BLUE ANGEL

The German Ecolabel



Flushing Water Additives Compatible with Wastewater Treatment Plants

DE-UZ 84b

Basic Award Criteria Edition March 2013 Version 2

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.

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

1 Introduction

1.1 Preface

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

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

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

1.2 Background

Mobile toilets are increasingly used in recreational vehicles and pleasure boats. Other places of use are construction sites, highway rest areas, mass events, tour coaches, planes, passenger trains and passenger ships. They mostly use both sanitation fluids and flushing water additives.

The task of flushing water additives is to keep the flushing water fresh and to ensure the proper working and the hygiene of a mobile toilet. The reason why biocidal agents in flushing water additives are considered to be particularly problematic for wastewater treatment systems and the environment is their bacterial toxicity.

1.3 Objectives of the Environmental Label

Award of the Blue Angel eco-label to flushing water additives compatible with wastewater treatment plants is meant to promote the use of such additives in order to ease the load on disposal pathways and environment. Flushing water additives are used in a liquid form.

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



2 Scope

These Basic Criteria apply to flushing water additives without biocidal effect in wastewater treatment systems. The flushing water additives are used in a manner consistent with the intended use to keep the flushing water fresh and to ensure the proper functioning of mobile toilets.

3 Requirements

The Blue Angel eco-label shown on page 1 can be awarded to the products under para. 2, provided that the meet the requirements specified hereinafter.

3.1 Microbiocides

3.1.1 Exclusion of Biocidal Properties of the Mixture

The flushing water additives/product mixtures must not have any biocidal effect on the microorganisms in wastewater treatment plants nor may they have any other adverse impact on the disposal at wastewater treatment plants.

Compliance Verification

Compliance with the requirement shall be verified on the following basis: The disposal concentration¹ shall be diluted with water at a ratio of 1:3 corresponding to a dilution factor of F = 4. The disposal concentration shall be tested in accordance with

- DIN EN ISO 10712 Water quality Pseudomonas putida growth inhibition test (Pseudomonas cell multiplication inhibition test) or
- DIN 38412, Part 27 Pseudomonas oxygen consumption inhibition test (L 27) or
- DIN EN ISO 11348-1 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 (reference method) or
- DIN EN ISO 11348-2 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 (equivalent method) or
- DIN 38412, Part 30 acute toxicity on daphnia or
- DIN EN ISO 9509 Water quality Toxicity test for assessing the inhibition of nitrification of activated sludge microorganisms or
- OECD 209 Activated Sludge, Respiration Inhibition Test².

If testing according to one of these test methods does not show any effects it may be assumed that no significant inhibition (in terms of the test guideline) to the microbial activity has occurred.³

Testing laboratories referred to in paragraph 4 shall submit the test records for the data required. The testing laboratory shall prepare a complete test report in accordance with the requirements listed in the test guideline⁴ and confirm compliance with the requirement in accordance with the form in Annex x.

¹ Disposal concentration: Concentration of the product in the tank volume (TV), e.g. in mg/I TV or ml/I TV, according to manufacturer's instructions for maximum dosage (dosage recommendation for extreme situations/high temperatures) per tank volume according to para. 3.8.

² In contrast to a guideline-conforming test using dilution series for determining EC₁₀, EC₂₀, EC₅₀ etc. only the above-mentioned dilution (1:3) of the disposal concentration will be tested in a limit test.

³ If the product mixture contains compounds that are to release active oxygen the test shall be preceded by a deactivation phase in order to prevent specific disturbances of the test regime by activated oxygen.

⁴ To ensure timely processing of the applications the test reports submitted must be complete and validatable.

3.1.2 Exclusion of Biocidal Substances

Biocides within the meaning of the Biocidal Products Directive 98/8/EC (or EU Biocidal Products Regulation – Regulation (EU) No 528/2012 of 22 May 2012 – in force from September 1, 2013) must not be used. In-can preservatives or mixtures thereof (PA 6) in concentrations that need not be listed in the Material Safety Data Sheet (according to Regulation (EC) No 1907/2006, as amended by Regulation (EU) No. 453/2010), shall be exempt from this requirement. Also exempt are substances approved as food additives in Europe (e.g. citric acid) as well as fragrances and fragrance mixtures as specified under para. 3.5 (e.g. lavender oil)⁵. This also applies to surfactants which may have biocidal properties as well.

