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Očesna optika - Kontaktne leče - 4. del: Fizikalnokemijske lastnosti materialov za kontaktne leče (ISO 18369-4:2017)

Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact lens materials (ISO 18369-4:2017)

Augenoptik - Kontaktlinsen - Teil 4: Physikalisch-chemische Eigenschaften von Kontaktlinsenmaterialien (ISO 18369-4:2017)

Optique ophtalmique - Lentilles de contact - Partie 4: Propriétés physicochimiques des matériaux des lentilles de contact (ISO 18369-4:2017)

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en

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EUROPEAN STANDARD

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Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact lens materials (ISO 18369-4:2017)

Optique ophtalmique - Lentilles de contact - Partie 4:
Propriétés physicochimiques des matériaux des
lentilles de contact (ISO 18369-4:2017)

Augenoptik - Kontaktlinsen - Teil 4: Physikalisch-
chemische Eigenschaften von
Kontaktlinsenmaterialien (ISO 18369-4:2017)

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COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

This document (EN ISO 18369-4:2017) has been prepared by Technical Committee ISO/TC 172 “Optics and photonics” in collaboration with Technical Committee CEN/TC 170 “Ophthalmic optics” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2018, and conflicting national standards shall be withdrawn at the latest by March 2018.

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.

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According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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INTERNATIONAL
STANDARD

ISO
18369-4

Second edition
2017-08

**Ophthalmic optics — Contact lenses —
Part 4:
Physicochemical properties of contact
lens materials**

Optique ophtalmique — Lentilles de contact —

*Partie 4. Propriétés physicochimiques des matériaux des lentilles
de contact*

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html. (standards.iteh.ai)

This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*. [SIST EN ISO 18369-4:2017](https://standards.iteh.ai/catalog/standards/sist/ba4b71f8-81e7-4fa2-8ca4-1004b71fc018/iso-18369-4:2017)

This second edition cancels and replaces the first edition (ISO 18369-4:2006), which has been technically revised.

A list of all parts in the ISO 18369 series can be found on the ISO website.

Ophthalmic optics — Contact lenses —

Part 4:

Physicochemical properties of contact lens materials

1 Scope

This document specifies the methods of testing the physicochemical properties of contact lens materials. These are extraction, rigid lens flexure and breakage, oxygen permeability, refractive index and water content.

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 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 18369-1:2017, *Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications*

ISO 18369-3:2017, *Ophthalmic optics — Contact lenses — Part 3: Measurement methods*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18369-1 apply.

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 Physicochemical properties of contact lenses

4.1 Repeatability, test methods and units of measure

The physicochemical properties or conditions listed in [Table 1](#) are measurable characteristics of hydrogel and non-hydrogel materials that have been used to produce commercially available contact lenses.

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Table 1 — Physicochemical properties: Test methods and units of measure

Property	Units of	Test method	Repeatability
Extractables	mass %	4.2	b
Flexural deformation	g	4.3	b
Oxygen permeability	<i>Dk</i> units ^a	4.4	10 %
Refractive index	dimensionless	4.5	0,01
Water content	weight %	4.6	2 % absolute

^a *Dk* is reported in units of 10⁻¹¹ (cm²/s) ml O₂/(ml × mmHg) and called “*Dk* units” or barrer.

^b Repeatability of these test results shall be established in individual laboratories according to ISO 18369-1:2017, 3.1.12.8, 3.1.12.9, 3.1.12.9.1, 3.1.12.9.2 and 3.1.12.9.3.

[Clause 4](#) is applicable to testing laboratories, suppliers and users of contact lens products or services in which measurement results are used to demonstrate compliance to specified requirements.

Alternative test methods and equipment may be used provided the accuracy and precision are equivalent to or more capable than the test methods described.

In developing new test methods, these should be capable of measuring the various parameters with a precision (R&R) of ≤30 % of the allowed tolerance. Resolution greater than 10 % of the tolerance can be used but will affect determination of accuracy, precision, process capability and gauge capability. The number of independent measurements should be chosen for each method to ensure appropriate precision and accuracy.

