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EU Ecolabel criteria for paints and varnishes: assessment of derogation requests for biocide substances

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Contents

Abstract

This report is intended to provide the background scientific information for the European Commission to respond to a number of derogation requests received for certain hazardous substances in response to Commission Decision 2014/312/EU setting the EU Ecolabel criteria for the indoor and outdoor paints and varnishes product group.

To support the possible process of derogation from the EU Ecolabel criteria for indoor and outdoor paints and varnishes, this report consists of:

— a general background to the EU Ecolabel with emphasis on the application of Articles 6(6) and 6(7) of EU Ecolabel Regulation (EC) No 66/2010;

— the market situation and baseline information on hazardous substances, biocides and Regulation (EC) 1907/2006 (REACH) and Regulation (EC) 1272/2008 (CLP);

— a technical assessment of each substance derogation request.

This background information, combined with input received from the stakeholders involved, has been used to provide the final conclusions on the derogation requests received from stakeholders.

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Executive summary

This report provides the background scientific information to respond to a number of derogation requests received for certain hazardous substances in response to Commission Decision 2014/312/EU setting the EU Ecolabel criteria for the indoor and outdoor paints and varnishes product group.

The JRC collects and analyses the scientific evidence necessary for the implementation of product-specific EU Ecolabel criteria under the EU Ecolabel Regulation (Regulation (EC) 66/2010)[1]. According to Article 6(6) of the EU Ecolabel Regulation, '*the EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR), in accordance with 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*[2]*, nor to goods containing substances referred to in Article 57 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency*[3]'. However, in Article 7 of the EU Ecolabel Regulation it is stated that '*only in the event that it is not technically feasible to substitute them as such, or via the use of alternative materials or designs, or in the case of products which have a significantly higher overall environment performance compared with other goods of the same category, the Commission may adopt measures to grant derogations from paragraph 6*'.

In line with this, a process for amendment of the Regulation can be started. In general, after receiving a derogation request, an initial consultation between the JRC and DG ENV takes place. After information has been gathered, the derogation request is presented to members of the EU Ecolabelling Board (EUEB) for initial opinions. If such a consultation proceeds with positive feedback, the proposed amendments to the legal text are sent for Interservice Consultation (ISC) with other DGs of the Commission. Afterwards, the EUEB formally votes on the proposed amendments to the legal text of the EU Ecolabel criteria. A complete description of this process is explained in Chapter 3 of this report.

This report is structured in four main chapters. In Chapter 1, a general background to the EU Ecolabel with emphasis on the application of the above-mentioned Articles 6(6) and 6(7) is provided. Chapter 2 lays out the market situation while also including a further description of information on hazardous substances and biocides used in paints and varnishes. Chapter 3 presents the technical assessment for each substance derogation request. Chapter 4 summarises the final conclusions.

The EU Ecolabel, the official voluntary labelling scheme of the EU, promotes the production and consumption of products (goods and services) with a reduced environmental impact over their life cycle, and is aimed at products with an excellent environmental performance. Established in 1992, it has become a key policy instrument within the European Commission's Sustainable Consumption and Production and Sustainable Industrial Policy (SCP/SIP) Action Plan (COM(2008) 397) and the Roadmap for a Resource-Efficient Europe (COM/2011/0571). The EU Ecolabel was mentioned as having an important role in the new Circular Economy Action Plan (CEAP) from March 2020.

The EU Ecolabel was also mentioned in the chapeau Communication on making sustainable products the norm. This Communication accompanies a package of measures proposed in the CEAP and adopted on 30 March 2022[4], including: a proposal for the Ecodesign for Sustainable Products Regulation, an EU strategy for sustainable and circular textiles, a proposal for a revised Construction Products Regulation, and a proposal for empowering consumers in the green transition. The Communication mentions the EU Ecolabel as an important tool whose criteria will be developed in synergy with future Ecodesign measures.

The assessment of the derogation requests showed the potential for acceptance of some of them, mainly for sodium pyrithione (NaPT) for its use as an in-can preservative and for 3-iodo-2-propynyl butylcarbamate (IPBC). Nevertheless, given the low support from EUEB members to proceed with an amendment, it was decided to keep monitoring the issues raised during the derogation process and to reassess the requests during the upcoming full criteria revision process planned for Q4 2023.

[1] Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel, OJ L 27, 30.1.2010, p. 1–19. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010R0066

[2] OJ L 353, 31.12.2008, p. 1.

[3] OJ L 396, 30.12.2006, p. 1.

[4] https://ec.europa.eu/environment/strategy/circular-economy-action-plan_en

1 Introduction

The main purpose of this report is to present the background research and scientific information for the European Commission to respond to a number of derogation requests received for certain hazardous substances that would, if accepted, result in the need to amend Commission Decision 2014/312/EU setting EU Ecolabel criteria for paint and varnish products.

For the sake of completeness, and for readers that are less familiar with the EU Ecolabel policy, this introduction section explains the general background to the EU Ecolabel, with a particular focus on how the EU Ecolabel deals with hazardous substances. A brief history of previous amendments to Commission Decision 2014/312/EU is also provided for context.

1.1 The EU Ecolabel policy

The EU Ecolabel is a voluntary policy whose aim is to promote products with a reduced environmental impact during their entire life cycle. To do this, it is first necessary to define criteria that aim to target the top 10% to 20% of products on the market within a defined product group or service. Third-party verification of compliance with such criteria then enables suppliers to market their products or services with a simple label that can be used as an accurate, non-deceptive and science-based proof of the excellent environmental performance of their product or service.

EU Ecolabel Regulation (EC) No 66/2010 sets the framework, general procedures and comitology for how EU Ecolabel criteria should be developed and revised. The whole process of developing or revising criteria, from the first step to the final adoption of new criteria, can take 2 to 3 years. Once criteria are formally adopted and published in the official languages of the EU, they have a defined validity of typically 4 to 8 years. During this validity period, the actual criteria can be amended for various reasons. One type of amendment is to simply extend the validity period of all the criteria – which would require an explanatory note justifying why the criteria continue to be relevant and suitably ambitious. However, the amendment of the actual content of existing criteria often requires more detailed justifications and consultation – in proportion to how major the changes being introduced are.

One of the most common drivers for amending EU Ecolabel criteria are changes in hazardous substance classification, which create the need to either insert new derogations or modify existing derogations for hazardous substances. The primary aim of this report is to present the JRC assessment of a number of hazardous substance derogation requests received for EU Ecolabel paints and varnishes. Consequently, it is necessary to present some further background to:

- the general approach to horizontal hazardous substance restrictions in the EU Ecolabel Regulation, and
- the general approach to hazardous substance classification procedures.

Once this overall background is explained, the specific derogation requests received for selected hazardous substances EU Ecolabel paints and varnishes can be understood by the reader and the JRC assessment presented.

1.2 Horizontal hazardous substance restrictions in EU Ecolabel products

A very ambitious common horizontal approach to restrict hazardous substances applies to all product groups. This approach basically restricts ALL substances with certain defined hazard classifications.

This horizontal approach is based on Articles 6(6) and 6(7) of EU Ecolabel Regulation (EC) No 66/2010. The legal text specifically states the following:

Box 1. Articles 6(6) and 6(7) of EU Ecolabel Regulation (EC) No 66/2010

6. The EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR), in accordance with 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, nor to goods containing substances referred to in Article 57 of 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.

7. For specific categories of goods containing substances referred to in paragraph 6, and only in the event that it is not technically feasible to substitute them as such, or via the use of alternative materials or designs, or in the case of products which have a significantly higher overall environment performance compared with other goods of the same category, the Commission may adopt measures to grant derogations from paragraph 6. No derogation shall be given concerning substances that meet the criteria of Article 57 of Regulation (EC) No 1907/2006 and that are identified according to the procedure described in Article 59(1) of that Regulation, present in mixtures, in an article or in any homogeneous part of a complex article in concentrations higher than 0,1% (weight by weight). Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 16(2).

For the sake of consistency and clarity, a Chemicals Task Force (CTF) was set up to make recommendations for the interpretation of this legal text when developing or revising EU Ecolabel criteria. Some of the most relevant recommendations were as follows:

- That the term '*containing*' should be considered applicable when the restricted substance is present in EU Ecolabel goods in quantities >0.10% (w/w) in products (or in component parts therein) that are articles, or in quantities >0.010% (w/w) in products that are mixtures.
- That restricted hazards referring to '*toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction*' should be explicitly stated in terms of hazard classes (see box below).
- That the restricted hazards should be grouped into three groups of hazard classes and, although the allowable limits are equally applicable, derogations should be easiest to justify for group 3 hazard classes and most difficult to justify for group 1 hazards (see box below).
- That additionally, in cases where exposure to users is considered relevant, additional category 1 hazards for respiratory and skin sensitisation may be included in the group 2 hazard classes.
- That a formal derogation procedure should be followed and a standard form filled out as part of each request.
- To respect the following level of certainty about hazardous properties: harmonised classification > joint entries > self-classification.

Box 2. Chemicals Task Force information on Hazard Classes

Hazard classes applicable for all product groups (unless denoted otherwise):

- Group 1 hazard classes: CMR - H340, H350, H350i, H360F, H360D, H360FD, H360Fd, H360Df.

- Group 2 hazard classes: CMR - H341, H351, H361f, H361d, H361fd, H362; Acute toxicity – H300, H310, H330, H304; Specific Target Organ Toxicity (STOT) – H370, H372; Hazardous to the aquatic environment – H400, H410, H411; Hazardous to the ozone layer – H420; Respiratory and skin sensitisation* – H317*, H334*.

- Group 3 hazard classes: Acute toxicity – H301, H311, H331, EUH070; Specific Target Organ Toxicity (STOT) – H371, H373; Hazardous to the aquatic environment – H412, H413.

*Only applied horizontally when potential exposure to users is a concern.

1.3 Hazard classification procedure

The two primary pieces of EU legislation that relate to the hazard classifications of ALL substances and mixtures on the EU market are Regulation (EC) 1907/2006 (later referred to as REACH) and Regulation (EC) 1272/2008 (later referred to as CLP). Complimentary to CLP, and of particular relevance to the subject matter of this report, is Regulation (EU) No 528/2012 on biocidal products (later referred to as BPR).

Due to REACH and CLP, it is necessary for manufacturers, importers, downstream users and distributors of substances or mixtures to communicate the hazard classification (if any) of the substances or mixtures being placed on the market. Information on hazard classification can pass through the supply chain via compliance with CLP requirements on the classification, labelling and packaging of substances and mixtures, and on information in safety data sheets (SDSs), produced in accordance with Article 31 of and Annex II to REACH.

Substances and mixtures are either self-classified or have a harmonised classification. In the first case, self-classification can mean that there are differences in hazard classifications declared by different manufacturers of the same substance or mixture. While undesirable, one example of how this could occur could be due to different impurity levels in the same substance made by different manufacturers. REACH and CLP require that notifiers and registrants make every effort to share data and come to an agreed joint entry for self-classifications.

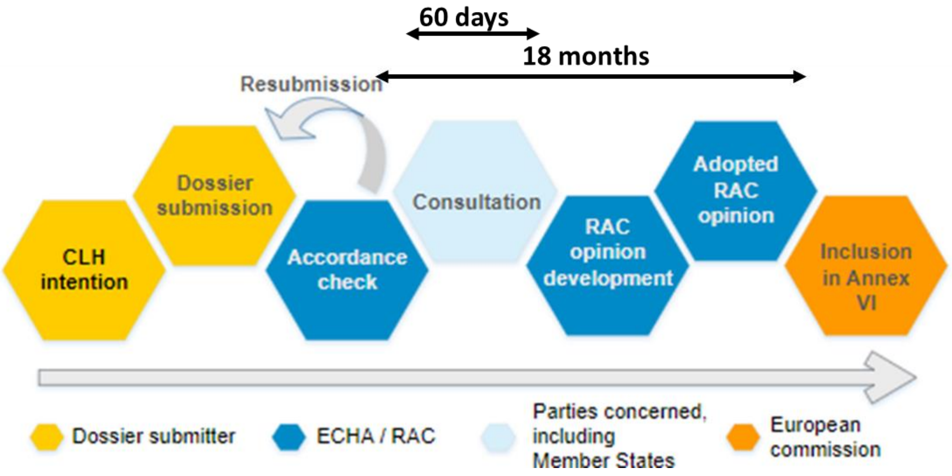
Harmonised classifications involve additional processes (Article 37 of CLP) and efforts to harmonise classifications have prioritised CMR and sensitising substances. It is also worth mentioning that the BPR aims to produce harmonised classifications for the biocidal active substances that are evaluated.

While both self-classifications and harmonised classifications are data-based, it is necessary to follow a formal process involving public consultation, comitology and scrutiny before concluding on harmonised classifications. Information about self-classifications, joint entries and harmonised classifications can be found for any registered substance on the C&L inventory of the European Chemicals Agency (ECHA) website[5].

When a harmonised classification is agreed for a substance or a mixture, it supersedes any contradictory self-classifications. Consequently, all producers of that substance or mixture must apply it to the labelling, packaging and safety data sheets of those products.

5 See: https://www.echa.europa.eu/information-on-chemicals/cl-inventory-database

Figure 1. The steps for the classification and labelling harmonisation (CLH) process



Source: ECHA[6].

Any Member State Competent Authority (MSCA) or manufacturer, importer or downstream user of substances or mixtures can communicate a CLH intention to ECHA. After checking, received intentions are published on the '[Registry of Intentions]' page of the ECHA website. The publication of such intentions has the advantages of: (i) preventing multiple registrations of intentions for the same substance/mixture, and (ii) attracts the attention of interested stakeholders with relevant information and experience to share.

The CLH dossier is a stand-alone document that needs to meet relevant requirements of the CLP Regulation and provide sufficient information for hazards to be assessed and for the Committee for Risk Assessment (RAC)[7] to develop an opinion later on. No confidential information should be in the dossier since the whole dossier should be made available for public consultation.

The public consultation lasts 60 days and comments are sought on the hazard class proposals. Comments are published on the ECHA website. Afterwards, the dossier submitter is invited to respond to comments (also published on the ECHA website). All of this information (dossier, comments and responses) is then forwarded to ECHA's RAC. The RAC may also respond to comments received during consultation and may conclude that different hazard classes and conditions apply to those originally proposed by the dossier submitter. There is a deadline of 18 months for developing the RAC opinion which starts when a submitted dossier is declared satisfactory by ECHA. If not satisfactory, the dossier is sent back to the respective authority for revision, with no determined deadline. Once the opinion is adopted by ECHA, it is sent to the European Commission for a decision on whether or not to proceed with the transposition of the RAC opinion into law. The Commission counts on the assistance of the expert group of the Competent Authorities for the REACH and CLP Regulations (CARACAL).

The adoption of harmonised classifications is formally published in the Official Journal of the European Union (OJEU) as **'adaptations to technical (and scientific) progress'** (later referred to as ATPs). A full and updated list of all harmonised classifications is maintained in Part 3 of Annex VI to CLP. As of February 2023, a total of 18 ATPs have been published[8]. While ATPs can also be used to implement changes to general

6 See: https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling
7 Committee for Risk Assessment - ECHA (europa.eu)
8 See under the 'CLP legislation and documents' tab at: https://single-market-economy.ec.europa.eu/sectors/chemicals/chemicals-legislation_en

classification rules and alignments with the Global Harmonised System (GHS), most of the ATP efforts are centred on introducing updates to harmonised classifications and amending Annex VI to CLP.

As mentioned earlier, the adoption of new harmonised classifications can trigger the need for amendments to certain EU Ecolabel criteria. This is because the horizontal EU Ecolabel restrictions on hazardous substances are hazard-specific and not substance-specific. The justification for such amendments are strongest when the reclassified substance is most important to the functionality or performance level of the product, when the use of the reclassified hazardous substance results in overall environmental benefits and when available less hazardous alternatives are few or none.

1.4 EU Ecolabel criteria for paints and varnishes

Commission Decision (EU) 2014/312[9] established the EU Ecolabel criteria for indoor and outdoor paints and varnishes. This Decision replaced Decisions 2009/543/EC and 2009/544/EC for EU Ecolabel indoor paints and outdoor paints, respectively. Since 2014, the criteria have been amended six times, with the subject matter of the amendments as follows:

— Decision (EU) 2015/886: (i) about half a dozen wording changes for corrections or greater clarity and (ii) the expansion of a list of restricted substance groups.

— Decision (EU) 2016/397: (i) to introduce a derogation for ADH (adipic acid dihydrazide, with restricted H411 classification) due to its ability to prolong the lifetime of paint coatings and the lack of less hazardous alternatives on the market; (ii) to introduce a derogation for methanol (with restricted H301[10], H311[11], H331[12], H370[13] classifications) because it can arise as a reaction product or impurity; (iii) to introduce a derogation for IPBC (3-iodo-2-propynyl butylcarbamate, with restricted H400[14] and H410[15] classifications) because it is an important dry-film preservative in outdoor paints and (iv) some wording changes to text referring to the Biocidal Products Regulation (Regulation (EU) No 528/2012).

— Decision (EU) 2018/666: to prolong the period of validity of the criteria and assessment and verification requirements until 31 December 2022.

— Decision (EU) 2020/503: (i) to extend the derogation for ZnO (zinc oxide, with restricted H400 and H410 classifications) from only applying when used as a stabiliser to also being applicable for use as an in-can preservative (IC) or a dry-film preservative (DF). The main reasons for this are that a similar logic had already been applied for zinc pyrithione and because ZnO is an alternative to isothiazolinones, many of which can only be dosed in extremely low concentrations without triggering classification of the paint/varnish mixture as H317[16].

— Decision (EU) 2021/1871: (i) to introduce a conditional derogation for the pigment titanium dioxide (TiO_2), in order to align with the new classification (H351[17]) for this substance as defined in the 14th ATP to CLP; (ii) to add a derogation for the pigment additive trimethylolpropane (TMP); (iii) to reduce allowed thresholds for MIT and OIT to 0.0015%, in order to align with new specific concentration limits for these substances defined in the 15th ATP to CLP.

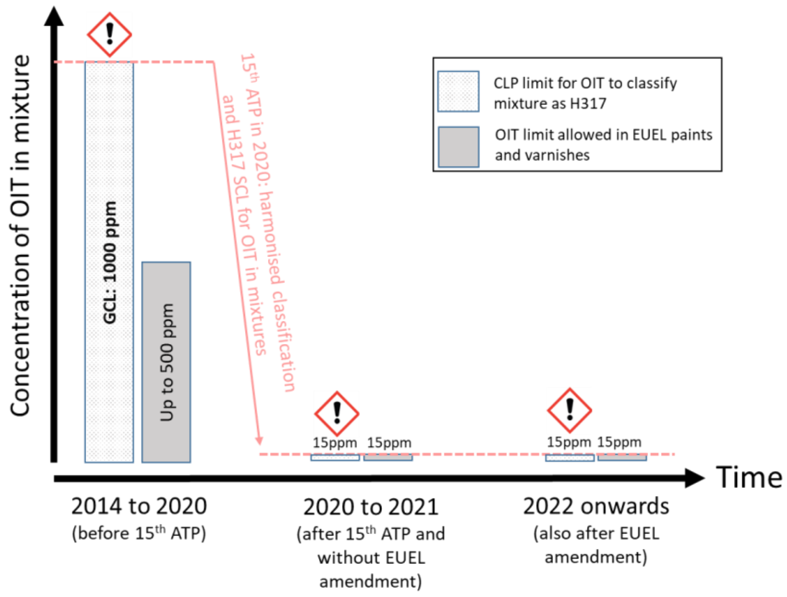
— Decision (EU) 2022/1229: to prolong the period of validity of the criteria and assessment and verification requirements until 31 December 2025.

9 See: https://eur-lex.europa.eu/eli/dec/2014/312/2022-07-18
10 Acute Toxicity, Cat. 3, Toxic if swallowed
11 Acute Toxicity, Cat. 3, Toxic in contact with skin
12 Acute Toxicity, Cat. 3, Toxic if inhaled
13 STOT, Cat. 1, Causes damage to organs
14 Hazardous to the aquatic environment, Cat. 1, Very toxic to aquatic life
15 Hazardous to the aquatic environment, Cat. 1, Very toxic to aquatic life with long-lasting effects
16 Respiratory and skin sensitisation, Cat. 1A, May cause allergic skin reaction
17 CMR, Cat. 2, Suspected of causing cancer

Paint and varnish products typically contain a number of substances with hazardous properties, and many of the EU Ecolabel criteria focus on restrictions on the types and quantities of hazardous substances allowed. Many of the amendments listed above refer to hazardous substances.

