
Final Project Summary

WO# 2009-05-0595

Final Report Date: 06/30/09

Customer information:

Company: iBody Science

Project Title: Challenge Study of 1 Skin Solution Oil Product

Background of Study: This sample was previously tested under WO# 2008-12-0636 for Antimicrobial Effectiveness and passed all required organisms.

Objective: Challenge product with *S. aureus* ATCC# 43300 (MRSA+) to determine susceptibility to microbial outgrowth over a 28 day period.

Study Outline: Unopened containers of the following product were provided by the client:
1) Skin Solution Oil Product Lot# 086290 Exp Date 092612

The product was divided into two sterile containers. One sample container was inoculated with *Staphylococcus aureus* (ATCC# 43300) at a target level of 10^5 to 10^6 CFU/g. The remaining sub sample was not inoculated with an organism and served as the negative control.

The inoculated sample and control were diluted in TAT broth plated in duplicate, using the TSA pour plate method. The plates were incubated at $35 \pm 1^\circ\text{C}$ for 72 hours and then enumerated and reported. Following inoculation, the control and inoculated samples were incubated at $23 \pm 1^\circ\text{C}$ for 28 days. Samples were assessed for outgrowth of the organism on days 0, 14, and 28.

This study is partially derived from the Antimicrobial Effectiveness Method (05-4-MC056) based on US Pharmacopeia 31 – NF 26 <51>.

Results:

iBody Science Skin Solution Oil Product
CFU/g (average of duplicate platings)

Day	MRSA(+) <i>S. aureus</i>	Uninoculated Control
Inoculation level	690,000	
Day 0	54,000	<10 est.
Day 14	<10 est.	<10 est.
Day 28	<10 est.	<10 est.

Conclusions:

The product was challenged with *Staphylococcus aureus* ATCC 43300 (MRSA+) at a level similar that recommended for bacteria in the Antimicrobial Effectiveness Method (05-4-MC056) based on US Pharmacopeia 31 – NF 26 <51>.

The in criteria for preservative effectiveness (based on US Pharmacopeia 31 - NF 26 <51>) of topically used products made with aqueous bases or vehicles, non-sterile nasal products and emulsions, including those applied to mucous membranes (category 2) is as follows:

Bacteria: Not less than 2.0 log reduction from the initial count at 14 days, and no increase from the 14 days' count at 28 days.

Based on the above criteria, the product tested, **iBody Science Skin Solution Oil Product**, is not susceptible to microbial outgrowth of *S. aureus* ATCC 43300 (MRSA+) over a 28 day period.

QC REVIEW FOR CONFIRMATION

Analyst: RRJ Initials RRJ Date 7/29/09
Supervisor or Data Reviewer: Ans Ans Date 6/29/09