BLUE ANGEL

The German Ecolabel



Biodegradable Lubricants and Hydraulic Fluids

DE-UZ 178

Basic Award Criteria
Edition January 2022
Version 2

The Environmental Label is supported by the following four institutions:









The Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection is the owner of the label. It regularly provides information on the decisions taken by the Environmental Label Jury.

The German Environmental Agency with its specialist department for "Ecodesign, Eco-Labelling and Environmentally friendly Procurement" acts as office of the Environmental Label Jury and develops the technical criteria of the Basic Criteria for Award of the Blue Angel.

The Environmental Label Jury is the independent, decision-making body for the Blue Angel and includes representatives from environmental and consumer associations, trade unions, industry, the trade, crafts, local authorities, academia, the media, churches, young people and the German federal states.

The RAL gGmbH is the awarding body for the Environmental Label. It organises the process for developing the relevant award criteria in independent expert hearings – which involve all relevant interest groups.

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This document is a translation of a German original. In case of dispute, the original document should be taken as authoritative.

1 Introduction

1.1 **Preface**

In cooperation with the Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection, the German Environmental Agency and considering the results of the expert hearings conducted by RAL gGmbH, the Environmental Label Jury has set up these Basic Criteria for the Award of the Environmental Label. RAL gGmbH has been tasked with awarding the Environmental Label.

Upon application to RAL gGmbH and on the basis of a Contract on the Use of the Environmental Label to be concluded with RAL gGmbH, the permission to use the Environmental Label may be granted to all products, provided that they comply with the requirements as specified hereinafter.

The product must comply with all the legal requirements in the country in which it is to be marketed. The applicant shall declare that the product meets this requirement.

1.2 **Background**

The environmental label DE-UZ 178 "Biodegradable Lubricants and Hydraulic Fluids" can be used to certify products where it is highly probable that they will be released into the environment during their intended use or there is a good likelihood that they could be released into the environment. The latter applies in the case of e.g. hydraulic fluids, which are actually used in enclosed systems but could nevertheless be released into the environment in certain quantities due to leakages or accidents.¹

The main requirement for the award of this ecolabel was and is the biodegradability of the ingredients in the products. There is generally no doubt that the release of the substances covered by the scope of these Basic Award Criteria will be somewhat problematic and could certainly cause environmental damage. However, this type of damage is limited due to the biodegradability of the components so that any affected habitats can recover and regenerate within a foreseeable period of time.

Lubricants are used in various applications where the substance is released into the environment as part of its intended use and/or its release cannot be fully avoided. These applications include, for example, the lubrication of switch points, rails, block trains and similar applications in which there is significant loss of the lubricant during the intended use (total-loss lubrication), as well as during formwork. Considerable amounts of lubricants, forming oils or bitumen release agents are used in these applications and may be released into the environment to a certain extent. Total-loss lubrication of motor saws during logging also causes the release of chain lubricants into the environment. Even if they are used as intended, hydraulic fluids may escape into the environment in an uncontrolled way due to leakages and other defects, such as accidents. These lubricants can thus also be certified with the Blue Angel in accordance with these criteria.

If the lubricants contain components that are toxic to humans or the environment or which have insufficient biodegradability, the release of these substances into the environment can have a significant adverse effect on the environmental media of soil and water. This negative impact should be minimized in order to preserve intact ecosystems and avoid any indirect effect on

Appropriate emergency measures should be taken in the event of incidents such as accidents and oil spills (see emergency measures in the event of accidents involving mineral oil: https://www.goec-ev.com/wp-content/uploads/2021/11/ListedergeprueftenOelbindemittel-10-<u>2021.pdf</u>)

human health. In the context of this ecolabel, this is achieved by restricting the use of substances that are toxic to humans or the environment and also restricting the use of hardly biodegradable and non-biodegradable substances to the level that is strictly necessary for technical reasons. The toxicity and environmental behaviour of the products are also tested using standard testing systems that are an accepted part of the regulatory framework, such as those found in the test methods regulation² as part of REACH³ or the collection of methods for the testing of chemicals published by the OECD⁴

Alongside the toxicity and environmental behaviour of the lubricant, the environmental impact caused during the production of the individual raw materials is becoming an increasingly important aspect. The Basic Award Criteria for this product group will thus place more emphasis on this aspect of the environmental impact of lubricants in future. For this purpose, criteria will be introduced that specifically focus on sustainability aspects during the production and processing of the raw materials. The information that is collected here will be used as the basis for future revisions of the Basic Award Criteria.

Against this background, the question of whether and to what extent it is practical to replace fossil raw materials with raw materials from renewable resources is becoming an increasingly important issue in political debates dealing with product policy. In the area of "Biodegradable Lubricants and Hydraulic Fluids", biogenic raw materials have been used as alternatives to mineral oil-based components for a long time due to their often better toxicological profile and beneficial environmental behaviour. Biogenic raw materials are particularly sustainable when they have been produced under environmentally friendly production conditions. A variety of certification systems have been established for this purpose. They address both the environmental and also the social aspects of biomass production and make it possible to verify the source of the biomass along the supply chain. The advantages offered by these farming methods will be emphasised in this Blue Angel ecolabel and will thus be established as the basis for the use of renewable resources in the production of the certified lubricants by placing requirements on the supply chains that will enable further developments in the future. Alongside the use of renewable resources, the use of post-consumer recycled materials (PCR) for the plastics in the packages and containers is another positive step for the conservation of resources. For this reason, the Basic Award Criteria will require a minimum proportion of PCR plastics in the plastic packages and containers in the future in order to generate demand for these materials and also to make a contribution to the achievement of the national targets for a circular economy and support the European "Circular Economy Strategy".

1.3 Objectives of the Environmental Label

The environmental label for "Biodegradable Lubricants and Hydraulic Fluids" should make it possible for users to select those final products that help to minimise environmental pollution and

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Council 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)

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

OECD Test Guidelines for Chemicals <u>https://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm</u>

significantly reduce the negative effects on flora and fauna due to their low (eco-)toxicological hazard potential and good biodegradability.

Another aim is to harmonize these criteria, where possible and reasonable, with the criteria for the EU ecolabel⁵. In particular, the aim is to further harmonise these Basic Award Criteria with the EU ecolabel with respect to the efficient use of renewable raw materials in the future.

In order to achieve this goal, these Basic Award Criteria contain a series of test and verification requirements with respect to the toxicological effect and degradation behaviour of the components used in the lubricant formulation. Lubricants and hydraulic fluids can be produced using high amounts of biogenic raw materials, which is already common practice in some areas. By imposing additional requirements with respect to the certified origins of the biomass, the Blue Angel aims to help make the production processes for these raw materials more sustainable. In addition, the requirements placed on the products themselves and their packages and containers are designed to promote the use of post-consumer recycled materials and thus support the goal of a circular economy.

Therefore, following benefits for the environment and health are stated in the explanatory box:



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- biodegradable
- · low level of harmful materials

1.4 Definitions

For the purpose of their use in these Basic Award Criteria, the following definitions are valid:

- **Additive**⁶: Substance or mixture whose primary functions are the improvement of the flow, ageing, lubricity, anti-wear properties or of contaminant suspension.
- Base fluid: A substance used as the base material for lubricants. This means a lubricating fluid or base 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.
- Book&claim: Sustainable plantations are promoted though the sale of certificates. Companies purchase these certificates via a trading platform (e.g. RSPO Credits) based on the quantity of oil required for the production of surfactants.
- **Component**: In the sense of these Basic Award Criteria, a component may be a substance or mixture that has been added to the formulation of a lubricant. This may be a base fluid, additive or thickener.
- **Final product**: Within the scope of these Basic Award Criteria, the final product describes the lubricant offered for sale on the market that should be labelled with the Blue Angel ecolabel.
- Grease: A mixture consisting of a base fluid, thickener and possibly additives.

See Commission Decision of 24 June 2011 (2018/1702/EU) http://data.europa.eu/eli/dec/2018/1702/oj

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The term additive should be equated with the definition given for additives (Paragraph 5.2) in the report CEN/TR 16227:2011 and the (open) list of functions for these additives contained therein.

- **Impurity**⁷: An unintended constituent present in a substance as manufactured. It may originate from the starting materials or be the result of secondary or incomplete reactions during the manufacturing process. While it is present in the final substance it was not intentionally added.
- **Lubricant**: All final products within the scope of these Basic Award Criteria. The term covers e.g. lubricating oils, greases, formwork release oils and hydraulic fluids. A lubricant is a preparation consisting of base fluids and additives.
- Mass balance: In the mass balance model, sustainable palm oil from certified plantations is mixed with conventional, non-certified palm oil in the value added chain. In this process, the proportion of the certified goods is checked and verified so that no more of the end product is labelled as being certified than the amount of certified palm oil before the mixing process. The certified palm oil is recorded and monitored administratively as it is transferred. The mass balance option thus enables sustainable goods to be verified at every stage of the product chain, without having to establish an additional infrastructure for a parallel supply chain. Due to the fact that the certified and conventional goods are not physically separated, it enables the mass balance goods to be traded within the supply chain really easily. This option is especially relevant for the use of palm kernel oil and its derivatives.
- **Mixture**⁴: Mix, mixture or solution composed of two or more substances.
- **Polymer**: A substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:
 - A simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;
 - Less than a simple weight majority of molecules of the same molecular weight. In the context of this definition, a "monomer unit" means the reacted form of a monomer substance in a polymer.
- **Post-consumer materials (PCR material):** Material generated by households or by commercial, industrial and institutional facilities in their role as end users of the goods or service which can no longer be used for its intended purpose. This includes returns of material from the distribution chain.
- **Segregation:** Palm oil from different production locations that is sourced from sustainable plantations is kept separate from other non-certified palm oils along the whole supply chain.
- **Substance**⁸: A chemical element and its compounds in the natural state or obtained by any manufacturing 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.

