

BLUE ANGEL

The German Ecolabel



Shampoos, shower gels, soaps and other so-called “rinse off” cosmetic products

DE-UZ 203

Basic Award Criteria
Edition January 2020
Version 5

The Environmental Label is supported by the following four institutions:



Federal Ministry
for the Environment, Nature Conservation
and Nuclear Safety

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.

If you require further information please contact:

RAL gGmbH

RAL UMWELT

Fränkische Straße 7

53229 Bonn

Tel: +49 (0) 228 / 6 88 95 - 190

E-Mail: umweltzeichen@ral.de

www.blauer-engel.de

Version 1 (01/2020): First edition, term until 31/12/2025

Version 2 (04/2020): Changes in chapter 3.10 and 3.11

Version 3 (06/2020): Editorial changes

Version 4 (01/2025): Prolongation without changes, Expiry date: December 31, 2028

Version 5 (01/2026): Change in chapter 3.6 a) (Footnote to substances with „Properties of concern“ and exemption for 2-phenoxyethanol)

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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 Federal 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 these conditions.

1.2 Background

Cosmetic products, so-called "rinse-off" cosmetic products, are used by the majority of the population on a daily basis. Around 790,000 t of cosmetic products are produced annually¹. All of these products contain ingredients that find their way into the waste water system and can have a negative effect on the environment. If these components cannot be completely retained or degraded in waste water treatment plants, they will enter into bodies of water and can be ingested by water organisms and, in some circumstances, enriched. In addition, cosmetic products can contain substances relevant to health.

An important component of "rinse-off" cosmetic products are surfactants. These can be manufactured based on petrochemicals and/or renewable raw materials. The use of sustainably produced raw materials makes a significant contribution to sustainable development. In order to ensure this is the case, the cultivation of the plants is subject to ecological, social and economic requirements. Criteria for sustainable cultivation are currently being discussed in different initiatives and reliable certification systems for recording and labelling this type of cultivation are being developed or are establishing themselves on the market. This is particularly true for palm (kernel) oil. Certification systems are part of the solution for achieving sustainable palm (kernel) oil production, although they cannot solve all of the problems in the sector on their own. There are a variety of trading models for buying and selling sustainable certified palm (kernel) oil. They differ in terms of the extent to which sustainable and conventional goods are kept physically separate or mixed during the supply chain and only the sustainability certificates are traded.

1.2.1 Overview of possible future requirements

The following points will be taken into account, where possible, in future revisions of these Basic Award Criteria:

- The general ready biodegradability of all organic substances,
- Requirements for the use of recycled materials,
- And, where relevant, the exclusion of substances with certain properties.
- The separation and traceability of the raw materials (segregation) for palm (kernel) oil used for the manufacturing of surfactants is not possible. As part of the next revision, it will be

¹ Environmental Toxicology and Chemistry, Vol. 28, No. 12, pp. 2485–2489, 2009

important to ensure that only certified and segregated palm (kernel) oil is exclusively used in the product from 2026 onwards. In addition, it will be important to ensure that other natural resources e.g. other oil plants or raw materials for the manufacture of citric acid or bioalcohol are integrated into the certification system. In future updates to the environmental label criteria, the further development of these certification systems for sustainable cultivation will be taken into account.

1.3 Objectives of the Environmental Label

The following criteria are designed to promote the use of those cosmetic products that in the interests of the environment, climate and nature conservation have been produced in such a way that they have the least possible impact on the environment and human health during their production, use and disposal. In addition, they should also help to reduce and prevent the risks posed to the environment and human health through the use of hazardous substances and to minimise packaging waste. Furthermore, information should be provided that enables consumers to use the product both efficiently and with the least possible impact on the environment. Preserving natural resources is also an important focus of this environmental label. Cosmetic products with the Blue Angel ecolabel should thus make a contribution to the protection of the environment through the use of renewable raw materials in their production that have been cultivated under sustainable conditions or which support sustainable cultivation.

The Blue Angel environmental label may be awarded to cosmetic products featuring the following environmental properties:

- Low impact on bodies of water
- Requirements for renewable raw materials
- Limits on packaging waste

The following benefits are stated in the explanatory box:



1.4 Definitions

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

Substance²: means 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.

Ingredients: Preservatives, fragrances and colouring agents, irrespective of their concentrations, and other intentionally added substances as well as by-products and impurities in the raw materials whose concentrations are at least 0.010 percent by mass in the finished formulation.

² REACH, Article 3, and CLP Regulation, Article 2

Active content (AC): The sum of the organic ingredients of the product (expressed in grams), calculated based on the finished formulation of the product, including propellant gases in spray cans. Abrasives are not taken into account in the calculation of the active content.

Impurity³: 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.

Mixture: Mix, mixture or solution composed of two or more substances.

End product: Within the scope of these Basic Award Criteria, the end product describes the cosmetic product offered for sale on the market that should be labelled with the Blue Angel ecolabel.

Microplastic: Solid plastic particles with a size of between 1.00 nm and 5.00 mm.

Plastic: A macromolecular substance with a water solubility < 1.0 mg/L, obtained through:

- a polymerisation process such as e.g. polyaddition or polycondensation or a similar process using monomers or other starting substances; or
- chemical modification of natural or synthetic micromolecules; or
- microbial fermentation.

Synthetic polymer: A macromolecular substance obtained through:

- a polymerisation process such as e.g. polyaddition or polycondensation or a similar process using monomers or other starting substances; or
- chemical modification of natural or synthetic micromolecules.

Abrasives: Particles of inorganic or organic substances used for exfoliation (e.g. the removal of flakes of skin) or the removal of heavy soiling.

Nanomaterial: means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm.⁴

Bioaccumulating: An ingredient is considered to be non-bioaccumulating if the bioconcentration factor (BCF) is < 100 or the log Pow is < 3.0. If the values for both the BCF and the log Pow are available, the highest measurement for the BCF is valid.

Sales packaging (in the context of these Basic Award Criteria): All of the packaging contained in one sales unit (primary packaging = direct contact with the contents and, if relevant, a secondary packaging) as it is offered to the end user or consumer at a retail outlet in its smallest sales unit.

Secondary packaging: Packaging that can be removed from the product without changing its properties and which contains a certain number of sales units that are sold together to the end user or consumer at a retail outlet or is solely designed for stocking the shelves in the retail outlet.

