

The logo for A.I.S.E. features the letters 'A·I·S·E' in a white serif font, with a white brushstroke underline beneath the letters. The logo is set against a teal rectangular background.

A·I·S·E

International Association for Soaps,
Detergents and Maintenance Products

Labelling of treated articles Case of detergents

ECHA Forum for Exchange of Information on Enforcement
and BPR Subgroup - Joint open session

14 November 2018

A vertical bar on the left side of the slide, composed of four colored squares: teal, blue, lime green, and purple.

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A.I.S.E. and biocides

Product-types of interest under BPR



- **Disinfectants PT1 to PT5**
- **Insecticides and repellents: PT18 and PT19**

⇒ A.I.S.E. members = biocidal products formulators

- **In-can preservatives: PT6**

⇒ A.I.S.E. members = downstream users

Used to preserve water-based formulations such as laundry detergents, surface cleaners, hand dish washing liquids, etc... (= treated articles)



- **Definition and examples**
- **Labelling of treated articles : case of detergents**
 - BPR Article 58.3 and Commission note CA-May15-Doc.6.1
 - A.I.S.E. guidance
 - Examples



Definition and examples



BPR Definition



- BPR Article 3.1. (l): *“treated article’ means any substance, mixture or article which has been **treated with**, or intentionally **incorporates**, one or more **biocidal products**”*
- BPR Article 3.1. (a): *“A treated article that has a primary biocidal function shall be considered a biocidal product”*

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



Commission guidance on treated articles



- FAQ on treated articles (CA-Sept13-Doc.5.1.e Revision 1, Dec. 2014)
- Appendix 1 : Product Examples



CA-Sept13-Doc.5.1.e
(Revision 1, December 2014)

EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate A - Green Economy
ENVA.3 - Chemicals

NOTE FOR GUIDANCE

This document is an attempt to provide guidance in the interest of consistency, and has been drafted by the Commission services responsible for biocidal products with the aim of finding an agreement with all or a majority of the Member States' Competent Authorities for biocidal products. Please note, however, that Member States are not legally obliged to follow the approach set out in this document, since only the Court of Justice of the European Union can give authoritative interpretations on the contents of Union law.

Subject: Frequently asked questions on treated articles

The purpose of this document is to provide guidance on the implementation of the second subparagraph of point (a) of Article 3(1), Article 58 and Article 94 of Regulation (EU) No 528/2012 (BPR).

It is structured in the form of questions and answers, addressing the most frequent issues raised in requests to the Commission.

Appendix 1

Product Examples

The examples below are indicative and refer to the typical categorisation of a listed product group. The assessment of whether any individual product is a treated article, a biocidal product or neither of the two must be made on a case-by-case basis, taking into account all its characteristics.

Biocidal product	Treated article	Not a treated article
Disinfecting wipe	Article in which a disinfectant was incorporated to generate an antimicrobial surface (e.g. chopping board or equipment in the production of foodstuff)	Components or intermediate forms which were disinfected (which are not themselves placed on the EU market)
	An article which has been disinfected (in the form as it is placed on the EU market) to render it sterile or reduce contamination	
	Wooden article, or wooden components of a complex article, impregnated with an insecticidal wood preservative in order to protect it from becoming infested	Wooden components of a complex article, or an intermediate form of a wooden article (which are not themselves placed on the EU market) that have been treated with an insecticide (e.g. by fumigation) in order to remove a present infestation
	Wooden article treated with an insecticide (e.g. by fumigation) in order to remove a present infestation	
	Speciality paper incorporating a preservative in order to protect the finished article during use such as anti-mould treated papers	Paper made of paper pulp (cellulose) incorporating a preservative in order to protect the pulp (an aqueous mixture) during storage before use in the manufacturing of paper; equally incorporation of a preservative in other intermediates such as starch, pigments, coatings or fillers during storage
		Paper resulting from a production process where slimicides were used in order to avoid slime development in the paper machine and in the process water system
	Mixtures like paints, glues, inks, detergents, etc. containing an in-can preservative	Complex articles containing e.g. glues, inks, paints which had in-can preservatives added in

