Health Canada Santé Canada

GUIDANCE DOCUMENT

Safety and Effectiveness Requirements for Contact Lens Disinfectants (2018)

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Health Products and Food Branch

Canada

Our mission is to help the people of Canada maintain and improve their health. *Health Canada*	The Health Products and Food Branch's mandate is to take an integrated approach to the management of the risks and benefits to health related products and food by: • minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and • promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. *Health Products and Food Branch*

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FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document ***may be*** acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents.

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1. INTRODUCTION

This guidance document outlines the information considered necessary to support the safety and effectiveness of contact lens disinfectants, which are regulated as medical devices under the *Medical Devices Regulations.*

The safety and effectiveness requirements specific to high-level disinfectants and sterilants for use on reusable semi-critical and critical medical devices, are addressed in the guidance document on *Safety and Effectiveness Requirements for High-Level Disinfectants and Sterilants for use on Reusable Semi-Critical and Critical Medical Devices* (2017).

1.1 Policy Objectives

The objective of this guidance document is to provide applicants of contact lens disinfectants the necessary information to comply with the *Medical Devices Regulations*.

1.2 Policy Statements

Applicants must provide Health Canada with sufficient information to support the safety, effectiveness and quality of a disinfectant device when used in accordance with the label's recommended conditions of use before market authorization can be granted.

Health Canada must evaluate this information and determine whether a medical device licence should be issued.

1.3 Scope and Application

This guidance document applies to products regulated as medical devices under the *Medical Devices Regulations* that are represented for use as contact lens disinfectants.

All contact lens disinfectant applications must also meet the labelling requirements set out by the *Medical Devices Regulations.*

2. GUIDANCE FOR IMPLEMENTATION

The effectiveness and safety requirements in this guidance document are not exhaustive and other appropriately validated test methods and protocols may be acceptable (e.g., those published by standards organizations or recommended by other international regulators). As the requirements and protocols within this guidance document are modelled on those recommended by the United States Food and Drug Administration (U.S. FDA), applicants are encouraged to additionally reference the U.S. FDA premarket notification 510(k) submission document:

- *Guidance for Industry: Premarket Notification [510(k)] Guidance Document for Contact Lens Care Products* (1997)

Applicants are encouraged to contact Health Canada in advance of submitting an application to determine the specific data requirements that may be considered necessary.

2.1 Effectiveness Requirements

The information in this section provides applicants with the effectiveness data requirements considered necessary to support a contact lens disinfectant.

2.1.1 Test Organisms

In order to receive market authorization for a contact lens disinfectant, applicants are required to submit data to support the effectiveness of the product against all of the following microorganisms: *Staphylococcus aureus* (ATCC 6538), *Pseudomonas aeruginosa* (ATCC 9027), *Serratia marcescens* (ATCC 13880), *Candida albicans* (ATCC 10231), *Fusasium solani* (ATCC 36031), and *Acanthamoeba sp.* (e.g., trophozoites and cysts of *A. castellannii* or *A. polyphaga*).

Currently Health Canada is not aware of any validated standard test methods for testing the effectiveness of contact lens disinfectants against *Acanthamoeba sp.*, however the representative species have been selected based on their clinical relevance for causing amoebic keratitis and therefore Health Canada encourages applicants to conduct effectiveness testing using these representative species. Applicants should provide a scientific rationale for the validation of proposed supporting data for effectiveness against *Acanthamoeba sp.*

2.1.2 Recommended Test Method

The ISO 14729 protocol is recommended for efficacy testing to support a contact lens disinfectant. This protocol includes the consideration that the antimicrobial activity of a contact lens disinfectant is aided by lens rubbing and rinsing regimens, and therefore consists of two parts to evaluate the relative effectiveness of a contact lens disinfection system. These include:

a) **Stand Alone Test**: evaluates the intrinsic antimicrobial activity of a contact lens disinfectant solution, through the addition of test product to an inoculum over a specified regimen soak time; and

b) **Regimen Test**: evaluates the antimicrobial effectiveness of the entire regimen described in the product labelling (e.g., rubbing, rinsing, and soaking), through the measurement of the recovery of microorganisms from inoculated carriers (i.e., contact

lenses) subjected to the regimen. The lens types and numbers tested should be representative of those for which the regime is intended to be used (e.g., hydrophilic and/or hydrophobic lenses).

