

MAINTENANCE SYSTEM FOR ALL TYPE OF SOFT CONTACT LENSES

It is a complete product for the maintenance of soft contact lenses. The product is especially suitable for wearers of disposable soft contact lenses and for anyone with sensitive eyes.

This Multi-purpose Solution rinses, cleans, disinfects and lubricates any type of hydrophilic contact lens:

1. It can rinse a soft contact lens because it is a saline solution that has been correctly adjusted to the pH and tonicity of the tear, and because it contains a group of water-soluble polymers that are perfectly tolerable to the human eye, as we have demonstrated in a clinical trial with a group of voluntary patients.
2. It can disinfect a soft contact lens in eight hours (overnight) because its composition contains PHMB (polyhexamethylenbiguanide), an agent that acts against bacteria, fungi and yeasts in extremely low concentrations. The advantage of this molecule is its
3. large structural size and large molecular weight, which hinder it from entering the matrix of the lens and thus prevent it from accumulating.
3. It can clean a contact lens because it contains a surface-active cellulose polymer that
4. helps to remove the deposits from the contact lens when you rub the lens with a finger. The mechanical friction caused by the finger is essential because it allows the surface-active agent to bind to the deposit, forming a micelle that breaks free from the lens, and thus the deposit disappears.

Figure 1 . Cleaning . Forming of micelles.

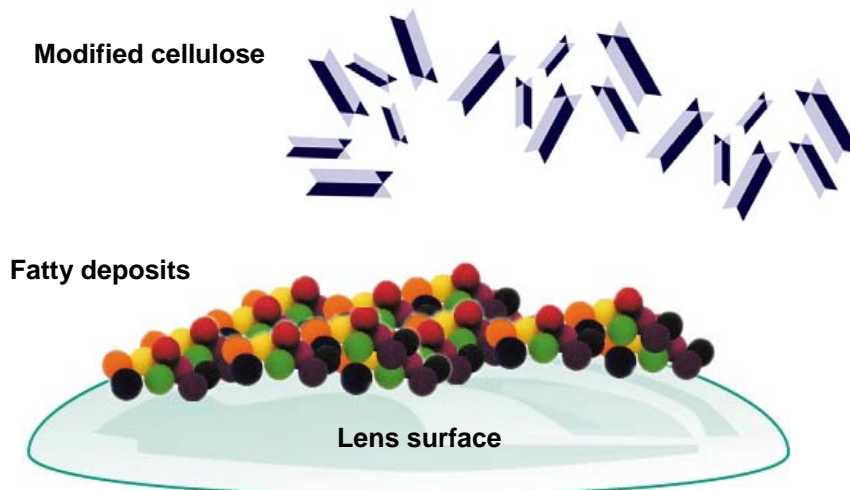
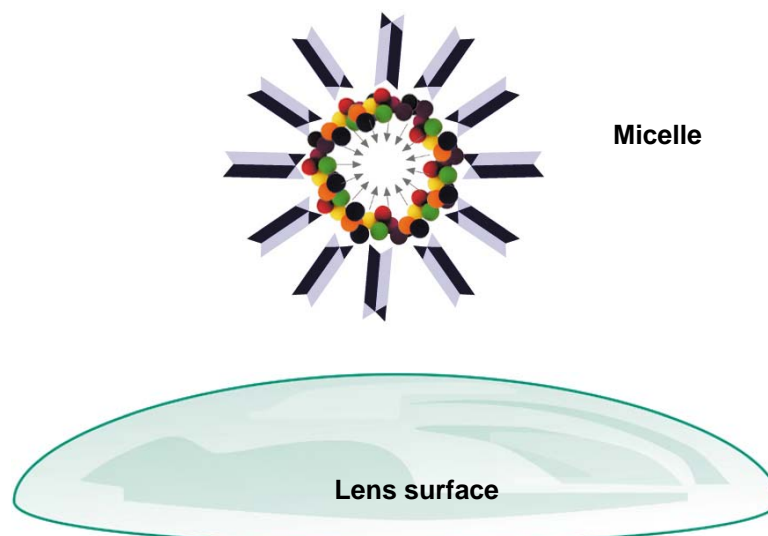


Figure 2 . Solvation



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It can lubricate a lens because it contains polyvinylpyrrolidone and hydroxyethylcellulose, wetting agents that are used to increase eye comfort. Both substances leave a coat on the surface of the lens that reduces friction between the lens and the cornea.

Clinical studies

The clinical and primary eye tolerance studies confirm the excellent tolerance of the formula:

- In the eye tolerance test the product is classified as non-irritating with a mean index of zero for the conjunctiva, iris and cornea.
- The clinical study of fifty patients at seven optician's demonstrated the high level of acceptance of the product. The results demonstrate that the preparation is suitable for its function. The majority of the patients noted full tolerance of the preparation after three months of continuous use. Only two of the fifty voluntary users rejected the product.

It was verified that 75% of the users used enzymatic cleaners on a weekly basis, as was recommended at the start of the study. 10% did not use enzymatic cleaners during the test and the remaining 15% did not know how often they used enzymatic cleaners.

Forty-eight voluntary users (96%) tolerated the multi-purpose solution perfectly (opinion A = acceptable or VC = very comfortable) and 40% of them actually said that the system was very comfortable (VC).

Studies of the disinfecting strength

PHMB (Polyhexamethylenbiguanide) is a wide-spectrum antimicrobial agent. The amount of preservative that is needed depends on the characteristics of the product in which it is to be used. We have proven that the PHMB content in this Multi-purpose Solution is enough to guarantee the properties of the product during its two-month lifetime, once the container has been opened, and inhibits the growth of microorganisms in the soft contact lenses while they are in the Multi-purpose Solution.

The **following results** were obtained in the studies of different microorganisms:

Microorganism	Time (hr)
Staphylococcus aureus	4 *
Pseudomona aeruginosa	4 *
Serratia marcescens	3 *
Cándida albicans	5 **
Aspergillus	4 **

* time to reduce in a 99.9% the microorganism

** time to reduce in a 90.0% the microorganism

