Rev 2: February 2020
FSN Ref: ECL-FSCA-001_1_CH_en_3 FSCA Ref: ECL-FSCA-001

Date: 2024-10-23

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 have found that a few customers had received some boxes of the product Incidin Oxywipe S that was not relabelled with the latest efficacy claims. Due to an error in our shipping process, a small quantity of the product was sent out without the updated relabelling. Not all products of lots mentioned below are affected.

As a precautionary measure, we kindly ask you to destroy the remaining quantity of the following batches of Incidin Oxywipe S that you have received:
Batch numbers are as follows:

Product name	Batch number	Product SKU
Incidin OxyWipe S	5443IN0602 5383IN0602 2453IN1002 4383IN0402 4443IN0302	3116020

We ask you to please review the information in this document and follow the appropriate actions outlined in section 3. Please confirm the destruction of the products by completing and returning the accompanying reply form.

We sincerely apologize for any inconvenience this may cause and appreciate your understanding and cooperation in this matter.

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

1. 2. Commercial name(s)

Incidin OxyWipe 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

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

All the batches of the following references:

Product	References
Incidin OxyWipe S	3116020

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.

16.10.2024 Update-

- We were notified that some batches of the products Incidin Oxywipe S put on the market did not have correct label with the updated efficacy claims. The product Incidin OxyWipe S was relabeled with updated information as part of the ECL-FSCA-001 corrective actions. However, preliminary investigations lead us to believe some non-reworked boxes of Incidin Oxywipe S were shipped by mistake. Due to different inflows with the same batch (customer returns, inbound of fresh stock, outbound of stock to be re-worked) some customers accidentally might have received not re-worked stock. This does not affect all products shipped, however, as a precautionary measure, we have decided to reopen the field safety corrective action.
-

2.	2. Hazard giving rise to the FSCA

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.

3. Type of Action to mitigate the risk		
3.	**1. Action To Be Taken by the User** ☒ Identify Device ☐ Quarantine Device ☒ Destroy device ☒ Inform all users within your facility	
3.	**2. Action To Be Taken by the Distributor** ☒ Identify Device ☐ Quarantine Device ☒ 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 ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ 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	Director, Quality, Quality & Process Engineering EU	[redacted]
		Senior Regulatory Affairs Manager	

	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.

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	ECL-FSCA-001_1_CH_en_3
FSN Date	23 October 2024
Product/ Device name	Incidin OxyWipe S
Product Codes and Batch Numbers	

Product name	Batch number	Product SKU
Incidin OxyWipe S	5443IN0602 5383IN0602 2453IN1002 4383IN0402 4443IN0302	3116020

2. Customer Details	
Healthcare Organisation Name	
Organisation Address	
Department/Unit	
Shipping address if different to above	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Customer action undertaken on behalf of Healthcare Organisation		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	
☐	I performed all actions requested by the FSN.	
☐	The information and required actions have been brought to the attention of all relevant users and executed.	
☐	I have the following devices on stock – enter number of devices on stock.	<table><tr><td>Product name and REF number</td><td>Quantity (Packs / Bottles)</td></tr><tr><td colspan="2">Incidin OxyWipe S</td></tr><tr><td>3116020</td><td></td></tr></table>
☐	I have >1 unopened pallet of stock left per batch number and a shelf life < 9 months: I confirm that I will return it to ECOLAB	
☐	I confirm that I have destroyed the products.	
☐	I do not have any affected devices.	
Print Name		
Signature		
Date		

4. Return acknowledgement to sender	
Email	vigilance@ecolab.com
Deadline for returning the customer reply form	24 November 2024

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.