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Guidance for identification and naming of substances under REACH and CLP, Version 2.1 May 2017, Chapter 2.2, P. 15, https://echa.europa.eu/documents/10162/23036412/substance id en.pdf/ee696bad-49f6-4fec-b8b7-2c3706113c7d

⁸ REACH, Article 3 and CLP Regulation, Article 2

- **Substances of very high concern**⁹: In the sense of these Basic Award Criteria, substances of very high concern are all substances that have been included in the list of candidates¹⁰ in Annex XIV to the REACH Regulation.
- **Thickener**: An organic or inorganic component used to achieve a certain consistency of the lubricant under the conditions of use of the lubricant.

2 Scope

These Basic Award Criteria apply to the following final products for commercial and private use¹¹: Lubricants designed for the following areas of application

- 2.1. Lubricants for processes where lubricant loss may occur when used as intended (total-loss lubrication).
 - 2.1.1. This includes lubricants that are released into the environment for the most part during their intended use, e.g. lubricants for switch points and rails, as well as lubricants for open bearings, guides or sealing purposes (including stern tube greases).
 - 2.1.2. Lubricants for the glass industry.
 - 2.1.3. Concrete release agents for use in formwork.
 - 2.1.4. Release agents for use in asphalt paving work.
- 2.2. Hydraulic fluids (pressure fluids) for use especially in eco-sensitive hydraulic systems, as well as tractor transmission oils.
- 2.3. Chain lubricants for motor saws.
- 2.4. Transmission lubricants¹² for industry and shipping.
- 2.5. Greases.

Motor oils are excluded from these Basic Award Criteria.

3 Requirements

The final products named under Paragraph 2 can be labelled with the environmental label illustrated on the first page of these Basic Award Criteria if they fulfil the requirements in all of the Paragraphs below.

Unless stated otherwise, the following requirements and compliance verifications apply equally to all final product groups. Deviating rules for certain final product groups will be highlighted in the relevant Paragraph to indicate any differentiation between different final product groups.

3.1 General product description

In order to apply for this ecolabel, the recipe for the product must be submitted to RAL gGmbH. All substances with a concentration of > 0.01 % by mass that are added to the product or which are formed due to a chemical reaction in the lubricant must be clearly stated with their name and mass concentration in the product, as well as their CAS number and EC number where

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⁹ REACH Article 57, substances of very high concern (SVHC).

¹⁰ Available from the European Chemicals Agency(ECHA) at http://echa.europa.eu/el/candidate-list-table. An unofficial German version can also be viewed on the German REACH-CLP Helpdesk at https://www.reach-clp-biozid-helpdesk.de/de/REACH/Kandidatenliste/Kandidatenliste.html.

¹¹ The scope can be expanded to cover other final products not classified in groups 2a) - 2e) if ratified by the Environmental Label Jury

¹² e. g. transmission lubricants for wind power plants

relevant. It is irrelevant here whether the added substances perform a function or are present in the final product as an impurity.

The individual components must be assigned to the categories "base fluids", "thickeners" and "additives":

- In the case of additives, the relevant group according to the LuSC list should also be stated.
- The basis for the base fluids should also be stated (mineral, biogenic). In the case of base fluids with a biogenic basis, the basic material must also be stated (e.g. rapeseed, palm oil, animal fat).
- In the case of substances classified as non-biodegradable substances according to these Basic Award Criteria, the applicant must submit their precise designation (name, CAS number), their content and their technical function.

Compliance verification

The applicant shall submit the recipe for the final product to the awarding body in Annex 2. In addition, the applicant shall enclose a safety data sheet with the application documents in accordance with Regulation (EC) No. 1907/2006 Article 31 under consideration of the CLP Regulation. If a substance is not covered by the REACH Regulation and there is thus no safety data sheet, the manufacturer/supplier of the substance must submit a declaration about this matter.

3.2 Requirements under European chemicals law to be met by the final product

The following requirements restrict or prohibit the use of certain substances in the formulation of the lubricants due to their intrinsic properties.

The following applies to all final products within the scope of these Basic Award Criteria: They must not meet any of the classification criteria according to Annex I to Regulation (EU) 1272/2008. This means that the final products themselves must not be classified.

3.2.1 Requirements under European chemicals law to be met by the substances and mixtures used as components of the lubricant

Final products within the scope of these Basic Award Criteria must not contain any substances or mixtures (column 2) with the classifications (column 1) listed in the following table. Impurities in substances and mixtures added to the product that meet the criteria described below in quantities above the stated limits (column 3) are not permitted.

Hazard category CLP Regulation		for substances 13 in the final	Limit [%] for impurities in the sub- stance ¹⁵	
Muta. 1[A,B]	H340	0	≤ classification limit	
Muta. 2	H341	0	≤ classification limit	
Carc. 1[A,B]	H350 H351i	0	≤ classification limit	
Carc. 2	H351	0	≤ classification limit	

¹³ This also applies to possible decomposition products where it must be assumed that they have carcinogenic, mutagenic and/or reprotoxic properties.

¹⁴ The classification limit refers to the respective concentration in the final product that would lead to a classification of the final product under the provisions of Regulation (EC) No 1272/2008.

¹⁵ The classification limit refers to the respective concentration in the substance that would lead to a classification of the substance under the provisions of Regulation (EC) No 1272/2008.

Hazard category according to CLP Regulation			Limit [%] for impurities in the sub- stance ¹⁵	
Repr. 1[A,B]	H360F H360D H360FD H360Fd H360Df	0	≤ classification limit	
Repr. 2	H361f H361d H361fd	0	≤ classification limit	
Lact.	H362	0	≤ classification limit	
Acute Tox. 1 Acute Tox. 2	H300 (oral)	0	≤ classification limit for Acute Tox. 4	
Acute Tox. 1 Acute Tox. 2	H310 (dermal)	0	≤ classification limit for Acute Tox. 4	
Acute Tox. 1 Acute Tox. 2	H330 (inhal.)	0	≤ classification limit for Acute Tox. 4	
Acute Tox. 3	H301 (oral)	0	≤ classification limit for Acute Tox. 4	
Acute Tox. 3	H 311 (dermal)	0	≤ classification limit for Acute Tox. 4	
Acute Tox. 3	H331 (inhal.)	0	≤ classification limit for Acute Tox. 4	
Acute Tox. 4	H302 (oral)	0.5 x classification limit for Acute Tox. 4	_	
Acute Tox. 4	H312 (dermal)	0.5 x classification limit for Acute Tox. 4	_	
Acute Tox. 4	H332 (inhal.)	0.5 x classification limit for Acute Tox. 4	_	
Asp. Tox. 1	H304	0.5 x classification limit ¹⁶ for Asp. Tox. 1	_	
STOT SE 1	H370 H372	0	≤ classification limit for STOT SE 2	
STOT SE 2	H371 H373	0.5 x classification limit for STOT SE 2	_	
STOT SE 3	H335 H336	< classification limit for STOT SE 3	_	
Skin Corr. 1[A,B,C]	H314	< classification limit for Skin Irrit. 2	_	
Skin Irrit. 2	H315	< classification limit for Skin Irrit. 2	_	
Eye Dam. 1	H318	< classification limit for Eye Irrit. 2	_	
Eye Irrit. 2	H319	< classification limit for Eye Irrit.	_	
Resp. Sens. 1[A,B]	H334	< classification limit for Resp. Sens. 1[A,B,C]	_	
Skin Sens. 1[A,B]	H317	< classification limit for Skin Sens. 1[A,B,C]	_	
Aquatic Acute 1	H400	0	< classification limit for Aquatic Acute 1	

 $^{^{16}}$ The concentration is the only criterion considered here. Viscosity has been removed as a criterion.

CLP Regulation		Limit [%] for substances ¹³ in the final product ¹⁴	Limit [%] for impurities in the sub- stance ¹⁵	
Aquatic Chronic 1	H410	0	≤ classification limit for Aquatic Chronic 1	
Aquatic Chronic 2	H411	< classification limit for Aquatic Chronic 3 and 4	_	
Aquatic Chronic 3	H412	< classification limit for Aquatic Chronic 3 and 4	_	
Aquatic Chronic 4	H413	< classification limit for Aquatic Chronic 3 and 4	_	

Moreover, no substances may be added to the final products within the scope of these Basic Award Criteria that are listed according to the current specifications of the German MAK Commission (MAK - maximum workplace concentration) in the corresponding MAK List¹⁷ as carcinogenic, mutagenic or reprotoxic or that may lead to decomposition products where it must be assumed that they have carcinogenic, mutagenic and/or reprotoxic properties.

The above-mentioned substances must not be used in final products to be awarded the Blue Angel ecolabel in accordance with these Basic Award Criteria.

3.2.2 Substances of very high concern

It is prohibited to use substances in final products to be certified with the Blue Angel ecolabel that have been identified in accordance with Article 57 of Regulation (EC) No. 1907/2006 and listed in accordance with Article 59 of the same regulation on the list of candidates⁸ for inclusion in the Annex of substances subject to authorisation. Impurities in substances added to the final product that are on the list of candidates are not permitted.

The label holder is obligated to take into account current developments on the list of candidates.

3.3 Substance restrictions for other relevant substance groups

In addition to the substance restrictions described in Paragraph 3.1, the use of the following substances and substance groups is also restricted. On the one hand, this is because these groups have been identified as being problematic for the environment within the framework of regulatory processes other than REACH and CLP and, on the other hand, because it is known that certain compounds generally represent a problem for the environment – in part during the waste phase of their life cycle.

3.3.1 Substance restrictions on the basis of other regulations

The use of the following substances in final products is prohibited within the scope of these Basic Award Criteria:

Substances on the OSPAR list¹⁸,

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The MAK Collection for Occupational Health and Safety, documentations and methods are compiled by some 100 experts of the Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area of the Deutsche Forschungsgemeinschaft (DFG, German Research Foundation). The Commission is internationally acknowledged for its neutrality, transparency and scientific criteria. Published on the website of the publisher Wiley VCH https://onlinelibrary.wiley.com/doi/book/10.1002/9783527812110

A full list of these substances that has been prepared by the OSPAR Commission can be viewed at http://www.ospar.org/documents?d=32745

- Substances on the EU list of priority substances according to the Water Framework Directive¹⁹,
- Substances categorized in Water Hazard Class (WHC) 2 or 3 according to their classification in the "Ordinance on facilities for handling substances that are hazardous to water" (AwSV)²⁰,

An exemption applies to the use of substances classified in WHC 2 for the production of lubricants according to Paragraphs 2b), 2d) and 2e)²¹.

