PD CEN/TR 17296:2018

BSI Standards Publication

Chemical disinfectants and antiseptics - Differentiation of active and non-active substances

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National foreword

This Published Document is the UK implementation of CEN/TR 17296:2018.

The UK participation in its preparation was entrusted to Technical Committee CH/216, Chemical disinfectants and antiseptics.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Published by BSI Standards Limited 2018

ISBN 978 0 539 01004 6

ICS 71.100.35; 11.080.20

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This Published Document was published under the authority of the Standards Policy and Strategy Committee on 30 November 2018.

Amendments/corrigenda issued since publication

Date	Text affected

TECHNICAL REPORT

RAPPORT TECHNIQUE

TECHNISCHER BERICHT

CEN/TR 17296

November 2018

ICS 11.080.20; 71.100.35

English Version

Chemical disinfectants and antiseptics - Differentiation of active and non-active substances

Antiseptiques et désinfectants chimiques - Différenciation des substances actives et des substances non actives

Chemische Desinfektionsmittel und Antiseptika - Differenzierung von aktiven und nicht-aktiven Substanzen

This Technical Report was approved by CEN on 12 October 2018. It has been drawn up by the Technical Committee CEN/TC 216.

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Ref. No. CEN/TR 17296:2018: E

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European foreword

This document (CEN/TR 17296:2018) has been prepared by Technical Committee CEN/TC 216 “Chemical disinfectants and antiseptics”, the secretariat of which is held by AFNOR.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

1 Scope

This document describes ways to establish whether or not a co-formulant in the concentration that is present in the product is an active substance within the framework of the European Biocidal Product Regulation and/or other regulations.

2 Normative references

There are no normative references in this document.

3 Terms and Definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

4 Requirements

When applying for authorization of a microbicidal product the applicant provides a composition statement in which one or more active substances and/or one or more co-formulant(s) are identified. In some cases the Competent Authority might regard one or more of the co-formulants as additional active substance(s). In some cases an explanation can be given and accepted. In cases where this is insufficient, tests can be performed to demonstrate the "non-activity" of the co-formulant(s). For chemical disinfectants the following strategy has been developed:

A) Three kinds of tests have been identified. The applicant may choose one, two or all of them – as necessary and appropriate.

Each test should be performed as a phase 2, step 1 test under the test conditions (test organism, interfering substance/soiling, contact time, concentration of the product) used for a product claim. Product claim means for example: "bactericidal activity: 1,5 %, 3 min, dirty conditions." For the purpose of the differentiation of active and non-active substances results from phase 2, step 2 tests should be ignored even if they require a higher product-concentration for the claim.

In all tests the pH of the formulation under test should be adjusted to the pH of the microbicidal product, if necessary.

Test 1: *The microbicidal product without active substance is tested.*

The active substance(s) are replaced by water or any other suitable substance(s). If the active substance(s) cannot be replaced for whatever reason, the concentration of the product without active substance has to be decreased accordingly. Example: Amount of the active substances is 30 g/100 g in the microbicidal product. Concentration used for claiming bactericidal activity is 2,0 %. Concentration in Test 1 should be 2,0 % of 70 % of the product (i.e. 70 g/100 g) = 1,4 %.

For an example illustrating how to draw conclusions from the test results see **C)**.

Test 2: *Each co-formulant under question is tested alone.*

The concentration (of the co-formulant) in the test has to be adapted to the relative amount of the co-formulant in the microbicidal product. Example: Amount of the co-formulant is 3 g/100 g in the microbicidal product. Concentration used for claiming bactericidal activity is 3,0 %, concentration of the co-formulant in Test 2 should be 3,0 % of 3,0 % of the product (i.e. 3 g/100 g) = 0,09 %.

For an example illustrating how to draw conclusions from the test results see **C)**.