



# FACT SHEET HOW TO LABEL A BIOCIDAL PRODUCT OR A TREATED ARTICLE?

## REGULATORY FRAMEWORK

Regulation (EU) No. 528/2012 of the European Parliament and of the Council, 22 May 2012, concerning the making available on the market and use of biocidal products

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 (CLP Regulation)

Decree of May 19, 2004 regarding the control of the placing on the market of biocidal active substances and the authorization of biocidal products.

Environmental Code, Book V, Title II.

## REMINDER DEFINITIONS

**Biocidal product:** - Any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,  
- Any substance or mixture, generated from substances or mixtures with do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism, by any means other than mere physical or mechanical action

**Treated article:** any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products.

### Borderline between treated article and biocidal product

Examples:

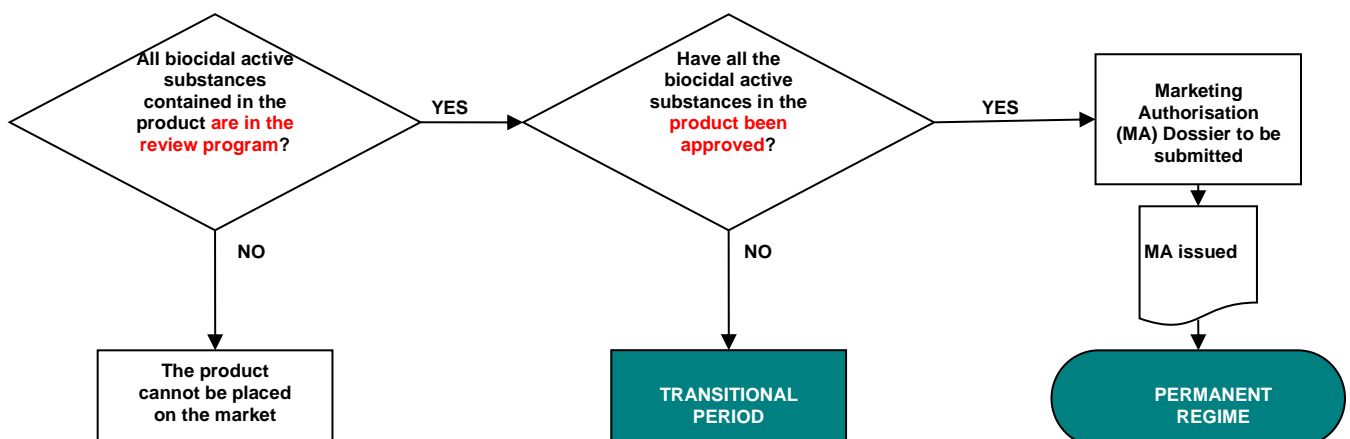
A disinfecting wipe claiming a disinfecting action is a biocidal product and not a treated article.

A detergent containing a preservative is a treated article.

An "anti-mold growth" paint for wet rooms is a biocidal product.

See Note for guidance, Frequently asked questions on treated articles, CA-Sept13-Doc.5.1.e (rev 1, Dec 2014) on CIRCABC, the European Commission's website.

### Transitional period/permanent regime (simplified flowchart)





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**FICTITIOUS EXAMPLE OF A LABEL FOR A BIOCIDAL PRODUCT WITHOUT A BPR MARKETING AUTHORIZATION (transitional period)**

**Article 10 of the decree of 19 May 2004**

The label must be written in French

b), d) and e) of article 10 of the decree of 19 May 2004 are not compulsory for a product in transitional regime

The terms "low-risk biocidal product", "non-toxic", "non-harmful", "natural", "environmentally friendly", "animal friendly", "biodegradable", or any other similar indication are prohibited

(h) Instructions for the safe disposal of the biocidal product and its packaging, including, where appropriate, a prohibition on reuse of the packaging

i) batch number and expiration date

j) Durations (See below)