Commission guidance on treated articles

Examples related to detergents (in Appendix 1)



Treated article	Not a treated article
Mixtures like paints, glues, inks, detergents , etc. containing an in-can preservative	Paint, detergents , etc. containing an additive, and that additive had an in-can preservative added in order to protect its during storage, where this preservative has no further preserving function in the final product



Example 1

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



Laundry liquid detergent A:

- Surfactant A
- Surfactant B
- Soap
- Perfume C
- Dye D
- In-can preservative E
- Water

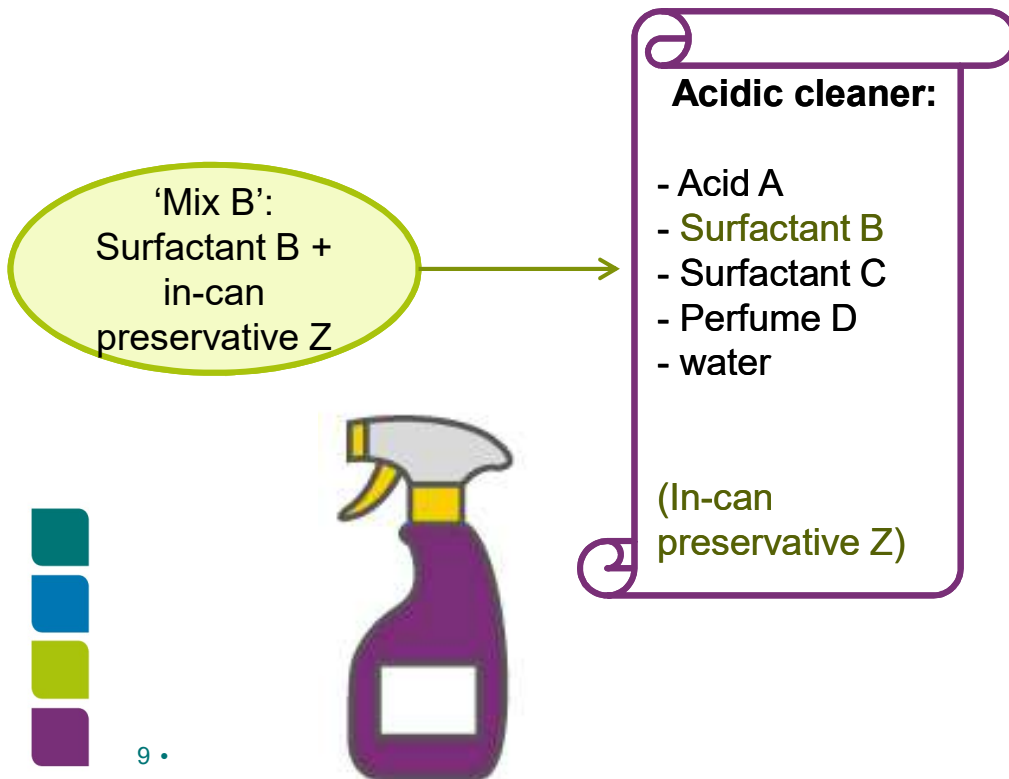
A laundry liquid detergent A is formulated with an in-can preservative E, that has a preserving function in the final product

=> Laundry liquid detergent A is a treated article



Example 2

- 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”*



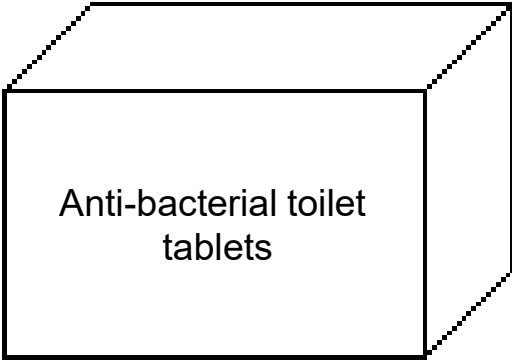
An acidic cleaner is formulated with a surfactant B that is supplied as a mix 'surfactant B + in-can preservative Z'