As a general rule, amendments to EU Ecolabel criteria cannot make the criteria more ambitious. However, this rule is not so simple when dealing with hazard reclassifications for substances. The recent example of OIT is illustrated below.

Figure 2. Example of CLP reclassification driving EUEL amendment: the case of OIT



Note: GLC stands for Generic Concentration Limit.

Source: JRC.

When interpreting Figure 2, it is important to understand that EU Ecolabel paints and varnishes are not permitted to be classified as category 1 skin sensitisers (H317) – something that would oblige the label on the packaging to carry the CLP pictogram with the exclamation mark. This condition is very clearly stated in criterion 5 of the EU Ecolabel criteria established in Commission Decision 2014/312/EU:

Box 3. Criterion 5 of the EU Ecolabel criteria established in Commission Decision 2014/312/EU

... 'The final product shall not be classified and labelled as being acutely toxic, a specific target organ toxicant, a respiratory or skin sensitiser, or carcinogenic, mutagenic or toxic for reproduction hazardous to the environment, in accordance with Regulation (EC) No 1272/2008 or Directive 67/548/EEC'.

Table 6

Final product classification: CLP* versus DSD** equivalence

CLP Mixture classification	DSD equivalent
Acutely toxic	T or T+
Specific target organ toxicant	T, T+ or Xn
A respiratory or skin sensitiser	-
A carcinogen, mutagen or reproductive toxicant	Carcinogen, Mutagen or Reproductive toxicant categories 1-3
Hazardous to the environment	N (excluding R53 and R52/53)

...

*CLP= Classification, Labelling and Packaging

**DSD= Dangerous Substances Directive

Looking at the longer table in Decision 2014/312/EU that comes immediately before the text quoted above, the interpretation of:

- 'acutely toxic' refers to H classes H300, H301, H310, H311, H330, H331, H304 and EUH070;
- 'specific target organ toxicant' refers to H classes H370, H371, H372 and H373;
- 'respiratory or skin sensitiser' refers to H classes H334 and H317 respectively;
- 'carcinogen, mutagen or reproductive toxicant' refers to H classes H340, H341, H350, H350i, H351, H360F, H360D, H360FD, H360Fd, H360Df, H361f, H361d, H360fd and H362;
- 'hazardous to the environment' refers to H classes H400, H410, H411, H412, H413 and EUH059.

What can be seen in the figure above is an initial situation (on the left) where up to 500 ppm of OIT could be used in EU Ecolabel (EUEL) products and not trigger classification of the whole paint or varnish mixture because the CLP limit is 1 000 ppm.

In the middle part of the figure above, the harmonised classification of OIT, set by the 15th ATP, effectively changes the concentration of OIT that would trigger classification of the mixture as a category 1 skin sensitiser (H317) from the generic limit of 1 000 ppm to a much lower specific limit of 15 ppm. This new limit is much lower than that permitted by the EU Ecolabel criteria – creating a conflict of logic. The conflict in the EU Ecolabel criteria is basically that the whole mixture cannot be classified as H317 (i.e. cannot now contain more than 15 ppm OIT). In this case, this specific derogation would not be applicable, as the use of OIT above 15 ppm would trigger classification. In practice, the harmonised classification of OIT, set by the 15th ATP, prevailed.

The final part of Figure 2 (right-hand side) shows the amendment of the EU Ecolabel to resolve the conflicting logic and to lower the allowable OIT in the derogation from 500 ppm to 15 ppm (to align with the more restrictive regulation, i.e. the 15th ATP[18]). While this can be argued as making the criteria more ambitious, in the context of the broader CLP system, the OIT limit allowed in EU Ecolabel paints is not more

[18] OJ L 261, 11.8.2020, p. 2 (15th ATP https://eur-lex.europa.eu/eli/reg_del/2020/1182/oj).

ambitious than before; in fact, you could argue that it is less ambitious because now it matches the CLP limit for H317 whereas beforehand it was 50% lower than the CLP limit.

A simple interpretation of the graph above would be that the grey column can never be above the red line (or the dotted column), but that legal developments beyond the control of the EU Ecolabel policy resulted in the red line being lowered significantly. Consequently, it becomes necessary to modify the legal text of the EU Ecolabel Decision so that the grey column can remain at or below the red line.

The type of reclassification of OIT is one of three main aspects of reclassifications that are most likely to trigger requests for derogations and amendments to EU Ecolabel criteria. These are as follows:

- Substances that were previously unclassified being assigned a harmonised classification for EU Ecolabel restricted hazards (e.g. previously unclassified TiO_2 becoming harmonised H351 via inhalation after the 14th ATP).
- The hazard classifications for a substance can become more severe (e.g. category 3 acute toxicity → category 2 acute toxicity) and/or include more hazards that are restricted by EU Ecolabel criteria (e.g. ZnPT becoming harmonised H360D after the 15th ATP).
- The threshold concentration at which a substance would trigger a whole mixture to be classified with a certain hazard can be lowered (e.g. previously 1 000 ppm of OIT was needed to classify a mixture as H317, now it is only 15 ppm after the 15th ATP).

Due to the major changes that have occurred in the hazardous substance classification landscape, it is necessary to reassess the EU Ecolabel criteria for paints and varnishes with a view to considering what amendments to the legal text of the criteria may be necessary and if new derogations are justifiable.

2 The market situation

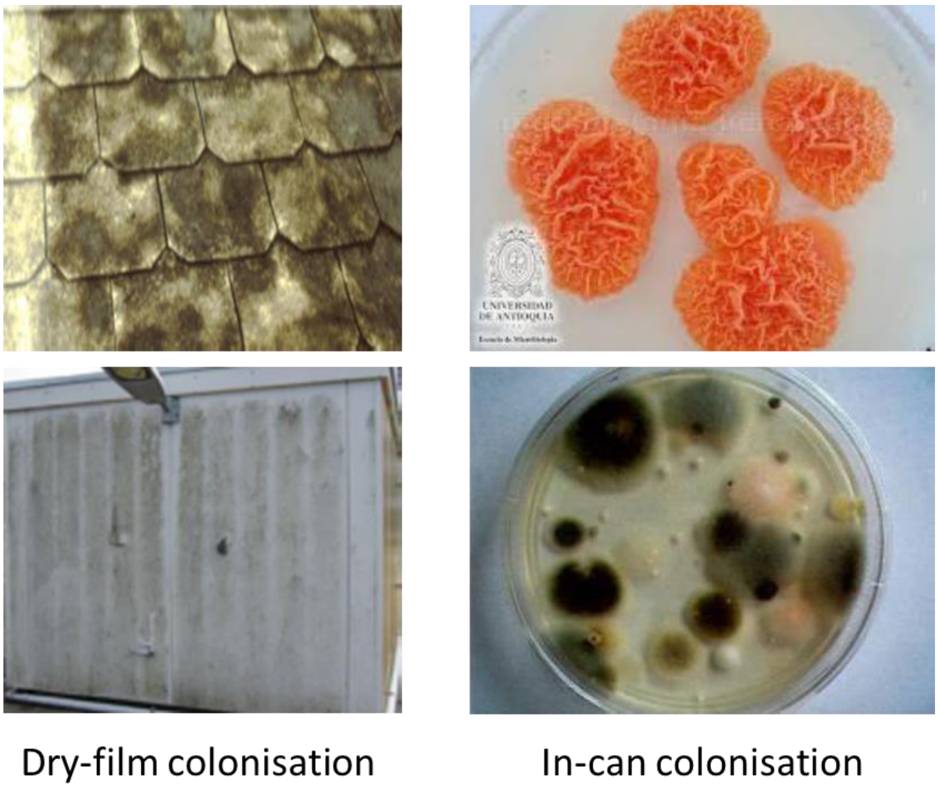
To provide the reader with an overview of the market situation with paints and varnishes, this section focuses on why biocidal active substances are used in paint and varnish products and what the main chemistries are. It then focuses on the specific biocidal active substances used to date and how their hazard classifications have changed since 2014 (when the current EU Ecolabel criteria for paints and varnishes were adopted).

2.1 Microbiological contamination of paints and varnishes

Paints and varnishes can be broadly split into water-based and organic solvent-based products. There has been a general shift to water-based paints and varnishes in Europe thanks to the VOC Directive (2004/42/CE) imposing tighter limits on VOC content in solvent-based products and due to market signals such as green building assessment schemes and national level VOC labelling schemes recognising the environmental benefits of water-based paints. The criteria for EU Ecolabel products effectively require that all compliant products shall be water-based. Such environmental benefits include reduced toxicity effects for humans and the wider environment and reduced ozone formation potential.

However, water-based paints and varnishes come with the disadvantage that they are susceptible to spoiling due to the growth of microorganisms, both in-can and on dry films of coating after application of the product. An important commercial aspect for paint products is their shelf life, i.e. the period of time that the product can remain unspoiled and in-specification prior to being opened (i.e. during time spent in warehouses, in retail stores or in customer sites). It is also important that the product will remain unspoiled for a minimum time after opening.

Figure 3. Examples of colonisation of dry films (left) and in-can product (right)

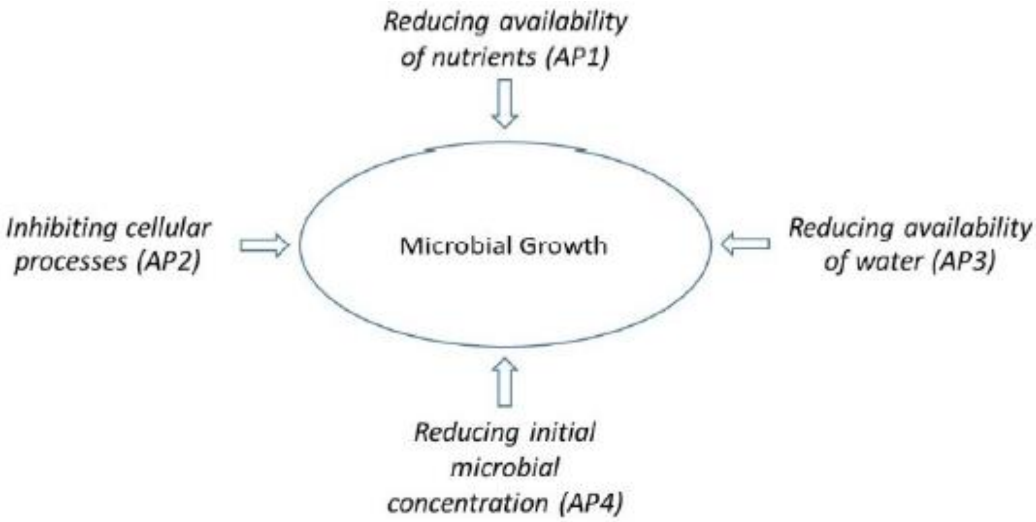


Sources: CEPE, 2018 and CEPE, 2016. CEPE is European Council of the Paint, Printing Ink and Artists' Colours Industry.

As a general rule, the colonisation of dry films is related to the action of fungi, which can colonise surfaces via spores from the surrounding environment or spores already present in the coating product. The colonisation of in-can products can be due to bacterial or fungal growth. Microorganisms (bacteria and fungi) end up inside on-shelf paint and varnish products due to their presence in raw materials used (especially open-mined materials), from air deposition of spores and bacteria at the production site when materials are mixed and deposited in containers, from biofilms in piping and tanks at the production site or from process water used.

When considering the different ingredients in water-based paints (e.g. fillers, binders, pigments and emulsifiers) some of them, especially cellulosic binders, can serve as a nutrient source for any microorganisms present in the formulation. Reducing the nutrient value of the coating formulation is one of the ways in which the risk of microbiological spoiling can be reduced.

Figure 4. Main factors to reduce risk of in-can spoiling of coating products



Source: Danish EPA, 2018.

Apart from reducing nutrient availability, reducing the availability of water and reducing the initial quantity of microbially contaminated material entering the formulation can both contribute to reducing the risk of microbial spoiling. To guarantee control against microbial spoiling, the addition of biocidal active substances to inhibit cellular processes is the key measure used by producers of water-based coatings today. Potential future approaches are summarised later in Chapter 4.

Approaches today tend to use combinations of biocidal active substances in order to provide a broad spectrum effect against different types of bacteria and fungi and to provide preservation both 'in-can' and on the 'dry film' after application. Biocidal products that provide in-can preservation are listed under 'Product Type 6' (PT6) and products providing dry-film preservation are listed under 'Product Type 7' (PT7) in line with the BPR.

Table 1. Examples of microorganisms found in water-based paints

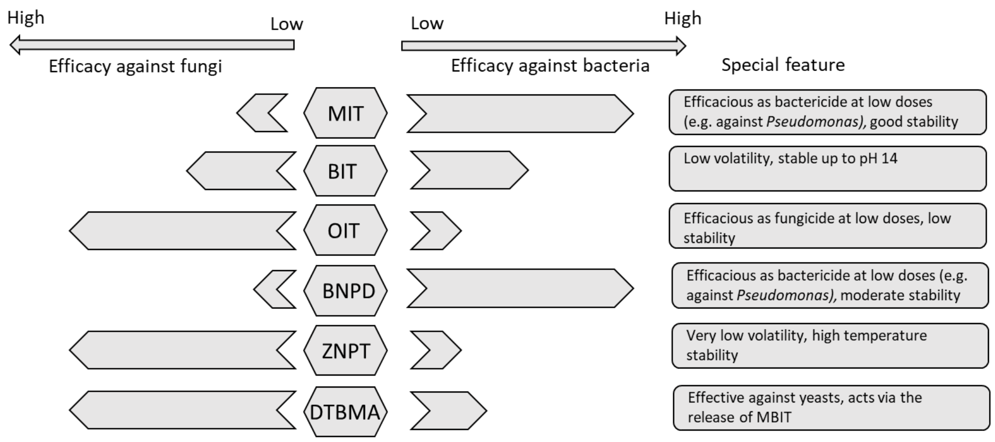
Reference	Bacteria	Fungi / Yeast
Kurovski et al., 2017	*Bacillus mycoides, Flavobacterium marinum* and *Sarcina flava*	*Alternaria dianthicola, Aureobasidium pullulans, Aspergillus flavus, Cephalosporium carpogenum, Cladosorium sphaerospermum, Cladosporium sp., Helminthosporium spiciferum, Penicillium oxalicum, Phoma glomerata, Stemphylium consortial* and *Torula nigra*
Danish EPA, 2018	*Enterococcus casseliflavus, Pseudomonas aeruginosa, Pseudomonas sp., Pseudomonas putida* and *Citrobacter freundii*	*Penicillium brevicompactum, Acremonium sp.* and *Sarocladium sp*

Source: JRC.

A diverse range of microorganisms have been identified in paints. These species represent gram-positive and gram-negative bacteria of different forms, species that need aerobic conditions or species that are facultative anaerobes. Any given mechanism of biocidal action to inhibit or kill bacteria and fungi will have different degrees of success due to the inherent differences in resistance of these different types of microorganism. Consequently, in-can preservatives might be very efficient at producing a fungicidal effect but very inefficient as a bactericide, or vice versa. This is indicated by the diagram in Figure 5.

Generally speaking, the different types of biocidal action can be classified in different ways. For example, the region of microorganisms that are targeted by the biocide (i.e. membrane-active; permeabilising, cell-wall-inhibiting, cytotoxic or genotoxic biocides), the reaction chemistry (i.e. oxidising, non-oxidising or electrophilic biocides) or chemical structure-related classifications (i.e. isothiazolines, halogen-releasers, formaldehyde releasers). The main chemistries used for in-can preservation are isothiazolines, formaldehyde releasers, pyrithiones and alkyl-halides (CEPE, 2018).

Figure 5. Overview of fungicidal and bactericidal efficacy of selected biocidal active substances



Source JRC adaptation from Leiter Technik VdL (German Paint and Printing Ink Association)[19].

MIT stands for Methylisothiazolinone; BIT for Benzoisothiazolinone; OIT for Octylisothiazolinone; BNDP for Bronopol; ZNPT for Zinc pyrithione and DTBMA for 2,2′-dithiobis[N-methylbenzamide] (EC number: 219-768-5, CAS number: 2527-58-4)

[19] Christof Walter, Leiter Technik VdL (German Paint and Printing Ink Association), 2019. Available at: https://www.linkedin.com/pulse/paints-need-protection-why-efficient-in-can-needed-protect-walter/

As illustrated in Figure 5, in many cases it could be necessary to use more than one biocidal active substance in order to provide a sufficiently broad biocidal action. In fact, the final use of a paint or varnish plays an important role in deciding the combination of biocides to use.

The use of combinations of biocidal active substances, and the periodical changing of formulations, is also necessary in order to minimise the chance of resistant strains arising in a given production site.

Furthermore, it should be noted that the information in the figure above is of a general nature; each particular product, depending on its composition and pH, may affect the real efficacy of any particular biocidal active substance against any particular group of microorganisms.

2.2 Specific biocidal active substances used in paints and varnishes

Looking at the ECHA list of biocidal active substances, it can be seen that there are currently (August 2022) a total of [62 active substances for PT6] and [36 active substances for PT7]. Only a fraction (around 20%) of these substances are actually considered suitable for use in paint and varnish products. Below is a table of PT6 and PT7 biocidal active substances that have been identified by industry experts (CEPE, 2016; CEPE, 2018) as being relevant for paint and varnish manufacturers, together with their review status under the BPR, the associated CLP hazards and the extent to which they are currently allowed in EU Ecolabel paints and varnishes.

Table 2. Overview of classification and EU Ecolabel restriction of relevant PT6 and PT7 biocidal active substances for paints and varnishes (up to August 2022).

PT	Chemical name	CAS No.	CLP classification*	H classes restricted by Article 6(6) to which a derogation is granted	H classes restricted by Article 6(6) to which a derogation is not granted	Effective EUEL limit	Relevant comments
6	(benzyloxy)methanol	14548-60-8	Self-classifications as: H302, H312, H315, H317, H318, H335.	H317	N/A	Falls under: (i) general 0.060% sum total derogation for in-can preservatives; (ii) the general 0.20% sum total derogation for tinting machine preservatives (max. 0.10% due to GCL** for H317). Actual limit allowed for in-can preservation will depend on extent of formaldehyde release (free formaldehyde concentration cannot be more than 0.010% in-can).	Strong bactericide but some Pseudomonas species are tolerant. Limited effect on moulds and yeasts. Is a formaldehyde releaser good headspace activity in-can. Initial application for BPR approval in progress. No information about classifications in 2014 obtained.
6	2,2′-dithiobis[N-methylbenzamide] (DTBMA)	2527-58-4	Self-classifications for: H302, H312, H315, H317, H318, H319, H332, H400, H410.	H317, H400, H410.	N/A	Falls under: (i) general 0.060% sum total derogation for in-can preservatives; (ii) the general 0.20% sum total derogation for tinting machine preservatives (max. 0.10% due to GCL for H317). Depending on M-factor(s) for aquatic toxicity hazards, a stricter limit could apply (e.g. M=100 for chronic H410 could mean effective limit of 0.0025% to prevent mixture from being H412).	Bactericide and fungicide, releases MBIT under certain conditions, giving a similar behaviour to isothiazolines. Initial application for BPR approval in progress. Was classified with same EUEL restricted hazard classes of H317, H400 and H410 back in 2014.
6	(ethylenedioxy)dimethanol (Reaction products of ethylene glycol with paraformaldehyde (EGForm))	3586-55-8	Self-classifications for: H302, H315, H318, H319, H332, H335.	N/A	N/A	No horizontally applicable limit. However, maximum dose allowed in product will depend on amount of free formaldehyde in in-can product (limit for free formaldehyde in product is 0.010%).	Bactericide, some tolerant strains of Pseudomonas. Headspace activity in-can. Limited effect

PT	Chemical name	CAS No.	CLP classification*	H classes restricted by Article 6(6) to which a derogation is granted	H classes restricted by Article 6(6) to which a derogation is not granted	Effective EUEL limit	Relevant comments
							against mould and yeast. A formaldehyde releaser. Initial application for BPR approval in progress. Similar self-classifications back in 2014.
6	Bronopol	52-51-7	Harmonised (ATP1st): H302, H312, H315, H318, H335, H400 (M=10) More recent self-classification (proposal): H301, H331, H312, H315, H318, H335 (respiratory system), H400 (M=10), H411.	H400, H301, H331, H411.	N/A	Falls under: (i) general 0.060% sum total derogation for in-can preservatives; (ii) the general 0.20% sum total derogation for tinting machine preservatives. To be decided if considered as a formaldehyde donor or not. This will mean that dosing rate could be limited by free formaldehyde content in-can (limit is 0.010% or 0.0010% depending on whether the chemical is a formaldehyde donor or not).	Strong bactericide but not stable, formaldehyde is released upon degradation. High doses can result in discoloration. An alkyl halide with formaldehyde release when degraded. Initial application for BPR approval in progress. Same harmonised classifications applied back in 2014.
6	2-bromo-2-(bromomethyl)pentanedinitrile (DBDCB)	35691-65-7	Self-classifications for: H302, H315, H317, H318, H400. Also H302, H315, H318; or H302, H317, H318, H330, H335, H411 or H302, H330, H318, H317, H411	H317, H400, H411	H330	If self-classified with H330, none of the existing derogations would be valid, meaning it could only be used up to 0.010% (the limit set by horizontal restrictions). Otherwise, and assuming that H317 is associated with the generic 1000ppm limit, the substance would, if compliant with biodegradability and formaldehyde release conditions, fall under: (i) general 0.060% sum total derogation for in-can preservatives; (ii) up to 0.10% in the general 0.20% sum total derogation for tinting machine preservatives and (iii) up to 0.10% in indoor (high-humidity) or outdoor paints/varnishes under the sum total limits for dry-film	Broad spectrum biocide, including against Pseudomonas. Typically combined with other biocides. An alkyl halide. Approved under BPR until 31 December 2027. No information about classifications in 2014 obtained.