3.3.2 Substance restrictions due to the substance belonging to certain substance groups

The use of the following substances in final products is prohibited within the scope of these Basic Award Criteria:

The use of the following substances in final products is prohibited within the scope of these Basic Award Criteria:

- Organic halogen compounds,
- Nitrite compounds,
- Metals and metal compounds, except for compounds containing
 - Na,
 - K,
 - Mg,
 - Ca
- as metal atoms.
- **Thickeners** are **also** permitted to contain the following metals:
 - Li,
 - Al.
- Mineral oils for use in release agents for asphalt laying operations,
- Mineral oils for use in chain lubricants for motors saws. The following exemption applies: chain lubricants may have a cumulative mineral oil content of 5 % in the final product if this is exclusively due to the addition of additives.

Compliance verifications for Paragraphs 3.2 and 3.3

Verification of compliance shall be provided in the form of the documents submitted for Paragraph 3.1.

The following also applies for substances of very high concern:

The applicant shall declare compliance with the requirements in Annex 1. In the event of changes to the list of candidates that affect the final product from the applicant, the applicant shall submit a new declaration of compliance to RAL gGmbH within one month to verify that the final product complies with this criterion. The declaration of compliance should be sent to:

RAL gGmbH RAL Environment Fränkische Straße 7

¹⁹ Annex X to Directive 2000/60/EC, updated by Annex II to Directive 2008/105/EC

http://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBl&jumpTo=bgbl117s0905.pdf

If the application of the new AwSV results in any inconsistencies with the current status quo, this will be discussed by RAL and the German Environment Agency.

53229 Bonn

3.4 Additional requirements regarding aquatic toxicity

The applicant must comply with the requirements in either Paragraph 3.4.1 or 3.4.2. Compliance verifications must only be provided for one of these two paragraphs. If testing is carried out in accordance with Paragraph 3.4.1, it may, however, also be necessary to generate additional data for individual components in accordance with Paragraph 3.4.2 as this is required in other sections of these Basic Award Criteria.

No additional compliance verifications according to Paragraphs 3.4.2 and 3.5.1 need to be presented for components appearing on the Lubricant Substance Classification (LuSC) List²² as these components may be considered to have already been adequately tested with regards to these criteria. However, data pursuant to Paragraph 3.5.2 must be additionally provided. The bioaccumulation potential must be determined for inherently biodegradable and non-biodegradable substances. Furthermore, the substances on the LuSC List must be additionally tested for the hazard statements and maximum quantities listed in these Basic Award Criteria.

3.4.1 Requirements to be met by the final product

In terms of the acute or chronic aquatic toxicity of the final product, additional test data must be presented for algae, daphnia and fish.

The following testing methods may be used for algae:

Acute and chronic:

- ISO 10253²³,
- ISO 8692²⁴,
- OECD²⁵ 201 or Part C.3 of the Annex to Regulation (EG) No 440/2008²⁶.

The following testing methods may be used for daphnia:

Acute:

- ISO 6341²⁷,
- OECD 202 or Part C.2 of the Annex to Regulation (EG) No 440/2008.

Chronic:

OECD 211 or Part C.20 of the Annex to Regulation (EG) No 440/2008.

The following testing methods may be used for fish:

Acute:

- OECD 203 or Part C.1 of the Annex for Regulation (EG) No 440/2008 (if already available),
- OECD 236 or Part C.49 of the Annex to Regulation (EG) No 440/2008.

http://ec.europa.eu/environment/ecolabel/documents/LuSC-%20list.pdf

ISO 10253:2016-11 Water quality - Marine algal growth inhibition test with Skeletonema sp. and Phaeodactylum tricornutum https://www.iso.org/standard/34811.html

²⁴ EN ISO 8692, 2012-06. Water quality - Fresh water algal growth inhibition test with unicellular green algae, https://www.iso.org/standard/54150.html

OECD tests for biotic systems: http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-test-ing-of-chemicals-section-2-effects-on-biotic-systems 20745761

²⁶ OECD tests and tests pursuant to Regulation (EC) No. 440/2008 should not be regarded as alternatives, but rather as different sources for the same test.

²⁷ EN ISO 6341, 2013-1. Water quality - Determination of the inhibition of the mobility of Daphnia magna Straus (Cladocera, Crustacea) - Acute toxicity test, https://www.iso.org/standard/54614.html

Chronic:

- OECD 210 or Part C.47 of the Annex to Regulation (EG) No 440/2008,
- OECD 212 or Part C.15 of the Annex to Regulation (EG) No 440/2008,
- OECD 215 or Part C.14 of the Annex to Regulation (EG) No 440/2008.

From the acute tests, only the following tests will be accepted: (72 h) EC50 for algae²⁸, (48 h) EC50 for daphnia²⁹ and (96 h) LC50 for fish³⁰. From the chronic tests, only the respective NOEC will be accepted for the three levels.

If no fish tests according to the above-mentioned regulations exist, they must not be regenerated for the purpose of verifying compliance within the scope of the Blue Angel. An exception exists for OECD 236 or Part C.49 of the Annex to Regulation (EC) No 440/2008, which is not regarded as a vertebrate test and, accordingly, may be conducted. If tests are regenerated, OECD 236 or Part C.49 of the Annex to Regulation (EC) No 440/2008 must be used as the test methods for daphnia or algae or for fish. Tests for least two trophic levels must be verified.

Lubricants according to Paragraphs 2.1, 2.3 and 2.5 must comply with a threshold of 1000 mg/l in acute tests and 100 mg/l in chronic tests.

Lubricants according to Paragraphs 2.2 and 2.4 must comply with a threshold of 100 mg/l in acute tests and 10 mg/l in chronic tests.

Compliance verification

The applicant shall declare compliance with the requirements in Annex 1. In addition, the application shall preferably be accompanied by the test reports, or at least the robust study summaries³¹, for the above-mentioned tests. If the applicant is required to submit declarations, documentation, analyses, test reports or other compliance verifications to the competent body to prove compliance with the criteria, these can come from the applicant and/or his/her suppliers and/or their suppliers, etc. The suppliers of substances are entitled to directly present the corresponding information to the competent body. The tests must be carried out by laboratories that meet the general requirements of the EN ISO 17025 standard or an equivalent standard (e.g. GLP). Compliance with these requirements shall be verified in writing by the respective testing laboratories in the form of a corresponding certificate. If required, the competent bodies may ask for additional verification documents.

 E_r C50 = median inhibitory concentration of the growth rate

²⁹ EC50 is the statistically calculated concentration of a substance that is expected to make 50 % of the exposed daphnia unable to swim within the test period.

The median acute lethal concentration LC50 is the statistically calculated concentration of a substance that is expected to cause the death of 50 % of the exposed fish within the test period.

^{31 &}quot;Robust study summary: A detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study and minimising the need to consult the full study report." ECHA "Guidance on Registration", Version May 2012, p. 80

http://echa.europa.eu/documents/10162/13632/registration_de.pdf. There is a practical guide available from ECHA that provides further details on the creation of a robust study summary, including some examples, at: http://echa.europa.eu/documents/10162/13643/pg report robust study summaries de.pdf

3.4.2 Requirements to be met by the components

a) If data on the components in the final products³² are provided, the following criteria must be met.

In terms of the chronic aquatic toxicity of the components, chronic test data (No Observed Effect Concentration – NOEC) must be submitted for two of the three trophic levels: daphnia and fish.

If no corresponding chronic data (NOEC) are available, the acute test data for each of the three trophic levels – algae, daphnia and fish – can be used.

Components are considered "non-toxic" in the sense of this criterion if:

- acute aquatic toxicity > 100 mg/l or
- NOEC> 10 mg/l.

Such components may be used in unlimited quantities in final products within the scope of these Basic Award Criteria.

Components are considered "harmful" in the sense of this criterion if:

- 10 mg/l < acute toxicity ≤ 100 mg/l or
- 1 mg/l < NOEC \leq 10 mg/l.

The following thresholds apply to the use of such components:

If they are used in lubricants according to Paragraphs 2a) and 2e), their cumulative content may not exceed a maximum of 25 %.

If they are used in lubricants according to Paragraphs 2b) and 2d), their cumulative content may not exceed a maximum of 20 %.

If they are used in lubricants according to Paragraph 2c), their cumulative content may not exceed a maximum of 5 %.

Components are considered "toxic" in the sense of this criterion if:

- 1 mg/l < acute toxicity ≤ 10 mg/l or
- 0.1 mg/l < NOEC ≤ 1 mg/l.

The following thresholds apply to the use of such components³³:

If they are used in lubricants according to Paragraphs 2a) and 2e), their cumulative content may not exceed a maximum of 1 %.

If they are used in lubricants according to Paragraphs 2b) and 2d), their cumulative content may not exceed a maximum of 5 %.

If they are used in lubricants according to Paragraph 2c), their cumulative content may not exceed a maximum of 0.5 %.

Components are considered "very toxic" in the sense of this criterion if:

Data must only be submitted for components with a content ≥ 0.1 % by mass in the final product where an upper limit of 0.5 % by mass for non-evaluated substances may not be exceeded.

These substances can, in certain circumstances, be classified as "Hazardous to the Aquatic Environment – Chronic Hazard Category 2" or "Category 3" (depending on its degradation behaviour and its degradability). In such cases, the requirement 3.2.1 for "Category 2" substances results in an upper limit of 2.5 % since otherwise the final product would have to be classified and, as a consequence, this criterion would no longer be met (Category 3 would allow a maximum of 25 % of such substances so that this criterion would result in a further restriction of substances hazardous to water.).

NOEC $\leq 0.1 \text{ mg/l}^{34}$.

The following thresholds apply to the use of such components³⁵:

If they are used in lubricants according to Paragraphs 2.1 and 2.5, 2.2 and 2.3, their cumulative content may not exceed a maximum of 0.1 %.

If they are used in lubricants according to Paragraph 2.4, their cumulative content may not exceed a maximum of 1 %.

The following testing methods may be used:

Chronic:

- 21-day daphnia test (OECD 211 or Part C.20 of the Annex to Regulation (EC) No 440/2008),
- Chronic fish tests (OECD 210, 212 or 215 or Part C.14 or C.15 of the Annex to Regulation (EC) No 440/2008).