The basic principle of the ISO 14729 protocol is that if a test product meets primary performance criteria using the Stand Alone Test then additional testing using the Regimen Test is not considered necessary, given that the test product alone would have exhibited a high level of antimicrobial activity without the additional step of evaluating the effectiveness of the entire regimen described in the product labelling (i.e., the addition of the rubbing and rinsing step).

The following performance criteria are applicable to contact lens disinfectant effectiveness testing using the ISO 14729 protocol, and are summarized in Appendix 2.

2.1.2.1 Stand Alone Test: Primary Performance Criteria

The primary performance criteria must be achieved in order for the Stand Alone Test alone to be considered valid to support the effectiveness of a contact lens disinfectant include:

- For bacteria: A minimum 3 $\log_{10}$ reduction is required at regimen soaking time for each bacterial species; and
- For fungi: A minimum 1 $\log_{10}$ reduction is required at regimen soaking time for each fungal species.

For test products that do not meet these primary criteria, the Regimen Test must be used to evaluate the effectiveness of the test product when the entire regimen described in the product labelling (e.g. rubbing, rinsing, and soaking) is followed.

2.1.2.2 Stand Alone Test: Secondary Performance Criteria

For products which meet the primary performance criteria of the Stand Alone Test, the following secondary performance criteria must also be met as a qualification to proceed with the Regimen Test:

- For bacteria: A minimum 1 $\log_{10}$ reduction at regimen soaking time is required for each bacterial species, and the sum of the average log reductions for the three challenge bacteria must equal 5 $\log_{10}$ or more; and
- For fungi: Stasis must be demonstrated at regimen soaking time for each fungal species, $\pm$ 0.5 $\log_{10}$.

For test products that do not meet these secondary criteria, the Regimen Test should not be conducted as the test product is considered to have failed to demonstrate a sufficient level of antimicrobial activity to support its use as a contact lens disinfectant.

2.1.2.3 Regimen Test: Performance Criteria

The performance criterion required for the Regimen Test to be considered valid is:

- An average regimen recovery count for each microbial species and batch tested of no more than 10 colony forming units (CFU) for each contact lens type/disinfectant combination.

2.1.3 Batch Replication Requirement

Testing against 3 samples of the test product, representing 3 separately compounded batches per microorganism as specified in the ISO 14729 test method is required. All 3 batches should be formulated at or below the lower active ingredient limit.

2.1.4 Testing of Product Effectiveness at the Proposed Shelf-Life

Unless otherwise prescribed in the ISO 14729 protocol, the effectiveness of a contact lens disinfectant should be evaluated under "worst-case" conditions in order to establish that the product will remain effective for the duration of the shelf life (i.e., by conducting testing using batches which have been formulated at or below the lower active ingredient limit and aged to the limit of the product's proposed shelf life).

In the absence of real-time aged samples of the test product, effectiveness testing using at least one accelerated batch of the product (i.e., where the test product is stored at an elevated temperature and relative humidity for a defined number of days) is acceptable to estimate the effectiveness of the product at the end of the shelf life. In general, effectiveness testing conducted with an accelerated batch which is at least 60 days old is considered to estimate a 1-year shelf-life stability.

2.1.5 Organic Burden

The addition of a representative soil load (e.g., composed of bovine serum and inactivated *Saccharomyces cerevisiae* yeast cells to simulate tears) to the test inoculum for the Regimen Test is recommended.

2.1.6 Good Laboratory Practice

Efficacy testing should be conducted in accordance with Good Laboratory Practice (GLP) principles endorsed by Health Canada to ensure that the data is of high quality and reliable. Acceptable standards include those published by the Organisation for Economic Co-Operation and Development (OECD), and the United States Environmental Protection Agency (U.S. EPA), and the United States Food and Drug Administration (U.S. FDA). Applicants should reference the following guidance document for information on providing evidence to Health Canada that efficacy studies adhere to the principles of Good Laboratory Practice:

- *Guidance Document Non-Clinical Laboratory Study Data Supporting Drug Product Applications and Submissions: Adherence to Good Laboratory Practice*

2.1.7 Efficacy Data Reporting

Efficacy data submitted should be presented in a report format, and should include the following information:

- The identification of the testing laboratory or organization (i.e., the name and address) and the dates on which the study was initiated and completed, terminated or discontinued;
- A statement of Good Laboratory Practice (GLP) compliance;
- The test method used, and any deviations or modifications made to the standard test parameters or methodologies;
- For alternate test methods not expressly recommended by Health Canada (i.e., for in-use testing or simulated-use testing), complete testing protocols should be submitted, including an overview of the materials and procedures employed in testing;
- The test organisms used, including identification of the specific strain and stock supplier (e.g., the American Type Culture Collection identifier);
- The product name or identification number, and the number of batches tested;
- The concentration of the active ingredient(s) for each batch tested, and if any were aged or stressed, for how long and under what conditions;
- For products that are diluted from a concentrated formulation, how the dilution was prepared;
- The level of water hardness used in the test, if the test product was diluted;
- The type and level of soil load used in the test;
- The initial inoculums of the test organisms;
- The number and type of carriers or replicates used in the test;
- The identification of all material or procedural options employed, where such choice is provided for or recommended in the test method selected (e.g., growth media,

drying time for inoculated carriers, neutralization confirmation and/or subculture media, secondary sub-culturing);
- The test exposure conditions used in the test (i.e., contact time, temperature, and relative humidity);
- The inoculum counts or carrier counts required to validate the test;
- Any control data essential to establish the validity of the test;
- An overview of the statistical plan and assumptions for analyzing the data;
- The raw data obtained, in tabular form (i.e., the numerical test results obtained through the study should be submitted for assessment; the submission of test summaries alone is not considered acceptable) and;
- A conclusion, describing whether the product meets the specific performance criteria relative to the test method(s) employed.

2.1.8 Neutralization

Neutralization procedures should be employed at the completion of the contact time for all efficacy tests in order to preclude residual effects of the active ingredients in the subculture medium. Health Canada recommends the ASTM E1054 method be used to validate the neutralizers used for disinfectant tests for all microorganisms except for viruses.

2.2 Safety Requirements

The information in the following sections provides applicants with the safety data requirements considered necessary to support a contact lens disinfectant.

For contact lens disinfectant formulations which contain active or inert ingredients which have been previously characterised physically and toxicologically for their represented uses in disinfecting contact lenses, the submission of existing compatibility testing and toxicity data as adequate evidence to establish its comparative safety with a Canadian reference product (i.e., a marketed predicate contact lens disinfectant) may be considered acceptable. Additionally, where appropriate the submission of a supporting scientific rationale based on the extrapolation of published hazard potentials(s) for similar formulations (e.g., from scientific literature references) may be considered acceptable.

2.2.1 Material Compatibility

Products used to reprocess contact lenses have the potential to cause damage or lead to deterioration of the lenses, and therefore the assessment and evaluation of the potential for detrimental interactions between contact lens disinfectants with lenses and lens cases is required, including:

- Data demonstrating the compatibility of a contact lens disinfectant with any specific types of lenses (e.g., soft contact lenses; rigid gas-permeable contact lenses; hydrophilic and/or hydrophobic lenses) that are indicated within the product's labelling. This data may be based on preclinical results and/or determined during the clinical testing phase.
- Data demonstrating the compatibility of a contact lens disinfectant with any specific types or brands of lens cases (e.g., a lens case with a neutralizer disk for hydrogen peroxide formulations) that are recommended or required for use with the product (i.e., used to store contact lenses in when they are not being worn).

Testing using the following protocol published by the International Organization for Standards (ISO) is recommended to evaluate the physical compatibility of contact lens disinfectants with contact lenses and for determining whether any observed changes are reversible:

- Physical compatibility of contact lenses & contact lens disinfectant (ISO 11981)

Testing using the following protocol published by the International Organization for Standards (ISO) is recommended to evaluate the potential for preservatives within a contact lens to be absorbed and released by the matrix of the contact lenses:

- Preservative uptake and release (ISO 11986)

2.2.1 Biocompatibility

The assessment and evaluation of the potential toxicity consequences resulting from the use of a contact lens disinfectant is required to determine the potential hazards associated with the use of product and to establish its comparative safety with a Canadian reference product (i.e., a marketed predicate contact lens disinfectant). Non-clinical testing using the following exposure endpoints is commonly required for contact lens disinfectant applications, and protocols published by the International Organization for Standards (ISO) or as specified within the United States Food and Drug Administration premarket notification 510(k) submission document for contact lens disinfectants are recommended:

- Ocular Biocompatibility (*in-vivo*)
  - Primary Ocular Irritation (ISO 10993-10)
  - 22-Day Ocular Irritation (ISO 9394)
- Dermal Sensitization (ISO 10993-10)
- Systemic Toxicity (acute oral) (FDA 510k) (ISO 10993-11)
- Cytotoxicity (*in-vitro)* (ISO 10993-5)

For contact lens disinfectants that form part of a disinfection system, the use of a neutralizing solution (e.g., the use of catalase for hydrogen peroxide formulations) or a specially designed lens case may be required (e.g., for hydrogen peroxide formulations)

to neutralize the irritating and toxic effects associated with residual product remaining on the lenses after soaking in the contact lens disinfectants. For these products, toxicity testing should be performed on the neutralized disinfection solution (i.e., spent solution).

2.2.2 Clinical Testing Requirements

The submission of clinical test data is required to establish the comparative safety of a proposed contact lens disinfectant with a Canadian reference product (i.e., a marketed predicate contact lens disinfectant). Applicants are expected to conduct non-clinical tests first to demonstrate that human subjects can use a device safely in a clinical trial.

Applicants should ensure that claims of substantial equivalence of safety using clinical testing directly compare the type of regimen (e.g., rub-and-rinse vs. no-rub) recommended for the proposed contact lens disinfectant, and that testing is conducted using the type of lenses (e.g., soft contact lenses; rigid gas-permeable contact lenses; hydrophilic and/or hydrophobic lenses) for which a contact lens disinfectant is recommended for use.

Health Canada recommends that the United States Food and Drug Administration (U.S. FDA) premarket notification 510(k) submission document for contact lens disinfectants be referenced for appropriate guidance on the recommended minimum numbers for the size and duration of a clinical study for a contact lens disinfectant. The recommended minimum numbers include:

- For contact lens disinfectants with claims of substantial equivalence based upon the same active ingredients in higher or lower concentrations or with different inactive ingredients, it is recommended that the clinical study involve at least 30 subjects followed for at least 1 month.
- For contact lens disinfectants with claims of substantial equivalence based upon new or different active ingredients, it is recommended that the clinical study involve at least 60 subjects followed for at least 3 months.

In addition to the clinical study guidances recommended by the United States Food and Drug Administration (U.S. FDA) in their premarket notification 510(k) submission document for contact lens disinfectants, applicants should reference the following standard published by the International Organization for Standards (ISO) for guidance on conducting clinical investigations of contact lenses:

- Guidance for Clinical Investigations (ISO 11980)

This ISO standard provides guidance on appropriate clinical study design; procedures for the evaluation of safety, physiological performance and the effects on ocular tissues; the evaluation of visual, refractive and lens performance; and subject acceptance criteria.

It is expected that a proposed contact lens disinfectant should demonstrate a risk-benefit profile which is comparable or better than the marketed predicate contact lens disinfectant. The following parameters should be evaluated during the clinical investigation:

- **Adverse reaction data**: including hazardous, sight-threatening conditions (e.g., corneal ulcers; severe corneal abrasion > 2 millimetre in diameter; iritis or other ocular infections or inflammations; corneal scarring; or permanent loss of vision);
- **Slit lamp findings**: including non-sight threatening events (e.g., giant papillary conjunctivitis; epiphora; dry eyes; and irritation) using an appropriate classification scale (e.g., which measures edema; corneal neovascularization; corneal staining; bulbar hyperemia; and palpebral conjunctival observations);
- **Symptoms/problems/complaints**: including subjective data on the test subject's comfort wearing the contact lenses, vision and handling with insertion and removal of contact lenses;
- **Visual acuity (VA) data**: distance acuity measurements should be taken at each visit with the test subjects in order to compare the visual acuities of the test subjects at the initial and final visits;
- **Average Wear Time (AWT)**: a tabulated report should be provided to test subjects to complete during the study, allowing for the number of hours or days, as appropriate for the type of contact lens, of wear time to be documented;
- **Discontinuations**: complete data should be provided on all discontinued test subjects, including the reason for discontinuation and visual status at their final visit; and
- **Lens Replacements:** for any test subjects that required lens replacement during the course of the study, the reason for the replacement should be tabulated to allow for trend analysis to be conducted.