Transport packaging: Transport packaging or delivery packaging is packaging that facilitates the transport of goods, protects the goods against damage during transport or which is used for reasons of safety of the transport.

³ Guidance for identification and naming of substances under REACH and CLP, Version 2.1 March 2017, Chapter 2.2, P. 17, http://echa.europa.eu/documents/10162/23036412/substance_id_de.pdf

⁴ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:DE:PDF>

Recyclate: Recyclates are products from post-consumer waste, sourced using waste recovery methods, that are used as substitutes for new products in typical material applications.

Identity preserved: Palm (kernel) oil from a specific production location that is sourced from sustainable plantations is kept separate from other palm oils along the whole supply chain.

Segregation: Palm (kernel) 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.

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.

Book & claim: Sustainable plantations are promoted through 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 the raw material.

2 Scope

The product group "rinse-off" cosmetic products comprises all rinse-off substances or mixtures within the scope of Regulation (EG) No. 1223/2009 of the European Parliament and of the Council⁵ that are designed for application on the skin and/or hair exclusively or mainly for cleaning purposes, to improve the condition of the hair or to protect the skin and moisten hair before shaving.

Therefore, the following products are permitted:

- Shampoos (including solid shampoos),
- Shower gels,
- Liquid soaps (including pastes),
- Solid soaps (including solid hair soaps),
- "Rinse-off" hair-care products,
- Shaving foams,
- Shaving gels,
- Shaving creams,
- Solid shaving soaps.

The product group "Rinse-off" cosmetic products comprises products that are intended for private and/or commercial use.

⁵ Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342 from 22/12/2009, p. 59).

Excluded from the scope of these Basic Award Criteria are:

- Products in pressurised gas containers
- Products that are specially marketed for disinfection or antibacterial purposes

3 Requirements

The end 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 following requirements.

If the applicant is required to submit declarations, documentation, analysis reports or other documentation in order to verify compliance with the criteria, these can come from the applicant and/or his/her suppliers and/or their suppliers, etc.

3.1 Assessment and testing requirements

Reference is made below to the European "Detergent Ingredient Database" (DID list), which contains the most widely used substances in this product category. The data found in this list shall be used for deriving the calculations for the Critical Dilution Volume (CDV) and for assessing the biodegradability of the substances. In the case of those substances not included in Part A of the DID list, the DF and TF values should be derived using Part B of the DID list. If no data from the DID list guidelines can be used, the worst case approach according to the Appendix "Additional_information_for_substances_not_listed_in_the_DID_list" must be used.

In certain cases, RAL gGmbH can request additional verification and carry out independent tests.

3.1.1 Measurement thresholds

Every substance that exceeds a concentration of 0.010% by mass in the final formulation must comply with these Basic Award Criteria. This also applies to the raw materials used in the product, any listed additives and impurities.

In the case of substances dealt with by the following criteria, a deviating measurement threshold of 0.0010% by mass in the final formulation applies:

- 3.4.3 Biodegradability of organic substances
- 3.5 Toxicity to aquatic organisms
- 3.6 a) Substances of very high concern (SVHC)
- 3.7 Exclusion of substances
- 3.8 Requirements for specific substances

There is no lower measurement threshold for fragrances.

Table 1: Overview of the measurement thresholds for the requirement criteria

Chapter	Criterion	Measurement threshold in percent by mass [% (w/w)]
3.2	Renewable raw materials in surfactants	≥ 0.010
3.3	Requirements for renewable raw materials produced from palm oil and palm kernel oil	≥ 0.010
3.4.1	Biodegradability of surfactants	≥ 0.010
3.4.2	Biodegradability of synthetic polymers	≥ 0.010
3.4.3	Biodegradability of organic substances	≥ 0.0010 (Colouring agents: no lower limit)

Chapter	Criterion	Measurement threshold in percent by mass [% (w/w)]
3.5	Toxicity to aquatic organisms	≥ 0.0010 (Colouring agents: no lower limit)
3.6 a)	General exclusion of substances with certain properties – a) Substances of very high concern (SVHC)	≥ 0.0010 (Colouring agents: no lower limit)
3.6 b)	General exclusion of substances with certain properties – b) Substances classified with the H-phrases listed in accordance with Regulation (EC) No 1272/2008	≥ 0.010 (Colouring agents: no lower limit)
3.7	Exclusion of substances	≥ 0.0010
3.8.1	Requirements for specific substances – biocides	≥ 0.0010
3.8.2	Requirements for specific substances – fragrances	≥ 0.0010
3.8.3	Requirements for specific substances – colouring agents	no lower limit

3.1.2 Testing institutions

The tests to be submitted to verify compliance with the requirements, with the exception of the tests for the product's fitness for use, shall be carried out by testing institutions that fulfil at least the following or higher standards:

- The tests comply with the requirements of Good Laboratory Practice (Annex 1 of German Chemicals Act (ChemG)) or
- The testing institution has been notified or accredited according to DIN EN 17025 and these tests form part of this accreditation in terms of the fields being tested and the processes and specifications used.

Compliance verification

Verification of compliance shall be provided in the form of certification in accordance with Article 19b of the German Chemicals Act (ChemG) and a written declaration from the testing institution that the test was carried out according to the principles of Good Laboratory Practice or through submission of the accreditation certificate from Germany's National Accreditation Body (DAKKS) or another national accreditation system that has been included in the Multilateral Agreement (MLA). In the case of higher standards, the applicant shall provide a precise explanation of these higher standards.

3.2 Renewable raw materials in surfactants

The proportion of renewable carbon in the total carbon in the surfactant system must be at least 70%.

Compliance verification

The applicant shall confirm compliance with the requirement in Annex 1. The proportion of renewable carbon shall be calculated based on the organic carbon (Annex 2) and verified with a declaration by the surfactant manufacturer. The calculation shall be based on the annual production volume. (See Appendix B)

3.3 Requirements for renewable raw materials produced from palm oil and palm kernel oil

If raw materials produced from palm oil and palm kernel oil are used, the sustainable cultivation of the oil plants on certified plantations must be verified.

The renewable raw materials for all of the ingredients added to the product that are produced from palm oil and/palm kernel oil must be sourced from plantations cultivated under sustainable conditions. Raw materials produced from palm (kernel) oil must be certified at least in accordance with the "mass balance" model.

Compliance verification

The applicant shall confirm compliance with the requirement in Annex 1.

