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

March 15, 2022

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 6126554 may contain particulate matter.**
- **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 due to shortages of this product.**
    - **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 the affected lot of Sodium Acetate Injection, USP for non-Total Parenteral Nutrition (TPN) therapies, use a 5 micron filter needle to withdraw the required calculated volume and use a 0.22 micron in-line filter when administering the final intravenous admixture to patients.**
    - **When using the affected lot of Sodium Acetate Injection, USP for 2-in-1 (amino acids and carbohydrates) TPN therapies, use a 5 micron filter needle to withdraw the required calculated volume of sodium acetate then use a 0.22 micron in-line filter for the final admixture.**
    - **ONLY for the administration of 3-in-1 (lipid, amino acids, and carbohydrates) TPN therapies, when using the affected lot of Sodium Acetate Injection, USP, use a 5 micron filter needle to withdraw the required calculated volume of sodium acetate then use a 1.2 micron in-line filter for the final admixture.**

What is the issue?
Fresenius Kabi Canada Ltd. has identified visible particulate matter in certain vials of Sodium Acetate Injection, USP from lot 6126554 during routine retention sample testing.

The distributed vials from the affected lot are **not** being recalled due to shortages of this product.

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.

There have been no reports of adverse events to date for the affected lot.

Products affected

Product	Product Code	Package Size	Market Authorization Holder	DIN	Lot/ Expiry Date
Sodium Acetate Injection, USP, 328 mg/mL	C32B1	100 mL vial	Fresenius Kabi Canada Ltd.	02139529	6126554/ 2023DE

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 before and after dilution, regardless of the lot. If particulate matter is observed, the product should **NOT** be administered.

- Due to shortage concerns of this product, consider clinical alternatives to sodium acetate for patients when possible and conserve product only for medically necessary use.
- When using the affected lot of Sodium Acetate Injection, USP for non-Total Parenteral Nutrition (TPN) therapies, use a 5 micron filter needle to withdraw the required calculated volume and use a 0.22 micron in-line filter when administering the final intravenous admixture to patients.
- When using the affected lot of Sodium Acetate Injection, USP for 2-in-1 (amino acids and carbohydrates) TPN therapies, use a 5 micron filter needle to withdraw the required calculated volume of sodium acetate then use a 0.22 micron in-line filter for the final admixture.
- **ONLY** for the administration of 3-in-1 (lipid, amino acids, and carbohydrates) TPN therapies, when using the affected lot of Sodium Acetate Injection, USP, use a 5 micron filter needle to withdraw the required calculated volume of sodium acetate then use a 1.2 micron in-line filter for the final admixture.

Action taken by Health Canada
Health Canada is communicating this important safety information to healthcare professionals and Canadians via the Recalls and Safety Alerts Database on the Healthy Canadians Web Site. This communication will be further distributed through the MedEffect™ e-Notice email notification system.

Health Canada has directed Fresenius Kabi Canada Ltd., the market authorization holder for Sodium Acetate Injection, USP, 328 mg/mL, 100 mL vial, to ensure that they inform all impacted healthcare professionals and other personnel involved in administering, handling, or distributing this product.

Health Canada is monitoring the company's implementation of any necessary corrective and preventative actions. If additional safety information is identified, Health Canada will take appropriate action and inform Canadians as needed.

Report health or safety concerns
Health Canada's ability to monitor the safety of marketed health products depends on healthcare professionals and consumers reporting adverse reactions and medical device incidents. 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

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) for information on how to report online, by mail or by fax.

For other health product inquiries related to this communication, contact Health Canada at:

Health Product Compliance Directorate, Regulatory Operations and Enforcement Branch
E-mail: hpce-cpsal@hc-sc.gc.ca
Telephone: 1-800-267-9675

March 15, 2022

Dara Man,

National Safety Officer, Vigilance

Fresenius Kabi Canada Ltd.

Images

Sodium Acetate Injection, USP, 328 mg/mL, 100 mL vial by Fresenius Kabi Canada Ltd.