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**Očesna optika – Kontaktne leče – 4. del: Fizikalnokemijske lastnosti  
materialov za kontaktne leče (ISO 18369-4:2006)**

Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact  
lens materials (ISO 18369-4:2006)

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English Version

Ophthalmic optics - Contact lenses - Part 4: Physicochemical  
properties of contact lens materials (ISO 18369-4:2006)

Optique ophtalmique - Lentilles de contact - Partie 4:  
Propriétés physicochimiques des matériaux des lentilles de  
contact (ISO 18369-4:2006)

Augenoptik - Kontaktlinsen - Teil 4: Physikalisch-  
chemische Eigenschaften von Kontaktlinsenmaterialien  
(ISO 18369-4:2006)

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COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

## Foreword

This document (EN ISO 18369-4:2006) has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" 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of an identical text or by endorsement, at the latest by February 2007, and conflicting national standards shall be withdrawn at the latest by February 2007.

This document supersedes EN ISO 10339:1999, EN ISO 10340:1996, EN ISO 11984:1999, EN ISO 9913-1:1998, EN ISO 9913-2:2000, EN ISO 9914:1996.

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

## Endorsement notice

The text of ISO 18369-4:2006 has been approved by GEN as EN ISO 18369-4:2006 without any modifications.

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**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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 18369-4 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This first edition cancels and replaces ISO 9913-1:1996, ISO 9913-2:2000, ISO 9914:1995, ISO 10339:1997, ISO 10340:1995 and ISO 11984:1999, which have been technically revised.

ISO 18369 consists of the following parts, under the general title *Ophthalmic optics — Contact lenses*:

- Part 1: *Vocabulary, classification system and recommendations for labelling specifications*
- Part 2: *Tolerances*
- Part 3: *Measurement methods*
- Part 4: *Physicochemical properties of contact lens materials*



## Introduction

The ISO 18369 series applies to contact lenses, which are devices worn over the front surface of the eye in contact with the precorneal tear film. This part of ISO 18369 covers rigid (hard) corneal and scleral contact lenses, as well as soft contact lenses. Rigid lenses maintain their own shape unsupported and are made of transparent optical-grade plastics, such as polymethylmethacrylate (PMMA), cellulose acetate butyrate (CAB), polyacrylate/siloxane copolymers, rigid polysiloxanes (silicone resins), butylstyrenes, fluoropolymers, and fluorosiloxanes, etc. Soft contact lenses are easily deformable and require support for proper shape. A very large subset of soft contact lenses consists of transparent hydrogels containing water in concentrations greater than 10 %. Soft contact lenses can also be made of non-hydrogel materials, e.g. flexible polysiloxanes (silicone elastomers).

The ISO 18369 series is applicable to determining allowable tolerances of parameters and properties important for proper functioning of contact lenses as optical devices. The ISO 18369 includes tolerances for single vision contact lenses, bifocal lenses, lenses that alter the flux density and/or spectral composition of transmitted visible light (tinted or pigmented contact lenses, such as those with enhancing, handling, and/or opaque tints), and lenses that significantly attenuate ultraviolet radiation (UV-absorbing lenses). The ISO 18369 series of standards covers contact lenses designed with spherical, toric, and aspheric surfaces, and recommended methods for the specification of contact lenses.

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# Ophthalmic optics — Contact lenses —

## Part 4: Physicochemical properties of contact lens materials

### 1 Scope

This part of ISO 18369 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 referenced documents are indispensable for the application 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 18369-1:2006, *Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications*

ISO 18369-3:2006, *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.

## 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 nonhydrogel materials that have been successfully manufactured into contact lenses. In addition, Table 1 includes repeatability, test methods, and units of measure for these characteristics. If alternative methods are used, they should be so stipulated.

Table 1 — Physiochemical properties: Repeatability, test methods and units of measure

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

<sup>a</sup> *Dk* is reported in units of  $10^{-11}$  (cm<sup>2</sup> / s) ml O<sub>2</sub> / (ml × hPa) and called "*Dk* units".

<sup>b</sup> Repeatability of these test results shall be established in individual laboratories according to the terms and definitions given in ISO 18369-1.

## 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.

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### 4.2.2 Principle

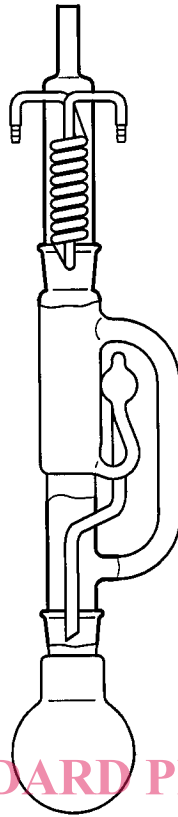
This method uses a normal Soxhlet extraction apparatus. Water and at least one suitable organic solvent are used for extraction. In selecting the organic solvent(s) to be used, consideration should be given to the effect of the solvent upon the matrix of the material. Ideally, a solvent should not swell 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.

### 4.2.3 Apparatus

A 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 shall be used. A perforated stainless steel, sintered glass, paper or equivalent extraction thimble fitted with a glass wool plug or other suitable closure shall be used. A vacuum oven or equivalent drying apparatus and an analytical balance capable of weighing to 0,1 mg are required.

### 4.2.4 Reagents

Distilled or deionized water complying with Grade 3 of ISO 3696:1987 shall be used. The appropriate organic solvent (see Table 2) should be analytical grade or better. Laboratory-grade boiling stones or anti-bumping granules are required along with a suitable active desiccant. Selection of the desiccant will depend upon the characteristics of the test material.



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Figure 1 — Extraction apparatus

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Table 2 — Guide to the selection of solvents for use in extraction of contact lenses

Material	Solvent	Corresponds to
Hydrogels	Water (distilled or deionized)	Mild extraction (simulates in-eye extraction)
	<i>n</i> -Hexane	Mild extraction (non-polar solvent)
	Ethanol or methanol	Extraction of majority of uncrosslinked material (but swells and may degrade material)
	Dichloromethane or chloroform	Extraction of all uncrosslinked material (but swells and is likely to degrade material)
Hard and RGP and silicone elastomers	Water (distilled or deionized)	Mild extraction (simulates in-eye extraction)
	<i>n</i> -Hexane	Mild extraction (non-polar solvent)
	Dichloromethane or chloroform	Extraction of all uncrosslinked material (but swells and is likely to degrade material)