In the case of RSPO "Mass Balance", "Segregation" or "Identity Preserved" certification, the manufacturing company shall verify their membership of the RSPO (as an Ordinary Member) (in the case of first-time applications, to be applied for after the issuing of the contract) if they source more than 500t of palm oil products. A list of RSPO members is published here: <https://www.rspo.org/members/all>

The following shall be submitted to RAL gGmbH at the latest after the Blue Angel ecolabel has been used for the first 15 months and then annually:

- For "Ordinary Members": RSPO membership number and a corresponding certificate and the audit report. The audit must be carried out by a certification body accredited by the RSPO: <https://www.rspo.org/certification/bodies/page/>*

For applicants that only use RSPO certified raw materials (and less than 500t PO/PKO): Proofs of purchase (delivery notes/invoices) for the corresponding raw materials. The RSPO certification number for the manufacturer of the raw materials must be stated on the documents. To verify that sufficient raw materials have been purchased, the annual production volume (for the formulation included in the application) must be stated in the sheet "Results-2" of the Excel table and the form of verification "Delivery notes/invoices (segregated or MB)" must be selected in column E. For raw materials produced from palm oil and palm kernel oil, the amount of the raw material required can then be calculated for a defined period. If multiple products are certified with the Blue Angel ecolabel, the calculations must be carried out for all products and the results (for identical raw materials) added together. Alternatively, a supply chain audit can be carried out. A supply chain audit is obligatory if using "MB claim transfer cross referencing".

3.4 Biodegradability

3.4.1 Biodegradability of surfactants

All of the surfactants contained in the end product must be readily biodegradable⁶ under aerobic conditions and biodegradable under anaerobic conditions.

Compliance verification

The applicant shall confirm compliance with the requirement in Annex 1.

⁶ According to the regulations in EU Regulation No. 648/2004/EC

The precise formulation of the end product shall be submitted to RAL gGmbH together with an explanation of the function of every individual substance in Annex 2. Part A of the DID list indicates whether a certain surfactant is aerobically or anaerobically biodegradable (those surfactants with an "R" in the column for aerobic biodegradability are readily biodegradable, while those surfactants with a "Y" in the column for anaerobic biodegradability are biodegradable under anaerobic conditions). The list is not comprehensive, but guidance is given in Part B of the list concerning the determination of the relevant calculation parameters for substances not present on the DID list. For those surfactants which are not included in Part A of the DID list or those surfactants classified with an "O" in the column for anaerobic biodegradability, relevant information from literature or other sources or corresponding test results shall be submitted to verify that these surfactants are biodegradable under anaerobic conditions.

The reference test for anaerobic degradability shall be the OECD test 311, the ISO standard 11734, the ECETOC test No. 28 (June 1988) or an equivalent test method, with the requirement of 60 % ultimate degradability under anaerobic conditions. In order to verify at least 60% ultimate degradability under anaerobic conditions, test processes can also be used that simulate the conditions in a corresponding anaerobic environment.

3.4.2 Biodegradability of synthetic polymers

All of the synthetic polymers in the end product must be inherently biodegradable under aerobic conditions. Silicone and silicone derivatives are excluded from this criteria.

Compliance verification

The applicant shall confirm compliance with the requirement in Annex 1.

The precise formulation of the end product shall be submitted to RAL gGmbH together with an explanation of the function of every individual substance in Annex 2. Part A of the DID list indicates whether a certain synthetic polymer is aerobically biodegradable (those synthetic polymers with an "I" in the column for aerobic biodegradability are inherently biodegradable). The list is not comprehensive, but guidance is given in Part B of the list concerning the determination of the relevant calculation parameters for substances not present on the DID list. For those synthetic polymers which are not included in Part A of the DID list or those synthetic polymers classified with an "O" in the column for aerobic biodegradability, relevant information from literature or other sources or corresponding test results shall be submitted to verify that these surfactants are inherently biodegradable under aerobic conditions.

The reference test for inherent degradability under aerobic conditions shall be the OECD test OECD 302 C (MITI II test) or an equivalent test method, with the requirement of 60 % degradability under aerobic conditions. The biodegradability shall be expressed as a percentage of the theoretical maximum CO₂ production (ThCO₂), based on the amount of the test substance originally used. Biodegradability of > 60% ThCO₂ within 28 days in this test shows that the test substance is inherently biodegradable under aerobic conditions. The MITI II test (OECD 302 C) requires the use of a very specific mixture of different inocula, combined with a pre-incubation phase – an inoculum taken from other sources, such as activated sludge or a mixture of other inocula from different environmental compartments, is also acceptable.

If using a DOC-based test (such as the Zahn-Wellens Test according to OECD 302 B), the possibility of elimination due to adsorption must be carefully examined and documented – the

3-hour value in the Zahn-Wellens Test should thus always be reported, even if there is no particular suspicion of adsorption.

3.4.3 Biodegradability of organic substances in total

The content of aerobically not readily biodegradable (aNBO) and anaerobically non-biodegradable (anNBO) organic substances in the product must not exceed the limits stated in Table 2.

Abrasives should not be taken into account here.

Table 2: Maximum limits for the content of not readily biodegradable organic substances based on the product, where aNBO = aerobically not readily biodegradable; anNBO = anaerobically non-biodegradable; values stated in mg/g active content (AG).

Type of product	aNBO	anNBO
Shampoos, shower gels and liquids	25 mg/g active content (AG)	25 mg/g active content (AG)
Solid soaps	10 mg/g active content (AG)	10 mg/g active content (AG)
Hair-care products	45 mg/g active content (AG)	45 mg/g active content (AG)
Shaving foams, gels and creams	70 mg/g active content (AG)	40 mg/g active content (AG)
Solid shaving soaps	10 mg/g active content (AG)	10 mg/g active content (AG)

Compliance verification

The applicant shall confirm compliance with the requirement in Annex 1.

In order to calculate the aNBO and anNBO values, there is an Excel file available for this purpose on the Blue Angel website (Annex 2).

The DID list is authoritative here. In the case of ingredients not included in Part A of the DID list, relevant information from literature or other sources or corresponding test results shall be submitted to verify that these ingredients are biodegradable under aerobic and anaerobic conditions (as described in Part B of this list).

