

## **TOXICOLOGY & MICROBIOLOGY STUDIES**

TOX-071

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## SilSense® PE-100 Silicone

## Microbiological Summary

SilSense® PE-100 silicone has been tested for Preservative Efficacy (Challenge Testing) using the "Mixed Innoculum Preservative Efficacy Test" protocol. The unpreserved silicone passes the standard challenge test using this test method. The product as supplied does not contain a classical preservative.

The organisms used in the testing are the following:

- 1. Bacteria Mix: Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus
- 2. Candida albicans
- 3. Aspergillus niger

The preservative efficacy for the product was evaluated according to the following criteria:

Bacteria: Not less than a 2.0 log reduction from the initial calculated at 14

days, and; no increase from the 14 day count at 28 days.

Yeast and Mold: No increase in the initial calculated count at 14 and 28 days.

No increase is defined as not more than  $0.5 \log_{10}$  units higher than the previous value.

SilSense PE-100 silicone, when used in a formulated system, does not promote or prevent microbial growth. We recommend normal microbial testing of your finished product.

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