BLUE ANGEL

The German Ecolabel



Biodegradable Lubricants and Hydraulic Fluids

DE-UZ 178

Basic Award Criteria
Edition July 2014
Version 5

The Environmental Label is supported by the following four institutions:









The Federal Ministry for the Environment, Nature Conservation and Nuclear Safety 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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Tel: +49 (0) 228 / 6 88 95 - 0 E-Mail: <u>umweltzeichen@ral.de</u> <u>www.blauer-engel.de</u> Version 1 (06/2013): First Edition, Expiry date: December 31, 2017

Version 2 (06/2014): Amended Version

Version 3 (06/2015): Editorial amendments to the Compliance Verifications of paras. 3.2. and 3.4

- Amended limits specified in para. 3.4.1
- Amended requirements in para. 3.4.2
- Amendments to Annexes 1, 2 and 16
- Amendment to Appendix 2

Version 4 (12/2016): Extended by 2 years, Expiry date: December 31, 2018

Version 5 (12/2017): Extended by 4 years, Expiry date: December 31, 2022

- Editorial amendments to the formatting of the Award Criteria
- New sorting of chapters
- Addition and adaptation of the aspects for a future revision
- Editorial amendments to para. 3.2
- Updated reference to the latest version of the Ordinance on facilities for handling substances that are hazardous to water (Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (AwSV)) in para. 3.4.1
- Updated references to the standards
- Extension of the exceptions in para. 3.6
- New BCF limit in para. 3.6.2
- Addition of OECD guidelines 107 und 117 for determining the partition coefficient
- Addition of an upper threshold for the bioaccumulation potential of 10
- Amended reference to DIN 51517 by adding a reference to Parts 1-3

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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 and Nuclear Safety, 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

Lubricants are used in various applications where entry of substances into the environment may occur during their intended use and/or cannot be completely avoided.

During the lubrication of switch points, rails, block trains and in similar applications where significant loss of lubricant may occur during the intended use (total-loss lubrication), as well as during formwork considerable amounts of lubricants, forming oils or bitumen release agents are used and may - to a certain extent - enter the environment.

Also, total-loss lubrication during logging causes an annual release of about 10,000 tons of chain lubricants into the environment.

Even if used as intended hydraulic fluids may escape in an uncontrolled way into the environment due to leakages and other defects, such as accidents.¹

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

1.3 Objectives of the Environmental Label

The Environmental Label for Biodegradable Lubricants and Hydraulic Fluids is to enable the user to choose those final products that owing to a low (eco-)toxicological hazard potential and, above all, a good biodegradability help significantly reduce environmental impacts as well as negative effects on flora and fauna.

Another aim is to harmonize these award criteria, where possible and reasonable, with the criteria of the European Ecolabel². This particularly applies to further harmonization with the EU Ecolabel with regard to an efficient future use of renewable raw materials.

In order to achieve this goal, these Award Criteria include a series of test and verification requirements regarding the toxicological effect and the degradation behaviour of the

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The appropriate emergency measures are to be taken in the case of incidents, such as accidents and oil pollution (cf. Sofortmaßnahmen bei Mineralölunfällen (emergency measures in the case of mineral oil accidents): http://www.goec-ev.com/images/pdf/ListedergeprueftenOelbindemittel.pdf

cf. Commission Decision of 24 June 2011 (2011/381/EU)
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:169:0028:0039:DE:PDF

components used in the lubricant formulation. Lubricants and hydraulic fluids can be produced using high portions of biogenic raw materials - and this is already common practice in some places. These award criteria do not, however, include a principally conceivable requirement for a minimum content of such renewable raw materials for the purpose of conserving resources. The current state of discussion about appropriate criteria and corresponding independent certification systems to safely prevent negative environmental impact in other application areas is not yet sufficient for a pioneering label like the Blue Angel.

This is why the benefit logo lists the following benefits to environment and health:



1.4 Compliance with Legal Requirements

It is a matter of course for Blue Angel eco-labelled final products to comply with current laws and regulations.

The substance requirements defined by EU Chemicals Regulation REACH (1907/2006/EC)³ and CLP Regulation (1272/2008/EC)⁴ are observed.

1.5 Definitions

For the purpose of these Award Criteria, the following definitions shall apply:

- **Additive**⁵: Substance or mixture whose primary functions are, for example, the improvement of the flow, ageing, lubricity, anti-wear properties or of contaminant suspension.
- Substances of Very High Concern⁶: Within the meaning of these Award Criteria Substances of Very High Concern shall be all substances that have been included in the Candidate List⁷ under Annex XIV to REACH in accordance with the process laid down in 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

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 (CLP-Regulation)

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.

⁶ REACH Article 57, Substances of Very High Concern (SVHC).

Please go the European Chemicals Agency (ECHA) at http://echa.europa.eu/el/candidate-list-table. For an unofficial German version please go to German REACH-CLP Helpdesk https://www.reach-clp-biozid-helpdesk.de/de/REACH/Kandidatenliste/Kandidatenliste.html.

- **Component**: Within the meaning of these 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:** A final product within the meaning of these Award Criteria means the lubricant placed on the market that is to be Blue Angel eco-labelled.
- **Mixture**⁴: A mixture or solution composed of two or more substances.
- **Base fluid**⁸: A substance used as 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.
- 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;
- **Grease:** A mixture consisting of base fluid, thickener and additives, if any.
- **Lubricant**⁸: All finals product within scope of these Award Criteria. The term comprises e.g. lubricating oils, greases, formwork release oils and hydraulic fluids. Lubricant means a preparation consisting of base fluids and additives.
- **Substance**⁹: A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve the stability of the products 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.
- Impurity¹⁰: 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 manufacture process. While it is present in the final substance, it was not intentionally added.
- **Thickener**: An organic or inorganic component used to achieve a certain consistency of the lubricant under the conditions of use of the lubricant.