Compliance Verification

The manufacturer shall declare compliance with the requirement and submit the formulation (see Annex 2) of the product sold under a brand or trade name as well as the Material Safety Data Sheet.

3.2 Biodegradability / Eliminability

Both the individual ingredients as well as the mixture shall be tested.

The requirements for fragrances/components of fragrance mixtures are set forth in para. 3.5, thus rendering additional testing of the biodegradability/eliminability unnecessary.

Surfactants shall meet the requirements set forth in the Detergent Regulation (EC) No 648/2004.

3.2.1 Degradability of the Ingredients

The ingredients of the products must be degradable or eliminable in a wastewater treatment plant. If the product contains purely inorganic compounds (for example, minerals, inorganic salts, peroxides) they shall be left out of consideration. The content of fragrances and colorants or mixtures thereof shall not exceed 3 weight percent. Their percentage of non-biodegradable or non-tested colorants shall not exceed 0.2 weight percent based on the overall formulation.

Compliance Verification

The individual ingredients shall meet the requirements for easy biodegradability⁶ on the basis of the following alternative test methods:

- DOC Die Away Test (OECD 301 A, EC C.4 A, DIN EN ISO 7827)
- Modified OECD-Screening Test (OECD 301 E, EC C.4 B, DIN EN ISO 7827)
- CO₂ Evolution Test (OECD 301 B, EC C.4 C, DIN EN ISO 9439)
- Manometric Respirometry Test (OECD 301 F, EC C.4 D, DIN EN ISO 9408)
- Closed Bottle Test (OECD 301 D, EC C.4 E, DIN EN ISO 10707)
- MITI-(I)-Test (OECD 301 C, EC C.4 F)
- Headspace-Test (OECD 310, DIN EN ISO 14593)
- Two-Phase Closed Bottle Test (BODIS; ISO 10708)

⁵ According to COMMISSION REGULATION (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives.

⁶ Assessment in accordance with Directive 67/548/EEC, Annex VI

Compliance shall be verified on the basis of the Material Safety Data Sheet indicating the test method used.

3.2.2 Degradability of Surfactants

The surfactants used shall meet the biodegradability requirements as set forth in Detergent Regulation (EC) No 648/2004, Annex III.

Compliance Verification

The applicant shall submit the corresponding declaration from the supplier.

3.2.3 Degradability of the Product Mixture / Working Strength Solution

Also, the applicant shall verify compliance with the requirement for the product mixture. If the product contains purely inorganic compounds (for example, minerals, inorganic salts, peroxides) they shall be left out of consideration.

If fragrances are the only organic components of the product the requirement in para. 3.5 shall apply.

Compliance Verification

Eliminability of 80% in the Zahn-Wellens⁷ Test (OECD 302 B; DIN EN ISO 9888; 88/302/EEC, C.9)

Testing laboratories referred to in paragraph 4 shall submit the test record. They shall submit a complete test report meeting the requirements set forth in the test guideline providing all raw data, including those of parallel approaches.⁸

If the physicochemical properties of the products call for modifications in sample preparation technique such modifications shall be indicated and substantiated.

The testing laboratory shall confirm compliance with the requirement in the test report.

3.3 General Exclusion of Substances with Certain Properties

The following substances must not be used:

a) Substances identified as being of very high concern under the Chemicals Regulation REACH (Regulation (EC) No 1907/2006) and included in the list drawn up in accordance with Article 59 (1) of the REACH Regulation (so-called "Candidate List"), as amended at the time of application⁹. If the substance is a component of a mixture its concentration shall not exceed 0.1% by weight. If – according to the criteria of the GHS Regulation (Regulation (EC) No 1272/2008) - a more stringent specific concentration limit exists for a substance in a mixture the latter shall apply.

⁷ Not withstanding the Directive, the test period shall be 7 days (instead of 28 days).

⁸ To ensure timely processing of the applications the test reports submitted must be complete and validatable.

