Rev 2: February 2020

FSN Ref: AN-FSCA-009_1_EN_en_3 FSCA Ref: AN-FSCA-009

Date: 2024-12-13

Field Safety Notice
Aniospray quick, Anios quick Wipes

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

Dear customer,

We have noticed that you have been delivered products with incorrect information on the label. The products in scope of this FSN are as follows:

Product Name	Packaging	SKU
ANIOSPRAY QUICK	4x5L	2084034Z2/ ECL3098890
	12X1L	2087073AB/ ECL3113790
ANIOS QUICK WIPES	12X1L	2087073AB/ ECL3113790 2333421ZS/ ECL3133582

Please kindly request you to review the information in this document and follow the appropriate actions outlined in section 3.

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
On behalf of Laboratoires Anios

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Field Safety Notice (FSN)

1. Information on Affected Devices	
1.	1. Device Type(s)
	Medical devices
1.	2. Commercial name(s)
	Aniospray quick, Anios quick Wipes
1.	3. Primary clinical purpose of device(s)
	Technical performance – No direct clinical purpose
1.	4. Device Model/Catalogue/part number(s)
	All the batches of the following references:

Product Name	Packaging	SKU
ANIOSPRAY QUICK	4x5L	2084034Z2/ ECL3098890
	12X1L	2087073AB/ ECL3113790
ANIOS QUICK WIPES	12X1L	2087073AB/ ECL3113790 2333421ZS/ ECL3133582

2. Reason for Field Safety Corrective Action (FSCA)

2. 1. Description of the product problem

We were informed by a distributor that the translations Romanian language for a product were not correct.

Therefore, as a part of due diligence, Laboratoires Anios decided to check the portfolio for similar errors and discovered some errors in the Ukrainian language as well. We found that the Ukrainian and Romanian translations for specific Stock Keeping Units (SKUs) have incorrect information about contact times data related to Tuberculocidal, Fungicidal and limited spectrum virucidal claims.

Please be aware that the errors are limited to SKUs mentioned in the table in page 2.

Product Name	Errors in Ukrainian	Correct in Ukrainian	Errors in Romanian	Correct in Romanian
ANIOSPRAY QUICK	Tuberculocidal acc. To EN 14348* in 5 sec. Adenovirus in 30min.	Tuberculocidal acc. To EN 14348* in 5 min. Adenovirus in 30 sec.	Fungicidal acc. To EN13624*/EN17387* in 5 sec. Tuberculocidal acc. to EN 14348* in 30min. Limited spectrum virucidal acc. To EN 14476*/EN16777* in 30min.	Fungicidal acc. To EN13624*/EN17387* in 5 min Tuberculocidal acc. to EN 14348* in 30 sec. Limited spectrum virucidal according to EN 14476*/EN 16777* in 5 min (Adenovirus in 30 sec / Norovirus (MNV) in 5 min).
ANIOS QUICK WIPES	Not Applicable	Not Applicable	Fungicidal acc. To EN13624*/EN17387* in 5 sec. Tuberculocidal acc. To EN 14348* in 30min.	Fungicidal acc. To EN13624*/EN17387* in 5 min Tuberculocidal acc. to EN 14348* in 30 sec.

2. 2. Hazard giving rise to the FSCA

This might lead to a risk of cross contamination and infection in high-risk patients.

3. Type of Action to mitigate the risk

3. 1. Action To Be Taken by the User in Ukraine and Romania

☒ Identify Device

☒ Destroy the device

☒ Inform all users within your facility

☒ Fill in the customer reply form

	Action To Be Taken by the User Outside Ukraine and Romania ☒ Identify Device ☒ Inform all your users to refer to your local language on the label ☒Fill in the customer reply form	
3.	**2. Action To Be Taken by the Distributor in Ukraine and Romania** ☒ Identify Device ☒ Destroy the device ☒ Inform all customers about the actions to be taken ☒ Fill in the customer reply form **Action To Be Taken by the Distributor Outside Ukraine and Romania** ☒ Identify Device ☒ Inform all your users to refer to your local language on the label ☒ Fill in the customer reply form	
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 attached
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None All new batches have been produced with new labels.	

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	Laboratoires Anios
	b. Address	1 RUE DE L'ESPOIR 59260 LEZENNES FRANCE
	c. Website address	www.anios.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
		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.