European Union Ecolabel application pack for lubricants

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Attention!

This manual serves only as a guiding document. In any case, the legal basis for being awarded the EU Ecolabel is Regulation (EC) No 66/2010 of November 25th 2009 on the EU Ecolabel and the Commission Decision of 24 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel to lubricants (2011/381/EU).

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General Information

The purpose of this User's Manual is to describe the requirements in form of data and documentation that the applicant has to compile in order to apply for the EU Ecolabel for lubricants. In addition, this manual describes the requirements for demonstrating continued compliance once the label has been granted.

The basis for the manual is Commission Decision of 24 June 2011, establishing the ecological criteria for the award of the EU Ecolabel to lubricants (2011/381/EU).
This user Manual describes how the EU Ecolabel 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.

A "√" indicates that the applicant needs to fill a specific table, column and/or section of the application form.

Application forms for the EU Ecolabel shall be provided in two copies bearing original signatures. The application form will be provided by any of the Competent Bodies responsible for the European Scheme. For any information, please get in contact whit the Ecolabel Helpdesk (Ecolabel@biois.com).

For which products can applications be made?

The criteria cover hydraulic fluids, tractor transmission oils, greases, stern tube greases, chainsaw oils, concrete release agents, wire rope lubricants, two-stroke oils, industrial and marine gear oils, stern tube oils and other total loss lubricants for use by private consumers and professional users.

Compiling documentation

The applicant must compile documentation for all relevant criteria for the product. For this purpose the User manual contains pre-made forms of declarations and test reports stating the information needed for the application. Two different levels for declarations are often used: declarations from the applicant/producer and declarations from the supplier. In case where the supplier must provide information which he wants to be held confidential to the applicant it can be sent directly to the Competent Body, which is assigned to treat information confidential.

All relevant documentation has to be sent to the Competent Body together with the application. A copy of all material must be kept at the applicant.

All information on the EU Ecolabel product/products should refer to the requirements in the criteria document.

The applicant shall assemble a dossier containing all relevant data and manufacturers´ declarations related to the ecolabelled product. This dossier should be presented as a part of the application to verify compliance to the criteria.

If there is more than one candidate product, the information in the application dossier might be separated into one product specific part and one site specific part, in order to avoid duplicates that are common to several candidate parts. If the product is produced in more than one site a site-specific dossier must be provided for each site.

For each ecolabelled product covered by the application, the applicant has to specify the product composition.

Who can apply for the EU Ecolabel?

Manufacturers, importers, services providers, traders and retailers, may submit applications for the Ecolabel. Traders and retailers may submit applications in respect of products placed on the trade market under their own brand names.

If a product is being sold in a single Member State the application shall be presented in this Member State. If a product is being sold in the same form in several Member States the application may be presented in any of these Member States.

If a product originates from outside the Union the application may be presented in any of the Member States in which the product is to be, or has been, placed on the market.

What does an application/contract cover

At application the applicant must report the trade names and identification or reference numbers of the products in question. All chemicals used for the ecolabelled product must be reported in the application, as well. When the application has been processed by the Competent Body and when the results of the process is positive, a certificate is sending to the company referring to the company, to the range of products and to the different trade names of the products certified. In the case when there are other demands and other products certified in the same product group an extra certificate is sent. With the certificate a contract specifying the reference of the decision for product group must be signed by the company and by the competent body. In case the contract holder wants to extend his range of products the following conditions apply:

- Extension with new identification/reference commercial names, which do not affect the criteria, can be done by sending specific information to the Competent Body. In this case a letter of prolongation is sent to the competent body with the new trademark and the name of the product which has been certified before with the same characteristics. After validation of the new environmental labelling, a certificate with the new commercial reference is sent.

- Extension with new technical characteristics (for example chemicals, etc) or for a new type of product, as far as these are affected by the criteria, must be approved by the Competent Body prior to use. This must be done by informing the Competent Body with an extension letter and the necessary documentation for these (including an updated ‘List of Chemicals’).

- Extension with new suppliers can be done by providing the Competent Body with documentation for the suppliers' compliance with the criteria. Besides an updated list of suppliers must be provided.

Choice of analytical laboratory

In the criteria document, the Assessment and verification requirements, paragraph 4 says: "Where possible, the testing should be performed by laboratories that meet the general requirements of EN ISO 17025 or equivalent". There is a need for a common practice on how this shall be interpreted, and this document describes a hierarchy of situations and conditions for acceptance of a laboratory.

The situation in paragraph 1 is preferred, if this is not possible, paragraph 2 comes into force, etc. The national competent body or eco-labelling board will consider the applications individually taking into account the following approach and making a decision according to the concrete situation without prejudice to the credibility of the European eco-labelling scheme.

(1) Laboratory tests shall be performed by laboratories that are accredited for the specified test method according to ISO 17025 or GLP, where possible. The Competent Bodies accept accredited laboratories in all Member States in the EU/EEA and in countries that have signed the mutual recognition agreement according to ILAC, the international accreditation organisation. If in the Member State where the applicant submits its dossier or where the company or the concerned production plant or service is based, one or more laboratories are accredited according to ISO 17025 or GLP, applicants shall use such a laboratory, either in that Member State or another.

(2) Laboratories with an accreditation for other tests than those required by the criteria can be accepted if they submit a declaration that the tests are done following the same quality management procedures as the tests for which they obtained an accreditation. In case of doubt, the competent body or national board shall inspect the lab that carries out the tests or shall select an accredited auditor who will be charged to do so.

(3) If neither point 1 or 2 is possible, applicants should call on a non-accredited independent laboratory certified or approved by a Government Department or other public body in a Member State In case of doubt, the competent body or national board shall inspect the lab that carries out the tests or shall select an accredited auditor who will be charged to do so.

(4) If none of points 1 - 3 are possible, applicants may have the tests performed by an independent laboratory that is neither accredited nor approved by authorities according to point 3. Laboratories with a quality management system shall be preferred. A laboratory situated in an organisation holding an ISO 9001- certificate, may be accepted if the scope of the certification includes the laboratory. The competent body or national board shall verify the competence of the laboratory that carries out the tests or shall select an accredited auditor who will be charged to do so.

(5) If none of the above mentioned points can be fulfilled, the applicant may have the tests carried out in a company laboratory (that is not accredited ISO 17025 or GLP, as this would be covered by point (1). The competent body or national board shall ensure that the tests are properly carried out or shall select an accredited auditor who will be

charged to do so. In this case, the laboratory shall have a quality management system. A laboratory within an organisation holding an ISO 9001- certificate, is accepted as being under appropriate quality management, if the scope of the certification includes the laboratory. This option may also be used for continuous monitoring of the production, including discharges and emissions, and for testing fitness for use when no standard test method exists.

Continuous control – the responsibility of the applicant
The applicant has the responsibility to keep the product performance in continued compliance with the EU Ecolabel criteria.

After the EU Ecolabel has been granted, the applicant must keep the dossier continuously up to date. In the case where continued tests or measurements are required, the contract holder or his supplier is responsible for keeping a journal containing the test results and other relevant documentation. This documentation does not need to be sent to the Competent Body, but must be available at any time, if requested.

If data shows that the product, during the validity period of the license, no longer complies with the criteria, this must be reported to the Competent Body immediately together with a statement of the reasons for the non-compliance. The Competent Body will in each individual case decide the consequences of the non-compliance, e.g. a demand for additional measurements, suspension of the label etc.

Assessment of the compliance to the criteria
The Competent Body may undertake any necessary investigations to monitor the ongoing compliance by the holder of the EU Ecolabel license as regards to both the product group criteria and the terms of use and provisions of the contract. To this end, the Competent Body may request, and the holder shall provide, any relevant documentation to prove such compliance.

Further, the Competent Body may, at any reasonable time and without notice, request, and the holder shall grant, access to the premises.

Applicant may download from the EU Ecolabel website, a small tool to verify whether their final lubricant complies with criterion 3, 4 and 5a (Ecolabel check vs 1.0). This is NOT a supported tool.

Costs
The applicant must pay all expenses for tests and verifications related to the application, holding and use of the EU Ecolabel. The Competent Body can require reasonable costs to cover the assessment procedure.

The application process
To get the EU Ecolabel licence, it is mandatory to apply using the online application tool, Ecat_admin. Please register at the following address: https://webgate.ec.europa.eu/ecat_admin.