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

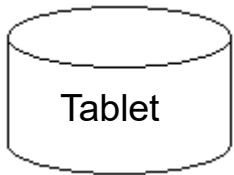
=> The Acidic cleaner is NOT a treated article



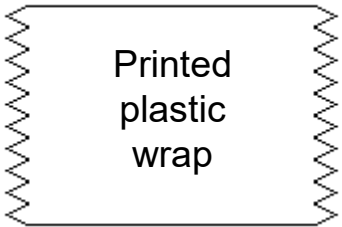
Example 3



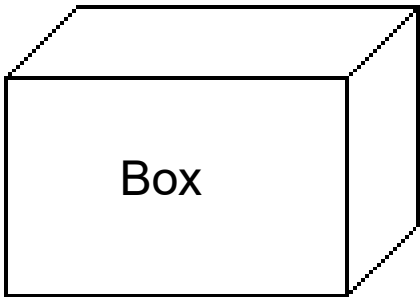
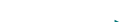
Anti-bacterial toilet tablets composed of:



Biocidal claim
PT2 Active
= biocidal product



Uses ink that contains preservative to protect ink before printing
= Not a treated article



Contains preservative to stop box going mouldy in damp bathroom.
No claim, but intended activity.
= treated article



Labelling of treated articles

Case of detergents



BPR Article 58 (3) : labelling provisions

BPR Art. 58 (3):

“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.*

This paragraph shall not apply where at least equivalent labelling requirements already exist under sector-specific legislation for biocidal products in treated articles to meet information requirements concerning those active substances.”



BPR Article 58 (3) : when to apply

- “The person responsible for the placing on the market of 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.*”

⇒ 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)



Commission note CA-May15-Doc.6.1-Final 'labelling of treated articles'



CA-May15-Doc.6.1 - Final



EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE GENERAL
Safety of the food chain
Pesticides and Biocides

NOTE FOR DISCUSSION WITH COMPETENT AUTHORITIES FOR BIOCIDAL PRODUCTS

This document is an attempt to provide guidance in the interest of consistency, and has been drafted by the Commission services responsible for biocidal products with the aim of finding an agreement with all or a majority of the Member States' Competent Authorities for biocidal products. Please note, however, that Member States are not legally obliged to follow the approach set out in this document, since only the Court of Justice of the European Union can give authoritative interpretations on the contents of Union law.

Subject: Labelling of treated articles

1. Background and purpose of the document

- (1) Article 58(3) of Regulation (EU) No 528/2012¹ (BPR) provides that the person responsible for the placing on the market of a treated article shall ensure that the label provides the information listed in the second paragraph, where [...] in relation to the active substance 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 so require (**hereafter referred to as 'the specific labelling provisions'**).
- (2) Article 58(4) of the BPR provides that notwithstanding the labelling requirements set out in paragraph 3, the person responsible for the placing on the market of a treated article shall label it with any relevant instruction for use, including any precautions to be taken, if this is necessary to protect humans, animals and the environment (**hereafter referred to as 'the general labelling requirement'**).



Commission note CA-May15-Doc.6.1-Final

Case of skin sensitisation

(11) **The specific labelling provisions** of treated articles should therefore be introduced in the decision to approve a substance under the following conditions:

1) **A use (or more)**, among others, of an active substance is **restricted** [...] and it must be ensured that substance, mixtures or articles lawfully treated with that substance for other purposes, can be placed on the market and used in a manner which do not give rise to the same major concern, which was the ground for the restriction¹¹.

2) Where the active substance meets the **exclusion criteria** set in Article 5(1), but would benefit from derogation to the exclusion on the basis of Article 5(2)¹².