PT	Chemical name	CAS No.	CLP classification*	H classes restricted by Article 6(6) to which a derogation is granted	H classes restricted by Article 6(6) to which a derogation is not granted	Effective EUEL limit	Relevant comments
						preservatives.	
6	2-methyl-1,2-benzothiazol-3(2H)-one (MBIT)	2527-66-4	Harmonised (ATP15th): H301, H312, H314, H317 (>0.0015%), H318, H400, H410, H411 and EUH071 (M=1). ATEs****: 1100 mg/kg bw (dermal); 175 mg/kg bw (oral).	H301, H317, H400, H410, H411, EUH071	N/A	Falls under: (i) general 0.060% sum total derogation for in-can preservatives; (ii) the general 0.20% sum total derogation for tinting machine preservatives. Cannot be used more than 0.0015% due to SCL*** for H317 classification.	Bactericide and fungicide, isothiazoline. Approved under BPR until 30 June 2028. A new product. Initial proposal for classification in 2017 was H301, H312, H314, H317, H318, H332, H400, H411.
6	1,2-benzisothiazol-3(2H)-one (BIT)	2634-33-5	Harmonised (ATP11th): H302, H315, H317 (>0.05%), H318, H400.	H317, H400	N/A	Falls under: (i) general 0.060% sum total derogation for in-can preservatives; (ii) the general 0.20% sum total derogation for tinting machine preservatives. Cannot be used more than 0.050% due to SCL for H317 classification.	Bactericide and fungicide, weakly active against Pseudomonas. Very stable and combinable. An isothiazoline. Initial application for BPR approval in progress. In 2014, no specific limit for H317 but restricted H code of H411 also applied in some cases.
6	2-methyl-2H-isothiazol-3-one (MIT)	2682-20-4	Harmonised (ATP13th): H301, H311, H314, H317 (>0.0015%), H318, H330, H400 (M=10), H410 (M=1) and EUH071.	H301. H311, H317, H330, H400, H410	N/A	Falls under: (i) general 0.060% sum total derogation for in-can preservatives; (ii) the general 0.20% sum total derogation for tinting machine preservatives. Cannot be used more than 0.0015% due to SCL for H317 classification.	Strong bactericide, also against Pseudomonas. Compatible and stable. An isothiazline. Initial application for BPR approval in progress. In 2014, no specific limit for H317 less than 0.1% and H411 applied instead of H410 today.
6	Mixture of 5-chloro-2-methyl-	55965-84-	Harmonised (ATP13th):	H301, H310,	N/A	Falls under: (i) general 0.060% sum total derogation for	Broad spectrum biocide,

PT	Chemical name	CAS No.	CLP classification*	H classes restricted by Article 6(6) to which a derogation is granted	H classes restricted by Article 6(6) to which a derogation is not granted	Effective EUEL limit	Relevant comments
	2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT)	9	H301, H310, H314, H317 (>0.0015%), H318, H330, H400 (M=100), H410 and EUH071.	H317, H330, H400, H410		in-can preservatives; (ii) the general 0.20% sum total derogation for tinting machine preservatives. Cannot be used more than 0.0015% due to SCL for H317 classification. M factor of 100 for H410 effectively means a limit of 0.0025% in order to prevent mixture from being classified as H412.	easily combinable but if used at low doses only, some tolerant Pseudomonas species found. An isothiazoline. Approved under BPR until 30 June 2027. Limit of 0.0015% already applied for EU Ecolabel back in 2014.
6+7	2-butyl-benzo[d]isothiazol-3-one (BBIT)	4299-07-4	Harmonised (ATP11th): H314, H317, H400, H410.	H317, H400, H410	N/A	Falls under: (i) general 0.060% sum total derogation for in-can preservatives; (ii) the general 0.20% sum total derogation for tinting machine preservatives and (iii) the general 0.10% (indoor, high-humidity) or 0.30% (outdoor) sum total limits for dry-film preservatives. Assuming H317 generic limit of 1000ppm applies, effective limit is 0.060% as in-can preservative in indoor products or up to 0.10% in tints or as dry-film preservative in outdoor products.	Fungicide. Not effective against bacteria and has a short shelf life. An isothiazoline. Initial application for BPR approval in progress. In 2014, H318 classification also applied.
6+7	2-octyl-2H-isothiazol-3-one (OIT)	26530-20-1	Harmonised (ATP15th): H301, H311, H314, H317 (0.0015%), H318, H330, H400 (M=100), H410 and EUH071. ATEs: 0.27 mg/L (inhalation, dusts/mists); 311 mg/kg bw (dermal); 125 mg/kg bw (oral).	H301, H311, H317, H330, H400, H410	N/A	Falls under: (i) general 0.060% sum total derogation for in-can preservatives; (ii) the general 0.20% sum total derogation for tinting machine preservatives and (iii) the general 0.10% (indoor, high-humidity) or 0.30% (outdoor) sum total limits for dry-film preservatives. Cannot be used more than 0.0015% due to SCL for H317 classification. H410 classification and chronic M factor of 100 mean that using more than 0.0025% would classify the mixture as H412.	Good fungicide, weak bactericide. Should be combined with bactericides. An isothiazoline. Initial application for BPR approval in progress. Had the same classifications in 2014 except that H331 is now H330 and that M factors associated with H400 and H410 are now 100 instead of 10 or 1.
6+7	Pyrithione zinc (Zinc	13463-41-	Harmonised (ATP15th):	H301, H330,	H360D	Falls under: (i) general 0.060% sum total derogation for	Fungicide, weak

PT	Chemical name	CAS No.	CLP classification*	H classes restricted by Article 6(6) to which a derogation is granted	H classes restricted by Article 6(6) to which a derogation is not granted	Effective EUEL limit	Relevant comments
	pyrithione)	7	H301, H318, H330, H360D, H372, H400 (M=1000), H410. ATEs: 0.14 mg/L (inhalation, dusts/mists); 221 mg/kg bw (oral)	H372, H400 H410.		in-can preservatives; (ii) the general 0.20% sum total derogation for tinting machine preservatives and (iii) the general 0.10% (indoor, high-humidity) or 0.30% (outdoor) sum total limits for dry-film preservatives. Now not allowed more than 0.010% due to H360D reclassification invalidating existing derogations. H400 (M=1000) also results in effective limits of 0.025% for classification as H400.	bactericide, esp. against Pseudomonas. Sensitive to oxidation if not stabilised. A pyrithione. Initial application for BPR approval in progress. Classified as H301, H318, H331, H400 and H410 in 2014 and derogated use up to 0.050% permitted for in-can or dry-film preservation.
6+7	Pyridine-2-thiol 1-oxide, sodium salt (Sodium pyrithione)	3811-73-2	Harmonised classification applicable from 23 November 2023 (ATP18th): H302, H311, H315, H317, H319, H331, H372 (nervous system), H400 (M=100), H411 and EUH070. ATEs: 0.5 mg/L (inhalation dusts/mists); 790 mg/kg bw (dermal); 500 mg/kg bw (oral).	H311, H317, H331, H372 H400, H411	N/A	Due to H311 and H372 reclassification, can only be used up to 0.010%. Apart from that, the M factor of 100 for H400, places an effective limit of 0.25% to prevent classification of the mixture as H400. The applicable classification thresholds for NaPT as defined in the 18th ATP are for H400 = > 0.25% (25% generic threshold with a MFAC of 100 applied), for H410 = N/A, for H411 = > 25% and for H412 = > 2.5%.	Fungicide. Needs to be used in high doses to be effective. Risk of discoloration. A pyrithione. Initial application for BPR approval in progress. In 2014, same classifications except: (i) was H312, now H311; (II) no H317 before; (iii) no H372 before and (iv) no M factors before.
6+7	3-iodo-2-propynylbutylcarbamate (IPBC)	55406-53-6	Harmonised (ATP6th): H302, H317, H318, H331, H372 (larynx), H400 (M=10), H410 (M=1)	H317, H331, H372, H400 H410	N/A	Falls under: (i) general 0.060% sum total derogation for in-can preservatives; (ii) a specific 0.10% sum total derogation for tinting machine preservatives and (iii) the general 0.10% (indoor, high-humidity) or 0.65% (outdoor) sum total limits for dry-film preservatives. However, an oversight in H372 derogation technically means it should not be used more than the 0.010% horizontal limit (clarification needed on this matter).	Good fungicide, poor bactericide. Can be combined with bactericides but is unstable in SB alkyd systems. An alkyl halide. Approved under BPR until 30 June 2025.

PT	Chemical name	CAS No.	CLP classification*	H classes restricted by Article 6(6) to which a derogation is granted	H classes restricted by Article 6(6) to which a derogation is not granted	Effective EUEL limit	Relevant comments
							Prior to ATP6 in 2014, classifications were the same except: (i) was H332 instead of H331; (ii) H335 or H336 now gone and (iii) H372 now here.
7	3-(4-isopropylphenyl)-1,1-dimethylurea/ Isoproturon	34123-59-6	Harmonised (ATP13th): H351, H373 (blood), H400 (M=10), H410 (M=10)	H373, H400, H410	H351	Falls under the general 0.10% (indoor, high-humidity) or 0.30% (outdoor) sum total limits for dry-film preservatives. Due to H351 and H373 classifications not fitting in with derogated hazards, can only be used up to 0.010%.	Algaecide. Initial application for BPR approval in progress. Same classifications in 2014, except that now H373 as well.
7	4,5-Dichloro-2-octylisothiazol-3(2H)-one (4,5-Dichloro-2-octyl-2H-isothiazol-3-one (DCOIT))	64359-81-5	Harmonised (ATP15th): H302, H314, H317 (>0.0015%), H318, H330, H400 (M=100), H410 (M=100) + EUH071. ATEs: 0.16 mg/L (inhalation dusts/mists); 567 mg/kg bw (oral).	H317, H330, H400, H410	N/A	Falls under the general 0.10% (indoor, high-humidity) or 0.30% (outdoor) sum total limits for dry-film preservatives. Cannot be used more than 0.0015% due to SCL for H317 classification. Effective CLP limit of 0.0025% due to H410 classifying mixture as H412.	Fungicide and algaecide. Initial application for BPR approval in progress. In 2014, same classifications except: (i) now no longer H311; (II) H317 SCL was higher (0.025%); (iii) now no longer H335 and (iv) no H410 previously.
7	Diuron	330-54-1	Harmonised (ATP11th): H302, H351, H373, H400, H410 (M=10)	H373, H400, H410	H351	Falls under the general 0.10% (indoor, high-humidity) or 0.30% (outdoor) sum total limits for dry-film preservatives. Due to H351 and H373 classifications not fitting in with derogated hazards, can only be used up to 0.010%.	Algaecide. Initial application for BPR approval in progress. Same classifications applied back in 2014.
7	Terbutryn	886-50-0	Self-classifications as: H302, H317, H319, H400 (M=10), H410, H413	H317, H400, H410, H413	N/A	Falls under the general 0.10% (indoor, high-humidity) or 0.30% (outdoor) sum total limits for dry-film preservatives. Assuming H317 generic limit of 1000ppm applies, effective limit is 0.10% as dry-film preservative.	Algaecide. Initial application for BPR approval in progress. Similar self-

PT	Chemical name	CAS No.	CLP classification*	H classes restricted by Article 6(6) to which a derogation is granted	H classes restricted by Article 6(6) to which a derogation is not granted	Effective EUEL limit	Relevant comments
						Some entries had an M factor of 10 of 100 for H400 and H410. In the latter case, this could mean just 0.0025% of H410 (M=100) classifying the mixture as H412.	classifications back in 2014, but no possible to fully confirm.

** GCL stands for Generic Concentration Limit and *** SCL stands for Specific Concentration Limit, both in the context of CLP rules for mixture classification.*

**** ATE stands for Acute Toxicity Estimate.*

Source: JRC.

Considering the information presented in Table 2 and according to the industries that provided feedback, there are a total of 18 industrially relevant biocidal active substances for use in paint and varnish products (CEPE, 2016; CEPE, 2018). It is worth explaining in some more detail how the different limits apply in EU Ecolabel criteria.

- The general horizontal limit of 0.010% applies due to the interpretation of Article 6(6) of the EU Ecolabel Regulation for products that are mixtures (see Section 1.2 for more details of what hazard classes this limit applies to).
- Even stricter limits can apply due to specific concentration limits set for certain substances which, if exceeded, would result in the whole mixture being classified as category 1 skin sensitising (H317). Mixture classification of paints and varnishes as H317 (and a number of other hazard classes) is prohibited in criterion 5 of the EU Ecolabel criteria. These stricter limits generally apply to isothiazolines (MBIT >0.0015%; BIT >0.0500%; MIT >0.0015%; CMIT:MIT >0.0015% and OIT >0.0015%.
- A number of derogations to the general limit of 0.010% are provided in the Appendix of the EU Ecolabel criteria that allow higher concentrations of preservatives in certain cases. A simplified explanation of these current derogations (excluding some associated conditions) is given below:
    - A general limit of up to 0.050% for any combination of izothiazoline compounds for indoor paints and up to 0.20% for outdoor paints (this derogation limit is now quite unrealistic due to much stricter CLP limits imposed on most individual isothiazoline compounds in the last few years).
    - A general limit of up to 0.060% for any individual in-can preservative or combination of in-can preservatives (PT6) that are classified with no EU Ecolabel restricted classifications except H317, H331, H400, H410, H411 or H412 (in principle, a case could be made for also extending this derogation to the less severe H413 as well). Within this limit, specific allowance for up to 0.050% is allowed for both zinc pyrithione and N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine as an in-can preservative.
    - For indoor paints marketed for use in high-humidity areas, up to a further 0.10% of IPBC as a dry-film preservative is allowed by derogation.
    - For paints mixed in tinting machines, a general limit of up to 0.20% for preservatives that are classified as H317, H331, H400, H410, H411 or H412 (in principle, a case could be made for also extending this derogation to the less severe H413 as well). Within this 0.20% limit, specific individual limits of 0.10% for IPBC, 0.050% for zinc pyrithione (invalidated now due to H360D so the maximum concentration allowed in EU ecolabelled paints is 0.010%) and 0.050% for N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine.
    - For outdoor paints, in addition to the 0.060% allowance for in-can preservatives, an additional 0.30 % is allowed in general for dry-film preservatives (PT7) that are classified with no EU Ecolabel restricted classifications except H317, H400, H410, H411 or H412 (in principle, a case could be made for also extending this derogation to the less severe H413 as well).
    - For outdoor paints, an additional 0.30% for dry-film preservatives can be used. This additional 0.30% can be increased up to 0.65% only in cases when IPBC is used.
    - In addition to the limits for preservatives, zinc oxide is granted a derogation for concentrations of 0.030%, 0.040% or 0.050% when used as a preservative stabiliser depending on what preservative it is combined with and the final purpose of the preservation effect.

As can be seen, the hazardous substance criteria for the use of preservatives in the EU Ecolabel are complex and link specific concentration limits to certain names of biocidal active substance and certain hazard classes. Every time one of these active substances is reclassified, this could potentially render the active substance no longer suitable for EU Ecolabel products.

Due to uncertainties with future CLP classifications and specific concentration limits, and wider uncertainties caused by the BPR (such as the banning of certain substances for this uses as a result of the evaluation under BPR), biocide manufacturers are finding it difficult to justify investment in R&D to develop new and effective biocides when it is difficult to predict at what concentrations they would be allowed to be used in coating products. All in all, uncertainties remain due to the complexity of the systems used in risk assessments and the various hazard situations paint and varnish products are exposed to (Pellizzato, 2024).

The lack of new alternatives and the relatively limited number of suitable existing active substances on the market mean that industry representatives have submitted a number of derogation requests to ensure that certain biocidal active substances can continue to be used in EU Ecolabel products, or that they can be used at least in high enough concentrations to compensate for more efficacious active substances no longer being permitted (CEPE, 2016; CEPE, 2018; bi-lateral discussion with industries).

2.3 Impact of CLP reclassifications on suitable biocidal active substances

To illustrate the extent to which reclassifications have affected the biocides market, a cross-check of the 18 potentially relevant biocidal active substances listed in Table 1 and the ATPs published since 2014 (when the EU Ecolabel criteria were originally published) is shown below (an 'X' and red cells imply reclassification).

Table 3. Cross-check of reclassifications of relevant biocidal active substances since 2014 (August 2022).

Biocidal active substance (short name)	Adaptations to Technical (and scientific) Progress												
	6th	7th	8th	9th	10th	11th	12th	13th	14th	15th	16th	17th	18th
	2014	2015	2016	2016	2017	2018	2019	2018	2020	2020	2021	2021	2022
Benzyloxymethanol	No harmonised classifications yet.												
DTBMA	No harmonised classifications yet.												
MBIT										X			
BIT						X							
MIT								X					
DBDCB	No harmonised classifications yet.												
EGForm	No harmonised classifications yet.												
Bronopol	Already harmonised earlier (since 1st ATP in 2009), being evaluated again.												
CMIT/MIT								X					
Zinc pyrithione										X			
OIT										X			
Sodium pyrithione													X
BBIT						X							
IPBC	X												
Isoproturon								X					
DCOIT										X			
Diuron						X							
Terbutryn	No harmonised classifications yet.												

Source: JRC

Exactly two thirds (12 of 18) of the relevant biocidal active substances have been reclassified with harmonised classifications in the last 8 years, since the current EU Ecolabel criteria for paints and varnishes were originally adopted. According to dialogue with biocide producers, all of the biocidal active substances most commonly used in paints and varnishes have now been reclassified (or soon will be, in the case of sodium pyrithione).

Another way to look at the situation is to consider how the reclassifications have affected the total amount of biocidal active substances allowed in EU Ecolabel products. This consideration would involve looking at the classification situation in 2014 and today (in 2022) and comparing them to the currently valid EU Ecolabel criteria. Since the amount is directly related to the classification, the applicable EU Ecolabel limits for ready-to-use products can be presented in terms of time via the ATPs.

Table 4. Effective EUEL limits for relevant biocidal active substances in paints and varnishes (August 2022).