1.6 Outlook on Possible Future Requirements

The next revision of these Award Criteria is expected to consider requirements in the following fields in particular:

^{2011/381/}EU: Commission Decision of 24 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel to lubricants (2011/381/EU), Article 2 (Update required depending on the progress of the parallel EU process).

⁹ REACH, Article 3 as well as CLP Regulation, Article 2

Guidance for identification and naming of substances under REACH and CLP, Version 2.1 May 2017, Chapter 2.2, p. 15,

 $[\]underline{\text{https://echa.europa.eu/documents/10162/23036412/substance_id_en.pdf/ee696bad-49f6-4fec-b8b7-2c3706113c7d}$

- Review of the requirements and compliance verifications for the classification of the components of lubricants as hazardous to water.
 - The requirements for inherent degradability should be adapted to the European Chemicals Law. Said law considers substances as inherently degradable if they almost meet the criteria for ready biodegradability.
 - Checking the possibility of including terrestrial ecotoxicity tests into the catalogue of criteria (standards, assessment criteria).
 - Compliance verification regarding the final degradability (mineralisation) by excluding DOC-based tests for ready or inherent degradability on the basis of DIN EN 16807.
- The possibility of safely preventing possible negative environmental impacts of the cultivation and processing of renewable raw materials using a tailored set of criteria and verification obligations (e.g. via appropriate certificates).
- On this basis and with the goal of preserving resources substantial requirements for the minimum content of such raw materials could be included.
- If in the course of such investigation it turns out that at the time of the next review of these Award Criteria a set of instruments for verifying the sustainability of renewable raw materials will be available a new "renewable raw materials" criterion is expected to be included on the basis of the EU Ecolabel.

2 Scope

These Award Criteria shall apply to the following final products for commercial and private use: Lubricants for the following application areas

- a) Lubricants for processes where lubricant loss may occur when used as intended (total-loss lubrication). This includes
 - lubricants that for the most part escape into the environment 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).
 - lubricants for the glass industry.
 - concrete release agents for use in formwork.
 - release agents for use in asphalt paving work
- b) Hydraulic fluids (pressure fluids) for use especially in eco-sensitive hydraulic systems, as well as tractor transmission oils.
- c) Chain lubricants for motor saws.
- d) Transmission lubricants¹¹ for industry and shipping.
- e) Greases.

Additional final products that cannot be classified as any of the above categories 2a) - 2e) may be added if so decided by the Environmental Label Jury. Motor oils shall be excluded from these Award Criteria.

3 Requirements

The Blue Angel Eco-Label shown on the cover sheet may be awarded to the final products under paragraph 2, provided they meet the requirements specified in the paragraphs below.

¹¹ e.g. transmission lubricants for wind power plants

Unless stated otherwise the following requirements and compliance verifications shall apply to all final product groups alike. Divergent regulations for certain final product groups will be marked with reference to the differentiation of final product groups mentioned herein.

3.1 Requirements under the European Chemicals Law to be met by the Final Product

The following requirements were included in consideration of the fact that due to intrinsic substance properties the use of such substances in the formulation of lubricants shall be restricted or prohibited.

The following shall apply, as a matter principle, to all final products within the scope of these Basic Criteria for Award of the Blue Angel: they must not meet any of the classification criteria under Annex I to Regulation (EU) 1272/2008. This means they themselves must not be classified.

3.1.1 Requirements under the European Chemicals Law to be met by the Substances and Mixtures used as Components of the Lubricant

Final products within the scope of these Award Criteria must not contain any substances or mixtures (column 2) with classifications listed in one of the following tables (column 1). Impurities of the substances and mixtures with substances meeting the below criteria in quantities above the given limits (column 3) shall not be permitted.

Hazard Category under the CLP Regulation		Limit [%] for substances ¹² in the final product ¹³	Limit [%] for impurities in the substance ¹⁴
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
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

¹² This also applies to possible decomposition products where it must be assumed that they have carcinogenic, mutagenic und/or reprotoxic properties.

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.

Here, 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 Cate the CLP Reg	gory unaer	Limit [%] for substances ¹² in the final product ¹³	Limit [%] for impurities in the substance ¹⁴	
Acute Tox. 1 Acute Tox. 2		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 ¹⁵ 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. 2	_	
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		0	< classification limit for Aquatic Acute 1	
Aquatic Chronic 1	H410	0	≤ classification limit for Aquatic Chronic 1	
Aquatic Chronic 2	H411	< classification limit for Aquatic Chronic 3 and 4	_	
Aquatic	H412	< classification limit for Aquatic	_	

¹⁵ Here, the concentration is the only criterion considered for the Blue Angel. Viscosity is dropped as a criterion.

Hazard Category under the CLP Regulation		for substances 12 in the final	Limit [%] for impurities in the substance ¹⁴
Chronic 3		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 Award Criteria that are listed under the current specifications of the German MAK Commission [MAK - maximum workplace concentration] in the corresponding MAK List¹⁶ as carcinogenic, mutagenic or reprotoxic or that may lead to decomposition products where it must be assumed that the latter have carcinogenic, mutagenic und/or reprotoxic properties.

The above-mentioned substances must not be used in final products to be awarded the Blue Angel eco-label under these Award Criteria.