3) The active substance has **intrinsic properties**¹³, which [...], having particular regard for the possibility of contact with humans or the release to the environment, justify enforcing a systematic labelling of treated articles in accordance with Article 58(3). This would apply to substances having one of the following intrinsic properties:

(a) Skin sensitiser¹⁴

The active substance meets the criteria to be classified as a skin sensitiser category 1 or sub-category 1A in accordance with Regulation (EC) No 1272/2008.

Commission note CA-May15-Doc.6.1-Final Consequences & Example



- For treated articles for which the **active substance concerned is skin sensitiser Cat 1 or Cat 1A, provisions of BPR Art. 58(3) should apply**
- This specific labelling provision will be imposed through the substance approval decision

Commission Implementing Regulation (EU) 2016/131 of 1 February 2016 approving C(M)IT/MIT (3:1) as an existing active substance for use in biocidal products for product-types 2, 4, 6, 11, 12 and 13

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (%)	Date of approval	Expiry date of approval	Product type	Specific conditions
						<p>The placing on the market of treated articles is subject to the following conditions:</p> <p>(1) In view of the risks identified for human health, mixtures treated with or incorporating C(M)IT/MIT (3:1) and placed on the market for use by the general public shall not contain C(M)IT/MIT (3:1) at a concentration triggering classification as skin sensitiser, unless exposure can be avoided by other means than the wearing of personal protective equipment.</p> <p>(2) In view of the risks identified for human health, liquid detergents treated with or incorporating C(M)IT/MIT (3:1) and placed on the market for use by professional users shall not contain C(M)IT/MIT (3:1) at a concentration triggering classification as skin sensitiser, unless exposure can be avoided by other means than the wearing of personal protective equipment.</p> <p>(3) In view of the risks identified for human health, mixtures treated with or incorporating C(M)IT/MIT (3:1), other than liquid detergents, and placed on the market for use by professional users shall not contain C(M)IT/MIT (3:1) at a concentration triggering classification as skin sensitiser, unless exposure can be avoided, including by the wearing of personal protective equipment.</p> <p>(4) The person responsible for the placing on the market of a treated article treated with or incorporating C(M)IT/MIT (3:1) shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.</p>

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A.I.S.E. guidance on how to address BPR Art. 58(3) requirements in the cases where the active substance concerned is skin sensitiser (1)



BPR Article 58 (3)	How to address in the case of detergents, cleaning & maintenance products
<i>(a) a statement that the treated article incorporates biocidal products</i>	Include ‘contains preservative’ in the ingredient labelling
<i>(b) where substantiated, the biocidal property attributed to the treated article</i>	Include ‘contains preservative’ in the ingredient labelling (NB: the treated article is preserved so it has a biocidal property)



Fictive example of ingredient labelling

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(PL) Składniki: 5-15% Anionowe środki powierzchniowo czynne, Niejonowe środki powierzchniowo czynne; <5% Fosfoniany, Mydła; Enzymy, Rozjaśniacze optyczne, Benzisothiazolinone, Methylisothiazolinone, Kompozycje zapachowe, Alpha-isomethyl ionone, Citronellol, Geraniol, Linalool. **(CZ) Složení:** 5-15% Anionové povrchově aktivní látky, Neionové povrchově aktivní látky; <5% Fosfonáty, Mýdla; Enzymy, Optické zjasňovače, Benzisothiazolinone, Methylisothiazolinone, Parfémy, Alpha-isomethyl ionone, Citronellol, Geraniol, Linalool. **(SK) Zloženie:** 5-15% Aniónové povrchovo aktívne látky, Neiónové povrchovo aktívne látky; <5% Fosfonáty, Mydlo; Enzymy, Optické zosvetľovače, Benzisothiazolinone, Methylisothiazolinone, Parfúmy, Alpha-isomethyl ionone, Citronellol, Geraniol, Linalool. **(DE) Inhaltsstoffe:** 5-15% anionische Tenside, nichtionische Tenside; <5% Phosphonate, Seife; Enzyme, optische Aufheller, Benzisothiazolinone, Methylisothiazolinone, Duftstoffe, Alpha-isomethyl ionone, Citronellol, Geraniol, Linalool.

