC) or equivalent methods and a report on the calculation of the Theoretical Oxygen Demand.

OECD 302 C or ISO 14593 study

Fill in DATA TABLE 6A as method in the column ‘Biodegradation potential method’ ‘OECD 302 C or ISO 14593’ and as result the mean percentage degradation after 28 days \pm standard deviation. The standard deviation should be smaller than 1/5th (20%) of the mean value.

Submit the underlying report according to the outline stated under “Test Report” of the OECD guidelines 302 C or ISO 14593 or an equivalent test.

Read-across’ results

Fill in DATA TABLE 6A as method in the column ‘Biodegradation potential method’ ‘based on read-across’ and as result the mean percentage degradation of the chemically similar substance (reference substance) after 28 days \pm standard deviation. The standard deviation should be smaller than 1/5th (20%) of the mean value.

Submit for the reference substance, which is used for the read across method equivalent documentation as depicted above. Indicate in supporting documentation the difference in the functional group between the substance in the lubricant and the reference substance used for ‘read across’. 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 or -C(=S)-N]. If the reference substance shows an inherent or ultimate biodegradation, then the substance in the lubricant may also be considered respectively as inherent or ultimate biodegradable.

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. A third party should check the documentation and provide a signed statement.

Fill in column “Bioaccumulation Potential Result” (DATA TABLE 6A) with the corresponding results. The results are considered as valid only if they meet certain **quality criteria**.

OECD 305

Fill in DATA TABLE 6A as method in the column ‘Bioaccumulation potential method’ ‘OECD 305’ and as result the mean value of steady-state bio-concentration factor (BCF_{ss}) and/or kinetic concentration factor (BCF_k) \pm standard deviation. The standard deviation should be smaller than 1/5th (20%) of the mean value.

Submit the underlying report according to the outline stated under “Test Report” of the OECD guidelines 305 or an equivalent tests.

OECD 107, 117 or the draft 123 (experimentally determined octanol/water partition coefficient (K_{ow})).

Fill in DATA TABLE 6A as method in the column ‘Bioaccumulation potential method’ ‘OECD 107, 117 or the draft 123’ and as result the mean value of the octanol/water partition coefficient (K_{ow}) \pm standard deviation. The standard deviation should be smaller than 1/10th (10%) of the mean value). Fill in the same field also the logarithm of the mean octanol/water partition coefficient ($\log K_{ow}$).

Submit the underlying report according to the outline stated under “Test Report” of the OECD guideline 107, 117 or the draft 123 or equivalent test method.

Calculations of log Kow

Fill in DATA TABLE 6A as result in the “Bioaccumulation column” the highest value of $\log K_{ow}$ calculated by using the latest update version of the CLOGP method (for a $\log K_{ow}$ between 0 and 9); the KOWWIN (for a $\log K_{ow}$ between -4 and 8) and the AUTOLOGP (for a $\log K_{ow}$ greater than 5).

Evidence based on Molecular Mass

Fill in DATA TABLE 6A as result in the column 'Bioaccumulation column' 'MM > 800 Dalton'.
Submit underlying report with the molecular formula and the calculation of the molecular mass.

Evidence based on Molecular Diameter

Fill in DATA TABLE 6A as result in the column 'Bioaccumulation potential' "Mol. Diameter > 15 Å". Submit scientific evidence from a peer-reviewed journal.

| |
|--|
| Step 7 - Aquatic toxicity requirements / Criterion 2 |
|--|

The lubricant may contain a limited amount of harmful, toxic or very toxic substances for the aquatic compartment. Depending on the availability of aquatic toxicity data the product has to comply with one of the two following requirements 7-I **or** 7-II:

7-I) Requirements for each substance / Criterion 2.2

or

7-II) Requirements for the preparation and main components / Criterion 2.1

| |
|--|
| MAKE FIRST A SELECTION OF HOW TO ASSESS THE AQUATIC TOXICITY OF YOUR PRODUCT AND CONTINUE WITH EITHER 7-I OR 7-II. |
|--|

| |
|---|
| IF THE CANDIDATE PRODUCT IS A GREASE CONTAINING A THICKENER SHOWING A DEGRADATION > 20% BUT < 70% ACCORDING THE OECD 302 C THEN ONLY 7-I MAY BE USED. |
|---|

Data and documents to be submitted

7-I) Requirements for each substance

Data are required that allow for the evaluation of the aquatic toxicity of all substances present in the product.

The applicant fills in the data tables submits, supporting documentation and signs the declaration included in **step 7-I** of the application form in annex I

More specifically, for each substance which has been classified as A, B, C and B_T in step 6, the applicant indicates whether the substance is to be classified as:

D= Not toxic

E = Harmful

F = Toxic

G = Very toxic

The definition of a substance as 'Not toxic', 'Harmful', 'Toxic' and 'Very toxic' is given in the criteria document criteria document and cited in this manual under the heading "Definition and description of terms used in this manual".

The applicant adds up all mass percentages of substances within the categories **2, 3, and 4** to confirm that the next condition is met:

| | |
|---|---|
| $\Sigma (\mathbf{E}) \leq 20 \%$ $\Sigma (\mathbf{F}) \leq 5 \%$ $\Sigma (\mathbf{G}) \leq 1 \%$ | Hydraulic fluids |
| $\Sigma (\mathbf{E}) \leq 25 \%$ $\Sigma (\mathbf{F}) \leq 1 \%$ $\Sigma (\mathbf{G}) \leq 0.1 \%$ ($\Rightarrow \Sigma (\mathbf{G}) = 0 \%$)* | Greases Two-stroke oils |
| $\Sigma (\mathbf{E}) \leq 5 \%$ $\Sigma (\mathbf{F}) \leq 0.5 \%$ $\Sigma (\mathbf{G}) \leq 0.1 \%$ ($\Rightarrow \Sigma (\mathbf{G}) = 0 \%$)* | Chain saw oils Concrete release agents and other total loss lubricants |

*The condition $\Sigma (\mathbf{G}) \leq 0.1 \%$ means in practice $\Sigma (\mathbf{G}) = 0\%$. This is due to the fact that the concentration of substances in the candidate product, which implies a requirement for documentation of compliance with the environmental criteria is defined at $\geq 0,1\%$ by weight of the product.

Annex V provides the sequence of operations for the classification of each substance constituting $> 0,1\%$ (w/w) of the candidate product in one of the above-mentioned categories D, E, F and G.

The definition of a substance as ‘Not toxic’, ‘Harmful’, ‘Toxic’ and ‘Very toxic’ is given in the criteria document criteria document and cited in the main text of the manual under the heading “Definitions”.

QUALITY OF DATA AND REPORTING ON AQUATIC TOXICITY (step 7-I)

DATA TABLE 7 – I

For each substance fill the results of OECD 201 and 202 or equivalent tests in DATA TABLE 7 – I or provide other relevant data in column “Other evidence” of the Application Form in annex I.

“Other evidence” means

1. reference to the list of substances in annex II; substances on this list are considered not toxic
2. evidence based on the Molecular Mass (MM) or Molecular Diameter (MD) of the substance; substances with $MM > 800$ dalton or $MD > 1.5\text{nm}$ (1.5\AA) are considered non –toxic
3. evidence based on the solubility of the substance; highly insoluble substances are considered non-toxic (water solubility $< 10\mu\text{g/l}$ according to OECD 105 or equivalent tests)
4. chronic aquatic toxicity data (NOEC according to OECD 210 and 211); if available chronic toxicity data are preferable

OECD 201 and 202 (acute aquatic toxicity)

Fill in DATA TABLE 7-I as result the EC_{50} / IC_{50} value in mg/L and the 95% confidence interval (C.I.). The C.I. should be smaller than the EC_{50} / IC_{50} -value. Note that the OECD 201 and 202 tests may be applied on the on the water accommodated fraction (WAF).

Submit the underlying reports according to the outline stated under “Test Report” of the OECD 201 and 202 guidelines.

OECD 210 and 211 (chronic aquatic toxicity)

Fill in DATA TABLE 7 –I under ‘Other evidence’ the NOEC value in mg/L and the 95% confidence interval (C.I.). The C.I. should be smaller than the NOEC-value. Note that the OECD 210 and 211 tests may be applied on the on the water accommodated fraction.

Submit the underlying reports according to the outline stated under “Test Report” of the OECD 211 and 211 guidelines.

Reporting evidence based on the solubility of the substance (OECD 105)

Fill in DATA TABLES 7 –I in the column ‘Other evidence’ the aqueous solubility of the substance in µg/L and the 95% confidence interval of this value. The confidence interval should be smaller than the solubility value itself.

Submit underlying report according to the outline stated in ‘Reporting’ of the OECD guideline 105 or an equivalent test.

Reporting evidence based on Molecular Mass

Fill in DATA TABLE 7-I under ‘Other evidence’ ‘MM > 800 Dalton’.

Submit underlying report with the molecular formula and the calculation of the molecular mass.

Reporting evidence based on Molecular Diameter

Fill in DATA TABLE 7-I under ‘Other evidence’ ‘Mol. Diameter > 15 Å’

Submit scientific evidence from a peer-reviewed journal.

Reporting evidence based on the fact that the substance is included in the list provided in annex II.

Fill in DATA TABLE 7-I under ‘Other evidence’ ‘annex II substance’

7-II. Requirements for the preparation and main components

The applicant fills in the data tables, submits supporting documentation and signs the declaration(s) included in step 7-II of the application form in annex I

According to 7-II aquatic toxicity data shall be provided for each main component (each substance above 5 % (w/w)) and the lubricant. The aquatic toxicity of each main component is determined by OECD 201 and 202 or equivalent test methods. The aquatic toxicity of the full product is determined by OECD 201, 202 and 203.

The applicant provides the data and confirms that the next condition is met:

| | |
|--|--|
| <i>For hydraulic fluids</i> | <p>Aquatic toxicity of each main component \geq 100mg/l according to OECD 201 and 202 <u>or</u> \geq 10mg/l according to OECD 210 and 211.</p> <p>AND</p> <p>Aquatic toxicity of the lubricant \geq 100mg/l according to OECD 201, 202 and 203</p> |
| <i>For greases, two-stroke oils, chain saw oils, concrete release agents and other total loss lubricants</i> | <p>Aquatic toxicity of each main component \geq 100mg/l according to OECD 201 and 202 <u>or</u> \geq 10mg/l according to OECD 210 and 211.</p> <p>AND</p> <p>Aquatic toxicity of the lubricant \geq 1000mg/l according to OECD 201, 202 and 203</p> |

Compliance can be demonstrated by test reports or copy of published data.

