

COMMISSION DECISION (EU) 2018/1702
of 8 November 2018
establishing the EU Ecolabel criteria for lubricants
(notified under document C(2018) 7125)
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel ⁽¹⁾, and in particular Article 8(2) thereof,

After consulting the European Union Eco-labelling Board,

Whereas:

- (1) Under Regulation (EC) No 66/2010, the EU Ecolabel may be awarded to those products with a reduced environmental impact during their entire life cycle.
- (2) Regulation (EC) No 66/2010 provides that specific EU Ecolabel criteria are to be established according to product groups.
- (3) Commission Decision 2011/381/EU ⁽²⁾ established the criteria and the related assessment and verification requirements for lubricants. The period of validity of those criteria and requirements was extended to 31 December 2018 by Commission Decision (EU) 2015/877 ⁽³⁾.
- (4) The EU Ecolabel Fitness check (REFIT) of 30 June 2017, reviewing the implementation of Regulation (EC) No 66/2010 ⁽⁴⁾, concluded on the need to develop a more strategic approach for the EU Ecolabel, including streamlined criteria for selecting products. In line with those conclusions, and in consultation with the EU Ecolabelling Board, it is appropriate to revise the criteria for lubricants product group, taking into consideration the current success, stakeholders' interest in the product and potential future windows of opportunity for increased uptake and market's demand on sustainable products. The definition of the product group 'lubricants' should be modified to include a reference to the functionality of the product instead of its composition. This is to ensure that the definition clearly covers all relevant lubricant compositions.
- (5) In order to take into account recent market developments and innovations that have taken place in the intervening period, it is appropriate to establish a new set of EU Ecolabel criteria for the product group 'lubricants'. The aim of those criteria should be to promote products that have a limited impact on the aquatic environment, contain a limited amount of hazardous substances and performance as well as or better than a conventional lubricant available on the market. In line with the objectives of the European strategy for plastics in a circular economy ⁽⁵⁾, the criteria should also seek to facilitate the transition to a more circular economy by encouraging improved design and by further incentivising the demand for recycled materials.
- (6) The new criteria, as well as the related assessment and verification requirements, should remain valid until 31 December 2024, taking into account the innovation cycle for that product group.
- (7) For reasons of legal certainty, Decision 2011/381/EU should be repealed.

⁽¹⁾ OJ L 27, 30.1.2010, p. 1.

⁽²⁾ Commission Decision 2011/381/EU of 24 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel to lubricants (OJ L 169, 29.6.2011, p. 28).

⁽³⁾ Commission Decision (EU) 2015/877 of 4 June 2015 amending Decisions 2009/568/EC, 2011/333/EU, 2011/381/EU, 2012/448/EU and 2012/481/EU in order to prolong the validity of the ecological criteria for the award of the EU Ecolabel to certain products (OJ L 142, 6.6.2015, p. 32).

⁽⁴⁾ Report from the Commission to the European Parliament and the Council on the review of implementation of Regulation (EC) No 122/2009 of the European Parliament and of the Council on 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS) and the Regulation (EC) No 66/2010 of the parliament and of the Council of 25 November 2009 on the EU Ecolabel (COM(2017) 355).

⁽⁵⁾ COM(2018) 28 final.

- (8) A transitional period should be allowed for producers whose products have been awarded the EU Ecolabel for lubricants on the basis of the criteria set out in Decision 2011/381/EU, so that they have sufficient time to adapt their products to comply with the revised criteria and requirements. For a limited period after adoption of this Decision, producers should also be allowed to submit applications based either on the criteria established by Decision 2011/381/EU or on the revised criteria established by this Decision. Where the EU Ecolabel was awarded on the basis of the criteria established by Decision 2011/381/EU, use of it should not be permitted after 31 December 2019.
- (9) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 16 of Regulation (EC) No 66/2010,

HAS ADOPTED THIS DECISION:

Article 1

The product group 'lubricants' shall comprise any lubricant falling within one of the following sub-groups:

- (a) the Total Loss Lubricants (TLL) sub-group, which shall comprise chainsaw oils, wire rope lubricants, concrete release agents, total loss greases and other total loss lubricants;
- (b) the Partial Loss Lubricants (PLL) sub-group, which shall comprise gear oils intended for the use in open gears, stern tube oils, two-stroke oils, temporary protection against corrosion and partial loss greases;
- (c) the Accidental Loss Lubricants (ALL) sub-group, which shall comprise hydraulic systems, metalworking fluids, closed gear oils intended for the use in closed gears and accidental loss greases.