Acute:

- Daphnia test for acute toxicity (OECD 202 or Part C.2 of the Annex to Regulation (EC) No 440/2008),
- Algae test (OECD 201 or Part C.3 of the Annex to Regulation (EC) No 440/2008),
- Fish test (OECD 203, OECD 236 or Part C.1 or Part C.49 of the Annex to Regulation (EC) No 440/2008).

If there is no acute or chronic fish test available for the product, performing a new test as verification for the Blue Angel is not permitted because this involves testing vertebrate animals (exception OECD 236 or Part C49 of the Annex for Regulation (EG) No 440/2008). If tests are regenerated, OECD 236 or Part C49 of the Annex to Regulation (EC) No 440/2008 must be used as the test methods for daphnia and algae or for fish. Tests for least two trophic levels must be verified.

- b) In the case of complex or multi-component substances, the Water Accommodated Fraction (WAF) concept is the method of choice to verify the harmlessness of the components. This test must be conducted in accordance with the guidance provided in the following standards:
 - OECD 2019, Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, OECD Series on Testing and Assessment, No. 23 (Second Edition),
 - ISO 5667-16,

• ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R.7b: Endpoint specific guidance Version 4.0 June 2017³⁶.

The threshold for an acute test would automatically lead to a classification as "Hazardous to the Aquatic Environment - Acute Hazard Category 1 (H400)". However, these substances are excluded from use in principle pursuant to Paragraph 3.2.1. Acute test data are thus not required in this case.

An evaluation on the basis of chronic toxicity must not necessarily lead to a classification as "Hazardous to the Aquatic Environment – Chronic Hazard Category 1" but can also lead to classification in "Category 2". A maximum cumulative content of 2.5 % would thus be admissible for these substances (according to Paragraph 3.2.1). M-Factors are not taken into account in this criterion because substances containing these factors are excluded from use in accordance with Paragraph 3.2.1.

https://echa.europa.eu/documents/10162/13632/information_requirements_r7b_en.pdf/1a551efc-bd6a-4d1f-b719-16e0d3a01919

c) In addition, the criterion is considered to be fulfilled if the component is found to be non-toxic at the limit of its water-solubility in one of the above-mentioned tests. For this purpose, the water solubility of the components must be expressed in mg/l.

Compliance verification

The applicant shall declare compliance with the requirements in Annex 1. In addition, the application shall preferably be accompanied by the test reports, or at least the robust study summaries, for the above-mentioned tests. If the applicant is required to submit declarations, documentation, analyses, test reports or other compliance verifications to the competent body to prove compliance with the criteria, these can come from the applicant and/or his/her suppliers and/or their suppliers, etc. The suppliers of substances are entitled to directly present the corresponding information to the competent body. The tests must be carried out by laboratories that meet the general requirements of the EN ISO 17025 standard or an equivalent standard (e.g. GLP). Compliance with these requirements shall be verified in writing by the respective testing laboratories in the form of a corresponding certificate. If required, the competent bodies may ask for additional verification documents.

3.5 Degradability and bioaccumulation potential of the substances

Substances used in lubricants within the scope of these Basic Award Criteria must be tested for their biodegradability and their bioaccumulation potential³⁷.

The following substance groups are exempt from this requirement:

- a) inorganic additives (mineral additives),
- b) inorganic thickeners (mineral thickeners)³⁸,
- c) thickeners made of water-insoluble biopolymers (from naturally occurring components, such as polysaccharides, waxes and resins),
- mineral thickeners or thickeners made of chemically modified biopolymers, which are nonbiodegradable and, at the same time, immobile (leachability by water from the lubricant < 1 mg/l),
- e) polymers if:
 - water solubility L < 1 mg/l
 and
 - the percentage of molecules with a molecular weight ≤ 1000 g/mol is less than 1 %,
- f) substances with a solubility $< 10 \mu g/l$,
- g) substances unlikely to cross biological membranes. This would be the case if
 - the molar mass (MM) > 1100 g/mol and
 - the molecule diameter > 1.7 nm (> 17 Å).

For all substances that fall under these exemptions, it is assumed that they are non-biodegradable. In addition, these substances must be tested to verify their ecotoxicological impact. The compliance verification must be carried out in accordance with Paragraph 3.4.2 of these Basic Award Criteria.

The immobility of modified thickeners and polymers must be verified using OECD test 105 or Part A.6 of the Annex to Regulation (EC) No 440/2008). The low-molecular weight content of

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Data must only be submitted for substances with a content ≥ 0.1 % by mass in the final product where an upper limit of 0.5 % by mass for non-evaluated substances may not be exceeded for this criterion.

³⁸ This includes e.g. graphite as the mineral form of carbon.

polymers must be verified on the basis of the relevant material-specific DIN ISO or DIN EN standards.

3.5.1 Biodegradability

Biodegradability is subdivided into three categories:

- a) The substances are readily biodegradable.
- b) The substances are inherently biodegradable in a 28-day test.
- The substances do not comply with the previous criteria and are thus considered to be nonbiodegradable.

The content of readily biodegradable substances in a final product within the scope of these Basic Award Criteria must be at least 95 % by mass. The proportion of non-biodegradable substances must not exceed 2 % by mass of the final product³⁹. The final products listed in Paragraph 2a) bullet point 1 and 2c) under "Scope" are exempt from this requirement. For these final products, the content of readily biodegradable substances must be at least 90 % by mass. The proportion of non-biodegradable substances must not exceed 2 % by mass of the final product⁴⁰. If phenolic antioxidants are used, however, the proportion of non-biodegradable substances must not exceed 3 % by mass. Moreover, the substances must not exhibit any bioaccumulation potential pursuant to Paragraph 3.5.2 of these Basic Award Criteria. Compliance must be verified in accordance with this paragraph of the Basic Award Criteria.

- a) The substances are readily biodegradable. Substances are considered to be readily biodegradable if, in either of the tests below, they achieve more than 60 % of the theoretical maximum value on the basis of oxygen consumption or CO_2 formation.
- b) The substances are inherently biodegradable if
 - ullet biodegradability > 70 % can be verified in an inherent degradation test or
 - more than 20 % but less than 60 % of the theoretical maximum value is achieved in a test for ready biodegradability on the basis of oxygen consumption or CO₂ formation.
- c) The substances do not comply with the previous criteria and are thus considered to be non-biodegradable.

The following tests⁴¹ may be used to verify full biodegradability: To verify compliance with the requirements in a):

19/20

³⁹ The following are excluded from this requirement: inorganic additives, inorganic thickeners, thickeners made of water-insoluble biopolymers as well as chemically modified mineral thickeners or chemically modified thickeners made of biopolymers which are non-biodegradable and used in greases (Paragraph 2.5 of the Scope). The total of the proportions of inherently biodegradable components, the proportions of non-biodegradable components and the proportions of the tested exempted substances pursuant to Paragraph 3.5 (except for polymers) must not exceed 20 % by mass in the final product.

The proportion of polymers used in the final products under Paragraphs 2.1.1 and 2.3 must be added to the proportion of inherently biodegradable substances.

⁴¹ The 10-day window principle does not have to be applied in these tests for full biodegradability. If a substance reaches the pass level for biodegradability within 28 days but not within the 10-day window, a lower degradation rate may be assumed.

- 28-day test determination of ready biodegradability C.4 (C-F) of the Annex to Regulation (EG) No 440/2008 or OECD 301 (B,C,D,F),
- 28-day test determination of ready biodegradability C.4 (C- C.29 of the Annex to Regulation (EG) No 440/2008 or OECD 310,
- OECD 306 or C.42 of the Annex to Regulation (EG) No 440/2008. A substance-specific or DOC measurement is not permitted in this test.

The following tests may be used to verify inherent biodegradability:

To verify compliance with the requirements in b), bullet point 1:

- OECD 302 B or Part C.9 of the Annex to Regulation (EG) No 440/200842,
- OECD 302 C.

To verify compliance with the requirements in b), bullet point 2:

- 28-day test according to Part C.4 (C-F) of the Annex to Regulation (EG) No 440/2008 or OECD 301 (B,C,D,F),
- OECD 306 or C.42 of the Annex to Regulation (EG) No 440/2008. A substance-specific or DOC measurement is not permitted in this test.
- OECD 310 or C.29 of the Annex to Regulation (EG) No 440/2008.

Testing the biodegradability of poorly water-soluble substances places high demands on the addition of the test substance. Technical advice is provided in the following documents:

- OECD 301, Annex III: Evaluation of the biodegradability of poorly soluble compounds,
- ISO 10634:2018-10 Water quality Preparation and treatment of poorly water-soluble organic compounds for the subsequent evaluation of their biodegradability in an aqueous medium,
- ASTM D6081-20 Standard Practice for Aquatic Toxicity Testing of Lubricants: Sample Preparation and Results Interpretation,
- ECETOC-technical report Nr. 20 Biodegradation Tests of Poorly-Soluble Compounds (1986)⁴³.

Compliance verification

The applicant shall declare compliance with the requirements in Annex 1. In addition, the application shall preferably be accompanied by the test reports, or at least the robust study summaries, for the above-mentioned tests. If the applicant is required to submit declarations, documentation, analyses, test reports or other compliance verifications to the competent body to prove compliance with the criteria, these can come from the applicant and/or his/her suppliers and/or their suppliers, etc. The suppliers of substances are entitled to directly present the corresponding information to the competent body. The tests must be carried out by laboratories that meet the general requirements of the EN ISO 17025 standard or an equivalent standard (e.g. GLP). Compliance with these requirements shall be verified in writing by the respective testing laboratories in the form of a corresponding certificate. If required, the competent bodies may ask for additional verification documents.

⁴² DOC-based tests are only suitable for water-soluble compounds with a low tendency for absorption.

^{43 &}lt;a href="http://www.ecetoc.org/wp-content/uploads/2014/08/ECETOC-TR-020.pdf">http://www.ecetoc.org/wp-content/uploads/2014/08/ECETOC-TR-020.pdf

3.5.2 Bioaccumulation potential of the substances

If substances used in lubricants within the scope of these Basic Award Criteria are considered to be inherently biodegradable or non-degradable, they must be tested for their biodegradability potential.

