

NATRIUM PRODUCTS, INC.

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Re: Shelf Life of Natrium Products, Inc. Sodium Bicarbonate

Natrium Products, Inc. does not assign expiration or retest dates for sodium bicarbonate. Sodium bicarbonate is chemically stable and when properly stored will have a shelf life of at least 3 years for most applications.

The shelf life of Natrium Products sodium bicarbonate that is intended for hemodialysis is dependent on the carbonate (CO_3) content in the product, which cannot exceed the USP specification limit of 0.23%. Therefore, the shelf life is a function of the initial carbonate content at the time of manufacture and any carbonate formation that may occur during storage.

For hemodialysis grade sodium bicarbonate produced by Natrium Products, the rates of carbonate formation in two package types have been estimated from shelf life studies and are summarized below.

50-lb. Bags: 0.0035% CO_3 per month

2300-lb. Polyethylene-lined bulk bags ("Super Sacks"): 0.0012% CO_3 per month

Based on these estimates, a Natrium Products lot that contains the average level of carbonate at the time of manufacture (0.15% CO_3) has an estimated shelf life of approximately 23 months in 50-lb. bags, and greater than 3 years in bulk bags. The shelf life for any individual lot will vary depending on the carbonate content at the time of manufacture.



Andrew F. Hoffmann
Regulatory Manager