Article 2

For the purposes of this Decision, the following definitions shall apply:

- (1) 'lubricant' means a product that is capable of reducing friction, adhesion, heat, wear or corrosion when applied to a surface or introduced between two surfaces in relative motion, or is capable of transmitting mechanical power. The most common ingredients are base fluids and additives;
- (2) 'base fluid' means a lubricating fluid which flow, ageing, lubricity and anti-wear properties, as well as its properties regarding contaminant suspension, have not been improved by the inclusion of additive(s);
- (3) 'additive' means a substance or mixture which primary functions are the improvement of one or several of the following aspects: flow, ageing, lubricity, anti-wear properties and contaminant suspension;
- (4) 'substance' means a chemical element and its compounds in the natural state or obtained by any production process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
- (5) 'total loss' means that the lubricant is fully released to the environment during use;
- (6) 'partial loss' means that the lubricant is partially released to the environment during use and the non-released part can be recovered for re-processing, recycling or disposal;
- (7) 'accidental loss' means that the lubricant is used in a closed system and can be released to the environment only incidentally and, after use, can be recovered for re-processing, recycling or disposal;
- (8) 'chainsaw oil' means a lubricant that is used to lubricate the bar and chain on one or more types of chainsaw;
- (9) 'wire rope lubricant' means a lubricant that is used to lubricate wire ropes which consist of several strands of metal wire held together to form a rope;
- (10) 'concrete release agent' means a lubricant that is used in the construction industry to prevent freshly placed concrete adhering to a surface, usually plywood, overlaid plywood, steel or aluminium;
- (11) 'grease' means a solid or semi-solid lubricant which contains a thickener in order to thicken or modify the rheology of the base fluid;
- (12) 'gear oil' means a lubricant made specifically for transmissions, transfer cases, and differentials in automobiles, trucks, and other machinery;

- (13) 'stern tube oil' means a lubricant used in the stern tube of a ship;
- (14) 'two-stroke oil' means a lubricant used in two-stroke engines;
- (15) 'temporary protection against corrosion' means a lubricant that is applied to a metal surface as a thin film in order to prevent water and oxygen from coming into contact with the metal surface;
- (16) 'hydraulic systems' means a lubricant by means of which power is transferred in hydraulic machinery;
- (17) 'metalworking fluid' means a lubricant designed for metalworking processes, such as cutting and forming, and whose main functions are cooling, reducing friction, removing metal particles, and protecting the work pieces, the tool, and the machine tool from corrosion.

Article 3

In order to be awarded the EU Ecolabel under Regulation (EC) No 66/2010, a lubricant shall fall within the product group 'lubricants' as defined in Article 1 of this Decision and shall comply with the criteria and related assessment and verification requirements set out in the Annex to this Decision.

Article 4

The criteria for the product group 'lubricants' and the related assessment and verification requirements shall be valid until 31 December 2024.

Article 5

For administrative purposes, the code number assigned to the product group 'lubricants' shall be '027'.

Article 6

Decision 2011/381/EU is repealed.

Article 7

1. Notwithstanding Article 6, applications for the EU Ecolabel for products falling within the product group 'lubricants' submitted before the date of adoption of this Decision shall be evaluated in accordance with the conditions laid down in Decision 2011/381/EU.
2. Applications for the EU Ecolabel for products falling within the product group 'lubricants' submitted within two months from the date of adoption of this Decision may be based either on the criteria set out in Decision 2011/381/EU or on the criteria set out in this Decision. Those applications shall be evaluated in accordance with the criteria on which they are based.
3. Where the EU Ecolabel is awarded, in accordance with the criteria set out in Decision 2011/381/EU, the EU Ecolabel may be used only until 31 December 2019.

Article 8

This Decision is addressed to the Member States.

Done at Brussels, 8 November 2018.

For the Commission
Karmenu VELLA
Member of the Commission

ANNEX

FRAMEWORK
EU ECOLABEL CRITERIA

Criteria for awarding the EU Ecolabel to lubricants

CRITERIA

1. Excluded or limited substances
2. Additional aquatic toxicity requirements
3. Biodegradability and bioaccumulative potential
4. Renewable ingredients requirements
5. Packaging/container requirements
6. Minimum technical performance
7. Consumer information regarding use and disposal
8. Information appearing on the EU Ecolabel

ASSESSMENT AND VERIFICATION

(a) Requirements

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

Where the applicant is required to provide the competent bodies with declarations, documentation, analyses, test reports, or other evidence to show compliance with the criteria, these may originate from the applicant and/or their supplier(s), as appropriate.

Competent bodies shall preferentially recognise attestations which are issued by bodies accredited in accordance with the relevant harmonised standard for testing and calibration laboratories (General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2005)) or with the principles of Good Laboratory Practice (GLP); and verifications by bodies that are accredited in accordance with the relevant harmonised standard for bodies certifying products, processes and services. Accreditation shall be carried out in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council ⁽¹⁾.

