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FIELD SAFETY NOTICE

Product: octenidol® md mouthwash

Kind of corrective action: Recall

Norderstedt, 18.12.2018

Sender: Schülke & Mayr GmbH

Recipient: Pharmacists, doctors, clinics, retirement homes, wholesaler, purchaser

Affected product

Product name: **octenidol® md mouthwash**
Article No.: 70000769
LOT: 1500548, 1502589, 1502724, 1504482, 1504870, 1507056, 1507320, 1507799, 1510193, 1510617, 1511550, 1511688

Root cause

MPC INTERNATIONAL S. A. communicates the recall throughout the distribution chain of the LOTs listed above. This recall is related to a voluntary recall for the product octenidol® md mouthwash #70000769 (Batch: **1513962**) which was initiated in Germany in August 2018, because of a potentially microbiological contamination with the bacteria *Burkholderia cepacia*. The recall is being implemented as the LOTs listed above were filled at the same facility as Lot # 1513962. In patients with a weakened immune system or those with chronic lung diseases such as cystic fibrosis, the bacterium can cause serious infections.

Although the contamination could be limited to the batch # 1513962, we are extending the recall at the request of the German authorities. We would like to emphasize that, according to our findings, there is no detectable contamination of the batches listed above. To date, no complaints have been registered regarding possible contamination of these batches and no incident reports for these batches have been documented.

Measures to be undertaken

1. Please ensure that the batches of the product are not used.
2. We would also request that you check your stock and return all products with the LOTs listed above by 11/01/2019 together with the confirmation form via the delivery route, or destroy the goods and send the confirmation form to us by mail, e-mail or fax. For simplification, we offer to destroy all recalled LOTs of octenidol® md mouthwash or to return them.

Forward the information

Please make sure that in your organization all users of the above listed products are informed of this field safety notice. If you have given the products to third parties, please forward a copy of this information or inform the

contact person listed below. Please retain this information at least until the action has been completed.

The Federal Institute for Drugs and Medical Devices (BfArM) has received a copy of this "Field Safety Notice".

Contact

If you have any further question please do not hesitate to contact us:

Schülke & Mayr GmbH, Robert-Koch-Str. 2, 22851 Norderstedt, Germany
Customer Sales Service
Tel.: +494052100 - 666
Fax: +494052100 - 660
E-Mail: info@schuelke.com

We apologize for the inconvenience caused by this field safety notice and thank you for your cooperation and understanding.

Kind regards,

ppa Dr. Werner Weltgen
Direktor Quality & HSE
Schülke & Mayr GmbH

i.V. Julian Schmidt
Head of Quality Management
Schülke & Mayr GmbH

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CONFORMATION SHEET

Please complete the confirmation form and send it to:

Schülke & Mayr GmbH, Robert-Koch-Str. 2, 22851 Norderstedt, Germany
Customer Sales Service
Fax: +494052100 - 660
E-Mail: info@schuelke.com

We hereby confirm that we have received and understood the field safety notice and that the information has been forwarded to all concerned persons, to each department or to our customers who have received the affected product(s).

We have reviewed our stock and identified and isolated the following affected products:

Product	Batch number	No. of packages			No stock
		In stock isolated	Disposed	Returned	
octenidol® md mouth wash	1500548				□
	1502589				□
	1502724				□
	1504482				□
	1504870				□
	1507056				□
	1507320				□
	1507799				□
	1510193				□
	1510617				□
	1511550				□
	1511688				□

Confirmation of review

We hereby confirm that the above mentioned products were withdrawn from the market.

Name and organization (in block letters)	
Customer number, Name, telephone for any queries	
Date	
Signature	