If verification is missing for the requirements stated above, an exemption can be granted for the required biodegradability under anaerobic conditions for ingredients that are not surfactants if the following condition is satisfied:

- Ready biodegradability and no bioaccumulation

An ingredient is considered to be non-bioaccumulating if the bioconcentration factor (BCF) is < 100 or the log P_{ow} is < 3.0. If the values for both the BCF and the log P_{ow} are available, the highest measurement for the BCF is valid.

3.5 Toxicity to aquatic organisms

The critical dilution volume $CDV_{chronic}$ is the sum of the critical dilution volume $CDV(i)$ for each substance (i) in the end product (excluding abrasives), standardised as the active content (AG) in the end product:

$$KVV_{chronisch} = \sum_{i=1}^n KVV_{(i)} = KVV_{(1)} + KVV_{(2)} + \dots + KVV_{(n)}$$

mit

$$KVV_{(i)} = \frac{Gewicht_{(i)} \cdot AW_{(i)} \cdot 1000}{TW_{chronisch(i)}}$$

DF(i) is the degradation factor and TF_{chronic}(i) is the value for the chronic toxicity of the substance (in milligrams/litre).

The parameters DF and TF_{chronic} shall be taken from Part A of the Detergent Ingredient Database (DID list) (Appendix). If the substance in question is not included in Part A of the DID list, the applicant shall estimate the values in accordance with the approach stated in Part B of the DID list (Appendix). The sum of CDV_{chronic} for the individual substances gives the CDV_{chronic} for the end product.

The CDV_{chronic} must not exceed the limits stated in Table 3:

Table 3: Maximum limits for the CDV_{chronic} of the end product, standardised to the active content (AG) of the end product:

Type of product	Maximum permissible CDV _{chronic}
Shampoos, shower gels and liquids	18,000 l/g AC
Solid soaps	3,300 l/g AC
Hair-care products	25,000 l/g AC
Shaving foams, gels and creams	20,000 l/g AC
Solid shaving soaps	3,300 l/g AC

Compliance verification

The applicant shall confirm compliance with the requirement in Annex 1.

The precise formulation of the end product, together with the individual details of the calculation of the CDV_{chronic} demonstrating compliance with this criterion, shall be submitted to RAL gGmbH in Annex 2.

3.6 General exclusion of substances with certain properties

The use of the following substances is not permitted in order to protect the environment and human health. In the case of mixtures e.g. fragrances where it is not possible to obtain information about the individual substances, the classification rules for mixtures shall be applied.

a) Substances of very high concern (SVHC), substances in end products labelled 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 candidates⁷ for inclusion on the Annex of substances subject to authorisation. Impurities in substances added to the end product that correspond to the above named criteria are not permitted.

This requirement also applies to suspected SVHC, which are classified on the ECHA website under <https://echa.europa.eu/de/information-on-chemicals/registered-substances> on the

⁷ <http://echa.europa.eu/web/guest/candidate-list-table>

infocard for the substance under "Properties of concern" as suspected PBT, CMR or ED and thus are subject to a substance evaluation. Impurities in the raw materials with a concentration of < 0.1% are excluded from this requirement for suspected SVHC.⁸

The label holder is obligated to take into account current developments on the list of candidates and the latest publications by the ECHA.

b) Substances which according to the criteria of Regulation (EC) No 1272/2008⁹ are assigned the following H Phrases named in Table 4 or which meet the criteria for such classification.

Table 4: Restrictive hazard classifications and their assignment to the categories

EC Regulation 1272/2008 (CLP Regulation)	Wording
Toxic substances	
H300	Fatal if swallowed
H301	Toxic if swallowed
H304	May be fatal if swallowed and enters airways
H310	Fatal in contact with skin
H311	Toxic in contact with skin
H330	Fatal if inhaled
H331	Toxic if inhaled
EUH070	Toxic by eye contact
H370	Causes damage to organs
H371	May cause damage to organs
H372	Causes damage to organs through prolonged or repeated exposure
H373	May cause damage to organs through prolonged or repeated exposure
Carcinogenic, mutagenic and reprotoxic substances	
H340	May cause genetic defects
H341	Suspected of causing genetic defects
H350	May cause cancer
H350i	May cause cancer if inhaled
H351	Suspected of causing cancer
H360F	May damage fertility
H360D	May damage the unborn child
H360FD	May damage fertility May damage the unborn child
H360Fd	May damage fertility Suspected of damaging the unborn child
H360Df	May damage the unborn child Suspected of damaging fertility

⁸ In case of a classification of a used substance with a "property of concern" on the ECHA-website, the license holder arranges a plan for substitution with RAL gGmbH and the German Environmental Agency (UBA). RAL/UBA determine the grace period for substitution. - Exemption: 2-Phenoxy-ethanol used as a preservative can be used until the classification as ED.

⁹ 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, as well as amending Regulation (EC) No. 1907/2006 (GHS Regulation).

EC Regulation 1272/2008 (CLP Regulation)	Wording
H361f	Suspected of damaging fertility
H361d	Suspected of damaging the unborn child
H361fd	Suspected of damaging fertility Suspected of damaging the unborn child
H362	May cause harm to breast fed children
Water-hazardous substances	
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long-lasting effects
H411	Toxic to aquatic life with long-lasting effects
H412	Harmful to aquatic life with long lasting effects
H413	May cause long lasting harmful effects to aquatic life
Other Health and Environmental Effects	
H420	Hazardous to the ozone layer
Sensitizing substances	
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H317	May cause an allergic skin reaction

The use of substances or mixtures which upon processing change their properties (e.g. become no longer bioavailable, undergo chemical modification) in a way that the identified hazard no longer applies are exempted from the above requirement.

Deviations: The following substances or mixtures are specifically exempted from the above requirement:

EC Regulation 1272/2008 (CLP Regulation)	Wording
Surfactant (*)	H400 Very toxic to aquatic life
	H412 Harmful to aquatic organisms with long lasting effects
Preservatives	H411: Toxic to aquatic organisms with long-lasting effects
	H412 Harmful to aquatic organisms with long lasting effects
H413: May cause long lasting harmful effects to aquatic life	

(*) This is also valid for impurities from the starting substances

Compliance verification

The applicant shall declare compliance with the requirements in Annex 1.

In the event of changes to the list of candidates, the applicant shall inform RAL gGmbH within one month in the event that the end product does not comply with this criterion.

