Fresenius Kabi – Recall of sodium acetate injection

- On March 7, 2022, Fresenius Kabi announced a user-level recall of seven lots of sodium acetate injection due to the presence of particulate matter composed of carbon and oxygen with varying amounts of iron and trace amounts of sodium, silicon, chromium, aluminum and cellulose, found in reserve and/or stability sample vials.

- The recalled lots were distributed between September 2020 and November 2021.

Product Description	NDC#	Lot # (Expiration Date)
Sodium acetate injection, 400 mEq/ 100 mL (4 mEq/mL), 100 mL fill in a 100 mL vial	63323-032-00	6124193 (5/2022); 6124196 (5/2022); 6124226 (5/2022); 6124532 (6/2022); 6125333 (12/2022); 6125678 (1/2023); 6126846 (8/2023)

- Sodium acetate injection is indicated as a source of sodium, for addition to large volume IV fluids to prevent or correct low blood sodium levels in patients with restricted or no oral intake. It is also useful as an additive for preparing specific IV fluid formulas when the needs of the patient cannot be met by standard electrolyte or nutrient solutions.

- The administration of an injectable product that contains particulate matter may result in local irritation or swelling or infection in response to the foreign material. If the particulate matter reaches the blood vessels it can travel to various organs and block blood vessels in the heart, lungs or brain which can cause stroke and even lead to death.

- Per Fresenius Kabi, no adverse event reports have been received to date for these recalled lots, which were produced and sold in 2020 and 2021.

- Anyone with an existing inventory of the recalled product should stop distribution and quarantine the product immediately.

- Patients should contact their physician or health care provider if they have experienced any problems that may be related to taking or using the recalled sodium acetate injection product.

- Contact Fresenius Kabi at **1-866-716-2459** for more information about the recall.