<table>
<tr><th rowspan="3">Biocidal active substance (short name)</th><th colspan="13">Adaptations to Technical (and scientific) Progress</th></tr>
<tr><th>6th</th><th>7th</th><th>8th</th><th>9th</th><th>10th</th><th>11th</th><th>12th</th><th>13th</th><th>14th</th><th>15th</th><th>16th</th><th>17th</th><th>18th</th></tr>
<tr><th>2014</th><th>2015</th><th>2016</th><th>2016</th><th>2017</th><th>2018</th><th>2019</th><th>2018</th><th>2020</th><th>2020</th><th>2021</th><th>2021</th><th>2022</th></tr>
<tr><td>Benzyloxymethanol</td><td colspan="13">0.060% IC</td></tr>
<tr><td>DTBMA</td><td colspan="13">0.060% IC</td></tr>
<tr><td>MBIT</td><td colspan="9">No previous information. Seems to be a new compound (0.010% IC due to H301 in original assessment report).</td><td colspan="4">0.0015% IC</td></tr>
<tr><td>BIT</td><td colspan="5">0.050% IC</td><td colspan="8">0.050% IC</td></tr>
<tr><td>MIT</td><td colspan="7">0.020% IC</td><td colspan="6">0.0015% IC</td></tr>
<tr><td>DBDCB</td><td colspan="13">0.010% IC (if self-classified with H330) or 0.060% IC if not</td></tr>
<tr><td>EGForm</td><td colspan="13">Up to 0.060% IC, but probably less due to free formaldehyde release (see 7(a) in Appendix of Decision 2014/312)</td></tr>
<tr><td>Bronopol</td><td colspan="13">Up to 0.060% IC, but probably less due to free formaldehyde release (see 7(a) in Appendix of Decision 2014/312)</td></tr>
<tr><td>CMIT/MIT</td><td colspan="7">0.0015% IC</td><td colspan="6">0.0015% IC</td></tr>
<tr><td>Zinc pyrithione</td><td colspan="9">0.050% IC and 0.050% DF</td><td colspan="4">0.010% IC and 0.010% DF</td></tr>
<tr><td>OIT</td><td colspan="9">0.050% IC</td><td colspan="4">0.0015% IC</td></tr>
<tr><td>Sodium pyrithione</td><td colspan="12">0.060% IC and 0.10% DF for indoor paints in high humidity areas or up to 0.30% DF in outdoor paints</td><td>0.010% IC or 0.010% DF</td></tr>
<tr><td>BBIT</td><td colspan="5">0.060% IC and 0.10% DF</td><td colspan="8">0.060% IC and 0.10% DF</td></tr>
<tr><td>IPBC</td><td colspan="13">Intention has been: 0.060% IC and 0.10% DF for indoor paints in high humidity areas or up to 0.65% DF in outdoor paints. But need amendment to criteria to account for H331 and H372 hazard classes.</td></tr>
<tr><td>Isoproturon</td><td colspan="7">0.010% DF</td><td colspan="6">0.010% DF</td></tr>
<tr><td>DCOIT</td><td colspan="9">Either 0.010% DF (underogated H311) or 0.025% DF (H317 SCL)</td><td colspan="4">0.0015% DF</td></tr>
<tr><td>Diuron</td><td colspan="5">0.010% DF</td><td colspan="8">0.010% DF</td></tr>
<tr><td>Terbutryn</td><td colspan="13">0.10% DF (H317 GCL) or 0.0025% DF (H410 if M factor is 100)</td></tr>
</table>

'IC' is shorthand for 'as in-can preservative', i.e. PT6. 'DF' is shorthand for 'as dry-film preservative', i.e. PT7.

The limits for DF only apply for indoor paints in high-humidity areas or for outdoor paints.

**Initial suggestion of 0.060% IC for MBIT is based on data in an assessment report submitted by Poland for the classification of MBIT, which included H317 at the generic limit (i.e. 0.10%) and not the specific limit of 0.0015% which was later adopted. Assuming the original proposed limit of 0.10% for H317 would have meant up to 0.060% being allowed as IC.*

Source: JRC

It should be noted that the Information about allowed limits in the white cells in the table above depend on available information at present, and this is not always accurate when self-classifications are involved because time-stamps for these are not available. In the case of self-classifications, worst cases are generally assumed and also assumed to be in place when the current EU Ecolabel criteria were adopted in 2014.

It should also be noted that allowable contents of biocidal active substances due to the old EU Ecolabel criteria still in force under the transition period defined in Decision 2014/312/EU have been ignored because this would just make it more difficult to present the information.

From the table above, it is clear that the effect of reclassifications had a variable effect on allowable concentrations in EU Ecolabel paints and varnishes, as shown by the following examples:

- Reclassifications making no difference to contents in EU Ecolabel paints and varnishes: BIT, CMIT/MIT, BBIT, Isoproturon and Diuron.
- Reclassifications making a major difference to allowable contents in EU Ecolabel paints and varnishes: MIT (-92.5%), Zinc pyrithione (-80%), OIT (-97%), Sodium pyrithione (-83%, -90% or -97%) and DCOIT (-85%).

- The need for amendment due to oversight in existing harmonised classifications (IPBC being explicitly granted a derogation but not linking the derogation to H372 (IC, in-can preservative and DF, dry-film preservative) and H331 (DF) hazard classes).

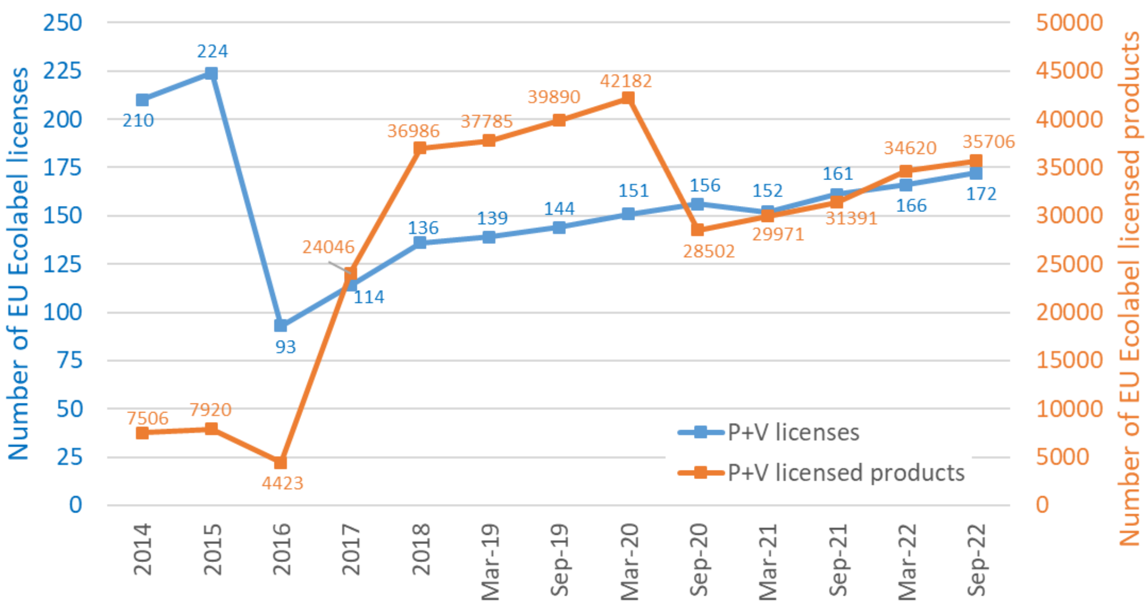
Against this ever stricter classification landscape, it is inevitable that derogation requests are being received for EU Ecolabel paints and varnishes. In the next section, each of the derogation requests are presented individually, together with the outcomes of consultations held, the JRC recommendation and, for cases where the JRC recommends accepting the request, a brief demonstration of what changes in the legal text of Decision (EU) 2014/312 would be triggered by accepting such a request.

2.4 Impact of CLP reclassifications on EU Ecolabel licensed products

Paints and varnishes are one of, if not the most successful of the 20+ different product groups covered by the EU Ecolabel. A look at trends[20] in total EU Ecolabel license-holders and total EU Ecolabel licensed products in comparison to numbers just for paints and varnish products shows that:

- consistently 5% to 10% of all EU Ecolabel license-holders are paint or varnish manufacturers;
- the share of EU Ecolabel products that are paints and varnishes has grown from 10-20% prior to 2017 to 30+% since 2017.

Figure 6. Trends in EU Ecolabel paint and varnish license-holders (top) and licensed products (bottom)



Source: EU Ecolabel Statistics – European Commission.

It is interesting to note in the data from Figure 6 that there was a significant dip (around -30%) in EU Ecolabel licensed paint and varnish products between March 2020 and September 2020. This particular period coincided with the entry into force of the MIT reclassification, which effectively reduced the quantity of MIT that could be used in EU Ecolabel products from 0.020% to 0.0015%, a 92.5% reduction.

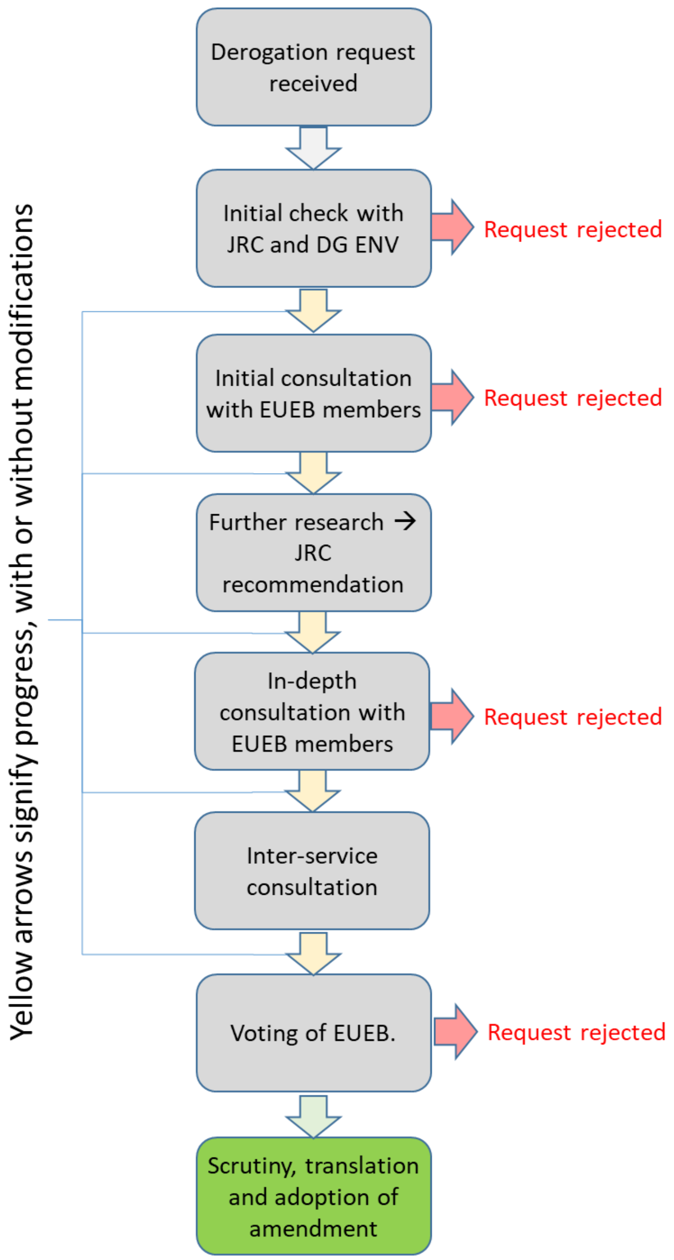
It remains to be seen what effect the reclassifications of biocides such as zinc pyrithione, sodium pyrithione, OIT and DCOIT will have on EU Ecolabel licensed product numbers.

[20] EU Ecolabel Statistics – European Commission – EU Ecolabel facts and figures: https://environment.ec.europa.eu/topics/circular-economy/eu-ecolabel-home/business/ecolabel-facts-and-figures_en

3 Derogation requests

Before presenting the actual derogation requests received for EU Ecolabel paints and varnishes, the general derogation procedure is described below.

Figure 7. General procedure for dealing with derogation requests for EU Ecolabel criteria



Source: JRC.

After receiving a derogation request, an initial consultation between the JRC and DG ENV takes place to check if there are any major deficiencies in the request that would justify its rejection. In many cases, further information may be requested.

Once sufficient information has been gathered to permit an informed debate, the derogation request is presented to members of the EU Ecolabelling Board (EUEB) for initial opinions. At this point, it is possible that opinions are already negative enough to justify the rejection of the request(s).

Otherwise, the JRC proceeds with further research and prepares a report for more in-depth consultation with EUEB members. At this point, the potential wording of the legal text and associated derogation conditions should be available for consultation. As before, it is also possible that opinions are sufficiently negative to justify rejection of the request. Especially at this point, if not rejected, it may be that modifications are requested, for example to thresholds allowed or to associated derogation conditions.

If the in-depth consultation proceeds well, then the proposed amendments to the legal text are sent for ISC with other DGs of the Commission. The JRC report may be shared as supporting background information. Modifications could also be requested during discussions at this stage.

After the ISC, the EUEB will formally vote on the proposed amendments to the legal text of the EU Ecolabel criteria (due to the acceptance of the derogation request(s)). If a positive vote is attained, then the amendment to the legal text is subjected to scrutiny of the European Parliament and the Council, and translated into the official languages of the European Union. These last two steps typically take 6 months and the overall process can take 12 to 18 months, depending on the complexity of consultations and further research required.

Receipt of derogation requests

A number of derogation requests have been received for the extended use of biocidal active substances in EU Ecolabel paints and varnishes. These requests were received individually and at different times during the period between 2020 and 2022. Due to the relatively low number of suitable biocidal active substances on the market, it is necessary to consider all of the derogation requests in the context of other requests received.

Simultaneously, some issues relating to a potential error in the existing derogation for IPBC and a query about how encapsulated biocides should be treated in the context of EU Ecolabel criteria were also raised.

A total of six derogation requests and two additional issues are presented in the eight subsections of this chapter.

3.1 Bronopol and associated free formaldehyde condition

Box 4. Bronopol (and associated free formaldehyde) request
Current limit in the criteria: theoretically up to 600 ppm (0.060% w/w) as in-can preservative. In reality it is limited by other factors, especially free formaldehyde.
Request 1: to increase free formaldehyde limit from 10 ppm to 25 ppm (0.0010% to 0.0025% w/w) when bronopol is used.
Request 2: to also derogate for H301 for bronopol, because new evidence suggests that this hazard also applies, in addition to existing harmonised hazards.

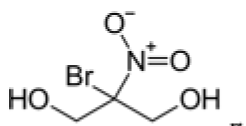
Background

Bronopol[21] is a bactericide that can currently be used for in-can preservation, but is not very stable. More specifically, bronopol undergoes degradation in an aqueous medium to form bromonitroethanol from a retroaldol reaction with the liberation of an equimolar amount of formaldehyde. Formaldehyde is therefore a degradation product of bronopol. Bromonitroethanol further decomposes to form more formaldehyde and bromonitromethane (PubChem, 2022).

However, this degradation process itself produces a biocidal effect. High doses of bronopol can result in discoloration of white base paints.

Despite the fact that one of the degradation products (formaldehyde) is a category 1B carcinogen, the use of bronopol is becoming more attractive in EU Ecolabel paints. The main reason is because its current harmonised classification means that the only CLP hazard code of concern is H400, which is already covered by the existing derogation for in-can preservatives. Another advantage is that bronopol does not have foreseeable issues as an H317 skin sensitiser – unlike biocides belonging to the isothiazoline family.

Table 5. Basic details (CAS numbers, ECHA infoCard, EU Ecolabel limits and CLP hazard classes) of bronopol

Name	Bronopol
Preferred IUPAC name	2-Bromo-2-nitropropane-1,3-diol
CAS number	52-51-7
ECHA InfoCard	100.000.131
Chemical formula	$C_3H_6BrNO_4$
Chemical structure	
CLP classification	Harmonised (1st ATP): H302, H312, H315, H318, H335, H400 (M=10)

Source: JRC

However, the release of formaldehyde during degradation means that formluations using bronopol will have more free formaldehyde than if non-formaldehyde-donating preservatives were used. This issue is important because the EU Ecolabel sets two limits for free formaldehyde (0.0010% or 0.010%), depending on whether

[21] https://echa.europa.eu/substance-information/-/substanceinfo/100.000.131

or not the biocides used are recognised as formaldehyde donors. The more stringent limit should technically apply to bronopol because, technically speaking, it is not a formaldehyde donor. If the free formaldehyde limit of 0.0010% applies, it is effectively limiting its use of bronopol as an alternative to isothiazolines.

Derogation request

Based on the fact that bronopol sits somewhere in between the groups of 'formaldehyde donors' and 'non-formaldehyde donors', a request was made to align with a recent amendment to the [Nordic Ecolabel criteria for indoor paints and varnishes](#) that set a separate free formaldehyde limit in cases when bronopol is used. More specifically, version 3.10 of the Nordic Ecolabel states the following under criterion O6 (see box to the right):

> - The level of free formaldehyde (from formaldehyde not intentionally added) in the final product must not exceed 10 ppm (0.0010% by weight, 10 mg/kg)*.
> - In case bronopol (CAS#: 52-51-7) or formaldehyde releasers are required for in-can preservation, the level of free formaldehyde must not exceed 25 ppm (0,0025% by weight, 25 mg/kg) in the final product*.

The request is basically the insertion of a text similar to the second bullet point in the box immediately above in entry 7(a) of the Appendix to Commission Decision 2014/312/EU.

Consultation

Initial consultations were to check if this derogation was actually needed in the first place. The EU Ecolabel criteria allow up to 100 mg/kg or 100 ppm of free formaldehyde[22] (0.010%) in cases where formaldehyde donors are used for preservation, and the derogation is only asking for 25 mg/kg (0.0025%) free formaldehyde to be allowed when bronopol is used. Consequently, the first question was to determine if it would be acceptable to just consider bronopol as a formaldehyde donor. However, the Investigation Report on Formaldehyde and Formaldehyde Releasers from ECHA (2017) explains on page 61 that bronopol *'can release low levels of formaldehyde due to its decomposition. These levels are not sufficient to work as biocide therefore bronopol cannot be considered a formaldehyde releaser ... [ ]. Relevant research studies demonstrate that levels of formaldehyde released by bronopol are so low that the substance cannot be considered a formaldehyde releaser'*[23]. Consequently, it was concluded that bronopol should not be considered as a formaldehyde donor for the purposes of interpreting compliance with the EU Ecolabel criteria.

Consultation with industry stakeholders revealed that bronopol has a theoretical maximum 15% decomposition-related release rate of formaldehyde (it depends on pH and other factors) and that respecting the existing 10 ppm limit (0.0010%) for free formaldehyde when using bronopol resulted in suboptimal preservation. If the limit for free formaldehyde was raised to 25 ppm, then sufficient doses of bronopol could be used (e.g. 150 ppm to 300 ppm, or 0.015% to 0.030%) depending on the pH etc.

When asked for initial opinions (May 2022) about the derogation request for free formaldehyde (up to 0.0025%, 25 ppm) when bronopol is used, the following feedback was received:

- From EUEB members: 10 in favour, 1 abstained, 0 against.
- From EUEL license-holders: 10 in favour, 0 abstained, 0 against.

Given the initial support for the derogation request on free formaldehyde, a proposal to change the wording of the legal text was presented in the European Ecolabelling Board (EUEB) meeting in November 2022.

[22] https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/-/discli/details/55163

[23] ECHA, 2017 (European Chemical Agency). Investigation report on formaldehyde and formaldehyde releasers. Available at: https://echa.europa.eu/documents/10162/13641/annex_xv_report_formaldehyde_en.pdf/58be2f0a-7ca7-264d-a594-da5051a1c74b?msclkid=bad33e5ed11b11ecb26772cd7d7d1cd7

Example of changes to legal text if JRC recommendation accepted

Proposed changes to the wording of the Appendix in the legal text of Decision 2014/312/EU are presented below.