3.1.2 Substances of Very High Concern

Substances that have been identified in accordance with Article 57 of Regulation (EC) No 1907/2006 and have been registered under said Regulation on the Candidate List⁷ for adoption into the annex listing substances subject to approval shall be banned from use in Blue Angel eco-labelled final products. These substances must not be used in final products to be awarded the Blue Angel eco-label under these Award Criteria. Impurities of the substances used with any of the substances included on the Candidate List shall not be permitted.

The applicant shall undertake to take future updates of the Candidate List into account.

3.2 Substance Restrictions for Other Relevant Substance Groups

In addition to the substance restrictions mentioned in para. 3.1, the use of the following substances and substance groups shall also be 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.

3.2.1 Substance Restrictions on the Basis of Other Regulations

The following shall be banned from use in the final products within the scope of these Award Criteria:

- Substances on the OSPAR List¹⁷,
- Substances on the EU list of priority substances according to the Water Framework Directive ¹⁸,

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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 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 prepared by the OSPAR Commission can be viewed at: http://www.ospar.org/documents?d=32745

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

- Substances categorized in Water Hazard Class (WHC) 2 or 3 (German: WGK) according to their classification under the Ordinance on facilities for handling substances that are hazardous to water (Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (AwSV))¹⁹,
- Notwithstanding the above, the use of substances classified in WHC 2 shall be permitted for the production of lubricants under paras. 2b), 2d) and 2e)²⁰.

3.2.2 Substance Restrictions based on the Substance's Belonging to Certain Substance Groups

The following shall be excluded from use in final products within the scope of these Award Criteria:

- Organic halogen compounds,
- Nitrite compounds,
- Metals and metal compounds, except for compounds containing
 - Na,
 - K,
 - Mq,
 - Ca

as metal atoms.

Thickeners may **additionally** contain the following two metals:

- Li,
- Al.
- Mineral oils for use in release agents for asphalt laying operations,
- Mineral oils for use in chain lubricants for motors saws. Notwithstanding this, chain lubricants may have a cumulative mineral oil content of 5 percent in the final product, if the latter is due to an addition of additives.

Compliance Verifications with respect to Paras. 3.1 and 3.2

The applicant shall declare compliance with the requirements in Annex 1 and submit in Annex 2 the formulation of the final product to the label-awarding body. The application documents shall include a Safety Data Sheet according to Article 31 of Regulation (EC) No 1907/2006 for those substances that must be accompanied by such data sheet.

All substances that have been added in a concentration > 0.01 wt/% and/or formed in the lubricant used as a result of a chemical reaction shall be specified by their name, their mass concentration in the product as well as by their CAS No or EC No, if any.

Here, it is irrelevant whether the added substances perform a function or have made their way into the final product as an impurity.

Substances of Very High Concern:

The applicant shall declare compliance with the requirements in Annex 1. In the event of changes to the Candidate List that will affect applicant's final product the applicant shall, within a period of one month, submit a new declaration to reconfirm the conformity of the final product with this criterion. Such declaration shall be addressed to:

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

Should any inconsistency with the hitherto status quo arise from the application of the new AsWV it shall be discussed between RAL and Federal Environmental Agency.

RAL gGmbH Fränkische Straße 7 53229 Bonn

3.3 **Additional Requirements regarding Aquatic Toxicity**

The applicant shall comply with the requirements in either paragraph 3.3.1 or 3.3.2. Compliance verification need only to be provided for one of the two paragraphs. In the event of testing in accordance with paragraph 3.3.1, it may, however, be necessary to generate additional data for individual components in accordance with para. 3.3.2 as this is required in other sections of these Award Criteria.

No additional compliance verifications according to paras. 3.3.2 and 3.4 need to be submitted for components appearing on the list of tested lubricant components in Appendix 1²¹.

No additional data according to paras. 3.3.2 and 3.4.1 need to be presented for components appearing on the Lubricant Substance Classification (LuSC) List²² as these components may be considered as adequately tested with regard to these criteria. However, data pursuant to para. 3.4.2 must be additionally provided. The bioaccumulation potential must be determined for inherently biodegradable and non-biodegradable substances. Moreover, the substances on the LuSC-List must be additionally tested for the Hazard Statements listed herein.

3.3.1 Requirements to be met by the Final Product

As regards the acute or chronic aquatic toxicity of the final product, additional test data shall 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 (EC) 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 (EC) No 440/2008.

Chronic:

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

²¹ Conformity will be checked by RAL gGmbH.

²² http://ec.europa.eu/environment/ecolabel/documents/LuSC-%20list.pdf

²³ ISO 10253:2006 Water quality - Marine algal growth inhibition test with Skeletonema costatum 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

²⁵ OECD Tests for biotic systems: http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the- testing-of-chemicals-section-2-effects-on-biotic-systems_20745761

OECD Tests and tests pursuant to Regulation (EC) Nr. 440/2008 are not to be regarded as alternatives. They rather represent different sources for the same tests.

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

The following testing methods may be used for fish:

Acute:

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

Chronic:

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

From among the acute tests the only tests accepted are (72 h) EC50 for algae²⁸, (48 h) EC50 for daphnia²⁹ and (96 h) LC50 for fish³⁰. From among the chronic tests 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 compliance verification 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 shall be used as methods for daphnia or algae or for fish. Tests for at least two throphic levels must be verified.

Lubricants under paras. 2a), 2c) and 2e) must meet a threshold of 1000 mg/l in acute tests and 100 mg/l in chronic tests.

