



RUCODEM

Aspects regarding the treated articles

Treated articles are covered by the rules set in the Regulation (EU) 528/2021 on biocidal products (BPR) with further modifications.

Article 3(1)(l) of the BPR provides that:

- a treated article is any substance, mixture or article which has been treated with, or intentionally incorporates, one or more **biocidal products**.

To note: a treated article is treated with (or intentionally incorporates) a biocidal product, not an active substance.

A treated article that has a primary biocidal function is considered a biocidal product.

Examples provided in the Commission guidance on treated articles - Examples related to detergents (in Appendix 1):

. **Treated articles:** Mixtures like paints, glues, inks, detergents, etc. containing an in-can preservative.

. **Not a treated article:** Paint, detergents, etc. containing an additive, and that additive had an in-can preservative added in order to protect it during storage, where this preservative has no further preserving function in the final product.

In Article 3.1. (a) is provided: “A *treated article that has a primary biocidal function shall be considered a biocidal product*”.

A disinfecting wipe for surfaces (with a biocidal claim e.g. kills bacteria) is a treated article with primary biocidal function = biocidal product.

Examples of detergents that are considered Treated Articles:

Laundry liquid detergent L:

- surfactant A
- surfactant B
- soap
- perfume C
- in-can preservative E
- water

A laundry liquid detergent L is formulated with an in-can preservative E, that has a preserving function in the final product.



Example of detergents that are not Treated Articles:

Acidic cleaner:

- acid A
- surfactant B
- surfactant C
- perfume D
- water

(in-can preservative Z)

An acidic cleaner is formulated with a surfactant B that is supplied containing in-can preservative Z.

In-can preservative Z has no preserving function in the final acidic cleaner, because it is inefficient at low pH. The acidic cleaner does not need to be preserved due to its low pH.

Example of products formed by different elements that are or are not treated articles:

Anti-bacterial toilet tables

- Tablet → biocidal claim PT2 = biocidal product;
- Printed plastic wrap – uses inks containing preservatives to protect the ink before being used for printing = not a treated article;
- Box – contains preservative to stop box getting mould in the damp of the bathroom – not biocidal claim, but intended activity = treated article;

Aspects on Active Substances

“A *treated article shall not be placed on the market unless all active substances contained in the biocidal products that it was treated with or incorporates are included in the list drawn up in accordance with Article 9(2), for the relevant product-type and use, or in Annex I, and any conditions or restrictions specified therein are met.*” (Article 58 (2))

With 1 September 2013, the active substance (AS) contained in the biocidal product used to treat the article has to be either already approved, or under evaluation in the Review Program for the relevant PT, or in BPR annex I.

If the active substance is not in the Review Program:

- Possibility to submit an application for AS/PT until 1 September 2016;

- Possible to place the TA on the market until 1 Mar 2017;
 ⇒ After 1 March: the AS has to be approved or under evaluation or in BPR Annex I.

In case of decisions for non-approval, after 1 September 2016, if the active substance is not approved under the review program, then it has 180 days (after that non-approval decision) to stop placing on the market.

Aspects on labelling of Treated Articles

Labeling provisions are presented in Article 58(3) of the BPR.

The provisions are applied when:

- *"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"*



(- The majority of 'regular/normal' detergents & cleaning products are not subject to this requirement (e.g. regular laundry detergent or surface cleaner));

- Applies only in specific cases: claim and/or market positioning regarding the biocidal properties of the product (e.g. mould resistant polish))

- *"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."

A.I.S.E. guidance on how to address BPR Article 58(3) requirements in the cases where the active substance concerned is skin sensitiser:

- how to address Article 58(3) in case of detergents:

. *a statement that the treated article incorporates biocidal products:* Include 'contains preservative' in the ingredient labelling,

. *where substantiated, the biocidal property attributed to the treated article:* Include 'contains preservative' in the ingredient labelling,

(NB: the treated article is preserved so it has a biocidal property)

. *without prejudice to Article 24 of Regulation (EC) 1272/2008, the name of all active substances contained in the biocidal products:* Already covered by the Detergent Regulation labelling requirements: name of the in-can preservative(s) shall be listed on label (INCI name)*,

(* For products not subject to the Detergent Regulation labelling requirements (e.g. Industrial and Institutional detergents), then the name of all active substances contained in the biocidal products need to be added on the label)

. *the name of all nanomaterials contained in the biocidal products, followed by the word 'nano' in brackets:* A priori irrelevant (PT6 biocidal products are very unlikely to contain nanomaterials),

. *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:* As appropriate (left to companies to decide).

Examples of labeling:

Mop head with natural fibres

- Mop head treated with preservative "X" to prevent spoilage by odour-causing mould and bacteria;
- Claim on biocidal property is made: 'germ resistant mop';
- No primary biocidal function = treated article;

→ Treated article labelling - implementation of Article 58(3):

- Contains preservative ("X") (Article 58(3)(a), (b) & (c));
- + any relevant instructions for use & any precautions to be taken, considered by the manufacturer (Article 58(3)(e));

Hand dishwashing detergent containing an in-can preservative

- Product contains preservative to prevent spoilage in storage;
- No primary biocidal function = treated article;
- No biocidal claims nor claims on the biocidal property gained are made;

No biocidal claims nor claims on the biocidal property gained are made on product, therefore the treated article label is not required unless required by the conditions of the active substance approval.

Example with skin sensitising preservative

Laundry detergent containing preservative which is a skin sensitiser and with a labelling requirement in the substance approval decision

- Contains preservative “X” to prevent spoilage of liquid from microbial growth;
 - Preservative “X” is a known skin sensitiser Cat 1A (no SCL); its concentration in the detergent is 0.15%;
 - No primary biocidal function = treated article;
 - No biocidal claims nor claims on the biocidal property gained are made;
- **Treated article labelling – implementation of BPR Article 58(3) ***:
- Contains preservative (“X”). May cause an allergic skin reaction. (BPR Article 58(3)(a), (b) & (c), CLP (H317 statement));
 - + any relevant instructions for use & any precautions to be taken, considered by the manufacturer (BPR Article 58(3)(e));

(* Other requirements from CLP and Detergents Regulation apply. Overall classification and additional precautions will need to be considered and conform with CLP)



Q&A

Q: A preserved liquid detergent is manufactured in France. Does the in-can preservative (PT6 biocidal product) have to be authorised in France? Can the detergent be sold in other EU countries?

A: Yes, the in-can preservative has to be authorised in France, otherwise it cannot be made available on the market or used in France (refer to BPR Article 17).

A: Yes, the detergent (= the treated article) can be sold in other EU countries, since it is subject only to BPR Article 58 requirements for placing on the market of treated article (unless the treated article is considered as a biocidal product).

Q: Do treated articles imported from outside the EU need to comply with BPR?

A: Yes, in addition to more general regulations like REACH, CLP and Detergent, the BPR also applies to imported products that have been manufactured and treated with biocide(s) outside the EU. All active substances in treated articles have to be approved, under review or on Annex I for the related use/PT. Imported treated articles are no exception to this.



Sources:

ECHA:

<https://echa.europa.eu/ro/regulations/biocidal-products-regulation/treated-articles>

AISE: www.aise.eu

Images:

©A.I.S.E. and ©IKW/Dennis Möbus

Disclaimer:

This material was developed by RUCODEM and aims to provide information on treated articles - EU Regulation 528/2012 on the making available on the market and use of biocidal products. The information contained in this material is general in nature and is not intended to address the specific circumstances of a legal person/entity, having the purpose of documentation. Always consult the regulations published in the Official Gazette of Romania and in the Official Journal of the European Union.