

## A MULTIPURPOSE SOLUTION FOR ALL TYPES OF SOFT DISPOSABLE CONTACT LENSES, SPECIALLY FOR DISPOSABLE CONTACT LENSES

At **Disop**, we have developed a formula capable of keeping lenses brand new without using any other products. Enzymatic cleaning is not necessary, given that the formula is capable of removing daily protein deposits.

It rinses, cleans, disinfects, preserves and lubricates disposable contact lenses.

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 surface-active agent that is perfectly tolerable to the human eye, as we have demonstrated in a clinical trial with a group of voluntary patients.

It can disinfect a soft contact lens in six 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 large structural size and large molecular weight, which hinder it from entering the matrix of the lens, in this way eliminating the toxicity potential and sensibility reactions.

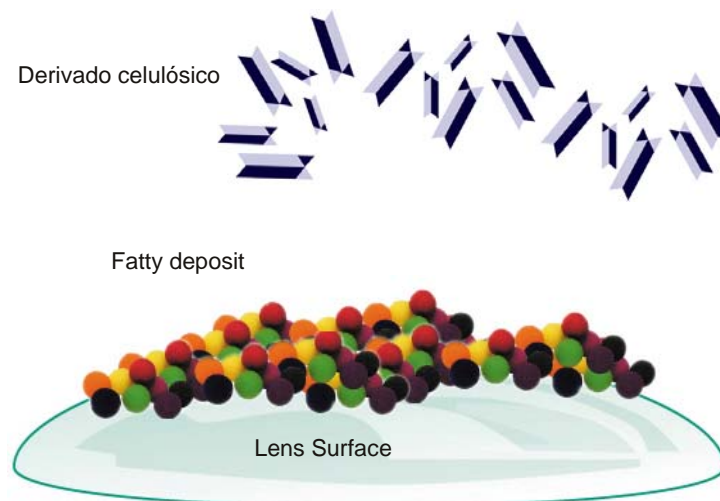
**PHMB** selectively attacks the cell walls of the microorganisms, not having any effect on the cell walls of the ocular structure.

It can clean a contact lens because it contains a surface-active cellulose polymer that helps to remove the deposits from the contact lens when you rub the lens with a finger.

The surfactant used is a copolymer of ethylene oxide - polypropylene oxide, characterised by a null toxicity level. Similar to the conservant, the surfactant has a high molecular weight preventing the accumulation of the product within the contact lens, eliminating the potential risk of eye irritation.

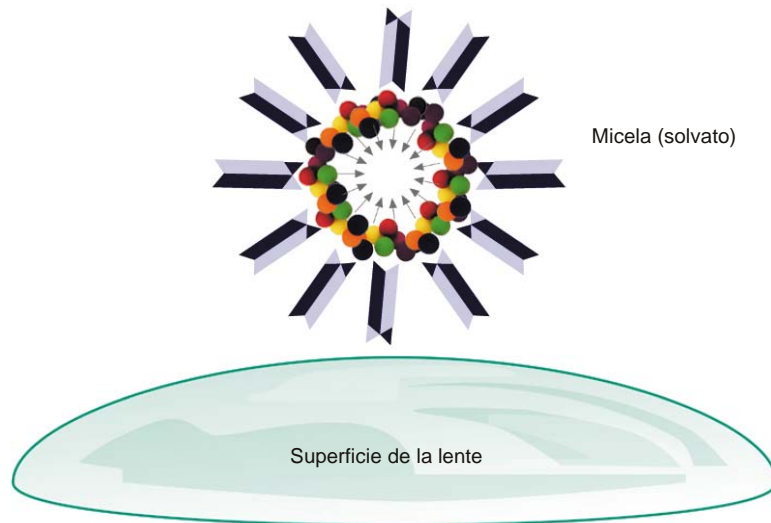
The action mechanism consists of the union of the surfactant with the deposit, the hydrophobic centres (apolar centre, repelling the water), forming a micelle which stabilises in water through the negative charges of the hydrophilic centres (polar) of the surfactant. In this way, as the lens is rubbed, the deposit is gradually transferred from the lens surface to the liquid medium.