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

Where appropriate, competent bodies may require supporting documentation and may carry out independent verifications or site visits.

As a prerequisite, the product shall meet all applicable legal requirements of the country or countries in which the product is intended to be placed on the market. The applicant shall declare the product's compliance with this requirement.

The Lubricant Substance Classification list (LuSC list), available on the EU Ecolabel website ⁽²⁾, contains substances and brands that have been assessed by a competent body with regard to the relevant requirements included in this Decision and the data can be used directly in the application process.

A Letter of Compliance issued by one of the EU Ecolabel competent bodies can be used directly in the application process.

A list of all intentionally added substances and/or formed intentionally after any chemical reaction in the applied lubricant at or above the concentration of 0,010 % weight by weight in the final product shall be provided to the competent body, indicating the trade name (if existing), the chemical name, the CAS No, the ingoing quantity, the function and the form present in the final product formulation. All listed substances present in the form of nanomaterials shall be clearly indicated on the list with the word 'nano' written in brackets.

⁽¹⁾ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

⁽²⁾ <http://ec.europa.eu/environment/ecolabel/>

For each substance listed, the Safety Data Sheets (SDS) in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽¹⁾ shall be provided. Where an SDS is not available for a single substance because it is part of a mixture, the applicant shall provide the SDS of the mixture.

(b) Measurement thresholds

Compliance with the ecological criteria is required for the final product and its constituent substances that are intentionally added and/or formed intentionally after any chemical reaction in the applied lubricant as indicated within each criterion.

In addition, the total fraction of the listed substances where the formulated criteria 2 and 3 do not apply shall remain below 0,5 % (w/w).

Note: Where grease can be used as both TLL and PLL (as in the case of multifunctional grease), criteria applicable to the TLL sub-group shall apply. If grease can be used as PLL and ALL, but not as TLL, then the criteria applicable to the PLL sub-group shall apply.

For gear oils used in open gears criteria applicable to the PLL sub-group shall apply while for gear oils used in closed gears criteria applicable to the ALL sub-group shall apply. When a gear oil can be used in both types of gears criteria applicable to the PLL sub-group shall apply.

CRITERION 1 — EXCLUDED OR LIMITED SUBSTANCES

For the purpose of criterion 1 impurities stated in the SDS, whose presence in the final product equals or exceeds 0,010 %, shall comply with the same requirements as the intentionally added substances.

1(a) Hazardous substances

(i) Final product

The final product shall not be classified in accordance with any of the hazard statements included in Table 1.

(ii) Substances

Substances that meet the criteria for classification with the hazard statements listed in Table 1 shall not be intentionally added or formed in the final product as specified by the respective limit values.

Where stricter, the generic or specific concentration limits determined in accordance with Article 10 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽²⁾ shall take precedence.

Table 1

Restricted hazard statements

Hazard statement	Limit value
H340 May cause genetic defects	≤ 0,010 % weight by weight per substance in the final product
H350 May cause cancer	
H350i May cause cancer by inhalation	
H360F May damage fertility	

⁽¹⁾ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

⁽²⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

Hazard statement	Limit value
H360D May damage the unborn child	
H360FD May damage fertility. May damage the unborn child	
H360Fd May damage fertility. Suspected of damaging the unborn child	
H360Df May damage the unborn child. Suspected of damaging fertility	
H341 Suspected of causing genetic defects	
H351 Suspected of causing cancer	
H361f Suspected of damaging fertility	
H361d Suspected of damaging the unborn child	
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child	
H362 May cause harm to breast-fed children	
H300 Fatal if swallowed (oral)	
H310 Fatal in contact with skin (dermal)	
H330 Fatal if inhaled (inhal.)	
H304 May be fatal if swallowed and enters airways	$\leq 0,5 \times$ Final product classification limit for H304
H301 Toxic if swallowed	$<$ Final product classification limit for H301
H311 Toxic in contact with skin	$<$ Final product classification limit for H311
H331 Toxic if inhaled	$<$ Final product classification limit for H331
EUH070 Toxic by eye contact	$\leq 0,010$ % weight by weight per substance in the final product
H370 Causes damage to organs	
H372 Causes damage to organs through prolonged or repeated exposure	
H371 May cause damage to organs	
H373 May cause damage to organs through prolonged or repeated exposure	$<$ Final product classification limit for H373
H335 May cause respiratory irritation	$\leq 0,010$ % weight by weight per substance in the final product
H336 May cause drowsiness or dizziness	$<$ Final product classification limit for H336
H317: May cause allergic skin reaction	$<$ Final product classification limit for H317
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	$\leq 0,010$ % weight by weight per substance in the final product
H314 Causes severe skin burns and eye damage	$<$ Final product classification limit for H314

