# EuPIA guidance note
# "Labelling of Treated Articles" - revision 2

**November 2017**

*This guidance supersedes revision 1 issued in March 2016 (which was linked to the final position that the EU Commission took in October 2015 on the labelling conditions for treated articles into the biocide active substance approval Regulations.)*
*Because members met difficulties in complying with both the CLP and the additional labelling provisions of the BPR, this second revision includes principles and practical examples to comply with both labelling requirements for skin sensitizers.*

## Introduction

The BPR (Biocidal Products Regulation 528/2012), published on 27 June 2012, is the Regulation replacing the BPD (Biocidal Product Directive 98/8/EC). It applies since 1 September 2013. One of the changes introduced by the BPR is the extension of its scope to **treated articles**.

The definition is the following (Art. 3)[1]:

> *'treated article' means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products*

The BPR also includes substances and mixtures as potential 'treated articles'. Hence, as explained in the examples below, many EuPIA members' products will fall under the BPR definition of treated articles and new obligations derive from it.

Its Article 58 introduces new obligations for the placing on the market of "Treated Articles". This industry guidance document focuses on point 3 of the Art. 58, which describes the labelling requirements of Treated Articles under certain conditions. Two additional topics also related to treated articles, but not related to labelling issues, are covered in the Annex.

EuPIA members are generally users of biocides as Product Type PT6 (in-can preservatives. Some are also involved in PT2 (disinfectants) activities.
The first important differentiation is to be made between "biocidal product" and "treated article". It should be noted here that the BPR considers that a product that has a primary biocidal **function** shall be considered a biocidal product.

The second important aspect to understand is when a treated article has to be labelled, and this can take place on two occasions: 1) once a biocidal **property** is claimed, and 2) if the **approval conditions of the active substance** require specific provisions for treated articles. This document aims at clarifying the subject for EuPIA members.

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[1] In REACH: Registration, Evaluation Authorization and Restriction of Chemicals, Regulation 1907/2006, an article is defined as "an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition".

## A. Biocidal product or treated article?

The definition of a biocidal product that has been applied up to now under the BPD (1998/8) remains on the whole valid. Basically, the claim[2] is of key importance. Under the BPD as soon as a claim was made for an external biocidal effect, the product became a biocidal product. Under the BPR the term 'internal effect' or 'external effect' is not employed any more, rather the key criterion is whether a treated article has a 'primary biocidal function'. What 'primary' means is still subject to debate and is not of key importance for EuPIA to understand whether you place on the market a biocidal product or a treated article.

Examples:

- **I am an ink maker**:

1. I use a bactericide to protect my water based printing ink against microbial deterioration in the wet stage (in the can). There is no biocidal claim. The bactericide is used solely to protect the ink. The ink is not a biocidal product, but is a treated article.

2. I use a bactericide to protect a fountain concentrate against microbial deterioration in the wet stage. The level of biocide in the concentrate is far higher than is required to preserve the concentrate, but when diluted down it is adequate to protect the dampening solution on press. There is no external claim. We regard this as a treated article.

3. I use a bactericide to protect my fount solution against microbial deterioration in the wet stage (in the can) but I claim that it has an effective preservative system that will eliminate odour problems in pipes, fount pans or in the water system at the customer. To prevent the development of microbes in the customer's facilities, I claim an enhanced microbial control. Because the claim is for a primary biocidal function (the bactericide is used not (solely) to protect the fount but to have an effect of a nature outside the fount), the fount is a biocidal product and needs to be authorized under the BPR for PT2.

4. I supply a fount system cleaner to remove impurities from recirculating systems such as ink residues or build-up of scale, but I also claim it will prevent microbial development. The bactericide is obviously not present to protect the fount system cleaner but has a primary biocidal function. The cleaner is a biocidal product and needs to be authorized under the BPR for PT2.

- **I am a printer:**

1. I use a water based printing ink protected against microbial deterioration in the wet stage (in the can) so the ink is a treated article. The ink is used for printing on e.g. paperboard. When applied, the dry print is not a treated article subject to BPR Art. 58.

2. I use a fount solution protected against microbial deterioration in the wet stage (in the can). I can read on the pails or the TDS that the supplier claims that it has an effective preservative system that will eliminate odour problems in pipes, fount pans or in the water system in my facilities. The fount solution will not deteriorate itself as it is protected, but in addition it will provide an external biocidal effect to remove odours

[2] NB: be careful that a claim made in other documentation than the label, such as a Technical Data Sheet, or promotion in any form, such as on internet, would also be regarded as a relevant claim by the controlling Authorities

(caused by micro-organisms). The fount solution is a biocidal product as described under point 3 above. The final print is not a treated article.