Substance group	Scope of restriction and/or derogation	Concentration limits (where applicable)	Assessment and verification
[.....]	[.....]	[.....]	[.....]
7. Residual substances that may be present in the final product			
(a) Formaldehyde Applicability: All products	Free formaldehyde shall not be intentionally added to the final product. The final product shall be tested in order to determine its free formaldehyde content. The sampling requirements for testing shall reflect the product range. The following sum total limit value shall apply: The following derogations are made from the requirement set out in the first paragraph: (i) Where preservatives that are formaldehyde donors are required as an in-can preservative to protect a specific type of paint or varnish and where the formaldehyde donor is used in the place of isothiazolinone preservatives. (ii) Where polymer dispersions (binders) provide, through residual levels of formaldehyde, the function of formaldehyde donors instead of in-can preservatives. (iii) Where bronopol is used as an in-can preservative and neither points (i) or (ii) also apply. In ~~both~~ points (i), ~~and~~ (ii) and (iii), the sum total shall not exceed the following limit values:	0,0010 % w/w 0,010 % w/w 0,010 % w/w 0,0025 % w/w	Verification: The free formaldehyde content shall be determined for the white base or transparent tinting base predicted to contain the highest theoretical amount of formaldehyde. The content of the colour tint which is predicted to contain the highest theoretical amount of formaldehyde shall also be determined. Test method: 0,0010 % limit value: Determination of the in-can concentration using the Merckoquant method. If the outcome is not definitive according to this method then high- performance liquid chromatography (HPLC) shall be used to confirm the in-can concentration. 0,010 % or 0,025 % limit value: (1) All paints: Determination of the in-can formaldehyde concentration by means of analysis using VdL- RL 03 or high-performance liquid chromatography (HPLC) (2) Indoor paints and varnishes [...].

The conclusions were presented in the November 2022 EUEB meeting and written comments were later received. A summary of the positions and answers of EUEB members is as follows:

- EUEB members: 14 in favour, 1 abstained, 2 against.

- EUEB members against this derogation explained: '*an allergy study in Denmark among blue collar workers showed that bronopol was one of the biocides that showed frequent contact dermatitis for the workers (Mose et al., 2012)*[24]*. The results of Mose et al. (2012) also showed that formaldehyde is a common allergen among painters. Similarly, Moura et al. found that formaldehyde had caused sensitization in painters with occupational dermatitis*[25]'.

[24] Mose, Anja & Lundov, Michael & Zachariae, Claus & Menné, Torkil & Veien, Niels & Laurberg, Grete & Kaaber, Knud & Avnstorp, Christian & Andersen, Klaus & Paulsen, Evy & Mortz, Charlotte & Sommerlund, Mette & Danielsen, Anne & Thormann, Jens & Kristensen, Ove & Kristensen, Berit & Andersen, Bo & Vissing, Susanne & Nielsen, Niels & Johansen, Jeanne. (2012). Occupational contact dermatitis in painters - An analysis of patch test data from the Danish Contact Dermatitis Group. Contact dermatitis. 67. 293-297. 10.1111/j.1600-0536.2012.02074.x.

[25] Moura C, Dias M, Vale T. Contact dermatitis in painters, polishers and varnishers. Contact Dermatitis 1994: 31: 51–53.

Further investigations

> Formaldehyde
>
> **Indoor paints and varnishes:**
>
> - The emissions of formaldehyde of the final product must not exceed 0.06 mg/m³ measured in the air of a test chamber according to EN 16516.
>
> **Outdoor paints and varnishes and industrial paints:**
>
> The level of free formaldehyde in the final product must not exceed 25 ppm (0.0025% by weight, 25 mg/kg) measured by HPLC or similar methods*.
>
> ** The Merckoquant method can also be used, but the level must then be max 20 ppm.*

Meanwhile, in December 2022, a new proposal for the revised criteria for indoor and outdoor paints and varnishes was published by Nordic Swan[26]. In this proposal, the reference to the level of 25 ppm for free formaldehyde when bronopol or when formaldehyde releasers are used (for indoor paints) is removed. In its place, the new requirement has two parts, one for indoor paints and the other for outdoor[27] paints.

In exchanges with Nordic Swan, they explained that although the new proposal is different from the requirements currently in place, they still seek the derogation as the new proposal will take over 1 year to be finalised and published with the new requirements. Their recent proposal is modified in line with Annex 1 to the EU Taxonomy Climate Delegated Act of 21 April 2021[28], which for '*indoor paints and varnishes is 0.06 mg/m³ measured in the air of a test chamber according to EN 16516 and for outdoor paints and varnishes and industrial paints is 25 ppm (0.0025% by weight, 25 mg/kg) measured by HPLC or similar methods in the final product'.*

Similar requirements are set by the <u>draft</u> Commission Regulation (EU) amendment to Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards formaldehyde and formaldehyde releasers[29] where: '*(28) The Commission therefore concludes that the most appropriate Union-wide measure to address the risk of formaldehyde in indoor air and in the interior of road vehicles is a restriction setting the limit value of 0.062 mg/m³ for wood-based articles and furniture, applied to the whole complex product, as well as in the interior of road vehicles; and of the limit value of 0.08 mg/m³ for all other articles'.*

In the end, Nordic Swan opted for an emission requirement for indoor air quality to decrease the exposure to formaldehyde via inhalation in order to guarantee a higher level of protection for consumers. Then for outdoor and industrial paints and varnishes, a free formadehyde limit of 25 ppm is proposed, regardless of the use of other compounds including formaldehyde releasers, bronopol, etc.

As a result, EU Ecolabel cannot accept a derogation for indoor paints when the European Commission is drafting a Regulation for formaldehyde and formaldehyde releasers to be measured in indoor air at levels much lower than 25 ppm, i.e. 0.062 mg/m³ for wood-based articles and furniture or 0.08 mg/m³ for all other articles.

Second issue raised with bronopol

Apart from the issue with free formaldehyde, another issue with bronopol was raised by a leading biocide manufacturer, which was that, in addition to existing harmonised classifications, they had found evidence of other classifications (some more severe) that also apply to bronopol. This is also in line with the new application to the registry of CLH intentions recently submitted[30].

In line with Section 1.2.1 of Annex VI to CLP, manufacturers or importers are obliged to communicate and apply these new and more severe classifications if they have access to data justifying those hazards. The differences are as follows (classes in red are restricted by the EU Ecolabel and not currently derogated up to 0.060% for in-can preservatives, classes in orange are restricted by the EU Ecolabel but already derogated up to 0.060% for in-can preservatives):

[26] https://www.nordic-ecolabel.org/product-groups/group/?productGroupCode=096

[27] Note that the Merckoquant method (colorimetric test) is not selective at 25 ppm, as it can only detect formaldehyde in specific ranges of 10 ppm, 20 ppm and 40 ppm etc. So if the limit is 25 ppm, it does not show if the limit is actually <25 ppm as it is the colour of <20 ppm or <40 ppm (due to the colorimetric test).

[28] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=PI_COM:C(2021)2800

[29] https://ec.europa.eu/growth/tools-databases/tbt/en/search/?tbtaction=search.detail&Country_ID=EU&num=888&dspLang=en&basdatedeb=&basdatefin=&baspays=EU&basnotifnum=&basnotifnum2=&baskeywords=&bastypepays=&baskeywords=

[30] Registry of CLH intentions until outcome for bronopol, https://echa.europa.eu/de/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e188642fce

- Current harmonised classification: H302, H312, H315, H318, H335, H400.
- Current 'self-classification', registry of CLH intention and potential future harmonised classification: H301, H331, H312, H315, H318, H335 (respiratory system), H400 (M=10), H411[31].

The timeline before new harmonised classifications may be adopted for bronopol and appear mandatorily in all safety data sheets could be a few months[32]. For this reason, it is not advised to insert a new classification for bronopol in the EU Ecolabel criteria for paints and varnishes until the final harmonised classification is adopted.

The situation would be different if the revision process were ongoing, for which the latest application to the registry of CLH intentions would be used. This would mean that, in the case of bronopol, the insertion of H301 (Acute Toxicity Category 3, toxic if swallowed) onto the list of hazard classes in entry 1(a) of the appendix of Decision 2014/312/EU, either in general, or only specifically for bronopol, would be necessary. Given the request is for an amendment of the current criteria in place, the recommendation is to be cautious.

Box 5. Hazard classes applicable for all product groups (unless denoted otherwise)

- Group 1 hazard classes: CMR - H340, H350, H350i, H360F, H360D, H360FD, H360Fd, H360Df.

- Group 2 hazard classes: CMR - H341, H351, H361f, H361d, H361fd, H362; Acute toxicity – H300, H310, H330, H304; Specific Target Organ Toxicity (STOT) – H370, H372; Hazardous to the aquatic environment – H400, H410, H411; Hazardous to the ozone layer – H420; Respiratory and skin sensitisation* – H317*, H334*.

- Group 3 hazard classes: Acute toxicity – H301, H311, H331, EUH070; Specific Target Organ Toxicity (STOT) – H371, H373; Hazardous to the aquatic environment – H412, H413.

*Only applied horizontally when potential exposure to users is a concern.

As shown above, the additional H301 hazard is one of the group 3 hazards, which are supposed to be the easiest of the three groups to justify derogations for.

Ambition level of other ecolabels

With respect to bronopol, the situation is as follows:

- The Blue Angel criteria, version 6 (January 2019, UZ 12a), for low-emission and low-pollutant paints and varnishes set a specific limit of 200 ppm for bronopol.
- The Blue Angel criteria, version 4 (January 2019, UZ 102), for low-emission wall paints do not permit the intentional use of in-can or dry-film preservatives and do not make any specific reference to bronopol.
- The Austrian Ecolabel criteria (UZ 17, version 9.1) for wall paints also set a limit of 200 ppm for bronopol and require traces of bronopol to be less than 2 ppm in any products making 'preservative-free' claims.
- The Nordic Ecolabel criteria (v3.10) for indoor paints and varnishes do not set a specific limit for bronopol, but do set a higher limit of 25 ppm for free formaldehyde when bronopol is used. However, the new proposal only keeps this requirement for outdoor paints as previously explained.

[31] Please, note that according to Table 4.1 of the Guidance on the Application of the CLP criteria (page 552), which provides guidance on which hazard statement could appear on the label for products that are classified as hazardous to the aquatic environment, for substances classified as Acute 1 and Chronic 2, they can carry the H410 hazard statement (i.e. the associated hazard statement in the label when both H400 and H411 are present would be H410). Available at: https://echa.europa.eu/documents/10162/2324906/clp_en.pdf/58b5dc6d-ac2a-4910-9702-e9e1f5051cc5?t=1499091929578

[32] Deadlines for updating https://echa.europa.eu/it/support/registration/respect-the-deadlines-for-updating

Box 6. FINAL CONCLUSION (Bronopol and associated free formaldehyde)

Current limit in the criteria: theoretically up to 600 ppm as in-can preservative. In reality it is limited by other factors, especially free formaldehyde.

Request 1: to increase free formaldehyde limit from 10 ppm to 25 ppm when bronopol is used.

Request 2: to also derogate for H301 for bronopol, because new evidence suggests that this hazard also applies, in addition to existing harmonised hazards.

JRC recommendation: to reject request 1, as it is not considered appropriate to align with Nordic Swan Ecolabel requirements that are currently being revised to introduce different measurement methods and different thresholds, and given the new proposal for air quality from the European Commission in relation to free formaldehyde. To reject request 2, since a new harmonised classification and labelling for bronopol is still not in place (it was submitted in December 2022 and may still undergo changes). These aspects may be reconsidered in the upcoming criteria revision process.

3.2 Isothiazolines: total combined limit permitted

Box 7. Isothiazolines request
Current limit in the criteria: up to 500 ppm allowed, as defined in the first part of Appendix 1.
Request: to increase the limit to 600 ppm to compensate for the effective banning of more powerful isothiazolines and to align with Nordic Ecolabel.

Background

Isothiazolines are a family of compounds based on five-membered heteroaromatic rings that were discovered relatively recently, in the 1960s. One of the principal uses of isothiazolines has been as an antimicrobial agent in a diverse range of products, including coating formulations.

As highlighted in Sections 2.2 and 2.3, reclassifications of almost all industrially relevant isothiazolines has affected their potential as preservation solutions. This is especially due to stringent specific concentration limits for the hazard of category 1 skin sensitiser (H317) that are more than 90% lower than the general concentration limits that would trigger classification of the whole formulation as a skin sensitiser.

Derogation request

Especially stringent reclassification limits for the more powerful isothiazolines mean that, in order to deliver a given preservation effect with weaker isothiazolines, the overall total concentrations of isothiazolines needed would be higher. This is the principal argument behind the derogation request.

The request was made to increase the total limit for isothiazolines from 500 ppm to 600 ppm, in order to align with criterion 05 of version 3.10 of the Nordic Ecolabel criteria for indoor paints and varnishes (see Table 6).

Table 6. Specific restrictions on isothiazolinones in the final product in NS criteria version 3.10.

Preservative	Concentration limit
Total amounts of isothiazolinones	600 ppm (0.0600% w/w)
2-methyl-2H-isothiazol-3-one (CAS# 2682-20-4) (MIT**)	15 ppm (0.0015% w/w)
5-Chloro-2-Methyl-2H-Isothiazol-3-one/2-Methyl-2HIsothiazol-3- one (3:1) (CAS#: 55965-84-9) (CMIT/MIT)	15 ppm (0.0015% w/w)

** Note that the shortening MI may also be used.

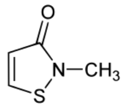
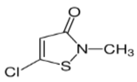
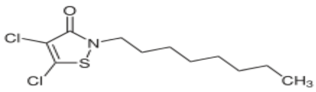
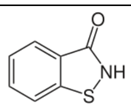
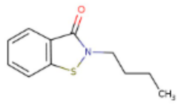
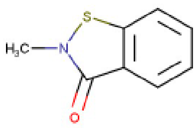
Note that Dithio-2,2'-bis-benzmethylamide (DTBMA) is to be included in the total amount of isothiazolinones.

Source: JRC, adapted from Nordic Swan criteria for in indoor paints and varnishes version 3.10.

Consultation

Before deciding on whether or not to recommend the derogation request, it was necessary to identify the principal isothiazoline substances used for in-can preservative of coating formulations.

Table 7. Basic details (CAS numbers, ECHA infoCard, EU Ecolabel limits and CLP hazard classes) of the main isothiazolines used in paints and varnishes.

Name	Methylisothiazolinone (MIT)	Name	Octylisothiazolinone (OIT)
CAS number	2682-20-4	CAS number	26530-20-1
ECHA InfoCard	100.018.399	ECHA InfoCard	100.043.404
Chemical structure		Chemical structure	
EUEL limit	0.0015% (15 ppm)	EUEL limit	0.015% (15 ppm)
CLP hazard codes:	Harmonised (ATP13): H301, H311, H314, H317 (>0.0015%), H318, H330, H400 (M=10), H410 (M=1) and EUH071.	CLP hazard codes:	Harmonised (ATP15): H301, H311, H314, H317 (0.0015%), H318, H330, H400 (M=100), H410 (M=100) and EUH071.
Name	Chloromethylisothiazolinone (CMIT)	Name	Dichlorooctylisothiazolinone (DCOIT)
ECHA InfoCard	100.043.167	ECHA InfoCard	100.058.930
Chemical structure		Chemical structure	
EUEL limit	0.0015% (15 ppm)	EUEL limit	0.0015% (15 ppm)
CLP hazard codes:	Harmonised (ATP13): H301, H310, H314, H317 (>0.0015%), H318, H330, H400 (M=100), H410 (M=100) and EUH071.	CLP hazard codes:	Harmonised (ATP15): H302, H314, H317 (>0.0015%), H318, H330, H400 (M=100), H410 (M=100) + EUH071. ATEs: 0.16 mg/L (inhalation dusts/mists); 567 mg/kg bw (oral).
Name	Benzoisothiazolinone (BIT)	Name	2-butyl-benzo[d]isothiazol-3-one (BBIT)
ECHA InfoCard	100.018.292	ECHA InfoCard	100.101.927
Chemical structure		Chemical structure	
EUEL limit	0.050% (500 ppm)	EUEL limit	0.10% (1000 ppm)
CLP hazard codes:	Harmonised (ATP11): H302, H315, H317 (>0.05%), H318, H400	CLP hazard codes:	Harmonised (ATP11): H314, H317, H400, H410
Name	2-methyl-1,2-benzothiazol-3(2H)-one (MBIT)		
ECHA InfoCard	100.225.087		
Chemical structure			
EUEL limit	0.0015% (15 ppm)		
CLP hazard codes:	Harmonised (ATP15): H301, H312, H314, H317 (>0.0015%), H318, H400, H410, H411 and EUH071 (M=1).		

Bold orange H classes are derogated in EU Ecolabel for indoor and outdoor paints and varnishes.

Source: JRC.

The information in Table 7 shows that five of the seven main isothiazolines cannot be used at concentrations greater than 15 ppm in EU Ecolabel products. While BIT can be used at concentrations up to 500 ppm right now, it is likely that this limit will be lowered (the current proposal is to lower it to 360 ppm). While these lower concentrations could potentially be compensated for by BBIT, which can be used in concentrations up to 1 000 ppm, this substance only demonstrates a very limited bactericidal effect.

When asked for initial opinions (in May 2022) about the requested amendment to the derogation for total isothiazolines to increase the total from 0.050% to 0.060%, the following feedback was received:

- From EUEB members: 2 in favour, 1 abstained, 9 against.
- From EUEL license-holders: 2 in favour, 8 against.

One EUEB member strongly opposed the request, sharing information from the tests performed by the consumer organisation *'60 million consumers'* in France. It was stated that: '*This organisation tested several paints, out of 48 paints tested, 47 contained different isothiazolinones. However, the average combined concentration of those substances was 150 ppm. Some products contained below 50 ppm, while for others this was up to 500 ppm. But they did not mention concentrations above 500 ppm. This raises the question whether increasing the concentration level to 600 ppm is really needed [...]*'.

Formulations provided by licence-holders via two CBs showed that isothiazolinones are the most widely used in-can preservatives. However, total concentrations are usually kept below 500 ppm.

When this conclusion was presented in the November 2022 EUEB meeting, all responses agreed on the JRC recommendation, i.e. not to proceed with the derogation.

Ambition level of other ecolabels

With respect to total limits for isothiazolines, the situation is as follows:

- The Blue Angel criteria, version 6 (January 2019, UZ 12a), for low-emission and low-pollutant paints and varnishes set limits for specific isothiazolines solely for the purposes of in-can preservation. These consist of: 400 ppm for BIT; 15 ppm for CIT/MIT+CIT and up to a further 15 ppm of unintended residual levels for BBIT/OIT/BBIT.
- The Blue Angel criteria, version 4 (January 2019, UZ 102), for low-emission wall paints do not permit the intentional use of in-can or dry-film preservatives and do not set any specific limits for total isothiazolines.
- The Austrian Ecolabel criteria (UZ 17, version 9.1) for wall paints set specific limits of 15 ppm for CIT, 15 ppm for MIT, 15 ppm for CIT/MIT and 200 ppm for BIT. This totals around 245 ppm of isothiazolines.
- The Nordic Ecolabel criteria (v3.10) for indoor paints and varnishes set a specific limit of 600 ppm for total isothiazolines, which also encompasses specific limits of 15 ppm for MIT and 15 ppm for CMIT/MIT. This is kept in its new proposal.

Since no amendment is recommended here by the JRC, no proposed amendment text is presented for this derogation request.

Box 8. FINAL CONCLUSION (Isothiazolines)

Current limit in the criteria: up to 500 ppm allowed, as defined in the first part of Appendix 1.

Request: to increase the limit to 600 ppm to compensate for the effective banning of more powerful isothiazolines and to align with Nordic Ecolabel.

JRC recommendation: to reject this request, because the specific limits for the main isothiazoline compounds of interest are already very low and existing combinations tend to use an isothiazoline <500 ppm in combination with a non-isothiazoline biocidal active substance.

These aspects may be reconsidered in the upcoming criteria revision process.

3.3 In-can preservatives: total combined limit permitted

Box 9. In-can preservatives request
Current limit in the criteria: up to 600 ppm allowed, as defined in the first part of Appendix 1.
Request: to increase the limit to 900 ppm to compensate for the effective banning of more powerful in-can preservatives and to align with Nordic Swan Ecolabel.

Background

Also in line with the arguments in Section 3.2, where the most popular in-can preservatives are being restricted to the point that they need to be substituted for weaker alternatives, another derogation request was to increase the total quantity of in-can preservatives allowed from 0.060% (600 ppm) to 0.090% (900 ppm).

Such an increase would mean alignment with the total limit for preservatives of 900 ppm, as set out in criterion 05 of version 3.10 of the Nordic Ecolabel criteria for indoor paints and varnishes (see inset screenshot below right) which is also kept in its new requirement proposal. This Nordic Swan limit was raised from 700 ppm on March 2021 in order to handle preservation issues after phasing out MIT (as set out in their background document). The total amount of preservatives currently allowed for indoor paints in the EU Ecolabel is 600 ppm.

