

BLUE ANGEL

The Environmental Label



Sanitary Additives Compatible with Wastewater Treatment Plants

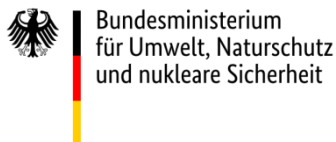
DE-UZ 84a

Basic Award Criteria

Edition January 2021

Version 2

The environmental label is underpinned by the following institutions:



The Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (Bundesministerium für Umwelt, Naturschutz und nukleare Sicherheit) is the owner of the label. It regularly provides information on the decisions taken by the Environmental Label Jury.



The German Environment Agency with its specialist department for "Ecodesign, Eco-Labeling 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.



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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Table of contents

1	Introduction.....	5
1.1	Preface	5
1.2	Background	5
1.3	Objectives of the environmental label	5
1.4	Definitions	5
2	Scope	6
3	Requirements	6
3.1	Testing institutions	7
3.2	Microbiocides	7
3.2.1	Exclusion of biocidal properties of the end product	7
3.2.2	Exclusion of biocidal substances	8
3.2.3	In-can preservatives	8
3.3	Biodegradability/eliminability	9
3.3.1	Degradability of the ingredients	9
3.3.2	Degradability of Surfactants	9
3.3.3	Degradability of the end product	10
3.4	General exclusion of substances with certain properties	10
3.5	Exclusion of substances.....	13
3.6	Requirements for fragrances and fragrance mixtures	15
3.7	Microorganisms	15
3.8	Enzymes	16
3.9	Colouring agents	16
3.10	Dosage system and safety	16
3.11	Packaging materials.....	16
3.12	Consumer information.....	16
3.13	Fitness for use	17
3.14	Overview of possible future requirements	17
4	Applicants and parties involved	17
5	Use of the Environmental Label	18

Anhang A	Quoted laws and standards, literature.....	19
Anhang B	Method for testing the fitness for use of sanitary additives for the purpose of odour reduction in mobile toilet systems	21

1 Introduction

1.1 Preface

In cooperation with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, the German Environment 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

Mobile toilets are being increasingly used in camping vehicles and recreational boats, as well as at construction sites, motorway service stations and major events or in tourist coaches, planes, passenger trains and passenger ships. These toilets usually use sanitation fluids that contain biocides.

Alongside aldehydic agents (e.g. formaldehyde, glutardialdehyde, glyoxal, paraformaldehyde), cationic surfactants (e.g. benzalkonium chlorides) can also be used. Their task is to eliminate the odour of putrefactive processes and prevent the formation of gas in the accumulated faecal matter. Biocidal agents in sanitary additives are considered to be particularly problematic for wastewater treatment systems and the environment due to their bacterial toxicity.

1.3 Objectives of the environmental label

The award of this environmental label is designed to promote the use of sanitary additives compatible with wastewater treatment plants in order to reduce the impact on disposal channels and the environment.

Therefore, the following benefits for the environment and health 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:

- **Biocide:** A substance or mixture of one or several substances that is capable of destroying harmful substances, rendering them harmless or controlling them in another way.
- **Substance**¹: 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.
- **Impurity**²: 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**³: Mix, mixture or solution composed of two or more substances.
- **End product:** Product labelled with the Blue Angel ecolabel and offered for sale on the market.
- **Microbiocides:** A biocide according to the definition in Directive (EU) No. 528/2012 that is effective against microorganisms.
- **Microorganism:** A microbiological entity, especially single-cell bacteria, that are capable of replication or transferring genetic material. For these Basic Award Criteria, only aerobic and anoxic microorganisms are taken into account, not anaerobic microorganisms.

2 Scope

These Basic Award Criteria apply to sanitary additives without a biocidal effect in wastewater treatment systems. The sanitary additives are used in accordance with their intended use to reduce odour nuisance and gas formation in mobile toilets. Sanitary additives are available in various solid and liquid forms, e.g. as a concentrate, tablet, granulate or powder, with the latter also being offered in water-soluble portioned sachets.

These Basic Award Criteria apply to the respective product form for the additives.

3 Requirements

The 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.

