cleadew MPS

ADVANCED CARE SYSTEM

FOR ALL SOFT CONTACT LENSES

INCLUDING SILICONE HYDROGEL LENSES

Ophtecs

Multi-Purpose Solution for disinfecting, cleaning, rinsing and storing for all soft contact lenses

Disinfect

Superior Disinfecting Efficacy through Dual Disinfectants: Polyhexamethylene Biguanide Hydrochloride+Alexidine Dihydrochloride

cleadew MPS is the world's first MPDS which contains the dual disinfectants polyhexamethylene biguanide hydrochloride and alexidine dihydrochloride. In 4 hours, **cleadew MPS** exerts a high disinfecting effect not observed in conventional MPDS's.

The excellent disinfecting efficacy reduces the risk of ocular infection.

Comfort

Super Moist Dew Technology Improves Lens Wettability

Super Moist Dew Technology, which newly using hyaluronic acid derivatives, allows users to successfully keep their contact lenses moisturized for a long time.

Improved tear stability ensures comfortable lens wear and quality of vision until the day of lens replacement.

Safety

Coexistence of Disinfecting Efficacy and Safety

Findings indicate that **cleadew MPS** is safe for the eyes as well as having excellent disinfecting efficacy against microorganisms.

Reliable lens care system with high disinfecting effect and safety

FEATURE 1

Disinfect

Superior Disinfecting Efficacy through Dual Disinfectants: Polyhexamethylene Biguanide Hydrochloride + Alexidine Dihydrochloride

cleadew MPS is the world's first MPDS containing the two ingredients polyhexamethylene biguanide hydrochloride and alexidine dihydrochloride. These two disinfectants act on the cell membrane of microorganisms, resulting in a high disinfecting effect that the conventional MPDS did not have. **cleadew MPS** meets the primary criteria of the ISO 14729 stand-alone test. It also exerts a high efficacy against Acanthamoeba and clinically-isolated bacteria in only 4 hours.

Stand-alone test bacteria (Standard strain)*A

	P.aeruginosa	*S.aureus*	*S.marcescens*	*C.albicans*	*F.solani*
Log reduction value (log/mL)	>4.6	>4.6	>4.7	>4.6	>4.3

(Ophtecs data)

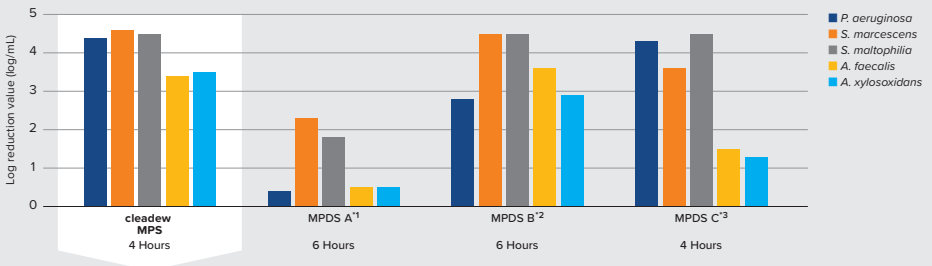
Acanthamoeba*B

	Acanthamoeba castellanii (ATCC 50370)	
	Trophozoite	Cyst
Log reduction value (log/mL)	>3.2	>2.2

(Ophtecs data)

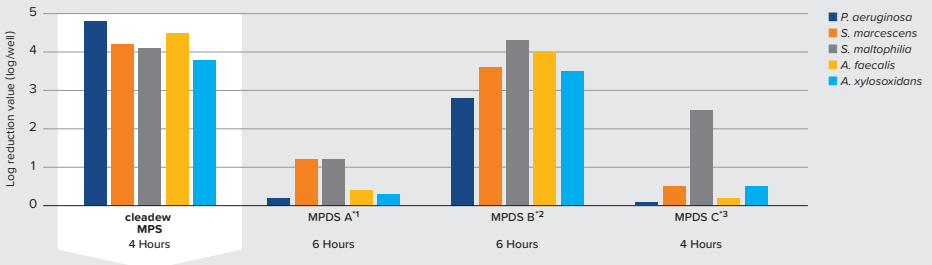
Clinically-isolated bacteria

Planktonic*C



(Ophtecs data)

Biofilm*D



(Ophtecs data)

*1 **MPDS A:** contains polydronium chloride+myristamidepropyl dimethylamine

*2 **MPDS B:** contains alexidine dihydrochloride+polydronium chloride

*3 **MPDS C:** contains polyhexamethylene biguanide hydrochloride

***A Test method:** In accordance with the stand-alone test, $1.0\times10^5-10^6$ cfu/mL of the test strains are inoculated in the disinfectant and allowed to stand for the period as directed. The viable count is measured after that period.