3. I am a printer where there is a dispensing unit (containing water based concentrates and technical varnishes) in place and I ask my ink supplier for a bactericide because some water based concentrates have undergone a microbial attack. Therefore I want to use the bactericide for a curative treatment of my concentrate in my plant. The supplied bactericide is a biocidal product but treated concentrates are still treated articles. In fact they already contained an in-can preservation bactericide, but it was not sufficient and I had to 'post-add' additional amounts.

Now that everyone understands the difference between biocidal product and treated article, we will in the next pages address the issue of the labelling of treated articles.

## B. Labelling of treated articles

Once you know that you are placing on the market a treated article (because you have used a biocide – your product was treated with or intentionally incorporates a biocidal product), the next question is: when do you have to label it?

The Article 58 (3) states:

> *3. The person responsible for the placing on the market of such a treated article shall ensure that the label provides the information listed in the second subparagraph, where:*
> - *in the case of a treated article containing a biocidal product, **a claim is made** by the manufacturer of that treated article regarding the biocidal properties of the article, or*
> - ***in relation to the active substance(s) concerned**, having particular regard to the possibility of contact with humans or the release into the environment, the conditions associated with the approval of the active substance(s) so require.*

There are therefore **two situations** that require labelling:

**Situation 1**: you make a claim regarding a biocidal property. Again you have to carefully understand the consequence of making a claim. The term 'property' must be differentiated from the term 'function'. A product that has a primary biocidal function must be regarded as a biocidal product, but a treated article may still contain biocidal products that deliver a certain property to the article. A 'property' is a characterizing quality. However, a 'function' refers more specifically to the intended purpose of a product.

**We are not aware of any situation for the ink sector where this condition would apply.**

**Example:** you use an in-can preservative to protect your water based ink. Of course you do not claim that it is protected for microbial deterioration: it is obvious since without it you would be unable to use the product once the can is opened. In this case you would not need BPR labelling, except if the second condition in Art. 58(3) applies.

**Situation 2**: in 2013 we were writing: '*this is not within the control of EuPIA members, but depends on the outcome of the BPD/BPR assessment of the relevant active(s) and cannot be predicted today*[3]*. This condition means that if the outcome of the risk assessment for the use of the relevant active(s) would have demonstrated some remaining concerns (for human health and/or for the environment), then the end-use product (your ink) will have to warn the user of certain dangers/risks/risk mitigation measures and comply with the labelling elements of Art 58(3) outlined below.'*

The situation has now evolved as the EU Commission with the support of Member States agreed in October 2015 that labelling provisions will apply for **all skin sensitizing substances classified as category 1 or 1A** (which means most of them as few are only 1B)[4].
They have now started to include a standard provision in the approval regulation of these substances (see the example of propiconazole PT7 No 2015/1609):

[3] Of course the question is always: 'When do we expect the revision of existing actives to be finalised?' Initially it was May 2010, then it became May 2014 and today the EU Commission got another postponement up to 2025.
[4] For further details see the EU COM document CA-May-15-DOC.6.1-final 'Labelling of treated articles'

*The placing on the market of treated articles is subject to the following condition: the person responsible for the placing on the market of a treated article treated with or incorporating propiconazole shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the Regulation (EU) No 528/2012.*

It must be pointed out that there are other hazard based classification criteria that will also trigger the labelling requirements: vP or vB, P and B, respiratory sensitizers, other substances identified as SVHC under REACH (could be due to endocrine disruptive effects or specific organ target toxicity etc.), and also if a use is restricted or if the active fulfils the exclusion criteria. It is expected in practice that skin sensitizers will be the substances that will mostly trigger such new labelling requirements.

**Important note**: this condition does not involve any threshold concentration. Hence, as soon as you intentionally add a biocide that meets one of these criteria in your product, the new labelling provisions apply. This also means that the biocide that your raw material supplier added to preserve his own product does not fall in scope (at a relevant concentration to preserve that product and not at higher concentration that would preserve your own product).

**NB: There can be situations where EuPIA members would re-sell an in-can preservative. This situation does not fall within the scope of this paper.** However we take the opportunity to clarify the responsibilities that the EuPIA member may have to face in cases where the packaging and/or labelling of the biocidal product would be modified.

