

Ref: CAPA-2021-07
MHRA Ref: 2021/005/005/601/530
20/05/2021

Dear Sirs/Madams,

Clinell Universal Wipes – Urgent recall REF CW200

ISSUE

Recent, routine testing of five Lots/batches of Universal Wipes, REF CW200 manufactured in one of our smaller factories has identified low-level contamination with *Burkholderia cepacia*.

Burkholderia cepacia complex (BCC), often referred to simply as *Burkholderia cepacia* (*B. cepacia*) is the name given to a group of closely related gram-negative bacilli found widely in the natural environmental including soil and water.

Described as ‘opportunistically pathogenic’ *B. cepacia* poses little medical risk to healthy individuals but can cause serious infections in those with compromised immune systems notably individuals with cystic fibrosis and chronic granulomatous disease.

B. cepacia is a known cause of infections in hospitalised patients, particularly those with weakened immune systems, spread by person to person contact or contact with contaminated surfaces.

Treatment of individual infections with *B. cepacia* present a challenge as it is often resistant to many of the more commonly used antimicrobials. Over the last couple of decades, outbreaks of *B. cepacia* infection have been linked to contaminated environments, devices, solutions and medications.

GAMA Healthcare are initiating an immediate recall of the batches identified whilst continuing the ongoing investigation at the factory.

The batches identified were manufactured in July 2020 and were distributed between 11th September and the end of December, 2020. You have received the affected products as listed below.

LOT	GAMA Document	Date	G/L Acct/BP Name	Customer Order Reference	Qty
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GAMA Healthcare Ltd.,

The Maylands Building, Maylands Avenue,
Hemel Hempstead, Hertfordshire,
HP2 7TG, UK.

T +44 (0)20 7993 0030
E info@gamahealthcare.com
gamahealthcare.com



UBV6032920A	140035054	15/10/2020	Fannin Ltd	4510082808	5616
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ACTION

Please identify and isolate any of this batch of wipes remaining in stock or issued within your organisation. The LOT number is printed in black on the top edge of the pack, above the expiry date. For cartons, the Lot number is printed on a label on the side of the box. Once isolated, please complete the attached form and return to GAMA as soon as possible but, in any case, no later than the 4th June, 2021.

GAMA Healthcare would prefer for you to destroy any identified stock, but we can coordinate return and destruction if needed. A credit will be issued upon return of the attached Return Notice.

For any queries about this recall, please contact GAMA Regulatory Team;

Regulatory@gamahealthcare.com, or by calling GAMA by phone on +44 (0) 207 993 0030 and selecting the Regulatory option from the menu.

As a GAMA distributor, you may coordinate the recall and replace GAMA details as first contact in any of the bold text above, but must complete and return the Customer Reply Form attached.

A handwritten signature in blue ink, appearing to read 'G. Milward'.

Graham Milward
Deputy Regulatory Affairs & Quality Assurance Director
GAMA Healthcare Ltd

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	CAPA-2021-07
FSN Date*	21/05/2021
Product/ Device name*	Clinell Universal Wipes - Pack of 200
Product Code(s)	CW200
Batch/Serial Number (s)	UBV6032920A
	UBV1033020A
	UBV2033020A
	UBV3033020A
	UBV4033020A

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation			
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A	
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A	
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A	
<input type="checkbox"/>	I have returned affected devices - enter number of	Qty:	Lot/Serial Number:
		Qty:	Date Returned (DD/MM/YY):
		N/A	Comments:

	devices returned and date complete.		
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:
		Qty	Lot/Serial Number:
		N/A	Comments:
<input type="checkbox"/>	No affected devices are available for return/ destruction	Customer to complete or enter N/A	
<input type="checkbox"/>	Other Action (Define):		
<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A	
<input type="checkbox"/>	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query	
Print Name*		Customer print name here	
Signature*		Customer sign here	
Date*			

4. Return acknowledgement to sender	
Email	regulatory@gamahealthcare.com
Customer Helpline	+44 (0) 207 993 0030
Postal Address	GAMA Healthcare Ltd., The Maylands Building, Maylands Avenue, Hemel Hempstead Industrial Estate, Hemel Hempstead, Hertfordshire, HP2 7TG United Kingdom
Web Portal	www.gamahealthcare.com
Fax	N/A
Deadline for returning the customer reply form*	4 th June, 2021

Mandatory fields are marked with *

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It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.