Annex V shows the sequence of operations needed and the type of data that can be used to verify whether a product meets the requirements for the main components and the preparation.

QUALITY OF DATA AND REPORTING ON AQUATIC TOXICITY (step 7-II)

DATA TABLE 7 – II

For each main component fill the results of OECD 201 and 202 or equivalent tests in DATA TABLE 7 - II or provide other relevant data in column ‘Other evidence’. Additionally, fill in for the preparation the results of OECD 201, 202 and 203.

“Other evidence” means:

1. reference to the list of substances in annex II; substances on this list are considered non-toxic
2. evidence based on the Molecular Mass (MM) or Molecular Diameter (MD) of the substance; substances with MM > 800 dalton or MD > 15Å are considered non –toxic
3. evidence based on the solubility of the substance; highly insoluble substances are considered non-toxic (water solubility < 10µg/l according to OECD 105 or equivalent tests)
4. chronic aquatic toxicity data (NOEC > 10mg/l)

OECD 201, 202 and 203 (acute aquatic toxicity)

Fill in DATA TABLE 7-II as result the EC₅₀ / IC₅₀/ LC₅₀-value⁵ in mg/L and the 95% confidence interval (C.I.). The C.I. should be smaller than the EC₅₀ / IC₅₀-value. Note that the OECD 201, 202 and 203 tests may be applied on the on the water accomodated fraction (WAF).

Submit the underlying reports according to the outline stated under “Test Report” of the OECD 201, 202 and 203 guidelines.

OECD 210 and 211 (chronic aquatic toxicity)

Fill in DATA TABLE 7 -II under ‘Other evidence’ the NOEC value in mg/L and the 95% confidence interval (C.I.). The C.I. should be smaller than the NOEC-value. Note that the OECD 210 and 211 tests may be applied on the on the water accommodated fraction.

Submit the underlying reports according to the outline stated under “Test Report” of the OECD 211 and 211 guidelines.

Reporting evidence based on the solubility of the substance (OECD 105)

Fill in DATA TABLES 7 -II in the column ‘Other evidence’ the aqueous solubility of the substance in µg/L and the 95% confidence interval of this value. The confidence interval should be smaller than the solubility value itself.

Submit underlying report according to the outline stated in ‘Reporting’ of the OECD guideline 105 or an equivalent test.

Reporting evidence based on Molecular Mass

Fill in DATA TABLE 7-II under ‘Other evidence’ ‘MM > 800 Dalton’.

Submit underlying report with the molecular formula and the calculation of the molecular mass.

⁵ The IC50-value is equivalent to the EbC50 (0-72h) value from the OECD 201 (Algal inhibition test) or any other equivalent test

Reporting evidence based on Molecular Diameter

Fill in DATA TABLE 7-I under 'Other evidence' 'Mol. Diameter > 15 Å'

Submit scientific evidence from a peer-reviewed journal.

Reporting evidence based on the fact that the substance is included in the list provided in annex II.

Fill in DATA TABLE 7-II under 'Other evidence' 'annex II substance'.

| |
|-------------------------------------|
| Step 8 – Box 2 / Criterion 7 |
|-------------------------------------|

Confirm that once the European Eco-label has been awarded to the product, its label contains the text:

- Reduced harm for water and soil during use
- Reduced CO₂ emissions

Data and documents to be submitted

The applicant submits to the Competent Body a signed declaration included in step 8 of the application form in annex I together with a sample of the product's packaging showing the label.

ANNEX I –Application form

Print this application form from your browser, fill it out, and post it in duplicate with all required documentation to your Competent Body. Provide one hardcopy for each product.

| A. The applicant | |
|--|--|
| Full name of applicant company: | |
| Address: | |
| Contact name, and function: | |
| Tel no, and fax no: | |
| E-mail: | |
| Web-site: | |
| B. The product | |
| Registered trade name(s) of product or product range: | |
| Model names (or internal reference numbers) for products to be covered by the label within the product range above: | |
| Name and address of manufacturing site (if different from above): Where the product is made outside the EU, please confirm that it has been or will be placed on the market in the <i>[insert name of Competent Body's country]</i> | |
| Other EU countries in which this product is manufactured in the same form (please give addresses of manufacturing sites): | |
| Other EU countries in which this product is sold (if sold under different names, please give names): | |
| Rough estimate of annual volume of product produced <i>[e.g. 200,000 kg]</i> | |
| Rough estimated value of annual sales, excluding VAT, in the European Economic Area (i.e. the European Community plus Norway, Iceland and Liechtenstein) of the product at ex-factory prices (in € / £ etc., please specify currency). | |

| C. This application | |
|--|--|
| <p>Is this the first application for the EU Eco-label for this product? (if not, when and where was the first application made, and with what outcome?)</p> | |
| <p>Please name any other environmental labelling schemes under which the product has already been registered, such as the Nordic Swan, Blue Engel, NF-Environment, Swedish Standard etc:</p> | |
| <p>The Competent Body will invoice applicants for a non-returnable application fee on receipt of the application. If the application is successful, the Competent Body will invoice the licensee for an annual fee and apply all relevant reductions.</p> <p>In the case of SMEs or product manufacturers of developing countries the fees will be reduced by at least 25%. Applicants who have already received certification under EMAS or ISO 14001 may be granted additional reductions in the annual fee.</p> <ol style="list-style-type: none"> 1. Is the company a SME? If so, please provide proof of status. 2. Is the company situated in a developing country (for definition see the Competent Body) ? If so, please provide proof of status. 3. Is the company registered under EMAS or certified under ISO 14001 and has the company in its environmental policy promised to keep the product group criterion in the standard-contracts period of validity, and is this promise established in the companies environmental objective? | |

| D. Criteria verification | |
|---|--|
| STEP 1 – PRODUCT DEFINITION | DOCUMENT(S) TO BE SUBMITTED TO THE COMPETENT BODY |
| ARTICLE 1 OF THE DECISION | |
| <p>The candidate product is a:</p> <ul style="list-style-type: none"> <input type="checkbox"/> hydraulic fluid <input type="checkbox"/> grease <input type="checkbox"/> chainsaw oil <input type="checkbox"/> two-stroke oil <input type="checkbox"/> concrete release agent <input type="checkbox"/> other total loss lubricant <p>(Select where appropriate)</p> | <p>Product technical data sheet. (optional)</p> |
| STEP 2 – R-PHRASES | DOCUMENT(S) TO BE SUBMITTED TO THE COMPETENT BODY |
| CRITERION 1 OF THE DECISION | |
| Applicant’s declaration step 2 | |
| <p>I/We as responsible for the manufacture/supply⁶ of the candidate product declare that</p> <p>a) the candidate product does not carry any of the following R-phrases R20, 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, R39, R 40, R 41, R 42, R 43, R 45, R 46, R 48, R 49, R 50, R 51, R52, 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</p> <p><u>and</u></p> <p>b) sufficient data are available to allow for the evaluation of the environmental hazards (indicated by the R-phrases: R50, R51/53, R52, R52/53, R53) of the candidate product</p> | <p>MSDS of the lubricant * and main components. In case that the product is non-hazardous en thus has no MSDS the declaration is sufficient⁷.</p> |
| <p>Name:</p> <p>Signed:</p> <p>Position:</p> <p>Date:</p> <p>Company stamp or seal:</p> | |
| STEP 3 – TECHNICAL PERFORMANCE | DOCUMENT(S) TO BE SUBMITTED TO THE COMPETENT BODY |
| CRITERION 6 OF THE DECISION | |

⁶ Cross out what is not applicable

⁷ Please note that manufacturers are under no obligation to produce MSDS's for non-hazardous materials However, some manufacturers/suppliers do produce MSDS also for non-hazardous products. These MSDS can be provided as relevant documents.

Applicant's declaration step 3

I/We as responsible for the manufacture/supply⁸ of the candidate product declare that the product meets the following criterion

- the technical performance criteria laid down in ISO 15380 for hydraulic fluids
- the technical performance criteria laid down in RAL-UZ 48 of the Blue Angel for chain saw oils
- the technical performance criteria laid down in “NMMA Certification for two-stroke cycle gasoline engine lubricants’ of NMMA TC-W3 for two stroke oils.
- the product is “fit for purpose” in the case of in the cases of greases and concrete release agents.

(Select where appropriate)

A documented case study or copy of published data.

Name:

Signed:

Position:

Date:

Company stamp or seal:

⁸ Cross out what is not applicable

STEP 4 – EXCLUSION OF SPECIFIC SUBSTANCES**CRITERION 4 OF THE DECISION**

Fill in for every substance which has been deliberately added in the candidate product and which constitutes more than 0,1 % (w/w) of the product's content the following table

| FILL IN DATA TABLE 4 | | | | | | | |
|----------------------------|----------------------|---------------------------|-------------------------|-----------------------------|-----------------|------------------|----------------------------|
| Chemical name of substance | EINECS- No or CAS-No | Function of the substance | OSPAR list ⁹ | Dir 2000/60/EC ⁹ | Organic halogen | Nitrite compound | Metal or metallic compound |
| | | | Y/N | Y/N | Y/N | Y/N | Y/N |
| | | | Y/N | Y/N | Y/N | Y/N | Y/N |
| | | | Y/N | Y/N | Y/N | Y/N | Y/N |
| | | | Y/N | Y/N | Y/N | Y/N | Y/N |
| | | | Y/N | Y/N | Y/N | Y/N | Y/N |
| | | | Y/N | Y/N | Y/N | Y/N | Y/N |

Extend this table to the number of rows necessary

Applicant's declaration step 4

I/We as responsible for the manufacture/supply¹⁰ of the candidate product declare that the product does not contain

- substances appearing in the Community list of priority substances in the field of water policy (2000/60/EC),
- substances appearing in the OSPAR list,
- organic halogens,
- nitrite compounds and
- metals or metallic compounds (with the exception of sodium, potassium, magnesium and calcium and for thickeners for greases also with exception of lithium and/or aluminium compounds).