***B Test method:** $1.0\times10^4-10^5$ cells/mL of trophozoites and $1.0\times10^3-10^4$ cells/mL of cysts are inoculated in the disinfectant and allowed to stand for the period as directed. The viable count is measured after that period.

***C Test method:** $1.0\times10^5-10^6$ cfu/mL of the test strains are inoculated in each disinfectant and allowed to stand for the prescribed period of each disinfectant. The viable count is measured after that period.

***D Test method:** 1.0×10^7 cfu/mL of the test strains are inoculated in a plate and allowed to stand for 24 hours to form a biofilm. Then, each disinfectant is added to the plate and allowed to stand for the prescribed period of each disinfectant. The viable count is measured after that period.

FEATURE 2

Comfort

Super Moist Dew Technology Improves Lens Wettability

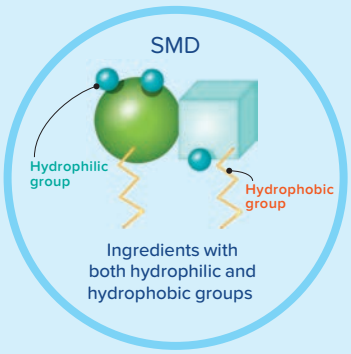
cleadew MPS introduces a new technology, Super-Moist Dew Technology, to keep the lens surface moisturized for a long time. SMD improves lens wettability not achieved with existing moisturizing ingredients such as sodium hyaluronate. This increases tear stability, leading to comfortable lens wear and quality of vision until the day of lens replacement.

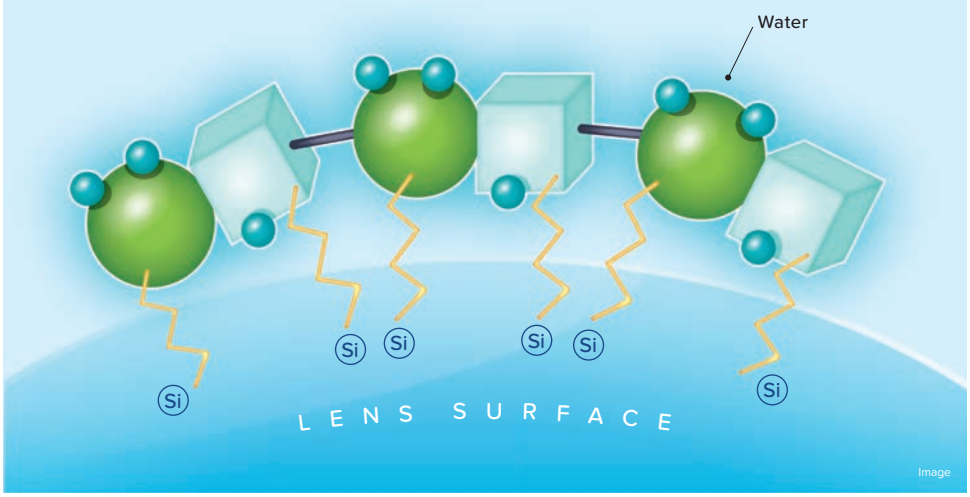
What is Super Moist Dew (SMD) Technology?

The SMD Technology is a new development that introduces the hyaluronic acid derivative "SMD", which coats the contact lens surface.

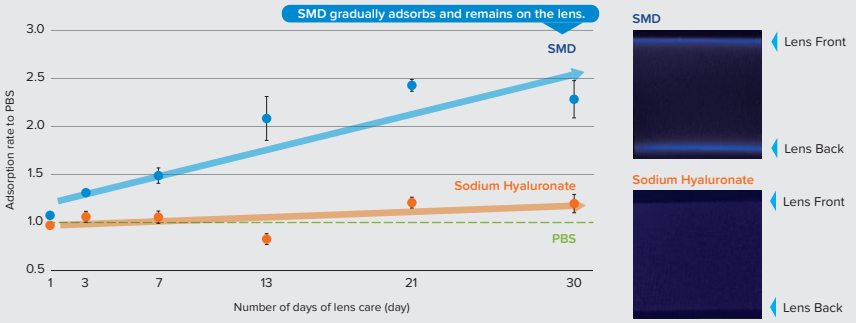
The hydrophobic group of SMD has an affinity for silicon (Si) on silicone hydrogel lenses, thereby making the lens surface hydrophilic and keeping it moisturized for a long time.

