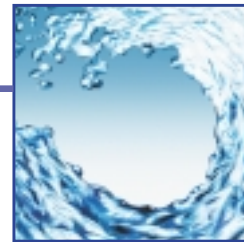


Biocidal Efficacy

Proven In a Multi-Purpose Contact Lens Solution



Background

Complications with contact lens wear typically have no long-term visual significance and usually resolve when the lens care regimen is changed or the lens is removed or replaced. However, microbial keratitis represents a serious complication that may result in permanent visual damage. Inadequate hygienic practices and non-compliance with lens care regimens (such as cleaning, rinsing, and disinfecting), have been associated with development of ocular infections.

To help improve patient compliance with lens care systems, manufacturers have introduced simpler, more convenient multi-purpose solutions. Multi-purpose contact lens solutions contain a complex mixture of ingredients, allowing a single product to perform multiple functions. As these solutions become more complex, it is essential that specific functions are not compromised. In addition to disinfecting ingredients, solution formulation components such as buffers, preservatives, and surfactants will impact how efficiently and effectively a product destroys microorganisms.

Manual cleaning helps remove tear components, environmental debris and microorganisms from the surface of a worn lens and is a required step in the regimen for all multi-purpose chemical lens care products. However, it is important to understand the inherent biocidal activity of various multi-purpose contact lens solutions. Bausch & Lomb's ReNu MultiPlus® Multi-Purpose Solution contains DYMED® as the principle component for antimicrobial action, that works together with the borate buffer system and Edetate Disodium.

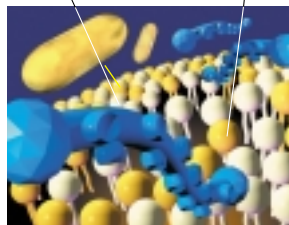
Mechanism of Action

There are several important structural features of DYMED which account for the high antimicrobial activity and low toxicity of ReNu MultiPlus Multi-Purpose Solution. The structure of a microorganism includes a cytoplasmic membrane (consisting of acidic phospholipids, neutral

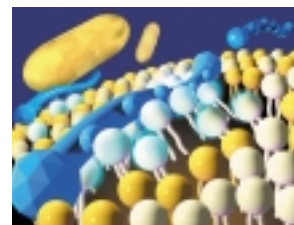
phospholipids, and proteins) that contains the cell components of the microorganism. Damaging this cytoplasmic membrane will cause the cell components to be released, ultimately resulting in cell death.

DYMED is a polymer with repeating units of biguanide groups, which attack and disrupt the acidic phospholipid groups in a microorganism's cytoplasmic membrane. These repeating biguanide groups are separated by six carbon chains, allowing a single DYMED molecule to interact with multiple acidic phospholipid groups.

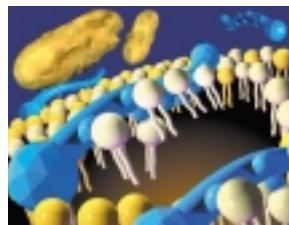
Acidic phospholipids Neutral phospholipid



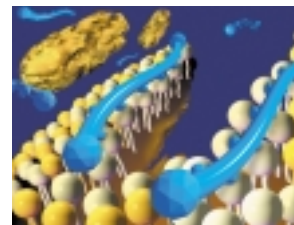
1. THE ANATOMY OF A MICROORGANISM CELL MEMBRANE
The cell membrane consists of a layer of linked acidic phospholipids, neutral phospholipids and proteins that hold the membrane together.



2. ATTRACTION
The DYMED molecule attacks microorganisms by binding to acidic phospholipids of the cell membrane.



3. DISRUPTION
DYMED causes a disruption of phospholipids in cell membrane.



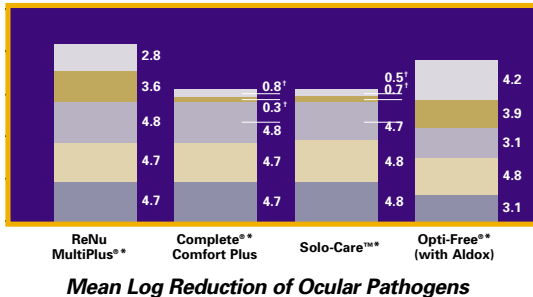
4. DISINTEGRATION
Cell membrane disintegrates and results in cell death.

When the DYMED molecules attack and disrupt the cytoplasmic membrane's acidic phospholipid groups, the membrane disintegrates and the microorganism's cell components are released, resulting in death.

"TechTalk" Proven Biocidal Efficacy

In its Guidance Document for Contact Lens Care Products, the FDA has outlined specific procedures to evaluate the inherent microbiocidal activity of a disinfecting solution

- *Fusarium solani*
- *Candida albicans*
- *Serratia marcescens*
- *Pseudomonas aeruginosa*
- *Staphylococcus aureus*



using a stand-alone test¹. These same procedures are being reviewed for approval by the International Organization for Standardization². The stand-alone method provides a quantitative measure by which disinfecting solutions are evaluated against FDA and ISO/DIS performance criteria, and it may be used to assess the relative antimicrobial efficacy of different disinfecting solutions.

In an evaluation of antimicrobial efficacy performed in accordance with the FDA and ISO/DIS procedures, several commercially available multi-purpose contact lens solutions (ReNu MultiPlus Multi-Purpose Solution, Opti-Free Express with Aldox, Complete Comfort Plus, and SoloCare) were evaluated according to the manufacturers' labeled disinfection time³. The results of this study indicated the following:

1. ReNu MultiPlus Multi-Purpose Solution met the FDA and ISO/DIS stand-alone primary acceptance criteria for all required microorganisms (bacteria, mold, and yeast) within the manufacturer's recommended disinfection time (4 hours).
2. ReNu MultiPlus Multi-Purpose Solution demonstrated a significantly higher mean log reduction of *S. aureus* and *S. marcescens* (within 4 hours) than the reduction achieved by Opti-Free Express with Aldox within the manufacturer's recommended disinfection time (6 hours).

3. ReNu MultiPlus Multi-Purpose Solution demonstrated a higher mean log reduction of *C. albicans* and *F. solani* than Complete Comfort Plus and Solo-Care within a disinfection time of 4 hours.

In a separate study, ReNu MultiPlus Multi-Purpose Solution used in regimen also demonstrated unsurpassed power against acanthamoeba, including the elimination of trophozoites and cysts (the more resistant form of acanthamoeba).⁴

Conclusion

Compliance with recommended lens care regimens is essential to help minimize the risk of developing infectious keratitis. The ability of a multi-purpose lens care solution to satisfy the FDA and ISO/DIS stand-alone disinfection criteria provides a simple method to compare performance characteristics of various multi-purpose solutions.

As measured against FDA and ISO/DIS stand-alone disinfection criteria, ReNu MultiPlus Multi-Purpose Solution's combination of ingredients offers excellent biocidal efficacy against a broad range of ocular pathogens.



Focused on performance

- Reference:**
1. Premarket Notification (510(k)) Guidance Document For Contact Lens Care Products (May 1997)
 2. ISO/DIS 14729 Ophthalmic Optics – Contact Lens Care Products Microbiological Requirements and Testing Methods (Pending)
 3. Data on file
 4. Kilvington S. CLAO Annual Meeting, 1999

TTRMP-Art.1-0 (1-00)

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