Download the E-Catalogue User Manual at http://ec.europa.eu/environment/ecolabel/how-to-apply-for-eu-ecolabel.html. It will help you navigate the online system. If you have any problems using the system, contact your Competent Body.

Please note that the required paper file will also need to be submitted to the relevant Competent Body once the application in Ecat_admin has been made.

After receiving an application the Competent Body will go through the dossier including the documentation sent directly from the suppliers. The Competent Body has the possibility to ask for further information, if necessary.

The officer at the Competent Body assessing the application makes a list of missing documentation, which is communicated to the applicant. The applicant makes sure that the listed requirements are met and provides the Competent Body the missing documentation. In most cases it may be necessary to send more than one list of missing documentation.

As part of the assessment process, the Competent Body may carry out an on-site visit to the applicant and/or his suppliers.

When all requirements have been met, the Competent Body will sign a contract with the applicant specifying the terms of use of the EU Ecolabel, following the standard contract on Annex IV of the Regulation (EC) No 66/2010 of 25 November 2009.

When criteria documents are revised, the license holders will have to apply for re-assessment of their license according to the revised criteria. A transition period for adjusting the products and apply for re-assessment will apply. This will be announced by the European Commission.

General about Ecological Criteria

To apply for the EU Ecolabel, the lubricants have to meet requirements for performance, show limited toxicity to aquatic organisms, have high biodegradability and low potential for bioaccumulation and contain a high fraction of renewable raw materials.

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 acute 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
- contain a large fraction of biobased material.

The criteria for this product category and background information are available at:
http://ec.europa.eu/environment/ecolabel/products-groups-and-criteria.html

Definitions and descriptions of terms used in this User 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) "Substance" as defined in Regulation 1907/2006 (REACH)

d) "Stated substance" is substance that is stated on the application form. It is a substance that is intentionally added and/or that is formed after an intentional chemical reaction and present above 0.010% (w/w) in the applied lubricant.

e) "Preparation" as defined in Regulation 1907/2006 (REACH)

f) "Polymer" as defined in Regulation 1907/2006 (REACH)

g) "Thickener" means a substance in the base fluid used to thicken or modify the rheology of a lubricating fluid or grease;

h) "Main component" means any substance accounting for more than 5% by weight of the lubricant;

i) "Additive" means a substance or a package containing specific fractions of several substances whose primary functions are the improvement of the flow, ageing, lubricity, anti-wear properties or the reduction of contaminant suspension.

j) "Grease" means a solid to semi-solid preparation consisting of a thickener in a liquid lubricant.

k) "LuSC-list" or Lubricant Substance Classification list is a list of substances and brands that have been assessed on its biodegradation/bioaccumulation, aquatic toxicity, renewability and exclusion lists of substances by a competent body. The assessment is only based on a maximum treat rate allowed in a lubricant. The list is published on the EU Ecolabel website and the data can be used directly in the application form.

l) "LoC" or Letter of Compliance. This letter is emitted by one of the EU Ecolabel competent body indicating the assessment of a substance or brand used in a lubricant. It contains the same information as listed on the LuSC-list.

m) "Ultimately aerobically biodegradable" is a substance with EEL classification A, and which:

- may be listed on the Lubricant Substance Classification list (LuSC-list). This list is established by the Competent Bodies and can be viewed at the following URL: http://ec.europa.eu/environment/ecolabel/documents/LuSC-%20list.pdf
- 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 of -C(=S)–N].

- achieves at least 70% degradation within 28 days according to Reg 440/2008/C.4-A or C.4-B (DOC-die away test.

- achieves at least 60% degradation within 28 days according to one of the test according Reg 440/2008/C.4-C,D,E, F or the OECD 306 (biodegradation in seawater) or the OECD 310 (head space test)

- has a BOD5/COD or BOD5/ThOD ratio > 0.5

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

n) "Inherently aerobically biodegradable" is a substance with EEL classification B and which:

- may be listed on the Lubricant Substance Classification list (LuSC-list). This list is established by the Competent Bodies and can be viewed at the following URL: http://ec.europa.eu/environment/ecolabel/documents/LuSC-%20list.pdf
- achieves more than 70% degradation according to Regulation 440/2008/C.9 (OECD 302 B) or OECD 302 C test.

- achieves more than 20% but less than 60% degradation within 28 days according to one of the ultimately biodegradability tests based on oxygen depletion or carbon dioxide evolution.

- 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].

o) "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 Regulation 440/2008/C.13 (OECD 305).

- has a logKow< 3 or > 7 according to one of the tests in Regulation 440/2008/A.8 (OECD 107 or OECD 117 or OECD 123). In case of a organic substance other than a surfactant where no experimental value is available, a calculation method can be used. The following calculation methods are allowed: CLOGP, LOGKOW, (KOWWIN) and SPARC. If none of the estimated log Kow values by any of these calculation methods lay in-between the range of 3 to 7 the substance is not expected to bioaccumulate.

p) 'Not toxic to aquatic organisms' is a substance with EEL classification D and which:

- may be listed in on the Lubricant Substance Classification list (LuSC-list). This list is established by the Competent Bodies and can be viewed at the following URL: http://ec.europa.eu/environment/ecolabel/documents/LuSC-%20list.pdf.
  - has a Molecular Mass > 800 Dalton.
  - is a polymer and its molecular weight fraction of 1000 g/mol is below 1%. The molecular weight fraction below 1000 g/mol of a polymer shall be determined according to Regulation 440/2008/A.19 (OECD 119).
  - has a Molecular Diameter > 1.5nm (15 Å).
  - is highly insoluble in water (solubility < 10µg/l) according to OECD 105.
  - has a NOEC > 10 mg /Ll according to Regulation 440/2008 C.14 (OECD 215) and Regulation 440/2008/C.20 (OECD 211).
  - has a EC50/LC50/IC50 > 100 mg/L according to OECD 201 and 202 (acute toxicity tests).

In case of slightly soluble substances (aquatic solubility < 10 mg/L) the applicant may apply the aquatic toxicity 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

q) "Harmful" is a substance with EEL classification E and which:

- may be listed on the Lubricant Substance Classification list (LuSC-list). This list is established by the Competent Bodies and can be viewed at the following URL: http://ec.europa.eu/environment/ecolabel/documents/LuSC-%20list.pdf
  - Has a NOEC between 1-10 mg /l according to Regulation 440/2008 C.14 (OECD 215) and Reg 440/2008/C.20 (OECD 211).
  - has a EC50/LC50/IC50 between 10-100 mg/L according to OECD 201 and 202 (acute toxicity tests) 4.

In case of slightly soluble substances (aquatic solubility < 10 mg/L) the applicant may apply the aquatic toxicity tests on the water accomodated 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

r) "Toxic" is a substance with EEL classification F and which:

- may be listed in on the Lubricant Substance Classification list (LuSC-list). This list is established by the Competent Bodies and can be viewed at the following URL: http://ec.europa.eu/environment/ecolabel/documents/LuSC-%20list.pdf.
- has a NOEC between 0,1-1 mg / L according to Regulation 440/2008 C.14 (OECD 215) and Regulation 440/2008/C.20 (OECD 211).

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

In case of slightly soluble substances (aquatic solubility < 10 mg/L) the applicant may apply the aquatic toxicity tests on the water accomodated 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

s) "Very toxic" is a substance with EEL classification G and which:

- has a NOEC ≤ 0,1 mg /L according to Regulation 440/2008/C.20 (OECD 211) and Regulation 440/2008/C.14 (OECD 215).

- has a EC50/LC50/IC50 ≤ 1 mg/L according to OECD 201 and 202 (acute toxicity tests).

Note: In a case the substance is found to be acute very toxic the multiplication factor, M, should be established according to Table 1b in Directive 2006/8/EC (Annex 1 of this user manual) from the acute toxicity data results on the test reports handed over to the competent body. This factor determines the maximum fraction of a very toxic substance allowed in your lubricant.
(E.g. if the IC50 value of a substance tested on algae turns out to be in between 0.01 and 0.001 mg/L then your multiplication factor turns out to be 100. Instead of 0.1% as a maximum you are only allowed to use 0.1%/100 = 0.001% of this substance in your final formulation).

In case of slightly soluble substances (aquatic solubility < 10 mg/L) the applicant may apply the aquatic toxicity tests on the water accomodated 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

t) "Highly insoluble" is a substance which has a water solubility < 10µg/l according to OECD 105.

u) "Slightly soluble" is a substance which has a water solubility < 10mg/l according to OECD 105.