The applicant shall submit the exact formulation of the end product in Annex 2. The applicant shall verify that the substances contained in the end product comply with this criterion by providing information that fulfills at least those requirements according to Annex VII of Regulation (EC) No. 1907/2006. Such information shall be specific to the particular form of the substance, including nanoforms, used in the end product. For that purpose, the applicant shall submit a

declaration of compliance with this criterion, together with information on the type (IUPAC nomenclature and CAS number) and content (% by mass) of all substances added to the product and the related safety data sheets in accordance with Annex II to Regulation (EC) No 1907/2006 for the end product, as well as for all substances or mixtures listed in the formulation(s). Concentration limits shall be specified in the safety data sheets in accordance with Article 31 of Regulation (EC) No. 1907/2006. The safety data sheets may not be older than two years. The manufacturer shall verify that he/she has requested that the suppliers of primary/intermediate products submit information on the content of substances with respect to the stated limits.

3.7 Exclusion of substances

The following substances are not permitted in the end product, either as part of the formulation or as part of any preparation included in the formulation:

- Alkyl phenol ethoxylates (APEOs) and derivatives thereof
- EDTA (ethylenediaminetetraacetic acid) and its salts
- DTPA (diethylenetriaminepentaacetic acid) and its salts
- Alkyl phosphonic acid derivatives (e.g. ATMP, HEDP, DTPMP) and their salts
- Inorganic phosphate(*) (e.g. monophosphoric, diphosphoric, triphosphoric and polyphosphoric acids and their salts)
- Benzotriazole and benzotriazole derivatives
- Reactive chlorine compounds (e.g. hypochlorite)
- Borate and perborate
- Perfluorinated organic compounds
- Halogenated hydrocarbons
- Aromatic hydrocarbons
- Triclosan
- 3-Jod-2-propinylbutylcarbamate
- Glutaral (glutaraldehyde)
- Organic ammonium compounds and polyquaternium compounds that are not readily biodegradable(**)
- Formaldehyde and formaldehyde releasers(***), e.g. (INCI designations):
 - 2-bromo-2-nitropropane-1,3-diol
 - 5-bromo-5-nitro-1,3-dioxane
 - Diazolidinyl urea
 - Sodium hydroxymethylglycinate
 - Dimethylol glycol
 - Dimethylol urea
 - Hydantoin
 - Quaternium-15
 - Tetramethylolglycoluril
- Nitromusks and polycyclic musks including e.g.
 - Musk Xylene (5-tert-Butyl-2,4,6-trinitro-m-xylene / musk xylol: 5-tert-Butyl-2,4,6-trinitro-m-xylool),
 - Musk ambrette (4-tert.-Butyl-3-methoxy-2,6-dinitrotoluene / musk ambrette: 4-tert-Butyl-3-methoxy-2,6-dinitrotoluol),
 - Moskene (1,1,3,3,5-Pentamethyl-4,6-dinitroindane / musk moskene: 1,1,3,3,5-Pentamethyl-4,6-dinitroindan),

- Tibetene (5-tert.-Butyl-1,2,3-trimethyl-4,6-dinitrobenzene / tibetene musk: 1-tert-Butyl-3,4,5-trimethyl-2,6-dinitrobenzol),
- Musk Ketone (4'-tert-Butyl-2',6'-dimethyl-3',5'-dinitroacetophenone / musk ketone: 4'-tert-Butyl-2',6'-dimethyl-3',5'-dinitroacetaphenol,
- Hexamethylindanopyran (HHCB; 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta-(g)-2benzopyran),
- 1-(5,6,7,8-Tetrahydro-3,5,5,6,8,8,-hexamethyl-2-naphthyl)ethan-1-one (AHTN; 6-Acetyl-1,1,2,4,4,7-hexamethyltetralin),
- Tetramethyl Acyloctahydronaphthalenes (OTNE; reaction mass of 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one)
- Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde (3- and 4-(4-Hydroxy-4-methylpentyl)cyclohex-3-ene-1-carbaldehyde; Lyral; HICC,)
- 2,6-Dihydroxy-4-methyl-benzaldehyde (Atranol)
- 3-Chloro-2,6-Dihydroxy-4-methyl-benzaldehyde (Chloratranol; Chloroatranol)
- Butylphenyl Methylpropional (2-(4-tert-Butylbenzyl)propionaldehyde; Lysmeral; Lilial)
- Nanosilver
- Rhodamin B (CI 45170)
- Microplastics

(*) Except for impurities or stabilisers with concentrations lower than 1.0% in the raw material and a total concentration in the end product lower than 0.010 %.

(**) Quaternary organic ammonium compounds or the polyquaternium compound must verify their biodegradability in a standard test for ready biodegradability. The 10-day window is not applied in the case of polymers.

(***) Except for impurities of formaldehyde in surfactants based on polyalkoxy compounds up to a concentration of 0.010 % by mass in the ingredient

3.8 Requirements for specific substances

These special requirements for specific substances are valid in addition to the general requirements for substances.

3.8.1 Biocides

- a) The end product may only include biocides in order to preserve the product and in the appropriate dosage for this purpose. This does not refer to surfactants, which may also have biocidal properties.

Compliance verification

The applicant shall confirm compliance with the requirement in Annex 1.

The applicant shall submit the safety data sheets for every preservative added to the product, as well as information about the exact concentrations of these substances in the end product. The manufacturer or supplier of the preservatives shall submit information about the dosage required to preserve the end product.

- b) It is prohibited to claim or suggest on the packaging or by any other means that the product has an antimicrobial action.

Compliance verification

The applicant shall confirm compliance with the requirement in Annex 1.

The applicant shall submit the texts and layouts used for each individual type of packaging and/or a sample copy of each individual type of packaging to RAL gGmbH.

- c) Biocides, either as part of the formulation or as part of any mixture included in the formulation, that are used to preserve the end product are permitted, but only if their log Pow (octanol-water partition coefficient) is < 3.0 or their experimentally determined bioconcentration factor (BCF) is < 100.

Compliance verification

The applicant shall confirm compliance with the requirement in Annex 1.

The applicant shall submit the log Pow or BCF value for the biocides (Annex 2).