Hazard statement	Limit value
H315 Causes skin irritation	< Final product classification limit for H315
H318: Causes serious eye damage	< Final product classification limit for H318
H319 Causes serious eye irritation	< Final product classification limit for H319
H400 Very toxic to aquatic life	$\leq 0,5 \times$ Final product classification limit for H400
H410 Very toxic to aquatic life with long-lasting effects	$\leq 0,5 \times$ Final product classification limit for H410
H411 Toxic to aquatic life with long-lasting effects	< Final product classification limit for H412 and H413
H412 Harmful to aquatic life with long-lasting effects	
H413 May cause long-lasting effects to aquatic life	
H420 Harms public health and the environment by destroying ozone in the upper atmosphere	$\leq 0,010$ % weight by weight per substance in the final product
EUH029 Contact with water liberates toxic gas	
EUH031 Contact with acids liberates toxic gas	
EUH032 Contact with acids liberates very toxic gas	
EUH066 Repeated exposure may cause skin dryness or cracking	< Final product classification limit for EUH066

Note: where final product classification limit (or $0,5 \times$ Final product classification limit) is mentioned, the maximum total concentration of all classified substances with the specific hazard statement(s) shall be considered.

This criterion does not apply to substances covered by Article 2(7)(a) and (b) of Regulation (EC) No 1907/2006 which sets out criteria for exempting substances within Annexes IV and V to that Regulation from the registration, downstream user and evaluation requirements. In order to determine whether that exclusion applies, the applicant shall screen any intentionally added/formed substance at or above the concentration of 0,010 % weight by weight in the final product.

1(b) Specified restricted substances

The substances listed below shall not be intentionally added or formed at or above the concentration of 0,010 % weight by weight in the final product:

- Substances appearing in the Union List of priority substances in the field of water policy in Annex X to Directive 2000/60/EC of the European Parliament and of the Council ⁽¹⁾ as amended by Decision No 2455/2001/EC ⁽²⁾ and the OSPAR List of Chemicals for Priority Action (<http://www.ospar.org/work-areas/hasec/chemicals/priority-action>),
- Organic halogen compounds and 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 up to concentrations limited by the other criteria included in the Annex to this Decision.

⁽¹⁾ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

⁽²⁾ Decision No 2455/2001/EC of the European Parliament and of the Council of 20 November 2001 establishing the list of priority substances in the field of water policy and amending Directive 2000/60/EC (OJ L 331, 15.12.2001, p. 1).

1(c) Substances of very high concern (SVHCs)

The final product shall not contain any intentionally added/formed substances that have been identified in accordance with the procedure described in Article 59(1) of Regulation (EU) No 1907/2006, which establishes the candidate list for substances of very high concern at or above the concentration of 0,010 % weight by weight in the final product.

Assessment and verification

The applicant shall provide a signed declaration of compliance with above sub-requirements, supported by declarations from suppliers, if appropriate; and the following supporting evidence:

To demonstrate compliance with 1(a)(i) the applicant shall provide the SDS of the final product.

To demonstrate compliance with 1(a)(ii), 1(b) and 1(c) the applicant shall provide:

- SDS of intentionally added mixtures and their concentration in the final product,
- SDS of intentionally added substances and their concentration in the final product.

For substances exempted from requirement 1(a)(ii) (see Annexes IV and V to Regulation (EC) No 1907/2006), a declaration to this effect by the applicant shall suffice to comply.

For requirement 1(c) reference to the latest list of substances of very high concern shall be made on the date of application.

The above evidence can also be provided directly to Competent Bodies by any supplier in the applicant's supply chain.

CRITERION 2 — ADDITIONAL AQUATIC TOXICITY REQUIREMENTS

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

2.1. Requirement for the lubricant and its main components

The critical concentration for the aquatic toxicity for both the freshly prepared lubricant and for each main component shall not be lower than the values specified in Table 2.

Main component means any substance accounting for more than 5 % by weight of the lubricant.

Table 2

Aquatic toxicity values for both freshly prepared lubricant and for each main component

		ALL	PLL	TLL
Aquatic toxicity for the freshly prepared lubricant	Critical concentration for acute aquatic toxicity OR	> 100 mg/l	> 1 000 mg/l	> 1 000 mg/l
	Chronic aquatic toxicity	> 10 mg/l	> 100 mg/l	> 100 mg/l
Aquatic toxicity for each main component	Critical concentration for acute aquatic toxicity OR	> 100 mg/l		
	Chronic aquatic toxicity	> 10 mg/l		

Available acute aquatic toxicity test data for each main component shall be provided on each of the following two trophic levels:

- crustacean (daphnia preferred),
- aquatic plants (algae preferred).