¹ REACH, Article 3, and CLP Regulation, Article 2

² Guidance for identification and naming of substances under REACH and CLP, Version 2.1 March 2017, Chapter 2.2

³ CLP Regulation (EC) No. 1272/2008

3.1 Testing institutions

The applicant must submit test reports from testing institutions to verify compliance with the requirements in Paragraphs 3.2.1, 3.3.1 and 3.3.3.

The testing institution must verify that:

- the tests used for all of the test results comply with the requirements of Good Laboratory Practice (Annex 1 of German Chemicals Act (ChemG)) or
- the testing institution is accredited according to DIN EN 17025 and the testing field, procedures and specifications used for those tests carried out to produce all of the required test results are part of this accreditation.

Compliance verification

Verification shall be submitted 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

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).

3.2 Microbiocides

3.2.1 Exclusion of biocidal properties of the end product

The end product must not have any biocidal effect on the microorganisms in wastewater treatment plants nor may it have any other adverse impact on disposal processes at wastewater treatment plants.

Compliance verification

Compliance with the requirement shall be verified on the following basis: The disposal concentration⁴ must be diluted with water at a ratio of 1:3. This corresponds to a dilution factor of $F = 4$. The disposal concentration must be tested in accordance with

- *DIN EN ISO 10712 Pseudomonas cell multiplication inhibition test or*
- *DIN EN ISO 11348-1 Determination of the inhibitory effect of water samples on the light emission of Vibrio fischeri (Luminescent bacteria test) - Part 1: Method using freshly prepared bacteria (reference method) or*
- *DIN EN ISO 11348-2 Determination of the inhibitory effect of water samples on the light emission of Vibrio fischeri (Luminescent bacteria test) - Part 2: Method using liquid-dried bacteria (comparable method) or*
- *DIN EN ISO 9509 nitrification inhibition test or*

⁴ Disposal concentration: Concentration of the product in the tank volume (TV), e.g. in mg/l TV or ml/l TV, according to the manufacturer's instructions for maximum dosage (dosage recommendation for extreme situations/high temperatures) per tank volume according to Paragraph 3.10.

- OECD 209 respiration inhibition test with activated sludge⁵ or
- DIN EN ISO 8192 Test for inhibition of oxygen consumption by activated sludge for carbonaceous and ammonium oxidation or
- DIN 38412-3 TTC-Test inhibition of dehydrogenase activity in activated sludge

The testing institution shall submit a test certificate in accordance with Paragraph 3.1. A full test report for the applied test method in accordance with the requirements of the testing guidelines must be submitted. If the end product contains compounds that release active oxygen, the relevant test must be preceded by a deactivation phase to avoid any specific disruptions of the test regime by active oxygen. The testing institution shall verify compliance with the requirement in the test report.

3.2.2 Exclusion of biocidal substances

The use of biocidal products, as defined in the Biocidal Products Regulation (EU) 528/2012, is not permitted. Substances approved as food additives in Europe (e.g. citric acid), as well as fragrances and fragrance mixtures as specified in Paragraph 3.6 (lavender oil) that have biocidal properties, are exempt from this requirement.⁶ In-can preservatives or their mixtures (PA 6) are subject to the requirements in Paragraph 3.2.3.

Compliance verification

The manufacturer shall declare compliance with the requirement (Annex 1) and submit the formulation (see Annex 2) of the product sold under a brand or trade name, as well as the safety data sheet. The safety data sheets may not be older than two years.

3.2.3 In-can preservatives

The end product may only include biocides in order to preserve the product and in the appropriate dosage for this purpose.

The isothiazolinone content in the end product must not exceed the following individual limits:

- BIT (1,2-benzisothiazol-3(2H)-one) $\leq 0.0010\%$ by mass
- MIT (2-methyl-4-isothiazolin-3-one) $\leq 0.0015\%$ by mass
- CIT (5-chloro-2-methyl-4-isothiazolin-3-one) $\leq 0.0010\%$ by mass
- CIT/MIT $\leq 0.0015\%$ by mass
- All other isothiazolinones $\leq 0.0020\%$ by mass, based on the individual substance
- Free formaldehyde $\leq 0.0010\%$ by mass

⁵ In contrast to a test in accordance with the guidelines using dilution series for determining EC10, EC20, EC50 etc., only the above-mentioned dilution (1:3) of the disposal concentration is subjected to a limit test.

