SLOVENSKI STANDARD
kSIST-TP FprCEN/TR 17296:2018

01-september-2018

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

Ta slovenski standard je istoveten z: **FprCEN/TR 17296**

ICS:

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

kSIST-TP FprCEN/TR 17296:2018 **en**

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Document type: **Error! Reference source not found.**
Document subtype: **Error! Reference source not found.**
Document stage: **Error! Reference source not found.**
Document language: **Error! Reference source not found.**

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European foreword

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

This document is currently submitted to the Vote on TR.

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 Requirements

When applying for authorization of a microbicidal product the applicant provides a composition statement in which one or more active substances are identified and one or more co-formulant(s). 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.