



Hydrosorb Dressings

Results of In Vivo and In Vitro Testing

Product Description

AquaClear is made of absorbent polyurethane polymers. The three-dimensional gel structure has a 60% water content, providing optimum moisture for healing. It is available in two forms – AquaClear and AquaClear Adhesive. AquaClear Adhesive is surrounded by an adhesive film border. Both are transparent to allow wound inspection and measurement *in situ*. AquaClear is particularly suitable for keeping granulation tissue and young epithelium moist, so is ideal for continuing phase-specific treatment.

Compatibility Studies

Non-Toxic

Aquaclear dressings from Paul Hartmann are non-toxic according to United States Pharmacopeia (USP) biological tests for Class V non-implantable plastics.¹ These tests are designed to measure the effects of substances that could leach out of a polymer while it is in contact with skin. Extracts of the test material are prepared with saline, alcohol/saline, polyethylene glycol 400 and cottonseed oil. These four extracts are injected systemically into albino mice and subcutaneously into New Zealand white rabbits. Animals are monitored for three days for occurrence of toxic reactions, erythema and oedema. Aquaclear elicited no toxic reaction.

Non-Haemolytic

Aquaclear dressings do not cause haemolysis (rupture of red blood cells). Extracts of Aquaclear were prepared in 0.9% saline. Rabbit blood was added to the extract and incubated for one hour at 37°C. The degree of haemolysis was determined by measuring by spectrophotometer the free iron released from ruptured red blood cells. Aquaclear elicited no haemolytic response.

Non-Irritating To Skin

Aquaclear dressings pass the Federal Hazardous Substance Act USA test for primary skin irritation.² Sample dressings (25 x 25mm) were applied to intact and abraded skins of New Zealand white rabbits for 24 hours. Test sites were then graded for erythema and oedema on a scale of 0 to 8 (Primary Irritation Index) 24 and 72 hours after sample application. A score of less than 5 is considered acceptable; Aquaclear scored 0.

Non-Irritation To Eyes

Aquaclear dressings pass the USP test for ocular irritation.¹ Saline (0.9%) and cottonseed oil extracts of Aquaclear were applied to New Zealand white rabbit eyes. The eyes were monitored at 24, 48 and 72 hours for reactions. Aquaclear elicited no response.

Non-Mutagenic

Aquaclear dressings do not induce mutations according to the Ames Mutagenicity test³, a standard test used to evaluate carcinogenic potential. The Ames test employs specific strains of *Salmonella typhimurium* that contain a mutation in the histidine operon, making the bacteria unable to grow in the absence of histidine. When placed in a cell medium free of histidine, only bacteria that mutate to the wild form can grow. An extract of Aquaclear prepared in 0.85% saline had no effect on the rate of spontaneous mutation of all five histidine-deficient strains of *Salmonella typhimurium* tested.

Effective Barrier Against Bacteria.

The outer layer of polyurethane film in Aquaclear dressings forms an effective bacterial barrier. *Pseudomonas diminuta*, a relatively small and motile bacteria, was inoculated onto the polyurethane side of the dressing. The dressing was placed gel side down on an agar plate. When the plate was incubated, no bacteria colonies grew, demonstrating that no bacteria passed through the dressing.

Non-Supportive To Growth of Micro-organisms

Aquaclear dressings do not provide a nutrient source for micro-organisms. Three species of bacteria (*Escherichia coli*, *Staphylococcus aureus* and *Pseudomonas aeruginosa*) and one species of yeast (*Candida albicans*) were inoculated onto the dressings, incubated at 30-35°C and examined for growth at 5, 24 and 30 hour intervals. The dressings did not support growth of these micro-organisms.

Conclusion

These studies, done under controlled laboratory conditions by an independent testing firm, demonstrate that Aquaclear dressings from Paul Hartmann are biocompatible. They elicit no toxic, irritant or mutagenic response and provide an inert barrier against microorganisms. Reference N⁴ also underscores the safety of the dressings when used clinically.

References

1. United States Pharmacopeia National Formulary. 1991.
2. Federal Hazardous Substance Act, Regulation 16 CFR 1500.
3. Ames BN, McCann J, Yamasaki E. Methods for detecting carcinogens and mutagens with the *Salmonella/mammalian-microsome* mutagenicity test. *Mutat Res* 1975; 31:347-64.
4. Fowler E, Papen JC. A new hydrogel wound dressing for the treatment of open wounds. *Ostomy Wound Management* 1991; 37:39-45.