A.I.S.E. guidance on how to address BPR Art. 58(3) requirements in the cases where the active substance concerned is skin sensitiser (2)



BPR Article 58 (3)	How to address in the case of detergents, cleaning & maintenance products
<i>(c) without prejudice to Article 24 of Regulation (EC) No 1272/2008, the name of all active substances contained in the biocidal products</i>	Already covered by the Detergent Regulation labelling requirements: name of the in-can preservative(s) shall be listed on label (INCI name) *

Detergents Regulation (EC) No 648/2004 - ANNEX VII - Labelling and ingredient data sheet

“A. Labelling of contents

The following provisions on labelling shall apply to the packaging of detergents sold to the general public. [...]

If added, preservation agents shall be listed, irrespective of their concentration, using where possible the common nomenclature established under Article 8 of Council Directive 76/768/EEC of 27 July 1976 on the approximation of laws of the Member States relating to cosmetic products (1).”



18 • *** 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**

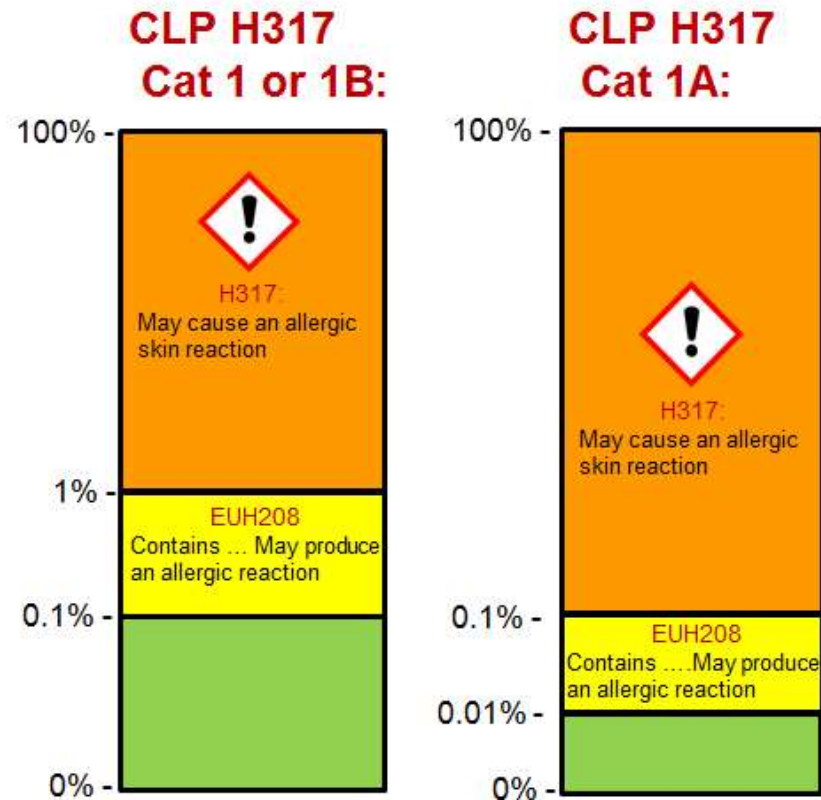
A.I.S.E. guidance on how to address BPR Art. 58(3) requirements in the cases where the active substance concerned is skin sensitiser (3)



BPR Article 58 (3)	How to address in the case of detergents, cleaning & maintenance products
<i>(d) the name of all nanomaterials contained in the biocidal products, followed by the word 'nano' in brackets</i>	A priori irrelevant (PT6 biocidal products are very unlikely to contain nanomaterials)
<i>(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.</i>	<p>As appropriate (left to companies to decide)</p> <p>As a general principle, A.I.S.E. believes that CLP is appropriate for informing and warning users about potential hazards and related precautions to be taken</p> <p>(see next slide case of skin sensitisation)</p>



