

## Preservation of cosmetic lotions with imidazolidinyl urea\* plus parabens

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### Synopsis

A model cosmetic LOTION containing 0.2 per cent METHYLPARABEN plus 0.1 per cent PROPYL-PARABEN was previously shown to be unsatisfactorily preserved because it failed to kill *Pseudomonas (P.) aeruginosa*. Addition of 0.3 per cent IMIDAZOLIDINYL UREA to the lotion gave an Imidazolidinyl Urea-PARABEN PRESERVATIVE SYSTEM, which was effective against both an initial challenge of *P. aeruginosa* and two rechallenges.

### INTRODUCTION

The evaluation of cosmetic lotion preservation using pure and mixed microbial culture challenges has been reported by the CTFA Microbial Preservation Subcommittee (1). In a study describing the results of challenging a "model" lotion with both pure and mixed cultures, the Subcommittee concluded that both types of challenge tests are valid, but that the information from pure culture tests can be "a valuable aid in reformulating borderline preservative systems."

The Subcommittee used two modifications of a model lotion (2) for evaluation, as shown in the following table taken from their report (1).

\*Germall 115, registered trademark of Sutton Laboratories, Inc., Roselle, New Jersey 07203.

Ingredients	Lotion A (Unpreserved) Per cent w/w	Lotion B (Preserved) Per cent w/w
1. Lanolin Alcohol*	6.0	6.0
2. Acetylated Lanolin†	2.0	2.0
3. Stearic Acid XXX	2.0	2.0
4. Glyceryl Monostearate—Acid Stable	2.0	2.0
5. Sodium Lauryl Sulfate (100 per cent)	1.0	1.0
6. Magnesium Aluminum Silicate‡	0.5	0.5
7. Methylparaben	—	0.2
8. Propylparaben	—	0.1
9. Propylene Glycol	5.0	5.0
10. Water (deionized)	81.5	81.2

(The first four items in the above table constitute the oil phase and the remaining items, the water phase).

Lotion A, which had a pH of 5.6, was prepared without any preservative. Lotion B, which had the same pH, contained a preservative system of 0.2 per cent methylparaben plus 0.1 per cent propylparaben. Both lotions were challenge tested by the participating laboratories in the Subcommittee's study with pure cultures of the following organisms (1): *Escherichia (E.) coli*, ATCC 11229; *Pseudomonas (P.) aeruginosa*, ATCC 13388 (QMB 1468); *Staphylococcus (S.) aureus*, ATCC 6538; and *Candida (C.) albicans*, ATCC 10231.

When challenged with approximately  $10^6$  organisms/ml, Lotion A killed *S. aureus* within 7 days, but failed to kill the other 3 microorganisms. Lotion B, which contained both methylparaben and propylparaben, killed *E. coli*, *S. aureus*, and *C. albicans*, but failed to kill *P. aeruginosa*, which remained at high levels throughout the 28-day study period. The Subcommittee noted that "both test solutions were considered to be unsatisfactorily preserved, although it is clear that Lotion B was better preserved than Lotion A" (1).

## METHODS

Since the parabens alone were not capable of adequately preserving this lotion, the authors decided to test the effect of adding Imidazolidinyl Urea at a level of 0.3 per cent to Lotion B, to give "Lotion B Modified." The pH of "Lotion B Modified" was 5.6, the same as that of Lotion B.

The detailed procedure for challenge testing with *P. aeruginosa* 13388 and evaluation by the quantitative pour plate count was described previously (1). All plate counts reported in Table I were carried out in triplicate. The efficacy and capacity of the preservative system was further tested by rechallenging the lotion two more times. One week after the initial challenge, sampling was done on the total sample. One-third of the sample was retained for further sampling, and the remaining two-thirds was

\*Amerchol L-101, registered trademark of Amerchol, Edison, New Jersey 08817.

†Modulan, registered trademark of Amerchol, Edison, New Jersey 08817.

‡Veegum, registered trademark of R. T. Vanderbilt Co., Inc., New York, N. Y. 10017.

Table I  
A

Result of Challenge of Lotion B with <i>P. aeruginosa</i> (Control Run)	
Time after Challenge	<i>Pseudomonas</i> Plate Count
0 days	$5.6 \times 10^5$
1 day	$6.8 \times 10^5$
2 days	$5.4 \times 10^6$
7 days	$7.1 \times 10^6$
14 days	$8.4 \times 10^6$
21 days	$8.2 \times 10^6$
28 days	$6.6 \times 10^6$

## B

Results of Challenge of "Lotion B Modified" (Lotion B plus Imidazolidinyl Urea) with <i>P. aeruginosa</i>	
Time after challenge	<i>Pseudomonas</i> Plate Count
0 day	$4.0 \times 10^5$
1 day	$1.3 \times 10^2$
2 days	0
7 days	0
14 days	0
21 days	0
28 days	0
Time after first rechallenge	
7 days	0
14 days	0
21 days	0
28 days	0
Time after second rechallenge	
7 days	0
14 days	0
21 days	0
28 days	0

challenged again with *P. aeruginosa*. This was sampled 1 week later and then subdivided into 2 portions. One portion was retained for further sampling, and the remaining portion was challenged again (a third time) with *P. aeruginosa*. All challenged samples were subcultured at 1, 2, 3, and 4 weeks. All were stored at room temperature.

