Date: 2023-12-15

**Field Safety Notice**

**Incidin Rapid**

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.

Thank you for your cooperation and understanding.

Best regards,

ECOLAB VIGILANCE

**Field Safety Notice (FSN)**

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| 1. **Information on Affected Devices** | |
| 1. | 1. Device Type(s) |
| Incidin Rapid: Concentrated liquid for surface disinfection |
| 1. | 1. Commercial name(s) |
| Incidin Rapid |
| 1. | 1. Primary clinical purpose of device(s) |
| Incidin Rapid: Surface disinfectant for medical surfaces and inventory |
| 1. | 1. Device Model/Catalogue/part number(s) |
| All the batches of all the references of the product are concerned:   |  |  | | --- | --- | | Product | References | | Incidin Rapid | 3025510  3028700  3040230  3041970  3096580  3097310  3097420  3097480  3601440 | |

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| 1. **Reason for Field Safety Corrective Action (FSCA)** | |
| 2. | 1. Description of the product problem |
| As a part of our remediation activities to achieve the European Medical Device Regulation 2017/745 (MDR), we performed new tests and, as a result, have decided to reduce the shelf-life of INCIDIN RAPID to 18 months.  Furthermore, there are some inconsistencies in INCIDIN RAPID antimicrobial efficacy leading to challenge to support the full bactericidal and virucidal activity. Post market surveillance of INCIDIN RAPID has not shown any incidents in relation to a lack of efficacy after 18 months, nevertheless, patient safety is our priority and, as a precautionary measure, we have decided to start a field safety corrective action to recall the concerned products. |
| 2. | 1. Hazard giving rise to the FSCA |
| INCIDIN RAPID is devised for the disinfection of non-critical surfaces in healthcare settings. Surface disinfection is considered an essential measure in preventing Hospital Acquired Infections (HAIs), along with other prevention measures such as hand hygiene and personal protective equipment.  Surface disinfection is a holistic process that includes both cleaning and disinfecting. The effectiveness of the disinfection process is influenced by various factors, such as the prior cleaning of the object, the presence of organic and inorganic load, the type and level of microbial contamination, the concentration of and exposure time to the germicide, the physical characteristics of the object (e.g., crevices, hinges, and lumens), the presence of biofilms, and the temperature and pH of the disinfection process.  Surfaces play a role in the transmission of microorganisms that can survive on inanimate objects. Therefore, it is crucial to diligently follow, manage, and accurately control all necessary measures. Failure to do so may increase the risk of cross-contamination, potentially leading to HAIs among vulnerable patients. |

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| 1. **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.** | 1. **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. | 1. By when should the action be completed? | Immediately | |
| 3. | 1. Is customer Reply Required?   (If yes, form attached specifying deadline for return) | | Yes |
| **3.** | 1. **Action Being Taken by the Manufacturer**   Product Removal  On-site device modification/inspection  Software upgrade  IFU or labelling change  Other: Product phased-out  None | | |

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