Derogation request

The request to align the EU Ecolabel with the Nordic Ecolabel here would apply to the limit for in-can preservatives set out in the Appendix of Decision 2014/312/EU.

There are multiple points in the Appendix where this general limit of 0.060% is mentioned. If changed, then the other parts where this limit is referred to should be amended in the same way to avoid any later confusion.

Table 8. Concentration limits for preservatives in the final product in NS criteria version 3.10.

Preservative	Concentration limit
Preservatives totally* (paints, varnishes, base paints with tinting paste etc.)	900 ppm (0.0900% w/w)
Wet room paints**	1600 ppm (0.1600% w/w)

This requirement only applies to preservatives classified with one or more classifications listed in requirement 03 and the total amounts of isothiazolinones from Table 5.

** Indoor paints intended for use in areas with high humidity, including kitchens and bathrooms.

Source: JRC, adapted from Nordic Swan criteria for in indoor paints and varnishes version 3.10.

It is worth noting that, from the example formulations shared by CBs and industry, it is observed that in most cases 600 ppm is not reached. However these data were from before the phasing out of zinc pyrithione and some isothiazolinones such as MIT. According to industry stakeholders and also as stated earlier, the future decrease of the isothiazolinone BIT (to 360 ppm) would provoke the need to use higher amounts of in-can preservatives as the permitted alternatives are less effective.

As explained by industry representatives, increasing the level from 600 ppm to 900 ppm for the total level of in-can preservatives would be a solution to guarantee the stability of the paints.

However, after carefully looking at possibilities for combinations of the different biocides used for in-can preservation, it is noted that the 900 ppm limit would not be reached in most cases. A compromise solution was given based on calculations and taking into account current combinations and anticipated future combinations.

In this sense, if a maximum of 300 ppm of bronopol combined with isothiazolinones (range around 400 ppm) or if pyrithiones (maximum 350 ppm) combined with isothiazolinones (around 400 ppm) are used, no more than 800 ppm would be needed. This is supported by some Nordic Ecolabel license-holder explanations:

- '*Due to the classification limits for isothiazolinones, other preservatives are needed as a complement to allow sufficient preservation. We have started to use bronopol as this has shown a good effect to cope with the problem of less well preserved binders providing a rather quick acting effect'*.
- '*Due to the problems to avoid contamination in our end products we see a need to increase the total amount of biocides allowed according to the table in Appendix, section 1. ii*) [of Decision 2014/312/EU]. *Please compare with the recent criteria change for Nordic Swan'*.

Another LH cited: '*Unfortunately, we can't be overly confident about this combination, we did have some problems with our previous setup and obtained bacteria in our plant due to insufficient preservatives, it does look better now but with every new limit of biocides the EU Commission gives us there is that fear to get back the problems. With the higher limits that the Nordic Swan give, we do get a bit more freedom to find a solution since lower limits on the more effective biocides leads to higher concentrations of less effective ones. Also since all the numbers are only theoretical concentrations and not the actual amount in the paint it makes it easier. The biocides degrade and the amount that our suppliers is given us is what they added, not what actually is in the product when we add them to our formula. Not even the biocides we add in production will still be in the paint when we fill the buckets. Several tests we made previously show that for example only a few ppm CIT/MIT will still be left, if we add a theoretical content of just under 15 ppm, the test will show 0-2 ppm left when the paint is finished. Still in the EU Ecolabel application we still need to write we have up to 15 ppm of it in the formulation'*.

This last point from the license-holder is an interesting aspect to discuss. Do the limits for biocidal active substances relate to the quantities added, or to the quantities remaining in the product?

A look at the wording of the legal text in Decision 2014/312/EU implies that the concentrations can be assessed as the levels remaining in the final product, for example when it links concentrations to '*in the ready-to-use product'*. However, to be clear, this interpretation should only be used in cases where the quantities added could classify the whole mixture – because then it would not be necessary to prove the absence of conflict with any CLP mixture rules, which may apply to quantities added in the first place.

Consultation

When asked for initial opinions (May 2022) about the request to amend the derogation for total in-can preservatives to increase the total from 0.060% to 0.090%, the JRC proposed a partial acceptance of the request (increase to 0.080% or 800 ppm), and received the following feedback on this compromise solution:

- From EUEB members: 7 in favour, 1 abstained, 3 against.
- From EUEL license-holders: 8 in favour, 0 abstained, 2 against (against 800 ppm because they wanted 900 ppm).

After the November 2022 EUEB meeting, the EUEB members were asked again to reiterate their answers: while 12 were in favour and 1 abstained, another 4 were against. In this case, among the respondents with a negative opinion were at least three 'big' Member States, meaning that in the event of a vote this amendment would not be supported.

Ambition level of other ecolabels

With respect to total limits for in-can preservatives, the situation is as follows:

- The Blue Angel criteria, version 6 (January 2019, UZ 12a), for low-emission and low-pollutant paints and varnishes set limits for specific preservatives solely for the purposes of in-can preservation. The total overall limit is 400 ppm.
- The Blue Angel criteria, version 4 (January 2019, UZ 102), for low-emission wall paints do not permit the intentional use of in-can or dry-film preservatives and set total limits for both.
- The Austrian Ecolabel criteria (UZ 17, version 9.1) for wall paints set 7 specific limits of biocidal active substances and for free formaldehyde that, when combined, shall be below 400 ppm.

- The Nordic Ecolabel criteria (v3.10) for indoor paints and varnishes set a specific limit of 900 ppm for total preservatives (or 1 600 ppm for 'wet room paints') with certain classifications. In its new proposal this is kept for indoor paints while for outdoor and industrial paints, the limitation levels are higher, 4 500 ppm (0.4500% w/w).

Finally, no amendment is recommended here by the JRC, so no proposed amendment text is presented for this derogation request.

Box 10. FINAL CONCLUSION (In-can preservatives)
Current limit in the criteria: up to 600 ppm allowed, as defined in the first part of Appendix 1.
Request: to increase the limit to 900 ppm to compensate for the banning of more powerful in-can preservatives and to align with Nordic Swan Ecolabel.
JRC recommendation: to reject the request, based on the limited support from EUEB members claiming that alternatives are available and that other ecolabelling schemes, such as Blue Angel and Austrian Ecolabel, already allow lower thresholds for in-can preservatives (400 ppm).
According to data received and analysed, however, increasing the current threshold for in-can preservatives by 200 ppm could allow for effective combinations of in-can preservatives to be used in paints (given the banning of more powerful biocidal active substances).
These aspects may be reconsidered in the upcoming criteria revision process.

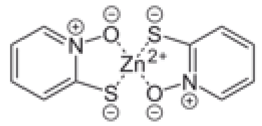
3.4 Zinc pyrithione (ZnPT): update to and possible extension of derogation

> Box 11. Zinc pyrithione (ZnPT) request
>
> Current limit in the criteria: although 500 ppm is stated in the current criteria, it is now effectively 100 ppm. ZnPT is derogated as an in-can preservative in paints, and in tint pastes, and as a dry-film preservative – as described in Parts 1(a), 1(b) and 1(c) of Appendix 1.
>
> Request: to modify the existing derogation for ZnPT so that it can continue to be used up to 500 ppm like before.

Background

Zinc pyrithione (ZnPT)[33] has a broad spectrum of efficacy that covers moulds, yeasts, bacteria and algae. It may be used as an in-can preservative or a dry-film preservative in coating formulations. Due to its lack of sensitising properties, it has been seen as a useful complement to isothiazolines or partial substitute for them.

Table 9. Basic details (CAS numbers, ECHA infoCard, EU Ecolabel limits and CLP hazard classes) of Zinc pyrithione

Name	Zinc pyrithione
Preferred IUPAC name	bis(2-pyridylthio)zinc 1,1'-dioxide
CAS number	13463-41-7
ECHA InfoCard	100.033.324
Chemical formula	$C_{10}H_8N_2O_2S_2Zn$
Chemical structure	
CLP classification	Harmonised (15th ATP): H301, H318, H330, **H360D**, H372, H400 (M=1000), H410 (M=10)

Source: JRC.

ZnPT remains under evaluation for all supported product types: PT02 (Disinfection), PT06 (Preservatives for products during storage), PT07 (Film preservatives), PT09 (Fibre, leather, rubber and polymerised materials preservatives), PT10 (Construction material preservatives) and PT21 (Antifouling products).

The NaPT derogation request received from industry has two parts, (i) for in-can preservation the requested limit value is 250 ppm, while for (ii) dry-film preservation it is 2 500 ppm.

The criteria set out in Decision 2014/312/EU for EU Ecolabel paints already permit derogations for the use of up to 0.050% (500 ppm) ZnPT as an in-can preservative, and a further 0.050% (500 ppm) as a dry-film preservative. However, the entry into force of the 15th CLP on 1 March 2022[34] meant that the existing derogations for ZnPT are invalid. Of the seven hazard classes identified in the new harmonised classification,

[33] https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/-/discli/details/89891
[34] OJ L 261, 11.8.2020, p. 2 (15th ATP https://eur-lex.europa.eu/eli/reg_del/2020/1182/oj).

one is not restricted by the EU Ecolabel criteria, two are restricted by EU Ecolabel but derogated for use (orange classes) and four are restricted by EU Ecolabel but not explicitly derogated (red classes).

Box 12. Restricted hazard classes applicable for all EU Ecolabel product groups (unless denoted otherwise)
- Group 1 hazard classes: CMR - H340, H350, H350i, H360F, H360D, H360FD, H360Fd, H360Df.
- Group 2 hazard classes: CMR - H341, H351, H361f, H361d, H361fd, H362; Acute toxicity – H300, H310, H330, H304; Specific Target Organ Toxicity (STOT) – H370, H372; Hazardous to the aquatic environment – H400, H410, H411; Hazardous to the ozone layer – H420; Respiratory and skin sensitisation* – H317*, H334*.
- Group 3 hazard classes: Acute toxicity – H301, H311, H331, EUH070; Specific Target Organ Toxicity (STOT) – H371, H373; Hazardous to the aquatic environment – H412, H413.
*Only applied horizontally when potential exposure to users is a concern.

The reclassification creates four deviations from the existing derogation requests involving one group 1 hazard, two group 2 hazards and one group 3 hazard (highlighted above). Such a major deviation, especially including a group 1 hazard, would require very strong supporting arguments.

As matters currently stand, a total of only up to 0.010% (100 ppm) ZnPT could be used in the formulation, in line with the horizontal restriction threshold.

Derogation request

The original derogation request received for ZnPT was to continue with the 500 ppm limits already in place, but just to update the derogated hazards to match the reclassifications. However, this was later modified to a two-pronged approach, with a lower derogation for ZnPT used as an in-can preservative (0.025%, 250 ppm), and a higher derogation when used as a dry-film preservative (0.25%, 2 500 ppm).

Consultation

A closer look at the new harmonised CLP classifications for zinc pyrithione and the CLP rules for mixtures (specifically Table 4.1.1. of Annex I to CLP) quickly ruled out the possibility of any derogation above 0.025% (250 ppm). This is due to the M factor of 1 000 for the acute aquatic toxicity hazard classifying the whole coating formulation as H400 if used in quantities >0.025% or >250 ppm.

This effective limit of 250 ppm would apply to the sum of zinc pyrithione used, whether as in-can preservative and/or as dry-film preservative. Any other ingredients in the coating formulation with acute aquatic toxicity hazard classes would also have to be considered since these hazards are additive (so in some cases even less than 250 ppm ZnPT might be permitted).

Perhaps ironically, the new group 1 hazard (H360D) would allow up to 0.30% (3 000 ppm) before the mixture would be classified with that hazard. However, as a category 1 CMR classification, this should imply the foreseeable non-approval of the use of zinc pyrithione as a biocide in the future. Whether or not a derogation for the continued use of zinc pyrithione can be granted at the level of the BPR remains to be seen.

When asked for initial opinions about the request to amend the derogation for ZnPT as an in-can preservative at levels above the horizontal cut-off of 0.010% (up to 0.025%), the following feedback was received:

- From EUEB members: 0 in favour, 1 abstained, 10 against.
- From EUEL license-holders: 0 in favour, 0 abstained, 10 against.

It was highlighted by a EUEB member that '*the EU Ecolabel will send the wrong message to users if it allows higher limits for a raw material classified as CMR as ZnPT*'.

One CB highlighted that the '*threshold proposed for zinc pyrithione also seems to raise questions, particularly in view of its CMR classification. In view of the very low thresholds currently used, we are therefore not in favor of raising it*'.

When this conclusion was presented in the November 2022 EUEB meeting, all responses agreed on the JRC recommendation, i.e. not to proceed with the derogation.

Ambition level of other ecolabels

With respect to total limits for ZnPT, the situation is as follows:

- The Blue Angel criteria, version 6 (January 2019, UZ 12a), for low-emission and low-pollutant paints and varnishes set a specific limit of 200 ppm for ZnPT, but this is earmarked for revision.
- The Blue Angel criteria, version 4 (January 2019, UZ 102), for low-emission wall paints do not permit the intentional use of in-can or dry-film preservatives and do not set any specific limits for ZnPT.
- The Austrian Ecolabel criteria (UZ 17, version 9.1) for wall paints do not set any specific limits for ZnPT and so it is presumed that ZnPT is not permitted.
- The Nordic Ecolabel criteria (v3.10) for indoor paints and varnishes set a transitory exemption for the continued use of ZnPT until 1 January 2023 in base paints and standard colours, and until 1 January 2024 for tinting pastes and tinting systems.

Example of changes to legal text if JRC recommendation accepted

Even rejecting the derogation request for ZnPT means that the following amendment would be needed to the wording of the Appendix in the legal text of Decision 2014/312/EU:

Substance group	Scope of restriction and/or derogation	Concentration limits (where applicable)	Assessment and verification
1. Preservatives added to colourants, binders and the final product			
[.....]			
(a) In-can preservatives Applicability: All products unless specified otherwise	In-can preservatives classified with the following derogated hazard classifications may be used in ecolabelled products: Derogated classifications: H331 (R23), H400 (R50), H410 (R50/53), H411 (R51/ 53), H412 (R52/53), H317 (R43) In-can preservatives classified with these derogated classifications shall also meet the following derogation conditions: — The sum total concentration shall not exceed 0,060 % w/w — Substances classified with H400 (R50) and/or H410 (R50/53) shall be non-bioaccumulative. Non-bioaccumulative substances shall have a Log Kow ≤ 3,2 or a Bioconcentration Factor (BCF) ≤ 100. — For those substances that are approved for use or are included in Annex I to Regulation (EU) No 528/2012 evidence shall be provided that the approval conditions are respected for the paint product. — Where preservatives that are formaldehyde donors are used then formaldehyde content and emissions from the final product must meet the requirements in substance restriction 7(a) Specific concentration limits applies to the following preservatives: ~~(i) Zinc pyrithione~~ (i~~i~~) N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	In-can preservatives Sum total in the final product: 0,060 % w/w Concentration limit ~~0,050 %~~ 0,050 %	Verification: Declaration by the applicant and their binder supplier supported by CAS numbers and classifications for the active substance in the final product and its binder. This shall include calculation by the applicant of the concentration of the active substance in the final product. All manufactured active substances for which 50 % or more of the particles in the number size distribution have one or more external dimensions in the size range 1 nm-100 nm shall be identified.
(b) Tinting (colorant) machine preservatives	The derogated hazard classifications and the derogation conditions listed under 1(a) shall apply also to preservatives used to protect colour tints whilst stored in machines prior to mixing with base paints. Preservatives added to protect tints that will be dispensed from machines shall not exceed a sum total of 0,20 % w/w.	Sum total preservatives in the colourant: 0,20 % w/w	Verification: Declaration by the applicant and/or their tint supplier supported by CAS numbers and classifications for the active substance in the final product and its binder. This shall include calculation of

	The following preservatives are subject to specific maximum concentration limits contributing to the sum total of preservatives in the colourant: (i) 3-iodo-2-propynyl butylcarbamate (IPBC) ~~(ii) Zinc pyrithione~~ (ii~~i~~) N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	0,10 % ~~0,050 %~~ 0,050 %	the concentration of the active substance in the final tint product. All manufactured active substances for which 50 % or more of the particles in the number size distribution have one or more external dimensions in the size range 1 nm-100 nm shall be identified.
(c) Dry-film preservatives Applicability: Outdoor paints, indoor paints for specific applications	Dry-film preservatives and their stabilisers classified with the following derogated hazard classifications may be used in all outdoor products and only specific indoor products: Derogated classifications: H400 (R50), H410 (R50/53), H411 (R51/53), H412 (R52/53), H317 (R43) Dry-film preservatives classified with these derogated classifications must also meet the following derogation conditions: — The sum total concentration shall not exceed 0,10 % w/w or 0,30 % w/w (as relevant). — Substances classified with H400 (R50) and/or H410 (R50/53) shall be non-bioaccumulative. Non-bioaccumulative substances shall have a Log Kow ≤ 3,2 or a Bioconcentration Factor (BCF) ≤ 100. — For those substances that are approved for use or are included in Annex I to Regulation (EU) No 528/2012 evidence shall be provided that the approval conditions are respected for the paint product. A higher sum total and a derogation from the requirements in criterion 5a which shall allow for the final product to become classified as hazardous for the aquatic environment (Chronic Category 3) and to carry the hazard statement H412 applies to the use of the following dry film preservative for the specified applications only: 3-iodo-2-propynyl butylcarbamate (IPBC) combinations Outdoor paints and varnishes Specific concentration limits applies to the following preservative: ~~Zinc pyrithione~~	Dry film preservatives Sum total in the final product: Indoor paints intended for use in areas with high humidity, including kitchens and bathrooms 0,10 % w/w All outdoor paint applications 0,30 % w/w Outdoor paints sum total for IPBC combinations: 0,650 % ~~0,050 %~~	Verification: Declaration by the applicant and their binder supplier supported by CAS numbers and classifications for the active substances in the final product and its binder. This shall include calculation by the applicant of the concentration of the active substances in the final product. All manufactured active substances for which 50 % or more of the particles in the number size distribution have one or more external dimensions in the size range 1 nm-100 nm shall be identified.

Box 13. FINAL CONCLUSION (ZnPT)

Current limit in the criteria: 100 ppm[35]. ZnPT is derogated as an in-can preservative in paints, and in tint pastes, and as a dry-film preservative – as described in Parts 1(a), 1(b) and 1(c) of Appendix 1.

Request: to modify the existing derogation for ZnPT so that it can continue to be used up to 500 ppm like before.

JRC recommendation: to reject this request, because it is not considered appropriate to derogate for a category 1 CMR biocidal active substance when non-CMR alternatives are available.

[35] Please note that although 500 ppm is written in the criteria, due to the 15th ATP to CLP, as of 19 May 2020 (that entered into force on 31 August 2020 and applicable from 1 March 2022), the actual ZnPT threshold allowed in EU Ecolabel paints, not triggering the classification of the final product is 100 ppm.

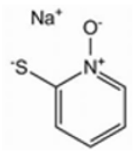
3.5 Sodium pyrithione (NaPT): derogation request

Box 14. Sodium pyrithione (NaPT) request
Current limit in the criteria: up to 100 ppm allowed because no existing derogation in place.
Request: to derogate up to 400 ppm as in-can preservative and 2 000 ppm as dry-film preservative, in part to compensate for the expected prohibition of ZnPT.

Background

Sodium pyrithione (NaPT)[36] is a widely used preservative for water-based functional fluids. Due to its activity spectrum, it is preferably applied when problems related to the growth of fungi have to be overcome. It may be used as an in-can preservative or a dry-film preservative in coating formulations. Sodium pyrithione is a highly effective microbiocide; the addition rates therefore are relatively low: 0.02–0.06% (BAuA, 2020).

Table 10. Basic details (CAS numbers, ECHA infoCard, EU Ecolabel limits and CLP hazard classes) of Sodium pyrithione

Name	Sodium pyrithione
Preferred IUPAC name	sodium 2-thioxopyridin-1(2H)-olate
CAS number	15922-78-8; 3811-73-2
ECHA InfoCard	100.036.405
Chemical formula	$C_5H_5NOS.Na$
Chemical structure	
CLP classification	Harmonised (18th ATP): H331, H302, H311, H372, H315, H319, H317, H400 (M=100), H411.

Source: JRC.