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

w) "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).

x) "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.

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

z) "Octanol/water partition coefficient" (Kow) means the ratio of a chemical's solubility in n-octanol and water at equilibrium.

aa) "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.

bb) "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).

cc) "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).

dd) "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.

Reference to nanomaterials and nanoforms

In the absence of general definition, the term "nanomaterial" is used in this paper as a general term to cover manufactured (or engineered) nano-sized and nanostructured materials, without further specifying whether these materials are substances, forms of substances etc.

The term "substance at nanoscale" describes substances with properties specific for nanomaterials. The term does not distinguish between substances which only exist at the nanoscale and nanoforms of substances which also exist in bulk form. The term "nanoscale" mainly refers to the size of the particles, where one or more external dimensions is in the size range 1 nm - 100 nm. .

The term "nanoform" will be useful in cases where reference is made to particular forms of a substance with nanomaterial properties, as opposed to the "bulk form" of the same substance, i.e. (the) form(s) of the substance without nanomaterial properties.

Many substances have internal structures at the nanoscale, for example atoms, molecules, crystal layers etc., that individually could be considered as being at the nanoscale. As long as these are embedded in the matrix of larger sized structures they will not exert the specific characteristics of the nanoscale units.

As defined by ISO (TS 27687), aggregates and agglomerates are "nanostructured materials". "Nanostructured materials" are a subcategory of the term "nanomaterial". Aggregates and agglomerates, often existing at a micro size, may have some of the behaviour and effects of their smaller sub units, e.g. due to an increased surface area. Thus, the terms nanomaterials, substances at nanoscale and nanoforms cover both 'nano-objects' and 'nano-structured materials' as defined by ISO (TS 27687).

How to apply

To apply for the European Ecolabel please:

a) Complete the Application Form.
b) Send a hardcopy of the completed form together with the supporting documents to the Competent Body.

Note: An applicant can only apply for one lubricant in a specific category. However the lubricant may consist of several grades, e.g. viscosity grades in the case of hydraulic fluids or NLGI grades in the case of greases.

Follow the 10 steps below to verify whether your product is eligible for the EU Ecolabel:

10 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-phrase or H-statement on environmental or human health hazards.	Criterion 1a
Step 3	Check whether the candidate product meets the minimum technical performance specifications	Criterion 6
Step 4	State on the application form **all** substances or brands from the LuSC-list of LoC that are added intentionally and/or are chemically formed after an intentional chemical reaction and present above 0.010%(w/w) in the candidate lubricant (the list of "*stated substances"*).	(Measurement thresholds)
Step 5	Check whether the candidate product contains any *stated substance* appearing in the OSPAR-listed; the Community list of priority substances in the field of water policy; organic halogens; nitrites; metals and metallic compounds except Na, K, Mg, Ca and for thickeners Li, Al; CMR cat 1,2 (R45, R46, R60 or R61); On the candidate list for eventual inclusion in Annex XIV of Regulation 1907/2006 (Substances of very high concern – SVHC);	Criterion 1b
Step 6	Check whether the candidate product meets the criteria concerning the use of renewable raw materials content for the *stated substances* above 0.1% (w/w)	Criterion 5
Step 7	Check whether the candidate product meets the biodegradation and bioaccumulation requirements for each *stated substance* above 0.10% (w/w)	Criterion 4
Step 8	Check whether the candidate product meets the aquatic toxicity requirements for each *stated substance* above 0.10% (w/w).	Criterion 3
Step 9	Check whether the total fraction of substances not assessed in the candidate lubricant on the biodegradation/bioaccumulation	(Measurement thresholds)

	or aquatic toxicity remains below 0.50% (w/w)	
Step 10	Confirm that once the European Ecolabel has been awarded to the product, its label contains the text: - Reduced harm for water and soil during use - Contain a large fraction of biobased material	Criterion 7

Note that the steps are not organized in the sequence of the actual criteria listed in Commission Decision 2011/381/EU of 24 June 2011. This is done for efficiency reasons. The first 6 steps guide you through the requirements that are relatively uncomplicated to check, the ones that can be verified at a glance assuming that you have stated all substances intentionally added or formed and present above 0.010% (w/w). Steps 7, 8 and 9 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 7, 8 and 9 if you have first checked for steps 1 to 6. Step 10 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 product group is divided into 5 categories. *Category 1* consists of hydraulic fluids and tractor transmission oils, *Category 2* consists of greases and stern tube greases, *Category 3* consists of stern tube oils chainsaw oils, concrete release agents, wire rope lubricants and other total loss lubricants, *Category 4* of two-stroke oils and *Category 5* of industrial and marine gear oils. Where criteria are defined for the specific category, the applicant selects the one that is applicable to the candidate product.

Note 1: Marine gear oils are gear oils used in gears for the power transmission of the vessel apart from the stern tube.

Note 2: When an applicant wishes to apply for the EU Ecolabel for a lubricant not belonging to one of the above mentioned categories, the lubricant will be assessed as a *total loss lubricant* (Category 3).

Note 3: A product range of a lubricant may consists of several grades (e.g. viscosity for hydraulic fluids or NLGI for greases) within the same category. Please indicate the different grades for which you would like to apply in section 2.1. of the application form.

- ✓ Tic the correspondent lubricant product group(s) at point 2.6 in the application form.

- ✓ Complete part 1 and part 2.1 to 2.6 of the application form.

Data and documents to be submitted for step 1

- ➢ If your product is registered under another environmental labelling scheme, such as the Blue Angel, Swedish Standard etc, indicate which one at section 2.5. The scheme should be valid for the candidate lubricant at the date of applying for the EU Ecolabel.

- ➢ Provide relevant evidence on the status of your company when requested. This is related to the application fees.

Step 2 - R-phrases or H-Statements / Criterion 1a

According to the Article 6(6) of Regulation (EC) No 66/2010 on the EU Ecolabel, the product or any part of it shall not contain substances (in any form, including nanoforms) meeting the criteria for classification with the hazard statements or risk phrases specified below in accordance with Regulation (EC) No 1272/2008 or Directive 67/548/EC nor shall it contain substances referred to in Article 57 of Regulation (EC) No 1907/2006. The risk phrases or hazard statements refer to each intentionally added substance including its forms (e.g. the nanoform). From this general requirement *derogations* are listed.

The candidate lubricant cannot be classified by one of the existing Health or Environmental Hazard statements or R-phrases stated in Regulation (EC) No 1272/2008 or Council Directive 99/45/EC and their updates. R-phrases or H-statements can vary due to the form of the substance. The form used in the candidate lubricant should coincide with its correspondent classification. *In short the EU Ecolabel lubricant cannot bear any R-phrase or H-statement related to health and environment.*

Data and documents to be submitted

- ✓ Fill in **column 6a and 6b of Table 3.2.1** of each stated substance (See also step 4 for preparing the list of stated substances)

- ➢ The MSDS of the candidate lubricant and if applicable the MSDSs of the suppliers of components of the candidate lubricant, should be added to the application form.

In case that components of the candidate product and the candidate product itself is non-hazardous en thus has no MSDS the declaration is sufficient[1].

- ✓ Confirm in sections 2.7 – 2.9 that each requirement is fulfilled.

[1] 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.

Step 3 – Minimum Technical performance / Criterion 6

The candidate product must meet minimum technical performance criteria to qualify for the EU Ecolabel. Compliance with the minimal technical performance criteria will be evaluated by an appropriate standard test in the case of *hydraulic fluids, industrial and marine gear oils, chain saw oils and two stroke oils*. For all other lubricants the applicant has to provide documents to show that the performance level is 'fit for purpose'.

Data and documents to be submitted

Hydraulic fluids

- For *hydraulic fluids* the applicant submits documentation demonstrating compliance with the technical performance criteria laid down in ISO 15380 Tables 2 to 5.
- A technical data sheet indicating which two (2) elastomers have been tested according to ISO 15380.

Chain saw oils

- For *chain saw oils* the applicant submits documentation demonstrating compliance with the technical performance criteria laid down in RAL-UZ 48 of the Blue Angel.

Two-stroke oils

- For *marine 2T-stroke oils* the applicant submits documentation demonstrating compliance with one the technical performance criteria laid down in "'NMMA Certification for two-stroke cycle gasoline engine lubricants' of NMMA TC-W3.
- For *Terrestrial 2T-oils* the applicant submits documentation demonstrating compliance with the technical performance criteria laid down as the EGD level in ISO 13738:2000.

