

Ophtecs

cleadew
ADVANCED CARE SYSTEM



Ophtecs

Works with all soft contact lenses

cleadew
ADVANCED CARE SYSTEM



FEATURES

1. Strong disinfectant efficacy due to Povidone iodine

The component povidone iodine is a broad spectrum antibacterial disinfectant, and it exhibits strong disinfectant efficacy not only against the stand-alone standard strain as defined by ISO 14729 but even against clinical isolates and *Acanthamoeba* that are resistant to disinfectants.

Benefit for patient

The risk of development of ocular infection can be reduced.

2. Excellent cleaning efficacy due to proteolytic enzyme

Protein contamination adhering to the lenses is strongly disintegrated, and the lenses are cleared by incorporating the cleaning component proteolytic enzyme in the two-layered tablet.

Benefit for patient

Contact lenses can be worn with comfort.

3. Highly safe for the eyes

The incorporated povidone iodine concentration is safe for the corneas and conjunctivae. It has been confirmed that the compatibility with Silicone Hydrogel Contact Lenses is extremely good.

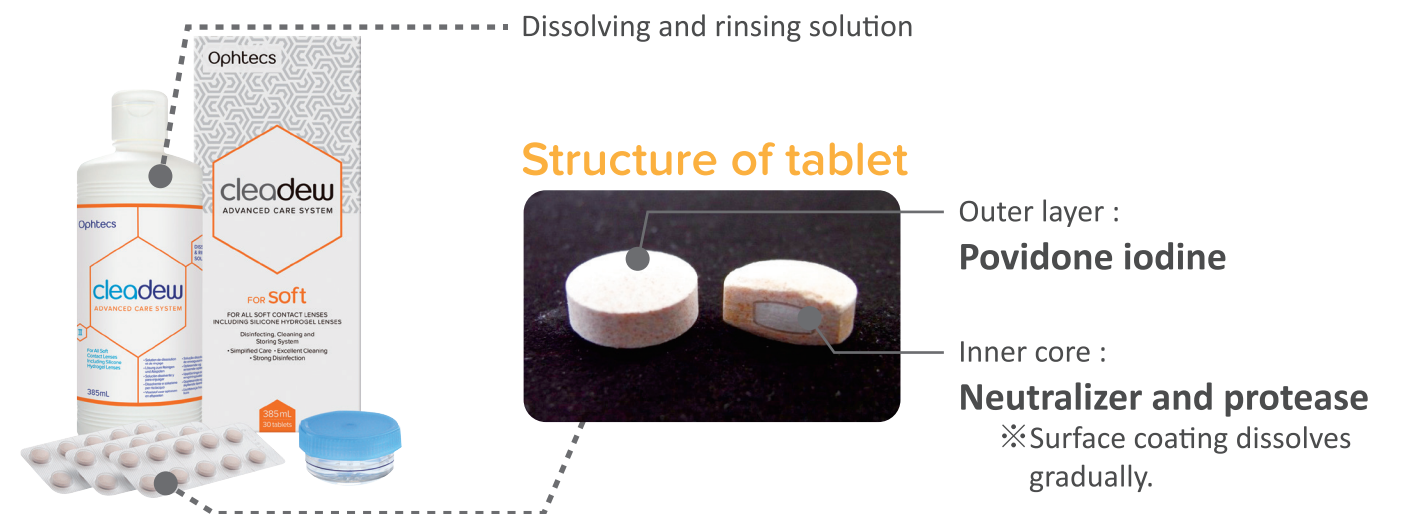
Benefit for patient

It can be used safely in all frequent replacement soft contact lenses.

Simple and easy cleadew usage method

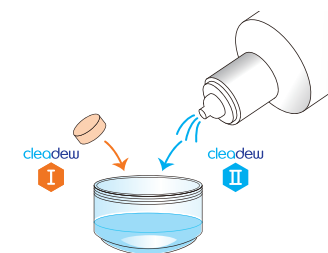
Tablet and liquid formulation are inserted in the lens case, it is left to stand, and it can be worn if rinsed lightly after 4 hours. Since disinfecting, cleaning, and neutralization are carried out automatically, improper use by forgetting the neutralization does not occur. The liquid displays an orange color when disinfecting and progress in care can be visually confirmed.

cleadew product lineup



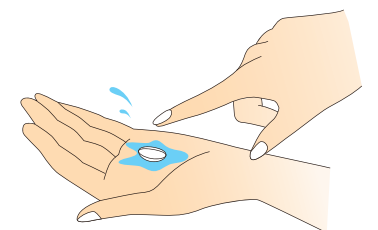
Usage

Insert the lens, put the disinfecting/neutralizing tablet and the dissolving and rinsing solution in the case up to the marked line and close the cover.