NaPT remains under evaluation for all supported product types: PT02 (Disinfection), PT06 (Preservatives for products during storage), PT07 (Film preservatives), PT09 (Fibre, leather, rubber and polymerised materials preservatives), PT10 (Construction material preservatives) and PT13 (Working or cutting fluid preservatives).

The NaPT derogation request received from industry has two parts, (i) for in-can preservation the requested limit value is 400 ppm, while for (ii) dry-film preservation it is 2 000 ppm.

Although not in force yet (1 December 2023 onwards under the 18th ATP), the new harmonised classifications are presented in the insert on the right.

Of the nine hazard classes identified in the new harmonised classification, three are not restricted by the EU Ecolabel criteria, three or four are restricted by EU Ecolabel but derogated for use (orange) and two or three are restricted by EU Ecolabel but not explicitly derogated (red). The H331 code is 'orange' in the case of in-can preservatives, but 'red' in the case of dry-film preservatives.

[36] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.036.405

Consultation

It is worth noting that the M factor of 100, associated with the H400 code, will automatically place an effective limit of 0.25% (2500 ppm) on NaPT in the mixture, above which the whole mixture would be labelled as toxic to the aquatic environment. It should be remembered that H400 is additive with other substances classified as H400, and H410 is additive with other substances classified as H410, H411 or H412, so it could be that the real limit allowed in specific formulations could be less than the 2 000 ppm being requested.

The applicable classification thresholds for NaPT as defined in the 18th ATP are as follows:

- H400 = > 0.25% (25% generic threshold with M=100 applied);
- H410 = N/A;
- H411 = > 25%;
- H412 = > 2.5%.

This means that, according to the methodology established in the CLP Regulation and taking into account the proposal for harmonised C&L of the 18th ATP, a concentration of 400 ppm for in-can preservation or a concentration of 2 000 ppm for dry-film preservation would not result in the classification of the final product.

Considering the H317 classification and the generic classification limit of 1 000 ppm, the effective limit of any NaPT actually allowed would be no more than 0.10% (1 000 ppm). This last limit is more stringent than the request of 2 000 ppm as a dry-film preservative.

When asked for initial opinions (in the May 2022 EUEB meeting) about the request to amend the derogation for NaPT as an in-can preservative to levels above the horizontal cut-off of 100 ppm (up to 250 ppm instead of the requested 400 ppm), the following feedback was received:

- From EUEB members: 7 in favour, 1 abstained, 3 against.
- From EUEL license-holders: 8 in favour, 0 abstained, 2 against (against because they wanted >250 ppm).

In terms of feedback from stakeholders, one CB stated that '*from their LHs, sodium pyrithione is not used in the certified products, while mainly BIT and CMIT-MIT are used*'.

Industry representatives have mentioned that NaPT is emerging as an alternative to ZnPT after the entry into force of the 15th ATP from 1 March 2022 onwards (ZnPT is now classified as Repr. 1B (H360D) under this reclassification). It is important to allow for the use of NaPT both as an in-can preservative and as a dry-film preservative, because it is currently allowed for both PT6 and PT7.

Another CB noted that '*their LHs do not use this NaPT, but as the threshold proposed by industry proposal does not seem to affect the hazard classification of the final paints product, it may be an alternative to the use of ZnPT, currently used by some of their LHs*'. A previous derogation request for NaPT (before any harmonised classification) was shared with CBs and EUEB members in 2020, in which a concentration of up to 0.0500% (500 ppm) was requested in the derogation, which would not impart any classification of the mixture. The derogation was to apply to in-can preservatives and dry-film preservatives. Back then, eight stakeholders were in favour of the derogation while one was against and another eight did not express an opinion.

The conclusions were presented in the November 2022 EUEB meeting where it was clear that there was not enough support to proceed with the derogation as some Member States (MS) were negative on the proposal. This was confirmed later in writing. A summary of the answers received is as follows:

- From EUEB members: 12 in favour, 1 abstained, 4 against.
- Of the 4 EUEB members against, 2 are actually would be in favour of 200 ppm for both in-can and dry-film preservation: '*From our perspective the pH-value can be increased up to 11 in order to have a comparable result. From our perspective, the current limit of*

100 ppm is also fine, but we would accept a limit of 200 ppm for both (we always have the limit for all preservatives in our minds). From our perspective we also could exclude NaPT for dry-film preservatives'.

Ambition level of other ecolabels

With respect to total limits for NaPT, the situation is as follows:

- The Blue Angel criteria, version 6 (January 2019, UZ 12a), for low-emission and low-pollutant paints and varnishes set a specific limit of 200 ppm for NaPT.
- The Blue Angel criteria, version 4 (January 2019, UZ 102), for low-emission wall paints do not permit the intentional use of in-can or dry-film preservatives and do not set any specific limits for NaPT.
- The Austrian Ecolabel criteria (UZ 17, version 9.1) for wall paints set a specific limit for NaPT of 200 ppm.
- The Nordic Ecolabel (v3.10) for indoor paints and varnishes does not make any specific mention of NaPT. The new requirements proposed do not make any specific mention either.

As a result of the comments received during and after the EUEB meeting in November 2022, further research on the nature of in-can and dry-film preservation and the possibility to raise the pH up to 11 was carried out.

NaPT as PT6 and PT7

In-can or PT6 preservation maintains the quality of paints and coatings and extents their shelf life, thus enables a more sustainable use of resources, minimizing paint waste while dry-film or PT7 preservation preserves the surface integrity of the paint film against fungi, e.g. when used in interior humid atmospheres such as kitchens or bathrooms. PT7's application is fundamentally different compared to PT6 as an effective dry-film protection prevents microbial deterioration of the exposed paint film and thus, allows meeting the increased need for protection of structures and buildings.

In the specific case of NaPT, industry requested a derogation of for its use in concentrations of up to 400 ppm for in-can preservation and up to 2 000 ppm for dry-film use. According to industry exchanges in bilateral meetings and *via* email, '*lower concentrations are not sufficient to guarantee its effective use across the different paint and coatings matrixes*'.

According to industry, the use of NaPT as an in-can preservative is effective and typically achieved in combination with other active substances, with minimum use concentrations <400 ppm of NaPT. Several test examples received from industry after the November EUEB meeting showed that in many cases 200 ppm (plus other combinations) could achieve the desired level of protection. However, the percentage of successful protection is limited to some data points (70% of the data received). Other studies recently performed[37] demonstrated that NaPT is only effective in higher concentrations against bacteria and fungi in latex paint at levels from 0.05% to 1.25% by weight (w/w) (i.e. from 500 ppm to 12 500 ppm).

When industry was requested to provide similar test examples or combinations for the use of NaPT as a dry-fim preservative, it was explained that '*NaPT is not well established on the market yet and thus, the database supporting effective in use concentrations is less strong than for in-can examples. Whereas a wide range of data is available on dry-film products incorporating ZnPT, a meta-analysis of that data confirmed that 5-10 times the amount of ZnPT is required to provide sufficient dry-film preservation compared to levels delivering adequate in-can preservation*'. For NaPT, although industry internal pool of data is much smaller, it is expected that the cited rule would also apply, with 5-10 times the NaPT concentration of that within an in-can product being sufficient for film preservation, hence the request for 2 000 ppm (5 x 400 ppm).

Although the answer given by industry may seem reasonable, the main issue is the absence of data from a real (or quasi-real) test result, thus is not totally appropriate to actually allow a higher concentration of NaPT for dry-film preservation in the EU Ecolabel until testing procedures or at least more insights into the behaviour of NaPT for dry-film preservation are developed.

[37] Confidential data from industries.

High-pH paints

In relation to increasing the pH to allow for better preservation, industry highlighted that it is not a feasible alternative to chemical preservation. There are examples of preservative-free paints with a high pH in the case of alkali silicate (waterglass) paints. However, as reported by the German Federal Environment Agency (UBA)[38], those paints are not effectively protected against microbial growth and spoilage. In these products preservation is achieved by raising the pH to values between 10.4 and 11.1. Nevertheless, whilst the paints provide protection against certain microorganisms, those species adapted to high-pH environments, including bacteria and yeasts, could still be detected in these paints. Furthermore, increasing the pH over the storage time cannot be excluded; therefore, protection against spoilage may not be effective for extended periods. The findings were confirmed in another survey of paints from the German market in 2019 showing that of 16 assessed paints, 11 paints were contaminated by microbes. Also, 11 out of 16 paints revealed a pH value of ≥11.5, although none were classified correctly according to the CLP Regulation and labelled as H314 'Corrosive to the skin'. Moreover, the pH 11 is only in the wet state. The dried layer will have a latent high pH which will drop over time due to absorption of CO_2 at the surface.

Information from industry suggests that NaPT and ZnO, contained within paints, act as metal and its ligand in a reversible process based on the pH of the medium to form ZnPT. This means that every single formula would need a full rework as 90% of raw materials will not be stable at a high pH. Internal benchmarks show that paints made at a high pH have a lower quality (i.e. lower durability) than paints at the current pH level.

In general, alkaline paints with a pH >11 are specific paints with a very low sale volume across Europe (except in Germany) where several bacteria will be killed without the use of biocides but some alkalophilic bacteria will remain alive in the wet paint as just outlined.

Silicate-based binders (colloquially known as water glass binders) have an intrinsic pH of >11. In these formulations there are no organic carbon compounds as the binder is based on silicate. As there is no organic carbon to be consumed by microorganisms and due to the high pH of the wet formulation these formulations are typically free of PT6 biocides. Sometimes an algicide is used in silicate-based paints when applied outdoors on facades because it can be a good substrate for growing of algae (algae need no organic carbon, only airborne CO_2).

Acrylic-based binders have organic carbon in their structure which can be used as a feedstock by microorganisms. Acrylic binders are made of acrylic esters. Ester bonds will be hydrolysed at pH 11, resulting in the correlated alcohols. These alcohols are VOCs, which lead to increased emissions. Also, the acrylic binder will lose its properties, resulting in a defective product. A paint/sealant based on acrylic/organic carbon binder at pH 11 and without PT7 biocides is sensitive to microbial attack when dried. Internal undisclosed studies have shown this.

Therefore, information suggests that there are multiple reasons not to raise the pH and subsequently lower the concentration of biocides.

Some key principles which are also worth mentioning are as follows:

- A pH of over 11 is mainly applicable for white matte wall paints, and thus it would limit the number and type of ecolabelled products on the market.

- At pH >9.5 certain species such as isothiazolones are not stable and will decompose, thus losing the protection. Moreover, species such as bronopol releases formaldehyde at this high pH and may cause discolouration.

- High-pH paints could cause damage to eyes so there is always a need for protective glasses and gloves.

- High-pH paints would be very sensitive to contamination picked up from raw materials or the manufacturing process, which is very difficult to control. Furthermore, they require specific technology in terms of designing and handling the production plant and its hygiene, and this is not available to all paint producers without major investment (in practice only new manufacturing sites).

[38] UBA, 2020. Available at : https://www.umweltbundesamt.de/sites/default/files/medien/376/publikationen/uba_vh_4108_endbericht_2020_final_002-sp-pb2_174-2020.pdf

- The pH of the product is artificially raised to a level at which the user should take extra steps to protect himself and also surfaces not intended to be treated.

Final conclusions

Given the reasons laid out above, as a first conclusion the JRC would recommend the increase of NaPT concentration for in-can preservation up to 200 ppm (and also the subsequent derogation of H311 and H372 only for this substance). In relation to NaPT as a dry-film preservative, the JRC could recommend 1 000 ppm (five times higher). This is because the options for dry-film preservation are much more limited now with the ZnPT and OIT reclassifications, and if results for ZnPT are extrapolated to NaPT there is a potential combination for dry-film preservation. However, in conversations with industry, the values mentioned do not seem sufficient to fulfil their needs.

From this, two opposing conclusions can be drawn. On the one hand, the EUEB members would not support a concentration limit higher than 200 ppm, while on the other hand, the industry stressed that, in its opinion, a 200 ppm threshold for in-can preservation could result in quality-deficient paints. Given these conclusions, the JRC recommends reassessing these aspects during the upcoming full criteria revision. This would allow industry to have more time to test combinations and to provide further data supporting the request to increment the allowed NaPT concentration in EU Ecolabel paints.

Since no amendment is finally recommended by the JRC for NaPT, no proposed amendment text is presented for this derogation request.

Box 15. FINAL CONCLUSION (NaPT)

Current limit in the criteria: up to 100 ppm allowed (no derogation in place).

Request: to derogate up to 400 ppm as in-can preservative and 2 000 ppm as dry-film preservative, in part to compensate for the expected prohibition of ZnPT.

JRC recommendation: to reassess this request during the upcoming criteria revision process, due to the low support from EUEB members for the proposal (a threshold of maximum 200 ppm for both in-can and dry-film preservation was proposed or, as an alternative, raising the pH of paints) and due to the absence of complete testing data for NaPT for dry-film (and in-can) preservation.

3.6 DBDCB (2-bromo-2-(bromomethyl)pentanedinitrile): derogation request

Box 16. DBDCB (2-bromo-2-(bromomethyl)pentanedinitrile) request

Current limit in the criteria: theoretically up to 600 ppm (0.060% w/w) as in-can preservative; however, depending on the self-classification (if it includes H330), only up to 100 ppm allowed (because no existing derogation in place for H330).

Request: to derogate for use up to 500 ppm for in-can preservation, to compensate for the effective banning of more powerful isothiazolines.

Background

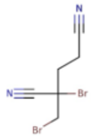
A late derogation request was received from industry in relation to DBDCB (2-bromo-2-(bromomethyl)pentanedinitrile) for its use as an in-can preservative with a maximum concentration of 500 ppm.

DBDCB is a PT6 (in-can preservative) approved under BPR for which there is no harmonised classification in place. General information about DBDCB is summarised on the right for the self-classification[39]. The highest number of notifiers (498) classify DBDCB as H302, H315, H317, H318, H400; another 447 applicants notify of H302, H315, H318; while 156 applicants notify of H302, H317, H318, H330, H335, H411.

However, the company requesting the derogation classifies DBDCB according to its internal studies as H302, H330, H318, H317, H411.

Of these nine hazard classes appearing in different self-classification notifications, three are not restricted by the EU Ecolabel criteria (black classes), two are restricted but derogated (orange) and one is restricted but not covered by derogations (red).

Table 11. Basic details (CAS numbers, ECHA infoCard, EU Ecolabel limits and CLP hazard classes) of DBDCB

Name	DBDCB
Preferred IUPAC name	1,2-dibromo-2,4-dicyanobutane
CAS number	35691-65-7
ECHA InfoCard	100.047.877
Chemical formula	$C_6H_6Br_2N_2$
Chemical structure	
CLP classification	Self-classified: H302, H315, H317, H318, H400.

Source: JRC.

[39] https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/-/discli/details/25868

Box 17. Hazard classes applicable for all product groups (unless denoted otherwise)

- Group 1 hazard classes: CMR - H340, H350, H350i, H360F, H360D, H360FD, H360Fd, H360Df.

- Group 2 hazard classes: CMR - H341, H351, H361f, H361d, H361fd, H362; Acute toxicity – H300, H310, H330, H304; Specific Target Organ Toxicity (STOT) – H370, H372; Hazardous to the aquatic environment – H400, H410, H411; Hazardous to the ozone layer – H420; Respiratory and skin sensitisation* – H317*, H334*.

- Group 3 hazard classes: Acute toxicity – H301, H311, H331, EUH070; Specific Target Organ Toxicity (STOT) – H371, H373; Hazardous to the aquatic environment – H412, H413.

*Only applied horizontally when potential exposure to users is a concern.

As shown above, H330 is a group 2 hazard, for which derogations are usually difficult to justify, although H331 of category 3 hazards has in fact already been granted a derogation.

As the company requesting the derogation classifies DBDCB according to its internal studies as H302, H330, H318, H317 and H411, in its opinion, the only hazard code that would require an additional derogation is H330.

According to the BPR assessment report presented by the Czech Republic in 2015, DCDCB has been used in cosmetics for over 25 years without any issues of microbial resistance developing. The expected efficacy range of DBDCB was estimated to be in the 0.08% to 0.15% (800 ppm to 1 500 ppm range).

Consultation

According to industry representatives, DBDCB is known as a broad spectrum preservative for water-based industrial products. The best efficacy is shown in combinations with actives covering other modes of actions like isothiazolinones. Its relevance for paints and coatings decreased in the past as BIT and MIT combinations became the standard. However, the recent reclassification of MIT has reawakened interest in DBDCB and other alternatives to isothiazolines, as options for in-can preservation.

The use of DBDCB at levels of less than 0.10% (1 000 ppm) means that the H330 code would not contribute to any potential calculation to determine if the mixture should be classified as acutely toxic. The main limiting factor to classifying the whole mixture is the H317 classification and generic concentration limit of 0.10% (1 000 ppm).

Normal formal positions were obtained from EUEB members of license-holders due to the late arrival of this particular derogation request. However, in terms of feedback from stakeholders, there was a general acceptance (after the May 2022 EUEB meeting) of derogating for DBDCB up to levels of 250 ppm, at which level it was considered as being useful for in-can preservation when combined with BIT or other izothiazolines.

The same conclusion was presented in the November 2022 EUEB meeting where most of the opinions were again in favour:

- EUEB members: 14 in favour, 1 abstained, 2 against.

- EUEB members against this derogation explained: DBDCB at 50 ppm in a leave-on product[40] can elicit contact dermatitis in sensitized persons. The authors state that they were unable to find a safe, still microbiocidal, concentration for leave-on products. The Scientific Committee on Consumer Products does not alter its previous opinion stating that no safe use level for DBDCB in rinse-off products has been established.

However, this study is specific to cosmetic products rather than paints.

After the EUEB meeting, it was discovered that this substance not only does not have harmonised classification, but is being scrutinised in the registry of CLH intentions the outcome date of which is not

40 https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_060.pdf

yet clear[41]. The application currently requests the classification as H302, H330, H318, H317 and H411, which also coincides with the classification of the company requesting the derogation. The currently ongoing process for the CLH was initiated in 2015.

Ambition level of other ecolabels

With respect to total limits for DBDCB, the situation is as follows:

- The Blue Angel criteria, version 6 (January 2019, UZ 12a), for low-emission and low-pollutant paints and varnishes set a specific limit of 400 ppm for DBDCB.
- The Blue Angel criteria, version 4 (January 2019, UZ 102), for low-emission wall paints do not permit the intentional use of in-can or dry-film preservatives and do not set any specific limits for DBDCB.
- The Austrian Ecolabel criteria (UZ 17, version 9.1) for wall paints do not set a limit for DBDCB.
- The Nordic Ecolabel criteria (v3.10) for indoor paints and varnishes do not make any specific mention of NaPT.

As explained above, given that this substance does not have harmonised classification, it would be complex to set certain conditions for its derogation while it is being scrutinised in the registry of CLH intentions. As previously explained for bronopol, the JRC opts to wait for the final conclusion of ECHA on the CLH and does not advise derogating for DBDCB.

Since no amendment is finally recommended by the JRC for DBDCB, no proposed amendment text is presented for this derogation request.

Box 18. FINAL CONCLUSION (DBDCB)
Current limit in the criteria: theoretically up to 600 ppm (0.060% w/w) as in-can preservative; however, depending on the self-classification (if it includes H330), only up to 100 ppm allowed (because no existing derogation in place for H330).
Request: to derogate for use up to 500 ppm for in-can preservation, to compensate for the effective banning of more powerful isothiazolines.
JRC recommendation: to reject the derogation request for DBDCB since it is not possible to derogate for a substance whose harmonised classification is not yet in place.
The derogation request for DBDCB may be reassessed during the upcoming full criteria revision.

41 https://echa.europa.eu/de/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e180a3f6d6

3.7 IPBC correction for H372 derogation

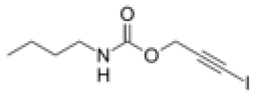
Box 19. IPBC (3-iodo-2-propynyl butylcarbamate) request
Current limit in the criteria: up to 600 ppm as in-can preservative, in normal indoor paints or up to 1 000 ppm in tinting pastes and up to 6 500 ppm in outdoor paints.
Request: it appears that there has been an oversight with some hazard classes in the IPBC classification not being explicitly derogated for in-can (H372) and for dry-film preservation (H331 and H372). Consequently, it is requested to amend the text to ensure that IPBC can be used as originally intended.