Industrial or marine gear oils

- For *Industrial or marine gear oils* the applicant submits documentation and a technical data sheet demonstrating compliance with *one* of the three technical performance criteria laid down in DIN 51517.

In all other cases 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.

- Submit the relevant technical reports showing compliance with the technical requirements of the OEM for the specific application.

✓ Confirm in all cases in section 4 of the application form compliance with the minimum technical performance of the candidate lubricant.

Step 4 – Listing the substances or approved brands / Measurement thresholds

All substances in the candidate lubricant intentionally added or formed after a chemical reaction at the moment of application and present *above 0.010% (w/w)* shall be unambiguously stated using a CAS RN and/or EC number (Criteria for measurements thresholds). This list forms the core of the application form.
(Note: Commercial names of brands or substances found on the LuSC-list or a valid LoC emitted by one of the EU Ecolabel Competent Bodies can be listed directly on the application form. *In this case it is also not required to add relevant documents to the application form to support its EEL classification*).

Before you prepare this list several checks are required because not every chemical substance that is present in the candidate lubricant needs to be stated.

The following points need to be considered:

1. Is the lubricant directly applied? In case it is not directly applied but something is added just before the application, then you need to include this addition in your application form because the ecolabel of the lubricant is only valid for the *applied product*.
2. Any substance you state should have been added intentionally.
3. The form of the substance, including the nanoform, as used in the lubricant must comply with each EEL criterion.
4. The substance you state needs to be present in a weight-fraction over 0.010% (w/w) in the applied lubricant.
5. You do not need to state unknown impurities but known impurities as stated on the MSDS are a normal part of the EEL assessment of the substances.
6. In case of a UVCB- substance (Unidentified substance of variable composition and/of biological origin) you may need to provide additional analytical proof that what is stated in the candidate lubricant is also used for testing the substance. The composition varies substantially not only by differences in the production process but even by modifying the production process conditions.
   (It can be important information when you know more of the chemical composition of your UVCB-substance since it may allow you to use a higher fraction in the candidate lubricant before the chemical substance with the highest fraction in this chemical mixture will reach the cut-off levels. If this information is necessary in the application consult your SHE-officer or a consultant well-known within the EU chemicals policy and the lubricant criteria).
7. In case the *thickener* is build up from a *intentional chemical reaction* you need to state the substance(s) that are formed, their weight fractions both added and formed, and the fraction(s) in excess in the final candidate lubricant.

Part 3 of the application form (substance specific information) is divided into several parts. Section 3.1 refers to the formation of chemical substances in a reactive thickening system after an intentional chemical reaction. *This is only possible in the case of greases.* Section 3.2 contains all the substance data relevant for the application. Table 3.2.1 is the core of the application form. Section 3.3 and 3.4 refer to additional data required after the self-assessment

of the substance by the applicant on its biodegradation and bioaccumulation potential and aquatic toxicity.

Using a reactive thickening system (Section 3.1)

- ✓ In case you use a reactive thickening system for your candidate grease first fill in section 3.1 of the application form. The content of table 3.1.2 returns in Table 3.2.1. The different steps are explained in Annex 2 of this user manual.

Not a reactive thickening system

- ✓ In case your lubricant is not composed of a reactive thickener, list all intentionally added substances and their fractions present in the applied lubricant in the designated **columns 1 to 5 of Table 3.2.1 at section 3.2** of the application form. (If applicable: the fraction of each substance in each different grade and the abbreviation of the grade must be stated in column 5a and 5b respectively. E.g. for hydraulic fluids you may fill in in table 5b *32 or 46* etc. for a substance or component).

You have created now your "*list of stated substances*" which forms the core of the application process.

Step 5 - Exclusion of specific substances / Criterion 1b and 2

In step 5 the applicant checks whether any of the stated substances is absent from a number of lists or R-phrases. *The applicant does not need to check these exclusion lists if the substances or brand is found on the LuSC-list or stated on the LoC.* This is part of the assessment of the substance or brand before the LoC is emitted or added to the LuSC-list. Automatically "***N***" can be stated in column 7 of Table 3.2.1.

One of the following R-phrases may not be found on the list of stated substances:

- R-phrases R45, R46, R49, R60, R61 (The so-called CMR 1 and 2 according to Dir 67/548/EEC and updates).

Any substance belonging to one of the following chemical groups may not be found on the list of stated substances:

- An organohalogen or a nitrite.

- Metals or metallic compounds with the exception of sodium, potassium, magnesium or calcium. For thickeners Li and Al may be used up to concentrations limited by one of the other criteria.

Any substance found on each of the following lists may not be found on the list of substances:

- The (candidate) list of substance of very high concern according to Regulation 1907/2006 - See URL: *http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp*

- The updated OSPAR list of chemicals for priority action - See URL: *http://www.ospar.org/content/content.asp?menu=00950304450000_000000_000000*

- Community list of priority substances in the field of water policy (Regulation 2000/60/EC) - See URL*: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:331:0001:0005:EN:PDF*

✓ The applicant fills in the designated **column 7 of Table 3.2.1**

Step 6 - Renewability content / Criterion 5

The candidate product must meet the criteria concerning the use of renewable raw materials content for all substances *present above 0.1% (w/w)* on the list of stated substances for criterion 5.

The EU Ecolabel 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 oils or fats.

The renewability in the EEL is based on the carbon content (C-atoms) of the substances. In this concept the renewability refers to the concept of reduced CO_2- or Greenhouse gas emission. Although important it is still debated how to operationalize this concept within the EU. The main discussion point is the production of certain vegetable oils in a CO_2 unfriendly way. It is more than expected that in subsequent EEL revisions sustainability, renewability and Greenhouse gas emissions will be quantified based on LCA-concepts. In CO2 emission calculations based on LCA methods three aspects always return being:

- ✓ The type of material the C-atoms consists of, b) whether this material is used as a primary or secondary source and c) the origin of the production of the renewable material.

The lubricant shall have a carbon content derived from renewable materials which is calculated in the following way:

- ✓ The applicant should fill in the designated **columns 8a, 8b, 8c and 8d in Table 3.2.1** of the application form.
  (**Note**: the renewable weight % of the substance in the candidate lubricant, column 8d, is a multiplication of the fraction of the substance present in the candidate lubricant and the fraction of renewable C-atoms in the substance or brand).

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

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)

- ✓ After filling in column 8 completely, the application add all entries in column 8d to find the overall fraction of renewable C-atoms in the candidate lubricant and fill this in section 3.6.

To be eligible for an EU Ecolabel 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
- ≥ 50 % for industrial or marine gear oils

The EEL check tool 1.0 which can be downloaded from the EU Ecolabel website may assist the applicant in the verification of this criterion.

CO_2 reduction cannot be quantified yet. Therefore only qualitative aspects are used. This returns in the data the applicant needs to state in Table 3.6.2.

- ✓ State in Table 3.6.1:
  - ♦ The main component (above 5% (w/w) of the lubricant that includes renewable C-atoms.

- ✓ State in Table 3.6.2.
  - ♦ The type of material of renewable C-atoms used in the main component, e.g. rape oil, palm oil
  - ♦ Whether the source of the renewable C-atoms is primary or secondary. *Primary source* is a first use of the renewable material after harvesting and processing, while *secondary source* is a re-use of the renewable material.
  - ♦ The origin of the renewable material or the country or region where it is harvested.

Note 1: Only one lubricant category can be filled in, but this may consist of several lubricant grades within this category.**Note 2**: the applicant must request the relevant information for table 3.6.2 from the supplier of the renewable component(s).

Note 3: Table 3.6.2. needs to be filled in, but additional support by documents is *not* required).

Last but not least:

- ✓ Confirm compliance with the requirements of criterion in section 3.6 of the application form.

Step 7 - Biodegradation and bioaccumulation requirements / Criterion 4

Any stated substance present above 0.10% shall be assessed on its biodegradation and when required on its bioaccumulation.

EEL biodegradation classes

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. These cumulative percentages are found in Table 1 of the criteria document (Annex 3 of this manual). Ultimately aerobically biodegradable substances should make up the biggest part of the product.

