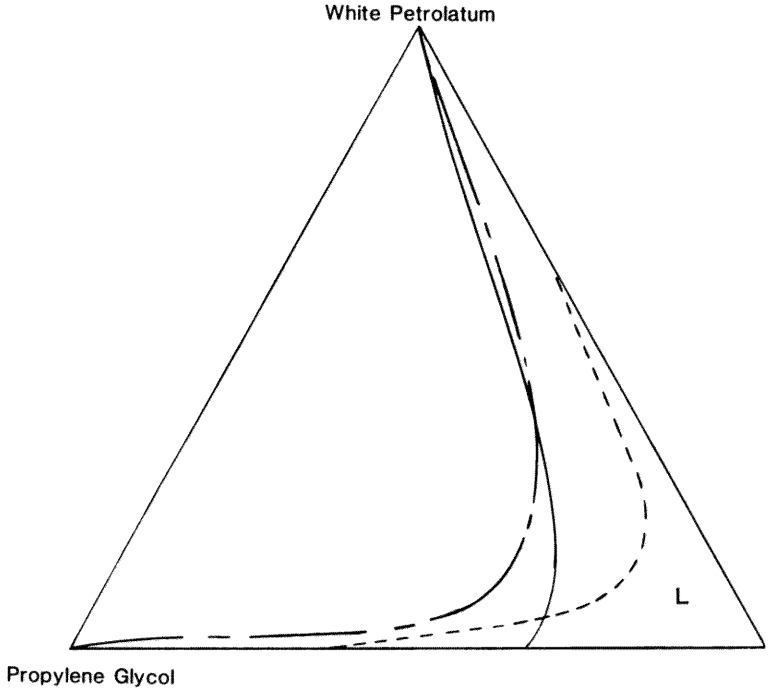

Figure 9.15 Pseudoternary diagram for the propylene glycol–white petrolatum–surfactant systems at 70°C. The mutually miscible solubility area is denoted by L for the surfactants ——— glycerol monostearate, —— – —— – —— sodium stearoyl lactylate, and ------ sorbitan monolaurate.

to be able to accommodate propylene glycol at ambient conditions for an indefinite period, the vehicle will spontaneously separate into two phases if not vigorously mixed when heated. Any separation of a propylene glycol-rich phase will contain high concentrations of the drug, resulting in content uniformity problems for the product. The replacement of glycerol monostearate with a less lipophilic surfactant, sodium stearoyl lactylate (SSL), gives phase behavior more suitable for the stabilization of a propylene glycol–white petrolatum ointment base. Although incorporation of 7% propylene glycol is not possible at higher than 65% white petrolatum, SSL is miscible with both propylene glycol and white petrolatum at 70°C. This implies that the surfactant is appropriately balanced between the polar