SLOVENSKI STANDARD
SIST-TP CEN/TR 17296:2019

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Kemična razkužila in antiseptiki - Razlikovanje med aktivnimi in neaktivnimi snovmi

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

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

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

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71.100.35	Kemikalije za dezinfekcijo v industriji in doma	Chemicals for industrial and domestic disinfection purposes

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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

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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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Contents

Page

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)**.

Test 3: *The microbicidal product without the co-formulant is tested*.

Two products are tested in parallel: the microbicidal product and the same product, but without the co-formulant that should be replaced by water or any other suitable substance(s). Separate testing may be performed for each co-formulant under question removing only one co-formulant at a time.

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

B) For all tests it is requested to show a definite lg reduction considering the detection limits of the respective tests, i.e. within the detection limits precise lg reduction values need to be given such as 2,68 lg instead of < 5,00 or 2,25 lg instead of < 4,00 lg. The EN tests may be adapted accordingly, if necessary. For instance extra dilution steps might be needed for these tests to show lg reductions around 3,00 and 3,50.

C) To demonstrate in tests 1 and 2, that the co-formulants under question are not active substances the lg reduction should be at least 2,00 lg lower than the lg reduction required to pass the EN standard performed. For test 3, the lg reduction of the two products should be similar, i.e. show no more than 1,50 lg difference.

Three examples shall illustrate this evaluation:

Test 1: The full product demonstrates a 5,00 lg bactericidal activity. If the product without active substance demonstrates a ≤ 3,00 lg inactivation, all co-formulants are not active ingredients.

Test 2: The full product demonstrates a 4,00 lg mycobactericidal activity. If the co-formulant under question alone demonstrates a ≤ 2,00 lg mycobactericidal inactivation, it is not an active ingredient.

Test 3: The full product demonstrates a 4,00 lg fungicidal activity. If the product without the co-formulant under question demonstrates a fungicidal inactivation of ≤ 2,50 lg, the co-formulant under question is an active ingredient.

D) These tests should generally be performed using bacteria (including mycobacteria and bacterial spores) as test organisms. If other test organisms are used to demonstrate non-activity only those that are claimed for the product are allowed.

E) In cases where more than one co-formulant is under question and test 1 shows low lg reduction, none of these co-formulants can be regarded as an active substance. However, if in this test 1 a high lg reduction is seen, further tests 2 and/or 3 with each co-formulant under question would be required to verify which co-formulant is causing this effect.