The EU Ecolabel for lubricants distinguishes the following classes on the biodegradation potential: "Ultimately aerobically biodegradable (A)", "Inherently aerobically biodegradable (B)", "Non-biodegradable and non-bioaccumulative (C)" and "Non-biodegradable and bioaccumulative (X)" or the biodegradation does not need to be assessed (-) e.g. in case the substance is stated and present below 0.1% but above 0.010% or when indicated on the LuSC-list or LoC. The definition of each class of biodegradation potential is given in the criteria document and cited in this manual under the heading "Definitions and description of terms used in this manual*". For each non-biodegradable substance the applicant should also evaluate its bioaccumulation potential.*

The classification on the biodegradation/bioaccumulation potential by the applicant can only be based on:

- *Self-assessment* by the applicant from high quality test reports or other documents in his possession. Relevant information must be stated in section 3.3. for each stated substance and the evidence must be attached to the application form or
- From the Lubricant Substance Classification list (*LuSC-lis*t) or
- From a valid letter of compliance *(LoC)* from a competent body stating this classification.

Overall biodegradation class and its basis in column 9

- ✓ The applicant indicates in the designated **column 9a and 9b of Table 3.2.1** for each stated substance present above 0.1% (w/w) the corresponding EEL-classification (A,B,C,X or -) and on what the applicant has based the classification upon (either Self-classification, LuSC-list, valid letter of compliance (LoC)).
- ✓ For each self-assessment of the biodegradation/bioaccumulation potential the applicant fills in Table 3.3.1. In case the substance is not biodegradable the applicant also fills in Table 3.3.2 for this specific substance. In all cases relevant documents must be submitted together with the application form.

Data and documents to be submitted on the biodegradation

For each stated substance where the biodegradation and bioaccumulation potential has been assessed by the applicant (*self-assessment*) submit also the relevant test reports.

For each stated substance where this assessment is based on a valid letter of compliance (LoC) submit a copy of this letter.
For each stated substance where the assessment is based on the Lubricant Substance Classification list (LuSC-list) no additional documents need to be submitted.

In case of a self-assessment
In case of a self-assessment the following sources are allowed. The relevant documents should be attached to the application form. The relevant documents should also indicate a high quality of the value of the relevant endpoint. Both points are explained below.

Source of self-assessment
The self-assessment can be derived from

- High quality test reports on the biodegradation of the substance itself. They can be test reports on the biodegradation in river water or marine water systems.
- High quality test reports on a substance that is so closely related to the substance present in the lubricant that the method of "read-across" can be applied. This method is explained in the manual under the heading "Definitions and description of terms used in this manual".
- Literature data of high quality indicating that the same test method has been used under GLP conditions.

Allowed studies on biodegradation
The following test reports on the biodegradation of the substance can be attached to the application form:

- A 28-day biodegradation study according to Regulation 440/2008/C.4 (OECD 301 A-F), OECD 306 or OECD 310 and in case they are not available:
- The BOD5 and COD studies according to Regulation 440/2008/C.5 for the BOD5 and for the COD according to Regulation 440/2008/C.6.

In case the applicant has no test reports available on the aerobic biodegradation of the substance, the applicant needs to provide measured data according to one of the Regulation 440/2008/C4 – C to F (OECD 301 C, D, E or F) or OECD 306 or 310 or equivalent tests. The applicant will select the most appropriate test method according to the intended use of the candidate lubricant. (e.g. in a marine environment the biodegradation is established in marine water)

Note: In these ultimately biodegradable tests the 10-day window principle will not necessarily apply.

High quality test reports on the biodegradation
High quality test reports on the biodegradation meet the following criteria:

For the OECD 301 A-F, 302, 306 and 310
The report shows that the standard deviation of the value is 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, 302, 306 or 310 or an equivalent test.

For the BOD5/COD or BOD5/ThOD ratio

BOD5 being the mean value (grams of BOD per gram of tested substance) after 5 days. The report shows that 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 report shows that 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 Regulation 440/2008/C 4 (Biodegradation determination of the "Ready" biodegradability).

Data and documents to be submitted on the Bioaccumulation potential

When to submit data on the bioaccumulation
Data on the bioaccumulation must be submitted if the substance is not ultimately nor inherently biodegradable. These data will lead to a distinction whether the substance is not biodegradable and not-bioaccumulative (EEL classification C) or not biodegradable and bioaccumulative (EEL classification X). Substances classified as X are not allowed above 0.1% in an ecolabelled product. In addition their total fraction is also limited.

What to fill in on the application form

- ✓ In case it is required to establish a **bioaccumulation potential** (the substance is not biodegradable), the applicant fills also **table 3.3.2.**

What type of evidence could be assessed
The bioaccumulation potential is established by test-reports or evidence from one of the following:

- 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;
- Evidence that the substance is a polymer and the MM <1000 Dalton is below 1% in the polymer itself;
- High quality test report on the bioaccumulation according to *Regulation 440/2008/C.13* (OECD 305) or any other equivalent test method. In case this test report is not available then;
- High quality test report on the log K_{ow} of the substance according to *Regulation 440/2008/A.8* (OECD 107 or OECD 117) or OECD 123 or any other equivalent test method. In case such a test report is not available and the substance is an organic substance other than a surfactant;
- A calculation can be used based on the following calculation methods, CLOGP, LOGKOW, (KOWWIN) *and SPARC*. If none of the estimated log Kow values by any of these calculation methods lay in-between the range of 3 to 7 the substance is not expected to bioaccumulate.

The use of one of these methods indicated above leads to the justification of the bioaccumulation potential. This justification (BCF < 100 L/kg, MM >800 D, MD > 1.5nm, Polymer, log Kow <3 or >3 but <7 or >7) is filled in the table 3.3.2 at the appropriate column.

High quality test reports

High quality test report on the bioaccumulation (potential) meets the following criteria:

For the OECD 305

The report shows that the standard deviation of the BCF-value is smaller than 1/5th (20%) of the mean value. The BCF-value can be derived from the steady state concentrations in fish and water or from the kinetic method using the uptake and elimination rate constant. Submit the underlying report according to the outline stated under "Test Report" of the OECD guidelines 305 or an equivalent test.

For the OECD 107, 117 or 123

The report must show that the 95% confidence interval of the log Kow- value is 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 107, 117 or 123 or from an equivalent test method.

Evidence based on Molecular Mass

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

Evidence based on Molecular Diameter

Submit scientific evidence from a peer-reviewed journal.

Data to be submitted for compliance with the criterion on biodegradation

- ✓ The applicant adds up all mass percentages of substances within the categories **A**, **B, C** and **X** in table 3.2.1 of the application form and state these percentages in **Section 3.5.1** of the application form. Applicant can only fill in one lubricant category, but this may consists of several grades, each of which must be checked for this criterion.

To be eligible for the EU Ecolabel the total mass fraction of each biodegradation class being A, B or C are compared to the allowed fractions according to the criteria. Please note that these fractions may vary according to the category.

Σ (**A**) $\geq$ 90 % Σ (**B**) $\leq$ 5 % Σ (**C**) $\leq$ 5 % Σ (**X**) = 0	Lubricants in Category 1, 3 and 5
Σ (**A**) $\geq$ 75 % Σ (**B**) + Σ (**C**) $\leq$ 25 % Σ (**X**) = 0	Lubricants in Category 2
Σ (**A**) $\geq$ 75 % Σ (**B**) $\leq$ 20 % Σ (**C**) $\leq$ 10 %	Lubricants in Category 4

Σ (**X**) = 0	

The EEL check tool 1.0 which can be downloaded from the EU Ecolabel website, may assist the applicant in the verification process of this criterion.

If the different biodegradation fractions are within the ranges stated in the criteria document then the applicant has successfully passed step 7.

Step 8 - Aquatic toxicity requirements / Criterion 3

Any stated substance present above 0.1% shall be assessed also on its aquatic toxicity.

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 8 – I **or** 8 -II:

8-I) Requirements for each stated substance above 0.1% / Criterion 3.2

or

8-II) Requirements for the preparation and main components / Criterion 3.1

MAKE FIRST A SELECTION OF HOW TO ASSESS THE AQUATIC TOXICITY OF YOUR PRODUCT AND CONTINUE WITH EITHER 8-I OR 8-II.

Experience has learned that in nearly all current applications criterion 3.2 (8-I) has been used.

8-I) Requirements for each substance (Criterion 3.2)

Data are required that allow for the evaluation of the aquatic toxicity of all stated substances present above 0.1% in the candidate lubricant.

