

**Important Safety Information  
Sodium Acetate Injection, USP -  
Potential for the Development of Particulate Matter**

February 23, 2023

**Audience**

Healthcare professionals including physicians, nurses, hospital pharmacists, and other personnel involved in the administration, handling, and distribution of Sodium Acetate Injection, USP.

**Key messages**

- **Vials of Sodium Acetate Injection, USP by Fresenius Kabi Canada Ltd. (DIN 02139529) from lot 6126849 may develop particulate matter over the course of its shelf life.**
- **In the event that particulate matter is inadvertently injected into a patient, there is potential for patient injury, such as local inflammation, phlebitis, abscesses, granulomas in visceral organs, allergic response, infections at the injection site and/or embolization in the body.**
- **Healthcare professionals are advised to:**
  - **Consider clinical alternatives to sodium acetate for patients when possible and conserve product only for medically necessary use**
  - **Carefully inspect all sodium acetate injectable products before and after dilution, regardless of the lot. If particulate matter is observed, the product should NOT be administered.**

**When using lot 6126849 of Sodium Acetate Injection, USP for non-Total Parenteral Nutrition (TPN) therapies, use a 5 micron nylon filter needle to withdraw the required calculated volume of sodium acetate from the vial. When administering the final admixture to patients, use the most suitable filter among the following:**

- **A 0.22 micron or 1.2 micron polyethylenesulfone (PES) in-line filter, OR**
- **A 0.22 micron or 1.2 micron nylon in-line filter, OR**
- **A 0.45 micron or 1.2 micron acrylic copolymer in-line filter.**

- **When using lot 6126849 of Sodium Acetate Injection, USP for 2-in-1 (amino acids and carbohydrates) TPN therapies, use a 5 micron nylon filter needle to withdraw the required calculated volume of sodium acetate from the vial, then use a TPN-compatible 0.22 micron in-line filter to administer the final admixture.**
  
- **When using lot 6126849 of Sodium Acetate Injection, USP for 3-in-1 (lipid, amino acids, and carbohydrates) TPN therapies, use a 5 micron nylon filter needle to withdraw the required calculated volume of sodium acetate from the vial, then use a TPN-compatible 1.2 micron in-line filter to administer the final admixture.**

### **What is the issue?**

There is a potential for the development of particulate matter in vials of Sodium Acetate Injection, USP (DIN 02139529) from lot 6126849 over the course of its shelf life.

The vials from lot 6126849 are being released into the Canadian market due to the medical necessity of the product and to prevent potential for product shortages.

Particulate matter (greater than 5 microns) could potentially obstruct blood flow through capillaries.

In the event that particulate matter is inadvertently injected into a patient, there is potential for patient injury, such as local inflammation, phlebitis, abscesses, granulomas in visceral organs, allergic response, infections at the injection site and/or embolization in the body.

Fresenius Kabi Canada Ltd., is providing information on proper handling, including the filters to be used, with distributed vials from this affected lot as a safety measure to mitigate the risk.

### **Products affected**

<b>Product</b>	<b>Product Code</b>	<b>Package Size</b>	<b>Market Authorization Holder</b>	<b>DIN</b>	<b>Lot/ Expiry Date</b>
Sodium Acetate Injection, USP, 328 mg/mL	C3250	50 mL vial	Fresenius Kabi Canada Ltd.	02139529	6126849/ APRIL 2024

### **Background information**

Sodium Acetate Injection, USP is indicated as a source of sodium, for addition to



large volume intravenous fluids to prevent or correct hyponatremia in patients with restricted or no oral intake. It is also useful as an additive for preparing specific intravenous fluid formulas when the needs of the patient cannot be met by standard electrolyte or nutrient solutions.

Sodium Acetate Injection, USP, 328 mg/mL, 100 mL vial from lot 6125334 and Sodium Acetate Injection, USP, 328 mg/mL, 50 mL vial from lot 6125335 were previously [recalled](#) due to the presence of particulate matter in the vials. Healthcare professionals are reminded that product from these two lots should **not** be used.

Fresenius Kabi Canada Ltd. has initiated investigations to determine the root cause and any corrective and preventive actions.

### **Information for healthcare professionals**

Healthcare professionals are advised to:

- Carefully inspect all sodium acetate injectable products, regardless of the lot, before and after dilution and all intravenous bags. If particulate matter is observed, the product should NOT be administered.
- Consider clinical alternatives to sodium acetate for patients when possible and conserve product only for medically necessary use.
- When using lot 6126849 of Sodium Acetate Injection, USP for non-Total Parenteral Nutrition (TPN) therapies, use a 5 micron nylon filter needle to withdraw the required calculated volume of sodium acetate from the vial. When administering the final admixture to patients, use the most suitable filter among the following:
  - A 0.22 micron or 1.2 micron polyethylenesulfone (PES) in-line filter, OR
  - A 0.22 micron or 1.2 micron nylon in-line filter, OR
  - A 0.45 micron or 1.2 micron acrylic copolymer in-line filter.
- When using lot 6126849 of Sodium Acetate Injection, USP for 2-in-1 (amino acids and carbohydrates) TPN therapies, use a 5 micron nylon filter needle to withdraw the required calculated volume of sodium acetate from the vial, then use a TPN-compatible 0.22 micron in-line filter to administer the final admixture.
- When using lot 6126849 of Sodium Acetate Injection, USP for 3-in-1 (lipid, amino acids, and carbohydrates) TPN therapies, use a 5 micron nylon filter needle to withdraw the required calculated volume of sodium acetate from the



vial, then use a TPN-compatible 1.2 micron in-line filter to administer the final admixture.

### **Report health or safety concerns**

Any case of serious or unexpected adverse reaction in patients receiving Sodium Acetate Injection, USP should be reported to Fresenius Kabi Canada Ltd. or Health Canada.

Fresenius Kabi Canada Ltd.  
165 Galaxy Boulevard, Suite 100  
Toronto, ON M9W 0C8  
Telephone: 905-770-3711  
Fax: 1-844-605-4465  
Email: [Canada\\_vigilance@fresenius-kabi.com](mailto:Canada_vigilance@fresenius-kabi.com)

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on [Adverse Reaction Reporting](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax.

A handwritten signature in blue ink that reads "Anabela Costa".

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**Images**

Sodium Acetate Injection, USP, 328 mg/mL, 50 mL vial by Fresenius Kabi Canada Ltd.