Lubricants under paras. 2b) and 2d) must meet 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, at least, however, by the robust study summaries³¹ of the above-mentioned tests. If the applicant is required to submit declarations, records, analyses, test reports or other compliance verifications to the competent body to prove compliance with the criteria these documents may originate from applicant and/or its supplier(s) and/or their sub-supplier(s) etc.. The suppliers of substances shall be entitled to directly present the corresponding information to the competent body. The tests shall be conducted by laboratories meeting the general requirements of EN ISO 17025 or an equivalent standard (e.g. GLP). Compliance with these requirements shall be verified in writing by the respective testing laboratories by means of a corresponding certificate. If required, the competent bodies may ask for additional verification.

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 $^{^{28}}$ E_rC50 = 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" means 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

3.3.2 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.

As regards the chronic aquatic toxicity of the components, chronic test data (No Observed Effect Concentration – NOEC) shall 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 shall be considered "non-toxic" within the meaning of this criterion if:

- acute aguatic 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 Award Criteria.

Components shall be considered "harmful" within the meaning of this criterion if:

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

The following thresholds must be met when using such lubricants:

If such substances are used in lubricants under paras. 2a) and 2e) their cumulative maximum content may not exceed 25%.

If such substances are used in lubricants under paras. 2b) and 2d) their cumulative maximum content may not exceed 20 %.

If such substances are used in lubricants under para. 2c) their cumulative maximum content may not exceed 5 %.

Components are "toxic" within the meaning of this criterion if:

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

The following thresholds must be met when using such components³³:

If such substances are used in lubricants under paras. 2a) and 2e) their cumulative maximum content may not exceed 1 %.

If such substances are used in lubricants under paras. 2b) and 2d) their cumulative maximum content may not exceed 5 %.

If such substances are used in lubricants under para. 2c) their cumulative maximum content may not exceed $0.5\,\%$.

-

Data need only be submitted for components ≥ 0.1 wt% in the final product where an upper limit of 0.5 wt% for non-evaluated substances may not be exceeded.

³³ Such a substance 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 of 3.1.1 for "Category 2" substances results in an upper limit of 2.5 percent 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 percent of such substances so that this criterion would result in a further restriction of substances hazardous to water.).

Components are "very toxic" within the meaning of this criterion if:

• NOEC \leq 0.1 mg/l³⁴.

The following thresholds must be met when using such components ³⁵:

If such substances are used in lubricants under paras. 2a) and 2e), 2b) and 2c) their cumulative maximum content may not exceed 0.1 %.

If such substances are used in lubricants under para. 2d) their cumulative maximum content may not exceed 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 no acute or chronic fish test exists such tests must not be regenerated for compliance verification within the scope of the Blue Angel as these are vertebrate tests (exception: OECD 236 or Part C.49 of the Annex to Regulation (EC) No 440/2008). If tests are regenerated, OECD 236 or Part C.49 of the Annex to Regulation (EC) No 440/2008 shall be used as methods for daphnia and algae or for fish. Tests for at least two throphic 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 shall be conducted in accordance with the guidance provided in the following standards:
 - OECD 2002, Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, OECD Series on Testing and Assessment, No. 23,
 - ISO 5667-16,

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

³⁴ 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 in principle from use pursuant to the criterion in para. 3.1.1. Hence, acute test data are left out of consideration here.

³⁵ 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 percent would be admissible for these substances (pursuant to the criterion in para. 3.1.1). M-Factors are not taken into account in this criterion because substances containing these factors are excluded from use in accordance with the criterion in para. 3.1.1.

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

c) In addition, the criterion shall be considered fulfilled if in one of the above-mentioned tests the component is found to be non-toxic at the limit of its water-solubility. For this purpose, the water solubility of the components shall 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, at least, however, by the robust study summaries of the above-mentioned tests. If the applicant is required to submit declarations, records, analyses, test reports or other compliance verifications to the competent body to prove compliance with the criteria these documents may originate from applicant and/or its supplier(s) and/or their sub-supplier(s) etc.. The suppliers of substances shall be entitled to directly present the corresponding information to the competent body. The tests shall be conducted by laboratories that meet the general requirements of EN ISO 17025 or an equivalent standard (e.g. GLP). Compliance with these requirements shall be verified in writing by the respective testing laboratories by means of a corresponding certificate. If required, the competent bodies may ask for additional verification.

3.4 Degradability and Bioaccumulation Potential of the Substances

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

The following substance groups shall be exempted from this requirement:

- inorganic additives (mineral additives),
- inorganic thickeners (mineral thickeners)³⁸,
- thickeners made of water-insoluble biopolymers (from naturally occurring components, as for example, 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),
- Polymers if:
 - water solubility L < 1 mg/l
 and
 - the percentage of molecules with a molecular weight ≤ 1000 g/mol is less than 1 percent,
- substances with a solubility < 10 μg/l,
- substances unlikely to cross biological membranes. This would be so if
 - ◆ the molar mass (MM) > 1100 g/mol and
 - the molecule diameter > 1.7 nm (> 17 Å).

All substances falling under the exceptions above shall be tested for their ecotoxicological impact. Compliance shall be verified in accordance with para. 3.3.2 of these Award Criteria. The immobility of modified thickeners and polymers shall 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

Data need only be submitted for substances ≥ 0.1 wt% in the final product where an upper limit of 0.5 wt% for substances not evaluated for this criterion may not be exceeded.

³⁸ This includes, for example, graphite, the mineral form of carbon.

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

3.4.1 Biodegradability

Biodegradability is subdivided in three categories:

- a) The substances are readily biodegradable.
- b) The substances are inherently biodegradable in a 28-day test.
- c) The substances do not comply with the foregoing criteria. Therefore, they are considered as non-biodegradable.