A potential for bioaccumulation is assumed if

- the bioconcentration factor (BCF) > 500, or if
- no experimentally determined BCF exists and if the log octanol/water partition coefficient log $P_{OW} \ge 3.0$ and ≤ 10

or if

the substance is surface active.

A substance is considered surface active if the surface tension in an aqueous solution is within the measurement range of 1 g/l < 50 mN/m (to be verified using OECD test 115 or Part A.5 of the Annex to Regulation (EC) No 440/2008).

In technically justified cases, substances with a log $P_{OW} > 6.0$ may be permissible.

The following tests may be used to verify the bioaccumulation potential:

- on the basis of the log Pow value: Part A.8 of Regulation (EG) No 440/2008 or OECD tests 107, 117 or 123 or
- on the basis of the BCF value: Part C.13 of Regulation (EG) No 440/2008 or OECD 305.

If the log P_{OW} value cannot be determined experimentally, it can be determined instead using the following calculation methods:

- CLOGP⁴⁴,
- LOGKOW⁴⁵,
- KOWWIN⁴⁶ and
- SPARC⁴⁷.

Log Pow values are only valid for organic substances. In the case of other compounds, the bioaccumulation potential must be determined using the BCF.

Compliance verification

The applicant shall declare compliance with the requirements in Annex 1. In addition, the application shall preferably be accompanied by the test reports, or at least the robust study summaries, for the above-mentioned tests. If the applicant is required to submit declarations, documentation, analyses, test reports or other compliance verifications to the competent body to prove compliance with the criteria, these can come from the applicant and/or his/her suppliers and/or their suppliers, etc. The suppliers of substances are entitled to directly present the corresponding information to the competent body. The tests must be carried out by laboratories that meet the general requirements of the EN ISO 17025 standard or an equivalent standard (e.g. GLP). Compliance with these requirements shall be verified in writing by the respective testing laboratories

46 http://esc.syrres.com/esc/kowwin.htm

^{44 &}lt;a href="http://www.organic-chemistry.org/prog/peo/cLogP.html">http://www.organic-chemistry.org/prog/peo/cLogP.html

⁴⁵ http://logkow.cisti.nrc.ca/

^{47 &}lt;a href="http://ibmlc2.chem.uga.edu/sparc/">http://ibmlc2.chem.uga.edu/sparc/

in the form of a corresponding certificate. If a substance with a log Pow > 6.0 must be used because it cannot be replaced for technical reasons by substances without bioaccumulation potential pursuant to these Basic Award Criteria, a corresponding justification shall be presented in writing. If required, the competent bodies may ask for additional verification documents.

3.6 Instructions for disposal

3.6.1 Hydraulic fluids (pressure fluids) for use especially in eco-sensitive hydraulic systems as well as tractor transmission oils

Used rapidly degradable hydraulic fluids must be identified and collected in accordance with the applicable provisions of the German Waste Oil Ordinance. In terms of waste law, they are classified as hazardous wastes (waste codes: 13 01 12*48, 13 02 07*, possibly 13 01 11* or 13 01 13*) and will be taken back by licensed waste management and recycling facilities named by the manufacturer and treated in accordance with the current waste management regulations. The users of the hydraulic fluids must be informed appropriately.

The relevant waste code pursuant to Annex 1 to the German Waste Oil Ordinance must be clearly indicated on the hydraulic liquid containers or alternatively in the accompanying product information. The user information must include recommendations for finding the appropriate disposal channels.

Compliance verification

The applicant shall declare compliance with the requirements in Annex 1. In addition, the applicant shall enclose a copy of the relevant user information and container labelling with the application.

3.6.2 Transmission lubricants for industry and shipping

Used rapidly degradable transmission lubricants must be identified and collected in accordance with the applicable provisions of the German Waste Oil Ordinance. In terms of waste law, they are classified as hazardous wastes (waste codes: mostly 13 02 07*, possibly 13 02 05*, 13 02 06* or 13 02 08*) and will be taken back by licensed waste management and recycling facilities named by the manufacturer and treated in accordance with the current waste management regulations. The users of the transmission lubricants must be informed appropriately.

The relevant waste code pursuant to Annex 1 to the German Waste Oil Ordinance must be clearly indicated on the transmission lubricant containers or alternatively in the accompanying product information. The user information must include recommendations for finding the appropriate disposal channels.

Compliance verification

The applicant shall declare compliance with the requirements in Annex 1. In addition, the applicant shall enclose a copy of the relevant user information and container labelling with the application.

⁴⁸ The "*" symbol indicates a hazardous waste pursuant to the European Waste Catalogue (implemented in German law in the Waste Catalogue Ordinance (Abfallverzeichnisverordnung).

3.6.3 Greases

Used rapidly degradable greases must be identified and collected in accordance with the applicable regulations. In terms of waste law, they are classified as hazardous wastes (waste codes: mostly 12 01 12*, possibly also 12 01 99) and will be taken back by licensed waste management and recycling facilities named by the manufacturer and treated in accordance with the current waste management regulations. The users of the greases must be informed appropriately. The relevant waste code pursuant to Annex 1 to the German Waste Oil Ordinance must be clearly indicated on the grease containers or alternatively in the accompanying product information. The user information must include recommendations for finding the appropriate disposal channels.

Compliance verification

The applicant shall declare compliance with the requirements in Annex 1. In addition, the applicant shall enclose a copy of the relevant user information and container labelling with the application.

3.7 Technical requirements and application areas

3.7.1 Lubricants for processes where lubricant loss may occur when used as intended (total-loss lubrication).

The lubricants and release agents must meet the relevant requirements for their fitness for use and safety in the respective area of application.

Compliance verification

The applicant shall indicate the main area of application for the final product and declare compliance with the requirement in Annex 1.

3.7.2 Hydraulic fluids (pressure fluids) for use especially in eco-sensitive hydraulic systems as well as tractor transmission oils

The hydraulic fluids must meet the minimum technical requirements according to ISO 15380. The areas of application for the hydraulic fluids must be indicated on the product data sheet. The container, as well as the product data sheet, must include the following text in connection with the Blue Angel ecolabel "meets the technical requirements of ISO 15380". If the product's viscosity class differs from this standard, the applicant must declare the product's fitness for use by way of analogy. In addition, the material code for the base fluid must be indicated.

Compliance verification

The applicant shall declare compliance with the requirements in Annex 1 and submit a test report verifying compliance with the technical requirements in this paragraph.

3.7.3 Chain lubricants for motor saws

The final product must be fit for use in accordance with the guidelines established by the "German Center for Forest Work and Technology" (KWF) (Kuratoriums für Waldarbeit und Forsttechnik) for the testing of chain lubricants for motor saws⁴⁹.

Compliance verification

The applicant shall declare compliance with the requirements in Annex 1 and submit a test report from the KWF every four years (term of the Basic Award Criteria) confirming compliance with the requirements defined above.

3.7.4 Transmission lubricants for industry and shipping

The transmission lubricants must meet the relevant requirements for their fitness for use and safety in the respective area of application in accordance with DIN 51517 Part 1-3. The performance classes must be indicated.

The fitness for use must also be declared for transmission greases.

Compliance verification

The applicant shall indicate the main area of application for the final product and declare compliance with the requirement in Annex 1.

3.7.5 Greases

The fitness for use for the respective area of application must be declared for greases.

Compliance verification

The applicant shall indicate the main area of application for the final product and declare compliance with the requirement in Annex 1.

3.8 Requirements for renewable raw materials

If base fluids based on renewable raw materials are used, the following requirements apply:

3.8.1 Palm oil or palm kernel oil or their derivatives

If renewable ingredients made out of palm oil or palm kernel oil or their derivatives are used, 100 % by mass of the renewable base fluid must comply with the requirements of a certification system for sustainable production, which is based on a multi-stakeholder organisation with a broad based membership (including NGOs, industry and government) and focuses on the impact on the environment, including on soil, biodiversity, stocks of organic carbon and the conservation of natural resources.

Compliance verification

To verify compliance with the sustainability requirements, the applicant must prove that the palm oil or palm kernel oil or their derivatives used in the product meet the requirements for sustainable biomass production according to the Roundtable on Sustainable Palm Oil (RSPO)⁵⁰.

⁴⁹ For further details, inquiries and a KFW contact, please go to http://www.kwf-online.org/home.html?no cache=1

⁵⁰ https://www.rspo.org/

It is not permitted to use purchased certificates based on the Book & Claim system. The proofs of purchase for the raw materials or semi-finished products must be based on processes according to the segregation or mass balance systems.

3.8.2 Other biogenic base fluids

If other biomass is used for the base fluid, 100 % by mass of this biomass must comply with the requirements of a certification system for sustainable production, which is based on a multistakeholder organisation with a broad based membership (including NGOs, industry and government) and focuses on the impact on the environment, including on soil, biodiversity, stocks of organic carbon and the conservation of natural resources. Alternatively, the biomass can be sourced from a recycling process (animal fat, used cooking oil) after it has already been used for another application.

Compliance verification

To verify compliance with the sustainability requirements, the applicant must prove that the biomass used in the product meets the requirements for sustainable biomass production according to one of the following certification systems:

- Roundtable on Sustainable Biomaterials (RSB)⁵¹.
- International Sustainability and Carbon Certification (ISCC PLUS)⁵².

If the base fluid is certified according to another system, the applicant shall state the raw material and the name of the certification system. Other certification systems include:

- RTRS
- REDcert
- REDcert2
- ISCC
- SAN
- Öko-Landbau-Siegel (German organic label, EU organic logo "Euro Leaf")

If it is not yet possible to provide this verification, it is permissible for the applicant to submit a plausible justification on an annual basis stating the name of the raw material.

In each of these three cases, the applicant shall also state whether the compliance verification is based on the Book & Claim, mass balance or segregation systems.

Quantities of recycled materials, such as animal fat or old cooking oil, are exempt from the requirement for certification. Verification from the recycling company must be submitted instead 53 .

3.9 Packages/containers

Lubricants may only be sold in plastic packages/containers if at least 25 % of the total mass of the package/container is accounted for by PCR plastic.