3. EFFECTIVE DATE

This guidance document will come into effect immediately upon the date of publication. All disinfectant medical device licence applications received after the effective date are expected to be filed with the updated supporting data requirements.

APPENDICES

APPENDIX 1: REFERENCES

ASTM: *E1054 Method: Standard Test Methods for Evaluation of Inactivators of Antimicrobial Agents*. *In* Annual Book of ASTM Standards. USA; Current edition.

ISO (2009): International Organization for Standards. *10993-5: Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.* Geneva, Switzerland; 2009.

ISO (2009): International Organization for Standards. *10993-11: Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.* Geneva, Switzerland; 2009.

ISO (2009): International Organization for Standards. *11981: Ophthalmic optics - Contact lenses and contact lens care products - Determination of biocompatibility by ocular study with rabbit eyes.* Geneva, Switzerland; 2009.

ISO (2010): International Organization for Standards. *10993-10: Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity.* Geneva, Switzerland; 2010.

ISO (2010): International Organization for Standards. *11986: Ophthalmic optics - Contact lenses and contact lens care products - Determination of preservative uptake and release.* Geneva, Switzerland; 2010.

ISO (2010): International Organization for Standards. *14729: Ophthalmic optics - Contact lens care products - Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses.* Geneva, Switzerland; 2010.

ISO (2012): International Organization for Standards. *11980: Ophthalmic optics - Contact lenses and contact lens care products - Guidances for clinical evaluation.* Geneva, Switzerland; 2012.

ISO (2012): International Organization for Standards. *9394: Ophthalmic optics – Contact lenses and contact lens care products - Determination of physical compatibility of contact lens care products with contact lenses.* Geneva, Switzerland; 2012.

US FDA (1997): United States Food and Drug Administration. *Guidance for Industry: Premarket Notification [510(k)] Guidance Document for Contact Lens Care Products*. Office of Device Evaluation, Division of Ophthalmic, Ear, Nose and Throat Devices, Center for Devices and Radiological Health. USA; 1997.

US FDA (2010): United States Food and Drug Administration. *Guidance for Industry and FDA Reviewers: Contact Lens Care Products Labelling (addendum to the Guidance for Premarket Notification [510(k)] Guidance Document for Contact Lens Care Products)*. Office of Device Evaluation, Division of Ophthalmic, Ear, Nose and Throat Devices Center for Devices and Radiological Health. USA; 2010.

APPENDIX 2: EFFECTIVENESS TESTING CRITERIA FOR CONTACT LENS DISINFECTANTS

<table>
<tr><th>Claim</th><th colspan="2">Recommended Test Methods</th><th>Test Organisms</th><th>Number of Batches per Organism & Carriers per Batch</th><th>Inoculum Count or Carrier Count</th><th>Performance Criteria for Effectiveness</th></tr>
<tr><td rowspan="3">Contact Lens Disinfectant</td><td rowspan="3">ISO 14729</td><td rowspan="2">Stand Alone Test: evaluates the intrinsic antimicrobial effect of the test product</td><td rowspan="3">Staphylococcus aureus (ATCC 6538)
AND
Pseudomonas aeruginosa (ATCC 9027)
AND
Serratia marcescens (ATCC 13880)
AND
Candida albicans (ATCC 10231)
AND
Fusarium solani (ATCC 36031)

AND

Acanthamoeba sp. (e.g., trophozoites and cysts of A. castellannii or A. polyphaga)
• Testing using ISO 14729 has not been validated for this organism, therefore a scientific rationale for the validation of proposed supporting data is required</td><td rowspan="2">• 3 batches
• Carriers are not required.</td><td rowspan="2">Unless otherwise prescribed:
• The inoculum should be 1 x 10^5 - 1 x 10^6 CFU/mL</td><td>Primary Criteria:
• Regimen test NOT required if these criteria are met.
• Regimen test REQUIRED if product does not meet these criteria.

Bacteria:
• ≥ 3 $\log_{10}$ reduction

Fungi:
• ≥ 1 $\log_{10}$ reduction</td></tr>
<tr><td>Secondary Criteria:
• These criteria must be met as a qualification to proceed with the Regimen Test.
• If these criteria are not met, then TEST FAILED and do NOT proceed with the Regimen Test.