The content of readily biodegradable substances in a final product within the scope of these Award Criteria must be at least 95 weight percent. The portion of non-biodegradable substances must not exceed 2 weight percent of the final product³⁹. The final products listed in para. 2a) bullet points 1 and 2c) under "Scope" shall be exempt from this requirement. Their content of readily biodegradable substances in a final product must be at least 90 weight percent. The portion of non-biodegradable substances must not exceed 2 weight percent of the final product⁴⁰. Moreover, the substances must not exhibit any bioaccumulation potential pursuant to para. 3.4.2 of these Award Criteria. Compliance shall be verified in accordance with this paragraph of the Award Criteria.

a) The substances are readily biodegradable.

Substances can be considered readily biodegradable if in either of the tests below

- they are degradable by more than 70 percent on the basis of dissolved carbon⁴¹ or
- achieve more than 60 percent of the theoretical maximum value on the basis of oxygen consumption or CO₂ formation.
- b) The substances are inherently biodegradable if
 - biodegradability > 70 percent can be verified in an inherent degradation test or
 - more than 20 percent but less than 60 percent 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 foregoing criteria. Therefore, they are considered as non-biodegradable.

The following tests⁴² may be used to verify full biodegradability: To verify compliance with the requirements under 1.

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³⁹ Excluded are 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 (para. 2e) of the Scope). The total of the portions of inherently biodegradable components, the portions of non-biodegradable components and the portions of the tested exempted substances pursuant to para. 3.4 (except for polymers) shall not exceed 20 wt% in the final product.

The portion of polymers used in the final products under para. 2a) bullet point 1, and 2c) shall be added to the portion of inherently biodegradable substances.

DOC-based tests are only suited for water-soluble substances with a low tendency for absorption.

⁴² The 10-day window principle is not necessarily applied in these tests for full biodegradability. If a substance reaches the biodegradation pass level within 28 days but not within the 10-day window a lower degradation rate shall be assumed.

- 28-day test determination of ready biodegradability C.4 (C-F) of the Annex to Regulation (EC) No 440/2008 or OECD 301 (B,C,D,F),
- 28-day test determination of ready biodegradability C.29 of the Annex to Regulation (EC)
 No 440/2008 or OECD 310,
- OECD 306 or C.42 of the Annex to Regulation (EC) No 440/2008.

The following tests may be used to verify inherent biodegradability:

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

- OECD 302 B or Part C.9 of the Annex to Regulation (EC) No 440/2008⁴³
- OECD 302 C.

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

- 28-day test according to Part C.4 (C-F) of the Annex to Regulation (EC) No 440/2008 or OECD 301 (B,C,D,F),
- OECD 306 or C.42 of the Annex to Regulation (EC) No 440/2008, (this test must be conducted without using substance-specific or DOC measurements),
- OECD 310 or C.29 of the Annex to Regulation (EC) No 440/2008.

Testing the biodegradability of poorly water-soluble substances puts high demands on the addition of the test substance. Here, the following documents provide technical advice:

- OECD 301, Annex III: Evaluation of the biodegradability of poorly soluble compounds,
- ISO 10634 Guidance for the preparation and treatment of poorly water-soluble organic compounds for the subsequent evaluation of their biodegradability in an aqueous medium,
- ASTM D6081-98 Standard Practice for Aquatic Toxicity Testing of Lubricants: Sample Preparation and Results Interpretation,
- ECETOC Technical Report No 20 Biodegradation Tests of Poorly Soluble Compounds (1986)⁴⁴.

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, at least, however, by the robust study summaries of the above-mentioned tests. If the applicant is required to submit declarations, records, analyses, test reports or other compliance verifications to the competent body to prove compliance with the criteria these documents may originate from applicant and/or its supplier(s) and/or their sub-supplier(s) etc.. The suppliers of substances shall be entitled to directly present the corresponding information to the competent body. The tests shall be conducted by laboratories that satisfy the general requirements of EN ISO 17025 or an equivalent standard (e.g. GLP). Compliance with these requirements shall be verified in writing by the respective testing laboratories by means of a corresponding certificate. If required, the competent bodies may ask for additional verification.

3.4.2 Bioaccumulation Potential of the Substances

If substances used in lubricants within the scope of these Award Criteria are considered as inherent or non-degradable they are to be tested for their bioaccumulation potential.

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⁴³ DOC-based tests are only suited for water-soluble compounds with a low tendency for absorption

⁴⁴ http://www.ecetoc.org/wp-content/uploads/2014/08/ECETOC-TR-020.pdf

A potential for bioaccumulation must be 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 measuring 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).

Notwithstanding this, substances with a log P_{ow} greater than 6.0 may be permissible in technically justified cases.

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

- on the basis of the log P_{OW} determination: Part A.8 of the Annex to Regulation (EC) No 440/2008 or OECD tests 107, 117 or 123 or
- on the basis of the BCF determination: Part C.13 of the Annex to Regulation (EC) No 440/2008 or OECD 305.

If the log P_{OW} cannot be determined by way of experiment it may, alternatively, be determined by means of the following calculation methods:

- CLOGP⁴⁵,
- LOGKOW⁴⁶
- KOWWIN⁴⁷ and
- SPARC⁴⁸.

 Log_{POW} values are only valid for organic substances. The bioaccumulation potential of other compounds shall be determined using the BCF.

The surface tension shall be determined in accordance with OECD test 115 or Part A.5. of Regulation (EC) No 440/2008.