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4.2 Extractables

4.2.1 General

Soxhlet extraction with different solvents is a standard method for quantitative determination of substances extractable from contact lenses. The contact lenses are dried to constant mass and the difference between the original dry mass of the lenses and the extracted dry mass determines the quantity of extractable substances (extractables).

Knowledge of the quantity and identity of extractable substances is helpful in evaluating new contact lens materials and in determining the subsequent pre-clinical examination programme. The material extracted from the contact lenses may be examined by appropriate chromatographic, spectrophotometric and wet analytical methods to identify residual monomers, cross-linking agents, catalysts, etc. that were employed in the polymerization process.

4.2.2 Principle

This method uses a normal Soxhlet extraction apparatus. Water and at least one suitable organic solvent are used for extraction. In selecting the organic solvent(s) to be used, consideration should be given to the effect of the solvent upon the matrix of the material. Ideally, a solvent should not swell or degrade the contact lens material. However, in the development of new contact lens materials, a solvent that causes reversible swelling may give valuable information relating to the possibility for extraction over extended periods of time. Choice of a solvent that degrades the polymer network during extraction is not recommended, as it will remove both uncrosslinked and crosslinked material, resulting in inaccurate measurement of extractables.

4.2.3 Apparatus

4.2.3.1 Standard borosilicate glass Soxhlet extraction apparatus (see [Figure 1](#)), consisting of the Soxhlet extractor (30 ml suggested), condenser, round bottom flask (100 ml suggested) and a heating mantle.

4.2.3.2 Perforated stainless steel, sintered glass, paper or equivalent extraction thimble fitted with a glass wool plug or other suitable closure.

4.2.3.3 Vacuum oven or equivalent drying apparatus and an analytical balance capable of weighing to 0,1 mg.

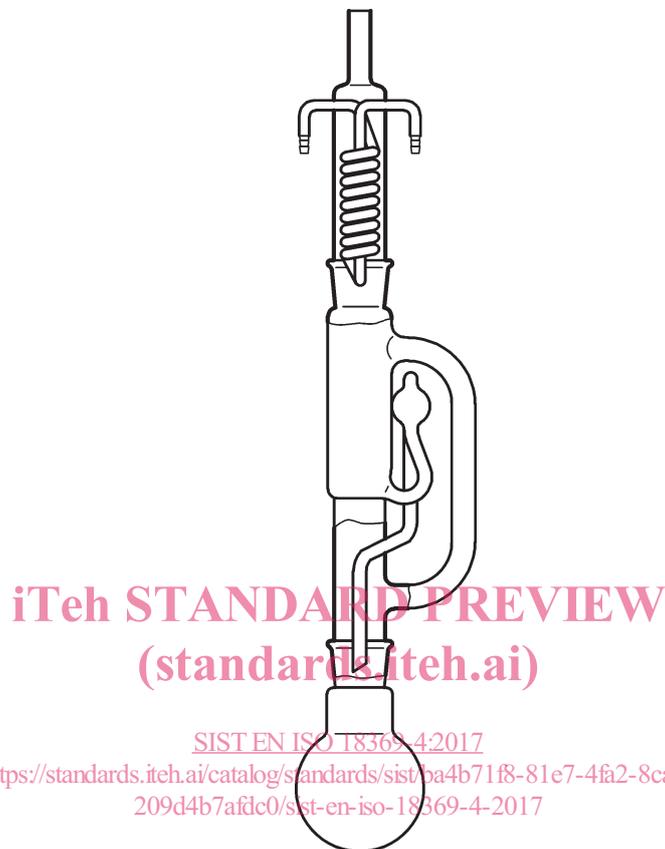


Figure 1 — Extraction apparatus

4.2.4 Reagents

4.2.4.1 Distilled or deionized water complying with ISO 3696:1987, Grade 3.

4.2.4.2 Appropriate organic solvent (see [Table 2](#)) of analytical grade or better.

4.2.4.3 Laboratory-grade boiling stones or anti-bumping granules, along with a suitable active desiccant. Selection of the desiccant will depend upon the characteristics of the test material.