Name:

Signed:

Position:

Date:

Company stamp or seal:

⁹ See for the OSPAR list and the list of priority substances in the field of water policy (2000/60/EC) annex III and IV.

¹⁰ Cross out what is not applicable

STEP 5 – RENEWABILITY CONTENT

CRITERION 5 OF THE DECISION

Products eligible for the Eco-label have a renewable raw materials content of

- ≥ 50 % for hydraulic oils
- ≥ 45 % for greases
- ≥ 70 % for chain saw oils, concrete release agents and other total loss lubricants
- ≥ 50 % for two-stroke oils

Calculate renewable raw materials content by using the formula

$$\sum \left(x \frac{C_{renewable}^X}{C_{total}^X} + y \frac{C_{renewable}^Y}{C_{total}^Y} + z \frac{C_{renewable}^Z}{C_{total}^Z} + etc. \right) = \dots\dots\dots \text{(to be filled in by the applicant)}$$

Where:

- x, y, z etc stand for the mass percentage (w/w%) of all substances X, Y, Z etc. constituting ≥ 0,1% (w/w) of the candidate product
- $C_{renewable}$ is the number of C atoms from vegetable and animal oils and fats
- C_{total} is the total number of C atoms (C atoms from vegetable and animal oils and fats AND C atoms from petrochemical origin)

Substances present in the candidate product in concentrations above 0,1% (w/w) **must** be listed in the following table

| FILL IN DATA TABLE 5 | | | | |
|----------------------------|---------------------|------------------------|--|--|
| Chemical name of substance | EINECS-No or CAS-No | Mass percentage (%w/w) | Number of renewable C atoms ($C_{renewable}$) | Number of total C atoms (C_{total}) |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

Extend this table to the number of rows necessary

Applicant’s declaration step 5

I/We as responsible for the manufacture/supply¹¹ of the candidate product declare that the product has a carbon content derived from renewable materials of % (w/w)

Name:

Signed:

Position:

Date:

Company stamp or seal:

¹¹ Cross out what is not applicable

STEP 6 – BIODEGRADATION AND BIOACCUMULATION DATA REQUIREMENTS

CRITERION 3 OF THE DECISION

Fill in, for every substance, which has been deliberately added in the candidate product and which constitutes more than 0,1 % (w/w) of the product's content, the following table and provide supporting documentation.

| FILL IN DATA TABLE 6A BIODEGRADATION AND BIOACCUMULATION | | | | | | | | | | |
|--|----------------------|--------------------------|--------|---|--------|--|--------------|--------------|--------------|---|
| Chemical name of substance | EINECS- No or CAS-No | Biodegradation potential | | Bioaccumulation potential (to be determined only for non-biodegradable substances) | | Indicate where appropriate A, B, C and X (% w/w) | | | | Documents to be submitted to the Competent Body |
| | | Method | Result | Method | Result | A | B | C | X | |
| | | | | | | | | | | Test reports of copy of published data |
| | | | | | | | | | | |
| | | | | | | | | | | |
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| | | | | | | | | | | |
| | | | | | | | | | | |
| Total | | | | | | $\Sigma(A)=$ | $\Sigma(B)=$ | $\Sigma(C)=$ | $\Sigma(X)=$ | |

Extend this table to the number of rows necessary

- A = Ultimately aerobically biodegradable
- B = Inherently aerobically biodegradable
- C = Non-biodegradable and non-bioaccumulative
- X = Non-biodegradable and bioaccumulative

Is the candidate product a grease containing a thickener showing a degradation > 20% (but < 70%) according to OECD 302 C or equivalent tests?

- Yes
- No

If “Yes” provide evidence of the absence or formation of stable intermediates. This requirement does not include the obligation to generate evidence by performing tests. However, there is an obligation to check available literature sources for data. Evidence should be provided in the form of copies of reports of existing scientific literature. Fill in, for each stable intermediate the following DATA TABLE 6B

(Step 6 continues in next page)

(Step 6, continuing from previous page)

FILL IN
DATA TABLE 6B

STABLE INTERMEDIATES

| Chemical name of stable intermediates | CAS No | Mass percentage* (%w/w) | Documents to be submitted to the Competent Body |
|---------------------------------------|--------|----------------------------|--|
| | | | Copy of published data |
| | | | |
| | | | |
| | | | |
| | | | |

Extend this table to the number of rows necessary

* The theoretical mass percentage present in the lubricant assuming full conversion to the stable metabolite from its parent compound unless scientific evidence indicates otherwise. It must be taken into account in the assessment of the aquatic toxicity of the candidate product (step 7-I).

Applicant's declaration step 6

I/We as responsible for the manufacture/supply¹² of the candidate product declare that the product meets the following requirements

- does / does not (cross off what is not applicable) contain a thickener that can form stable intermediates
- meets the requirements concerning the quality of data as stated in the user manual (under "QUALITY OF DATA AND REPORTING ON BIODEGRADATION AND BIOACCUMULATION POTENTIAL" p. 14 – 15)
- meets the following requirements

| | |
|--|--|
| <i>Hydraulic fluids, Chain saw oils, Concrete release agents and other total loss lubricants</i> | $\Sigma (\mathbf{A}) \geq 90 \%$ $\Sigma (\mathbf{B}) \leq 5 \%$ $\Sigma (\mathbf{C}) \leq 5 \%$ $\Sigma (\mathbf{X}) = 0 \%$ |
| <i>Greases, Two-stroke oils</i> | $\Sigma (\mathbf{A}) \geq 75 \%$ $\Sigma (\mathbf{B}) \leq 20 \%$ $\Sigma (\mathbf{C}) \leq 10 \%$ $\Sigma (\mathbf{X}) = 0 \%$ |

Name:

Signed:

Position:

Date:

Company stamp or seal:

(Step 6 continues in next page)

¹² Cross out what is not applicable

(Step 6, continuing from previous page)

Third party declaration for validity of “ read-across” data estimates step 6

I/We as independent third party declare that the provided read-across data are valid.

Name:

Signed:

Position:

Date:

Company stamp or seal:

Chose for either step 7-I or 7-II to complete the evaluation of your product.

STEP 7 –I – AQUATIC TOXICITY RERQUIREMENTS FOR EACH SUBSTANCE

CLASSIFIED AS A, B, B_T and C in step 6

CRITERION 2.2 OF THE DECISION

Fill in, for every substance, which has been deliberately added in the candidate product and which constitutes more than 0,1 % (w/w) of the product’s content, the following table and provide supporting documentation.

| FILL IN DATA TABLE 7-I AQUATIC TOXICITY | | | | | | | | | | | |
|---|---------------------|----------|-----|----------|-----|----------------|--|-------|-------|-------|---|
| Chemical name of substance | EINECS-No or CAS-No | OECD 201 | | OECD 202 | | Other evidence | Indicate where appropriate D, E, F and G (% w/w) | | | | Documents to be submitted to the Competent Body |
| | | Result | WAF | Result | WAF | | D | E | F | G | |
| | | | Y/N | | Y/N | | | | | | Test reports or copy of published data |
| | | | Y/N | | Y/N | | | | | | |
| | | | Y/N | | Y/N | | | | | | |
| | | | Y/N | | Y/N | | | | | | |
| | | | Y/N | | Y/N | | | | | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| Total | | | | | | | | Σ(E)= | Σ(F)= | Σ(G)= | |

Extend this table to the number of rows necessary

(Step 7-I continues in next page)

(Step 7-I continuing from previous page)

D = Not toxic

E = Harmful

F = Toxic

G = Very toxic

“Other evidence” means

1. reference to the list of substances in annex II; substances on this list are considered non-toxic
2. evidence based on the Molecular Mass (MM) or Molecular Diameter (MD) of the substance; substances with MM > 800 dalton or MD > 15Å are considered non-toxic
3. evidence based on the solubility of the substance; highly insoluble substances are considered non-toxic (water solubility < 10µg/l according to OECD 105 or equivalent tests)
4. chronic aquatic toxicity data (NOEC according to OECD 210 and 211); if available chronic toxicity data are preferable

Applicant's declaration step 7 - I

I/We as responsible for the manufacture/supply¹³ of the candidate product declare that

1. chronic toxicity data were used where available
2. the product meets the requirements concerning the quality of data as stated in the user manual (under QUALITY OF DATA AND REPORTING ON AQUATIC TOXICITY (step 7-I))
3. the product meets the following requirements

| | |
|--|---|
| $\Sigma (\mathbf{E}) \leq 20 \%$ $\Sigma (\mathbf{F}) \leq 5 \%$ $\Sigma (\mathbf{G}) \leq 1 \%$ | Hydraulic fluids |
| $\Sigma (\mathbf{E}) \leq 25 \%$ $\Sigma (\mathbf{F}) \leq 1 \%$ $\Sigma (\mathbf{G}) = 0 \%$ | Greases and Two-stroke oils |
| $\Sigma (\mathbf{E}) \leq 5 \%$ $\Sigma (\mathbf{F}) \leq 0.5 \%$ $\Sigma (\mathbf{G}) = 0 \%$ | Chain saw oils, Concrete release agents and other total loss lubricants |

Name:

Signed:

Position:

Date:

Company stamp or seal:

¹³ Cross out what is not applicable

STEP 7-II - AQUATIC TOXICITY REQUIREMENTS FOR THE PREPARATION AND THE MAIN COMPONENTS

CRITERION 2.1 OF THE DECISION

Fill in, for every substance which constitutes more than 5 %(w/w) of the product's content (main components), as well as for the preparation (the lubricant product) the following table and provide supporting documentation

| FILL IN DATA TABLE 7-II AQUATIC TOXICITY | | | | | | |
|--|---------------------|----------|----------|----------|----------------|---|
| Chemical name of substance | EINECS-No or CAS-No | OECD 201 | OECD 202 | OECD 203 | Other evidence | Documents to be submitted to the Competent Body |
| | | Result | Result | Result | | |
| | | | | | | Test reports or copy of published data |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| Results for the preparation | | | | | | Test reports or copy of published data |

Extend this table to the number of rows necessary

For each main component fill the results of OECD 201 and 202 or equivalent tests in DATA TABLE 7 - II or provide other relevant data in column 'Other evidence'. Additionally, fill in for the preparation the results of OECD 201, 202 and 203.

