

Dear

MHRA Field Safety Notice (FSN) Ref: 2021/005/005/601/530 – Clinell Universal Wipes (CW200) - Update

We are writing to update you on the voluntary recall and [Field Safety Notice](#) on Clinell Universal Wipe (CW200) that you received in May 2021.

Our initial investigations identified the 5 batches (**LOT UBV1033020A, LOT UBV2033020A, LOT UBV3033020A, LOT UBV4033020A, LOT UBV6032920A**) may contain the opportunistic environmental microorganism belonging to the Burkholderia cepacia complex (BCC). Further investigation has identified 4 further batches (**UBV3032520A and UBV3032520B LOT UBV1032720A, LOT UBV7032720A**).

The contamination occurred in 9 batches which were produced in June/July 2020 and were distributed between September 2020 to the December 2020. Analysis has confirmed the contaminant as *Burkholderia contaminans*. *B. contaminans* is a Gram-negative, aerobic, non-sporulating bacilli, that belongs to Taxon K (group K) of the Burkholderia cepacia complex.

We temporarily, suspended production and distribution of products from the effected site. Additional hygiene, monitoring and quality assurance protocols have been put in place. We have now re-started production where, out of an abundance of caution we continue to conduct enhanced testing of both finished products and raw materials.

We are committed to providing you with continued information on this isolated incident. Should you or your colleagues require further information on this Update, we would be grateful if you could please contact your sales representative who will be happy to connect you with GAMA Regulatory colleagues.

Alternatively, you can contact the GAMA Regulatory team directly at Regulatory@gamahealthcare.com, or by calling GAMA by phone on +44 (0) 207 993 0030 and selecting the Regulatory option from the menu.

Yours faithfully,

GAMA Healthcare

Frequently Asked Questions

Q. When was the product distributed?

A. The contaminated Clinell Universal CW200s were distributed between September 2020 to the end of December 2020.

Q. Did I receive affected products?

A. It is likely you received some of these batches in September 2020, but due to the volume of product used it is likely that the product has already been used. We have worked with your IPC and Recall Teams to remove any suspected packs from circulation.

If you do have any of the following batch codes still in existing stock, please isolate any of this batch of wipes remaining in stock.

(LOT UBV1033020A, LOT UBV2033020A, LOT UBV3033020A, LOT UBV4033020A, LOT UBV6032920A, LOT UBV3032520A, LOT UBV3032520B, LOT UBV1032720A, LOT UBV7032720A).

Q. Where can I find the LOT number?

A. 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.

Q. What should I do with the affected products?

A. Once isolated, please complete the attached form and return to GAMA as soon as possible. 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. The following Lot numbers are contaminated:

Q. What was the contamination?

A. An environmental microorganism belonging to the *Burkholderia cepacia* complex (Bcc). Bcc is a group of closely related Gram-negative bacilli found widely in the natural environment, including in soil and water. *Burkholderia contaminans* was identified as a novel species in 2009 and belongs to Taxon K (group K), a multi-species grouping within the Bcc encompassing *Burkholderia lata*, *Burkholderia aenigmatica* sp. nov. and *B. contaminans*.

Q. How was the contamination identified?

- A. Selective plating on *Burkholderia cepacia* selective agar (BCSA) identified the contaminant to be a *Burkholderia* strain. Through genetic sequence analysis the contaminant was indicated as belonging to the *Burkholderia cepacia* complex, with the species likely to be *Burkholderia contaminans*.

Conventional microbiology methods for identifying Bcc does not take into consideration enrichment and neutralisation steps to effectively isolate the contamination. We have engaged with external experts at Cardiff University to develop validated methods to address this. Given that speciation of Bcc is problematic we have used genetic sequencing of both the 16S rRNA and *recA* gene to accurately classify the taxonomic status of the contaminant.

Q. Where was the contamination located identified?

- A. The contamination was located to a single production line in one of our factories which occurred for a short duration of time.

Q. Is your product effective against BCC?

- A. Clinell Universal Wipes are effective against *Burkholderia cepacia* NCTC 10743 - a member of the Bcc group – when tested in accordance with EN13727 within 10 seconds.

Q. Was there any risk from this contamination?

- A. *B. contaminans* poses little medical risk to healthy individuals but like other Bcc organisms can cause serious infections in those with compromised immune systems notably individuals with cystic fibrosis and chronic granulomatous disease.

Q. The original FSN only identified 5 batches, now there are 9 batches?

- A. Our initial investigation identified 5 batches that were impacted. As we worked through a comprehensive testing programme, we have identified 4 additional batches LOT UBV3032520A, LOT UBV3032520B, LOT UBV1032720A, LOT UBV7032720A. All 9 batches were produced on a single production line in one of our factories, within a specified window.