**Example:** you may supply a bactericide to your customer where there is a dispensing kit in place because some water based concentrates have undergone a microbial attack. The bactericide is a biocidal product with a primary biocidal function. Therefore it has to be labelled accordingly by the biocidal authorization holder.
As a supplier of a biocidal product in the supply chain you are only allowed to sell biocidal products that have been authorized for such uses (currently under national legislation where applicable, in the future under the BPR). If you want to avoid any BPR constraints, we recommend in this case to simply re-sell the biocidal product as bought (preferably with the agreement of the original authorised supplier) and keep using the supplier's packaging – unopened and unchanged - which should comply with labelling requirements under BPR. Failing to do so may require specific authorization under the BPR.

## Labelling requirements

The second subparagraph of Art 58(3) states the following:

*The label referred to in the first subparagraph shall provide the following information:*

*(a) a statement that the treated article incorporates biocidal products;*

*(b) where substantiated, the biocidal property attributed to the treated article;*

*(c) without prejudice to Article 24 of Regulation (EC) No 1272/2008, the name of all active substances contained in the biocidal products;*

*(d) the name of all nanomaterials contained in the biocidal products, followed by the word 'nano' in brackets;*

*(e) any relevant instructions for use, including any precautions to be taken because of the biocidal products with which a treated article was treated or which it incorporates.*

Some explanations:

(a) Such statement could be as simple as 'This ink contains a biocidal product'.

(b) As mentioned previously, this is not currently believed to apply for any treated articles in the ink sector.

However if relevant, this could be included in the previous phrase and read e.g. 'This ink contains a biocidal product for the preservation of the dry film'.

The location of the claim is not specified in the BPR; therefore it does not need to be placed next to the other labelling requirements. This is also true for the other labelling requirements that can be placed in different locations. Hence it does allow some flexibility. For instance, where Decorative paints are sold in pre-printed cans the manufacturer would not want to have to change the labelling requirements when another biocidal product is used. Example: you switch the dry-film preservative from a product containing a certain fungicide active to another one. This requires changing the naming of the active. If this is placed on pre-printed cans the stock would have to be destroyed or a sticker placed on the label. In that situation the naming of the actives should be placed on another document accompanying the sale of the paint. On the other hand a typical precaution (see point (e)) could be 'do not apply above surface waters like ponds or rivers', and this would be applicable to both fungicide actives so it could be placed on the can.

(c) This requires the naming of the actives used. The question is what chemical name should be used? In order to save label space EuPIA advises using the shortest abbreviation possible, but still legally justifiable. See below under 'General principles for naming substances in products' for further explanation.

(d) This does limit the requirement to state nano forms of biocide actives linked to the biocidal property claim such as 'contains (nano) silver'

(e) Typically this should come from the outcome of the evaluation of the biocide products, when they will be authorized under the BPR and when such requirement would specifically apply. Example: 'Do not apply near or above surface waters like rivers or ponds'.

## Practical recommendations to implement the BPR labelling requirements in addition to the CLP requirements

When we issued the revised guidance (revision 1) in March 2016, members expressed difficulties to identify the relevant names of biocide substances to use and to combine the CLP and the BPR sentences when skin sensitization is involved. This section provides guidance to members on those aspects.
Warning: the information provided below has been developed to facilitate the implementation of the labelling requirements as much as possible. However, members may have to adopt this based on own considerations (IT system, customer expectations…).

### 1. General principles for naming substances in products

ECHA labelling and packaging guidance recommends following the hierarchy in CLP Article 18(2) for naming of substances in mixtures (Annex VI name; C&L inventory name; other internationally recognised name e.g. INCI nomenclature[6]), but states that it is preferable to use the name that is most well-known to the user/consumer, which is likely to be a shorter name. Also, if a substance has to be named on the label under both CLP and other legislation, the same name should be used for both.

The labelling requirements of BPR Article 58(3) require BPR names to be used. These are published in the approval regulations for the active substances.

EuPIA recommends using the abbreviation for a biocide if given as the name in the official approval regulation. Otherwise use the shortest name available, typically the INCI name.

Examples:

- **C(M)IT/MIT (3:1)** is used in Regulation 2016/131
  (CLP Annex VI name: reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1))

- **Methylisothiazolinone** in INCI/EU Cosmetics Glossary
  (C&L inventory: 2-methyl-2H-isothiazol-3-one; PT13 approval regulation: 2-methylisothiazol-3(2H)-one).