“Other evidence” means:

1. reference to the list of substances in annex II; substances on this list are considered non-toxic
2. evidence based on the Molecular Mass (MM) or Molecular Diameter (MD) of the substance; substances with MM> 800 dalton or MD > 15Å are considered non –toxic
3. evidence based on the solubility of the substance; highly insoluble substances are considered non-toxic (water solubility < 10µg/l according to OECD 105 or equivalent tests)
4. chronic aquatic toxicity data (NOEC > 10mg/l)

(Step 7-II continues in next page)

(Step 7-II continuing from previous page)

Applicant's declaration step 7-II

I/We as responsible for the manufacture/supply¹⁴ of the candidate product declare that

1. chronic toxicity data were used where available
2. the product meets the requirements concerning the quality of data as stated in the user manual (under QUALITY OF DATA AND REPORTING ON AQUATIC TOXICITY (step 7-II))
3. the product meets the following requirements

| | |
|--|---|
| <i>For hydraulic fluids</i> | Aquatic toxicity of each main component $\geq 100\text{mg/l}$ according to OECD 201 and 202 <u>or</u> $\geq 10\text{mg/l}$ according to OECD 210 and 211. AND Aquatic toxicity of the lubricant $\geq 100\text{mg/l}$ according to OECD 201, 202 and 203 |
| <i>For greases, two-stroke oils, chain saw oils, concrete release agents and other total loss lubricants</i> | Aquatic toxicity of each main component $\geq 100\text{mg/l}$ according to OECD 201 and 202 <u>or</u> $\geq 10\text{mg/l}$ according to OECD 210 and 211. AND Aquatic toxicity of the lubricant $\geq 1000\text{mg/l}$ according to OECD 201, 202 and 203 |

Name:

Signed:

Position:

Date:

Company stamp or seal:

¹⁴ Cross out what is not applicable

| STEP 8 – BOX 2 CRITERION 7 OF THE DECISION | DOCUMENT(S) TO BE SUBMITTED TO THE COMPETENT BODY |
|--|---|
| <p style="text-align: center;">Applicant's declaration step 8</p> <p>I/We as responsible for the manufacture/supply¹⁵ of the candidate product declare that Box 2 of the Eco-label shall contain the following text “reduced harm for water and soil during use; reduced CO2 emissions</p> <p>Name:</p> <p>Signed:</p> <p>Position:</p> <p>Date:</p> <p>Company stamp or seal:</p> <p style="text-align: right;">(end of the Application Form)</p> | <p style="text-align: center;">Sample of products packaging showing the label</p> |

¹⁵ Cross out what is not applicable

Annex II - Substances considered as ultimate biodegradable and not toxic to aquatic organisms

Substances which are considered ultimate biodegradable and not toxic to the aquatic environment on the basis of their intrinsic properties by the European Commission . List included in Council Regulation (EEC) 793/93 on the Control and Evaluation of the Risks of Existing Substances.

| EINECS no | Name/Group | CAS no |
|-----------|--|-----------|
| 200-061-5 | D-glucitol C ₆ H ₁₄ O ₆ | 50-70-4 |
| 200-066-2 | Ascorbic acid C ₆ H ₈ O ₆ | 50-81-7 |
| 200-075-1 | Glucose C ₆ H ₁₂ O ₆ | 50-99-7 |
| 200-294-2 | L-lysine C ₆ H ₁₄ N ₂ O ₂ | 56-87-1 |
| 200-312-9 | Palmitic acid, pure C ₁₆ H ₃₂ O ₂ | 57-10-3 |
| 200-313-4 | Stearic acid, pure C ₁₈ H ₃₆ O ₂ | 57-11-4 |
| 200-334-9 | Sucrose, pure C ₁₂ H ₂₂ O ₁₁ | 57-50-1 |
| 200-405-4 | α -tocopheryl acetate C ₃₁ H ₅₂ O ₃ | 58-95-7 |
| 200-432-1 | DL-methionine C ₅ H ₁₁ NO ₂ S | 59-51-8 |
| 200-711-8 | D-mannitol C ₆ H ₁₄ O ₆ | 69-65-8 |
| 201-771-8 | 1-sorbose C ₆ H ₁₂ O ₆ | 87-79-6 |
| 204-007-1 | Oleic acid, pure C ₁₈ H ₃₄ O ₂ | 112-80-1 |
| 204-664-4 | Glycerol stearate, pure C ₂₁ H ₄₂ O ₄ | 123-94-4 |
| 204-696-9 | Carbon dioxide CO ₂ | 124-38-9 |
| 205-278-9 | Calcium pantothenate, D-form C ₉ H ₁₇ NO _{5,1,2} Ca | 137-08-6 |
| 205-582-1 | Lauric acid, pure C ₁₂ H ₂₄ O ₂ | 143-07-7 |
| 205-590-5 | Potassium oleate C ₁₈ H ₃₄ O ₂ K | 143-18-0 |
| 205-756-7 | DL-phenylalanine C ₉ H ₁₁ NO ₂ | 150-30-1 |
| 208-407-7 | Sodium gluconate C ₆ H ₁₂ O ₇ .Na | 527-07-1 |
| 212-490-5 | Sodium stearate, pure C ₁₈ H ₃₆ O ₂ .Na | 822-16-2 |
| 215-279-6 | Limestone A noncombustible solid characteristic of sedimentary rock. It consists primarily of calcium carbonate | 1317-65-3 |
| 215-665-4 | Sorbitan oleate C ₂₄ H ₄₄ O ₆ | 1338-43-8 |

| EINECS no | Name/Group | CAS no |
|-----------|--|-----------|
| 216-472-8 | Calcium distearate, pure $C_{18}H_{36}O_{2.1/2}Ca$ | 1592-23-0 |
| 231-147-0 | Argon Ar | 7440-37-1 |
| 231-153-3 | Carbon C | 7440-44-0 |
| 231-783-9 | Nitrogen N_2 | 7727-37-9 |
| 231-791-2 | Water, distilled, conductivity or of similar purity H_2O | 7732-18-5 |
| 231-955-3 | Graphite C | 7782-42-5 |
| 232-273-9 | Sunflower oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids linoleic, and oleic. (<i>Helianthus annuus</i> , <i>Compositae</i>). | 8001-21-6 |
| 232-274-4 | Soybean oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids linoleic, oleic, palmitic and stearic (<i>Soja hispida</i> , <i>Leguminosae</i>). | 8001-22-7 |
| 232-276-5 | Safflower oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acid linoleic (<i>Carthamus tinctorius</i> , <i>Compositae</i>). | 8001-23-8 |
| 232-278-6 | Linseed oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids linoleic, linolenic and oleic (<i>Linum usitatissimum</i> , <i>Linaceae</i>). | 8001-26-1 |
| 232-281-2 | Corn oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids linoleic, oleic, palmitic and stearic. (<i>Zea mays</i> , <i>Gramineae</i>). | 8001-30-7 |
| 232-293-8 | Castor Oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acid ricinoleic (<i>Ricinus communis</i> , <i>Euphorbiaceae</i>). | 8001-79-4 |

| EINECS no | Name/Group | CAS no |
|-----------|---|------------|
| 232-299-0 | Rape oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids erucic, linoleic and oleic (<i>Brassica napus</i> , <i>Cruciferae</i>). | 8002-13-9 |
| 232-307-2 | Lecithins The complex combination of diglycerides of fatty acids linked to the choline ester of phosphoric acid. | 8002-43-5 |
| 232-436-4 | Syrups, hydrolyzed starch A complex combination obtained by the hydrolysis of cornstarch by the action of acids or enzymes. It consists primarily of d-glucose, maltose and maltodextrins. | 8029-43-4 |
| 232-442-7 | Tallow, hydrogenated | 8030-12-4 |
| 232-675-4 | Dextrin | 9004-53-9 |
| 232-679-6 | Starch High-polymeric carbohydrate material usually derived from cereal grains such as corn, wheat and sorghum, and from roots and tubers such as potatoes and tapioca. Includes starch which has been pregelatinised by heating in the presence of water. | 9005-25-8 |
| 232-940-4 | Maltodextrin | 9050-36-6 |
| 234-328-2 | Vitamin A | 11103-57-4 |
| 238-976-7 | Sodium D-gluconate $C_6H_{12}O_7 \cdot xNa$ | 14906-97-9 |
| 248-027-9 | D-glucitol monostearate $C_{24}H_{48}O_7$ | 26836-47-5 |
| 262-988-1 | Fatty acids, coco, Me esters | 61788-59-8 |
| 262-989-7 | Fatty acids, tallow, Me esters | 61788-61-2 |
| 263-060-9 | Fatty acids, castor-oil | 61789-44-4 |
| 263-129-3 | Fatty acids, tallow | 61790-37-2 |
| 266-925-9 | Fatty acids, C_{12-18} This substance is identified by SDA Substance Name: <i>C₁₂-C₁₈ alkyl carboxylic acid</i> and SDA Reporting Number: 16-005-00. | 67701-01-3 |

