

**RESEARCH INSTITUTE OF EYE
DISEASES, RUSSIAN ACADEMY OF
MEDICAL SCIENCES (FGBU NIIGB
RAMN), FEDERAL STATE BUDGETARY
ENTERPRISE**

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APPROVED

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EXPERT OPINION

based on the results of a study of Sanitelle hand sanitizers for contact lens users (manufactured by Bentus Laboratories (Russia))

The customer (Bentus Laboratories, Russia) provided the Research Institute of Eye Diseases with the following for the tests of the aforesaid product:

- samples of Sanitelle hand sanitizers for contact lens users
- formulation
- Specification TU 9158-014-70297148-2010
- hydrogel soft contact lenses (SCL):
 1. Hilafilcon B 59%, FDA II (Soflens Daily Disposable, Baush+Lomb, USA)
 2. Nelfilcon A 69%, FDA II (Dailies Aqua Comfort Plus, Alcon - Ciba Vision)
 3. Etafilcon A 58%, FDA IV (1-Day Acuvue Moist, Johnson&Johnson, USA)
- silicon-hydrogel soft contact lenses:
 1. Belafilcon A 36%, FDA III (Pure Vision2, Baush+Lomb, USA)
 2. Senofilcon A 38%, FDA I (Acuvue Oasys, Johnson&Johnson, USA)
 3. Lotrafilcon A 24%, FDA I (AirOptix Night&Day, Alcon - Ciba Vision)
- multi-purpose solution for SCL – ReNu Multi Plus, Baush+Lomb, USA
- Rewetting Drops OptiFree, Alcon, USA

The Institute tested the product to confirm its consumer properties with regard to the safety of the conjunctiva and contact lenses during long-term application, and prepared reports based on the test results.

Background.

Sanitelle hand sanitizers for contact lens users are ready-to-use products in the form of transparent colorless liquid with a characteristic odor of ethyl alcohol. Active substances are ethyl alcohol 66.2%, deionized water, Vitamin E, Aloe Vera and functional additives.

The product is manufactured in 10 mL polymer bottles.

The product shelf life is 3 years (36 months) when stored in the intact packaging.

Sanitelle hand sanitizers for contact lens users are intended for hand sanitizing.

The test results are sufficient to make the following conclusion.

1. No destructive effect of the product on contact lenses during long-term application was revealed, i.e.: there were no changes in the optical or physical parameters as well as position of soft contact lenses; there may be residual quantities of the product on the skin surface but they do not disturb the skin structure; the product leaves no fatty film on the hands or lens surface;

biomicroscopy revealed no depositions on the surface of soft contact lenses; the product does not affect the lens shelf life.

2. No conjunctiva or corneal dyeing was observed (with the use of dyers or dyeing test strips) based on the Efron scale:

- a) immediately after the contact lenses have been put on
- b) two hours after the contact lenses have been put on

3. There is no irritating effect on the conjunctiva provided the recommendations specified in the directions for use are complied with, i.e.: in case of a contact with the conjunctiva, residual quantities of the product on the skin surface do not produce subjective sensations for the lens user such as lacrimation, cutting, dryness or any other discomfort in the eye area.

4. There is no need to wash away the liquid with water or wiping hands with a tissue after the product has been used.

The recommendations given in the (package) Label on Sanitelle hand sanitizers for contact lens users are reasonable.

The test results for Sanitelle hand sanitizers for contact lens users (manufactured by Bentus Laboratories (Russia) prove that the product is highly efficient and safe when used as directed, and confirm the declared consumer properties with regard to the safety for the conjunctiva and contact lenses during long-term application.

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