Remove the lens, and after rinsing with dissolving and rinsing solution, it is ready to wear.

* For removing the contamination degraded material and destroyed bacteria, be sure to carry out the rinsing operation.



Color changes



Neutralizing



When the color changes from orange to clear, disinfection is complete. After that, the protease cleans the lenses.

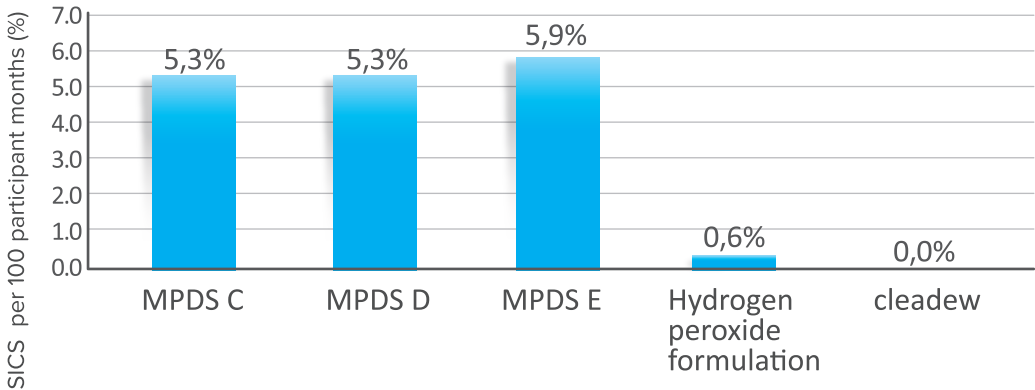
3. Highly safe for the eyes

Povidone iodine used in cleadew is used in a concentration that is safe for corneas and conjunctivae. Moreover, after neutralization, since lenses are worn after rinsing with the accompanying dissolving/ rising solution, the possibility of entry of the disinfecting component entering the eye is extremely low. The compatibility with Silicone Hydrogel Lenses is also good, and it can be worn with comfort.

Reduction in the risk of occurrence of corneal staining

As for the safety of the corneas and conjunctivae in the case of cleadew, when compared to other MPDS, it is clear that the rate of solution-induced corneal staining (SICS) is significantly low ($p \leq 0.011$). In addition, the rate is even lower than hydrogen peroxide formulation, and it has been confirmed that the safety of the corneas and conjunctivae is extremely high.

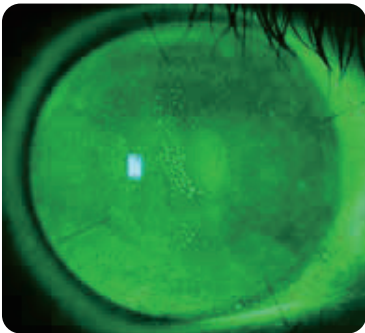
Rate of solution induced corneal staining



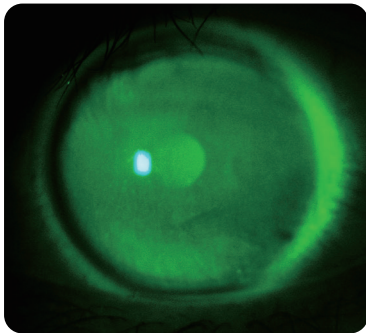
(Mark Willcox. cleadew for existing daily wear soft contact lens wearers. University of New South Wales, 2016)

Product is suitable even for Silicone Hydrogel Lenses

Since biological compatibility is high for povidone iodine, and it is automatically neutralized, the disinfecting component does not enter the eyes directly. Hence, it has been confirmed that even the effect on corneal epithelial cells is low and pathogenesis of superficial punctate keratitis (SPK) can be controlled.