## RESULTS

Challenge testing confirmed that Lotion B failed to kill *P. aeruginosa*, which continued to grow vigorously over the 28-day test period in spite of the presence of paraben preservatives. In contrast, Lotion B Modified did kill *P. aeruginosa* within 2 days, and continued to show the absence of *P. aeruginosa* throughout the 28-day test period (see Fig. 1 and Table I). Counts of "0" in Table I are actually "<10 organisms/ml," and are, therefore, plotted as  $10^1$  in Fig. 1.)

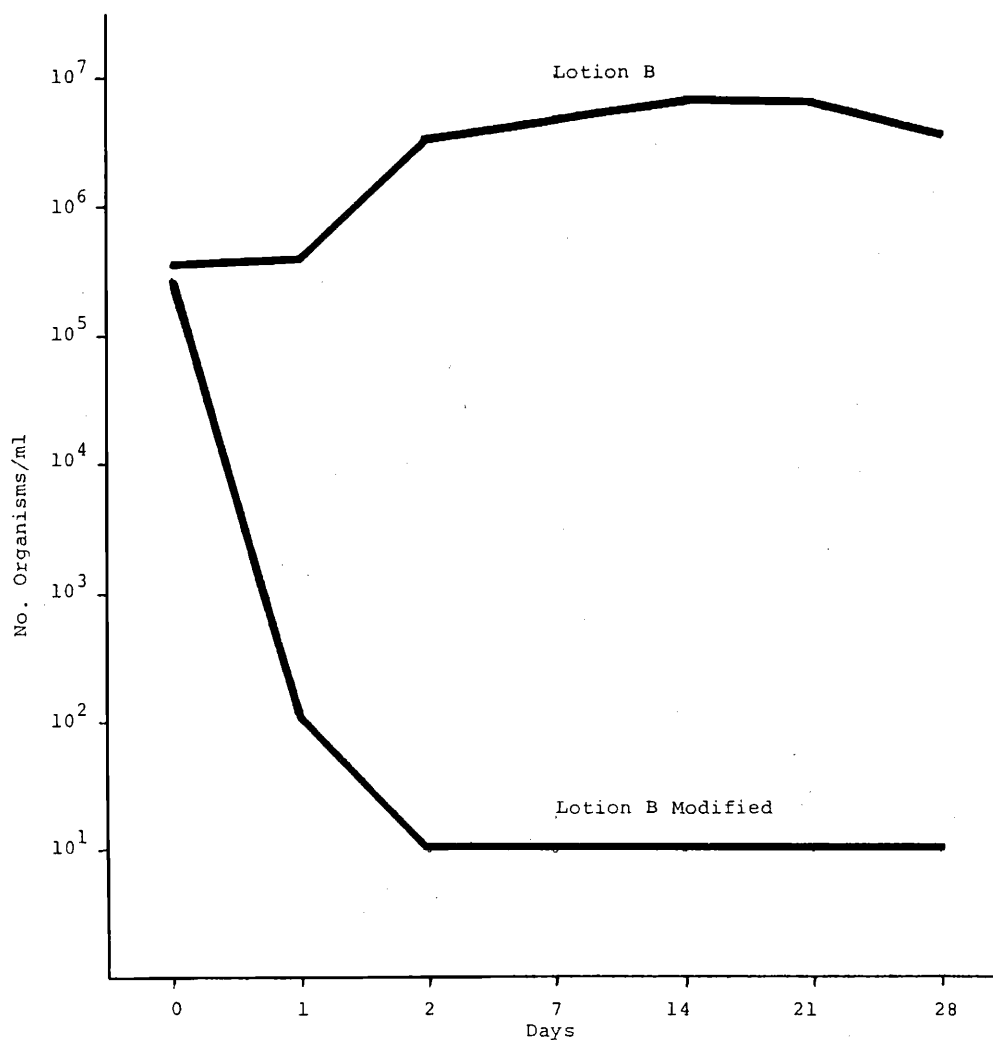


Figure 1. *P. aeruginosa* as challenge organism: test product Lotion B versus Lotion B modified

As can be seen from Table I, Lotion B Modified satisfactorily met the second challenge and the third challenge with *P. aeruginosa*, and no pseudomonads were detectable over the 28-day test period.

#### SUMMARY

Lotion B, containing 0.2 per cent methylparaben and 0.1 per cent propylparaben, was inadequately preserved. When 0.3 per cent Imidazolidinyl Urea was added to Lotion B, the Imidazolidinyl Urea-paraben preservative system was effective against both the initial challenge of *P. aeruginosa* and two rechallenges.

## REFERENCES

- (1) J. A. Rogers, G. Jacobs, E. M. Owen, D. C. Pease, Jr., A. F. Peterson, W. H. Riley, A. G. Schenkel, J. L. Smith, C. E. Stegmann, and J. A. Ramp, *CTFA Cosmet. J.*, 5, 2-7 (1973).
- (2) *Amerchol Laboratory Handbook*, p. 56, column 1.