### 2. General principles for combining CLP and BPR labelling

EuPIA recommends avoiding duplication and reducing the information on labels to a minimum as far as possible. Some principles for this:

- If a product contains several substances requiring EUH208, include all names in the same statement.
- If a product contains several biocides to be named according to BPR Art. 58(3) (point (c)), include all names in the same sentence.
- If a biocide requires both of the above, avoid duplication by using the first part of EUH208 to cover the naming of the active substance(s).
- If the approval regulation requires identification of a specific risk, such as skin sensitization, include short text for this at the end of the phrases **if** not already covered by EUH208 or other (supplemental) hazard statements.

NB: if a biocidal active substance is not yet approved, use CLP labelling elements only (e.g. EUH208).

[6] See the database here: http://ec.europa.eu/growth/tools-databases/cosing/index.cfm

## 3. Examples for single active substance under the following situations:

| BIOCIDE | % | CLP labelling | CLP and BPR labelling When applicable*: |
|---|---|---|---|
| BIT | >0,05 %<br>>500 ppm |  and H317 : "May cause an allergic skin reaction." |  and H317 : "May cause an allergic skin reaction."<br>"Contains a biocidal product: BIT" |
| | >0,005 %<br>>50 ppm | Until BPR labelling application :<br>EUH208: "Contains Benzisothiazolinone. May produce an allergic reaction." | "Contains a biocidal product: Contains BIT. May produce an allergic reaction." |
| | <0,005 %<br><50 ppm | | "Contains a biocidal product: BIT" |
| MIT<br>With the current classification | >0,1 %<br>>1000 ppm |  and H317 : "May cause an allergic skin reaction." |  and H317 : "May cause an allergic skin reaction."<br>"Contains a biocidal product: methylisothiazolinone" |
| | >0,01 %<br>>100 ppm | Until BPR labelling application :<br>EUH208: "Contains methylisothiazolinone. May produce an allergic reaction." | "Contains a biocidal product: Contains methylisothiazolinone. May produce an allergic reaction" |
| | <0,01 %<br><100 ppm | | "Contains a biocidal product: methylisothiazolinone" |
| MIT<br>With the new RAC proposed classification | >0,0015 %<br>>15 ppm |  and H317 : "May cause an allergic skin reaction." |  and H317 : "May cause an allergic skin reaction."<br>"Contains a biocidal product: methylisothiazolinone" |
| | >0,00015 %<br>>1,5 ppm | Until BPR labelling application :<br>EUH208: "Contains methylisothiazolinone. May produce an allergic reaction." | "Contains a biocidal product: Contains methylisothiazolinone. May produce an allergic reaction." |
| | <0,00015 %<br><1,5 ppm | | "Contains a biocidal product: methylisothiazolinone" |

* Assuming in all cases that these will be the official substance names used in the approval regulations (not guaranteed).

## 4. Examples for multiple active substances under the following situations:

| BIOCIDES | % | CLP labelling | CLP and BPR labelling When applicable: |
|---|---|---|---|
| BIT<br><br><br><br>MIT<br>With the new RAC proposed classification | >500 ppm<br><br><br><br><1,5 ppm |  and H317 : "May cause an allergic skin reaction." |  and H317 : "May cause an allergic skin reaction."<br>"Contains biocidal products: BIT, methylisothiazolinone" |
| BIT<br><br><br>MIT<br>With the new RAC proposed classification | >50 ppm<br><500 ppm<br><br>>1,5 ppm<br>< 15 ppm | Until BPR labelling application :<br>EUH208: "Contains benzisothiazolinone, methylisothiazolinone. May produce an allergic reaction." | "Contains biocidal products: Contains BIT, methylisothiazolinone. May produce an allergic reaction." |
| BIT<br><br>MIT<br>With the new RAC proposed classification | <50 ppm<br><br><1,5 ppm | | "Contains biocidal products: BIT, methylisothiazolinone" |

**Deadline for complying with the labelling requirements of Article 58 (3)**

For the first condition: the legislator had not foreseen the need to have a transitional period, so the requirements applied from 1 September 2013. This is valid for treated articles that are placed on the market from that deadline.

For the second condition: the date of approval of the active substance for the relevant PT (this is typically 18 months after the date of publication of the approval regulation).