**Fig. 1. Cleaning fatty deposits. Micelle formation.**



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2º Solvatación

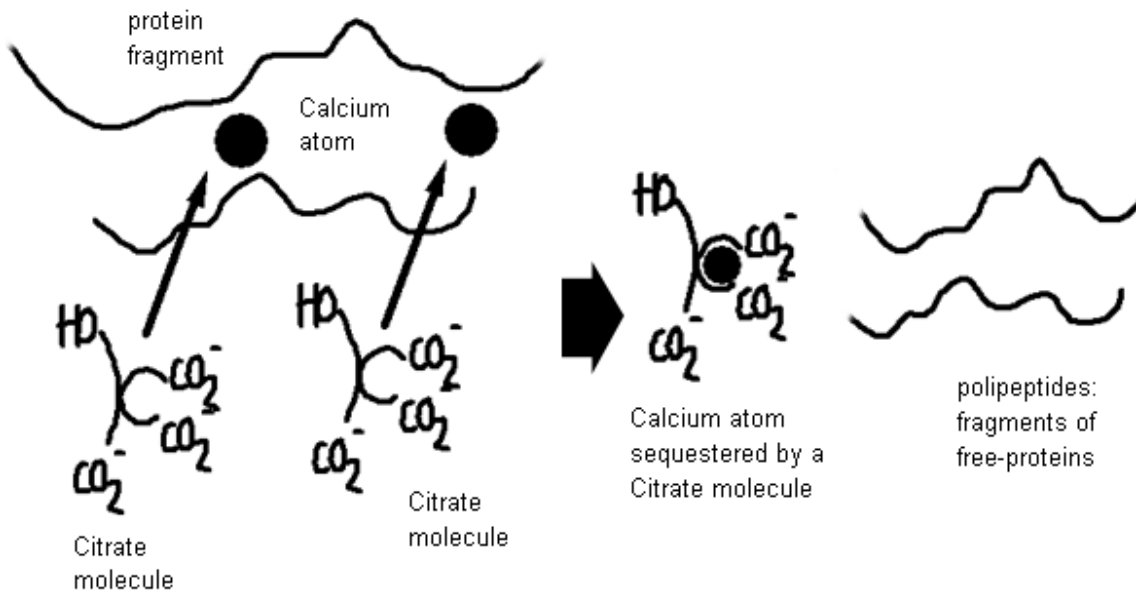


The protein deposits on a contact lens can be cleaned using sodium citrate, a multifunctional, negatively-charged molecule which is capable of interacting with the calcium and of preventing the protein chains from bonding. Hence, the deposits are broken down and readily released from the lens surface to then be trapped in the liquid medium due to the cleansing action of surface-active agent. In this case, no mechanical friction is necessary (NO RUB).

Sodium citrate is a metabolite found in the organism and is thus characterised by a null toxicity level.

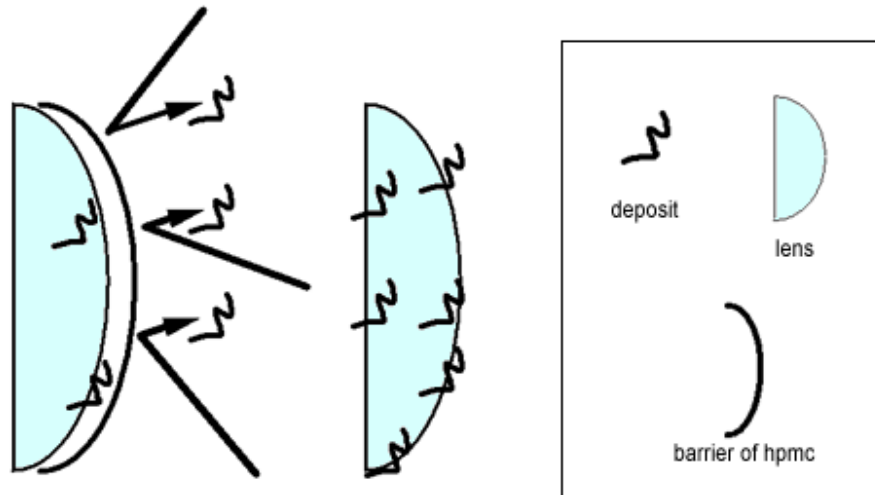
The action mechanism consists of the following:

The protein chains usually stabilise on the lens surface, electrostatic bonds being formed between the protein chains and the lens surface by way of calcium atoms (positively-charged). These bonds are known as links. Citrate is a negatively-charged molecule which has a great affinity for calcium. When the citrate bonds with the calcium, the links break into fragments of protein chains readily soluble by the presence of the surface-active polymer.



