

Date: 2025-12-02

Field Safety Notice
INCIDIN™ ALCOHOL WIPE

For Attention of*:Vigilance/Quality manager of the facility products.

Dear customer,

We are reaching out to inform you of an important issue regarding the product Incidin™ Alcohol Wipe as follows:

Product	SKU	Batch Numbers
Incidin™ Alcohol Wipe	3093960	4355IN0609
	3093980	3395IN0407 2395IN0407

Following customer feedback, we realized that some products were delivered in the French market without French labels. This may lead to a risk of misuse or mishandling of the product.

As a precautionary measure, we are releasing the attached Field Safety Notice to alert customers and recall and/ or destroy the products impacted.

We kindly ask you to take the following actions:

- Please do not use or distribute the identified products. If you have distributed these products to your customers, it is essential that you inform them about the issue and advise them to stop use or distribution.
- Complete the attached reply form: review the information in this document, follow the appropriate actions outlined in section 3, and confirm your understanding and compliance with the outlined measures. Please return the Customer Reply Form to us within four weeks after receiving the FSN. In case you have distributed the products to your customers, please collect their responses and complete a single reply form with aggregated data.

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)
INCIDIN™ ALCOHOL WIPE
Labels in French missing

1. Information on Affected Devices*									
1.	<p>1. Device Type(s)*</p> <p>Medical device classified as Class IIa according to MDD.</p>								
1.	<p>2. Commercial name(s)*</p> <p>INCIDIN™ ALCOHOL WIPE</p>								
1.	<p>3. Unique Device Identifier(s) (UDI-DI)</p> <p>N/A</p>								
1.	<p>4. Primary clinical purpose of device(s)*</p> <p>Incidin™ Alcohol Wipe is a fast-acting, ready-to-use surface disinfection wipe designed for use on alcohol-resistant medical devices in healthcare settings.</p>								
1.	<p>5. Device Model/Catalogue/part number(s)*</p> <table border="1"> <thead> <tr> <th>Product</th> <th>SKU</th> <th>Batch Numbers</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Incidin™ Alcohol Wipe</td> <td>3093960</td> <td>4355IN0609</td> </tr> <tr> <td>3093980</td> <td>3395IN0407 2395IN0407</td> </tr> </tbody> </table>	Product	SKU	Batch Numbers	Incidin™ Alcohol Wipe	3093960	4355IN0609	3093980	3395IN0407 2395IN0407
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1.	<p>6. Software version</p> <p>N/A</p>								
1.	<p>7. Affected serial or lot number range</p> <p>N/A</p>								
1.	<p>8. Associated devices</p> <p>N/A</p>								

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	<p>1. Description of the product problem*</p> <p>INCIDIN™ ALCOHOL WIPE products were delivered to the French market without French language on the label. The issue is identified through customer feedback.</p>
2.	<p>2. Hazard giving rise to the FSCA*</p> <p>If customers do not use the product according to the intended use and instructions for use, there is a chance of cross contamination leading to infection in high risk patients</p>

4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
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, Deutschland
	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:	Annex A: Customer reply form

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>

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	ECL-FSCA-007_FSN_Master_EN_en_1
FSN Date*	2 December 2025
Product/ Device name*	Incidin™ Alcohol Wipe
Product Code(s) and Batch/Serial Number (s)	See FSN

2. Customer Details	
Customer Account Number	
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										
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A								
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A								
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A								
<input type="checkbox"/>	I have returned affected devices - enter number of single units of devices returned and date complete.	<table border="1"> <thead> <tr> <th>Product</th> <th>Batch number</th> <th>Quantity (units of device)</th> <th>Date</th> </tr> </thead> <tbody> <tr> <td>Incidin™ Alcohol Wipe</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Product	Batch number	Quantity (units of device)	Date	Incidin™ Alcohol Wipe			
Product	Batch number	Quantity (units of device)	Date							
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<input type="checkbox"/>	I have destroyed affected devices – enter number of single units of devices destroyed and date complete.	<table border="1"> <thead> <tr> <th>Product</th> <th>Batch number</th> <th>Quantity (units of device)</th> <th>Date</th> </tr> </thead> <tbody> <tr> <td>Incidin™ Alcohol Wipe</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Product	Batch number	Quantity (units of device)	Date	Incidin™ Alcohol Wipe			
Product	Batch number	Quantity (units of device)	Date							
Incidin™ Alcohol Wipe										
<input type="checkbox"/>	No affected devices are available for return/ destruction	Customer to complete or enter N/A								
Print Name*		Customer print name here								
Signature*		Customer sign here								
Date*										

4. Return acknowledgement to sender	
Email	anios.vigilance@anios.com
Deadline for returning the customer reply form*	Within 4 weeks after receipt of the FSN

Mandatory fields are marked with *

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.