PHMB based MPDS



cleadew

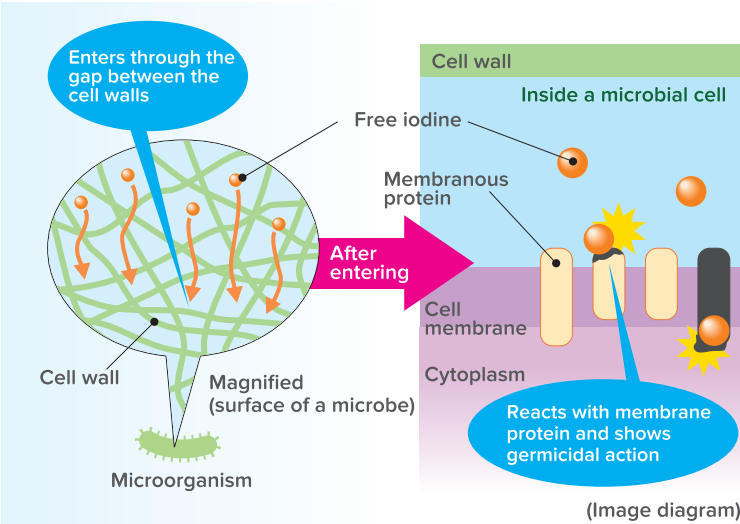
Testing method:
Treat balaafilconA lenses with cleadew and MPDS respectively. 16 hours later, wore the lenses and observed 2 hours later.
(Ophtecs company data)

1. Strong disinfectant efficacy due to povidone iodine

The disinfecting component povidone iodine has a wide antibacterial spectrum, and microorganisms adhering to the contact lenses are effectively destroyed by cleansing.

Disinfection mechanism of Povidone iodine

H_2OI^+ that is generated by oxidation of water by free iodine shows the bactericidal action by reacting with the membranous protein (-SH group, tyrosine, histidine) of bacterial and viral surface.



Povidone Iodine has a strong effect not only against stand-alone test (ISO 14729) bacteria but also against clinical isolates (planktonic bacteria/adhering bacteria)

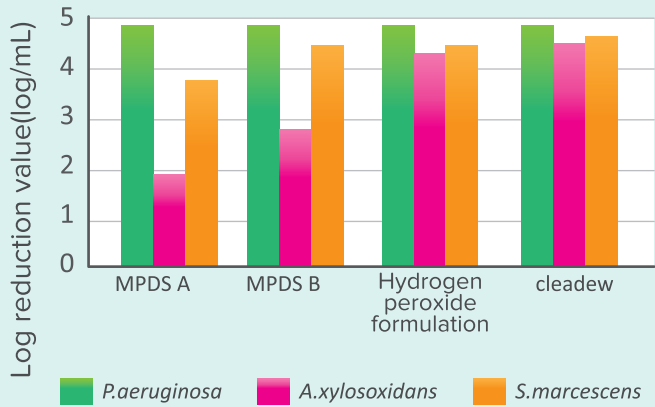
Povidone iodine exhibits strong disinfectant efficacy not only against the standard strain but also against clinical isolates. In addition to Planktonic bacteria, Adhering bacteria that are hard to be destroyed by cleansing can also be destroyed.

◆ Stand-alone test bacteria (standard strain)

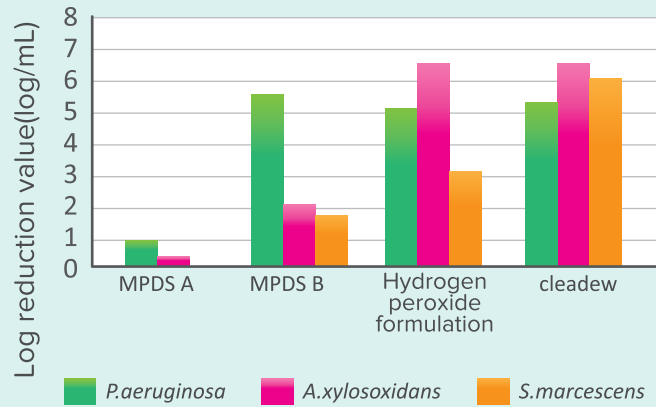
	<i>P. aeruginosa</i>	<i>S. aureus</i>	<i>S. marcescens</i>	<i>C. albicans</i>	<i>F. solani</i>
Log reduction value (log/mL)	4,3	4,0	4,6	2,5	4,5

Testing method: $1.0 \times 10^5 \sim 10^6$ cfu/mL Test bacteria are added to the disinfectant on the basis of the stand-alone test and made to stand for the period as directed. The viable bacterial count after that is measured.

◆ Clinical isolates (Planktonic bacteria)



◆ Clinical isolates (Adhering bacteria)



Testing method: The test bacteria $1.0 \times 10^5 \sim 10^6$ cfu/mL were added to each disinfectant and made to stand for the prescribed period of each disinfectant. The viable bacterial count after that was measured (Planktonic bacteria). The test bacteria 1.0×10^7 cfu/well were added to the plate, and case adhering bacteria were created. Each care product was added individually, and the viable bacteria count after standing for the prescribed period was measured (Adhering bacteria).

