SLOVENSKI STANDARD
oSIST prEN ISO 16187:2023

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Obutev in deli obutve - Preskusna metoda za ugotavljanje protibakterijskega delovanja (ISO/DIS 16187:2023)

Footwear and footwear components - Test method to assess antibacterial activity (ISO/DIS 16187:2023)

Schuhe und Schuhbestandteile - Prüfverfahren zur Bestimmung der antibakteriellen Wirkung (ISO/DIS 16187:2023)

Chaussure et composants de chaussure - Méthode d'essai pour évaluer l'activité antibactérienne (ISO/DIS 16187:2023)

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ICS:

61.060	Obuvala	Footwear

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DRAFT INTERNATIONAL STANDARD

ISO/DIS 16187

ISO/TC **216**

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Footwear and footwear components — Test method to assess antibacterial activity

Chaussure et composants de chaussure — Méthode d'essai pour évaluer l'activité antibactérienne

ICS: 61.060

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 216, *Footwear*.

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This second edition cancels and replaces the first edition (ISO 16187:2013), which has been technically revised.

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The main changes compared with ISO 16187:2013 are as follows:

— New term “neutralizer” and its definition have been added;

— Clause 4 principle has been added;

— AS No. has been revised to CGMCC No.;

— The light intensity of UV lamp has been added;

— The normative reference and bibliography have been revised and updated;

— TSA and TSB has been added for alternative culture medium;

— Annex D “Summarized results of round robin tests” has been deleted.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Footwear and footwear components — Test method to assess antibacterial activity

CAUTION — Test methods specified herein require the use of bacteria. These tests are only to be carried out in facilities with containment techniques for handling microorganisms and by persons with training and experience in the use of microbiological techniques.

1 Scope

This document specifies quantitative test methods to evaluate the antibacterial activity of footwear and footwear components.

This document is applicable to all types of footwear and footwear components employing non-diffusing antibacterial treatments.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7218, *Microbiology of food and animal feeding stuffs — General requirements and guidance for microbiological examinations*

ISO 19952, *Footwear — Vocabulary*

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3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 19952 and the following apply.

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
antibacterial activity
efficacy of a material or finish used to prevent or mitigate the growth of bacteria, to reduce the number of bacteria or to kill bacteria

3.2
control sample
material identical to the test material but without antibacterial treatment

3.3
neutralizer
chemical agents used to inactivate, neutralize, or quench the antibacterial properties of antibacterial agents

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4 Principle

The test specimens and control specimens are inoculated with a bacterial suspension of a selected test strain specified or claimed in independent tests with one Gram-positive and one Gram-negative bacterial test organism.

Three test methods are available to assess antibacterial activity in a challenge test procedure under static or under dynamic conditions.

Antibacterial performance is quantitatively determined by counting the number of viable cells and calculating the antibacterial activity ratio.

5 Safety

Handling of microorganisms which are potentially hazardous requires a high degree of technical competence and can be subject to current national legislation and regulations. Only personnel trained in microbiological techniques should carry out such tests.

NOTE Refer to country-specific codes of practice for personal hygiene, disinfection and sterilization.

It is recommended that the persons who perform the test should consult IEC 60068-2-10:2005, Appendix A, and ISO 7218.

6 Apparatus and materials

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6.1 General

Disposable apparatus is an acceptable alternative to re-usable glassware and plastic if it has suitable specifications.

Usual microbiological laboratory equipment in accordance with ISO 7218 and in particular the following.

6.2 Biological safety cabinet.

6.3 Incubator, capable of maintaining a temperature of (37 ± 2) °C.

6.4 Autoclave, capable of maintaining a temperature of (121 ± 2) °C and a pressure of (103 ± 5) kPa, for wet sterilization, used in accordance with ISO 7218.

6.5 Humidity chamber, capable of maintaining a temperature of (37 ± 2) °C and a relative humidity of (85 ± 5) %.

6.6 Ultraviolet lamp.

6.7 Wide mouth jars, with cap, 100 ml, capable of being used with an autoclave (6.4).

6.8 Cover film, that does not affect bacterial growth or absorb water, which can be made of either polyethylene, polypropylene or polyester [poly (ethylene terephthalate)]. Film that is 0,05 mm to 0,10 mm thick is recommended. For example, disposal bag suitable for use with an autoclave (6.4).

6.9 Vortex mixer.

6.10 Dimensional shaker, two dimensional or three dimensional, capable of adjusting to 50 rpm.

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6.11 Shaking incubator, capable of maintaining a temperature of (37 ± 2) °C and a rotational frequency of (120 ± 10) rpm.

7 Reagents and culture medium

7.1 General

The preparation and test shall be freshly prepared in order to ensure the culture quality.

NOTE This could be done according to ISO 11133, or according to national standards or regulations.