In case acute aquatic toxicity test data is missing in one or both trophic levels, available test data on chronic aquatic toxicity for both the crustacean (daphnia preferred) and fish trophic level shall be accepted.

QSARs could be used to fill data gaps for chronic toxicity or for acute toxicity in only one of the relevant trophic levels.

In case the aforementioned test data is not available for each main component, a test shall be performed to generate data for acute toxicity in the missing trophic level/s (i.e. crustacean and/or aquatic plants).

Available acute aquatic toxicity test data for the lubricant shall be provided on each of the following three trophic levels:

- crustacean (daphnia preferred),
- aquatic plants (algae preferred),
- fish.

In case acute aquatic toxicity test data for the applied lubricant is missing for any of the mentioned trophic levels available test data on chronic aquatic toxicity shall be accepted for the missing trophic level/s.

In case the above data is not available for the applied lubricant, a test shall be performed to generate data on acute aquatic toxicity for the missing trophic level/s.

2.2. Requirement for each intentionally added or formed substances at or above 0,10 % weight by weight in the final product

Substances exhibiting a certain degree of aquatic toxicity are allowed up to a cumulative mass concentration indicated in Table 3.

Table 3

Cumulative mass percentage (% w/w) limits for substances present in the product with respect to their aquatic toxicity

	Cumulative mass percentage (% weight by weight in the final product)		
	ALL	PLL	TLL
Acute aquatic toxicity > 100 mg/l or Chronic aquatic toxicity > 10 mg/l	Not limited		
Acute aquatic toxicity > 10 to ≤ 100 mg/l or 1 mg/l < Chronic aquatic toxicity ≤ 10 mg/l	≤ 10 (≤ 20 for ALL greases)	≤ 10 (≤ 15 for PLL greases)	≤ 2 (≤ 10 for TLL greases)
Acute aquatic toxicity > 1 to ≤ 10 mg/l or 0,1 mg/l < Chronic aquatic toxicity ≤ 1 mg/l	≤ 2,5 (≤ 1 for ALL greases)	≤ 0,6	≤ 0,4
Acute aquatic toxicity ≤ 1 mg/l or Chronic aquatic toxicity ≤ 0,1 mg/l	≤ 0,1/M (*)	≤ 0,1/M (*)	≤ 0,1/M (*)

(*) M-factors for highly toxic components of mixtures shall be applied in accordance with Article 10 of Regulation (EC) No 1272/2008 as described in Section 4.1.3.5.5.5 of Annex I to that Regulation.

Available chronic aquatic toxicity test data for each substance (each intentionally added or formed substances at or above 0,10 % weight by weight in the final product) shall be provided for each of the following two trophic levels:

- crustacean (daphnia preferred), and
- fish

In case chronic aquatic toxicity test data is missing in one or both trophic levels, available data on acute aquatic toxicity for both trophic levels, crustacean (daphnia preferred) and aquatic plants (algae preferred) shall be accepted.

QSARs could be used to fill data gaps for chronic toxicity or for acute toxicity in only one of the relevant trophic levels.

In case the above data is not available for each substance, a test shall be performed to generate data for acute toxicity in the missing trophic level/s (i.e. crustacean and/or aquatic plants).

Assessment and verification applicable to criteria 2.1 and 2.2

In case of self-assessment by the applicant, for each substance, main component or for the lubricant, the applicant shall provide test reports or literature data including the references demonstrating compliance with the requirements set in sub-criterion 2.1 or 2.2.

For each substance or main component where the assessment is based on a valid letter of compliance (LoC), a copy of the letter shall be provided. For each substance or main component selected from the Lubricant Substance Classification list (LuSC-list) the assessment can be based on the information reported in said list and no documents need to be submitted.

Either marine or freshwater toxicity data are accepted.

Acute aquatic toxicity data (available or generated for the application) shall originate from tests carried out according to:

- ISO 10253 or ISO 8692 or OECD Test Guideline 201 or Part C.3 of the Annex to Commission Regulation (EC) No 440/2008 ⁽¹⁾ for algae,
- ISO 6341 or OECD Test Guideline 202 or Part C.2 of the Annex to Regulation (EC) No 440/2008 for daphnia,
- ISO 7346 or OECD Test Guideline 203 or Part C.1 of the Annex to Regulation (EC) No 440/2008 for fish (only applies to available existing data),
- fish embryo toxicity (FET) (non-animal alternative) test according to OECD Test Guideline 236 or part C.49 of the Annex to Regulation (EC) No 440/2008 for fish (only applies when a test needs to be performed for the application).