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, at least, however, by the robust study summaries of the above-mentioned tests. If the applicant is required to submit declarations, records, analyses, test reports or other compliance verifications to the competent body to verify compliance with the criteria these documents may originate from applicant and/or its supplier(s) and/or their sub-supplier(s) etc.. The suppliers of substances shall be entitled to directly present the corresponding information to the competent body. The tests shall be conducted by laboratories meeting the general requirements of EN ISO 17025 or an equivalent standard (e.g. GLP). Compliance with these requirements shall be verified in writing by the respective testing laboratories by means of a corresponding certificate. If required, the

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

^{45 &}lt;u>http://www.organic-chemistry.org/prog/peo/cLogP.html</u>

⁴⁶ http://logkow.cisti.nrc.ca/

http://ibmlc2.chem.uga.edu/sparc/

competent bodies may ask for additional verification. If a substance with a log $P_{\rm OW}$ greater than 6.0 must be used because it cannot be replaced for technical reasons by substances without bioaccumulation potential pursuant to these Award Criteria a corresponding explanation shall be presented. If required, the competent bodies may ask for additional verification.

3.5 Instructions for Disposal

3.5.1 Hydraulic Fluids (Pressure Fluids) for use especially in Eco-sensitive Hydraulic Systems as well as Tractor Transmission Oils

Used rapidly degradable hydraulic fluids shall 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*49, 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 hydraulic fluids shall be informed appropriately.

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

Compliance Verification

The applicant shall declare compliance with the requirements in Annex 1 and attach a copy of the relevant user information and container labelling to the application.

3.5.2 Transmission Lubricants for Industry and Shipping

Used rapidly degradable transmission lubricants shall 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 code mostly 13 02 07* or, if applicable, 13 02 05*, 13 02 06*, 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 transmission lubricants shall be informed appropriately. The relevant waste code pursuant to Annex 1 to the German Waste Oil Ordinance shall be clearly indicated on the hydraulic liquid containers. The user information shall include recommendations for finding the appropriate disposal channels.

Compliance Verification

The applicant shall declare compliance with the requirements in Annex 1 and attach a copy of the relevant user information and container labelling to the application.

3.5.3 Greases

Used rapidly degradable greases shall be identified and collected in accordance with the applicable provisions. In terms of waste law, they are classified as hazardous wastes (waste code mostly 12 01 12* or, if applicable, 12 01 99*) and will be taken back by licensed waste management and recycling facilities named by the manufacturer and treated in accordance

⁴⁹ The asterisk symbol indicates a hazardous waste pursuant to the European Waste Catalogue (implemented in Germany by the Abfallverzeichnisverordnung (Waste Catalogue Ordinance).

with the current waste management regulations. The users of greases shall be informed appropriately.

The relevant waste code pursuant to Annex 1 to the German Waste Oil Ordinance shall be clearly indicated on the grease containers. The user information shall include recommendations for finding the appropriate disposal channels.

Compliance Verification

The applicant shall declare compliance with the requirements in Annex 1 and attach a copy of the relevant user information and container labelling to the application.

3.6 Technical Requirements and Application Areas

3.6.1 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 fitness-for-use and safety in the respective application area.

Compliance Verification

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

3.6.2 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 under ISO 15380.

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

3.6.3 Chain Lubricants for Motor Saws

The final product must be fit for use in accordance with the guidelines established by the "Kuratorium für Waldarbeit und Forsttechnik" (KWF) (German Center for Forest Work and Technology) for the testing of chain lubricants for motor saws⁵⁰.

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 award criteria) confirming compliance with the above requirements.

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For details, inquiries and a KFW contact please go to http://www.kwf-online.org/home.html?No_cache=1

3.6.4 Transmission Lubricants for Industry and Shipping

The transmission lubricants must meet the relevant requirements for fitness-for-use and safety in the respective area of application by analogy with DIN 51517, Parts 1-3. The performance classes are to be indicated.

The fitness for use shall be declared for transmission greases.

Compliance Verification

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

3.6.5 Greases

The fitness for use shall be declared for greases for the respective application areas.

Compliance Verification

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

3.7 Advertising Messages

- The type of lubricant according to para. 2 shall be named in combination with the product designation both on the container and in the technical data sheet.
- Advertising messages must not display any information that would downplay possible risks within the meaning of Article 48 of Regulation (EC) 1272/2008, (such as, for example, "non-toxic", "non-harmful", free from ...).
- Advertising messages must not include any vague and unspecific environmental statements. Product designations including name components or terms, such as "ecosave", "nature-friendly" and the like, shall not be permitted.
- The term "bio" may be used in accordance with the requirements of DIN CEN/TR 16227:2011-10⁵¹ as well as DIN EN 16807⁵². This requires the determination of the bio-based carbon content according to ASTM D-6866⁵³ or DIN CEN/TS 16137 (DIN SPEC 91236)⁵⁴ or CEN/TS 16640⁵⁵, its calculation as bio-based carbon content in relation to the total carbon content of the lubricant and its indication in increments of 5 percent.
- The advertising statement "bio" shall not be permissible for mineral oil-based lubricants and lubricants with a biomass content of less than 25 percent by mass in the final product. If so, it will not be necessary to determine the bio-based carbon content.

http://www.nmp.din.de/cmd?level=tpl-art-detailansicht&committeeid=54738983&artid=136544127&bcrumblevel=1&languageid=de

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

Kunststoffe – Bestimmung des biobasierten Kohlenstoffgehalts; Deutsche Fassung (Plastics - Determination of bio-based carbon content; German version) CEN/TS 16137:2011: DIN CEN/TS 16137 (SPEC 91236):2011-07

DIN CEN/TS 16640:2014-05; DIN SPEC 35800:2014-05 Biobasierte Produkte - Bestimmung des biobasierten Kohlenstoffanteils von Produkten mittels Radiokarbonmethode (Bio-based products -Determination of the bio-based carbon content of products using the radiocarbon method; German version)

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 present a test report on the final product in accordance with ASTM D 6866 or DIN CEN/TS 16137 (SPEC 91236): 2011-07.

