Fresenius Kabi Canada Ltd.

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DRUG RECALL – TYPE I – URGENT

Sodium Acetate Injection, USP

Date:	March 4, 2022
Risk Classification:	**Type I Recall *URGENT***
Drug:	Sodium Acetate Injection, USP
Product Code and Lots:	C32B1 Sodium Acetate Injection 400 mmol/100 ml Lot: 6125334 Exp: 06/2023 and C3250 Sodium Acetate Injection 200 mmol/50 ml Lot: 6125335 Exp: 06/2023
DIN:	02139529

Dear Customer/Healthcare Professional,

Fresenius Kabi Canada would like to inform you of our decision to recall two lots of the product Sodium Acetate Injection, USP.

This recall is being performed to the wholesaler and healthcare organization level. Fresenius Kabi has decided to take this action due to particulate matter found in retention and/or stability samples of two batches distributed in Canada. The investigation revealed that this issue is limited to the product batches indicated above. Health Canada has been informed of this issue and is aware of the recall proceedings.

Administration of products containing particulate matter could result in venous and arterial emboli, abscesses, granulomas in visceral organs, phlebitis, inflammatory reactions and infections at the injection site. No adverse event reports have been received for the batch numbers.

Please examine your inventory immediately to determine if you have any of the affected lot numbers. If yes, discontinue use and distribution of the affected lots immediately.

Please complete the Customer Reply Form provided as soon as possible. A reply is requested within 24 hours of receipt of this communication.

Return affected units to your point of purchase.

Affected units purchased directly from Fresenius Kabi Canada should be returned to the following site:
Fresenius Kabi Canada Ltd.
c/o Accuristix
109 Summerlea Road
Brampton, ON L6T 4P6

A Returned Goods Authorization (RGA) number is required to return units purchased directly from Fresenius Kabi Canada. A RGA will be provided by Customer Service upon receipt of a completed Customer Reply Form. For pick-up of product to be returned, please contact ATS at 1-877-694-4454 and utilize Account Number 4005154 for return of the product. All boxes being returned should have the RGA number listed on the exterior of the box.

Please ensure within your organization that every user of the concerned products and all other relevant persons or entities where the concerned products have been transferred are informed about this letter and the actions as described herein.

If you experience an adverse reaction with respect to this occurrence, please contact Fresenius Kabi Canada Vigilance at canada_vigilance@fresenius-kabi.com and identify the product and lot associated with the incident. Product Quality problems experienced can be reported to Fresenius Kabi Complaints department at Canada_Product_Complaints@Fresenius-Kabi.com. For general inquiries please contact Customer Service at 1-877-821-2108.

Please complete the attached Customer Reply Form to confirm that you have received this letter and return it to Fresenius Kabi Canada via the fax number or email address provided on the form within 24 hours of receipt.

Fresenius Kabi is committed to providing you with the highest level of service, product quality and reliability. We apologize for any inconvenience this has caused and we appreciate your attention to this matter.

Anabela Costa
Director, Quality
Fresenius Kabi Canada Ltd.

FRESENIUS KABI

DRUG RECALL – CUSTOMER REPLY FORM

Type I Recall - URGENT – Sodium Acetate Injection, USP

Please reply immediately

Please complete and return this form to the FAX number or EMAIL address listed below as confirmation that you have received this notification.

FAX: 1-877- 821-2108 (A fax cover sheet is not necessary)

Email: Canada_Product_Complaints@Fresenius-Kabi.com

Facility Name and Address:		
Reply Confirmation Completed By: *(Please Print Name)*		
Title: *(Please Print)*		
Phone Number: *(Including Area Code)*		
If purchased through a wholesaler, please list wholesaler name and account number:	Name:	Account Number:

Please check one

☐	We have received the above mentioned letter, understand the instructions and have disseminated this information to our staff and to other centers or facilities, as applicable, and have the following product and quantity in our inventory.		
	Material	Lot(s) Indicate lot(s) available in your inventory	Quantity (number of vials)
	C32B1 Sodium Acetate Injection 400 mmol/100 ml	6125334	
	C3250 Sodium Acetate Injection 200 mmol/50 ml	6125335	
☐	We have received the above-mentioned letter and have disseminated this information to our staff and to other centers or facilities, as applicable, and **DO NOT** have any of the listed products/lot numbers in our inventory.		

Signature/Date:

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Print Name, Sign and Date