⁶ According to Commission Regulation (EU) 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and the Council by establishing a Union list DER additives

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 on the precise concentrations of these substances in the end product (Annex 2). The safety data sheets may not be older than two years. The manufacturer or supplier of the preservatives shall submit information about the dosage required to preserve the end product.

3.3 Biodegradability/eliminability

Both the individual ingredients and also the mixture must be tested. The requirements for fragrances/components of fragrance mixtures are specified in Paragraph 3.6, whereby additional testing of the biodegradability/eliminability is unnecessary.

3.3.1 Degradability of the ingredients

The ingredients of the end product must be degradable or eliminable in a wastewater treatment plant. If the end product contains purely inorganic compounds (for example, minerals, inorganic salts, peroxides), these ingredients do not need to be considered. The content of fragrances and colouring agents, also in the form of mixtures, must not exceed 3% by mass. The percentage of non-biodegradable or non-tested colouring agents must not exceed 0.2% by mass, based on the total formulation.

Compliance verification

The individual ingredients must comply with the criteria for ready biodegradability⁷ based on one of the following alternative test methods:

- *DOC - Die Away Test (OECD 301 A, EG No. 440/2008 C.4 – A, DIN EN ISO 7827)*
- *CO₂ development test (OECD 301 B EG No. 440/2008 C.4 – C, DIN EN ISO 9439)*
- *MITI test (I) (OECD 301 C, EG No. 440/2008 C.4 - F)*
- *Closed bottle test (OECD 301 D, EG No. 440/2008 C.4 – E, DIN EN ISO 10707)*
- *Modified OECD screening test (OECD 301 E, EG No. 440/2008 C.4 – B, DIN EN ISO 7827)*
- *Manometric respirometry test (OECD 301 F, EG No. 440/2008 C.4 – D, DIN EN ISO 9408)*
- *Headspace test (OECD 310, DIN EN ISO 14593)*
- *Closed bottle test in two phases (BODIS; ISO 10708)*

Verification of compliance shall be provided in the form of a safety data sheet that states the test method used.

3.3.2 Degradability of Surfactants

The surfactants used in the product must meet the requirements for ready, aerobic biodegradability in accordance with the Detergent Regulation (EC) No 648/2004, Annex III.

Compliance verification

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

⁷ Evaluation according to CLP Regulation (EG) No. 1272/2008

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 list⁸ indicates whether a certain surfactant is aerobically biodegradable (those surfactants with an "R" in the column for aerobic biodegradability are readily biodegradable). The list⁹ 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 aerobic biodegradability, relevant information from literature or other sources or corresponding test results shall be submitted to verify that they are aerobically biodegradable. The test methods stated in Paragraph 3.3.1 can be used as guidelines for testing the ready biodegradability.

3.3.3 Degradability of the end product

Verification of compliance with the requirement for the end product must also be submitted. If the end product contains purely inorganic compounds (for example, minerals, inorganic salts, peroxides), verification of the degradability of the end product is not required. If the organic components of the product are only fragrances, the requirement in Paragraph 3.6 is applicable.

Compliance verification

Eliminability of 80% in the Zahn-Wellens¹⁰ test (OECD 302 B; DIN EN ISO 9888; Regulation (EC) No 440/2008 C.9)

The testing institution shall submit a test certificate in accordance with Paragraph 3.1. A full test report in accordance with the requirements in the testing guidelines that includes all of the raw data, also for parallel testing, shall be submitted.

Any modifications that are necessary for testing reasons during the preparation of the samples due to the physical/chemical properties of the product shall be stated and justified.

The testing institution shall verify compliance with the requirement in the test report.

3.4 General exclusion of substances with certain properties

The following substances may not be added:

a) Substances of very high concern (SVHC)

Substances which are identified as particularly alarming under the REACH Regulation (EC) No. 1907/2006 and which have been incorporated into the list drawn up in accordance with Article 59, Paragraph 1 of the REACH Regulation (so-called "list of candidates").¹¹ If the

⁸ https://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_a_de.pdf

⁹ https://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_b_de.pdf

¹⁰ In contrast to the EU Regulation, use a test period of 7 days (instead of 28 days).