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⁵¹ https://rsb.org

https://www.iscc-system.org/

In the case of recycled materials, the applicant shall also submit verification that the materials are free of toxic materials and biodegradable.

The minimum proportion of 25 % recycled plastic can also be calculated based on the total quantity of the packages/containers that are used for the products certified with the Blue Angel. This means that some packages/containers can contain 100 % recycled materials and some 0 % recycled materials, as long as the average proportion of recycled materials across the total quantity of packages/containers used for the product certified with the Blue Angel is 25 % by mass.

As an alternative to PCR plastic, reusable plastic containers⁵⁴ are also permitted. In this case, the applicant must submit documentation about the reusable container system and a description of how the reusable container system is communicated to customers. In addition, delivery notes or similar documents must be submitted to verify the reuse of the containers.

Compliance verification

The compliance verifications for this criterion can be provided in the following form:

- A declaration from the plastics manufacturer on the recycled content (stating the types of plastic used, both the new plastics and also the recyclates)
- A calculation by the lubricant manufacturer based on the total quantity of packages/containers used in one year

The following documents must be submitted for the reusable packages/containers:

- Documentation about the reusable container system
- A declaration on how the reusable container system is communicated to customers
- Additional verifications such as delivery notes that prove that the packages/containers have actually been reused.

3.10 Advertising messages

- The type of lubricant according to Paragraph 2 must be stated on the container and the technical data sheet together with the product designation.
- Advertising messages must not include any information that could play down the risks in the sense of Article 48 of Regulation (EC) 1272/2008, (e.g. "non-toxic", "non-harmful", "free of ...").
- Advertising messages must not include any vague and unspecific environmental statements. Product designations, including name components or terms, such as "eco-safe", "naturefriendly" or similar are not permitted.
- The term "bio" may be used in accordance with the requirements of DIN CEN/TR 16227:2011-10⁵⁵ and DIN EN 16807⁵⁶. In this case, the bio-based carbon content must be determined in accordance with ASTM D-6866⁵⁷ or DIN CEN/TS 16137 (DIN SPEC 91236)⁵⁸

⁵⁴ The reuse of the container is a waste avoidance measure (Article 3 (21) Circular Economy Act (KrWG)) by which products or components that are not waste are used again for the same purpose for which they were originally intended.

^{55 &}lt;u>http://www.nmp.din.de/cmd?level=tpl-art-detailansicht&committeeid=54738983&ar-</u> $\underline{tid} = 136544127 \& bcrumblevel = 1 \& languageid = de$

⁵⁶ DIN EN 16807 Liquid petroleum products - Bio-lubricants - Criteria and requirements of bio-lubricants and bio-based lubricants

http://www.astm.org/Standards/D6866.htm

⁵⁸ Plastics – Determination of the bio-based carbon content; German version CEN/TS 16137:2011: DIN CEN/TS 16137 (SPEC 91236):2011-07

- or CEN/TS 16640⁵⁹. The ratio of the bio-based carbon content to the total carbon content of the lubricant must also be calculated and indicated in increments of 5 %.
- In the case of mineral oil-based lubricants and lubricants with a biomass content of less than 25 % by mass in the final product, it is not permitted to use the advertising message "bio". It is not necessary to determine the bio-based carbon content in this case.

Compliance verification

The applicant shall declare compliance with the requirements and submit the corresponding technical data sheet, as well as the container text.

To verify the bio-based carbon content, the applicant shall submit a test report on the final product in accordance with ASTM D 6866 or DIN CEN/TS 16137 (SPEC 91236):2011-07.

3.11 Information for the end consumer

The container texts and the technical data sheets for lubricants intended for sale to end consumers must include the following information in an easy to read form (comparable wording is permitted):

- "Keep out of the reach of children",
- "Do not allow unused product to enter drains, water bodies, ground or soil",
- "Product residues must be disposed of at municipal collection facilities",
- "Only pass on empty containers for recycling".

The use of corresponding pictograms is also permitted.

Compliance verification

The applicant shall declare compliance with the requirement and submit the corresponding technical data sheet and the container text.

3.12 Overview of possible future requirements

In the event of a revision of the Basic Award Criteria, the following requirements are likely to be examined in particular:

- Examining whether the biodegradability of the lubricant formula should be tested.
- Examining whether to require certification of all of the biomass used in the product, based on the experience with the current rules according to Paragraph 3.9.
- Examining whether to introduce comparable sustainability criteria for the procurement of mineral oil-based raw materials, e.g.:
 - Minimising the environmental impact caused by the processing of mineral oil (e.g. carbon footprint of products, use of renewable energy sources to operate the plant, etc.).
 - Verification of the origin of the crude oil, from sources with the best possible environmental and social standards.
- Examining the availability of standardised test batteries for testing the terrestrial toxicity of individual components and/or the finished formula for the lubricant.

⁵⁹ DIN CEN/TS 16640:2014-05; DIN SPEC 35800:2014-05 Bio-based products - Determination of the bio-based carbon content using the radiocarbon method.

4 Applicants and Parties Involved

Manufacturers of final products according to Paragraph 2 shall be eligible for application.

Parties involved in the award process are:

- RAL gGmbH to award the Blue Angel Environmental Label,
- the federal state being home to the applicant's production site,
- Umweltbundesamt (German Environmental Agency) which after the signing of the contract receives all data and documents submitted in applications for the Blue Angel in order to be able to further develop the Basic Award Criteria.

5 Use of the Environmental Label

The use of the Environmental Label by the applicant is governed by a contract on the use of the Environmental Label concluded with RAL gGmbH.

Within the scope of such contract, the applicant undertakes to comply with the requirements under Paragraph 3 while using the Environmental Label.

Contracts on the Use of the Environmental Label are concluded to fix the terms for the certification of products under Paragraph 2. Such contracts shall run until December 31, 2026.

They shall be extended by periods of one year each, unless terminated in writing by March 31, 2026 or March 31 of the respective year of extension.

After the expiry of the contract, the Environmental Label may neither be used for labelling nor for advertising purposes. This regulation shall not affect products being still in the market.

The applicant (manufacturer) shall be entitled to apply to RAL gGmbH for an extension of the right to use the ecolabel on the product entitled to the label if it is to be marketed under another brand/trade name and/or other marketing organisations.

The Contract on the Use of the Environmental Label shall specify:

- Applicant (manufacturer)
- Brand/trade name, product description
- Distributor (label user), i.e. the above-mentioned marketing organisations.

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Appendix A Cited legislations and standards, literature

- American Society for Testing and Materials International, 2020, ASTM D6081-20, Standard Practice for Aquatic Toxicity Testing of Lubricants: Sample Preparation and Results Interpretation, http://www.astm.org/cgi-bin/resolver.cgi?D6081-20
- American Society for Testing and Materials International, 2021, ASTM D6866-21, Standard
 Test Methods for Determining the Biobased Content of Solid, Liquid, and Gaseous Samples
 Using Radiocarbon Analysis, http://www.astm.org/cgi-bin/resolver.cgi?D6866-21
- Federal Ministry of Justice and Consumer Protection, 2017, Ordinance on facilities for handling substances that are hazardous to water (AwSV), https://www.gesetze-im-internet.de/awsv/
- The Convention for the Protection of the Marine Environment of the North-East Atlantic, 2004, OSPAR List of Chemicals for Priority Action (Revised 2013), https://www.ospar.org/work-areas/hasec/hazardous-substances/priority-action
- German Institute for Standardisation (Deutsches Institut für Normung e.V.), 2000, DIN EN ISO 14024:2000-06, Environmental labels and declarations Type I environmental labelling Principles and procedures (ISO 14024:1999); German version prEN ISO 14024:2000, https://www.beuth.de/de/norm-entwurf/din-en-iso-14024/33104062
- German Institute for Standardisation (Deutsches Institut für Normung e.V.), 2011, DIN CEN/TR 16227:2011-10, DIN SPEC 51523:2011-10, Liquid petroleum products Bio-lubricants Recommendation for terminology and characterisation of bio-lubricants and bio-based lubricants; German version CEN/TR 16227:2011, https://dx.doi.org/10.31030/1734263
- German Institute for Standardisation (Deutsches Institut für Normung e.V.), 2011, DIN SPEC 51523:2011-10, Liquid petroleum products Bio-lubricants Recommendation for terminology and characterisation of bio-lubricants and bio-based lubricants; German version CEN/TR 16227:2011, https://dx.doi.org/10.31030/1734263
- German Institute for Standardisation (Deutsches Institut für Normung e.V.), 2012, DIN EN ISO 8692:2012-06, Water quality Fresh water algal growth inhibition test with unicellular green algae (ISO 8692:2012); German version EN ISO 8692:2012, https://dx.doi.org/10.31030/1858340
- German Institute for Standardisation (Deutsches Institut für Normung e.V.), 2013, DIN EN ISO 6341:2013-01, Water quality Determination of the inhibition of the mobility of Daphnia magna Straus (Cladocera, Crustacea) Acute toxicity test (ISO 6341:2012); German version EN ISO 6341:2012, https://dx.doi.org/10.31030/1911255
- German Institute for Standardisation (Deutsches Institut für Normung e.V.), 2014, DIN CEN/TS 16640:2014-05 DIN SPEC 35800:2014-05, Bio-based products Determination of the bio-based carbon content using the radiocarbon method; German version CEN/TS 16640:2014, https://www.beuth.de/de/technische-regel/din-cen-ts-16640/188006892
- German Institute for Standardisation (Deutsches Institut für Normung e.V.), 2014, DIN 51517-3:2014-02, Lubricants Lubricating oils Part 3: Lubricating oils CLP, Minimum requirements, https://www.beuth.de/de/norm/din-51517-3/195676544
- German Institute for Standardisation (Deutsches Institut für Normung e.V.), 2016, Liquid petroleum products Bio-lubricants Criteria and requirements of bio-lubricants and bio-based lubricants; German version EN 16807:2016, https://dx.doi.org/10.31030/2408093

