Date: 2024-01-03

Field Safety Notice
Sekusept Pulver

For the Attention of*: Vigilance manager of the facility and the users of the affected products.

Dear customer,

We ask you to please review the information in this document and follow the appropriate actions outlined in section 3. Please fill in the reply form accompanying this FSN and return it to us as soon as possible but no later than 9th February 2024.

Thank you for your cooperation and understanding.

Best regards,

ECOLAB VIGILANCE

Field Safety Notice (FSN)

1. Information on Affected Devices

1. 1. Device Type(s)

Sekusept Pulver : Disinfectant for manual reprocessing of medical instruments

1. 2. Commercial name(s)

Sekusept Pulver

1. 3. Primary clinical purpose of device(s)

Sekusept Pulver : Preparation for disinfecting medical instruments, anaesthetic equipment and endoscopes

1. 4. Device Model/Catalogue/part number(s)

All the batches of all the references of the product are concerned:

Product	References
Sekusept Pulver	3049400 3049420 3049430

2. Reason for Field Safety Corrective Action (FSCA)

2. 1. Description of the product problem

As a part of our post-market activities, we identified some gaps in SEKUSEPT PULVER antimicrobial efficacy according to the latest version of the norms for bactericidal and yeasticidal activity. Post market surveillance of SEKUSEPT PULVER has not shown any incidents in relation to a lack of efficacy, nevertheless, patient safety is our priority and, as a precautionary measure, we have decided to start a field safety corrective action on the concerned products.

2. 2. Hazard giving rise to the FSCA

SEKUSEPT PULVER is intended to disinfect medical instruments and endoscopes. The inefficient disinfection process of medical instruments might lead to a risk of patient infection.

Medical instruments and endoscopes are required to be cleaned and disinfected or sterilized according to their criticality based on the Spaulding classification. Achieving disinfection and sterilization through the use of disinfectants and sterilization practices is essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients.

There are multiple sources of medical devices contamination and each step of the reprocessing might be involved in the transmission of microorganisms (from the pre-treatment to the storage). Adherence to best practices in the reprocessing of medical devices is a Standard Precaution and essential to facilitate HAI prevention and occupational health programs. Therefore, it is crucial to diligently follow, manage, and accurately control all necessary measures.

3. Type of Action to mitigate the risk		
3.	**1. Action To Be Taken by the User** ☒ Identify Device ☒ Destroy Device ☒ Inform all users within your facility	
3.	**2. Action To Be Taken by the Distributor** ☒ Identify Device ☒ Destroy Device ☒ Inform End Users to proceed according to the section 3.1 “Action to be taken by the user”. ☒ Remove Device information from owned channels (ie website, catalogues) and stop promotion of the Device	
3.	3. By when should the action be completed?	Immediately
3.	4. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ Software upgrade ☒ Other: Product phased-out ☐ On-site device modification/inspection ☐ IFU or labelling change ☐ None	

4. General Information			
4.	1. FSN Type	New	
4.	2. Further advice or information already expected in follow-up FSN?	No	
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)		
	a. Company Name	Ecolab Deutschland GmbH	
	b. Address	Ecolab-Allee 1, 40789 Monheim am Rhein, Germany	
	c. Website address	www.ecolab.com	
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.		
4.	5. List of attachments/appendices:	FSN Reply Form;	
4.	6. Name/Signature	Franck Bardin (VP RD&E Healthcare Europe)	
		Christian Jost (Manager Regulatory Affairs)	

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.