



February 6th, 2019

RE: Benzocaine Topical Anesthetic Allergens

To Whom it may concern:

Benzocaine gels manufactured by Keystone Industries are safe and effective for use by most patients. The Drug Facts labeling provided with each unit of benzocaine topical anesthetic contains the directions for safe use, as well as warnings that should be read and understood prior to using the product. An abbreviation warning, which was acquired from Drug Facts labeling, regarding a known benzocaine allergy is noted below:

Allergy Alert: Do not use benzocaine anesthetics on patients with a history of allergies to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics.

Benzocaine itself may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in the blood. Please read the full Drug Facts provided with product labeling before using this product and ask patients if they have sensitivities to "caine" anesthetics prior to use.

Food Allergens:

To the best of our knowledge, and based on the information provided by our flavoring supplier, benzocaine gels manufactured by Keystone Industries DO NOT contain any of the following FOOD allergens: Gluten, Celery (root, leaves, stalk), Sulfites, Eggs or egg products, Wheat or wheat products, Milk or milk products, Seafood (fish or crustaceans), fruit or fruit derivatives, Peanuts or peanut products, Soybean or soybean products, Sunflower, sesame, poppy, or cotton seeds, Tree nuts: Almond, Beech Nut, Brazil Nut, Butternut, Cashew, Chestnut (Chinese, American, European, Sequin), Chinquapin, Coconut, Ginko Nut, Hazelnut/Filbert, Hickory Nut, Lichee Nut, Macadamia Nut/Bush Nut, Pecan, Pili Nut, Pine Nut/Pinon Nut, Pistachio Nut, Sheanut, Walnut (English, Persian, Black, Japanese, California), and Heartnut.

Dyes:

Benzocaine gels manufactured by Keystone Industries may contain the following dyes: blue #1, green #3, Green #5, red #3, red #28, red #40, yellow #5 (tartrazine), yellow #6, as a color additive.

Signed,
Mark Evans
Regulatory Affairs Associate
Keystone Industries