- German Institute for Standardisation (Deutsches Institut für Normung e.V.), 2017, DIN EN 16640:2017-08, Bio-based products Bio-based carbon content Determination of the bio-based carbon content using the radiocarbon method; German version EN 16640:2017, https://dx.doi.org/10.31030/2675158
- German Institute for Standardisation (Deutsches Institut für Normung e.V.), 2018, DIN EN ISO 10253:2018-08, Water quality Marine algal growth inhibition test with Skeletonema sp. and Phaeodactylum tricornutum (ISO 10253:2016); German version EN ISO 10253:2016, https://dx.doi.org/10.31030/2529892
- German Institute for Standardisation (Deutsches Institut für Normung e.V.), 2018, DIN EN ISO/IEC 17025:2018-03, General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2017); German and English version EN ISO/IEC 17025:2017, https://dx.doi.org/10.31030/2731745
- German Institute for Standardisation (Deutsches Institut für Normung e.V.), 2019, DIN EN 17228:2019-06, Plastics Bio-based polymers, plastics, and plastics products Terminology, characteristics and communication; German version EN 17228:2019, https://dx.doi.org/10.31030/3016405
- German Institute for Standardisation (Deutsches Institut für Normung e.V.), 2019, DIN EN ISO 5667-16:2019-03, Water quality Sampling Part 16: Guidance on biotesting of samples (ISO 5667-16:2017); German version EN ISO 5667-16:2017, https://dx.doi.org/10.31030/2590908
- German Institute for Standardisation (Deutsches Institut für Normung e.V.), 2020, DIN ISO 15380:2020-12, Lubricants, industrial oils and related products (class L) Family H (Hydraulic systems) Specifications for hydraulic fluids in categories HETG, HEPG, HEES and HEPR (ISO 15380:2016), https://dx.doi.org/10.31030/3196085
- European Chemicals Agency, 2016, Guidance on registration, https://echa.eu-ropa.eu/de/guidance-documents/guidance-on-reach
- European Chemicals Agency, 2017, Guidance on Information Requirements and Chemical Safety Assessment Chapter R.7b: Endpoint specific guidance, https://echa.europa.eu/doc-uments/10162/17224/information requirements r7b en.pdf/1a551efc-bd6a-4d1f-b719-16e0d3a01919
- European Commission, 2011, 2011/381/EU: COMMISSION DECISION of 24 June 2011 on establishing ecological criteria for the award of the EU Ecolabel to lubricants, http://data.europa.eu/eli/dec/2011/381/oj
- European Commission, 2018, COMMISSION DECISION (EU) 2018/1702 of 8 November 2018 establishing the EU Ecolabel criteria for lubricants, http://data.eu-ropa.eu/eli/dec/2018/1702/oj
- European Commission, 2018, Lubricant Substance Classification list (LuSC list), https://ec.europa.eu/environment/ecolabel/documents/LuSC-list%20vs%20200120%2018-1702%20without%20track%20changes.pdf
- European Parliament and Council of the European Union, 2000, 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, http://data.europa.eu/eli/dir/2000/60/oj
- European Parliament and Council of the European Union, 2004, DIRECTIVE 2004/9/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 February 2004 on the inspection and verification of good laboratory practice (GLP), http://data.europa.eu/eli/dir/2004/9/oj
- European Parliament and Council of the European Union, 2006, REGULATION (EG) 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, http://data.europa.eu/eli/reg/2006/1907/2014-04-10

- European Parliament and Council of the European Union, 2008, REGULATION (EG) 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, http://data.europa.eu/eli/reg/2008/1272/oj
- European Centre for Ecotoxicology and Toxicology of Chemicals, 1986, Technical Report No 20 Biodegradation Tests for Poorly-Soluble Compounds February 1986 ISSN 0773-8072, https://www.ecetoc.org/publication/tr-020-biodegradation-tests-of-poorly-soluble-com-pounds/
- International Organization for Standardization, 2016, ISO 10253:2016-11, Water quality —
 Marine algal growth inhibition test with Skeletonema sp. and Phaeodactylum tricornutum,
 https://www.iso.org/standard/66657.html
- International Organization for Standardization, 2018, ISO 10634:2018-10, Water quality —
 Preparation and treatment of poorly water-soluble organic compounds for the subsequent
 evaluation of their biodegradability in an aqueous medium, https://www.iso.org/stand-ard/69573.html
- Commission of the European Communities, 2008, Council Regulation (EG) 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), http://data.europa.eu/eli/reg/2008/440/oj
- Organisation for Economic Co-operation and Development, 1992, Test No. 301: Ready Biodegradability, OECD Guidelines for the Testing of Chemicals, Section 3, https://doi.org/10.1787/9789264070349-en
- Organisation for Economic Co-operation and Development, 1992, Test No. 302B: Inherent Biodegradability: Zahn-Wellens/ EVPA Test, OECD Guidelines for the Testing of Chemicals, Section 3, https://doi.org/10.1787/9789264070387-en
- Organisation for Economic Co-operation and Development, 1992, Test No. 306: Biodegradability in Seawater, OECD Guidelines for the Testing of Chemicals, Section 3, https://doi.org/10.1787/9789264070486-en
- Organisation for Economic Co-operation and Development, 1995, Test No. 105: Water Solubility, OECD Guidelines for the Testing of Chemicals, Section 1, https://doi.org/10.1787/9789264069589-en
- Organisation for Economic Co-operation and Development, 1995, Test No. 107: Partition Coefficient (n-octanol/water): Shake Flask Method, OECD Guidelines for the Testing of Chemicals, Section 1, https://doi.org/10.1787/9789264069626-en
- Organisation for Economic Co-operation and Development, 1995, Test No. 115: Surface Tension of Aqueous Solutions, OECD Guidelines for the Testing of Chemicals, Section 1, https://doi.org/10.1787/9789264069787-en
- Organisation for Economic Co-operation and Development, 1998, Test No. 212: Fish, Short-term Toxicity Test on Embryo and Sac-Fry Stages, OECD Guidelines for the Testing of Chemicals, Section 2, https://doi.org/10.1787/9789264070141-en

- Organisation for Economic Co-operation and Development, 2000, Test No. 215: Fish, Juvenile Growth Test, OECD Guidelines for the Testing of Chemicals, Section 2, https://doi.org/10.1787/9789264070202-en
- Organisation for Economic Co-operation and Development, 2004, Test No. 117: Partition Coefficient (n-octanol/water), HPLC Method, OECD Guidelines for the Testing of Chemicals, Section 1, https://doi.org/10.1787/9789264069824-en
- Organisation for Economic Co-operation and Development, 2004, Test No. 202: Daphnia sp. Acute Immobilisation Test, OECD Guidelines for the Testing of Chemicals, Section 2, https://doi.org/10.1787/9789264069947-en
- Organisation for Economic Co-operation and Development, 2006, Test No. 123: Partition Coefficient (1-Octanol/Water): Slow-Stirring Method, OECD Guidelines for the Testing of Chemicals, Section 1, https://doi.org/10.1787/9789264015845-en
- Organisation for Economic Co-operation and Development, 2006, Test No. 310: Ready Biodegradability - CO2 in sealed vessels (Headspace Test), https://doi.org/10.1787/9789264016316-en
- Organisation for Economic Co-operation and Development, 2011, Test No. 201: Freshwater Alga and Cyanobacteria, Growth Inhibition Test, OECD Guidelines for the Testing of Chemicals, Section 2, https://doi.org/10.1787/9789264069923-en
- Organisation for Economic Co-operation and Development, 2012, Test No. 211: Daphnia magna Reproduction Test, OECD Guidelines for the Testing of Chemicals, Section 2, https://doi.org/10.1787/9789264185203-en
- Organisation for Economic Co-operation and Development, 2012, Test No. 305: Bioaccumulation in Fish: Aqueous and Dietary Exposure, OECD Guidelines for the Testing of Chemicals, Section 3, https://doi.org/10.1787/9789264185296-en
- Organisation for Economic Co-operation and Development, 2013, Test No. 210: Fish, Early-life Stage Toxicity Test, OECD Guidelines for the Testing of Chemicals, Section 2, https://doi.org/10.1787/9789264203785-en
- Organisation for Economic Co-operation and Development, 2013, Test No. 236: Fish Embryo Acute Toxicity (FET) Test, OECD Guidelines for the Testing of Chemicals, Section 2, https://doi.org/10.1787/9789264203709-en
- Organisation for Economic Co-operation and Development, 2018, Series on Testing and Assessment. No 23 Second Edition Guidance Document on Aqueous-Phase Aquatic Toxicity Testing of Difficult Test Chemicals, https://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.html
- Organisation for Economic Co-operation and Development, 2019, Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, https://www.oecd.org/env/guidance-document-on-aquatic-toxicity-testing-of-difficult-sub-stances-and-mixtures-0ed2f88e-en.html
- Organisation for Economic Co-operation and Development, 2019, Test No. 203: Fish, Acute Toxicity Test, OECD Guidelines for the Testing of Chemicals, Section 2, https://doi.org/10.1787/9789264069961-en
- The Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area, 2002, The MAK Collection for Occupational Health and Safety, https://onlinelibrary.wiley.com/doi/book/10.1002/9783527812110

Appendix B Overview of the criteria

Other substance restrictions:

		Limit [%] for substances in the final product	Limit [%] for impurities in the substance
List of candidates ⁶⁰		0	0
	carcinogenic	0	-
MAK list	germ cell mutagenic	0	-
1150	reprotoxic	0	-

3.2 Substance restrictions for other relevant substance groups

Other lists:

	Limit [%] for substances in the final product	Limit [%] for impurities in the substance
OSPAR list	0	0
EU list of priority substances according to the Water Framework Directive	0	0

Water hazard classes (WHC):

	2.1	2.2	2.3	2.4	2.5
WHC 2	No	Yes	No	Yes	Yes
WHC 3	No	No	No	No	No

Certain substance groups:

	2.1	2.2	2.3	2.4	2.5
Organic halogen com- pounds	No	No	No	No	No
Nitrite com- pounds	No	No	No	No	No
Metals and metal compounds	No	No	No	No	No
• Na, K, Mg, Ca	Yes	Yes	Yes	Yes	Yes
• Li, Al	No	No	No	No	Yes, in thickeners
Mineral oils	Yes, except for use in release agents for as- phalt laying op- erations	Yes	No, cumulatively up to 5 % by addition of mineral oil con- taining additives	Yes	Yes

