

significant even 6 hr after application, the time at which the microcapsule system had returned to baseline (see Fig. 8).

A dose-response relationship was obtained in another test conducted *in vivo*. A Microsponge system was prepared with a proprietary emollient entrapped at 50% concentration and incorporated into a standard oil-in-water emulsion at 0.5%, 1%, and 3% levels. These creams were applied to the back of the hand of human subjects and periodic measurements of skin softening were made with the GBE. An increase in skin suppleness proportional to the concentration of emollient was obtained (Fig. 14).

Corticosteroids produce a localized blanching effect on the skin caused by vasoconstriction (6). To determine the release of corticosteroids entrapped in Microsponges, an *in vivo* vasoconstriction assay was conducted. A system containing 0.05% entrapped fluocinolone acetonide was applied to intact skin on both forearms of all test subjects. Blanching effects were measured at 8, 24, and 32 hr after application. One-half hour before reading, one arm was gently rubbed to effect a renewed release of the entrapped ingredient. Observations on the nonrubbed arm indicate that sustained release was effective even at 32 hr (Fig. 15). However, at each time-point, the blanching observed in the site rubbed 30 min earlier was greater than in the nonrubbed site.

Although most topical drugs must penetrate into the stratum corneum to be effective, sunscreens have greater efficiency when they remain on the skin surface to absorb ultraviolet light from the sun. After penetration, sunscreens can absorb radiation below the skin surface, but damage is already occurring that reduces sunscreen efficacy. Sunscreens can also be irritants and even skin sensitizers. If these ingredients can be kept on the skin surface for a longer length of time, and in controlled quantities, an increased efficacy and a reduced sensitivity to these materials would result. This could overcome the need for repeated applications and provide enhanced aesthetic appeal for the consumer.

To determine whether or not sunscreens entrapped in a Microsponge system would still be available for sun protection, octyl dimethyl PABA (Padimate 0) was entrapped at 50% payload; the Microsponges were incorporated into an oil-in-water emulsion at a 2.8% level to provide a 1.4% sunscreen concentration. The sun protection factor (SPF) of this formulation was compared with that of a similar formulation containing the same amount of sunscreen that was freely dispersed in the base. To assess the possible additive effects of free and entrapped sunscreen, a product containing 1.4% free and 1.4% entrapped Padimate 0 was also prepared. The lotion base alone and one containing 8% free homosalate were used as negative and positive controls. The SPF testing was performed on the backs of