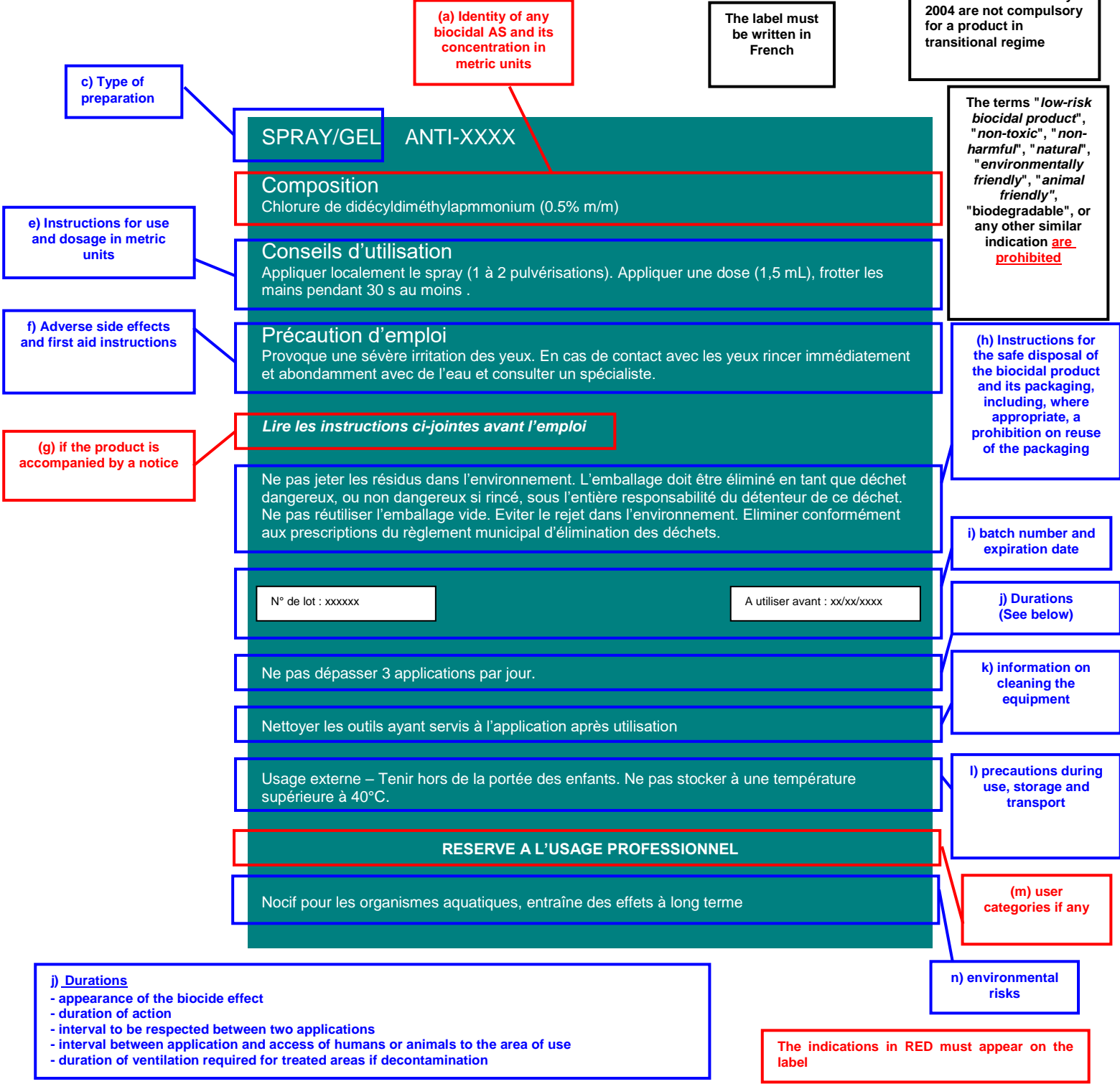
k) information on cleaning the equipment

l) precautions during use, storage and transport

(m) user categories if any

n) environmental risks

The indications in RED must appear on the label



c) Type of preparation

(a) Identity of any biocidal AS and its concentration in metric units

**SPRAY/GEL ANTI-XXXX**

**Composition**  
Chlorure de didécyldiméthylammonium (0.5% m/m)

**Conseils d'utilisation**  
Appliquer localement le spray (1 à 2 pulvérisations). Appliquer une dose (1,5 mL), frotter les mains pendant 30 s au moins .

**Précaution d'emploi**  
Provoque une sévère irritation des yeux. En cas de contact avec les yeux rincer immédiatement et abondamment avec de l'eau et consulter un spécialiste.

**Lire les instructions ci-jointes avant l'emploi**

Ne pas jeter les résidus dans l'environnement. L'emballage doit être éliminé en tant que déchet dangereux, ou non dangereux si rincé, sous l'entière responsabilité du détenteur de ce déchet. Ne pas réutiliser l'emballage vide. Éviter le rejet dans l'environnement. Eliminer conformément aux prescriptions du règlement municipal d'élimination des déchets.

N° de lot : xxxxxx

A utiliser avant : xx/xx/xxxx

Ne pas dépasser 3 applications par jour.

