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## FIELD SAFETY NOTICE

Product: octenidol® md mouthwash

Kind of corrective action: Recall

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Vienna, 20.12.2018

Sender: Schülke & Mayr GmbH

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

### Affected product

**Product name:** octenidol® md mouthwash  
**Article No.:** 70000769, 70000802, 70000803  
**LOT:** 1507799, 1502589, 1504870, 1510617, 1511688, 1504482, 1504871, 1507054, 1511548, 1505665, 1507053, 1510191, 1511687

### 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 to:  
Schenker&Co. AG, Freudenuer Hafenstr. 16, 1020 Vienna, Austria

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. Please retain this information at least until the action has been completed.

Your national authorization will receive a copy of this "Field Safety Notice".

## **Contact**

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

Schülke & Mayr GmbH  
Seidengasse 9  
1070 Vienna  
AUSTRIA

phone: +43 1 523 25 01  
fax: +43 1 523 90 35  
e-mail: [office.austria@schuelke.com](mailto:office.austria@schuelke.com)

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

Kind regards,



Dr. Christoph Klaus  
Marketing & International Scientific Affairs  
Commercial Law Director



Mag. Sven Schedenig  
General Manager

## CONFORMATION SHEET

Please complete the confirmation form and send it to:

Schülke & Mayr GmbH, Seidengasse 9, 1070 Vienna, Austria  
 e-mail: [office.austria@schuelke.com](mailto:office.austria@schuelke.com)  
 fax: +43 1 523 90 35

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	1507799				<input type="checkbox"/>
	1502589				<input type="checkbox"/>
	1504870				<input type="checkbox"/>
	1510617				<input type="checkbox"/>
	1511688				<input type="checkbox"/>
	1504482				<input type="checkbox"/>
	1504871				<input type="checkbox"/>
	1507054				<input type="checkbox"/>
	1511548				<input type="checkbox"/>
	1505665				<input type="checkbox"/>
	1507053				<input type="checkbox"/>
	1510191				<input type="checkbox"/>
	1511687				<input type="checkbox"/>

### 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	