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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.

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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*

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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.