as a safe and effective ingredient for such products. Specifically, the panel concluded that dimethicone was a safe and effective ingredient for a topical drug product used to provide temporary relief of minor skin irritations when used at a concentration from 1% to 30%. After reviewing comments from the public, the FDA issued a notice of proposed rule-making in 1983 in which the status of dimethicone as a safe an effective ingredient was retained (5).

The dimethicones most commonly used in topical formulations are in the viscosity range of 100 to 1000 cs. This represents a compromise between ease of formulation and the benefits that are typically sought by the inclusion of silicone in the formulation. High-viscosity dimethicones have increased skin protection benefits and are more substantive than low-viscosity dimethicones, but they are more difficult to incorporate into topical formulations. Dimethicones with viscosities below 100 cs are sometimes used when optimum spreading and lubricity are desired, but cyclic PDMS has largely replaced dimethicone in these instances because of its ease of formulation.

To the formulator who is attempting to incorporate unfamiliar ingredients into a topical formulation, one useful rule is that additives that are soluble in one or more ingredients of a known formulation can generally be included in small amounts without making any other formulation changes. The rule applies to both homogeneous (solution) and heterogeneous (emulsion) products. Vaughan has published a solubility parameter for dimethicone of 5.92 (6). A general rule (also given in the same publication) is that materials with solubility parameters within 2 units of the material of interest will be soluble. This suggests that dimethicone should be soluble in several nonpolar oils commonly used in topical formulations: mineral oil and petrolatum. In practice, however, this is not true for dimethicone, because solubility parameters do not work well for predicting the solubility of high polymers owing to factors arising from the entropy of mixing. Isopropyl myristate is one of the few commonly used organic ingredients that is miscible with dimethicone. The solubility of dimethicone in other organic ingredients is generally poor. The only exceptions are very low molecular weight dimethicones with viscosities of less than 5 cs.

Despite the insolubility of most dimethicones in typical topical formulation ingredients, they are not especially difficult to include in topical formulations. For emulsion products, a number of factors work in the formulators favor. First, the emulsifiers commonly used to stabilize topical formulations can usually accommodate a small amount of dimethicone, even though it has different solubility properties than the other oils used in the formulation. Second, most topical formulations are sufficiently viscous to stabilize the added