
**Ophthalmic optics — Contact lenses
and contact lens care products —
Cytotoxicity testing of contact lenses
in combination with lens care solution
to evaluate lens/solution interactions**

*Optique ophtalmique — Lentilles de contact et produits d'entretien
des lentilles de contact — Essais de cytotoxicité des lentilles de
contact en association avec une solution d'entretien des lentilles de
contact pour évaluer les interactions solution/lentille*

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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).

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For an explanation on 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.

The committee responsible for this document is ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

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Ophthalmic optics — Contact lenses and contact lens care products — Cytotoxicity testing of contact lenses in combination with lens care solution to evaluate lens/solution interactions

1 Scope

This International Standard describes an in vitro test method to assess the potential cytotoxic effects that may arise due to interaction of contact lenses with contact lens care solutions.

NOTE The potential of a contact lens or a contact lens care solution to cause cytotoxicity by itself can be evaluated in accordance with general guidance in ISO 10993-5.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

3 Terms and definitions

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

3.1

room temperature

temperature defined as 18 °C to 25 °C

4 Principle

The chemicals in a lens care solution can cause cytotoxic effects by direct contact with ocular tissues or by indirect contact through contact lenses. Uptake of the care product preservative or other solution ingredients by the lens and subsequent release of these chemicals in the ocular environment can compromise ocular biocompatibility. The potential interactions between a lens care product and various contact lens materials should be taken into account in designing the tests to fully evaluate the cytotoxicity potential of a new contact lens or a lens care product.

5 Direct contact cytotoxicity test for lens/lens care solution combination

5.1 General

The following protocol describes the test method for evaluating potential cytotoxic effects of contact lenses exposed to contact lens care solution. The cytotoxicity can result from contact lens/lens care solution interactions.

With the exception of daily disposable contact lenses, the potential interaction of a new contact lens with marketed representative multipurpose solutions to produce cytotoxicity shall be evaluated.