# Annex

## Other obligations for treated articles

Art. 58(2): Treated articles shall only use approved biocide actives for the supported Product Types (from which derive the uses).
The status of approval of active substances can be consulted on the ECHA website here:
http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances

Art. 95 on approved suppliers:
By 1 September 2013 only approved biocide suppliers were able to place on the market biocide actives. Two years later, from 1 September 2015, biocidal products can only be placed on the market if they contain a biocide active from the approved supplier list. Disposal and use of existing stocks of biocidal products containing actives coming from non-approved suppliers can then continue until 1 September 2016.
Hence, the manufacture of treated articles in Europe can only be made using biocidal products containing actives coming from approved suppliers, by 1 September 2016 latest.
The list of approved suppliers can be found here:
http://echa.europa.eu/web/guest/information-on-chemicals/active-substance-suppliers

Article 58.5:

> Art. 58.5 : *Notwithstanding the labelling requirements set out in paragraph 3, the supplier of a treated article shall, where a consumer so requests, provide that consumer, within 45 days, free of charge, with information on the biocidal treatment of the treated article*

In the absence of more accurate information on what precisely has to be communicated, it is recommended to obtain a legal opinion.

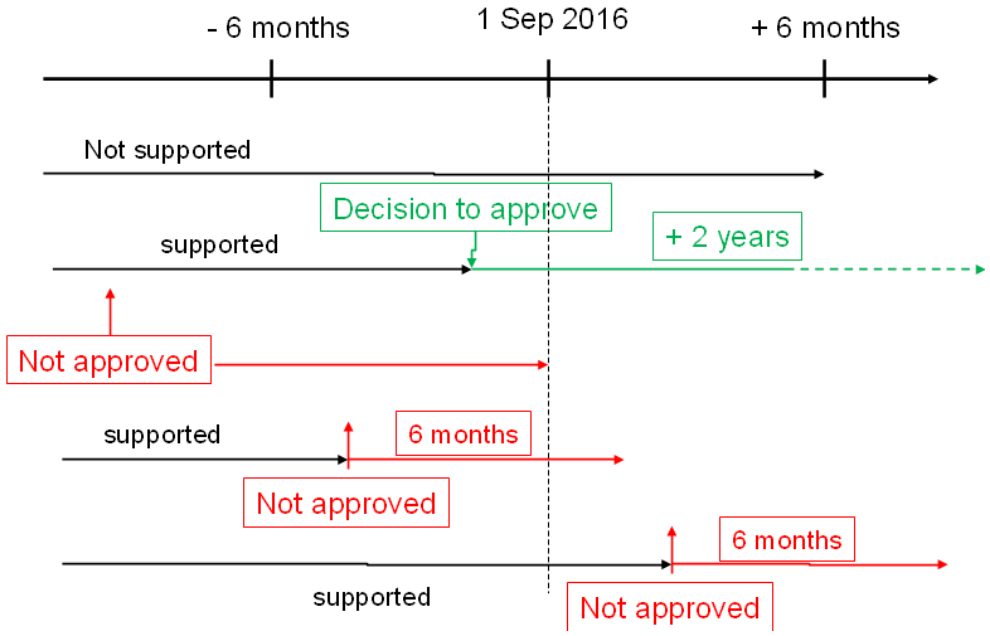
Deadlines for the placing on the market of treated articles (Art 94)

This section concerns the deadline for placing on the market treated articles when an active substance/Product Type/use combination is not supported any more or when a negative approval decision has been made.

Due to the transitional measure linked to the implementation of this new BPR provision of treated articles, the important deadline is situated around 1 September 2016. In the future, it is important to note that treated articles must no longer be placed on the market 180 days after a non-approval decision for an active substance contained in the biocidal product used to treat or intentionally incorporated in those treated articles. This is going to be the key date to follow for each relevant active/PT. Again we encourage EuPIA members to be vigilant in the future.

The situation can be summarized as follows:

NB: "supported active" means an active that is supported by Industry (biocide supplier(s)) and is being reviewed under the BPD/BPR. "Not approved" means that Authorities refused to grant authorisation or that Industry stopped supporting the dossier.




Examples:

1. I am currently placing on the market an ink that was made outside Europe and that contains an in-can preservative that is not supported under the BPD since 2006. The deadline for continuing such import (without prejudice to other legislations that may apply, such as REACH) is 1 September 2016 + 180 days.

2. On 1 May 2016, a non-approval decision for the active that I am using in my ink is made: I have 6 months to cease the placing on the market[7], i.e. 1 November 2016.

[7] Placing on the market: the first making available on the market.
Making available on the market: any supply for distribution or use in the course of a commercial activity, whether in return for payment or free of charge.