

action products, or degradation of an ingredient by silicone. The only troublesome interaction of silicones with other ingredients is their well-known defoaming properties, which can be very undesirable in a product that is intended to foam! If foaming is an important formulation attribute, then dimethicone copolyol should be used because this class of silicones exhibits defoaming behavior only at elevated temperatures.

C. The Use of Silicones in Topical Creams and Lotions

The term *lotion* is generally used to describe topical formulations that are pourable emulsions. *Creams* are similar to lotions, but higher in viscosity and not pourable. Often a lotion can be modified to produce a cream simply by increasing the proportion of oils used in the formulation. In describing the preparation of topical creams and lotions, it is convenient to group the ingredients into two categories: water-insoluble ingredients, which are referred to collectively as the *oil phase*, and water-soluble ingredients, which are collectively referred to as the *water phase*. Topical creams and lotions contain emulsifiers that allow stable mixtures of the oil phase and water phase to be prepared. Although emulsifiers, by their nature, are partially soluble in both phases, they are usually added as part of the oil phase.

Table 2 lists the ingredients for a lotion formulation based on the widely used stearate-cetyl alcohol emulsifier combination. The primary emulsifier for this formulation is triethanolamine stearate, which is formed from triethanolamine and stearic acid when the formulation components are mixed together. Cetyl alcohol is included as a secondary emulsifier to improve the stability of the lotion and provide a smooth texture. The other ingredients: dimethicone, mineral oil, and petrolatum could be considered the "active ingredients," as these are the most commonly used emollients in commercial skin care lotions. The same OTC panel that concluded that dimethicone is safe and effective for use in skin protectants (see Sect. II.A) also approved mineral oil and petrolatum for this purpose.

The basic lotion formulation is made by weighing the oil-phase ingredients and water-phase ingredients in separate containers. Each phase should be heated to approximately 70°C, and mixed until uniform. The hot oil phase is then added to the hot water phase while stirring with a propeller-type mixer. The mixer speed and addition rate should be such that the oil phase is rapidly dispersed in the water phase during the addition. However, the mixer speed should not be so high that a vortex is created that will draw air bubbles into the mixture. Air bubbles will interfere with the emulsification of the oil phase. Mixing must be continued as the lotion