⁹ For the candidate list, as amended, please go to: <u>http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp</u>

- b) Ingredients which under the criteria of Regulation (EC) No 1272/2008 (or Directive 67/548/EEC)¹⁰ are assigned the H Phrases (R Phrases) listed in the following table or meet the criteria for such classification. If the substance is a component of a mixture its concentration shall not exceed the generic cut-off values listed in the GHS Regulation (Regulation (EC) No 1272/2008). If a more stringent specific concentration limit exists for a substance in a mixture the latter shall apply.
- c) Exempt from rules a) and b) shall be impurities in concentrations that need not be listed in the Material Safety Data Sheet. The components to be indicated in the Material Safety Data Sheet must meet the requirements set forth in Annex II, No 3, to the REACH Regulation (Regulation (EC) No 1907/2006). If, according to this, the substance is a component of a mixture its concentration must not exceed the generic cut-off values specified in the GHS Regulation (Regulation (EC) No 1272/2008). If a more stringent specific concentration limit exists for a substance in a mixture the latter shall apply.

Also exempt shall be substances

- approved as food additives in Europe (e.g. citric acid),
- fragrances as specified in para. 3.4.2 (e.g. lavender oil)
- as well as surfactants in concentrations of less than 25 % in the product which are classified as H400/R50 (H400/R 50: Very toxic to aquatic life). This percentage is to be divided by the M-factor established in accordance with Regulation (EC) No 1272/2008.

Regulation (EC) No 1272/2008 (GHS Regulation)	Directive 67/548/EEC (Dangerous Substance Directive)	Text		
Toxic Substances				
H300	T+ R28	Fatal if swallowed		
H301	T; R25	Toxic if swallowed		
H304	Xn R65	May be fatal if swallowed and enters airways		
H310	T+ R27	Fatal in contact with skin		
H311	T; R24	Toxic in contact with skin		
H317	R43	May cause an allergic skin reaction		
H330	T+ R26	Fatal if inhaled		

Table – Exclusion of Ingredients pursuant to para. 3.3 b)

¹⁰ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (GHS Regulation).

The GHS Regulation (Globally Harmonized System) that has come into force on January 20, 2009, replaces the old Directives 67/548/EEC (Dangerous Substances Directive) and 1999/45/EC (Dangerous Preparations Directive). According to the said regulation, substances are classified, labelled and packed until December 1, 2010 according to Directive 67/548/EEC while mixtures (formerly preparations) are classified, labelled and packed until June 1, 2015 according to Directive 1999/45/EC. Thereafter, the GHS Regulation shall be applied. Until the 1st of June 2015, both the new indications of danger (H Phrases) and the hitherto applicable R Phrases (Risk Phrases) shall be indicated.

Regulation (EC)	Directive 67/548/EEC (Dangerous Substance Directive)	Text
H331	T; R23	Toxic if inhaled
H334	IR42	May cause allergy or asthma symptoms or breathing difficulties if inhaled

Н370	R39 in combination with T R23, T R24, T R25, T+ R26,T+ R27 and/or T+ R28	Causes damage to organs
H371	Xn R68 in combination with R20,21 and 22	May cause damage to organs
Н372	T R48 in combination with R23, R24 and/or R25	Causes damage to organs through prolonged or repeated exposure
Н373	Xn R48 in combination with R20,21, and 22	May cause damage to organs through prolonged or repeated exposure
EUH029	R29	Contact with water liberates toxic gas
EUH031	R31	Contact with acids liberates toxic gas
EUH032	R32	Contact with acids liberates very toxic gas
EUH066**		Repeated exposure may cause skin dryness or cracking.
EUH070	R39-41	Toxic by eye contact
Carcinogenic,	mutagenic and reprotoxic	substances:
H340	R46	May cause genetic defects.
H341	R68	Suspected of causing genetic defects.
H350	R45	May cause cancer.
H350i	R49	May cause cancer by inhalation.
H351	R40	Suspected of causing cancer.
H360F	R60	May damage fertility.
H360D	R61	May damage the unborn child.
H360FD	R60/61	May damage fertility. May damage the unborn child.
H360Fd	R60/63	May damage fertility. Suspected of damaging the unborn child.
H360Df	R61/62	May damage the unborn child. Suspected of damaging fertility.
H361f	R62	Suspected of damaging fertility.
H361d	R63	Suspected of damaging the unborn child.

Regulation (EC) No 1272/2008	Directive 67/548/EEC (Dangerous Substance Directive)	Text
H361fd	62/63	May damage fertility. May damage the unborn child.
H362	R64	May cause harm to breast-fed children.