¹¹ The current version of the list of candidates (<https://www.echa.europa.eu/de/candidate-list-table>) and classifications according to the CLP Regulation at the time of application are valid. The label holder is obligated to take into account current developments and classifications on the list of candidates. If an ingredient is newly added to the list of candidates or a substance is newly classified during the term of the Basic Award Criteria, the label holder must submit an informal notification within two months stating the name of the substance, its CAS number and possible substitutes. In consultation with the German Environment Agency, a deadline for substituting this ingredient or substance may then be defined.

substance is part of a mixture, its concentration must not exceed 0.10% by mass. If a stricter, more specific concentration limit is specified for a substance in a mixture in the criteria for the CLP Regulation (EC) No. 1272/2008 then this is valid. The label holder is obligated to take into account current developments on the list of candidates.

- b) Substances which according to the criteria of CLP Regulation (EC) No 1272/2008¹² are assigned the following H Phrases named in the table or which meet the criteria for such classification. If the substance in this case is part of a mixture then its concentration may not exceed the general generic cut-off values according to the CLP Regulation (EC) No. 1272/2008. If a stricter, more specific concentration limit is specified for a substance in a mixture then this is valid.

Table 1: Table for the exclusion of ingredients according to Paragraph 3.4b

Regulation (EC) No. 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.
H317	May cause an allergic skin reaction.
H330	Fatal if inhaled.
H331	Toxic if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H370	Causes damage to organs.
H371	May cause damage to organs.
H372	Causes damage to organs through prolonged and repeated exposure.
H373	May cause damage to organs through prolonged or repeated exposure.
EUH029	Contact with water liberates toxic gas.
EUH031	Contact with acids liberates toxic gas.
EUH032	Contact with acids liberates very toxic gas.
EUH066**	Repeated exposure may cause skin dryness or cracking.
EUH070	Toxic by eye contact.
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.

¹² 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

Regulation (EC) No. 1272/2008 (CLP Regulation)	Wording
H360Fd	May damage fertility. Suspected of damaging the unborn child.
H360Df	May damage the unborn child. Suspected of damaging fertility.
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	
H410	Very toxic to aquatic life with long-lasting effects.
H411	Toxic to aquatic organisms with long-lasting effects.
H412	Harmful aquatic organisms with long lasting effects.
H413	May cause long lasting harmful effects to aquatic organisms.
Other Health and Environmental Effects	
H420 ¹³	Hazardous to the ozone layer.
Endocrine substances with a negative effect on human health¹⁴	
EUH380	May cause endocrine disruption in humans
EUH381	Suspected of causing endocrine disruption in humans
Endocrine substances with a negative effect on environment¹⁵	
EUH430	May cause endocrine disruption in the environment
EUH431	Suspected of causing endocrine disruption in the environment
Persistent, bioaccumulative and toxic substances or very persistent and very bioaccumulative substances¹⁵	
EUH440	Accumulates in the environment and living organisms including in humans
EUH441	Strongly accumulates in the environment and living organisms including in humans
Persistent, mobile and toxic substances or very persistent and very mobile substances¹⁵	
EUH450	Can cause long-lasting and diffuse contamination of water resources
EUH451	Can cause very long-lasting and diffuse contamination of water resources

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

c) Substances with hazardous properties in concentrations that result in classification and labelling of the end product with one of the following GHS hazard pictogram for health and environmental hazards: GHS05 (Corrosive), GHS06 (Toxic), GHS07 (harmful), GHS08 (Health hazard) and GHS09 (Environmental hazard).

d) The following are exempt from requirements a) and b):

¹³ Commission Regulation (EC) 286/2011 of 10 March 2011 amending Regulation (EC) No. 1272/2008

¹⁴ The classification and labelling of substances according to the new hazard class is mandatory from 01/05/2025 onwards. This information must then be taken into account for the sanitary additives.

¹⁵ The classification and labelling of substances according to the new hazard classes is mandatory from 01/11/2026 onwards. This information must be taken into account for the sanitary additives.

- ♦ Impurities in concentrations that are not specified in the safety data sheet. The components listed on the safety data sheet must correspond with the regulations according to REACH Regulation (EC) No 1907/2006, amended by Regulation (EU) 2015/830. If the substance in this case is part of a mixture then its concentration may not exceed the general generic cut-off values according to the CLP Regulation (EC) No 1272/2008. If a stricter, more specific concentration limit is specified for a substance in a mixture then this is valid.
- ♦ Substances approved as food additives in Europe (e.g. citric acid)
- ♦ Fragrances as specified under Paragraph 3.6 (e.g. lavender oil)

Compliance verification

The applicant shall declare compliance with the requirements according to Annex 3 to the contract pursuant to DE-UZ 84a and submit the formulation of the product sold under a brand or trade name with information on the type (IUPAC nomenclature and CAS number) and content (% by mass) of all substances added to the product in accordance with Annex 2 to the contract pursuant to DE-UZ 84a.