(Ophtecs company data)

Povidone iodine has a strong effect even against *Acanthamoeba* that is hard to destroy.

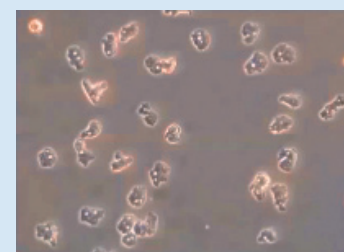
Ninety-nine percent or more of *Acanthamoeba* that causes of Acanthamoeba keratitis can be destroyed.

		Log reduction value
<i>Acanthamoeba castellanii</i> (ATCC 50370)	trophozoite	>2,5
	cyst	>2,2

Testing method:
1.0X10⁴ /mL *Acanthamoeba* are added to the disinfectant and it is made to stand for the period as directed.
Each microbial count after that is measured. (Ophtecs company data)

If povidone iodine disinfectant is injected into *Acanthamoeba* (trophozoite), the cytoplasmic membrane of the amoeba can be destroyed instantaneously and can be killed.

(Ophtecs company data)



Before disinfection

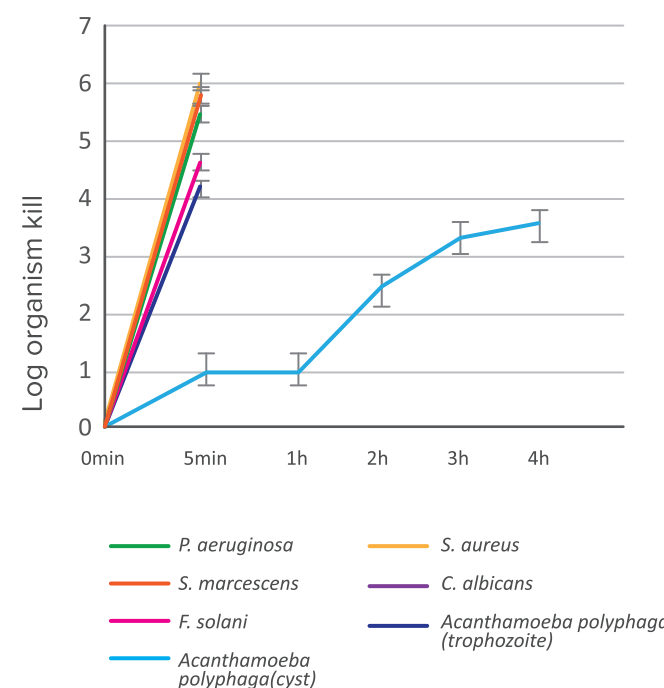


After disinfection

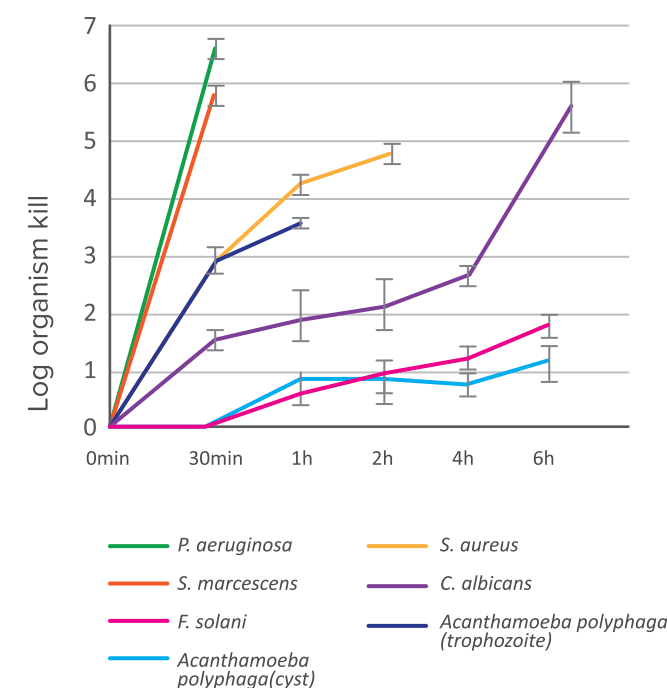
Microorganisms are destroyed instantaneously

By the instantaneous destruction of the cytoplasmic membrane of microorganisms, povidone iodine can kill the microorganisms instantaneously. For example, microorganisms that can change shape like *Acanthamoeba* can be destroyed by cleansing before the conversion into a cyst.

