INTERNATIONAL STANDARD

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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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Contents

Page

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 preocular 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.

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 %	*Dk* units[a]	4.4
Refractive index	0,01	dimensionless	4.5
Water content	2 % absolute	%	4.6

[a] *Dk* is reported in units of 10^{-11} (cm^2 / s) ml O_2 /(ml × hPa) and called "*Dk* units".

[b] 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.

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.

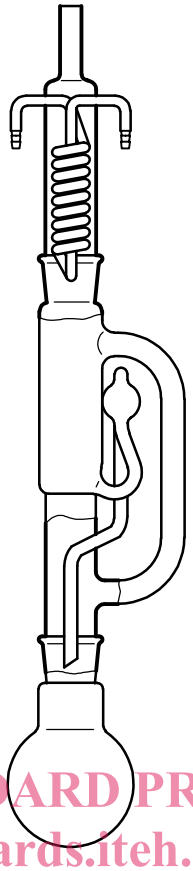


Figure 1 — Extraction apparatus

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)
	n-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)
	n-Hexane	Mild extraction (non-polar solvent)
	Dichloromethane or chloroform	Extraction of all uncrosslinked material (but swells and is likely to degrade material)

4.2.5 Test samples

Test samples shall be representative of the finished product and be in finished contact lens form. The method of preparing and finishing the lenses shall reflect as far as possible the normal production processes including sterilization. A sufficient number of lenses shall be used so that the total dry mass before extraction shall be no less than 200 mg.

Hydrophilic lenses are usually packaged in a solution containing inorganic salts. When using water as the extracting solution, an adjustment in the calculation should be made for the contribution of the inorganic salt of the packaging solution. The water content of the lenses will be required in order to accurately calculate the contribution of the inorganic salt to the extractables. Alternatively, the lenses may be equilibrated in at least two changes of water each for 24 h at room temperature prior to beginning the test.

4.2.6 Test procedure

Dry the lenses, preferably under vacuum, at 60 °C ± 5 °C to constant mass. Then allow the lenses to cool to room temperature under vacuum or in a closed container over active desiccant before weighing. Then weigh the dry lenses to ± 0,1 mg (m_1). Next place the lenses into the extraction thimble, place boiling stones in the flask, if necessary, and fill the flask to approximately 70 % of its capacity with the appropriate solvent (see Table 2). Place the round-bottom flask in the heating mantle. Place the extraction thimble into the Soxhlet apparatus. Then attach the Soxhlet apparatus to the flask. Place a condenser on top of the extraction apparatus. When using a volatile or flammable solvent, the extraction apparatus should be placed in a fume hood.

Turn on heat and water and extract the lenses for at least 4 h. Allow the solvent to cool to room temperature before removing the lenses from the extraction thimble. Dry the lenses to constant mass as described above and weigh to the nearest 0,1 mg (m_2).

4.2.7 Calculation of results

The quantity of extracted material shall be expressed as a mass fraction, $w_{\text{extracted}}$, in percent of the initial dry mass [Equation (1)]:

$$w_{\text{extracted}} = \frac{(m_1 - m_2)}{m_1} \times 100 \qquad (1)$$

where

m_1 is the mass of lenses prior to extraction;

m_2 is the mass of extracted lenses.

4.2.8 Test report

The test report for extractables shall conform to that in Clause 5 and contain the following information for hydrophilic material:

a) the composition of the initial hydrating solution;

b) a statement as to whether the percentage of extractable substances has been adjusted for the salt content of the hydrating solution;

c) if the contact lenses were equilibrated in water before the beginning of the test.

4.3 Rigid lens flexural deformation and rupture

4.3.1 Principle

The test, which is a destructive test, applies an increasing load at the edge of a rigid lens across the total diameter until ultimately the test sample fractures. The test is carried out in an apparatus which allows the load and flexural deformation to be monitored continuously. Both the flexural deformation strength and flexural deformation at rupture are determined as well as flexural deformation strength at 30 % deformation. The latter is derived from the flexural load-deformation curve. Both normal production or specially constructed rigid contact lenses can be tested.

It should be noted that variability in the test results may also result from inconsistencies in lens manufacturing method and may not necessarily be indicative of the material itself.

4.3.2 Sampling

4.3.2.1 General samples

In order to demonstrate the degree of resistance to breakage by the material, general samples for testing shall be normal, commercially available rigid, single vision contact lenses and shall not have been specially treated or adjusted.

Contact lenses which have toroidal zones or truncations shall not be used.