3.8 Information for the End Consumer

The container texts and the technical data sheets of lubricants for sale to the end consumer shall include in an easy-to-read form the following information (similar wordings may be used):

- "Keep out of reach of children",
- "Do not allow unused product to reach soil, sewage system or water bodies
- "Product remainders are to be disposed of at municipal collection facilities",
- "Only empty containers should be recycled".

The use of the corresponding pictograms shall be permissible.

Compliance Verification

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

4 Applicants and Parties Involved

Manufacturers of products under 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 application 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 applicant is governed by a contract on the use of the Environmental Label to be 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, 2022. They shall be extended by periods of one year each, unless terminated in writing by March 31, 2022 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 purpose. This regulation shall not affect products being still in the market.

The applicant shall be entitled to apply to RAL gGmbH for an extension of the right to use the eco-label to the product entitled to the label if it is to be marketed under another brand/trade name and/or other marketing organizations.

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

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

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Appendix A Classification List for Lubricant Components

→ Please see separate document: DE-UZ 178-201407-en Appendix A Einstufungsliste for Schmierstoffbestandteile.pdf

Overview of the Criteria Appendix B

3.1 Substance Restrictions due to Intrinsic Substance Restrictions under the European Chemicals Law (REACH, CLP)

Hazard Category under the CLP Regulation		Limit [%] for substances ⁵⁶ in the final product ⁵⁷	Limit [%] for impurities in the substance ⁵⁸
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
Repr. 1[A,B]	H360F 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 ⁵⁹ for Asp. Tox. 1	_

⁵⁶ This also applies to possible decomposition products where carcinogenic, mutagenic und/or reprotoxic

properties must be assumed.

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.

⁵⁸ Here, 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.

⁵⁹ Here, the concentration is the only criterion considered for the Blue Angel. Viscosity is dropped as a criterion.

Hazard Category the CLP Regulation		Limit [%] for substances ⁵⁶ in the final product ⁵⁷	Limit [%] for impurities in the substance ⁵⁸	
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. 2	_	
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	
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	_	

Other Substance Restrictions:

		Limit [%] for substances in the final product	Limit [%] for impurities in the substance
Candidate List ⁶⁰		0	0
MAK	carcinogenic	0	_
List	mutagenic	0	_
	reprotoxic	0	_

(MAK - maximum workplace concentration)

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 $^{^{\}rm 60}\,$ according to Articles 57 and 59 of Regulation (EC) No 1907/2006

3.2 Substance Restrictions for Additional Relevant Substance Groups

Additional 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: (German: WGK)

	2a)	2b)	2c)	2d)	2e)
WHC 2	No	Yes	No	Yes	Yes
WHC 3	No	No	No	No	No

Certain Substance Groups:

	2a)	2b)	2c)	2d)	2e)
Organic halogen compounds	No	No	No	No	No
Nitrite compounds	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 asphalt laying operations	Yes	No, - cumulatively up to 5% by addition of mineral oil containing additives	Yes	Yes

3.3 Additional Requirements regarding Aquatic Toxicity

3.3.1 Requirements to be met by the Final Product

Permissible Tests:

Algae	• ISO/DIS 10253 • ISO 8692 • OECD 201 • Part C.3 of the Annex to Regulation (EC) No 440/2008			
Daphnia (acute)	• ISO 6341 • OECD 202 • Part C.2 of the Annex to Regulation (EC) No 440/2008			
Daphnia (chronic)	NOEC			
• OECD 203 • Part C.1 of the Annex to Regulation (EC) No 440/ • OECD 236 • Part C.49 of the Annex to Regulation (EC) No 440/		only 96 h LC50		
Fish (chronic) ⁶¹	 OECD 210 Part C.47 of the Annex to Regulation (EC) No 440/2008 OECD 212 Part C.15 of the Annex to Regulation (EC) No 440/2008 OECD 215 Part C.14 of the Annex to Regulation (EC) No 440/2008 	NOEC		

Thresholds:

	2a)	2b)	2c)	2d)	2e)
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

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⁶¹ If no fish tests according to the above-mentioned guidelines exist such tests must not be regenerated for compliance verification within the scope of the Blue Angel - with an exception for OECD 236 or Part C.49 of the Annex to Regulation (EC) No 440/2008 which is not considered as vertebrate test and, therefore, may be conducted.

Tests for all three throphic levels must be presented: Algae, daphnia (acute), fish (acute)

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

3.3.2 Requirements to be met by the Components

Permissible Tests:

Algae	OECD 201Part C.3 of the Annex to Regulation (EC) No 440/2008	only 72 h EC50
Daphnia (acute)	ISO 6341OECD 202Part C.2 of the Annex to Regulation (EC) No 440/2008	only 48 h EC50
Daphnia (chronic)	OECD 211Part C.20 of the Annex to Regulation (EC) No 440/2008	NOEC
Fish (acute) 61	 OECD 203 Part C.1 of the Annex to Regulation (EC) No 440/2008 OECD 236 Part C.49 of the Annex to Regulation (EC) No 440/2008 	only 96 h LC50
Fish (chronic) ⁶¹	 OECD 210 Part C.47 of the Annex to Regulation (EC) No 440/2008 OECD 212 Part C.15 of the Annex to Regulation (EC) No 440/2008 OECD 215 Part C.14 of the Annex to Regulation (EC) No 440/2008 	NOEC

Mass Percentage of the Components in wt%:

	Threshold	2a)	2b)	2c)	2d)	2e)
non toyio (D)	acute > 100 mg/I ⁶⁴			unlimitad		
non-toxic (D)	NOEC > 10 mg/l ⁶⁵			unlimited		
harmful (F)	$10 \text{ mg/I} < \text{acute} \le 100 \text{ mg/I}^{64}$	≤ 25	≤ 20	≤5	≤ 20	≤ 25
harmful (E)	$1 \text{ mg/I} < \text{NOEC} \le 10 \text{ mg/I}^{65}$	≥ 25	≥ 20	≥5	≥ 20	≥ 25
tovio (F)	1 mg/l $<$ acute \le 10 mg/l ⁶⁴	/ 1	≤ 5	\ C.E.	≤ 5	≤ 1
toxic (F)	$0.1 \text{ mg/I} < \text{NOEC} \le 1 \text{ mg/I}^{65}$	≤ 1	n /I	≤ 0,5	n /I	> 1
very toxic (G)	NOEC ≤ 0.1 mg/l ⁶⁵	≤ 0.1	≤ 0.1	≤ 0.1	≤ 1	≤ 0.1

Tests for all three throphic levels must be presented: Algae, Daphnia (acute), Fish (acute)
 Tests for two throphic levels must be presented: Daphnia (chronic), Fish (chronic)

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, as for example, 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 percent,
- f) substances with a solubility < 10 μg/l
- substances unlikely to cross biological membranes. This would be so if
 - the molar mass (MM) > 1100 g/mol and
 - the molecule diameter > 1.7 nm (> 17 Å).

Test to be presented for exempted substances:

Substance	Test
a), b), c)	Test according to para. 3.3.2
d)	 Test according to para. 3.3.2 OECD 105 or Part A.6 of the Annex to Regulation (EC) No 440/2008
e)	 Test according to para. 3.3.2 OECD 105 or Part A.6 of the Annex to Regulation (EC) No 440/2008 on the basis of using the relevant material-specific DIN ISO or DIN EN standards
f)	 Test according to para. 3.3.2 OECD 105 or Part A.6 of the Annex to Regulation (EC) No 440/2008
g)	Test according to para. 3.3.2Details of molar mass or molecule diameter

⁶⁶ Permitted in greases (2e)) up to 20 wt%, - in 2a) - 2d): non-biodegradable (C).

Permitted in 2a) bullet points 1 and 2c) up to 10 wt%, - in 2a) bullet points 2-4, 2b), 2d) and 2e): non-biodegradable (C).

3.4.1. Biodegradability

Permissible Tests:

Ready		 OECD 301 B Part C.4 C of the Annex to Regulation (EC) No 440/2008 OECD 301 C Part C.4 F of the Annex to Regulation (EC) No 440/2008 OECD 301 D
-	3.4.1a)	 Part C.4 E of the Annex to Regulation (EC) No 440/2008 OECD 301 F
		 Part C.4 D of the Annex to Regulation (EC) No 440/2008 OECD 306 Part C.43 of the Annex to Regulation (EC) No 440/2008
		 Part C.42 of the Annex to Regulation (EC) No 440/2008 OECD 310 Part C.29 of the Annex to Regulation (EC) No 440/2008
Inherent biodegradability (B)	3.4.1b) • 1	OECD 302 B Part C.9 of the Annex to Regulation (EC) No 440/2008 OECD 302 C
	3.4.1b) • 2	 OECD 301 B Part C.4 C of the Annex to Regulation (EC) No 440/2008 OECD 301 C of the Annex to Regulation (EC) No 440/2008 OECD 301 D Part C.4 E of the Annex to Regulation (EC) No 440/2008 OECD 301 F Part C.4 D of the Annex to Regulation (EC) No 440/2008 OECD 304 (closed battle)
		 OECD 306 (closed bottle) Part C.42 of the Annex to Regulation (EC) No 440/2008 OECD 310 Part C.29 of the Annex to Regulation (EC) No 440/2008

Thresholds:

Ready biodegradability (A)	Inherent biodegradability (B)			
3.4.1a)	3.4.1b) • 1	3.4.1b) • 2		
>70% (dissolved carbon)		20% < X ≤ 60%		
or	≥ 70%	(O2 consumption / CO2		
> 60% (O2 consumption/CO2 formation)		formation)		

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

Mass Percentage of the Components in wt%:

		2a) • 1	2a) • 2-4	2b)	2c)	2d)	2e)
Readily biodegradable (A)	_	≥ 90	≥ 95	≥ 95	≥ 90	≥ 95	≥ 80
Σinherently biodegradable (B) + non-biodegradable (C)	non- bioaccumulative	_	≤ 5	≤ 5		≤ 5	_
non-biodegradable (C)	non- bioaccumulative	≤ 2	≤ 2	≤ 2	≤ 2	≤ 2	_

		2a) •1	2a) • 2-4	2b)	2c)	2d)	2e)
Σinherently biodegradable (B) + non-biodegradable (C) + exempt tested substances (1 4.) - under para. 3.4	non- bioaccumulative	1			l	I	≤ 20
Σinherently biodegradable (B) + polymers tested (5.) under para. 3.4	non- bioaccumulative	≤10			≤10		_
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

Permissible Tests:

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

Bioaccumulative (X) if:

BCF	log P _{ow}	Surface tension
≥ 500	$3.0 \le \log P_{OW} < 10^{68}$	< 50 mN/m (within the measuring range 1 g/l)

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 $^{^{68}}$ Notwithstanding this, substances with a log $P_{\rm OW}$ greater than 6.0 may be permissible in technically justified cases.