Current safety data sheets shall be submitted for all chemical ingredients. 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 impurities (up to 0.010% by mass) and by-products.

In the event of any changes to the classification of substances and end products, as well as the inclusion of substances on the list of candidates, that are contrary to the requirements of the Blue Angel, the licence holder is obligated to inform RAL gGmbH about the non-conformity of the end product within one month.

3.5 Exclusion of substances

The following substances are not permitted in the product, either as part of the formulation or as part of any preparation included in the formulation: Production-related impurities may not exceed 0.010% by mass in the product. If a stricter, more specific concentration limit is specified for a substance in a mixture in the criteria for the CLP Regulation (EC) No. 1272/2008 then this is valid.

- Alkyl phenol ethoxylates (APEO) and derivatives thereof
- Phosphates and phosphonates
- EDTA (ethylenediaminetetraacetic acid) and its salts
- DTPA (diethylenetriaminepentaacetic acid) and its salts
- NTA (nitrilotriacetic acid)
- Reactive chlorine compounds (e.g. hypochlorite)
- Glutaral (glutaraldehyde)
- Organic ammonium compounds and polyquaternium compounds that are not readily biodegradable(*).
- Substances that contain mercury, lead, cadmium or chromium, as well as boron and halogenated oxidants.
- Nanosilver

- Rhodamin B (CI 45170)
- Formaldehyde and formaldehyde releasers(**), e.g. (INCI designations):
 - ♦ Bromo-5-nitro-1,3-dioxane
 - ♦ Diazolidinyl urea
 - ♦ Sodium hydroxymethylglycinate
 - ♦ Dimethylol glycol
 - ♦ Dimethylol urea
 - ♦ Hydantoin quartermium-15
 - ♦ Tetramethylolglycoluril

The following fragrances:

- 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-xylol),
 - ♦ 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 Acetyloctahydronaphthalenes (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; Lylal; 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)

(*) the degradability of the quaternary organic ammonium compounds or the polyquaternium compound must be verified 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.

Compliance verification

The applicant shall declare compliance with the requirement in Annex 1 to the contract.

3.6 Requirements for fragrances and fragrance mixtures

- a) All of the substances added to the product as fragrances/components of fragrance mixtures must have been manufactured, handled and/or applied in accordance with the code of practice of the International Fragrance Association (IFRA) ¹⁶ or they must be included on the GRAS list from the FDA.¹⁷
- b) Fragrances / components of fragrances¹⁸ classified as H317 (May cause an allergic skin reaction) must not be present in the end product in concentrations $\geq 0.10\%$. If lower classification limits exist in specific cases, these must be applied.
- c) Fragrances / components of fragrances¹⁵ classified as H334 (May cause allergy or asthma symptoms or breathing difficulties if inhaled) must not be present in the end product in concentrations $\geq 0.010\%$.

Compliance verification

The applicant shall declare compliance with the requirements (Annex 4) or submit a declaration from the fragrance suppliers confirming compliance with the requirements in Annex 4 to the contract.

For criteria b) and c), the applicant shall submit a declaration about compliance with these criteria with information on the amount of fragrances contained in the end product (Annex 4, Annex 2). In addition, the applicant shall also submit a declaration from the fragrance manufacturer (Annex 4) specifying the content of each of the substances contained in the fragrance, as well as the content of (other) substances which have been assigned the risk phrases H317 and/or H334.

3.7 Microorganisms

If microorganisms are added to the end product, the basic formulation must state the strains of the microorganisms and their manufacturers, as well as the quantities of colony-forming units per litre or kilogram of product (CFU/l or CFU/kg). Only those microorganism strains that according to current scientific knowledge are not pathogenic in humans, animals or plants and do not pose any risk to human health or the environment are permitted. This requirement will be considered to have been fulfilled if the microorganisms¹⁹ are exclusively classified in risk group 1 in the currently valid version of TRBA 466 "Classification of prokaryotes (bacteria and archaea) into risk groups".²⁰

Genetically modified microorganisms in the sense of the German Genetic Engineering Act (GenTG) and biocidal microorganisms in the sense of the Biocidal Products Regulation are not permitted.