Povidone iodine formulation



Hydrogen peroxide formulation



(Simon Kilvington. Antimicrobial efficacy of a povidone iodine (PI) and a one-step hydrogen peroxide contact lens disinfection system. Contact Lens & Anterior Eye 2004;27:209-212.)

2. Excellent cleaning efficacy due to proteolytic enzyme

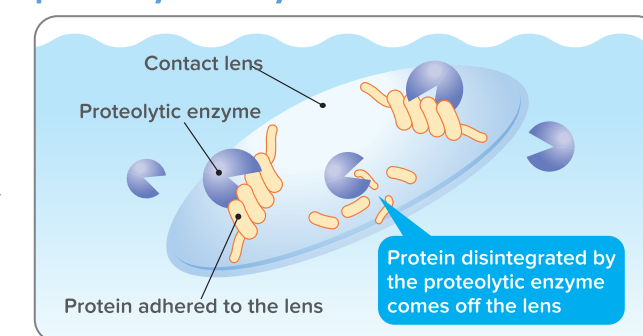
The contributory factor of the feeling of dryness and the feeling of discomfort when wearing contact lenses has been reported to be concerned with the protein material, lipocalin, in the lacrymal fluid.*¹ Deposits on the lenses may cause ocular lesions. The cleadew effectively disintegrates and removes the protein material by incorporating proteolytic enzymes.

*1 Negar Babaei Omali, Zhenjun Zhao, Hua Zhu, Daniel Tilia, Mark D.P. Willcox. Quantification of individual proteins in silicone hydrogel contact lens deposits. Molecular Vision 2013; 19 : 390-399

cleadew' s method of removing protein

General soft contact lenses care supplies remove the protein contamination by ionic movement. On the other hand, proteolytic enzymes incorporated in two-layered tablets of cleadew can disintegrate the protein material and can remove it from the lenses.

Mechanism of removal by proteolytic enzymes

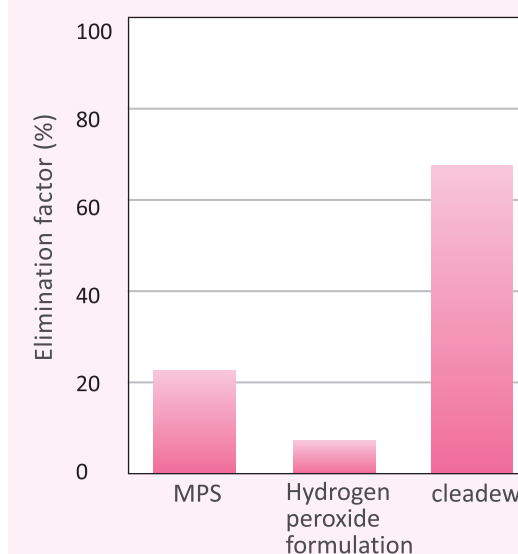


(Image drawing)

Effect of cleaning complex deposits of protein material/lipid and lipocalin

By removing complex deposits of protein material/lipid adhering to the lenses and lipocalin, wearer's comfort can be improved.

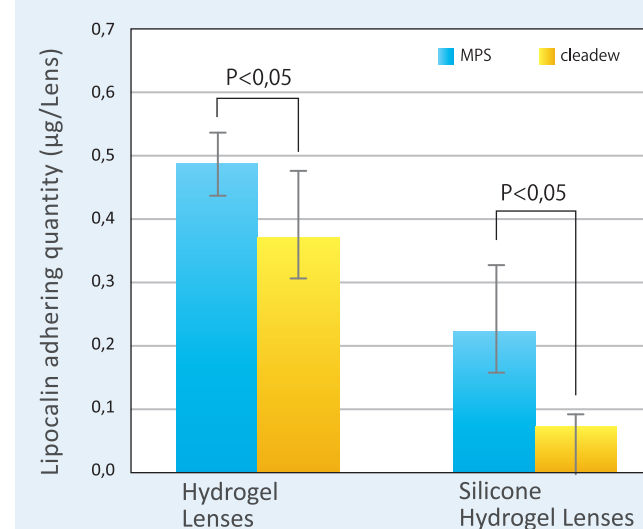
Cleaning efficacy with respect to complex deposits



Testing method:
Lenses to which complex deposits of protein material and lipids has adhered were processed as directed by various care supplies and the elimination factor was calculated.

(Ophtecs company data)

Cleaning efficacy with respect to lipocalin



Testing method:
After using for 2 weeks by combining each ionic lens with disinfectant, the lipocalin quantity adhering to each lens was metered by HPLC.

(Ophtecs company data)