| EINECS no | Name/Group | CAS no |
|------------------|--|---------------|
| 266-928-5 | Fatty acids C ₁₆₋₁₈ This substance is identified by SDA Substance Name: <i>C_{16-C₁₈ alkyl carboxylic acid}</i> and SDA Reporting Number: 19-005-00. | 67701-03-5 |
| 266-929-0 | Fatty acids, C ₈₋₁₈ and C ₁₈ -unsatd. This substance is identified by SDA Substance Name: <i>C_{8-C₁₈ and C₁₈ unsaturated alkyl carboxylic acid}</i> and SDA Reporting Number: 01-005-00. | 67701-05-7 |
| 266-930-6 | Fatty acids, C ₁₄₋₁₈ and C ₁₆₋₁₈ -unsatd. This substance is identified by SDA Substance Name: <i>C_{14-C₁₈ and C_{16-C₁₈ unsaturated alkyl carboxylic acid}}</i> and SDA Reporting Number: 04-005-00 | 67701-06-8 |
| 266-932-7 | Fatty acids, C _{16-C₁₈} and C ₁₈ -unsatd. This substance is identified by SDA Substance Name: <i>C_{16-C₁₈ and C₁₈ unsaturated alkyl carboxylic acid}</i> and SDA Reporting Number: 11-005-00 | 67701-08-0 |
| 266-948-4 | Glycerides, C ₁₆₋₁₈ and C ₁₈ -unsatd. This substance is identified by SDA Substance Name: <i>C_{16-C₁₈ and C₁₈ unsaturated trialkyl glyceride}</i> and SDA Reporting Number: 11-001-00. | 67701-30-8 |
| 267-007-0 | Fatty acids, C ₁₄₋₁₈ and C ₁₆₋₁₈ -unsatd., Me esters This substance is identified by SDA Substance Name: <i>C_{14-C₁₈ and C_{16-C₁₈ unsaturated alkyl carboxylic acid methyl ester}}</i> and SDA Reporting Number: 04-010-00. | 67762-26-9 |
| 267-013-3 | Fatty acids, C ₆₋₁₂ This substance is identified by SDA Substance Name: <i>C_{6-C₁₂ alkyl carboxylic acid}</i> and SDA Reporting Number: 13-005-00. | 67762-36-1 |
| 268-099-5 | Fatty acids, C ₁₄₋₂₂ and C ₁₆₋₂₂ unsatd. This substance is identified by SDA Substance Name: <i>C_{14-C₂₂ and C_{16-C₂₂ unsaturated alkyl carboxylic acid}}</i> and SDA Reporting Number: 07-005-00 | 68002-85-7 |
| 268-616-4 | Syrups, corn, dehydrated | 68131-37-3 |
| 269-657-0 | Fatty acids, soya | 68308-53-2 |

| EINECS no | Name/Group | CAS no |
|------------------|--|---------------|
| 269-658-6 | Glycerides, tallow mono-, di- and tri-, hydrogenated | 68308-54-3 |
| 270-298-7 | Fatty acids, C ₁₄₋₂₂ | 68424-37-3 |
| 270-304-8 | Fatty acids, linseed-oil | 68424-45-3 |
| 270-312-1 | Glycerides, C ₁₆₋₁₈ and C ₁₈ -unsatd. mono- and di- This substance is identified by SDA Substance Name: <i>C₁₆-C₁₈ and C₁₈ unsaturated alkyl and C₁₆-C₁₈ and C₁₈ unsaturated dialkyl glyceride</i> and SDA Reporting Number: 11-002-00. | 68424-61-3 |
| 288-123-8 | Glycerides, C ₁₀₋₁₈ | 85665-33-4 |
| 292-771-7 | Fatty acids, C ₁₂₋₁₄ | 90990-10-6 |
| 292-776-4 | Fatty acids, C ₁₂₋₁₈ and C ₁₈ -unsatd. | 90990-15-1 |
| 296-916-5 | Fatty acids, rape-oil, erucic acid-low | 93165-31-2 |

Annex III -OSPAR list

OSPAR CONVENTION FOR THE PROTECTION OF THE MARINE ENVIRONMENT
OF THE NORTH-EAST ATLANTIC

MEETING OF THE OSPAR COMMISSION

(OSPAR) REYKJAVIK: 28 JUNE – 1 JULY 2004

OSPAR List of Chemicals for Priority Action (Update 2004)

(Reference number 2004-12)

| <i>Type</i> | Group of substances / substances | CAS No | EINECS No | Identified at †: Lead country: Background document |
|---|---|------------|-----------|---|
| A: CHEMICALS WHERE A BACKGROUND DOCUMENT HAS BEEN OR IS BEING PREPARED | | | | |
| <i>Aromatic hydrocarbon</i> | 4-tert-butyltoluene | 98-51-1 | 202-675-9 | OSPAR 2000: Germany: Published 2003 (ISBN 1-904426-09-3) |
| <i>Metallic compound</i> | cadmium | | | OSPAR/MMC 1998: Spain: Published 2002 (ISBN: 0 946956 93 6) |
| <i>Metal/organometallic compounds</i> | lead and organic lead compounds | | | OSPAR/MMC 1998: Norway: Published 2002 (ISBN 1-904426-00-X) |
| | mercury and organic mercury compounds | | | OSPAR/MMC 1998: United Kingdom: Published 2000 (ISBN: 0 946956 54 5) |
| <i>Organometallic compounds</i> | organic tin compounds | | | OSPAR/MMC 1998: The Netherlands: Published 2000 (ISBN: 0 946956 56 1) addressing TBT and TPT |
| <i>Organic ester</i> | neodecanoic acid, ethenyl ester | 51000-52-3 | 256-905-8 | OSPAR 2001: United Kingdom |
| <i>Organohalogens</i> | perfluorooctanyl sulphonic acid and its salts (PFOS) '1 | 1763-23-1 | 217-179-8 | OSPAR 2003: United Kingdom |
| | tetrabromobisphenol A (TBBP-A) | 79-94-7 | 201-236-9 | OSPAR 2000: United Kingdom: Published 2004 (ISBN: 1-904426-39-5) |
| | hexachlorocyclopentadiene (HCCP) | 77-47-4 | 201-029-3 | OSPAR 2000: The Netherlands: Published 2004 (ISBN: 1-904426-40-9) |
| | 1,2,3-trichlorobenzene | 87-61-6 | 201-757-1 | OSPAR 2000: Belgium & Luxembourg: Published 2003 (ISBN 1-904426-10-7) |
| | 1,2,4-trichlorobenzene | 120-82-1 | 204-428-0 | OSPAR 2000: Belgium & Luxembourg: Published 2003 (ISBN 1-904426-10-7) |
| | 1,3,5-trichlorobenzene | 108-70-3 | 203-608-6 | OSPAR 2000: Belgium & Luxembourg: Published 2003 (ISBN 1-904426-10-7) |
| | brominated flame retardants | | | OSPAR/MMC 1998: Sweden: Published in 2001 (ISBN: 0 946956 70 7) addressing: polybrominated diphenylethers; polybrominated biphenyls; hexabromocyclododecane |
| | polychlorinated biphenyls (PCBs) * | | | OSPAR/MMC 1998: Germany & Belgium: Published 2001 (ISBN: 0 946956 78 2) |
| | polychlorinated dibenzodioxins (PCDDs) polychlorinated dibenzofurans (PCDFs) | | | OSPAR/MMC 1998: Denmark & Belgium: Published 2002 (ISBN: 0 946956 92 8) |
| | short chained chlorinated paraffins (SCCP) | | | OSPAR/MMC 1998: Sweden: Published 2001 (ISBN: 0 946956 77 4) |
| <i>Organic nitrogen compound</i> | 4-(dimethylbutylamino)diphenylamin (6PPD) | 793-24-8 | 212-344-0 | OSPAR 2002: Germany |
| <i>Organophosphate</i> | triphenyl phosphine | 603-35-0 | 210-036-0 | OSPAR 2001: Germany: Published 2003 (ISBN 1-904426-13-1) |
| Organosilicane | hexamethyldisiloxane (HMDS) | 107-46-0 | 203-492-7 | OSPAR 2000: France: Published 2004 (ISBN: 1-904426-41-7) |

| <i>Type</i> | Group of substances / substances | CAS No | EINECS No | Identified at †: Lead country: Background document |
|--|--|------------|-----------|---|
| Pesticides/Biocides/ Organohalogens | dicofol | 115-32-2 | 204-082-0 | OSPAR 2000: Finland: Published 2002 (ISBN: 0 946956 97 9) |
| | endosulphan | 115-29-7 | 204-079-4 | OSPAR 2000: Germany: Published 2002 (ISBN: 0 946956 98 7) |
| | hexachlorocyclohexane isomers (HCH) | | | OSPAR/MMC 1998: Germany: Published 2002 (ISBN: 0 946956 94 4) |
| | methoxychlor | 72-43-5 | 200-779-9 | OSPAR 2000: Finland: Published 2002 (ISBN: 0 946956 99 5) |
| | pentachlorophenol (PCP) | | | OSPAR/MMC 1998: Finland: Published 2001 (ISBN: 0 946956 74 X) |
| | trifluralin | 1582-09-8 | 216-428-8 | OSPAR 2002: Germany: Published 2004 (ISBN: 1-904426-37-9) |
| <i>Pharmaceutical</i> | clotrimazole | 23593-75-1 | 245-764-8 | OSPAR 2002: France: Published 2004 (ISBN: 1-904426-38-7) |
| <i>Phenols</i> | 2,4,6-tri-tert-butylphenol | 732-26-3 | 211-989-5 | OSPAR 2000: United Kingdom: Published 2003 (ISBN 1-904426-14- |
| | nonylphenol/ethoxylates (NP/NPEs) and related substances | | | OSPAR/MMC 1998: Sweden: Published 2001 (ISBN: 0 946956 79 0) |
| | octylphenol | 140-66-9 | 205-426-2 | OSPAR 2000: United Kingdom: Published 2003 (ISBN 1-904426-15- |
| <i>Phthalate esters</i> | certain phthalates: dibutylphthalate, diethylhexylphthalate | | | OSPAR/MMC 1998: Denmark & France |
| <i>Polycyclic aromatic compounds</i> | polyaromatic hydrocarbons (PAHs) § | | | OSPAR/MMC 1998: Norway: Published 2001 (ISBN: 0 946956 73 X) |
| <i>Synthetic musk</i> | musk xylene | | | OSPAR/MMC 1998: Switzerland: Published 2000 (ISBN: 0 946956 55 3) addressing musk xylene, musk ketone, moskene and musk tibetene. Revised Background Document: Published 2004 (ISBN: 1-904426-36- |

| <i>Type</i> | Group of substances / substances | CAS No | EINECS No | Identified at †: Lead country: Background document |
|---|--|-------------------------|-----------|--|
| <i>B: CHEMICALS WHERE NO BACKGROUND DOCUMENT IS BEING PREPARED BECAUSE THEY ARE INTERMEDIATES IN CLOSED SYSTEMS ‡</i> | | | | |
| <i>Aliphatic hydrocarbons</i> | 1,5,9 cyclododecatriene‡ | 4904-61-4 | 225-533-8 | OSPAR 2002: not applicable |
| | cyclododecane‡ | 294-62-2 | 206-033-9 | OSPAR 2002: not applicable |
| <i>C: CHEMICALS WHERE NO BACKGROUND DOCUMENT IS BEING PREPARED BECAUSE THERE IS NO CURRENT PRODUCTION OR USE INTEREST*</i> | | | | |
| <i>Organohalogens</i> | 2-propenoic acid, (pentabromo)methyl ester | 59447-55-1 | 261-767-7 | OSPAR 2003: not applicable |
| | 2,4,6-bromophenyl 1-2(2,3-dibromo-2-methylpropyl) * | 36065-30-2 | 252-859-8 | OSPAR 2001: not applicable |
| | pentabromoethylbenzene* | 85-22-3 | 201-593-0 | OSPAR 2001: not applicable |
| | heptachloronorborene* | 28680-45-7 2440-02-0 | 249-153-7 | OSPAR 2001: not applicable |
| | pentachloroanisole* | 1825-21-4 | - | OSPAR 2001: not applicable |

