Physical/chemical properties of the entrapped active ingredient, including volatility, viscosity, and solubility of the entrapped material

Physical/chemical properties of the polymeric microsponge, such as pore diameter and volume and resiliency of the polymeric sphere

Vehicle and product form in which the Microponges will be used (oils, lotions, creams, powders and other physical forms)

B. Release on Command

By proper manipulation of the aforementioned programmable parameters, Microsponges can be designed to release given amounts of active ingredients over time in response to one or more external triggers.

1. Pressure Release

Like an ordinary sponge, Microsponge systems release fluid when pressed or "squeezed," thereby replenishing the level of entrapped active ingredient onto the skin. This action results in renewed product efficacy (Fig. 8). The amount of ingredient released may also depend upon the pressure applied to the sponge and the resiliency of the microsphere.

2. Temperature Change

Some entrapped materials, such as sunscreens and emollients, can be too viscous at room temperature to flow spontaneously from the Microsponge onto the skin. When warmed by the skin temperature, the sun or other heat source, their viscosity may decrease, resulting in an increased flow rate (Fig. 9).

3. Solubility

By taking into account the solubility of the entrapped ingredient, the Microsponge system can be programmed to respond to water, perspiration, or other solvents. For example, dry Microsponges loaded with a water-soluble ingredient, such as antiperspirants or antiseptics, will release that ingredient in the presence of water (Fig. 10). Release can also be activated by diffusion, taking into consideration the partition coefficient of the ingredient between the Microsponge and the outside system.

VII. SAFETY SUBSTANTIATION

Microsponge systems are made of biologically inert polymers. More than 30 safety studies, including skin irritation (in rabbits and hu-