¹⁶ The code of practice is available on the IFRA website: <http://www.ifraorg.org>

¹⁷ https://www.ecfr.gov/cgi-bin/text-idx?SID=e956d645a8b4e6b3e34e4e5d1b690209&mc=true&node=pt21.3.182&rgn=div5#se21.3.182_11

¹⁸ in relation to the individual substance according to the CAS number

¹⁹ Definition of "microorganism" according to § 3 GenTSV and EU Directive 2000/54/EC

²⁰ Technical Rules for Biological Agents (TRBA) <https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRBA/TRBA.html>

Compliance verification

The manufacturer shall verify compliance with the requirements by completing Annex 5 to the contract pursuant to DE-UZ 84a.

3.8 Enzymes

It is only permitted to add encapsulated enzymes (solid) and enzymes in liquid form or as a suspension.

Compliance verification

The applicant shall submit a signed declaration of conformity (Annex 1) and, if relevant, supplier declarations or safety data sheets for the enzymes added to the product.

3.9 Colouring agents

The end product must not contain any colouring agents that are bioaccumulating. A colouring agent is considered to be non-bioaccumulating if it has a bioconcentration factor (BCF) < 100 or a log Pow < 3.0. If the values for both the BCF and the log Pow 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 a signed declaration of conformity (Annex 1) and, if relevant, supplier declarations or safety data sheets about the colouring agents added to the product and the values for their BCF or log Pow or documentation that verifies that the colouring agent is approved for use in foodstuffs.

3.10 Dosage system and safety

All sanitary fluids intended for direct sale to the final consumer, except for refill packs with a closure, must come with a scaled dosing system and a childproof closure.

Compliance verification

The manufacturer shall declare compliance with the requirement in Annex 1 to the contract.

3.11 Packaging materials

The packaging materials may not contain any PVC.

Compliance verification

The manufacturer shall declare compliance with the requirement in Annex 1 to the contract.

3.12 Consumer information

The sales packaging for the sanitary additive must provide the following information in an appropriate and easily readable form (e.g. inscription, label, instructions for use)

- the field of application (e.g. camping toilet, rental toilet, etc.) of the product;

- instructions for proper dosing;
- the application modalities required to ensure the product's fitness for use – at least the minimum and maximum dosage of the end product in relation to the tank volume, effective useful life and effective temperature range;
- the notes "Do not drain the holding tank anywhere other than at a designated dump station" and "Do not empty the holding tank on the ground or into water bodies";
- the note "Keep out of reach of children" (similar formulations may be used);
- information on proper product storage and shelf life;
- if the product contains genetically engineered enzymes, the note "Product contains genetically engineered enzymes"

Compliance verification

The applicant shall submit the label, instructions for use or other appropriate product information to verify compliance with the requirement.

3.13 Fitness for use

The product must meet the requirements for the product's fitness for use in the "Method for testing the fitness for use of sanitary additives for the purpose of odour reduction in mobile toilet systems" according to Appendix B of the Basic Award Criteria DE-UZ 84a.

Compliance verification

The applicant shall declare compliance with the fitness for use of the product (Annex 1). In addition, the applicant shall submit a test report according to the test method described in Appendix B to the Basic Award Criteria for DE-UZ 84a that was prepared by an independent testing institution according to Paragraph 3.1.

3.14 Overview of possible future requirements

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

- Requirements on the packaging (e.g. weight-benefit ratio, use of recycled materials)
- Where relevant, the exclusion of substances with certain properties.
- Requirements for surfactants from renewable raw materials.

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, (German Environment 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 December 2025.

