Date: 2023-12-05

Field Safety Notice
Incidin OxyWipe S and Incidin OxyFoam S

For 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.

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)

Incidin OxyWipe S: Ready to use cleaning and disinfection wipes
Incidin OxyFoam S: Ready to use cleaning and disinfection liquid

1. 2. Commercial name(s)

Incidin OxyWipe S
Incidin OxyFoam S

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

Incidin OxyWipe S: Cleaning and disinfection wipes for medical surfaces (incl. e.g. probes) and inventory
Incidin OxyFoam S: Cleaning and disinfection foam spray for medical surfaces (incl. e.g. probes) and inventory

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

All the batches of the following references:

Product	References
Incidin OxyWipe S	3104670 3104690 3116020 3116100
Incidin OxyFoam S	3091820 3104630 3115790 3115900

2. Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	• Ecolab have retested the product's efficacy of Incidin OxyWipe S and Incidin OxyFoam S against C. difficile according to the norm EN 17126. The test result has shown that these products passed the test for clean conditions but failed for dirty conditions. The testing methodology according to this new standard is challenging and can result in a high standard variation. In light of these findings, Ecolab has made the decision to withdraw the claim for these products in dirty conditions. • Due to the high standard variation observed, we have also decided to remove Method 19 claim for Incidin OxyWipe S. • Furthermore, we have retested the efficacy of Incidin OxyFoam S against poliovirus according to EN 14476. The test result has shown increased contact time requirement, from 2 minutes to 10 minutes. • We are currently in the process of updating the product labels and any other accompanying information for Incidin OxyWipe S, Incidin OxyFoam S. Patient safety is our priority and we have taken the proactive decision to start a field safety corrective action.
2.	2. Hazard giving rise to the FSCA
	Incidin Oxyfoam S and Incidin Oxywipe S: Clostridioides difficile (C. difficile): As published by the European Centre for Disease Prevention and Control Clostridioides difficile (C. difficile) is an anaerobic bacterium, widely distributed in soil and the intestinal tracts of animals. The clinical spectrum of C. difficile infection (CDI) ranges from mild diarrhoea to severe life threatening pseudomembranous colitis. CDI is generally, but not always associated with previous use of antibiotics. The transmission of C. difficile can be patient-to-patient, via contaminated hands of healthcare workers or by environmental contamination. **Incidin Oxyfoam S:** Enteroviruses (including poliovirus): Poliovirus is part of the enterovirus group. As published by the European Centre for Disease Prevention and Control Poliovirus infections can lead to a spectrum of clinical presentations, ranging from subclinical infection to paralysis and death. The majority of poliovirus infections are asymptomatic; up to 70% of infected individuals experience no symptoms and about 25% experience mild symptoms. As published by the European Centre for Disease Prevention and Control Enteroviruses are a group of viruses that cause a number of infectious illnesses which are usually mild. However if they infect the central nervous system, they can cause serious illness. The two most common ones are echovirus and coxsackievirus, but there are several others. Enteroviruses also cause polio and hand, foot and mouth disease (HFMD). The vast majority of people infected with enteroviruses – over 90% - will either have no symptoms or have non-specific symptoms, such as sudden fever. A wide range of symptoms can be caused by enteroviruses but most often include fever, mild respiratory symptoms, flu-like illness with fever and muscle aches, fever with a rash and gastrointestinal symptoms. Most illnesses caused by enteroviruses are mild but more severe diseases can sometimes develop in certain patients, including brain and heart conditions, pneumonia and hepatitis. Also, the viruses can spread to other organs such as the spleen, liver, bone marrow, skin and heart.

3. Type of Action to mitigate the risk		
3.	**1. Action To Be Taken by the User** ☒ Identify Device ☐ Quarantine Device ☒ Assess quantity of product left in stock: • If quantity is >1 unopened pallet per batch number and a shelf life < 9 months: Return device • All other cases: Destroy device ☒ Inform all users within your facility	
3.	**2. Action To Be Taken by the Distributor** ☒ Identify Device ☒ Quarantine Device ☒ Assess quantity of product left in stock: • If quantity is >1 unopened pallet per batch number and a shelf life < 9 months: Return device • All other cases: Destroy device ☒ Inform End Users to proceed according to the section 3.1 "Action to be taken by the user".	
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 ☐ 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	Bedrijfsgevoelige informatie	
	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	Persoonsgegevens	

	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.