| <i>Type</i> | Group of substances / substances | CAS No | EINECS No | Identified at †: Lead country: Background document |
|----------------------------------|--|---|---|--|
| <i>Organohalogenes (cont.)</i> | polychlorinated naphthalenes* , †† trichloronaphthalene* tetrachloronaphthalene* pentachloronaphthalene* hexachloronaphthalene* heptachloronaphthalene* octachloronaphthalene* naphthalene, chloro derivs. * | 1321-65-9 1335-88-2 1321-64-8 1335-87-1 32241-08-0 2234-13-1 70776-03-3 | 215-321-3 215-642-9 215-320-8 215-641-3 250-969-0 218-778-7 274-864-4 | OSPAR 2001: not applicable OSPAR 2001: not applicable OSPAR 2002: not applicable OSPAR 2001: not applicable OSPAR 2001: not applicable OSPAR 2001: not applicable OSPAR 2002: not applicable |
| <i>Organic nitrogen compound</i> | 3,3'-(ureylenedimethylene)bis(3,5,5-trimethylcyclohexyl) diisocyanate* | 55525-54-7 | 259-695-6 | OSPAR 2001: not applicable |
| Pesticides/Biocides | ethyl O-(p-nitrophenyl) phenyl phosphonothionate (EPN)* | 2104-64-5 | 218-276-8 | OSPAR 2001: not applicable |
| | flucythrinate* | 70124-77-5 | 274-322-7 | OSPAR 2001: not applicable |
| | isodrin* | 465-73-6 | 207-366-2 | OSPAR 2001: not applicable |
| | tetrasul* | 2227-13-6 | 218-761-4 | OSPAR 2001: not applicable |
| <i>Pharmaceutical</i> | diosgenin* | 512-04-9 | 208-134-3 | OSPAR 2002: not applicable |

Endnotes

- † The substances in this list were identified at the following OSPAR Commission meetings:
OSPAR/MMC 1998: Agreement reference number 1998-16 (Annex 2 to the OSPAR Strategy with regard to Hazardous Substances);
(Note: When identifying the substances or groups of substances, OSPAR/MMC 1998 has not allocated CAS and EINECS registration numbers. Background documents adopted by the OSPAR Commission for these substances or groups of substances may indicate which substances have been addressed so far by OSPAR)
OSPAR 2000: Agreement reference number 2000-10; OSPAR 2001: Agreement reference number 2001-2; OSPAR 2002: Agreement reference number 2002-18; OSPAR 2003: Agreement reference number 2003-19.
- ‡ The identification of these substances and the consequent action required is explained in § 7.6 of the OSPAR 2002 Summary Record. In brief, these substances have rankings in terms of persistency, liability to bioaccumulate and toxicity which are of equal concern as the other substances on this list. However, to the best of OSPAR's knowledge, on the basis of information from industry, OSPAR accepts that this substance is produced and used exclusively as an intermediate in closed systems in the production of other substances, under conditions where the safeguards applying are sufficient to avoid reasonable concerns that discharges, emissions or losses of the substance could reach the marine environment. Therefore, every five years, commencing in 2003, Contracting Parties and, where appropriate, observers representing the chemicals industries should report to OSPAR:
- whether they have found any evidence that these chemicals are being produced, used or discharged without being subjected to safeguards to avoid reasonable concerns that discharges, emissions or losses of the substances could reach the marine environment, and, if so, what that evidence is, and what action (if any) has been taken;
 - whether there have been any cases where applications have been made for approvals involving these chemicals, and, if so, what decision was taken.
- * The identification of these substances and the consequent action required is explained in § 4.13 of the OSPAR 2001 Summary Record. In brief, these substances have rankings in terms of persistency, liability to bioaccumulate and toxicity which are of equal concern as the other substances on this list. However, to the best of OSPAR's knowledge, there is no current production or use in the OSPAR states. Therefore, commencing in 2003 and every five years thereafter, or earlier, if information becomes available, Contracting Parties and, where appropriate, observers representing the chemicals industries should report to OSPAR:
- whether they have found any evidence that these chemicals are being produced, used or discharged, and, if so, what that evidence is, and what action (if any) has been taken;
 - whether there have been any cases where applications have been made for approvals involving these chemicals, and, if so, what decision was taken.
- †† Polychlorinated naphthalenes should be treated as a group of substances (OSPAR 02/21/1, § 7.7).
- ◆ PFOS is the highly persistent and toxic breakdown product of a number of perfluorooctanyl sulphonyl compounds. Several PFOS precursors have been selected on the OSPAR List of Substances of Possible Concern. The background document will identify these precursors and, if necessary, appropriate control measures will be proposed. CAS and EINECS numbers refer only to the acid form of PFOS.
- § The following substances belonging to the group of polyaromatic hydrocarbons have been deselected from the OSPAR List of Substances of Possible Concern on the grounds that they do not meet the cut-off values for persistence in the Selection Criteria used in the Initial Selection Procedure adopted by OSPAR 2001 (*Reference Number: 2001-1*) and are therefore not considered to be a priority for action by OSPAR: naphthalene, 2-methyl-(CAS No. 91576); 1-phenanthrenecarboxylic acid, 1,2,3,4,4a,4b,5,6,10,10a-decahydro-1,4a-dimethyl-7-(1-methylethyl)-, methyl ester, [1R-(1.alpha.,4a.beta.,4b.alpha.,10a.alpha.)]- (CAS No. 127253); 1-phenanthrenemethanol, 1,2,3,4,4a,4b,5,6,7,9,10,10a-dodecahydro-1,4a-dimethyl-7-(1-methylethyl)- (CAS No. 127366); 7H-dibenzo[c,g]carbazole (CAS No. 194592); 13H-dibenzo[a,i]carbazole (CAS No. 239645); 1H-3a,7-methanoazulene, 2,3,4,7,8,8a-hexahydro-3,6,8,8-tetramethyl-, [3R-(3alpha,3abeta,7beta,8alpha)]- (CAS No. 469614); 1-phenanthrenemethanol, 1,2,3,4,4a,4b,5,6,10,10a-

decahydro-1,4a-dimethyl-7-(1-methylethyl)-, [1R-(1.alpha.,4a.beta.,4b.alpha.,10a.alpha.)]- (CAS No. 666842); cedrene- (CAS No. 11028425); 1-phenanthrenemethanol, tetradecahydro-1,4a-dimethyl-7-(1-methylethyl)- (CAS No. 13393936); 1-phenanthrenecarboxylic acid, tetradecahydro-1,4a-dimethyl-7-(1-methylethyl)-, methyl ester, [1R-(1.alpha.,4.alpha.,4.alpha.)]- (CAS No. 19941287).

- ♥ The following substance belonging to the group of organic tin compounds has been deselected from the OSPAR List of Substances of Possible Concern on the grounds that it does not meet the cut-off value for persistence in the Selection Criteria used in the Initial Selection Procedure adopted by OSPAR 2001 (*Reference Number: 2001-1*) and is therefore not considered to be a priority for action by OSPAR: stannane, tributyl(1-oxododecyl)oxy- (CAS No. 3090366).
- ♠ The following substance belonging to the group of polychlorinated biphenyls has been deselected from the OSPAR List of Substances of Possible Concern on the grounds that it does not meet the cut-off value for persistence in the Selection Criteria used in the Initial Selection Procedure adopted by OSPAR 2001 (*Reference Number: 2001-1*) and is therefore and is therefore not considered to be a priority for action by OSPAR: 1,1'-biphenyl, 4,4'-dichloro- (CAS No. 2050682).
- ♥ The OSPAR Background Document on Hexachlorocyclopentadiene adopted by OSPAR 2004 indicates that HCCP does not meet the cut-off values for persistence and bioaccumulation in the Selection Criteria Used in the Initial Selection Procedure adopted by OSPAR 2001 (*Reference Number: 2001-1*) and does not fulfil the bioaccumulation criterion in the EC Technical Guidance Document. A decision on whether to delete HCCP from the OSPAR List of Chemicals for Priority Action will await the finalisation of the risk assessment report under EU Council Regulation (EEC) 793/93.