 $^{^{60}\,}$ according to Article 57 and 59 of the REACH Regulation (EC) No. 1907/2006

3.3 Additional requirements regarding aquatic toxicity

3.3.1 Requirements to be met by the final product

The following tests may be used:

The following tests may be used:						
Algae	 ISO/DIS 10253 ISO 8692 OECD 201 Part C.3 of the Annex to Regulation (EG) No 440/2008 	only 72 h EC50				
Daphnia (acute)	ISO 6341OECD 202Part C.2 of the Annex to Regulation (EG) No 440/2008	only 48 h EC50				
Daphnia (chronic)	 OECD 211 Part C.20 of the Annex to Regulation (EG) No 440/2008 	NOEC				
Fish (acute) ⁶¹	 OECD 203 Part C.1 of the Annex to Regulation (EG) No 440/2008 OECD 236 Part C.49 of the Annex to Regulation (EG) No 440/2008 	only 96 h LC50				
Fish (chronic) ⁶¹	 OECD 210 Part C.47 of the Annex to Regulation (EG) No 440/2008 OECD 212 Part C.15 of the Annex to Regulation (EG) No 440/2008 OECD 215 Part C.14 of the Annex to Regulation (EG) No 440/2008 	NOEC				

Thresholds:

	2.1	2.2	2.3	2.4	2.5
Threshold (acute) ⁶²	≥ 1000 mg/l	≥ 100 mg/l	≥ 1000 mg/l	≥ 100 mg/l	≥ 1000 mg/l
Threshold (chronic) ⁶³	≥ 100 mg/l	≥ 10 mg/l	≥ 100 mg/l	≥ 10 mg/l	≥ 100 mg/l

3.3.2 Requirements to be met by the components

The following tests may be used:

Algae	• OECD 201 • Part C.3 of the Annex to Regulation (EG) No 440/2008			
• ISO 6341 • OECD 202 • Part C.2 of the Annex to Regulation (EG) No 440/2008		only 48 h EC50		
Daphnia (chro- nic)				
Fish (acute) ⁶¹	 OECD 203 Part C.1 of the Annex to Regulation (EG) No 440/2008 OECD 236 Part C.49 of the Annex to Regulation (EG) No 440/2008 	only 96 h LC50		
Fish (chronic) ⁶¹	 OECD 210 Part C.47 of the Annex to Regulation (EG) No 440/2008 OECD 212 	NOEC		

If no fish tests according to the above-mentioned regulations exist, they must not be regenerated for the purpose of verifying compliance within the scope of the Blue Angel. An exception exists for OECD 236 or Part C.49 of the Annex to Regulation (EC) No 440/2008, which is not regarded as a vertebrate test and, accordingly, may be conducted.

⁶² Tests for all three trophic levels must be presented: algae, daphnia (acute), fish (acute)

⁶³ Tests for all three trophic levels must be presented: algae, daphnia (chronic), fish (chronic)

Part C.15 of the Annex to Regulation (EG) No 440/2008	
• OECD 215	
• Part C.14 of the Annex to Regulation (EG) No 440/2008	

Mass percentage of the component in % by mass:

	Threshold	2.1	2.2	2.3	2.4	2.5
Non toxic (D)	acute > 100 mg/l ⁶⁴			ام مانستاست		
Non-toxic (D)	NOEC > 10 mg/l ⁶⁵	unlimited				
	$10 \text{ mg/l} < \text{acute} \le 100 \text{ mg/l}^{64}$	- 2F	≤ 20	≤ 5	≤ 20	- 2F
Harmful (E)	$1 \text{ mg/l} < \text{NOEC} \le 10 \text{ mg/l}^{65}$	≤ 25				≤ 25
Tavia (F)	1 mg/l < acute \leq 10 mg/l ⁶⁴	<i>-</i> 1		- O F		<i>-</i> 1
Toxic (F)	$0.1 \text{ mg/l} < \text{NOEC} \le 1 \text{ mg/l}^{65}$	≤ 1	≤ 5	≤ 0.5	≤ 5	≤ 1
Very toxic (G)	$NOEC \le 0.1 \text{ mg/I}^{65}$	≤ 0.1	≤ 0.1	≤ 0.1	≤ 1	≤ 0.1

3.4 Degradability and bioaccumulation potential of the substances

Exempted substances:

- a) Inorganic additives (mineral additives)⁶⁶
- b) Inorganic thickeners (mineral thickeners)⁶⁶
- c) Thickeners made of water-insoluble biopolymers (from naturally occurring components, such as polysaccharides, waxes and resins)⁶⁶
- d) Mineral thickeners or thickeners made of chemically modified biopolymers, which are non-biodegradable and, at the same time, immobile⁶⁶ (leachability by water from the lubricant < 1 mg/l)
- e) Polymers⁶⁷, if
 - water solubility < 1 mg/l and
 - the percentage of molecules with a molecular weight ≤ 1000 g/mol is less than 1 %
- f) Substances with a solubility < 10μg/l
- g) Substances unlikely to cross biological membranes. This would be the case if
 - the molar mass (MM) > 1100 g/mol and
 - the molecule diameter > 1.7 nm (> 17 Å).

Tests to be presented for exempted substances:

	I .
Substance	Test
a), b), c)	• Test according to Paragraph 3.3.2
d)	 Test according to Paragraph 3.3.2 OECD 105 or Part A.6 of the Annex to Regulation (EG) No 440/2008
e)	 Test according to Paragraph 3.3.2 OECD 105 or Part A.6 of the Annex to Regulation (EG) No 440/2008 Test based on the relevant material-specific DIN ISO or DIN EN standards
f)	• Test according to Paragraph 3.3.2

⁶⁴ Tests for all three trophic levels must be presented: algae, daphnia (acute), fish (acute)

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⁶⁵ Tests for two trophic levels must be presented: daphnia (chronic), fish (chronic)

⁶⁶ For greases (2e)) up to 20 % by mass is permitted, for 2a) - 2d): non-biodegradable (C).

For 2a) bullet point 1 and 2c) up to 10 % by mass is permitted, for 2a) bullet points 2-4, 2b), 2d) and 2e): non-biodegradable (C).

	OECD 105 or Part A.6 of the Annex to Regulation (EG) No 440/2008
(1)	Test according to Paragraph 3.3.2Details of molar mass or molecule diameter

3.4.1. Biodegradability

The following tests may be used:

Ready biodegrada- bility (A)		 OECD 301 B Part C.4 C of the Annex to Regulation (EG) No 440/2008 OECD 301 C Part C.4 F of the Annex to Regulation (EG) No 440/2008 OECD 301 D Part C.4 E of the Annex to Regulation (EG) No 440/2008 OECD 301 F Part C.4 D of the Annex to Regulation (EG) No 440/2008 OECD 306 Part C.42 of the Annex to Regulation (EG) No 440/2008 OECD 310 Part C.29 of the Annex to Regulation (EG) No 440/2008
	3.5.1b) • 1	 OECD 302 B Part C.9 of the Annex to Regulation (EG) No 440/2008 OECD 302 C
Inherent biodegradability (B)	3.5.1b) • 2	 OECD 301 B Part C.4 C of the Annex to Regulation (EG) No 440/2008 OECD 301 C Part C.4 F of the Annex to Regulation (EG) No 440/2008 OECD 301 D Part C.4 E of the Annex to Regulation (EG) No 440/2008 OECD 301 F Part C.4 D of the Annex to Regulation (EG) No 440/2008 OECD 306 (closed bottle) Part C.42 of the Annex to Regulation (EG) No 440/2008 OECD 310 Part C.29 of the Annex to Regulation (EG) No 440/2008

Thresholds:

Ready biodegradability (A)	Inherent biodegradability (B)		
3.5.1a)	3.5.1b) • 1	3.5.1b) ● 2	
>70% (dissolved carbon) or > 60% (O2 consumption/CO2 formation)	≥ 70 %	20% < X ≤ 60% (O2 consumption / CO2 formation)	

All substances that do not meet these criteria are considered to be **non-biodegradable (C)**.

Mass percentage of the component in % by mass:

		2.1 •1	2.1 •2-4	2.2	2.3	2.4	2.5
Readily biodegradable (A)	_	≥ 90	≥ 95	≥ 95	≥ 90	≥ 95	≥ 80
ΣInherently biodegradable (B) + non-biodegradable (C)	non-bioaccumu- lative	ı	≤ 5	≤ 5	ı	≤ 5	_
Non-biodegradable (C)	non-bioaccumu- lative	≤ 2	≤ 2	≤ 2	≤ 2	≤ 2	_
Non-biodegradable (C) + phenolic antioxidants	non-bioaccumu- lative	≤ 3	≤ 3	≤ 3	≤ 3	≤ 3	_

		2.1 •1	2.1 •2-4	2.2	2.3	2.4	2.5
∑Inherently biodegradable (B) + non-biodegradable (C) + exempt tested substances (1 4.) from Paragraph 3.4	non-bioaccumu- lative	-	I	I	I	I	≤ 20
ΣInherently biodegradable (B) + tested polymers (5.) from Paragraph 3.4	non-bioaccumu- lative	≤ 10	-	_	≤ 10	1	1
Inherently biodegradable / non-biodegradable	bioaccumulative (X)	≤ 0.1	≤ 0.1	≤ 0.1	≤ 0.1	≤ 0.1	≤ 0.1

3.4.2 Bioaccumulation potential of the substances

The following tests may be used:

BCF	log Pow	Surface tension
• OECD 305 • Part C.13 of the Annex to Regulation (EG) No 440/2008	 OECD 107 OECD 117 OECD 123 Part A.8 of the Annex to Regulation (EG) No 440/2008 	• OECD 115 • Part A.5 of the Annex to Regulation (EG) No 440/2008
	Permissible calculation methods: CLOGP LOGKOW KOWWIN SPARC	

Bioaccumulative (X) if:

BCF	log Pow	Surface tension
≥ 500	3.0 ≤ log P _{OW} < 10 ⁶⁸	< 50 mN/m (within the measuring range 1 g/l)

-

 $^{^{68}}$ In technically justified cases, substances with a log POW > 6.0 may be permissible.