- d) Isothiazolinone 2-methyl-4-isothiazolin-3-one (MIT) and 5-chlor-2-methyl-4-isothiazolin-3-one/2-methyl-4-isothiazolin-3-one (CIT/MIT) may only be added up to the maximum permitted limits stated in Annex V (List of preservatives allowed in cosmetic products) of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.
 - 5-chlor-2-methyl-4-isothiazolin-3-one/2-methyl-4-isothiazolin-3-one: 0.0015 % by mass.
 - 2-methyl-4-isothiazolin-3-one: 0.0015 % by mass.If the permissible value according to Annex V of Regulation (EC) No. 1223/2009 at the time of application is lower, this lower value applies.

Compliance verification

The applicant shall confirm compliance with the requirement in Annex 1.

3.8.2 Fragrances

- a) All of the substances added to the end product as fragrances must have been manufactured and/or handled in accordance with the code of practice of the International Fragrance Association (IFRA)¹⁰.
- b) Fragrances, which must be specified according to Annex III of the cosmetics regulation (Regulation (EC) No. 1223/2009), may not be contained in the product in concentrations $\geq 0.010\% (\geq 100\text{ ppm})$ per substance.
- c) Cosmetic products that has been specially developed and marketed for children under 3 years old or allergy sufferers are not permitted to contain any fragrances.

Compliance verification

The applicant shall confirm compliance with the requirement in Annex 1.

The applicant shall submit a declaration of compliance with every requirement. For criterion (b), the applicant shall submit a declaration about compliance with this criterion with information about the amount of fragrances contained in the end product. In addition, the applicant shall also submit a declaration from the fragrance manufacturer specifying the content of each of the substances contained in the fragrance which are listed in Annex III of Regulation (EC) No.

¹⁰ The code of practice is available on the IFRA website: <http://www.ifra.org.org>.

1223/2009¹¹, as well as the content of (other) substances which have been assigned the risk phrases H317 and/or H334.

3.8.3 Colouring agents

The end product must not contain any colouring agents that are bioaccumulating.

A colouring agent is considered to be non-bioaccumulating if the bioconcentration factor (BCF) is < 100 or the log P_{ow} is < 3.0. If the values for both the BCF and the log P_{ow} are available, the highest measurement for the BCF is valid. If using colouring agents that have been approved for use in foodstuffs, no documentation about the bioconcentration factor needs to be submitted.

Compliance verification

The applicant shall submit safety data sheets about all colouring agents added to the product and the values for their BCF and/or log P_{ow} or documentation that verifies that the colouring agent is approved for use in foodstuffs.

3.9 Theoretical classification of the end product

Result (X) for the calculation in accordance with the following formula must not be ≥ 1 :

$$((WRH410/0.25\%) + (WRH411/2.5\%) + (WRH412/25\%)) = X$$

WRH410= Proportional weight of the ingredients in % that could be classified as H410.

WRH411= Proportional weight of the ingredients in % that could be classified as H411.

WRH412= Proportional weight of the ingredients in % that could be classified as H412.

Compliance verification

The applicant shall confirm compliance with the requirement in Annex 1.

In addition, the applicant shall submit the exact formulation of the end product in Annex 2, as well as the safety data sheets for the raw materials added to the end product and a theoretical calculation.

3.10 Fitness for use

The ability of the end product to perform its main function (e.g. washing, care) and all secondary functions (e.g. treating dandruff, colour protection) must be verified using a laboratory test or a consumer test.

1. Consumer test

The consumer test must be carried out anonymously i.e. the name of the standard comparative product must not be revealed.

At least 20 persons must participate in the test. The following aspects must be taken into account in all cases in the consumer survey:

- How do you evaluate the performance of the product in comparison to the standard product?
- In accordance with its intended use, how do you evaluate the dosability of the product in comparison to the standard product?
- How do you evaluate the application and rinseability of the product in comparison to the standard product?

¹¹ OJ L 342 from 22/12/2009

At least 80% of the consumers must be at least as equally satisfied with the product in comparison to the standard product.

2. Laboratory test

Laboratory tests will be accepted under the precondition that they cover the performance of the product and the aspects listed under the consumer test.

Compliance verification

The applicant shall declare compliance with the requirement in Annex 1 and submit the test results in accordance with the guidelines stated below. The applicant must document which test report was used to test the effectiveness of the product. The applicant shall submit the results of these tests that verify that the product fulfils the main and secondary functions stated on the product label or on the product packaging.

The verifications should comply with the "Guidelines for the Evaluation of the Efficacy of Cosmetic Products", which can be found under the following link:

<https://www.cosmeticseurope.eu/publications-cosmetics-europe-association/guidelines.html?view=item&id=23>

In particular, the following sections should be observed:

- ◆ *Section II for the general principles*
- ◆ *Section III for the test protocols*

Section IV for the test reports

3.11 Packaging requirements

a) The primary packaging comes into immediate contact with the contents. Any other packaging of the product, as it is offered for sale (e.g. a bottle in a cardboard box), is not permitted, unless it is secondary packaging in which two or more products are combined (e.g. the product and a refill container).

b) Packaging impact ratio

The packaging impact ratio (PIR) must be less than 0.28 grams per gram of product for each packaging unit in which the product is sold.

Pre-shave products in metal aerosol containers are exempted from this requirement.

The PIR value is calculated as follows (separately for each packaging):

$$\text{PIR} = (W + (W_{\text{refill}} \times F) + N + (N_{\text{refill}} \times F)) / (D + (D_{\text{refill}} \times F))$$

where:

W: The weight of the packaging (primary packaging + proportion of the secondary packaging¹², including the labels) [g]

W_{refill}: W: The weight of the refill packaging (primary packaging + proportion of the secondary packaging¹³, including the labels) [g]

¹² Proportional weight of the secondary packaging (e.g. 50% of the total weight of the secondary packaging if two products are sold together).

¹³ Proportional weight of the secondary packaging (e.g. 50% of the total weight of the secondary packaging if two products are sold together).

N: The weight of the non-renewable + non-recycled packaging¹⁴ (primary packaging + proportion of the secondary packaging¹⁵, including the labels) [g]

Nrefill: The weight of the non-renewable + non-recycled refill packaging¹⁶ (primary packaging + proportion of the secondary packaging¹⁷, including the labels) [g]

D: The weight of the product in the original packaging [g]

Drefill: The weight of the product in the refill packaging [g]

F: The number of refill packagings that are required to meet the total refillable quantity, which is calculated as follows:

$$F = V \times R/Vrefill$$

where:

V: The volume capacity of the original packaging [ml]

Vrefill: The volume capacity of the refill packaging [ml]

R: The refillable quantity. This is the number of times that the original packaging can be refilled. If F is not a whole number, it should be rounded up to the next whole number.