Only acute aquatic toxicity (72 or 96 hr) ErC₅₀ for algae, (48hr) EC₅₀ for daphnia and (96hr) LC₅₀ for fish are accepted.

Chronic aquatic toxicity data (available) shall originate from tests carried out according to:

- ISO 10253 or ISO 8692 or OECD Test Guideline 201 or Part C.3 of the Annex to Regulation (EC) No 440/2008 for algae,
- Part C.20 of the Annex to Regulation (EC) No 440/2008 or OECD Test Guideline 211 for daphnia,
- OECD Test Guideline 215 or Part C.14 of the Annex to Regulation (EC) No 440/2008 or ISO 12890 or OECD Test Guideline 212 or part C.15 of the Annex to Regulation (EC) No 440/2008 or OECD Test Guideline 210 for fish.

Only chronic toxicity data in the form of No Observed Effect Concentration (NOEC) data shall be accepted.

When QSARs are used to fill data gaps, the applicant shall provide the prediction generated for the target chemical. Results of (Q)SARs shall only be accepted if documentation on the validity and applicability domain of the applied model is provided by the applicant.

In the case of slightly soluble substances or mixtures (< 10 mg/l) the method of the water-accommodated fraction (WAF) can be used in the aquatic toxicity determination. The established loading level referred to as LL50 and related to the lethal loading or the EL50 related to the effective loading for acute aquatic toxicity and NOELR related to the no observable effect loading rate for chronic aquatic toxicity may be used directly in the classification criteria. The preparation of a water-accommodated fraction shall follow the recommendations set out according to one of the following guidelines: Appendix C to ECETOC Technical Report No 26 (1996), OECD 2002 Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures (OECD Series on Testing and Assessment, No 23), ISO 5667-16 Water quality — Sampling — Part 16 (Guidance on biotesting of samples),

⁽¹⁾ Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 142, 31.5.2008, p. 1).

ASTM D6081-98 (Standard practice for Aquatic Toxicity Testing for Lubricants: Sample Preparation and Results Interpretation) or equivalent methods. In addition, demonstration of the absence of toxicity for a substance at its limit of water solubility shall be deemed to have met the requirements of this criterion.

The following substances are exempted from requirements 2.1 and 2.2:

- any substance which is unlikely to cross biological membranes $MM > 800$ g/mol and with a molecular diameter $> 1,5$ nm (> 15 Å), or
- any substance which is a polymer and whose molecular weight fraction below 1 000 g/mol is less than 1 %, or
- any substance which is highly insoluble in water (water solubility < 10 µg/l)

The water solubility of substances shall be determined where appropriate according to OECD Test Guideline 105 or Part A.6 of the Annex to Regulation (EC) No 440/2008 or equivalent test methods.

A polymer molecular weight fraction below 1 000 g/mol shall be determined according to Part A.19 of the Annex to Regulation (EC) No 440/2008 or OECD Test Guideline 119 or equivalent test methods.

CRITERION 3 — BIODEGRADABILITY AND BIOACCUMULATIVE POTENTIAL

Requirements for the biodegradability of organic compounds and bioaccumulative potential shall be fulfilled by each intentionally added or formed substance at or above the concentration of 0,10 % weight by weight in the final product.

The lubricant shall not contain substances that are both non-biodegradable and (potentially) bioaccumulative. However, the lubricant may contain one or more substances with a certain degree of degradability and potential or actual bioaccumulation up to a cumulative mass concentration as indicated in Table 4.

Table 4

Cumulative mass percentage (%w/w) limits for substances present in the product with respect to their biodegradability and bio-accumulation potential

	ALL	PLL	TLL	Greases (ALL,PLL,TLL)
Readily aerobically biodegradable	> 90	> 75	> 95	> 80
Inherently aerobically biodegradable	≤ 10	≤ 25	≤ 5	≤ 20
Non-biodegradable and non-bioaccumulative	≤ 5	≤ 20	≤ 5	≤ 15
Non-biodegradable and bioaccumulative	$\leq 0,1$	$\leq 0,1$	$\leq 0,1$	$\leq 0,1$

Assessment and verification

For each substance where the assessment is carried out by the applicant, test reports or literature data including the references on the biodegradability and when required on the (potential) bioaccumulation shall be provided.

For each substance where the assessment is based on a valid letter of compliance (LoC), only a copy of the letter shall be provided.

For each substance selected from the Lubricant Substance Classification list (LuSC-list) the assessment can be based on the information reported in said list and no documents need to be submitted.

Biodegradation

'Inherently biodegradable' means a substance, which achieves the following level of degradation:

> 70 % after 28 days for inherent biodegradation test, or

> 20 % but < 60 % after 28 days in tests based on oxygen depletion or carbon dioxide generation.

