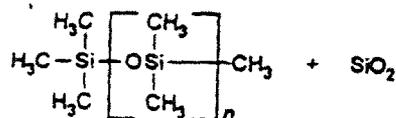


## **Appendix 5**

Summary data from The Procter & Gamble Company, Health Care Research Laboratory, Laboratory Notebook HH-0736 Dated June 1991, using the USP Simethicone Defoaming Activity Test.

## Simethicone



Simethicone.

$\alpha$ -(Trimethylsilyl)- $\omega$ -methylpoly[oxy(dimethylsilylene)], mixture with silicon dioxide [8050-81-5].

### Defoaming activity—

*Foaming solution*—Dissolve 1 g of octoxynol 9 in 100 mL of water.

*Test preparation*—Transfer 200 mg of Simethicone to a 60-mL bottle, add 50 mL of tertiary butyl alcohol, cap the bottle, and shake vigorously. [NOTE—Warm slightly, if necessary, to effect solution.]

*Procedure*—[NOTE—For each test, employ a clean, unused, 250-mL glass jar.] Add, dropwise, 500  $\mu$ L of the *Test preparation* to a clean, unused, cylindrical 250-mL glass jar, fitted with a 50-mm cap, containing 100 mL of the *Foaming solution*. Cap the jar, and clamp it in an upright position on a wrist-action shaker. Employing a radius of  $13.3 \pm 0.4$  cm (measured from center of shaft to center of bottle), shake for 10 seconds through an arc of 10 degrees at a frequency of  $300 \pm 30$  strokes per minute. Record the time required for the foam to collapse. The time, in seconds, for foam collapse is determined at the instant the first portion of foam-free liquid surface appears, measured from the end of the shaking period. The defoaming activity time does not exceed 15 seconds.

Attachment I

Supporting Data for BSS Plus Simethicone Product

In-vitro Foam Reducing Capacity

Sample	Sim. (Conc.)	Avg. Final Foam Height
Pepto Control	0 mg/oz	71.99 mm
Pepto B	30 mg/oz	8.66 mm
Pepto D	60 mg/oz	7.33 mm

Rat Gastroprotection

Sample	Stomach Score X mm/length	% Gastric Protection from ETOH
Pepto D	15.6 s,w	85%
Pepto Control	32.7 s,w	68%
Water Control	102.2	---
Simethicone	135.6	---

s = significantly different from simethicone,  $p < 0.05$   
w = significantly different from water,  $p < 0.05$

Stability Data (pH change over time)

Sample	Initial	pH			
		1 hr	1 day	1 week	2 weeks
Pepto B	3.59	3.64	---	3.78	3.86
Pepto D	3.58	3.67	3.76	3.84	3.91
Pepto Control	---	---	3.60	3.82	3.90