They shall be extended by periods of one year each, unless terminated in writing by 31 March 2025 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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Anhang A Quoted laws and standards, literature

- [1]** DID list: Detergents Ingredients Database
https://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_a_de.pdf
https://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_b_de.pdf
- [2]** DIN EN ISO 10712:2019-05: Water quality - *Pseudomonas putida* growth inhibition test (*Pseudomonas* cell multiplication inhibition test) (ISO 10712:1995); German version EN ISO 10712:1995
- [3]** DIN EN ISO 11348-1:2009-05: Water quality - Determination of the inhibitory effect of water samples on the light emission of *Vibrio fischeri* (Luminescent bacteria test) - Part 1: Method using freshly prepared bacteria (ISO 11348-1:2007); German version EN ISO 11348-1:2008
- [4]** DIN EN ISO 11348-2:2009-05: Water quality - Determination of the inhibitory effect of water samples on the light emission of *Vibrio fischeri* (Luminescent bacteria test) - Part 2: Method using liquid-dried bacteria (ISO 11348-2:2007); German version EN ISO 11348-2:2008
- [5]** DIN EN ISO 9509:2006-10: Water quality - Toxicity test for assessing the inhibition of nitrification of activated sludge microorganisms (ISO 9509:2006); German version EN ISO 9509:2006
- [6]** DIN EN ISO 8192:2007-05: Water quality - Test for inhibition of oxygen consumption by activated sludge for carbonaceous and ammonium oxidation (ISO 8192:2007); German version EN ISO 8192:2007
- [7]** DIN 38412-3:2010-10: German standard methods for the examination of water, waste water and sludge - Bio-assays (group L) - Part 3: Toxicity test for assessing the inhibition of the dehydrogenase activity of activated sludge microorganisms (TTC-Test) (L 3)
- [8]** DIN EN ISO 9888:1999-11: Water quality - Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium - Static test (Zahn-Wellens method) (ISO 9888:1999); German version EN ISO 9888:1999
- [9]** GRAS list: Generally Recognized as Safe (GRAS) list from the U.S. Food and Drug Administration
- [10]** List of candidates: Candidate List of Substances of Very High Concern for Authorisation (published according to Article 59, Paragraph 10 of the REACH Regulation, in the currently valid version
http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp
- [11]** OECD Test No. 209: Activated Sludge, Respiration Inhibition Test (Carbon and Ammonium Oxidation)
- [12]** OECD Test No. 302B: Inherent Biodegradability: Zahn-Wellens/ EVPA Test

- [13]** Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work
- [14]** Technical Rules for Biological Agents (TRBA) 466 Classification of prokaryotes (bacteria and archaea) into risk groups, in the currently valid version
- [15]** Code of practice of the International Fragrance Association (IFRA): The code of practice is available on the IFRA website (<http://www.ifraorg.org>)
- [16]** 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), as amended
- [17]** Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 concerning the classification, labelling and packaging of substances and mixtures, in short: CLP Regulation (Classification, Labelling and Packing), as amended
- [18]** Regulation (EU) No. 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, as amended
- [19]** Commission Regulation (EU) 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and the Council by establishing a Union list of food additives
- [20]** Regulation (EC) No. 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents, as amended
- [21]** Council Regulation (EU) No 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- [22]** Council Regulation (EU) No 286/2011 of 10 March 2011 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures
- [23]** Council Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), C.9 biodegradability (Zahn-Wellens method)
- [24]** Ordinance on the security levels and safety measures for genetic engineering operations in genetic engineering facilities (Genetic Engineering Safety Ordinance - GenTSV) § 3 Definitions

Anhang B Method for testing the fitness for use of sanitary additives for the purpose of odour reduction in mobile toilet systems

1 Purpose of the test

The purpose of the test is to assess the odour behaviour of mobile toilets when sanitary additives are used in accordance with the manufacturer's dosing instructions.

Odour nuisance during the draining process at a dump station is not taken into account. It is also not possible to take additional properties of the sanitary additives, such as the decomposition of toilet paper, into account.

2 Test method

The method is a laboratory test for testing the fitness for use of sanitary additives. It can be used as a single test and is based on the determination of odour from faecal substitute samples following the addition of sanitary products according to Paragraph 2 of DE-UZ 84a.

2.1 Test medium

Fresh pig manure (without litter or straw materials) and artificial urine should be used as the faecal substitute. The ingredients should be mixed with each other at a weight ratio of 1 : 6 : 6 (e.g. 10 g of pig faeces added to 60 g of artificial urine and 60 ml of water). This will produce a 130 ml test medium.

The artificial urine should be prepared based on the Chemielexikon Römpp (Römpp Chemistry Lexicon):

- 20 g of urea;
- 0.5 g of uric acid;
- 0.5 g of ammonium chloride;
- 2.0 g of glycine;
- 15 g of table salt
- and a spatula tip of yeast extract per 1000 ml of drinking water;
- The pH value is adjusted to 5.5 using citric acid.

