



TECHNICAL DATA SHEET

Product: Alpha-Caine® Topical Anesthetic Gel

Product Description: Flavored, topical anesthetic gel used to numb gums and other oral mucous tissues before an injection.

Indications for Use: Alpha-Caine® Topical Anesthetic Gel is for minor mouth irritations, ulcers, wounds, or relieving pain prior to injection.

Appearance: Semi-opaque gel available in variety of colors and flavors.

Curing Mechanism: Not applicable

Shelf-Life: 36 months

Filler Type: None

Main Composition (%w/w):

<u>Inactive Ingredients:</u>	
Polyethylene Glycol	70 – 80
Flavor	≤5
Sweetener	<3
Colorant(s)	<1
<u>Active Ingredient:</u>	
Benzocaine	20

Physical /Mechanical Properties: (Typical Values)

Appearance:	Semi-opaque gel
Color:	Strawberry red, mint green, cherry red & bubble gum pink
Odor/Flavor:	Strawberry, mint, cherry and bubble gum
pH (5% in water):	6.57
Specific Gravity:	1.12 at 25°C

Regulatory Classification: This product is in conformity with the following standard(s) or other normative documents:

21 CFR Part 211 – Current Good Manufacturing Practice for Finished Pharmaceuticals
Current USP Monograph – *Benzocaine Gel*

Signature/ Date: John Pontikis / 10/25/18

Name: John Pontikis
Position: Management Representative