Accordingly, the lens sustains its improved wettability until the day of lens replacement.





Evaluation of SMD adsorption*E



Difference from sodium hyaluronate

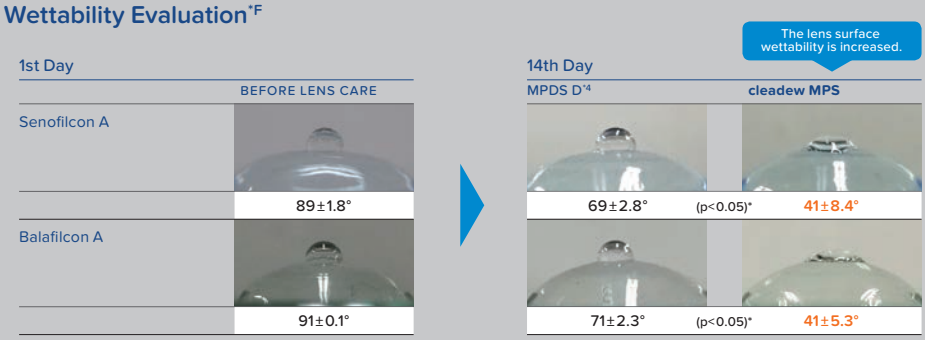
Moisturizing components such as sodium hyaluronate are washed away due to tear exchange during wear, disappearing from the lens surface.

In contrast, SMD, which has a high affinity with the lens surface, can adsorb on it for a long time.

(Ophtecs data)

***E Test method:** Silicone hydrogel lenses are immersed in fluorescent-labeled sodium hyaluronate or hyaluronate derivatives for 8 hours, and in ISO-PBS overnight. The volume of each adsorbed ingredient is measured after repeating this procedure 30 times, and the adsorption is observed under a confocal laser scanning microscope.

Wettability Evaluation*F



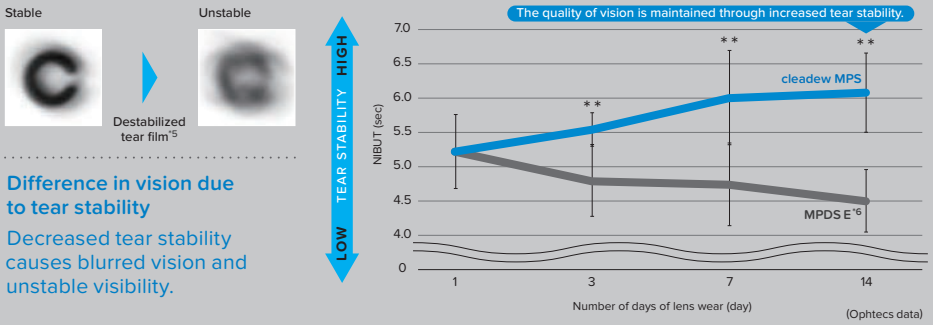
(Ophtecs data)

* p<0.05, Student's t-test

***4 MPDS D:** contains polyhexamethylene biguanide hydrochloride + polydronium chloride (with sodium hyaluronate)

***F Test method:** ISO-PBS was dropped on silicone hydrogel lenses that are repeatedly treated with MPDS D or **cleadew MPS** 13 times, and the contact angle is measured.

Evaluation of tear stability*G



Difference in vision due to tear stability

Decreased tear stability causes blurred vision and unstable visibility.

(Ophtecs data)

** p<0.01, Student's t-test (**cleadew MPS** vs MPDS E)

***5** Measured with the Wave front analyzer

***6 MPDS E:** contains polyhexamethylene biguanide hydrochloride (with sodium hyaluronate)

***G Test method:** Silicone hydrogel lenses with **cleadew MPS** or MPDS E are used for 2 weeks. Non-invasive break-up time (NIBUT) on the lenses is measured with DR-1 on the morning of day 1, and on the evening of day 3, day 7 and day 14.

FEATURE 3

Safety

Coexistence of disinfecting efficacy and safety

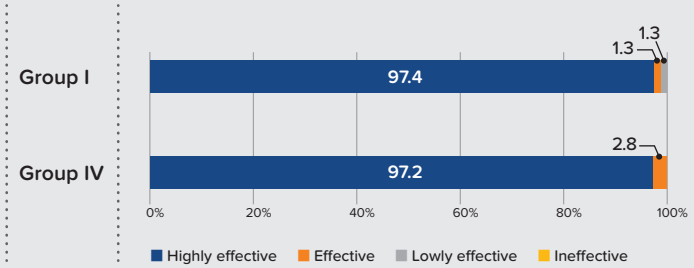
The well-balanced efficacy and safety of **cleadew MPS** has been verified in clinical trials.

