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Microbial survey of shared-use cosmetic test kits available to the public

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SUMMARY

Some people like to try cosmetics before purchasing them. With repeated use by different customers, however, the tester kits provided by many retail outlets can become potential vectors of microbial pathogens. A survey was conducted to assess the health risk from bacteria found on shared-use cosmetics. A total of 3027 shared-use cosmetic product samples were collected from 171 retail establishments throughout the contiguous United States. Eye, face and lip cosmetics were tested with *in situ* nondestructive swabbing and the use of the Transette 3R Modified Amies Charcoal Culture and Transport System. Bacteria were isolated from about 50% of the items for all three categories. Semiquantitatively-estimated mean densities were 2288, 1685 and 1088 CFU g^{-1} for eye, face and lip products, respectively. Ranges for all categories were 0–10^5 CFU g^{-1}. About 5% of the items had bacterial counts above 5000 CFU g^{-1} (eye products) or 10000 CFU g^{-1} (other products). More than 60% of isolates were typical of microflora from human skin; the remainder were environmental microbes. About 60% of the isolates were Gram-positive cocci: *Staphylococcus* spp. (especially *S. epidermidis*) and *Micrococcus* spp. The Gram-negative pathogen *Pseudomonas aeruginosa* constituted 0.07% of the isolates. The survey results suggest that the preservation systems of some of the cosmetics failed under excessive use (abuse), and indicated a potential for microbiological safety problems with shared-use cosmetics.

INTRODUCTION

The US Food and Drug Administration (FDA) regulates the microbiological safety of cosmetics. Both the industry and the FDA accept the use of preservatives, good manufacturing practices and rigorous quality control programs as the best means of achieving safe cosmetic products. As a result, microbial contamination during manufacture and the microbial quality of finished products are no longer issues of major concern. However, little information is available on the prolonged effectiveness of preservatives in cosmetic formulations under a wide spectrum of use and abuse conditions. Of special concern is the potential public health hazard that may result when consumers share makeup tester kits displayed at retail outlets.

For this study, shared-use cosmetics were swabbed at retailer counters and analyzed in the laboratory for the presence of microbes. A preliminary account of the bacteriological results has been presented [5] and the mycological results have been reported fully [4].

MATERIALS AND METHODS

Sampling

FDA investigators collected a total of 3027 cosmetic samples from 171 US retailers. Bacteriological data were obtained for 2892 samples of liquid mascara, eye shadows, liquid eyeliners, lipsticks, lip glosses, facial blushes, rouges, foundations and other products. Product samples were collected with the Transette III-R sampling and transport system (Spectrum Laboratories, Inc., Houston, TX, USA), which consists of a swab on a plastic shaft and a compartment containing 0.7 ml modified Amies Transport Medium and charcoal. The liquid-absorbing capacity of the swab was about 0.25 ml.

Solid cosmetics were sampled by rotating a swab over the available surface in an area of about 6 cm^2; the swab was dipped and rotated in liquid or in semisolid cosmetics. The cosmetic-loaded swabs were returned to the Transette III-R system. The system was weighed to the nearest milligram before and after sampling to estimate the amount of cosmetic collected.

Bacterial cultures

Swabs were used to inoculate three plates of agar culture medium for bacterial analysis. The analysts received explicit instructions about careful swabbing. The swab was rotated approximately 120° between plates and in the same direction so that a different portion of the surface was used to inoculate each of the three plates. The entire surface of each medium was inoculated.

The first medium inoculated was modified letheen agar (MLA) for unselected bacteria [3]; MacConkey agar was used for selective culture of Gram-negative bacteria. Residue on the swab was enriched by aseptically releasing the tip into modified letheen broth (MLB). Inoculated media were incubated at 30 ± 2 °C for 2 days, except MLB, which was incubated for 7 days.

Representative types of bacterial colonies or MLB cultures were streaked on MLA and incubated at 30 ± 2 °C for 2 days. Purified bacterial isolates were identified as described by Madden [3] or by the use of identification kits.

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The numbers of colonies on each plate were counted. Semiquantitative estimates of the number of total and Gram-negative bacteria per gram of sample swabbed were calculated from the colony counts. In this way it was possible to compensate for the amount of material on the swab, which varied widely between solid and semiliquid products, and to calculate the microbial density per gram of product readily removed by a customer. No correction was made for the approximate three-fold dilution of sample in the transport medium. A semiquantitative approach was required so that sampling would be non-destructive, thereby maintaining integrity of the product for future use by retailers.

RESULTS AND DISCUSSION

Even though cosmetics are not marketed as sterile products, microbial contamination was found in only 50% of 2802 shared-use cosmetics (Table 1). Positive results generally were obtained only by enrichment. The pattern of contamination was approximately the same for different cosmetic product categories: eye 49%; lip 50%; facial 54% (Table 1). In a previous survey, Dawson and Reinhardt [1] tested 15 different brands of eye shadow on display for customer use at various retail outlets in the Atlanta (GA, USA) area and found microbial contamination on 67% of 1345 swabs.

