

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 <Benzocaine Gel>