Inherent biodegradability shall be measured in accordance with the following tests:

- Regulation (EC) No 440/2008 (Part C.9 of the Annex), OECD 302 or equivalent methods,
- tests based on oxygen depletion or carbon dioxide generation: Regulation (EC) No 440/2008 (Part C.4 of the Annex), OECD 306, OECD 310, or equivalent methods.

'Readily biodegradable' means an arbitrary classification of chemicals which have passed certain specified screening tests for ultimate biodegradability; these tests are so stringent that it is assumed that such compounds will rapidly and completely biodegrade in aquatic environments under aerobic conditions. Substances are considered rapidly degradable in the environment if one of the following criteria holds true:

1. if, in 28-day ready biodegradation studies, at least the following levels of degradation are achieved:

- tests based on dissolved organic carbon: 70 %,
- tests based on oxygen depletion or carbon dioxide generation: 60 % of theoretical maximum.

These levels of biodegradation must be achieved within 10 days of the start of degradation which point is taken as the time when 10 % of the substance has been degraded, unless the substance is identified as an UVCB or as a complex, multi-constituent substance with structurally similar components. In this case, and where there is sufficient justification, the 10-day window condition may be waived and the pass level applied at 28 days; or

2. if, in those cases, where only BOD and COD data are available, when the ratio of BOD₅/COD is $\geq 0,5$; or

3. if other convincing scientific evidence is available to demonstrate that the substance can be degraded (biotically and/or abiotically) in the aquatic environment to a level > 70 % within a 28-day period.

Ready biodegradability shall be measured in accordance with the following tests:

- Regulation (EC) No 440/2008 (Part C.4, C.5 in conjunction with C.6 and C.42 of the Annex), OECD 301, OECD 306, OECD 310, or equivalent methods.

Note: Within the frame of this criterion, the 10-day window principle will not necessarily apply. If the substance reaches the biodegradation pass level within 28 days but not within the 10-day time-window a slower degradation rate is assumed.

'Non-biodegradable' means a substance which fails the criteria for ultimate and inherent biodegradability.

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

Bioaccumulation

The (potential) bioaccumulation does not need to be established when the substance:

- has a MM > 800 g/mol and has a molecular diameter $> 1,5$ nm (> 15 Å), or
- has an octanol-water partition coefficient, $\log K_{ow}$, value of < 3 or > 7 , or
- has a measured BCF of ≤ 100 l/kg, or
- is a polymer and its molecular weight fraction below 1 000 g/mol is less than 1 %.

Since most substances used in lubricants are quite hydrophobic the bioconcentration factor (BCF) value should be based on the lipid weight content and care must be shown to ensure a sufficient exposure time. The BCF shall be assessed according to Part C.13 of the Annex to Regulation (EC) No 440/2008 or equivalent test methods.

The log octanol/water partition coefficient ($\log K_{ow}$) shall be assessed according to Part A.8 of the Annex to Regulation (EC) No 440/2008 or OECD 123 or equivalent test methods. In case of an 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. Estimated log K_{ow} values obtained by any of these calculation methods < 3 or > 7 indicate that the substance is not expected to bioaccumulate.

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

CRITERION 4 — RENEWABLE INGREDIENTS REQUIREMENTS

- (a) In the specific case of renewable ingredients from palm oil or palm kernel oil, or derived from palm oil or palm kernel oil, 100 % w/w of the renewable ingredients used shall meet the requirements for sustainable production of a certification scheme that is a multi-stakeholder organisation with a broad membership, including NGOs, industry and government and that addresses environmental impacts on soil, biodiversity, organic carbon stocks and conservation of natural resources.
- (b) If the term 'bio-based' or 'bio-lubricant' is used, the minimum bio-based carbon content in the final product shall be 25 % in accordance with EN 16807.

Assessment and verification

To demonstrate compliance with criterion 4(a) evidence through third-party chain of custody certificates that the input materials used in the manufacturing originate from sustainably managed plantations shall be provided. Roundtable for Sustainable Palm Oil (RSPO) certificates or certificates of any equivalent or stricter sustainable production scheme demonstrating compliance to any of the following models: identity preserved, segregated, mass balance shall be accepted. For palm oil and palm kernel oil derivatives, the amounts of RSPO credits purchased and claimed in the RSPO PalmTrace system model during the most recent annual trading period shall be provided to demonstrate compliance to the Book and Claim supply chain model.

To demonstrate compliance with criterion 4(b) the applicant shall enclose the final product test report in accordance with EN 16807, ASTM D 6866, DIN CEN/TS 16137 (SPEC 91236), EN 16640 or EN 16785-1.