2.2 Test vessels

Sealable 1.5 litre glass vessels are used to simulate the faecal tank.

For the testing of sanitary additives for private camping use, the lid should be loosely placed on the vessel during the test period to allow pressure compensation.

Commercially used sanitary additives should be tested without a lid.

2.3 Test temperature

All of the samples must be kept at a constant temperature of $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$ during the entire test period.

2.4 Product sample

The amount of the sanitary additive required for the tank volume according to the manufacturer's instructions is dissolved in 60 ml of water. This solution is then placed into the test vessels.

2.5 Test period

Sanitary additives for private camping use are tested for a period of 96 hours (4 days), based on their service lives and draining processes in practice.

Sanitary additives for commercial use are tested for a period of 168 hours (7 days).

3 Test subjects

The odour intensity is collectively assessed by a panel of 10 test subjects. It must be ensured that the test subjects are fit enough to carry out the odour test. The odour threshold values of the individual people are not a criteria for selecting the test subjects.

4 Test procedure

For each sanitary additive, 5 reference vessels are filled with 60 ml of water and 5 product vessels are filled with 60 ml of the product sample defined in section 2.4. The test medium is dosed as follows into all of the glass vessels (5 product vessels for each sanitary additive + 5 reference vessels):

Private camping use <ul style="list-style-type: none">• from day 1 to day 4	<ul style="list-style-type: none">• 130 ml of the test medium per day
Commercial use <ul style="list-style-type: none">• from day 1 to day 4• and on day 7	<ul style="list-style-type: none">• 130 ml of the test medium per day• 130 ml of the test medium

The final volume increases to 580 ml or 710 ml respectively. This corresponds to around 1/3 or 1/2 of the volume of the vessel – or if transferred into practice around 1/3 or 1/2 of the tank volume.²¹

Depending on the product's field of application, the glass vessels are either loosely covered (camping use) or ventilated without a lid (commercial use) and kept at 25°C ± 2°C. They are placed into opaque containers for the odour test.

The odour intensity is measured on days 3 and 4 of the test series for camping products and on days 4 and 7 of the test series for commercially used sanitary additives.

The group of test subjects evaluates the odour intensity of the product vessels after the addition of the test medium and also evaluates all reference vessels at the same time. It is important to ensure that there is at least 3 hours between the addition of the test medium and the actual odour test. The test of the reference and product vessels by the test subjects must be randomised²².

5 Odour testing

A five-point intensity scale is used to assess the odour intensity.

²¹ It is assumed by approximation that, in practice, the tanks are drained as soon as they are filled to 1/3 of their volume.

²² carried out in random order

Odour intensity level	Assessment of the faecal odour
1	not noticeable
2	noticeable but not annoying
3	distinctive smell but still not annoying
4	annoying
5	unbearable

The odour intensity levels are determined by two groups of 5 test subjects, who evaluate all of the samples at the same time from a distance of about 20 cm. After 30 minutes, the samples are then tested by the second group. The odour intensity level may be graded in increments of 0.5 points. The room should be well ventilated after each test with the vessels closed. The groups of test subjects should perform their tests in the reverse order on the 2nd day of testing.

6 Analysis

The odour intensity levels form the basis for the calculation of the respective arithmetic average for the product sample test (PS) and the reference sample test (RS) for both test days. The figures are rounded to the first decimal place according to mathematical rules.

The sanitary additive is considered to be fit for use if the difference between the two average values PS and RS for each test day is at least 1.5.

$$RS - PS \geq 1.5$$

If the difference between the two average values PS and RS is less than 1.5, the tested product is not considered fit for use in the sense of this test method.

7 Hygiene measures

The use of animal faeces requires the observance of hygiene rules. When using this test method, it is important to observe the publication from the Federal Ministry of Labour and Social Affairs in the TRBA (Technical Rules for Biological Working Materials) of 1 September 1997, Ref. No. III b 4 - 34 504 - 7. According to this publication, the test method involves biological working materials loaded with organisms that may be pathogenic in humans. According to Section 5 of the German Occupational Safety and Health Act (ArbSchG), any risk to employees due to exposure must be prevented when carrying out the test method.