Nettoyer les outils ayant servis à l'application après utilisation

Usage externe – Tenir hors de la portée des enfants. Ne pas stocker à une température supérieure à 40°C.

**RESERVE A L'USAGE PROFESSIONNEL**

Nocif pour les organismes aquatiques, entraîne des effets à long terme

e) Instructions for use and dosage in metric units

f) Adverse side effects and first aid instructions

(g) if the product is accompanied by a notice

j) Durations  
- appearance of the biocide effect  
- duration of action  
- interval to be respected between two applications  
- interval between application and access of humans or animals to the area of use  
- duration of ventilation required for treated areas if decontamination



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The indications in RED must appear on the label

The information in BLUE may appear elsewhere on the packaging or be included in an explanatory sheet which accompanies the packaging and is an integral part of it

**FICTITIOUS EXAMPLE OF A LABEL FOR A BIOCIDAL PRODUCT WITH A BPR MARKETING AUTHORIZATION (permanent regime)  
Article 69 (2) of Regulation (EU) No 528/2012**

The label must be written at least in French (Art 69(3) of Regulation (EU) No 528/2012)

The terms "low-risk biocidal product", "non-toxic", "non-harmful", "natural", "environmentally friendly", "animal friendly", "biodegradable", or any other similar indication are prohibited

**a) Identity of each AS and its concentration in metric units**

**b) potential nanomaterials and their potential risks + indication (nano)**

**c) and d) the MA number + the name and address of the MA holder**

**e) Type of formulation**

**f) uses for which the biocidal product is authorized**

**g) Instructions for use, frequency of application and dosage to be applied in metric units**

**h) Adverse direct or indirect side effects and first aid instructions**

**i) if the product is accompanied by a notice**

**j) Instructions for the safe disposal of the biocidal product and its packaging, including, where appropriate, a prohibition on reuse of the packaging**

**k) batch number and expiration date**

**l) Durations and other measures (See below)**

**m) user categories, if any**

**n) environmental risks + protection of non-target organisms + measures to avoid water contamination**

**Composition**  
Chlorure de didécylidiméthylammonium (0,5% m/m)

N° d'AMM : FR-123-4567

Détenteur AMM :  
Entreprise ABC  
2, rue de l'étiquette  
75000 PARIS

**SPRAY/GEL ANTI-XXXX**

Produit de désinfection destiné à l'hygiène corporelle

**Conseils d'utilisation**  
Appliquer localement le spray (1 à 2 pulvérisations). Appliquer une dose (1,5 mL), frotter les mains pendant 30 s au moins .

**Précaution d'emploi**  
Provoque une sévère irritation des yeux. En cas de contact avec les yeux rincer immédiatement et abondamment avec de l'eau et consulter un spécialiste.

**Lire les instructions ci-jointes avant l'emploi**

L'emballage doit être éliminé en tant que déchet dangereux, ou non dangereux si rincé, sous l'entière responsabilité du détenteur de ce déchet. Ne pas réutiliser l'emballage vide. Eliminer conformément aux prescriptions du règlement municipal d'élimination des déchets.

N° de lot : xxxxxx

A utiliser avant : xx/xx/xxxx

Ne pas dépasser 3 applications par jour.  
Nettoyer les outils ayant servis à l'application après utilisation  
Usage externe – Tenir hors de la portée des enfants. Ne pas stocker à une température supérieure à 40°C.

**RESERVE A L'USAGE PROFESSIONNEL**

Nocif pour les organismes aquatiques, entraîne des effets néfastes à long terme.

- l) Durations and other measures**
- time needed to obtain the biocidal effect
  - interval between applications of the biocidal product or between application and the next use of the treated product,
  - human or animal access to the area of use
  - means and measures of decontamination and the necessary ventilation time
  - proper cleaning of equipment
  - precautions to be taken during use and transportation