CRITERION 5 — PACKAGING/CONTAINER REQUIREMENTS

- (a) Recycled content (applicable only in the case of lubricants sold in plastic packaging/container): plastic packaging/container shall be made of a minimum of 25 % of post-consumer plastic.
- (b) Design (applicable only in the case of lubricants designed to be sold to private end-consumers): the packaging/container should have an appropriate system (e.g. prolongation systems or narrow apertures) in order to avoid spillage during use.

Assessment and verification

The applicant shall provide the following evidence as applicable:

The composition of the plastic packaging/container and the shares of recycled and virgin material. If necessary, a declaration of compliance from the plastic packaging/container supplier shall be included.

Post-consumer plastic means plastic generated by households or by commercial, industrial and institutional facilities in their role as end-users of the product which can no longer be used for its intended purpose. This includes returns of plastic from the distribution chain.

Post-consumer plastic content shall be calculated as shown below. As there are no methods available for directly measuring the recycled content in a product or packaging, the mass of plastic obtained from the recycling process, after accounting for losses and other diversions, shall be used.

$$X(\%) = A/P \times 100$$

Where:

X is the (post-consumer) recycled content

A is the mass of the recycled (post-consumer) plastic

P is the mass of the packaging/container

A description of the design of the packaging/container, along with photos or technical drawings, shall also be provided.

CRITERION 6 — MINIMUM TECHNICAL PERFORMANCE

The lubricant product shall comply with the corresponding minimum technical performance requirements as specified in Table 5.

Table 5

Minimum technical performance for lubricant products

Lubricant category	Minimum technical performance
Chainsaw oils	KWF test version 2017 test or equivalent
— Wire rope lubricants — Concrete release agents — Other total loss lubricants — Stern tube oils — Metalworking fluids	'Fit for purpose' demonstrated by at least one 'applicant's clients' approval'
Gear oils	gear oils (closed gears): ISO 12925-1 or DIN 51517 (Section I, II or III) gear oils (open gears): 'Fit for purpose' demonstrated by at least one 'applicant's clients' approval'.
Two-stroke oils	two-stroke marine: NMMA TC-W3 two-stroke terrestrial: ISO 13738 (EGD)
Hydraulic systems	ISO 15380 (Tables 2 to 5) Fire resistant hydraulic fluids: ISO 15380 (Tables 2 to 5) + ISO 12922 (Table 1 to 3) or Factory Mutual Approval
Temporary protection against corrosion	ISO/TS 12928 or 'Fit for purpose' demonstrated by at least one 'applicant's clients' approval'.
Lubricating greases	Greases for temporary protection against corrosion: ISO/TS 12928 or 'Fit for purpose' demonstrated by at least one 'applicant's clients' approval'. Greases for closed gear: DIN 51826 Greases for roller bearings, plain bearings and sliding surfaces: DIN 51825 All other greases: ISO 12924 or 'Fit for purpose' demonstrated by at least one 'applicant's clients' approval'

Note: Multipurpose greases that include any of the above specified applications among their potential uses shall be tested according to the corresponding specific test of the relevant specified application.

Assessment and verification

The applicant shall provide a declaration of compliance with this criterion supported by testing results, where appropriate.

For hydraulic systems, it shall be indicated on the product information sheet which elastomers have been tested.

Applicant's clients' approval means a letter/document/statements issued by clients for a specific product, assuring that the product met their specifications and works correctly in its intended application.

CRITERION 7 — CONSUMER INFORMATION REGARDING USE AND DISPOSAL

In the case of lubricants designed to be sold to private end-consumers, the following information (in text form or pictograms) shall be present on the packaging/container (comparable text formulations are permitted):

'Avoid any spillage of unused product to the environment',

'Product residue and package/container should be disposed of in dedicated collection points'.

Assessment and verification

The applicant shall provide a sample of the product container/packaging or its artwork where the above information appears.

CRITERION 8 — INFORMATION APPEARING ON THE EU ECOLABEL

The optional label with text box may contain the following text:

- (a) 'Less hazardous substances ending up in the environment';
- (b) 'Verified performance';
- (c) 'X % of certified renewable ingredients used' (where relevant) ⁽¹⁾,

The guidelines for the use of the optional label with text box can be found in the 'Guidelines for the use of the EU Ecolabel logo' on the website:

http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf

Assessment and verification

The applicant shall provide a sample of the label. If statement c) is used, the applicant shall provide the relevant certificate(s) related to the percentage of certified renewable ingredient(s) used.

⁽¹⁾ If certified renewable ingredients are used, regardless of the type of biomass (e.g. rapeseed, sunflower, palm, soy, etc.), total content of certified ingredients can be indicated.