EEL ecotoxicity classes

The EEL classification on the ecotoxicity is based on results from aquatic toxicity experiments leading to the following aquatic toxicity classes. The aquatic toxicity of a substance is 'Not toxic (D)', 'Harmful (E)', 'Toxic (F)' or 'Very toxic (G)' and its limits are stated in Table 1 (Annex 1 in this manual) in the criteria document and cited in this manual under the heading "Definition and description of terms used in this manual".
In case the substance turns out to be very toxic to the aquatic environment (G) the multiplication factor according to Table 1b of Directive 2006/8/EU must be established.
(***E.g*** if the IC50 value of a substance tested on algae turns out to be in between 0.01 and 0.001 mg/L then your multiplication factor turns out to be 100. Instead of 0.1% as a maximum you are only allowed to use is 0.1%/100 = 0.001% of this substance in your final formulation).

- ✓ *Overall EEL classification and its basis in column 10 of Table 3.2.1*
  The overall EEL classification and its bases are entered in **column 10a, 10b and 10c of table 3.2.1**. The most toxic value leads to the EEL aquatic toxicity classification D,

E, F, or G of the substance. In case the *acute* aquatic toxicity of the substance turns out to be very toxic (G) the multiplication factor according to Table 1b of Directive 2006/8/EU must be established. This table is attached in Annex 1 of this manual.

Data and documents to be submitted on the aquatic toxicity

The assessment of the aquatic toxicity of the substance can be based one of the following:

- *Self-assessment* by the applicant from high quality test reports or other documents the applicant attaches to the application form. In this case for each substance where the classification is based on a self-assessment relevant information must be entered into Table 3.4.1.
- From the Lubricant Substance Classification list (*LuSC-list*).
- From a valid letter of compliance (*LoC*) from a competent body stating this classification. The competent body has assessed the specific property and has classified it accordingly.

For each stated substance where the aquatic toxicity has been assessed by the applicant (*self-assessment*) submit also the relevant test reports.
For each stated substance where this assessment is based on a valid letter of compliance (LoC) submit a copy of this letter.
For each stated substance where the assessment is based on the Lubricant Substance Classification list (LuSC-list) no additional documents need to be submitted.

Conducting the self-assessment
The assessment of the aquatic toxicity is based on data from chronic and acute toxicity experiments in the aquatic environment.

First chronic aquatic toxicity data then acute aquatic toxicity data
The aquatic toxicity assessment is based on chronic toxicity data of two trophic levels: daphnia and fish. No Effect Concentrations (NOEC-values) derived from standard chronic toxicity experiments are used. When these chronic toxicity data are not available, acute toxicity data can be used. They should also be based on two trophic levels: algae and daphnia. The two levels are therefore different. If one chronic toxicity data on fish is available the applicant selects one of the two possible acute toxicity trophic levels. In case a chronic toxicity data on a crustacean is available the applicant needs to assess the acute toxicity of algae.

Documents and data to be submitted on the aquatic toxicity

- ✓ In case the aquatic toxicity is based on an assessment by the applicant (a *self-assessment*), **Table 3.4.1** in the application form must be filled in for each self-assessed substance from the list of stated substances.

Basis of self-assessment
A self-assessment is based on the following:

- High quality test reports on the aquatic toxicity of the substance itself. Test reports on the aquatic toxicity can be based on river water or marine water systems.
- Literature data of high quality indicating that the same test method and methodology has been used under GLP conditions.

Allowed studies on the aquatic toxicity

Chronic aquatic toxicity
Both sea and freshwater toxicity tests are allowed. Chronic toxicity or No Observed Effect Concentration (NOEC) data on two trophic levels, daphnia (crustacean) and fish, are established by the following test methods; Regulation 440/2008/C.20 (OECD 211) for Daphnia (crustacean) and Regulation 440/2008 (OECD 215) or OECD 210 for fish respectively or equivalent test methods.

Acute aquatic toxicity
The acute toxicity tests in marine water are carried out according to and using relevant test species mentioned in the following guidelines: ISO/DIS 10253 for algae, ISO TC 147/SC5/W62 for crustacean and OECD 203 for fish. The tests in freshwater are carried out according to and using relevant test species mentioned in the following guidelines: Regulation 440/2008/C.3. (OECD 201) for algae, Regulation 440/2008/C.2. (OECD 202) for daphnia and Regulation 440/2008/C.1. (OECD 203) for fish. Only (72hr)E_rC50 for algae, (48hr)EC50 for daphnia and (96hr)LC50 for fish are accepted.

Not sufficient or no data available on the aquatic toxicity of the substance

In case the applicant does not have sufficient data available to make a self-assessment the following steps can be made.

1) The applicant can check for other methods stated in the criteria document to assess the substance. These other methods only leads to the aquatic toxicity classification as non-toxic to the aquatic environment (D).
2) Need to conduct the test.

1. Other methods that may classify the substance as non-toxic to the aquatic environment
In case the assessment is based on one of the alternative methods, sufficient evidence must be provided to the competent body. These alternative methods are based on the following and lead in all cases to the classification "non-toxic (D)" to the aquatic environment:

- ✓ The selected evidence for the specific substance must be entered in **Table 3.4.2 of the application form**.

Alternative methods
- The aqueous solubility of the substance established according to the OECD 105 test method or any other equivalent test method is below 10 μg/L.
- Evidence that Molecular mass of the substance exceeds 800 g/mol. State in the table 3.4.2 of the application form the molecular mass of the substance. Submit then an underlying report with the molecular formula and the calculation of the molecular mass.

- Evidence that the molecular diameter of the substance is larger than 1,5 nm (> 15 Å). State in the table 3.4.2 of the application form the molecular diameter and submit scientific evidence from a peer reviewed journal or,
- Evidence that the substance is a polymer and its molecular weight fraction of 1000 g/mol is below 1%. State in Table 3.4.2. the fraction below 1000 g/mol established by OECD 119.

2. Need to conduct the aquatic toxicity test.

In case the applicant needs to conduct experiments, the most appropriate choice need to be made. The appropriate choice for the EEL depends on the relevant aquatic environment, marine or fresh water, where the lubricant is applied. The chronic tests are preferred in marine or fresh water system but the relevant acute tests are also allowed.

High quality test reports

High quality test reports states or allows the derivation of the 95% confidence interval. The value of this interval should be lower than the measured value (e.g. 50 $\pm$ 25 mg/L (95% CI) is allowed but 50 $\pm$ 75 mg/L (95% CI) is not allowed. In the second case the value does not deviate significantly from zero).

Acute aquatic toxicity data on algae and daphnia (crustacean) in river or in marine waters

State the 95% confidence interval (C.I.) of the value based on data from the test reports. The C.I. should be smaller than the EC_{50} / IC_{50}-value. Note that the tests may be applied on the water accommodated fraction (WAF).

Chronic aquatic toxicity on two trophic levels, Fish and daphnia (crustacean)

State the 95% confidence interval (C.I.). The C.I. should be smaller than the NOEC-value. Note that the tests may be applied on the on the water accommodated fraction.

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

State the 95% confidence interval of this value. The confidence interval should be smaller than the solubility value itself.

Calculating the total fractions of the different aquatic toxicity classes

- ✓ The applicant adds up all mass percentages of substances with the same EEL classification on the aquatic toxicity and enters this percentage in **Section 3.5.2 of the application form**.

To be eligible for the EU Ecolabel the applicant compares these percentages with the fraction allowed for the specific category. The allowed fractions are stated in Table 1 of the criteria document and are stated below.

Σ (**E**) $\leq$ 20 % Σ (**F**) $\leq$ 5 % Σ (**G**) $\leq$ 0.1 %	Lubricants in Category 1

Σ (**E**) ≤ 25 % Σ (**F**) ≤ 1 % Σ (**G**) ≤ 0.1 %	Lubricants in Category 2 and 4
Σ (**E**) ≤ 5 % Σ (**F**) ≤ 0.5 % Σ (**G**) ≤ 0.1 %	Lubricants in category 3
Σ (**E**) ≤ 20 % Σ (**F**) ≤ 5 % Σ (**G**) ≤ 1 %	Lubricants in Category 5

If the different aquatic toxicity fractions are within the ranges stated in the criteria document then the applicant has successfully passed step 7.

The EEL check tool 1.0 which can be downloaded from the EU Ecolabel website may assist the applicant in the verification of this criterion.