Background

The specific reference to IPBC (3-iodo-2-propynyl butylcarbamate) in the general derogations for preservatives in the EU Ecolabel criteria for paints and varnishes allows up to 0.10% IPBC for tint preservatives and up to 0.65% IPBC as dry-film preservatives in outdoor paints.

Looking at the harmonised classifications for IPBC (see right), of the seven hazard classes identified, two are not restricted at all by the EU Ecolabel criteria (black classes), three or four are restricted by the EU Ecolabel but are derogated already (orange) and one or two are restricted but not explicitly derogated (red).

Table 12. Basic details (CAS numbers, ECHA infoCard, EU Ecolabel limits and CLP hazard classes) of IPBC

Name	IPBC
Preferred IUPAC name	3-iodo-2-propynyl butylcarbamate
CAS number	55406-53-6
ECHA InfoCard	100.054.188
Chemical formula	$C_8H_{12}INO_2$
Chemical structure	
CLP classification	Harmonised (6th ATP): H302, H317, H318, H331, H372 (larynx), H400 (M=10), H410

Source: JRC.

The harmonised classification for IPBC came with the 6th ATP (2014), coinciding with the adoption of the current original EU Ecolabel criteria in Decision 2014/312/EU. It appears that there was an oversight by the original authors and project team, whereby they missed the H372 classification of IPBC in the then-impending harmonised classification of IPBC. The H331 classification is covered by the derogation for in-can preservatives but not for dry-film preservatives. Consequently, there is a need to amend it if IPBC continues to be a relevant preservative for the industry.

Consultation

Discussions with Competent Bodies confirmed that IPBC is indeed used in EU Ecolabel paints and varnishes. Therefore, the need to amend the criteria is confirmed, even if this is not in response to a specific derogation request, but rather the flagging of an error in an already adopted derogation.

There are different ways in which the amendment can be made. The best option could be influenced by which other derogation requests are accepted in the end. One proposal from the JRC on how to amend the criteria is shown below.

Substance group	Scope of restriction and/or derogation	Concentration limits (where applicable)	Assessment and verification
1. Preservatives added to colorants, binders and the final product			
[.....]			
(a) In-can preservatives Applicability: All products unless specified otherwise	In-can preservatives classified with the following derogated hazard classifications may be used in ecolabelled products: Derogated classifications: H331 (R23), H372**, H400 (R50), H410 (R50/53), H411 (R51/ 53), H412 (R52/53), H317 (R43) **H372 derogation only applies to IPBC. In-can preservatives classified with these derogated classifications shall also meet the following derogation conditions: — The sum total concentration shall not exceed 0,060 % w/w — Substances classified with H400 (R50) and/or H410 (R50/53) shall be non-bioaccumulative. Non-bioaccumulative substances shall have a Log Kow ≤ 3,2 or a Bioconcentration Factor (BCF) ≤ 100. — For those substances that are approved for use or are included in Annex I to Regulation (EU) No 528/2012 evidence shall be provided that the approval conditions are respected for the paint product. — Where preservatives that are formaldehyde donors are used then formaldehyde content and emissions from the final product must meet the requirements in substance restriction 7(a) Specific concentration limits applies to the following preservatives: (i) Zinc pyrithione (ii) N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	In-can preservatives Sum total in the final product: 0,060 % w/w Concentration limit 0,050 % w/w 0,050 % w/w	Verification: Declaration by the applicant and their binder supplier supported by CAS numbers and classifications for the active substance in the final product and its binder. This shall include calculation by the applicant of the concentration of the active substance in the final product. All manufactured active substances for which 50 % or more of the particles in the number size distribution have one or more external dimensions in the size range 1 nm-100 nm shall be identified.
[.....]	[.....]	[.....]	[.....]
(c) Dry film preservatives Applicability: Outdoor paints, indoor paints for specific applications	Dry film preservatives and their stabilisers classified with the following derogated hazard classifications may be used in all outdoor products and only specific indoor products: Derogated classifications: H331*, H372*, H400 (R50), H410 (R50/53), H411 (R51/53), H412 (R52/53), H317 (R43) *The H331 and H372 derogations only apply to IPBC. Dry film preservatives classified with these derogated classifications must also meet the following derogation conditions: — The sum total concentration shall not exceed 0,10 % w/w or 0,30 % w/w (as relevant). — Substances classified with H400 (R50) and/or H410 (R50/53) shall be non-bioaccumulative. Non-bioaccumulative substances shall have a Log Kow ≤ 3,2 or a Bioconcentration Factor (BCF) ≤ 100. — For those substances that are approved for use or are included in Annex I to Regulation (EU) No 528/2012 evidence shall be provided that the approval conditions are respected for the paint product. A higher sum total and a derogation from the requirements in criterion 5a which shall allow for the final product to become classified as hazardous for the aquatic environment (Chronic	Dry film preservatives Sum total in the final product: Indoor paints intended for use in areas with high humidity, including kitchens and bathrooms 0,10 % w/w All outdoor paint applications 0,30 % w/w	Verification: Declaration by the applicant and their binder supplier supported by CAS numbers and classifications for the active substances in the final product and its binder. This shall include calculation by the applicant of the concentration of the active substances in the final product. All manufactured active substances for which 50 % or more of the particles in the number size distribution have one or more external dimensions in the size range 1 nm-100 nm shall be identified.

	Category 3) and to carry the hazard statement H412 applies to the use of the following dry film preservative for the specified applications only: 3-iodo-2-propynyl butylcarbamate (IPBC) combinations Outdoor paints and varnishes Specific concentration limits applies to the following preservative: Zinc pyrithione	Outdoor paints sum total for IPBC combinations: 0,650 % 0,050 %	

Box 20. FINAL CONCLUSION (IPBC)

Current limit in the criteria: up to 600ppm as in-can preservative, in normal indoor paints or up to 1 000 ppm in tinting pastes and up to 6 500 ppm in outdoor paints.

Request: it appears that there has been an oversight with some hazard classes in the IPBC classification not being explicitly derogated for in-can (H372) and for dry-film preservation (H331 and H372). Consequently, it is requested to amend the text to ensure that IPBC can be used as originally intended.

JRC recommendation: to acknowledge the request, as it seems to be a genuine oversight due to the harmonised classification of IPBC being adopted around the same time as the original EU Ecolabel criteria for paints and varnishes. These aspects can be corrected during the upcoming full criteria revision process.

3.8 Encapsulated OIT

Box 21. Encapsulated OIT request

Current limit in the criteria: the limit for ‘free’ OIT was recently reduced from 500 ppm to 15 ppm due to a reclassification with a specific concentration limit of 15 ppm for H317.

Request: to ask for clarification on whether more than 15 ppm of OIT are allowed in EU ecolabelled products when: a) it is added in encapsulated form and b) testing of the mixture shows no skin sensitisation.

Background

The use of OIT (octylisothiazolinone) in paints and varnishes is especially important for providing a fungicidal effect. However, the reclassification of OIT to a category 1 skin sensitiser (H317) with a specific concentration limit of 0.0015% has greatly lowered the total quantity of OIT that can be used in EU Ecolabel paints and varnishes from 0.050% (500 ppm) to 0.0015% (15 ppm) – a 97% drop. Recent reclassifications for other popular fungicides (DCOIT and ZnPT) that also greatly reduce the quantities that can be used in EU Ecolabel products has forced manufacturers to look for alternative solutions.

One approach has been to add OIT in an encapsulated form (EOIT), which under certain conditions will slowly release OIT. There are lots of possibilities in this field; for example, capsules that only open upon exposure to UV light could allow for a true distinction to be made between in-can and dry-film preservatives.

The gradual release of OIT can be considered advantageous in the sense that the presence of the biocidal active substance could perhaps be guaranteed for longer periods. Or the same longer term protection could potentially be achieved with a lower initial dose of EOIT than with OIT which was free at the beginning.

Encapsulation is a broader issue that needs to be interpreted at the level of REACH and CLP definitions. The first question is whether EOIT should be considered as a mixture of capsule polymer and OIT or simply as OIT inside a physical capsule (i.e. an article). This issue is further complicated by the variety of different forms of encapsulation and technologies involved. So far (as of February 2023), the authors believe there is not a formally agreed interpretation of encapsulated chemicals in the context of REACH and CLP. This has been a matter of discussion in previous CARACAL meetings but conclusions are not yet available.

Specifically with EOIT in paints and varnishes, it was claimed that free OIT levels were typically 10 times lower than EOIT, but that this can no doubt vary depending on environmental conditions and so the simple use of the CLP rule of mixtures with a factor of 10 adjustment cannot be applied with certainty. This means that testing of the mixture, as per Article 9 of CLP, would be necessary.

However, with testing of paint or varnish formulations with encapsulated additives *in vitro* for skin sensitisation, it was found that existing *in vitro* testing methods were not suitable for mixtures like paint, which are not fully soluble in water.

One producer has gone further and conducted *in vivo* (Local Lymph Node Assay, LLNA) tests for skin sensitisation. They concluded that using up to 500 ppm EOIT in a paint formulation also containing other biocidal active substances (BIT and IPBC) did not trigger skin sensitisation. They confirmed that they were currently marketing paints with EOIT >15ppm and without the H317 classification thanks to these test results. The producer wanted to know how EOIT would be considered in the context of EU Ecolabel criteria, since the criteria are as shown to the right:

> (iii) Permitted sum totals of isothiazolinone substances and compounds in the ready to use product
>
> The sum total of isothiazolinone compounds in any paint or varnish product shall not exceed 0,050 % (500 ppm) with the exception of outdoor wood paints and varnishes which shall not exceed 0,20 %. The following preservatives are derogated for use subject to specific limits on their contribution to the sum total of isothiazolinone compounds in the final ready to use product.
>
> ►M5 2-methyl-2H-isothiazol-3-one: 0,0015 % ◄
>
> 1,2-Benzisothiazol-2(2H)-one: 0,0500 %
>
> ►M5 2-octyl-2H-isothiazol-3-one: 0,0500 % (until 28 February 2022); 0,0015 % (from 1 March 2022 onwards) ◄

Since no distinction is made in the EU Ecolabel criteria about whether the 0.0015% limit for OIT refers to ‘free’ OIT or ‘encapsulated’ OIT, clarity is needed, either via amendment to the criteria or by clarification in the User Manual of the EU Ecolabel for indoor paints and varnishes. In order to reduce the potential amount of animal testing to the bare minimum, read-across of similar formulations and paint types should be encouraged, as well as data sharing.

Consultation

In the November 2022 EUEB meeting the possibility to add this clarification in the User Manual was explained. All the feedback from EUEB members during and after the meeting favoured rejecting the proposal allowing EOIT above 15 ppm and recommended awaiting the foreseen revision of the product group criteria with regards to encapsulated OIT.

Box 22. FINAL CONCLUSION (Encapsulated OIT)

Current limit in the criteria: the limit for 'free' OIT was recently reduced from 500 ppm to 15 ppm due to a reclassification with a specific concentration limit of 15 ppm for H317.

Request: to ask for clarification on whether more than 15 ppm of OIT are allowed in EU ecolabelled products when: a) it is added in encapsulated form and b) testing of the mixture shows no skin sensitisation.

JRC recommendation: to reject the request until clear indications on the safe use of encapsulated, classified substances are provided by REACH and CLP and, in any case, further investigations are to be carried out during the revision of the criteria.

4 Conclusions

This report summarises a total of six formal derogation requests received in 2022 and 2023 to Commission Decision 2014/312/EU setting EU Ecolabel criteria for paint and varnish products to permit the use of different biocidal active substances in EU ecolabelled paints and varnishes at levels above the horizontal limit of 100 ppm, and of two other issues flagged and consulted on in parallel i.e. the oversights regarding the harmonised classification of IPBC and the possibility of encapsulated OIT use.

EU Ecolabel Regulation (EC) No 66/2010 sets the framework, general procedures and comitology for how EU Ecolabel criteria should be developed and revised. During this validity period, the actual criteria can be amended for various reasons, apart from the type of amendment to simply extend the validity period of all the criteria, the amendment of the actual content of existing criteria can also take place. An amendment of the criteria requires detailed justifications and consultation also in proportion to how major the changes being introduced are. In this line, a common drivers for amending EU Ecolabel criteria are changes in hazardous substance classification, which create the need to either insert new derogations or modify existing derogations for hazardous substances.

This report showed the JRC assessment of a number of hazardous substance derogation requests received. Each of the issues have been assessed on a case-by-case basis, but in reality all of these situations are parts of a bigger picture of the regulatory challenges facing the biocides sector and paint and varnish producers. For this reason, each of these issues has been grouped together in a single section, together with a common background and assessment of the main market, environmental and technological considerations.

After each chapter, JRC's recommendations on how to proceed with each of the issues raised is summarised. To recap the main conclusions, <u>for the time being, the main received requests cannot be accepted (except for the correction on IPBC, which is suggested however to be fixed in the forthcoming criteria revision process) mainly due to the absence of further supporting evidence/data and/or a lack of support from EUEB members to proceed with an amendment. However, all the issues raised will continue to be monitored and will be reassessed during the upcoming full criteria revision process.</u>

Recommendations to provide to manufacturers of paints and varnishes or affected stakeholders wishing to modify the criteria are to develop the most up-to-date assessments as possible as to explain why criteria should be amended with data related to the aim of the amendment. However, stakeholders should keep in mind that the final decision is not taken by JRC but by the Member States who vote for the success of the proposals and recommendations made by JRC.

Summary of main recommendations

1. To reject the proposals to align with Nordic Swan Ecolabel for free formaldehyde limits of 0.0025% (25 ppm) when bronopol is used AND to reject, for the moment, the proposed derogation for bronopol with the H301 classification.
2. To reject the proposal to increase total allowed isothiazolines from 500 ppm to 600 ppm in order to align with Nordic Swan Ecolabel limits.
3. To reject the proposal to increase total in-can preservative limits from 600 ppm to 900 ppm in order to align with Nordic Swan Ecolabel limits.
4. To reject the proposal to update and increase the existing derogation for ZnPT so that it can continue to be used in EU Ecolabel for paints and varnishes up to 250 ppm (in-can preservation) or 2 500 ppm (dry-film preservation). This rejection effectively lowers the amount of ZnPT permitted to the horizontal threshold of 100 ppm.
5. To reject, for the time being, the proposal to derogate for the use of NaPT at levels of 400 ppm (in-can preservation) and 2 000 ppm (dry-film preservation).
6. To reject the proposal to derogate for the use of DBDCB up to 500 ppm (in-can preservation) until the harmonised classification is published.
7. To acknowledge the request on IPBC and the request to derogate the H372 code for in-can and H331 and H372 classes for dry-film preservation, which shall be corrected during the upcoming full criteria revision process.
8. To reject the request related to the use of encapsulated OIT in EU ecolabelled products.

Table 13. Summary of derogation requests

Substance	EU Ecolabel current threshold	Nordic Swan[42]	Blue Angel[43]	AT label[44]	Derogation request
Free formaldehyde	0.0010% (10 ppm)	10 or 25 ppm New proposal Indoor: 0.06 mg/m^3 Outdoor and industrial: 25 ppm	10 ppm	10 ppm	To align with Nordic Swan
Bronopol	∑0.0600% (600 ppm)	∑0.0900% (900 ppm) – however concentration limited by the release of free formaldehyde	0.0200% (200 ppm)	0.0200% or 200 ppm and requirements for traces of bronopol to be less than 2 ppm in any products making 'preservative-free' claims	300 ppm and addition of H301 code
Total level of Isothiazolinone	0,0500% (500 ppm) Isothiazolinone MIT 0.0015% (15 ppm) Isothiazolinone BIT 0.0500% (500 ppm) 0.0360% (360 ppm) RAC Isothiazolinone OIT 0.0015% (15 ppm) Isothiazolinone CMIT/MIT 0.0015% (15 ppm)	0,0600% (600 ppm) and specific limits of 15 ppm for MIT and 15 ppm for CMIT/MIT	400 ppm Specific isothiazolines solely for the purposes of in-can preservation. These consist of: 400 ppm for BIT; 15 ppm of CIT/MIT+CIT and up to a further 15 ppm of unintended residual levels of BBIT/OIT/BBIT (2 ppm)	400 ppm Specific limits of 15 ppm for CIT, 15 ppm for MIT, 15 ppm for CIT/MIT and 200 ppm for BIT. This totals around 245 ppm	To align with Nordic Swan
In-can preservatives: total combined limit permitted	0.060% (600 ppm)	900 ppm for total preservatives (or 1 600 ppm for 'wet room paints') with certain classifications	400 ppm. Limits for specific preservatives solely for the purposes of in-can preservation	400 ppm. And 7 specific biocidal active substances and for free formaldehyde	To align with Nordic Swan
Zinc pyrithione (ZnPT)	0.0100% (100 ppm)	0.0100% (100 ppm) Until 1 January 2023 in base paints and standard colours, and	0.0200% (200 ppm) marked for revision	Not mentioned as a specific limit	In-can preservatives: <250 ppm Dry-film

42 The Nordic Ecolabel (v3.10) for indoor paints and varnishes
43 The Blue Angel, version 6 (January 2019, UZ 12a) of the criteria for low-emission and low-pollutant paints and varnishes
44 The Austrian Ecolabel criteria (UZ 17, version 9.1) for wall paints

Substance	EU Ecolabel current threshold	Nordic Swan[42]	Blue Angel[43]	AT label[44]	Derogation request
		until 1 January 2024 for tinting pastes and tinting systems. Not mentioned in new proposal			preservatives: <2 500 ppm
Sodium pyrithione (NaPT)	0.0100% (100 ppm)	250 ppm Not mentioned in new proposal	0.0200% (200 ppm)	0.0200% (200 ppm)	In-can preservatives: 400 ppm Dry-film preservatives: 2 000 ppm
DBDCB (2-bromo-2-(bromomethyl)pentanedinitrile)	0.0100% (100 ppm)	Not mentioned as specific limit	400 ppm	Not mentioned as specific limit	In-can preservatives: 500 ppm
IPBC correction	Up to 600 ppm as in-can preservative, in normal indoor paints or up to 1 000 ppm in tinting pastes and up to 6 500 ppm in outdoor paints	Not mentioned as specific case	80 ppm	80 ppm	N/A
EOIT	Not mentioned as a specific case	Not mentioned as a specific case	Not mentioned as a specific case	Not mentioned as specific case	Clarification on whether more than 15 ppm of OIT are allowed in EU ecolabelled products when: a) it is added in encapsulated form and b) testing of the mixture shows no skin sensitisation

Source: JRC.

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List of abbreviations and definitions

ATP	Adaptations to Technical (and scientific) Progress
ASTM	American Society for Testing and Measurement
BA	Blue Angel Ecolabel
BAT	Best Available Technology
BBIT	2-butyl-benzo[d]isothiazol-3-one
BIT	Benzoisothiazolinone
CAS	Chemical Abstracts Service
CB	Competent Body
DCOIT	Dichlorooctylisothiazolinone
DG ENV	Directorate-General for Environment
CEPE	European Council of the Paint, Printing Ink and Artists' Colours Industry
CLH	Classification and Labelling Harmonisation
CMIT	Chloromethylisothiazolinone
CLP	Classification, Labelling and Packaging
CMR	Carcinogenic, mutagenic and reprotoxic
DSD	Dangerous Substances Directive
CTF	Chemicals Task Force
C&L	Classification and Labelling
DQR	Data Quality Rating
ECHA	European Chemicals Agency
EDC	Endocrine disrupting chemicals
EN	European Norm
EU	The European Union
EUEB	The European Union Eco-labelling board
EUEL	EU Ecolabel
GLC	Generic Concentration Limit
ISC	Interservice Consultation
ISO	International Standardisation Organisation
JRC	Joint Research Centre
LH	License-holder
MBIT	2-methyl-1,2-benzothiazol-3(2H)-one
MIT	Methylisothiazolinone
MSCA	Member State Competent Authority

NaPT	Sodium pyrithione
NGO	Non-governmental organization
NS	Nordic Swan Ecolabel
OIT	Octylisothiazolinone
PBT	Persistent, bioaccumulative and toxic
PT6	Product Type 6
PT7	Product Type 7
RAC	Committee for Risk Assessment
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
STOT	Specific Target Organ Toxicity
SVHC	Substances of very high concern
VOC	Volatile Organic Compound
vPvB	Very persistent and very bioaccumulative
ZnPT	Zinc pyrithione

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