Annex IV - List of priority substances in the field of water policy (Directive 2000/60/EC)⁽¹⁾

| | CAS number ⁽¹⁾ | EUNumber ⁽²⁾ | Name of priority substance | Identified as priority hazardous substance |
|------|---------------------------|-------------------------|--|--|
| (1) | 15972-60-8 | 240-110-8 | Alachlor | |
| (2) | 120-12-7 | 204-371-1 | Anthracene | (X) (***) |
| (3) | 1912-24-9 | 217-617-8 | Atrazine | (X) (***) |
| (4) | 71-43-2 | 200-753-7 | Benzene | |
| (5) | not applicable | not applicable | Brominated diphenylethers (**) | X (****) |
| (6) | 7440-43-9 | 231-152-8 | Cadmium and its compounds | X |
| (7) | 85535-84-8 | 287-476-5 | C ₁₀₋₁₃ -chloroalkanes (**) | X |
| (8) | 470-90-6 | 207-432-0 | Chlorfenvinphos | |
| (9) | 2921-88-2 | 220-864-4 | Chlorpyrifos | (X) (***) |
| (10) | 107-06-2 | 203-458-1 | 1,2-Dichloroethane | |
| (11) | 75-09-2 | 200-838-9 | Dichloromethane | |
| (12) | 117-81-7 | 204-211-0 | Di(2-ethylhexyl)phthalate (DEHP) | (X) (***) |
| (13) | 330-54-1 | 206-354-4 | Diuron | (X) (***) |
| (14) | 115-29-7 | 204-079-4 | Endosulfan | (X) (***) |
| | 959-98-8 | not applicable | (alpha-endosulfan) | |
| (15) | 206-44-0 | 205-912-4 | Fluoranthene (*****) | |
| (16) | 118-74-1 | 204-273-9 | Hexachlorobenzene | X |
| (17) | 87-68-3 | 201-765-5 | Hexachlorobutadiene | X |
| (18) | 608-73-1 | 210-158-9 | Hexachlorocyclohexane | X |
| | 58-89-9 | 200-401-2 | (gamma-isomer, Lindane) | |
| (19) | 34123-59-6 | 251-835-4 | Isoproturon | (X) (***) |
| (20) | 7439-92-1 | 231-100-4 | Lead and its compounds | (X) (***) |
| (21) | 7439-97-6 | 231-106-7 | Mercury and its compounds | X |
| (22) | 91-20-3 | 202-049-5 | Naphthalene | (X) (***) |
| (23) | 7440-02-0 | 231-111-4 | Nickel and its compounds | |

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| | CAS number (1) | EU number (2) | Name of priority substance | Identified as priority hazardous substance |
|------|----------------|----------------|-------------------------------|--|
| (24) | 25154-52-3 | 246-672-0 | Nonylphenols | X |
| | 104-40-5 | 203-199-4 | (4-(para)-nonylphenol) | |
| (25) | 1806-26-4 | 217-302-5 | Octylphenols | (X) (***) |
| | 140-66-9 | not applicable | (para-tert-octylphenol) | |
| (26) | 608-93-5 | 210-172-5 | Pentachlorobenzene | X |
| (27) | 87-86-5 | 201-778-6 | Pentachlorophenol | (X) (***) |
| (28) | not applicable | not applicable | Polyaromatic hydrocarbons | X |
| | 50-32-8 | 200-028-5 | (Benzo(a)pyrene), | |
| | 205-99-2 | 205-911-9 | (Benzo(b)fluoranthene), | |
| | 191-24-2 | 205-883-8 | (Benzo(g,h,i)perylene), | |
| | 207-08-9 | 205-916-6 | (Benzo(k)fluoranthene), | |
| | 193-39-5 | 205-893-2 | (Indeno(1,2,3-cd)pyrene) | |
| (29) | 122-34-9 | 204-535-2 | Simazine | (X) (***) |
| (30) | 688-73-3 | 211-704-4 | Tributyltin compounds | X |
| | 36643-28-4 | not applicable | (Tributyltin-cation) | |
| (31) | 12002-48-1 | 234-413-4 | Trichlorobenzenes | (X) (***) |
| | 120-82-1 | 204-428-0 | (1,2,4-Trichlorobenzene) | |
| (32) | 67-66-3 | 200-663-8 | Trichloromethane (Chloroform) | |
| (33) | 1582-09-8 | 216-428-8 | Trifluralin | (X) (***) |

(*) Where groups of substances have been selected, typical individual representatives are listed as indicative parameters (in brackets and without number). The establishment of controls will be targeted to these individual substances, without prejudicing the inclusion of other individual representatives, where appropriate. (**) These groups of substances normally include a considerable number of individual compounds. At present, appropriate indicative parameters cannot be given. (***) This priority substance is subject to a review for identification as possible "priority hazardous substance". The Commission will make a proposal to the European Parliament and Council for its final classification not later than 12 months after adoption of this list. The timetable laid down in Article 16 of Directive 2000/60/EC for the Commission's proposals of controls is not affected by this review.

(****) Only Pentabromobiphenylether (CAS-number 32534-81-9).

(*****) Fluoranthene is on the list as an indicator of other, more dangerous Polyaromatic Hydrocarbons.

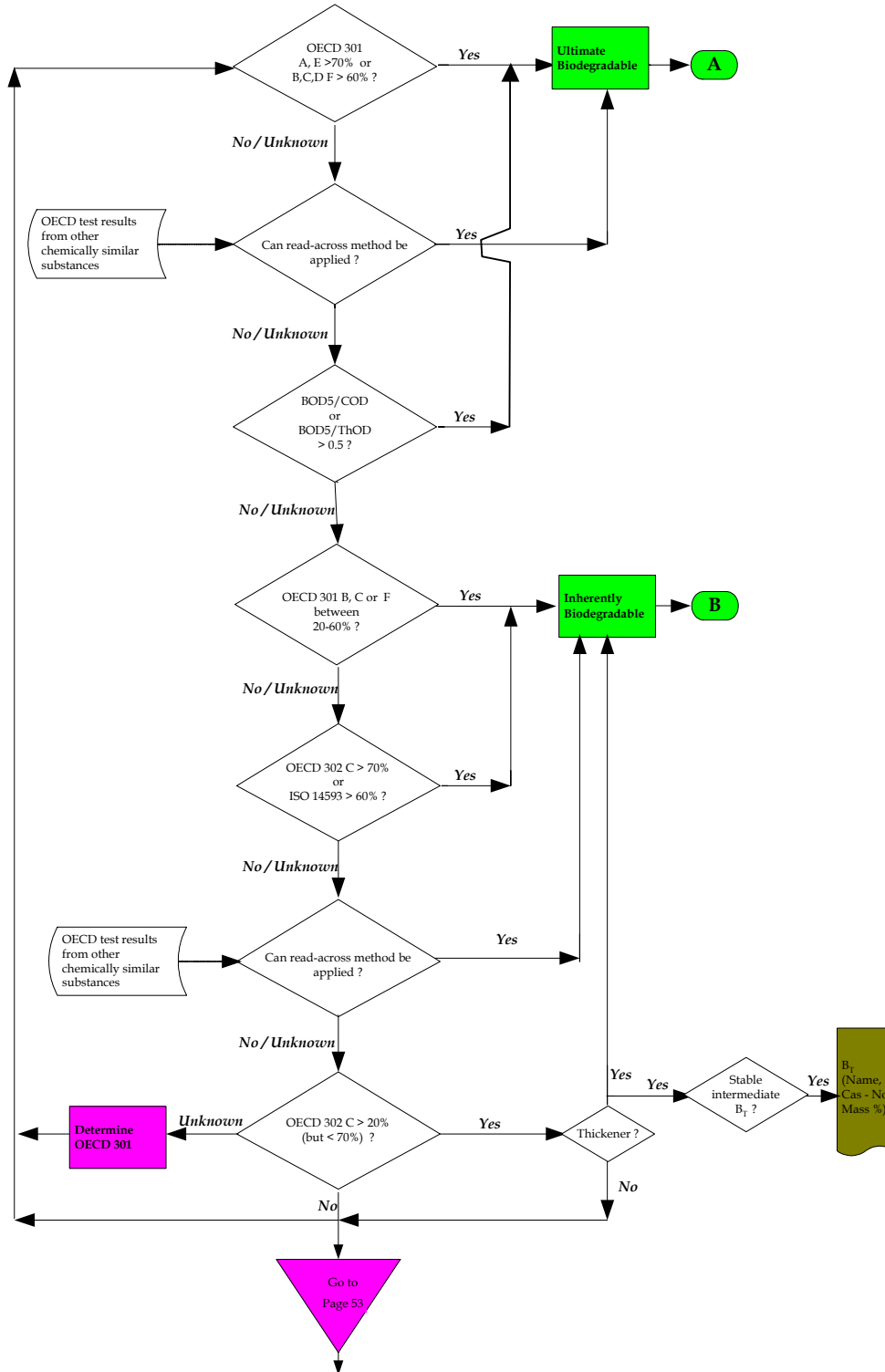
(1) CAS: Chemical Abstract Services.

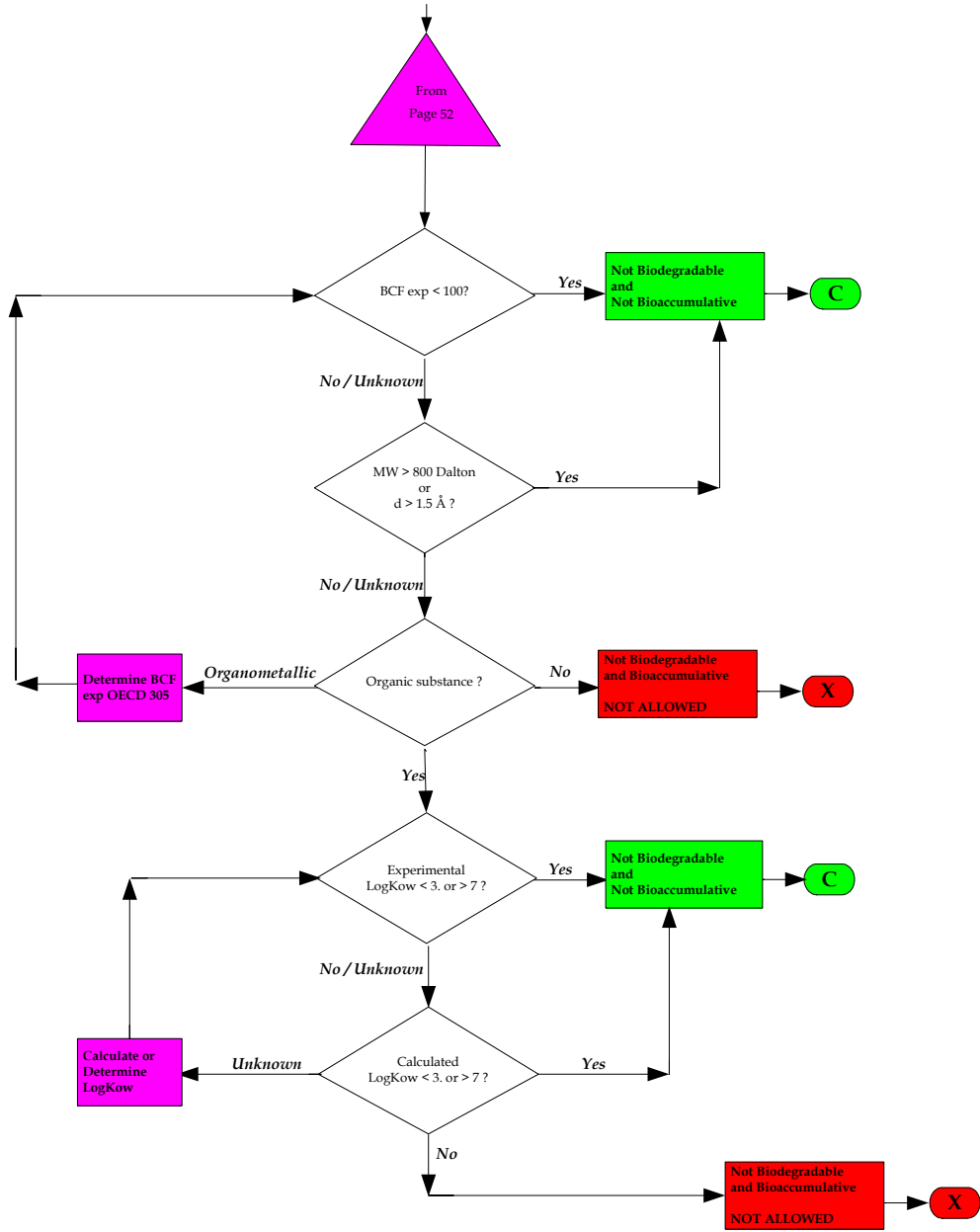
(2) EU-number: European Inventory of Existing Commercial Chemical Substances (EINECS) or European List of Notified Chemical Substances (ELINCS).'