Dehydrated products available on the commercial market are recommended for use in preparing the culture media. The manufacture user's instructions for the preparation of these products should be strictly followed.

Reagents used in tests shall be of analytical grade and/or suited for microbiological purposes.

7.2 Water

Water used in tests shall be analytical-grade water for microbiological media preparation, which is freshly distilled and/or ion-exchanged and/or ultra-filtered and/or filtered with RO (Reverse Osmosis).

It shall be free from all toxic or microorganism inhibitory substances.

NOTE Water Grade 3 according to ISO 3696 can be used.

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7.3 Nutrient broth (NB)

7.3.1 Composition

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Beef extract	3,0 g
Peptone	5,0 g
Sodium chloride (NaCl)	5,0 g
Water	1 000 ml

7.3.2 Preparation

Stir and adjust pH to (7,2 ± 0,2) (at room temperature). Heat with stirring on a hotplate or in a boiling-water bath until the components are completely dissolved. Sterilize with autoclave (6.4) at (121 ± 2) °C for 15 min.

7.4 Nutrient agar (NA)

7.4.1 Composition

Beef extract	5,0 g
Peptone	10,0 g
Sodium chloride (NaCl)	5,0 g
Agar	15,0 g
Water	1 000 ml

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NOTE If solidification is insufficient, 15 g to 18 g of agar can be used.

7.4.2 Preparation

Stir and adjust pH to (7,2 ± 0,2) (at room temperature). Heat with stirring on a hotplate or in a boiling-water bath until the components are completely dissolved. Sterilize with autoclave (6.4) at (121 ± 2) °C for 15 min. Cool and shake solution well, then pour into the Petri dishes.

7.5 Tryptic Soy Broth (TSB)

7.5.1 Composition

Tryptone, pancreatic digest of casein	17,0 g
Soya peptone, papain digest of soya	3,0 g
Sodium chloride (NaCl)	5,0 g
Glucose	2,5 g
Dipotassium hydrogen phosphate	2,5 g
Water	1 000 ml

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7.5.2 Preparation

Stir and adjust pH to (7,2 ± 0,2) (at room temperature). Heat with stirring on a hotplate or in a boiling-water bath until the components are completely dissolved. Sterilize with autoclave (6.4) at (121 ± 2) °C for 15 min.

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7.6 Tryptone soy agar (TSA)

7.6.1 Composition

Tryptone, pancreatic digest of casein	15,0 g
Soya peptone, papain digest of soya	5,0 g
Sodium chloride (NaCl)	5,0 g
Agar	15,0 g
Water	1 000 ml

7.6.2 Preparation

Stir and adjust pH to (7,2 ± 0,2) (at room temperature). Heat with stirring on a hotplate or in a boiling-water bath until the components are completely dissolved. Sterilize with autoclave (6.4) at (121 ± 2) °C for 15 min. Cool and shake solution well, then pour into the Petri dishes.

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7.7 Soybean casein digest broth with lecithin and polyoxyethylene medium (SCDLP)

7.7.1 Composition

Peptone, digest of casein	17,0 g
Peptone, digest of soybean	3,0 g
Sodium chloride (NaCl)	5,0 g
Potassium dihydrogen phosphate	2,5 g
Glucose	2,5 g
Lecithin	1,0 g
Polysorbate 80	7,0 g
Water	1 000 ml

If the neutralizing power is insufficient, the content of polysorbate 80 or lecithin may be adjusted or another neutralizing agent may be added. The use of any unspecified neutralizer shall be recorded along with the name and concentration.

NOTE Information about selection and evaluation of alternative antibacterial neutralizing agents can be found in ASTM E 1054 and EN 1040.

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7.7.2 Preparation

After mixing well, adjust pH to (7,2 ± 0,2) (at room temperature) and sterilize with autoclave (6.4) at (121 ± 2) °C for 15 min.

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7.8 Sodium chloride solution (physiological saline)

7.8.1 Composition

Sodium chloride (NaCl)	8,5 g
Water	1 000 ml

7.8.2 Preparation

After mixing well, adjust pH to (6,9 ± 0,2) (at room temperature) and sterilize at (121 ± 2) °C for 15 min.

8 Test microorganisms

8.1 Test strains

The following species shall be used in all antibacterial activity tests.

a) *Staphylococcus aureus* CGMCC 1.89 or ATCC® 6538™ or WDCM 00032.

b) *Klebsiella pneumoniae* CGMCC 1.1736 or ATCC® 4352™ or WDCM 00192.

NOTE 1 If required, other species or other strains can be used. However, the selected organisms should contain at least one Gram-positive and one Gram-negative organism as the antibacterial agents may have different activities.

Test strains shall be obtained from agencies of the World Federation of Culture Collection (WFCC).

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