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A lens can be lubricated due to hydroxypropylcellulose (Hpmc). The product is linked to the contact lens surface through hydrogen bonding. This link is very intense and remains for a long time, such that the lens has a very high wetting degree during the useful life of the lens. This elevated wetting, besides efficiently stabilising the tear on the lens, physically shields the lens from deposits.



### 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 five 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. None of the fifty voluntary users rejected the product.

The results of the study revealed that this product is tolerated very well, the

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.

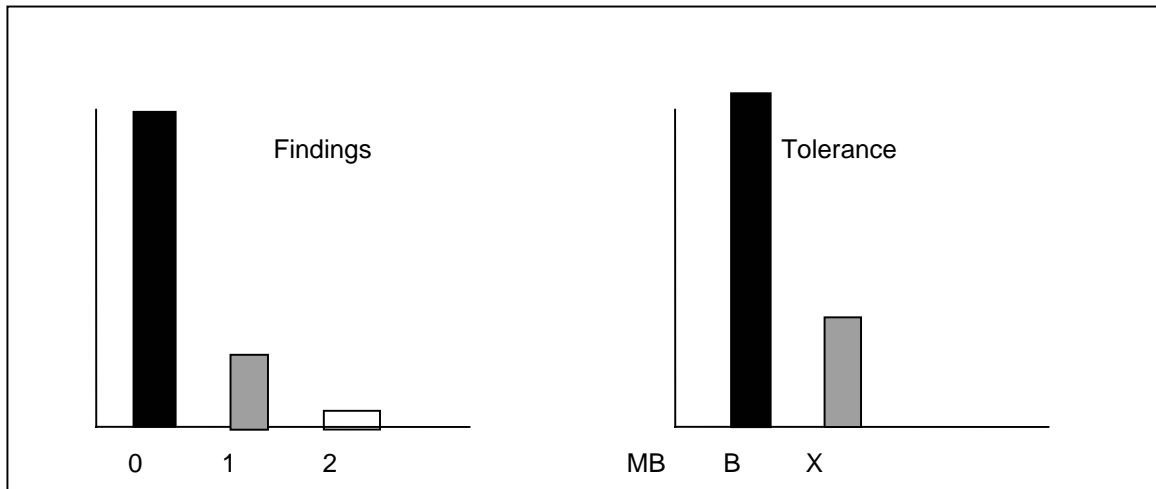
The study results showed that the product is tolerated very well. Examination with the slit lamp detected 15% findings (7), of which the majority (6) were considered negligible since the evaluation was 1 (very slight).

The only noticeable result (value 2) corresponded to a patient who had a tendency towards conjunctival hyperaemia even before the study. His tolerance to the product was good.

74% of the patients (37) had a very good tolerance, 26% a good tolerance.



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Regarding the subjective evaluation of the patient at the end of the test, 40% considered the product optimum, and 60% considered it good.

The examination of the lenses revealed that in no case did the condition of the contact lens worsen during the test period as compared to its starting condition. This fact proves cleaning with enzyme tablets to be unnecessary.

With respect to the wetting properties of the hydroxypropylcellulose, it was shown that it suitably wets and lubricates the lens at night time (when leaving the lenses submerged in the lens case), since during the examinations, neither symptoms of fuzzy vision, nor the sensation of dryness appeared, being the typical symptoms of tear rupture provoked by the lack of wetting of the contact lens.

The effect the product had over one patient, should be remarked, since his problem of feeling initial dryness (value 2 = sensitive), gradually decreased and disappeared in the final examination after three months; and the determination of a patient to substitute the comfort drops for this product.

### Studies on Disinfecting Capacity

PHMB (Polyhexamethylenebiguanide) is a wide spectrum anti-microbial agent. The amount of preservative required depends on the characteristics of the product where it is going to be used. We have verified that the PHMB content in this solution is sufficient to inhibit the growth of microorganisms when soft contact lenses are submerged in the Multipurpose Solution .

In the studies performed on different microorganisms, the following results were obtained:.

<u>Microorganism</u>	<u>Reduction after 6 hours (value D)</u>
Pseudomona aeruginosa	4.0
Serratia marcescens	4.0
Staphylococcus aureus	4.5
Candida albicans	1.5
Fusarium solanii	4.0

### The action mechanism of the preservative is as follows:

Due to the positive charge of the conservant, an attraction is produced towards the bacteria surface, which is linked to the molecule through the cell wall. The conservant molecule can overcome the exclusion mechanisms of the cell wall and destroy the cytoplasmatic membrane with the resulting irreversible loss of the macromolecular components, for example, nucleotides