Water-Hazardous Substances				
H400	R50	Very toxic to aquatic life.		
H410	R50/53	Very toxic to aquatic life with long-lasting effects.		
H411	R51/53	Toxic to aquatic life with long-lasting effects.		
H412	R52/53	Harmful to aquatic life with long lasting effects.		
H413	IR53	May cause long lasting harmful effects to aquatic life.		
Other Health and Environmental Effects				
EUH059 (H420) ¹¹	R59	Hazardous to the ozone layer.		

Compliance Verification

The applicant shall declare compliance with the requirements in Annex 3 to the Contract pursuant to DE-UZ 84b and submit the formulation of the product sold under a brand or trade name including information on type (IUPAC nomenclature and CAS registry number) as well as on the percentage (weight percent) of all substances used in accordance with Annex 2 to the Contract pursuant to DE-UZ 84b.

Current Material Safety Data Sheets¹² shall be presented for all chemical ingredients.

The manufacturer shall provide evidence of having requested the suppliers of primary products to submit information on the impurity content (up to 0.01 weight percent) and by-products.

3.4 Exclusion of Ingredients

The following substances must not be added to product mixtures:

- Alkylphenol ethoxylates
- Phosphates and phosphonates
- NTA or EDTA
- Formaldehyde
- Formaldehyde-releasing preservatives
- Quaternary ammonium compounds that are not easily biodegradable
- Substances containing mercury, lead, cadmium or chromium as well as boron and halogen-based oxidants.

Production-related impurities shall not exceed 0.01 weight percent in the product.

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¹¹ COMMISSION REGULATION (EU) No 286/2011 of 10 March 2011 amending Regulation (EC) No 1272/2008

¹² In order to be current the print date of a Material Safety Data Sheet shall not date back more than 2 years

Compliance Verification

The applicant shall declare compliance with the requirement in Annex 6 to the Contract.

3.5 Requirements for Fragrances and Fragrance Mixtures

- a) The product shall not contain any aromatic substances containing nitro musk or polycyclic musk compounds.
- b) All substances added to the product as fragrance/components of fragrance mixtures shall be manufactured, treated and/or used in accordance with the code of practice of the International Fragrance Association (IFRA)¹³ or shall be listed on the FDA's GRAS list.¹⁴
- c) Fragrances / components of fragrances mixtures¹⁵ classified as H317/R43 (May cause an allergic skin reaction) must not be present in the product mixture in concentrations ≥ 0.1 %.
- d) Fragrances / components of fragrance mixtures¹⁵, classified as H334/R42 (May cause allergy or asthma symptoms or breathing difficulties if inhaled) must not be present in the product mixture in concentrations ≥ 0.1 %.

Compliance Verification

The applicant shall declare compliance with each criterion under a) and b). For compliance with the criterion under c) the applicant shall present a declaration signed by the fragrance manufacturer confirming compliance with this criterion.

3.6 Labelling

The product mixture must not be classified in accordance with Annexes I and VI to Directive 1272/2008/EC or Directive 67/548/EEC, each as amended, as:

- dangerous to the environment and assigned the hazard symbol GHS09 or N in combination with the following H or R phrases:
 - H400 or R50 (Very toxic to aquatic organisms)
 - H410 or R50/53 (Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment)
 - H411 or R51/53 (Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment)
 - H412 or R52/53 (Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment)
 - R52 (Harmful to aquatic organisms)
 - H413 or R53 (May cause long-term adverse effects in the aquatic environment) or
 - EUH059 or H420 or R59 (Dangerous for the ozone layer)
 - caustic classified with the hazard symbol GHS05 or C,
- dangerous to health classified with the hazard symbol GHS07 or Xn or
- sensitizing classified with GHS08 or Xi in combination with
 - H334 or R42 (May cause sensitisation by inhalation)

or

H317 or R43 (May cause sensitisation by skin contact).

¹³ For the IFRA Code of Practice please go to: <u>http://www.ifraorg.org</u>

¹⁴ <u>http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/default.htm</u>

¹⁵ in relation to the individual substance according to CAS number

Compliance Verification:

Compliance shall be verified on the basis of the Material Safety Data Sheet.

