# SockIt!® Oral Pain Gel
## *Inhibits the Growth of Microorganisms Implicated in Various Oral Infections*


### Abstract

There are more than 400 hydrogels available for external-use; however, toxicity associated with many ingredients and preservatives limits their use in the oral cavity. An ideal hydrogel for the mouth would be made completely out of food ingredients at concentrations found in food, so that it could be safely used by everyone, regardless of age or current health conditions. Moreover, it would not create drug interaction concerns, not contain any ingredients that cause allergic reactions, and still be effective when diluted 50% by saliva.

However, if the ingredients are not properly selected, the hydrogel could promote growth of bacteria commonly found in the oral cavity. SockIt! is the first of a new class of oral hydrogels, made entirely of food plant ingredients, and it does not promote the growth of pathogen bacteria implicated in oral diseases of concern to dental professionals. Blind samples were sent for preservative challenge testing, time kill (TK), and minimum inhibitory concentration (MIC) studies were conducted by an independent commercial lab and the following results were obtained. Apparently, Hippocrates was right. We should "let our food be our medicine, and our medicine be our food."


### Introduction

SockIt!® Oral Pain Gel is composed of food ingredients that naturally control the growth of bacteria. The Food and Drug Administration (FDA) has reviewed the ingredients in SockIt! and has allowed it to be marketed for the management of all oral wounds and the associated pain. You can safely add SockIt! to your dental practice and provide a new approach to pain control and wound management. Any dental practitioner would want to know that a product made entirely out of food would not promote the growth of potential pathogenic organisms. To relieve any concerns, an independent commercial lab tested SockIt! against the organisms in the standard Preservative Challenge Test (PCT) and other pathogenic microorganisms that are implicated in some oral infections. The dental professional can have confidence in using SockIt!, knowing that potential pathogens of concern will be safely managed.

There are three primary functions of wound dressings, they: physically protect the wound, optimize moisture, and prevent microbial infection. The optimization of moisture is limited in oral wound dressings, due to the already moist environment. Most products that aim at inhibiting the growth of microorganisms are toxic when applied to the oral cavity. Moreover, the majority of the compounds designed to eliminate harmful microbes are and can also cause further damage to already compromised cells and tissues. Conversely, SockIt! is composed of 100% natural food ingredients at concentrations found in foods. So, there is no fear of additional damage, and the food ingredients found in SockIt! Oral Pain Gel are natural and effective antimicrobials. The data presented below illustrate the ability of SockIt! to control microbial growth in under 30 seconds.

### Inhibition of Microbial Growth in Preservative Challenge Test

SockIt! Oral Pain Gel is a multi-use product, so it had to undergo the United States Pharmacopoeia (USP) <51> Preservative Challenge Testing. This test is required by law to ensure that bacterial contamination of the product will not occur during the time of use, specifically that the product will not promote the growth of the common opportunistic microorganisms *Escherichia coli*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Candida albicans*, and *Aspergillus niger*. Microbiological testing showed that, in a standard preservative challenge test (USP 51), SockIt! prevented growth of these organisms for 28 days (<10 cfu/ml).

Concerns arise with the application of food ingredients to exposed or damaged tissue because

they might serve as a food source for opportunistic and/or pathogenic microorganisms, such as those implicated in such diseases as dental caries, periodontitis, endodontic infections, and infective endocarditis. The literature was reviewed to identify the most common pathogens associated with these diseases, and the data in this paper presents the results of the MIC and the TK tests conducted on these oral pathogens.

The first table under each section demonstrates the results of the TK studies. The red shading represents time points in which a reduction of 2 logs or higher was attained, for a log reduction of two (100 times lower) is considered "antimicrobial" by the FDA. The second table under each subsequent section demonstrates the results of the MIC studies conducted on these microorganisms. Here, the red shading indicates the dilutions that inhibited microbial growth. Overall, this demonstrates that SockIt! is still effective even when its diluted with saliva.

Most hydrogel wound dressings are composed of either synthetic or natural polysaccharide thickening or emulsifying agents. There is sufficient amount of literature that illustrates how some naturally occurring polysaccharides can control (i.e. inhibit or kill) bacteria by binding to bacterial mannose-binding lectins (MBLs) and sequestering free calcium ions ($Ca^{2+}$) from the surrounding environment. For example, both seaweed and algae contain these mucilage polysaccharides and are able to thrive in and around areas of sewage waste disposal. This toxic sewage contains countless quantities and varieties of potentially harmful microorganisms; however, the seaweed and algae both use this natural defence mechanism (i.e. binding to bacterial MBLs and sequestering free $Ca^{2+}$). In essence, foods and its various components can control mechanically bacteria and other microbes. For instance, mayonnaise is made of eggs, olive oil, and lemon juice. It is the citric acid and other dicarboxylic acids found in lemon juice that can bind free $Ca^{2+}$ and prevent the growth of bacteria.

All in all, selecting a proper array of food ingredients and components can create a natural mechanism to control opportunistic and/or pathogenic microorganisms. SockIt! is composed of such ingredients and thus exhibits natural and potent antimicrobial activity. Ultimately, this means dental practitioners can use SockIt! to control pain and protect any wound without concern for creating a medium conducive to microbial growth.

**Table 1: SockIt! Oral Pain Gel Preservative Challenge Results**

| Organism | Inoculation level | Day 7 | Day 14 | Day 21 | Day 28 |
|---|---|---|---|---|---|
| ***E. coli*** **(ATCC 8739)** | **$2.50x10^5$** | **NG** | **NG** | **NG** | **NG** |
| ***S. aureus*** **(ATCC 6538)** | **$2.75x10^5$** | **NG** | **NG** | **NG** | **NG** |
| ***P. aeruginosa*** **(ATCC 9027)** | **$4.13x10^5$** | **NG** | **NG** | **NG** | **NG** |
| ***C. albicans*** **(ATCC 10231)** | **$7.76x10^5$** | **NG** | **NG** | **NG** | **NG** |
| ***A. niger*** **(ATCC 16404)** | **$2.15x10^5$** | **NG** | **NG** | **NG** | **NG** |
| ***G = GROWTH, *NG = NO GROWTH** | | | | | |