CAREFUL FORMULATION TECHNIQUES CAN ENSURE THAT pH-CONTROLLED HYPOCHLOROUS ACID (pHA) WOUND CLEANSERS* REMAIN STABLE IN A TIGHTLY CONTROLLED PH RANGE OVER ITS ENTIRE SHELF LIFE.

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INTRODUCTION

Pure Hypochlorous Acid (pHA) based cleansers are recommended for use by several important guidelines. Much clinical research supports the concept of using pHA as a safe and effective method to cleanse wounds of germs, microbial colonies, and debris. A pHA solution remains pure only between pH 3.5 to 5.5. Change from this range on the lower side will create toxic chlorine gas. On the higher side, highly cytotoxic hypochlorite ion (bleach) will begin to form. Hypochlorous acid in solution is inherently unstable, and special formulation and packaging techniques are essential to retain a pHA solution in this range over many months.

METHOD

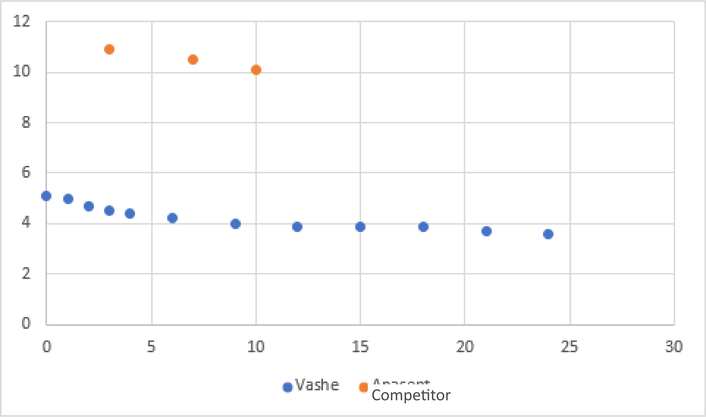
We present the data from the analysis of a commonly used cleanser as its pH changes over time, proving that it remains within this range during storage and use over the shelf life of the product. The cleanser bottles were aged in ambient condition and the pH of the contents checked over time. The pH and time were plotted against each other. A high pH product was also tested for pH over time.

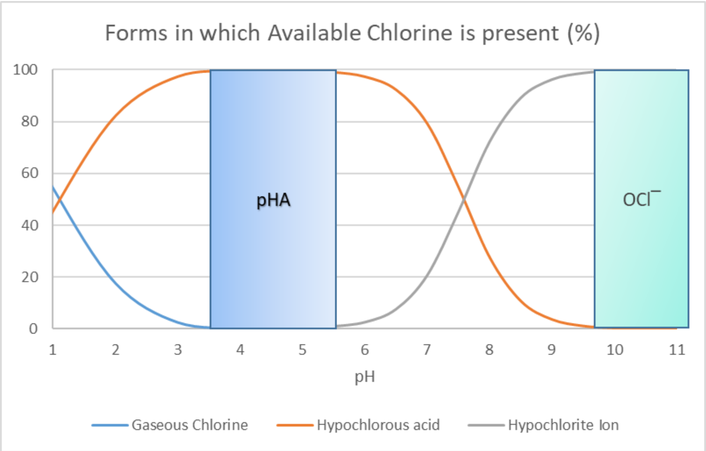
RESULT & DISCUSSION

We prove that the pHA based cleanser is held always a lower or mildly acidic pH in the desired range of 3.5 to 5.5, conducive with the concept of wound acidification. It was maintained in this tightly controlled lower pH range not only when manufactured, but over its entire shelf life. Previous research has shown that the product's antimicrobial preservative activity remains in force throughout its shelf life.

In this study we prove that this is in part due to the ability of the product to remain in a very tight pH range due to proprietary stabilization and packaging techniques.

In our analysis we show that a product that is also another antimicrobial preserved cleanser product, and which contains the same ingredient as the cytotoxic Dakin's solution, has a much higher pH. This higher pH's implications are well known due to the laws of physical chemistry and the equilibrium curve that is known to exist between the hypochlorite anion and the protonated and neutral, far less cytotoxic hypochlorous acid. A high pH in the competitive product proves the absence of hypochlorous acid in the product, and the fact that the pH remains alkaline over time indicates that the hypochlorous acid levels zero or close to it over its storage. The high pH product studied over time is stable at this high pH, no doubt, however, the pH level of higher than 8 for this product (it is actually above 10 at 10 months) is too alkaline to be conducive to amenable to wound healing, in addition to the fact, already discussed, that the high levels of hypochlorite are likely cytotoxic to human cells.





CONCLUSION

pH of wound cleansers/products is important. An emergent concept in wound healing is wound acidification. The acidic environment in a wound de-selects against pathogens, while the alkaline pH clearly selects for pathogens over time. A highly alkaline wound is likely a chronic, and also likely an infected wound.

Wound cleansers that are based on the noncytotoxic hypochlorous acid should be kept at a pH range of 3.5 -5.5 through its shelf life. This fact has been now been proven for the pHA based product discussed herein.

Such a lower pH range is associated (in these chlorinated cleansers) with relative non cytotoxicity to sensitive human cells, and this low pH is of course appropriate for the desirable wound acidification recommendations seen in peer reviewed literature. Some other cleansers using chlorinated agents, though, such as the product also analyzed here in, contain no HA, based on their pH which are in a very high range (>8). This pH is associated with the existence of the cytotoxic relative of Hypochlorous Acid (HA), which is hypochlorite.

*Vashe Wound Solution, Urgo Medical North America

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