3.7 Additives Containing Microorganisms

If the flushing water additives/product mixtures contain microorganisms the basic formulation shall show the strains of microorganisms and their manufacturers as well as their quantities of colony-forming units per litre or kilogram of product (CFU/I or CFU/kg). The only microorganism strains permitted for use are those which according to the state of the scientific knowledge are not pathogenic in humans, animals or plants and do not pose a risk to human health and the environment. This requirement shall be considered met if the microorganisms¹⁶ are exclusively classified in risk group 1 of the "Liste risikobewerteter Spender- und Empfängerorganismen für gentechnische Arbeiten" (List of risk-assessed donor and recipient organisms for genetic engineering studies)¹⁷ as amended, and/or in the leaflets B004 (viruses), B005 (parasites), B006 (bacteria), B007 (fungi) of the Berufsgenossenschaft Rohstoffe und Chemische Industrie (German Social Accident Insurance Institution for the Raw Materials and Chemical Industry).¹⁸

Genetically modified microorganisms within the meaning of the German Gentechnikgesetz (GenTG) (Genetic Engineering Act) shall not be permitted.

Compliance Verification

For compliance with the requirement the manufacturer shall complete Annex 4 to the Contract pursuant to DE-UZ 84b.

3.8 Dosing System and Safety

All flushing water additives intended for direct sale to the final consumer, except for refill packs with a closure, shall 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.

3.9 Packaging Materials

The packaging materials must not contain PVC.

Compliance Verification:

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

3.10 Consumer Information

The sales packaging of the flushing water additive shall in an appropriate and easily readable form (e.g. inscription, label, instructions for use)

¹⁶ Definition of "microorganisms" according to Section 3 GenTSV (Gentechnik-Sicherheitsverordnung -Genetic Engineering Safety Regulation) and Directive 90/679/EU

¹⁷ Publication according to Section 5, para. 6, Gentechnik-Sicherheitsverordnung (Genetic Engineering Safety Regulation) of 14 March 1995, last amended on December 16, 2008

¹⁸ Sichere Biotechnologie, Eingruppierung biologischer Agenzien (Safe Biotechnology, Classification of Biological Agents) Berufsgenossenschaft Rohstoffe und chemische Industrie (Social Accident Insurance Institution for the Raw Materials and Chemical Industry)

- give the field of application (e.g. camping toilet, rental toilet etc.) of the product;
- include instructions for proper dosing;
- specify the application modalities required to ensure serviceability minimum and maximum dosage of the product mixture in relation to the tank volume, effective useful life and the effective temperature range;
- include 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";
- include the note "Keep out of reach of children" (similar formulations may be used);
- provide information on proper product storage and shelf life;
- include the note "Product contains genetically engineered enzymes" if the product contains genetically engineered enzymes.

Compliance Verification

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

3.11 Testing Laboratories

The applicant shall present test reports prepared by testing laboratories confirming compliance with the requirements in paras. 3.1.1, 3.2.1 and 3.2.3.

The testing laboratory shall provide evidence that

• the tests forming the basis of all test results meet the requirements for Good Laboratory Practice (Annex 1 to the German Chemicals Act)

or

• the testing laboratory is accredited according to DIN EN 17025 and the tests forming the basis of the test results form part of this accreditation in terms of testing fields, methods and specifications.

Compliance Verification

Compliance shall be verified by submission of the following documents:

• certificate according to Section 19b, German Chemicals Act (ChemG)

and

• written declaration from the testing laboratory stating that the test has been performed in accordance with the principles of Good Laboratory Practice

or

• accreditation certificates issued by Deutscher Akkreditierungsrat (DAkkS) (national accreditation body) or another national accreditation body being a signatory to the Multilateral Recognition Agreement (MLA).

Tests conducted according to the principles of GLP prior to the publication of these Basic Criteria will be recognised if they meet the test requirements of these Basic Criteria.

4 Applicants and Parties Involved

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

Parties involved in the award process are:

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

5 Use of the Environmental Label

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

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

Contracts on the Use of the Environmental Label are concluded to fix the terms for the certification of products under Paragraph 2. Such contracts shall run until December 31, 2021. They shall be extended by periods of one year each, unless terminated in writing by March 31, 2021 or March 31 of the respective year of extension.

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

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

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

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

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