The specified back vertex power (F'_v) shall be the same for all samples and shall be between + 0,50 D and − 0,50 D.

The specified back optic zone radius (r_0), or radius of the vertex sphere, shall be the same for all samples and shall be between 7,75 mm and 7,85 mm.

4.3.2.2 Samples for material comparison

When special samples are prepared in order to compare materials, the contact lenses shall have the following specifications:

— front surface: single cut, radius of curvature 8,00 mm ± 0,025 mm;

— back surface: single cut, radius of curvature 7,80 mm ± 0,025 mm;

— total diameter 9,5 mm ± 0,1 mm;

— centre thickness: 0,20 mm ± 0,01 mm;

— edge thickness: 0,24 mm ± 0,01 mm;

— edge form: rounded;

— maximum prismatic error: 0,5 cm/m.

The method of manufacture shall be stated in the test report.

4.3.2.3 Quantity

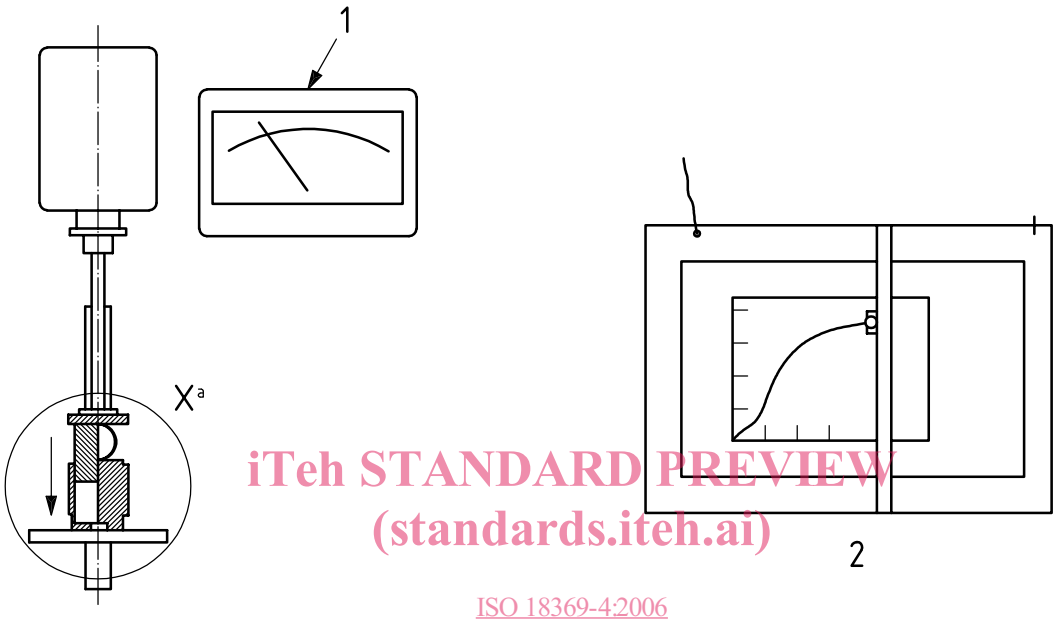
Three contact lenses from each of three different material lots (total of nine contact lenses) shall be tested where a claim is made regarding flexure or strength.

4.3.3 Preparation of samples

Samples shall be stored in standard saline solution conforming to ISO 18369-3:2006, 4.7, for at least 48 h prior to testing. The temperature of this saline solution shall be 20 °C ± 5 °C.

4.3.4 Apparatus

4.3.4.1 **Testing machine** (see Figure 2), applying a load to the sample at a fixed rate in either the horizontal or vertical plane, and composed of the units described in 4.3.4.2 to 4.3.4.4.



Key

1 load indicator
2 recorder

a See Figure 3 for detail X.

Figure 2 — Testing machine

4.3.4.2 **Sample holding jig** (see Figure 3), applying the load to the edge of the sample.

The sample is set at the centre of the upper and lower contact faces so that the whole load is applied in the plane containing the edge.

NOTE The contact faces are constructed so that the load is the only force applied to the sample.

4.3.4.3 **Load indicator**, capable of indicating the total load applied to the sample.

4.3.4.4 **Data recorder**, to which the testing machine is connected, and which, after commencement of application of the load to the sample, provides a recording of the total load applied to the sample as a function of time.

Although it is conventional to use a paper-strip (chart) recorder, other devices may be utilized. If a paper-strip recorder is used a minimum paper speed of 1 cm/s is recommended.