➢ The applicant's next step is step 9 (page 29 of this manual)

8-II) Requirements for the preparation and main components

This requirement only uses the EEL classifications non-toxic (D) for its main components. Documents and data must be handed over to the competent body when required. Additionally the aquatic toxicity of the freshly prepared lubricant mixture/preparation must be measured and assessed. This requirement, Criterion 3.1, is based on the fact that the EU chemicals policy allows a change in the environmental hazard classification if the preparation/mixture is tested and its results indicate that the hazard classification based on the individual substances leads is too high.
*(***Note:** *such a requirement does not and cannot exist for biodegradation)*

Overall requirements
According to 8-II *acute aquatic toxicity* data shall be provided for each main component (each substance above 5 % (w/w)) and the lubricant. The acute aquatic toxicity of each main component is determined on two trophic levels, algae and daphnia (crustacean) and most be classified according to the EEL criteria as non-toxic (D). The acute aquatic toxicity of the full product is determined on three trophic levels algae, daphnia (crustacean) and fish.

✓ *What to enter in column 10 of Table 3.2.1 on the application form*
The EEL classification of the main components is entered in **column 10a, 10b and 10c of Table 3.2.1.**

✓ *What to enter in Table 3.4.1 on the application form*
The acute aquatic toxicity test results on all *three* trophic levels of the mixture/preparation of the applied lubricant must be entered in Table 3.4.1.

Basis of the assessment on aquatic toxicity
For the main components

The assessment of the acute aquatic toxicity of the main component can be based on the following:

- *Self-assessment* by the applicant from high quality test reports or other documents the applicant attaches to the application form.
- From the Lubricant Substance Classification (*LuSC-list*) (http://ec.europa.eu/environment/ecolabel/ecolabelled_products/categories/lubricants_en.htm).
- From a valid letter of compliance (*LoC*) from a competent body stating this classification. The competent body has assessed the specific property and has classified it accordingly.

For the freshly prepared lubricant (mixture/preparation)
The assessment of the acute aquatic toxicity of the **product** can only be based on high quality test reports on all three trophic levels, algae, daphnia (crustacean) and fish.

Documents to be submitted on the aquatic toxicity

Only documents supporting the self-classification of the main component and the applied lubricant needs to be submitted.

Basis of the assessment on acute aquatic toxicity of the main component
In case the aquatic toxicity of the main component is derived by the applicant (a *self-assessment*), this assessment can only be based on the following:

- High quality test reports on the aquatic toxicity of the substance itself. Test reports on the aquatic toxicity can be based on river water or marine water systems.
- Literature data of high quality indicating that the same test method and methodology has been used under GLP conditions.

Both marine and freshwater tests are allowed
Both marine and river water systems can be used on each trophic level. The tests in marine water are carried out according to and using relevant test species mentioned in the following guidelines: ISO/DIS 10253 for algae, ISO TC 147/SC5/W62 for crustacean and OECD 203 for fish. The tests in river water are carried out according to and using relevant test species mentioned in the following guidelines: Regulation 440/2008/C.3. (OECD 201) for algae, Regulation 440/2008/C.2. (OECD 202) for Daphnia and Regulation 440/2008/C.1. (OECD 203) for fish. Only (72hr)E_rC50 for algae, (48hr)EC50 for Daphnia or crustacean and (96hr)LC50 for fish are accepted.

Other methods that may classify the main components as non-toxic to the aquatic environment
In case the assessment is based on one of the alternative methods, sufficient evidence must be provided to the competent body. This evidence must be stated in **Table 3.4.2** of the application form. These alternative methods are based on the following and lead in all cases to the classification "non-toxic (D)" to the aquatic environment:

- The aqueous solubility of the substance established according to the OECD 105 test method or any other equivalent test method is below 10 µg/L.

- Evidence that Molecular mass of the substance exceeds 800 g/mol. State in the table 3.4.2 of the application form the molecular mass of the substance.
- Evidence that the molecular diameter of the substance is larger than 1.5 nm (> 15 Å).

High quality test reports

High quality test reports states or allows the derivation of the 95% confidence interval. The value of this interval should be lower than the measured value (*e.g.* 50 ± 25 mg/L (95% CI) is allowed but 50 ± 75 mg/L (95% CI) is not allowed. In the second case the value does not deviate significantly from zero).

Acute aquatic toxicity data on algae and daphnia (crustacean) and fish in river or in marine waters

State the 95% confidence interval (C.I.) of the value based on data from the test reports. The C.I. should be smaller than the LC_{50}/EC_{50} / IC_{50}-value. Note that the tests may be applied on the water accommodated fraction (WAF).

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

State the 95% confidence interval of this value. The confidence interval should be smaller than the solubility value itself.

Compliance with criterion 3.1.

The applicant checks and confirms that the following condition is met:

For lubricants in Category 1 and 5	Acute aquatic toxicity of each main component ≥ 100mg/L AND Aquatic toxicity of the candidate lubricant ≥ 100 mg/L according for each of the three trophic level algae, daphnia (crustacean) and fish
For lubricants in category 2, 3 and 4	Acute aquatic toxicity of each main component ≥ 100mg/L on two trophic levels, algae and daphnia (crustacean) AND Aquatic toxicity of the candidate lubricant ≥ 1000 mg/L according for each of the three trophic level algae, daphnia (crustacean) and fish

- The applicant has now fulfilled criterion 3.1.

Step 9 – Fraction not assessed on biodegradation/bioaccumulation and aquatic toxicity/Measurement thresholds criterion

The applied lubricant allows a small fraction of substances that are not assessed or not allowed (X) on its biodegradation/ bioaccumulation potential or aquatic toxicity. This is caused by the fact that the biodegradation and aquatic toxicity of each substance is only assessed above 0.1% but the list of stated substances starts form 0.010%. In order to limit the number of substances just below 0.1% and are therefore not assessed, a limit of 0.5% (w/w) has been set for biodegradation or aquatic toxicity (criterion on measurement thresholds).

How to calculate the unassessed fraction of the lubricant on biodegradation/bioaccumulation

- ✓ Add the fractions of all unassessed (-) or not allowed (X) substances on the biodegradation from column 9a in table 3.2.1. for each grade separately (if applicable). This fraction for each grade separately (if applicable) should be stated on the application form in the designated cell of **section 3.5.3**. This fraction should remain below 0.5% to apply successfully for the EU Ecolabel.

How to calculate the unassessed fraction of the lubricant on aquatic toxicity

- ✓ Add the fractions of all unassessed (-)on the aquatic toxicity from column 10a in table 3.2.1 for each grade separately (if applicable). This fraction for each grade separately (if applicable) should be stated the designated cell of **section 3.5.3** in the application form. This fraction should also remain below 0.5% to apply successfully for the EU Ecolabel.

The EEL check tool 1.0 which can be downloaded from the EU Ecolabel website may assist the applicant in the verification of this criterion.

- ✓ Confirm on the application form compliance with criterion 2, 3 and 4 in Section 3.5

Step 10 – Box 2 / Criterion 7

Confirm that once the European Union Ecolabel has been awarded to the product, the box 2 of the EU Ecolabel logo shall contain the text:

- Reduced harm for water and soil during use
- Contain a large fraction of bio-based material

Data and documents to be submitted

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

Last but not least

- ✓ **Do not forget to undersign the complete application form in part 3**
- ✓ **Check whether you have confirmed that the applicant lubricant fulfils each criterion**
- ✓ **Check whether you have attached all required documents to your application form**

You deserve the EU Ecolabel!

Annex 1

Table to establish the multiplication factor M for very acute toxic substances..

LC50 or EC50 value ("L(E)C50") of substance	**multiplication factor (M)**
0.1 < L(E)C50 ≤ 1	1
0.01 < L(E)C50 ≤ 0.1	10
0.001 < L(E)C50 ≤ 0.01	100
0.0001 < L(E)C50 ≤ 0.001	**1000**
For substances with a lower LC50 or EC50 value than 0.0001 mg/l, the corresponding concentration limits are calculated accordingly (in factor 10 intervals).'	

Annex 2

Treating a reactive thickener in the case of a grease

Reactive thickeners are typically produced in-situ during the grease production process. In this chemical reaction usually (fatty) acids react with metal-hydroxides, often lithium hydroxide or combinations thereof, to form metal soaps and water. As this intended chemical reaction of a major formulation component leads to a new chemical substance, the toxicity and environmental assessment should be related to the products rather than to the single constituents (reactants).