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**EXAMPLE OF A FICTITIOUS LABEL OF TREATED ARTICLE**

**Article 58 (3) of Regulation (EU) No 528/2012**

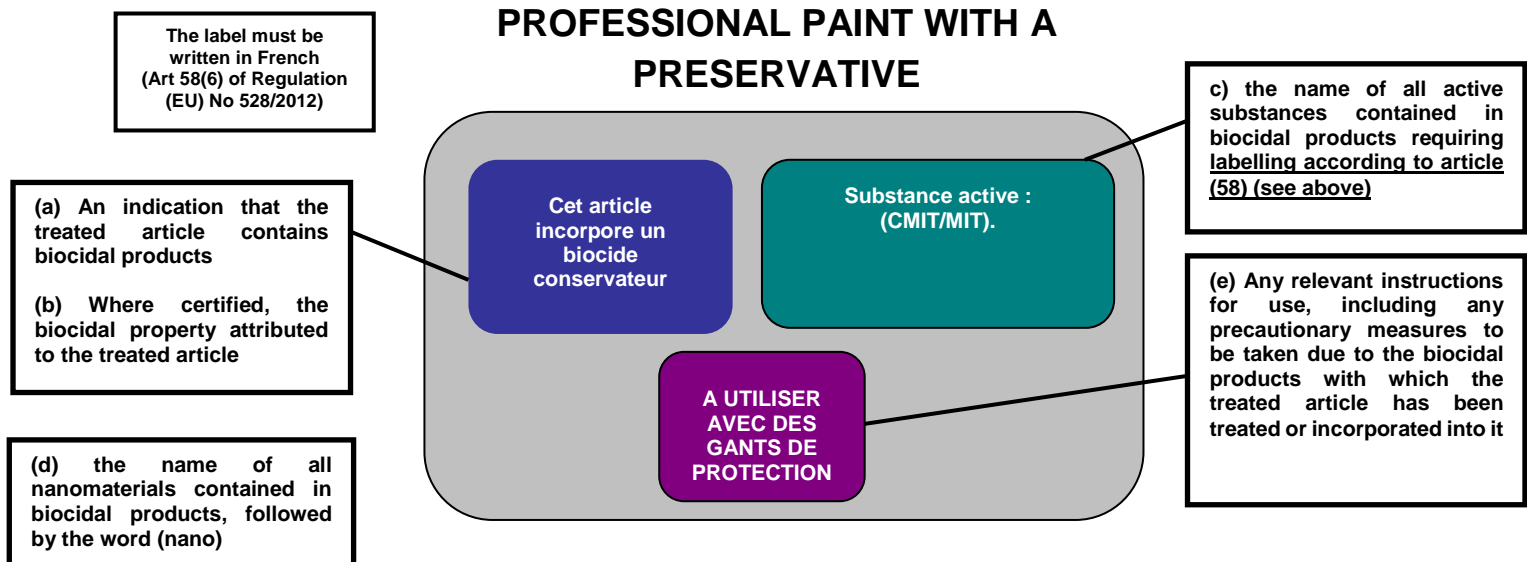
Need for specific labeling:

- If a **claim** is made regarding the **biocidal properties** of the article (anti-bacterial, ...)

**OR**

- If the **approval implementing decisions** of active substances set **specific labelling requirements** (i.e. once the active substance is approved),

The label must include the following:



**Note:** Article 58(3) does not apply where at least equivalent labelling requirements for biocidal products in treated articles already exist in the sectoral legislation and fulfill the information requirements for these active substances.

**Suggestion for the labelling of properties (indicative, in French)**

TP	Propriété	Variante ou complément
TP6	Conservateur	Produit de protection pendant le stockage
TP7	Produit de protection des peintures ou produit pour la protection du film sec	Pellicules, plastiques, enduits étanches, adhésifs muraux, liants, papiers, œuvres d'art, etc ...
TP8	Produit de protection du bois	Contre les champignons, contre les insectes, etc...
TP9	Produit de protection des fibres	Du cuir, du caoutchouc et des matériaux polymérisés
TP10	Produit de protection des matériaux de construction	Identifier les matériaux protégés (plâtre, etc) contre les moisissures, les algues, etc ...
TP11	Produit de protection des liquides de process contre les microbes	Contre les algues, contre les moules
TP12	Produit anti-biofilm	
TP13	Produit de protection des fluides de coupe	
TP18	Insecticide	Acaricide, etc...
TP19	Répulsif ou appât	Insectifuge



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## USEFUL DOCUMENTS

On the European Commission website - [www.circabc.europa.eu](http://www.circabc.europa.eu)

Note for guidance, Frequently asked questions on treated articles, CA-Sept13-Doc.5.1.e (rev 1, Dec 2014).

Note for discussion with competent authorities for biocidal products, labelling of treated articles, CA-May15-Doc.6.1 - Final.

On the ECHA website - [www.echa.europa.eu/en](http://www.echa.europa.eu/en)

Fact Sheet "Everything you need to know about treated articles", ECHA-18- B-11-EN

On the Anses website - [www.helpdesk-biocides.fr/](http://www.helpdesk-biocides.fr/)

On the website of the Ministry of the Economy - [Practical guide to environmental claims](#) (under revision)

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**The application of the provisions concerning the labelling of biocidal products must be done without prejudice to other regulations which may apply (CLP, detergent...).**