

Date: 2023-11-28

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.	<p>1. Device Type(s)</p> <p>Incidin OxyWipe S: Ready to use wipes Incidin OxyFoam S: Ready to use cleaning and disinfection liquid</p>
1.	<p>2. Commercial name(s)</p> <p>Incidin OxyWipe S Incidin OxyFoam S</p>
1.	<p>3. Primary clinical purpose of device(s)</p> <p>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</p>
1.	<p>4. Device Model/Catalogue/part number(s)</p> <p>Incidin OxyFoam S:</p> <ul style="list-style-type: none"> • 3091820 • 3082080 • 3104630 • 3082910 • 3115830 <p>Incidin OxyWipe S:</p> <ul style="list-style-type: none"> • 3104670 • 3082280

2. Reason for Field Safety Corrective Action (FSCA)	
2.	<p style="text-align: center;">1. Description of the product problem</p> <p>Ecolab have retested the products Incidin OxyWipe S and Incidin OxyFoam S efficacy against <i>C. difficile</i> according to the norm EN 17126. The test result for clean conditions has passed but failed for dirty conditions. The testing methodology according to this new standard is still challenging and can result in a high standard variation. In light of this finding, Ecolab decided to withdraw the claim in dirty conditions for these products. Due to the high standard variation, we also took the decision to remove Method 19 claim for Incidin OxyWipe S.</p> <p>In addition, we have retested the efficacy of Incidin OxyFoam S against poliovirus according to EN 14476. The test result has shown increased contact time from 2 min. to 10 min.</p> <p>We are currently in the process of updating the product labels and any other information accompanied with Incidin OxyWipe S and Incidin OxyFoam S. Patient safety is our priority and we have taken the proactive decision to start a field safety action and inform our customers of the change in our claim and provide updated instruction on the best use and application.</p>
2.	<p style="text-align: center;">2. Hazard giving rise to the FSCA</p> <p><u>Clostridioides difficile (C. difficile):</u> As published by the European Centre for Disease Prevention and Control <i>Clostridioides difficile</i> (<i>C. difficile</i>) is an anaerobic bacterium, widely distributed in soil and the intestinal tracts of animals. The clinical spectrum of <i>C. difficile</i> 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 <i>C. difficile</i> can be patient-to-patient, via contaminated hands of healthcare workers or by environmental contamination.</p> <p><u>Enteroviruses (including poliovirus):</u> 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.</p> <p>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).</p> <p>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.</p> <p>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.</p>

3. Type of Action to mitigate the risk	
3.	<p>1. Action To Be Taken by the User</p> <p> <input checked="" type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device </p> <p> <input checked="" type="checkbox"/> Inform all users within your facility </p> <p> <input checked="" type="checkbox"/> Take note of amendment / reinforcement of Instructions For Use (IFU): </p> <p><u>Incidin OxyWipe S:</u> In case of <i>C. difficile</i> precautions, clean surfaces prior to disinfect them with Incidin OxyWipe S with a 60min contact time. Other usages remain the same with same condition of use.</p> <p>Take single wipe. Wet surface thoroughly, ensuring contact with entire surface. Let it dry and do not rinse. Do not reuse wipe: Disinfection can no longer be guaranteed. Close lid after use. Respect the indicated contact time and conditions for the required antimicrobial activity. If used under clean conditions, clean surface upfront (use new wipe for each step). The use of a cleaning and disinfection wipe does not replace regular cleaning. Do not use on surfaces sensitive to oxidative agents such as marble, copper or brass. For reprocessing of medical devices always observe manufacturers' instructions for use, incl. material compatibility. Terminal disinfection of semi-critical medical devices (i.e. probes & TEE probes): If immersion is not possible, clean the device and then disinfect by wiping as described above. Rinse thoroughly with water of drinking quality in this case after contact time elapsed.</p> <p><u>Incidin OxyFoam S:</u> In case of transmission-based precautions requiring a full virucidal efficacy (i.e.: enterovirus contamination) or in case of semi-critical reprocessing (i.e.: endocavity probe reprocessing) clean the devices prior to disinfect them with Incidin OxyFoam S with a 10 minute contact time. In case of <i>C. difficile</i> precautions, clean surfaces prior to disinfect them with Incidin OxyFoam S with a 60 minute contact time. Other usages remain the same with same condition of use.</p> <p>750 ml: Spray surface from approx. 30 cm, ensuring the surface is completely wet. Wipe the surface with a clean wipe and leave to dry. Alternatively, apply the product to a clean wipe, wipe the surface and leave to dry. Do not rinse. Respect the indicated contact time and conditions for the required antimicrobial activity. If used under clean conditions, clean surface upfront (use clean, fresh cloth / mop for each step). The use of a cleaning and disinfection product does not replace regular cleaning. Do not use on surfaces sensitive to oxidative agents such as marble, copper or brass. For reprocessing of medical devices always observe manufacturers' instructions for use, incl. material compatibility. Terminal disinfection of semi critical medical devices (i.e. probes & TEE probes): If immersion is not possible, disinfect the device by wiping as described above. Rinse thoroughly with water of drinking quality in this case after contact time elapsed.</p> <p>5 l drum: Apply the product ensuring the surface is completely wet. Wipe the surface with a clean wipe (e.g. Incidin Dry Wipes System) and leave to dry. Alternatively, apply the product to a clean wipe, wipe the surface and leave to dry. Do not rinse. Respect the indicated contact time and conditions for the required antimicrobial activity. If used under clean conditions, clean surface upfront (use clean, fresh cloth / mop for each step). The use of a cleaning and disinfection product does not replace regular cleaning. Do not use on surfaces sensitive to oxidative agents such as marble, copper or brass. For reprocessing</p>

	of medical devices always observe manufacturers' instructions for use, incl. material compatibility. Terminal disinfection of semi critical medical devices (i.e. probes & TEE probes): If immersion is not possible, disinfect the device by wiping as described above. Rinse thoroughly with water of drinking quality in this case after contact time elapsed.	
	2. Action To Be Taken by the Distributor <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input checked="" type="checkbox"/> Inform End Users <input checked="" type="checkbox"/> Update device information on owned channels, i.e. website, brochures, etc. <input checked="" type="checkbox"/> Take note of amendment / reinforcement of Instructions For Use (IFU): Please refer to section 3.1 of this document.	
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 <input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input checked="" type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> 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	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.</p>