Our findings have demonstrated that **cleadew MPS** has excellent safety based on the decreased absorption of polyhexanide hydrochloride, a disinfectant ingredient, into the contact lens. Therefore, it reduces the risk of corneal staining. Thanks to its coexistence of disinfecting effect and safety, **cleadew MPS** is well-suited for all soft contact lenses.

Clinical studies*H

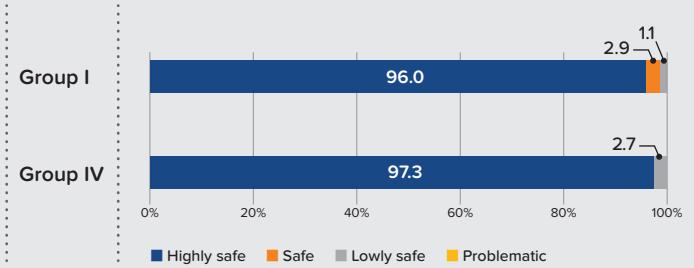
Efficacy against microbial contamination

HIGHLY EFFECTIVE IN 97% OR MORE OF THE CASES



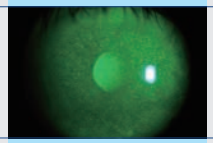
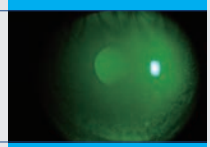
Safety for eyes and lenses

HIGHLY SAFE IN 96% OR MORE OF THE CASES



Corneal staining test*I

Reduced risk of corneal staining

	MPDS C*7	cleadew MPS
Surface of the eye		
Total Score	9.0	1.0

(Ophtecs data)

Compatibility of **cleadew MPS** with contact lenses

According to the notification*8, physical, chemical, and biological evaluation were conducted on the lenses after treating Group I and IV lenses 30 times.

The findings showed that **cleadew MPS** can be used for all types of soft contact lenses.

(Ophtecs data)

*7 **MPDS C:** contains polyhexamethylene biguanide hydrochloride

*8 ISO 11981, FDA 510 (k)

*H **Test method:** With **cleadew MPS**, the subjects wear Group I or IV soft contact lenses for 6 months and 3 months, respectively.
The efficacy (findings of ocular infection and microbiological test) and safety (changes in lens properties and presence of adverse reactions) are assessed.
[Number of cases]
Group I: 172 eyes of 86 patients (safety evaluation), 152 eyes of 76 patients (efficacy evaluation)
Group IV: 80 eyes of 40 patients (safety evaluation), 72 eyes of 36 patients (efficacy evaluation)

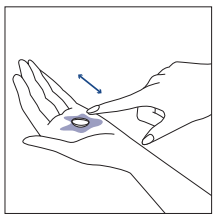
*I **Test method:** After immersion of the silicone hydrogel lenses in MPDS C or **cleadew MPS**, the subjects wear them. Two hours later, the condition of the eye surface and total score* are evaluated. *Area x Density Score

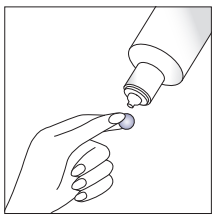
PRODUCT LINEUP

1 **cleadew MPS:** 360mL×1
Polyhexamethylene biguanide hydrochloride (0.00011%), Alexidine dihydrochloride (0.0004%), Poloxamer

2 **Lens case:** 1

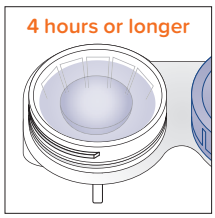
HOW TO USE





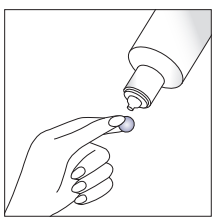
1

Remove each contact lens from your eye and place it on your palm. Place a few drops of **cleadew MPS** on each lens surface and rub 20–30 times with your finger. Rinse each lens thoroughly for 5 seconds with fresh **cleadew MPS**.



2

Fill the lens case with **cleadew MPS** and place the lenses into the lens case. Close the lens case tightly. Soak the contact lenses for at least 4 hours (or overnight) until ready to wear.



3

Rinse the contact lenses for 5 seconds with **cleadew MPS** before wearing.

CAUTION

After the lens care, rinse the lens case with **cleadew MPS** and allow to air dry.

Ophtecs