The environmental assessment of the formed metal soap can be advantageous. For example the aquatic toxicity of Lithium hydroxide is much higher (showing e.g. lower LC50 values) than of Lithium 12-hydroxystearate based on the Lithium-ion only. The mass fraction of Lithium in Lithium hydroxide is much higher (20%) than in Lithium 12-hydroxystearate (2.2%). Therefore according to the EEL criteria a higher percentage of the latter can be used compared to the former.

The evaluation of a reactive thickener according to the EEL-requirement in general requires knowledge on the chemical reaction that occurs and on the reactant that is added in excess. Although it involves some chemistry, the chemistry itself is rather straightforward. For the EEL assessment three points are important:

I) Which chemical reaction occurs?
II) Which reactant has been added in excess?
III) What is the mass fraction of the substance(s) formed and the substance(s) in excess present in the final formulation?

Thus:
A) State the intended **chemical** reaction equation or reaction equations for (each of) the reactive thickening system(s).

Intended chemical reaction:

by the names of the substance:
(*e.g.* Lithium hydroxide + 12-hydroxystearic acid → Lithium 12-hydroxystearate + water)

` by chemical formulas:
(*e.g.* $LiOH + HOOCC_{17}H_{35}O \rightarrow Li^{+}\ ^{-}OOCC_{17}H_{35}O + H_2O$)

B) Name the substance added in excess: in this case for example LiOH in the example given above.

C) What is the fraction of the reactant(s) and the fraction in excess in the final formulation?

E.g. For a 100 g of the final grease: 0.8 g of LiOH is added to 10 g of 12-hydroxystearic acid. This leads to 10.2 g Li-12-hydroxystearate in 100 g grease (10/305*311) resulting in **10.2%** (w/w) in the final product.

D) To have the complete hydroxystearate reacting with the LiOH it is needed 10/305*24 = 0.79 g of LiOH. Since 0.80 gram of LiOH was added in excess, 0.01 g might remain in the final 100 g of the grease relating to 0.010% or **100 ppm**.

In this way the fraction of Lithium 12-hydroxystearate and the excess of LiOH in the final lubricant can be obtained based on the assumption that pure products are used.
Based on this example the tables in Section 3.1 of the application form will look as follows:

Table 3.1.1 Information on the reactants of the thickening system

Chemical name	CAS RN	EC No	Mass (g) of reactant added to 100 g of the formulated grease	Tic which reactant is used in excess
Lithium hydroxide	1310-66-3		0.8	✓
12-hydroxystearic acid	106-14-9	203-366-1	10	

- ✓ **Write down the intended chemical reaction of the reactive thickening systems using the chemical names of the reactants stated above**

Lithium hydroxide + 12-hydroxystearic acid. → Lithium 12-hydroxystearate + water

Table 3.1.2 Information on the substances formed after the intended chemical reaction of the thickening systems.

The substance(s) FORMED after the intended chemical reaction	**Chemical name**	**CAS RN of the formed substance**	**Mass (g) of the substance FORMED based on 100 g of the formulated grease**
	Lithium 12-hydroxystearate	7620-77-1	10.2
	water	7732-18-5	0.6
The substance(s) remaining in EXCESS after the intended chemical reaction	**Chemical name**	**CAS RN of the formed substance**	**Mass (g) of the substance IN EXCESS based on 100 g of the formulated grease**
	Lithium hydroxide	1310-66-3	0.010

Annex 3

Table 1 of the EEL Directive showing

		Category 1	Category 2	Category 3	Category 4	Category 5
Category **Criteria**		Hydraulic fluids, tractor transmission oils	Greases, stern tube greases	Chain saw oils, concrete release agents, wire rope lubricants and other total loss lubricants	Terrestrial and marine two-stroke oils	Industrial and marine gear oils
Hazard statements and R-phrases indicating environmental and human health hazards (Derogation for Criterion 1a)		**Category 1**	**Category 2**	**Category 3**	**Category 4**	**Category 5**
Health or Environmental Hazard statement or R-phrase of the lubricant at the time of application		None (Lowest classification limit in Regulation (EC) No 1272/2008 or Council Directive 99/45/EC)	None (Lowest classification limit in Regulation (EC) No 1272/2008 or Council Directive 99/45/EC)	None (Lowest classification limit in Regulation (EC) No 1272/2008 or Council Directive 99/45/EC)	None (Lowest classification limit in Regulation (EC) No 1272/2008 or Council Directive 99/45/EC)	None (Lowest classification limit in Regulation (EC) No 1272/2008 or Council Directive 99/45/EC)
Exclusion of specific substances (Criterion 1b and 2)		**Category 1**	**Category 2**	**Category 3**	**Category 4**	**Category 5**
OSPAR-listed; the Union list of priority substances in the field of water policy; organic halogens; nitrites; metals and metallic compounds except Na, K, Mg, Ca and for thickeners Li, Al; CMR cat 1,2 (R45, R46, R49, R60 or R61); Annex XIV to Regulation (EC) No 1907/2006;		< 0.010%	< 0.010%	< 0.010%	< 0.010%	< 0.010%
Aquatic toxicity (Criterion 3.2 only)		**Cumulative mass percentages (% w/w) of substances present in**				
		Category 1	**Category 2**	**Category 3**	**Category 4**	**Category 5**
Not toxic (D)	Acute toxicity > 100 mg/L or NOEC > 10 mg/L	Not limited				
Harmful (E)	10 mg/L<Acute toxicity ≤ 100 mg/L or 1 mg/L < NOEC ≤ 10 mg/L	≤ 20	≤ 25	≤ 5	≤ 25	≤ 20
Toxic (F)	1 mg/L < Acute toxicity ≤ 10 mg/L or 0.1 mg/L < NOEC ≤ 1 mg/L	≤ 5	≤ 1	≤ 0.5	≤ 1	≤ 5
Very toxic (G)	Acute toxicity ≤ 1 mg/L or NOEC ≤ 0.1 mg/L	≤ 0.1/M(*)	≤ 0.1/M(*)	≤ 0.1/M(*)	≤ 0.1/M(*)	≤ 1/M(*)
Biodegradation and Bioaccumulation (Criterion 4)		**Cumulative mass percentages (%w/w) of substances present in**				
		Category 1	**Category 2**	**Category 3**	**Category 4**	**Category 5**
Ultimately aerobically biodegradable (A)		> 90	> 75	> 90	> 75	> 90
Inherently aerobically biodegradable (B)		≤ 5	≤ 25	≤ 5	≤ 20	≤ 5
Non-biodegradable AND non-bioaccumulative (C)		≤ 5		≤ 5	≤ 10	≤ 5
Non-biodegradable AND bioaccumulative (X)		≤ 0.1	≤ 0.1	≤ 0.1	≤ 0.1	≤ 0.1
Fraction not assessed on aquatic toxicity (Criterion 3.2) or biodegradation/bioaccumulation (Criterion 4)		**Cumulative mass percentages (%w/w) of substances present in**				
		Category 1	**Category 2**	**Category 3**	**Category 4**	**Category 5**
		< 0.5	< 0.5	< 0.5	< 0.5	< 0.5
Renewability (Criterion 5)		**Cumulative mass percentages (%w/w) of substances present in**				
		Category 1		**Category 1**		**Category 1**
Based on carbon		≥ 50%	≥ 45%	≥ 70%	≥ 50%	≥ 50%

	Category 1	Category 2	Category 3	Category 4	Category 5
Minimal Technical performance (Criterion 6)	Hydraulic fluids: ISO 15380 Tables 2 to 5. Tractor transmission oils: fit for purpose.	Fit for purpose	Chain saw oils: as in RAL UZ 48. Others: fit for purpose	Marine 2T-oils: as in NMMA TC-W3. Terrestrial 2T-oils: as the EGD level in ISO 13738:2000.	Industrial and marine gear oils DIN 51517

Annex 4

Aquatic toxicity requirements for the different lubricant categories – Data requirements for the lubricant and its main components

Criterion 3.1	Category 1	Category 2	Category 3	Category 4	Category 5
Acute aquatic toxicity for the freshy prepared lubricant on three trophic levels, algae, crustaceann and fish	> 100 mg/L	> 1000 mg/L	> 1000 mg/L	> 1000 mg/L	> 100 mg/L
Acute aquatic toxicity for each main component on each of two trophic levels, algae and crustaceann	> 100 mg/L	> 100 mg/L	> 100 mg/L	> 100 mg/L	> 100 mg/L