If no refill packaging is offered, the PIR value should be calculated as follows:

$$PIR = (W + N)/D$$

The manufacturer must state the number of anticipated refills or the default value (R = 5 for plastic, R = 2 for cardboard).

c) Design of the primary packaging

The primary packaging must be designed to make correct dosage easy (e.g. the opening must not be too large) and to ensure that at least 90% of the product can be easily removed from the container

The residual quantity (R) of the product remaining in the container, which must not exceed a maximum value of 10%, should be calculated as follows:

$$R = ((m_2 - m_3) / (m_1 - m_3)) \times 100 \text{ (%)}$$

Key for the calculation formula:

m₁: Primary packaging and product [g]

m₂: Primary packaging and residual quantity of the product under normal use [g]

m₃: Primary packaging, empty and cleaned [g]

d) Packagings, sleeves, labels or closures made out of halogenated polymers, e.g. PVC, are not permitted.

e) The use of halogenated polymers and aluminium is not permitted.

f) If adhesive labels are used, it should be possible to remove them in the recycling process.

g) Paper/cardboard used in the sales packaging must be manufactured using at least 80% recycled materials. In the case of secondary packaging that also serves as transport packaging, the proportion of recycled materials must be at least 70%.

h) Recycling-oriented design

¹⁴ Packaging materials are considered recycled if product waste (post-consumer waste) has been subjected to a material recycling process.

¹⁵ Proportional weight of the secondary packaging (e.g. 50% of the total weight of the secondary packaging if two products are sold together).

¹⁶ Packaging materials are considered recycled if product waste (post-consumer waste) has been subjected to a material recycling process.

¹⁷ Proportional weight of the secondary packaging (e.g. 50% of the total weight of the secondary packaging if two products are sold together).

Plastic packaging must be designed for the purpose of easy recycling i.e. where possible no potentially hazardous materials and incompatible materials should be used that are known to hinder the separation or recycling of the materials or reduce the quality of the recycled materials. No individual or combination of materials or components listed in Table 5 may be contained in the labels or sleeves, closures and, if relevant, barrier coatings. Pump mechanisms are exempt from this requirement.

Table 5 Materials and components that are excluded from use as a packaging component:

Packaging component	Excluded materials and components (*)
All components	Components in the EuPIA list (exclusion list for printing inks and related products)
Label or sleeve	PS label or PS sleeve in combination with a PP, HDPE or PET bottle A PETG or PETC label or a PETG sleeve or PETC sleeve in combination with a PET bottle Sleeves made of a different polymer than the bottle Other plastic materials for sleeves/labels with a density $> 1 \text{ g/cm}^3$ in combination with a PET bottle Other plastic materials for sleeves/labels with a density $< 1 \text{ g/cm}^3$ in combination with a PP or HDPE bottle Labels or sleeves that are metallised or labels or sleeves that are welded without a seam to a packaging body (in mould labelling) with PET bottles Non water-soluble adhesives in combination with moisture-resistant labels with a PE or PP bottle, non-soluble adhesive (in water or alkaline at 80°C) for PET bottles
Closures	A PS closure in combination with a PP, HDPE or PET bottle PETG closures and/or PETG closure material and other plastic closure components with a density of above 1 g/cm ³ in combination with a PET bottle Closures made of metal, glass, EVA Closures made of silicone. Exempted are silicone closures with a density $< 1 \text{ g/cm}^3$ in combination with a PET bottle and silicone closures with a density $> 1 \text{ g/cm}^3$ in combination with a PP or HDPE bottle Silicon components with PE and PP bottles Components made out of foamed elastomers with a PE and PP bottle Elastomer components with a density $> 1 \text{ g/cm}^3$ with a PET bottle Metallic foils or seals which remain fixed to the bottle or its closure after the product has been opened

(*) EVA — Ethylene vinyl acetate, EVOH — Ethylene vinyl alcohol, HDPE — High-density polyethylene, PET — Polyethylene terephthalate, PETG — Polyethylene terephthalate glycol-modified, PETC — Crystalline polyethylene terephthalate, PP — Polypropylene, PS — Polystyrene, PVC — Polyvinyl chloride

Please note: the combinations PP and HDPE and also PE and LLDPE, LDPE or HDPE are permitted.

Compliance verification

The applicant shall confirm compliance with the requirements in Annex 1.

The applicant shall submit the calculation for the PIR value of the product. A calculation formula is available for this purpose in Annex 2. If the product is sold in different packaging units (i.e. with different volumes), the calculation must be given for every packaging size for which the "Blue Angel" environmental label should be issued.

The applicant must submit a description of the dosage device and a test report with the results of the measurement of the residual quantity of the cosmetic product in the packaging (residual quantity). The test method for measuring the residual quantity is described in Appendix C.

The applicant must submit a signed declaration about the proportion of recycled materials or materials sourced from renewable raw materials contained in the packaging, as well as a description, where relevant, of the refill system offered (type of refill packaging, volumes). In order for the refill packaging to be approved, the applicant or the retailer shall provide documentation to verify that the refill packs are available on the market.

The applicant shall state which adhesive has been added and whether this is removable during the recycling process (i.e. soluble adhesive – in water or alkaline at 80°C – in combination with moisture-resistant labels).

3.12 Consumer information

3.12.1 Advertising claims

It is not permitted to advertise the product in combination with the word "nano". It is prohibited to state or suggest on the packaging or by any other means that the product has an antimicrobial action.

Compliance verification

The applicant shall declare compliance with the requirement in Annex 1 and submit a product label to RAL gGmbH.

3.12.2 Information on the packaging

The primary packaging must contain information on reuse, recycling and the proper disposal of the packaging.

Compliance verification

The applicant shall declare compliance with the requirement in Annex 1 and submit a product label to RAL gGmbH.

4 Applicants and Parties Involved

Manufacturers or distributors of 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, (Federal 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 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 31/12/2028.

They shall be extended by periods of one year each, unless terminated in writing by 31/03/2028 or 31 March 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 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 organizations.

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

- Applicant (manufacturer/distributor)
- Brand/trade name, product description
- Distributor (Label User), i.e. the marketing organization.

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Appendix A Statutory regulations, testing standards and other literature

The currently valid versions of the relevant regulations and standards at the time of application apply, unless reference is made to a particular version of the regulation or standard in the criteria.