Annex V- Flow chart to the flower.....

1st

Determination of the
 BIODEGRADATION AND BIOACCUMULATION FOR EACH SUBSTANCE
 present in the product in a concentration >0.1% (w/w)





2nd

**AFTER ALL SUBSTANCES (present in the product in a concentration > 0.1% (w/w))
ARE CLASSIFIED AS A, B and C CHECK WHETHER THE FOLLOWING CONDITION IS MET**

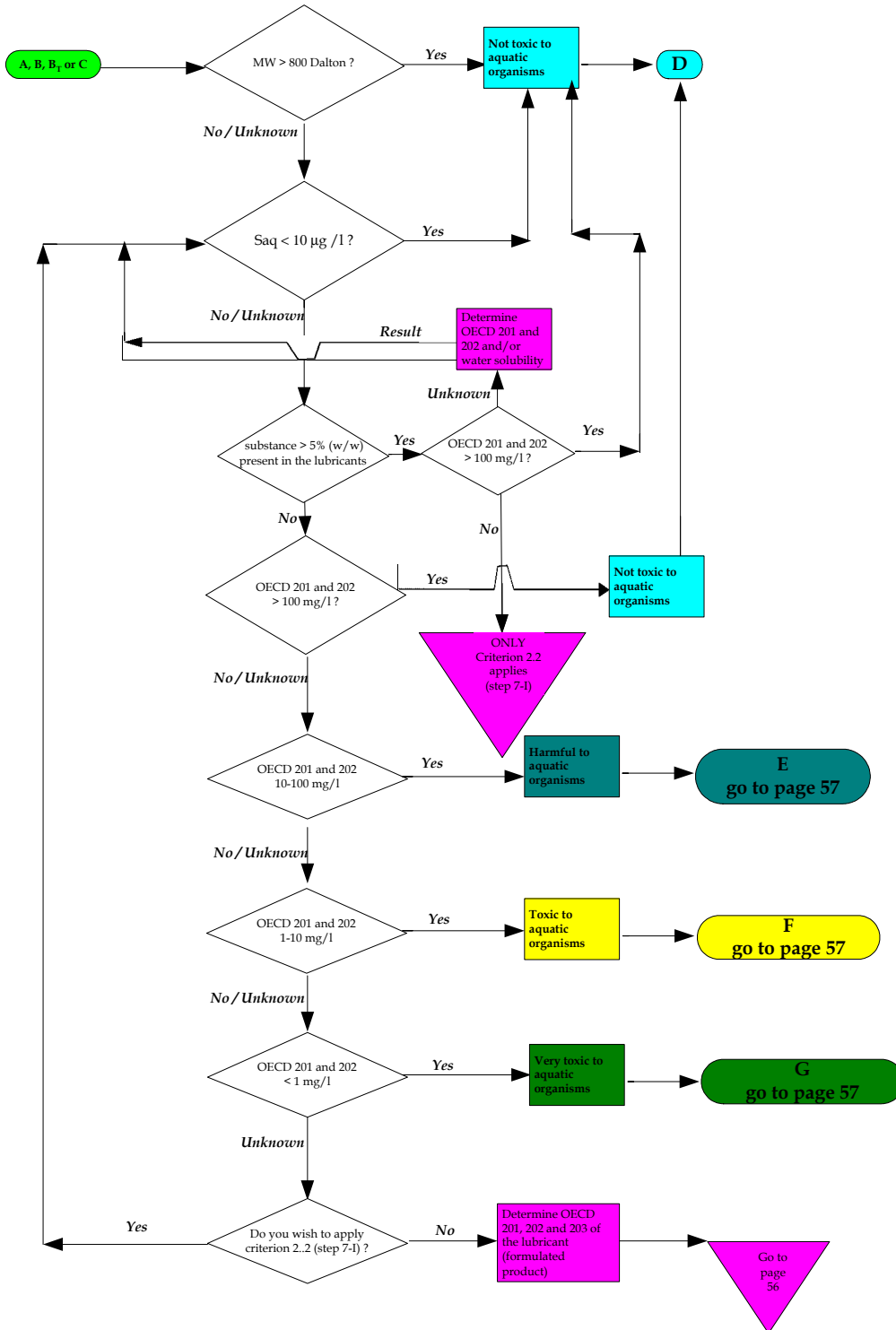
| | |
|---|---|
| $\Sigma (A) \geq 90$ AND $\Sigma (B) \leq 5$ AND $\Sigma (C) \leq 5$ AND $\Sigma (X) = 0$ | For Hydraulic fluids, Chain saw oils, Concrete release agents and other total loss lubricants |
| $\Sigma (A) \geq 75$ AND $\Sigma (B) \leq 20$ AND $\Sigma (C) \leq 10$ AND $\Sigma (X) = 0$ | For Greases and Two-stroke oils |

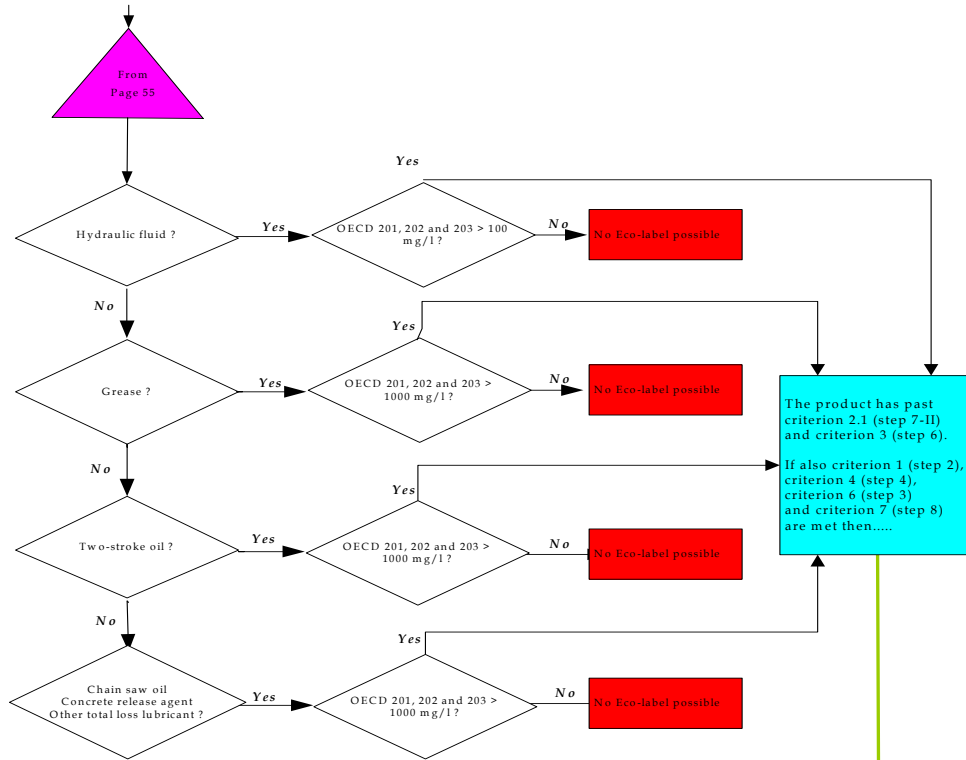
If NO no European Eco-label possible

If YES continue with next page (page 55)

3rd

Determination of the AQUATIC TOXICITY FOR EACH SUBSTANCE IDENTIFIED AS A, B, B₁ and C





Yes!!!! You deserve the flower... ..



4th

AFTER ALL SUBSTANCES ARE CLASSIFIED AS E, F and G CHECK WHETHER THE FOLLOWING COMNDITION IS

MET

| | |
|---|---|
| $\Sigma (\mathbf{E}) \leq 20 \%$ $\Sigma (\mathbf{F}) \leq 5 \%$ $\Sigma (\mathbf{G}) \leq 1 \%$ | Hydraulic fluids |
| $\Sigma (\mathbf{E}) \leq 25 \%$ $\Sigma (\mathbf{F}) \leq 1 \%$ $\Sigma (\mathbf{G}) \leq 0.1 \%$ ($\Rightarrow \Sigma (\mathbf{G}) = 0 \%$)* | Greases Two-stroke oils |
| $\Sigma (\mathbf{E}) \leq 5 \%$ $\Sigma (\mathbf{F}) \leq 0.5 \%$ $\Sigma (\mathbf{G}) \leq 0.1 \%$ ($\Rightarrow \Sigma (\mathbf{G}) = 0 \%$)* | Chain saw oils Concrete release agents and other total loss lubricants |

*The condition $\Sigma (\mathbf{G}) \leq 0.1 \%$ means in practice $\Sigma (\mathbf{G}) = 0\%$. This is due to the fact that the concentration of substances in the candidate product, which implies a requirement for documentation of compliance with the environmental criteria is defined at $\geq 0,1\%$ by weight of the product.

If NO, no Eco-label possible

If YES and if also criteria 1,4,5,6,7 are met.....

Yes!!!

You deserve the flower.....

