

## **bibag® – Church & Dwight Approved As Additional Supplier of Sodium Bicarbonate**

### **PRODUCT NOTIFICATION**

Dear Valued Customer:

Thank you for being a loyal FMCNA customer. We appreciate your business and would like you to know that we've approved Church & Dwight as an additional supplier of sodium bicarbonate that's used to manufacture *bibag*.

#### **Why are we approving Church & Dwight as an alternate supplier for *bibag*?**

- Increased global demand for sodium bicarbonate and *bibag*
- Our current supplier Solvay is experiencing supply and manufacturing constraints
- Approval of Church & Dwight enables greater flexibility to use either supplier and it also helps mitigate any potential supply interruptions

#### **Does Church & Dwight supply sodium bicarbonate for any other FMCNA products?**

Yes, USP grade sodium bicarbonate supplied by Church & Dwight is currently used in the following products:

- 08-4110-6 NaturaLyte Dry Pack RX10
- 08-4112-2 NaturaLyte Dry Pack RX12
- 08-4400-1 NaturaLyte Dry Pack Bicarbonate Carton
- *bibag* – Original supplier from 2014 – 2017, until manufacturing moved to France

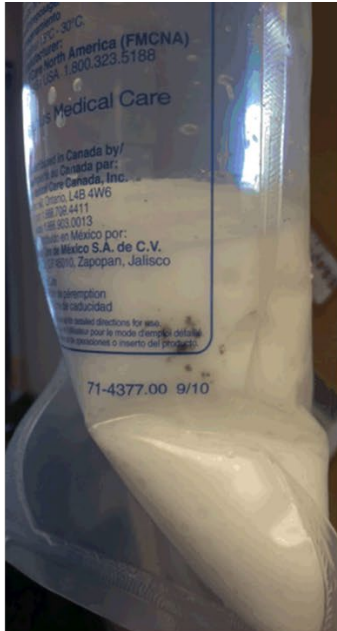
#### **How does the Church and Dwight sodium bicarbonate for *bibag* differ from the Solvay sodium bicarbonate for *bibag*?**

There are two processing methods for sodium bicarbonate.

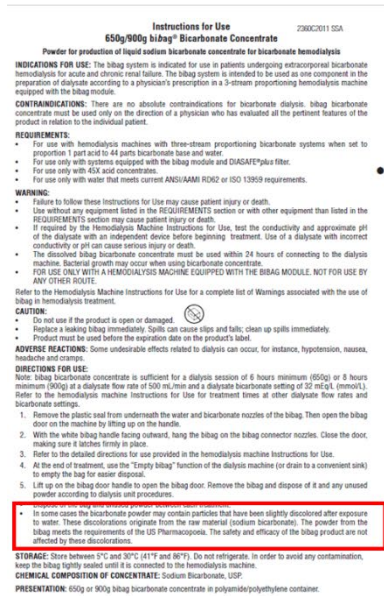
1. One method is to mine Trona or Soda Ash from the ground and then add water and carbon dioxide during production to yield sodium bicarbonate. This is the method used by Church and Dwight. Since the source of the raw material is the earth, it can contain some organic elements, even though the raw material is USP grade.
2. The second method is to react carbon dioxide (from heated limestone) with ammonia and a salt brine to produce sodium bicarbonate. This method, discovered by Ernest Solvay in the 1860s, doesn't contain the same organic elements as Trona that's mined.

## What implications does this have for bi bag produced with Church & Dwight Bicarbonate?

- You may observe an area of gray discoloration appearing in the bag approximately 2 – 2.5 hours into the treatment. This “gray matter” is an agglomeration of silica particles caused by the special conditions created by dissolution and filtration of the sodium bicarbonate inside the bag. Silica is a naturally occurring component of soda ash.
  - Slightly massaging the bag at the time of appearance will disperse the hydrated silica matrix and may keep the gray matter from concentrating
  - It is not mandatory to massage the bag, massaging the bag is for aesthetic purposes.
- Images of the occurrence of gray matter



The discoloration phenomenon is described in the bibag IFU, as was identified during the product's launch in 2014.



In some cases the bicarbonate powder may contain particles that have been slightly discolored after exposure to water. These discolorations originate from the raw material (sodium bicarbonate). The powder from the bibag meets the requirements of the US Pharmacopoeia. The safety and efficacy of the bibag product are not affected by these discolorations.

This phenomenon does not occur in bibags produced with Solvay bicarbonate due to the process in which the sodium bicarbonate is manufactured.

It is important to understand that both suppliers, Church & Dwight and Solvay, supply us with USP grade sodium bicarbonate to be used in producing bibag. Neither supplier can satisfy the worldwide demand for sodium bicarbonate used in bibag, so it is imperative that we have the flexibility to source the raw material from both.

It is highly likely that shipments of bibag may alternate between sources of sodium bicarbonate.

We anticipate shipments using Church & Dwight bicarbonate to begin leaving our distribution centers in the first quarter of 2023.

Please contact Fresenius Medical Care Customer Service at 800-323-5188 for further information. Thank you for your continued support of our Fresenius Renal Technologies hemodialysis products.

Sincerely,

Stephen Jaquith  
Product Director, Concentrates and Dialyzers

Please forward this letter to the Nurse Manager, Chief Technician and Patient Care Staff

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