- 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, 93/105/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, as well as amending Regulation (EC) No. 1907/2006
- Recommendation (2011/696/EU) of the European Commission from 18 October 2011 for the definition of nanomaterials
- Guidance for identification and naming of substances under REACH and CLP, May 2017, Version 2.1
- Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products
- DIN EN ISO/IEC 17025:2018-03 General requirements for the competence of testing and calibration laboratories
- OECD No. 311 (2006) Anaerobic Biodegradability of Organic Compounds in Digested Sludge: By Measurement of Gas Production
- DIN EN ISO 11734:1998-11 Water quality - Evaluation of the "ultimate" anaerobic biodegradability of organic compounds in digested sludge - Method by measurement of the biogas production
- ECETOC, 1988, European Centre for Ecotoxicological and Toxicological Safety Assessment of Chemicals, Evaluation of Anerobic Biodegradation. Technical Report No. 28, Brussels, Belgium
- OECD No. 302 C (2009) Modified MITI Test (II)
- OECD No. 302 B (1992) Zahn-Wellens Test / EMPA Test
- Guidelines for the Evaluation of the Efficacy of Cosmetic Products, Revised version, May 2008

Environmental Toxicology and Chemistry, Vol. 28, No. 12, 2485-2489, 2009

Appendix B Renewable raw materials in surfactants

The proportion of renewable carbon in the total carbon in the surfactant system must be at least 70%.

A declaration from the manufacturer or supplier of the surfactant shall be enclosed with the application as verification for every surfactant (or surfactant raw material) added to the product. (Declaration of the manufacturer/retailer of raw materials for detergents).

In the declaration, the manufacturer or supplier of the surfactant shall certify the proportion of renewable carbon in the total carbon for the surfactant or surfactant raw material.

In Annex 2 to DE-UZ 203 (Excel file), this value shall be entered for every surfactant or surfactant raw material added to the product (value between 0 and 100).

The subsequent calculation is carried out in Annex 2 as follows:

For every surfactant/surfactant raw material added to the product:

- $G(i)$ = Proportional weight of the surfactant/surfactant raw material i (column C)
- $R(i)$ = Proportion of renewable carbon in the total carbon for the surfactant or surfactant raw material i (column E)

The proportion of renewable carbon in the total carbon in the surfactant system (value in cell F62) is calculated using the following formula:

$$\frac{\sum G(i) \times R(i)}{G(i)}$$

If the surfactant system in the formulation changes during the term of the contract, an amended Annex 2 and a declaration from the new manufacturer of the surfactant shall be submitted. In the annual production volume, the proportion of renewable carbon in the total carbon in the surfactant system must be at least 70%.

P_1 = Production volume in the calendar year with the "old" surfactant system

P_2 = Production volume in the calendar year with the "new" surfactant system

R_1 = Proportion of renewable carbon in the total carbon in the "old" surfactant system

R_2 = Proportion of renewable carbon in the total carbon in the "new" surfactant system

R_J = Average yearly proportion of renewable carbon in the total carbon (must be $\geq 70\%$)

$$R_J = ((P_1 \times R_1) + (P_2 \times R_2)) / (P_1 + P_2)$$

Appendix C Test procedure for measuring the residual quantity

1 Definition of the indicator

One function of the packing is to facilitate the use of the product. The **restitution rate** shows the percentage of product actually consumable.

The coefficient of restitution shall be verified in accordance with the normal use of each product:

(1) If a pressure on a container is usually requested for the use of a product, this same pressure must be applied to determine the coefficient of restitution. The emptying is considered to be completed once no product comes out while respecting the usual conditions of use.

(2) For certain products when it's possible, consideration should be given to a practice already used by many users: At the end of use, it is possible for the user by pulsing in a water supply, to introduce a bit of water in the container to make less thick the content so as to finish the remaining product inside. When this operation is feasible, the coefficient of restitution should take into account a little bonus.

Residual amount (R): amount of product remaining in the container after the consumer has emptied the container. The rate is expressed as a weight percentage and defined as follows:
 $R = \text{mass of the product residue} / \text{mass of product in the container} \times 100$

2 Measurements

Measurements aim at determining precisely the mass of product and packaging.

Measurements are adapted to each product based on the characteristics of the packaging and are defined in dedicated specifications.

The following masses are measured:

- Primary packaging and product: **m1** (g)
- Primary packaging and product residue in normal conditions of use (see below): **m2** (g)
- Primary packaging emptied and cleaned: **m3** (g)

3 Results

From previous measurements, we have:

- The mass of product in the container

$$m_{\text{product}} = m_1 - m_3$$

- The mass of product residue in normal conditions of use

$$m_{\text{residues}} = m_2 - m_3$$

We deduce:

$$R = ((m_2 - m_3) / (m_1 - m_3)) \times 100 (\%)$$

Normal conditions of use

- **Tube:** Applying for three minutes successive pressures on the body of the primary packaging in direct contact, with the cap in downward position. The test is considered complete when no amount of liquid will flow after five successive pressures on the body of the primary packaging in direct contact. Neither the cap is dismantled, nor water is introduced inside the packaging.
- **Spray:** Applying successive pressures on the tip of the spray by pressing the spring down entirely. Wait until the spring has returned to its initial position prior to applying a new pressure. Repeat until no amount of product flows from the spray after five successive pressures. Neither the cap is dismantled, nor water is introduced inside the packaging
- **Pot:** The product is removed using the index and middle fingers by rubbing the edges and the bottom of the pot carefully but relentlessly. Neither the cap is dismantled, nor water is introduced inside the packaging
- **Vial/flask:** Returns the vial upside down, with the cap in downward position. After the trickle is not continuous, the bottle is left in the same position for another two minutes. Neither the cap is dismantled, nor water is introduced inside the packaging

The packaging must be designed to make correct dosage easy (e.g. by ensuring that the opening at the top is not too wide) and to ensure that at least a 90% of the product can be removed easily from the container. The residual amount of the product in the container (R), which must be below 10%, shall be calculated as follows:

$$R = ((m_2 - m_3) / (m_1 - m_3)) \times 100 \text{ (%)}$$

Where:

m₁ - Primary packaging and product (g)

m₂ - Primary packaging and product residue in normal conditions of use (g)

m₃ - Primary packaging emptied and cleaned (g)