On average, 30 mg of cosmetic product was taken up in each swab (range 1–100). Total bacterial and Gram-negative bacterial contaminants were recovered in amounts ranging from 1 to 20 and 1 to 11 CFUs, respectively, per plate. The positive bacterial sample enrichment rates for the different cosmetic types were eye, 43% (650/1505); lip, 48% (333/698); face, 50% (284/564), and others, 14% (5/33). The distributions of total and Gram-negative bacterial density are shown in Table 2. The predominant density incidences were due to Gram-positive bacteria.

The mean aerobic plate count (APC) per gram of cosmetic product was 2288, 1088 and 1865 for eye, lip and facial makeup products, respectively. Only about 1/4 of a swab was used for APC analysis. The possible use of somewhat more than 1/4 of a swab would result in a two-fold overestimate of counts per gram. This could be compensated for by the fact that not all of the product was removed by swabbing, permitting residue enrichment; or by an uncorrected three-fold dilution factor in the transport medium. Furthermore,

TABLE 1

Microbially contaminated cosmetics

Category	Number of samples	
	Tested	Contaminated (%)
Eye makeup products	1505	735 (49)
Lip makeup products	698	350 (50)
Facial makeup products	564	305 (54)
Others	35	6 (17)
Totals	2802	1396 (50)

TABLE 2

Incidences of bacterial densities in cosmetics

Density (CFU g^{-1})	Density incidences/cosmetic type*				
	Eye	Lip	Face	Other	All†
0	1096	570	394	21	2081 (2416)
10^1–10^3	61	29	29	1	120 (6)
10^3–10^5	124	37	66	1	228 (28)
Over 10^5	19	5	7	0	31 (10)

* CFU = colony forming units. Average sample weights (mg) per cosmetic type: eye, 27; lip, 33; face, 44; other, 34.
† Parenthetic values represent the pooled numbers of Gram-negative isolates for the four cosmetic types.

microbial contamination of solid and semisolid cosmetics occurs primarily, if not exclusively, on the product's surface. The APC per gram might not be significantly increased or decreased if the entire makeup tester (average weight 3 g) were used instead of surface swabbing. The APC would then represent microbial loads in 3 g of product. Considering these possible analytical errors, the reported mean APCs could be reduced sixfold to 380 CFU g^{-1} for eye, 180 CFU g^{-1} for lip and 310 CFU g^{-1} for facial cosmetics.

An estimated 5% or more of the cosmetic samples were carrying microbial loads considered unacceptable under the current guidelines of not more than 500 CFU g^{-1} (ml) for eye-area products and not more than 1000 CFU g^{-1} (ml) for other cosmetics [2].

Of the 1655 isolates, 89% were Gram-positive, consisting of 60% coccal forms and 29% rod forms. The majority belonged to the genera *Staphylococcus, Bacillus* and *Corynebacterium*, representing common skin flora and contaminants that originated in soil or were airborne. Thirty-five genera of bacteria were identified; seven species in five genera (*Acinetobacter, Klebsiella, Pseudomonas, Serratia* and *Staphylococcus*) are considered potential opportunistic pathogens and were found in about 2% of all products analyzed. *Pseudomonas aeruginosa*, a most feared cause of eye infection related to cosmetics use [8], was encountered in only two instances: once from a lip and once from a facial cosmetic. *Staphylococcus aureus* was isolated from 2% (64 of 2802) of swabs. Only 11% of isolates were Gram-negative bacteria and these were mainly rod forms. This may be an underestimate since reliance was placed on the inherent neutralizing properties of the transport and MacConkey media. No neutralizers were added to the MacConkey medium, but the low isolation rate of Gram negatives from the total count plates was consistent with the Gram positives being the dominant contaminant group.

Results of a follow-up microbiological examination (data not shown) of 407 previously unopened cosmetics equivalent to the above-mentioned 5% suspected shared-use products suggested that these products were adequately preserved for storage conditions before use. This was expected as many laboratories use a rechallenge test to ensure that preservative sys-

tems are still active after 30 days. However, chemical analysis, microbial challenge and in-use testing of seven of the 407 products [7] indicated that the antimicrobial preservative activity of some of these products may have been overwhelmed by repeated microbial insults during use.

Both the cosmetic industry and FDA should develop and validate microbiological testing methods to ensure preservative efficacy in cosmetic formulations and safe products for consumers. Recommendations for increasing the safety of shared-use cosmetic test kits are as follows:

- Provide days-of-use limits for consumer shared-use cosmetic kits.
- Add desiccating agent to the bottom of consumer shared-use cosmetic cases and keep kits covered and well above floor level at all times.
- Promote single-use disposable sampling devices (swabs, brushes) that are sterile and prevent finger sampling.
- Use two kits, initiate a scheduled rotation of availability to provide sufficient time for kits to 'recover' from repeated microbial insults by consumers, i.e. give the preservative time to act (initial results of the direct contact membrane method for evaluating efficacy in pressed eye shadows indicated that surface bacterial contamination should be inactivated in about 9 days [6]).
- Institute the Hazard Analysis and Critical Control Points (HACCP) concept in the cosmetic industry for consumer shared-use cosmetics on a regular basis to identify and replace substandard product.

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