Bacteria:
• ≥ 1 log reduction for each bacterial species; and
• Sum of average log reductions for the three bacteria species ≥ 5 $\log_{10}$

Fungi:
• stasis ± 0.5 $\log_{10}$</td></tr>
<tr><td>Regimen Test: evaluates the antimicrobial effectiveness of the entire regimen (e.g., rubbing, rinsing and soaking)</td><td>• 3 batches
• Number of carriers and type prescribed in current version of test method.</td><td>Unless otherwise prescribed:
• The inoculum should be 1 x 10^5 - 1 x 10^6 CFU/carrier</td><td>For each microbial species and batch tested:
• An average recovery count of ≤10 colony forming units (CFU) for each lens type/disinfectant combination</td></tr>
</table>

APPENDIX 3: LABELLING CONSIDERATIONS FOR CONTACT LENS DISINFECTANTS

This section is intended to assist applicants in preparing appropriate labelling for contact lens disinfectants; however, these are **recommendations only**, and are **not** regulatory requirements. These labelling recommendations are not exhaustive, however they provide the information that minimally is recommended by Health Canada to address the regulatory requirement for clear and adequate labelling directions for use for contact lens disinfectants.

1.0 Types of Contact Lenses

The type of contact lenses (e.g., soft contact lenses; rigid gas-permeable contact lenses; hydrophilic and/or hydrophobic lenses) which are recommended to be reprocessed by the contact lens disinfectant should be specified on the label.

2.0 Types or Brands of Contact Lens Cases

The types or brands of contact lens cases which are recommended or required for use in combination with the contact lens disinfectant should be specified on the label (e.g., a lens case with a neutralizer disk for hydrogen peroxide formulations).

3.0 Formulations Requiring a Neutralization Step:

Any requirement for the use of a neutralizing solution (e.g., the use of catalase for hydrogen peroxide formulations) or a specially designed lens case (e.g., a lens case with a neutralizer disk for hydrogen peroxide formulations) to neutralize the irritating and toxic effects associated with residual product remaining on contact lenses after soaking in the contact lens disinfectant, where applicable, should be specified prominently on the label.

Statements to the effect of the following are considered appropriate by Health Canada to promote the safe use of contact lens disinfectants with hydrogen peroxide formulations:

- Always neutralize contact lenses before applying them to eyes; or
- Use only lens case provided with this product; and
- If disinfecting solution accidentally comes in contact with eyes, it may cause burning, stinging or redness. Remove lens(es) immediately and flush eyes with a large amount of water or sterile saline. If burning or irritation continues, consult eye care practitioner.

4.0 Products Represented for Use as a "Multi-Purpose Solution"

Contact lens disinfectants labelled as being a "multi-purpose solution" should have the potential for all of the following uses: cleaning, disinfecting, storing and rinsing contact lenses. Therefore,

a contact lens solution that cannot perform all of these functions should not be labelled as a "multi-purpose solution". Applicants should ensure that the labelling for these products specify adequate directions for all the intended uses of the product (e.g., rubbing and rinsing times for daily cleaning; soak times for disinfection; and maximum storage times following disinfection).

5.0 Requirement for "Rub and Rinse" Regimen

Applicants are encouraged to indicate "rub and rinse" instructions on the labelling of all contact lens disinfectants. These should include the "rubbing" step to pre-clean the lenses prior to disinfection; rubbing, rinsing and soak times to achieve disinfection; and the maximum period of time that a contact lens may safely be stored in the disinfectant solution. Statements to the effect of the following are considered appropriate by Health Canada to promote the effectiveness of contact lens disinfectants:

- Rub and rinse lenses for "X" seconds or more and then repeat with the second side; and
- Follow the complete recommended lens rubbing and rinsing times in the labelling to adequately disinfect lenses and reduce the risk of contact lens infection.

6.0 Hand Washing Requirement

The labelling for all contact lens disinfectants should include a requirement for the user to wash and dry their hands thoroughly before handling their contact lenses.

7.0 General Warning Statements

Statements to the effect of the following are recommended to be indicated on contact lens disinfectant labelling, as appropriate to the potential hazard:

- If irritation develops with the use of this product, discontinue use and consult eye care practitioner;
- Do not touch tip of the bottle to any surface since this may contribute to contamination of the solution;
- Always keep bottle tightly closed; and
- Always use fresh solution and discard after use. Do not reuse solution.