CLP requirements with regard to skin sensitisers in mixtures



The figure above illustrates the case of Generic Concentration Limit, in case of Specific Concentration Limit (SCL), EUH208 applies at 1/10 of the SCL



Example of labelling



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

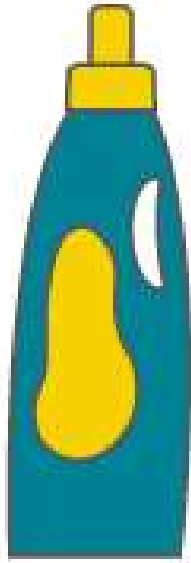
Treated article labelling - implementation of Article 58(3):

BPR Art. 58.3 (a), (b) & (c) → Contains preservative (“X”)

BPR Art. 58.3 (e) → + any relevant instructions for use & any precautions to be taken, considered by the manufacturer



Example of “non-labelling”



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

Since no biocidal claims nor claims on the biocidal property gained are made on product, 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

BPR Art. 58.3 (a), (b) & (c)
CLP (H317 statement)



Treated article labelling - implementation of BPR Art. 58(3) *:
Contains preservative (“X”). May cause an allergic skin reaction.



BPR Art. 58.3 (e)



+ any relevant instructions for use & any precautions to be taken, considered by the manufacturer

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

Thank you for your attention

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Back-up slides



Provisions for treated articles in active substances approval decisions: when to apply?

- Specific conditions related to the placing on the market of treated articles can be included in the Commission's active substance approval decisions (COM implementing regulations)
- When do the specific conditions apply?
 - ⇒ **From the date of approval of the active substance***
 - ⇒ **When a treated article contains multiple preservatives with different active substances, these active substances will probably have different approval dates. Companies may have to adjust their labelling multiple times.**

* Commission FAQ on Treated Articles (CA-Sept13-Doc.5.1.e Revision 1, December 2014), Q&A # 54 : "Labelling requirements imposed by conditions in the active substance approval apply from the date of approval."



Example : C(M)IT/MIT



Commission Implementing Regulation (EU) 2016/131 of 1 February 2016 approving C(M)IT/MIT (3:1) as an existing active substance for use in biocidal products for product-types 2, 4, 6, 11, 12 and 13

Specific conditions for PT6:

“The placing on the market of treated articles is subject to the following conditions:

- (1) In view of the risks identified for human health, mixtures treated with or incorporating C(M)IT/MIT (3:1) and placed on the market for use by the general public shall not contain C(M)IT/MIT (3:1) at a concentration triggering classification as skin sensitiser, unless exposure can be avoided by other means than the wearing of personal protective equipment.
- (2) In view of the risks identified for human health, liquid detergents treated with or incorporating C(M)IT/MIT (3:1) and placed on the market for use by professional users shall not contain C(M)IT/MIT (3:1) at a concentration triggering classification as skin sensitiser, unless exposure can be avoided by other means than the wearing of personal protective equipment.
- (3) In view of the risks identified for human health, mixtures treated with or incorporating C(M)IT/MIT (3:1), other than liquid detergents, and placed on the market for use by professional users shall not contain C(M)IT/MIT (3:1) at a concentration triggering classification as skin sensitiser, unless exposure can be avoided, including by the wearing of personal protective equipment.
- (4) The person responsible for the placing on the market of a treated article treated with or incorporating C(M)IT/MIT (3:1) shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.”

Date of approval of the AS: 1 July 2017

⇒ the specific conditions apply as of the 1st of July 2017

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (%)	Date of approval
C(M)IT/MIT (3:1)	IUPAC Name: Reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one (3:1) EC No: n/a CAS No: 55965-84-9	579 g/kg (theoretical, calculated dry weight) The active substance is manufactured as a technical concentrate (TK) with different solvents and stabilisers.	1 July 2017

