

Rev 2: February 2020

FSN Ref: AN-FSCA-0012_1_EN_en_2

FSCA Ref: AN-FSCA-012

Date: 26 November 2024

Field Safety Notice

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

Dear customer,

We have noticed that you have received products with incorrect data on the secondary packaging CLP labels for the products ANIOSYME XL3 (formula code- 2381) and ANIOS CLEAN EXCEL D (Formula code- 2416).

The labels on the secondary packaging are not compliant to CLP regulation but the product characteristics itself and the label on the on the bottles (primary packaging) and the Safety Data Sheet accompanied with the products are in compliance with the applicable regulations.

There is no immediate user/ patient risk with the SDS information.

The product should have the following information on the secondary packaging:

Product names	Current information on secondary packaging (WRONG)	CLP classification (CORRECT)
ANIOSYME XL3	Not Classified	Skin irritant Cat 2, Eye Damage cat 1, Acute Aquatic Tox Cat 1, Chronic Aquatic Tox Cat 3,
ANIOS CLEAN EXCEL D	Not Classified	Skin Irritant Cat 2, Eye Damage cat 1, Acute Aquatic Tox Cat 1, Chronic Aquatic Tox Cat 3

Table1- Product information

We kindly ask you to refer to Safety Data Sheet (SDS) while handling these products and 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.	<p style="text-align: center;">1. Device Type(s)</p> <p>Medical Devices</p>									
1.	<p style="text-align: center;">2. Commercial name(s)</p> <p>See below</p>									
1.	<p style="text-align: center;">3. Primary clinical purpose of device(s)</p> <p>All products are medical devices used for disinfection classified as Class IIb according to MDD.</p>									
1.	<p style="text-align: center;">4. Device Model/Catalogue/part number(s)</p> <p>All the batches of the following references:</p> <p>Table 2- Detailed information with SKU and Batch number</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 33%;">Product</th> <th style="width: 33%;">SKU</th> <th style="width: 33%;">Batch Numbers</th> </tr> </thead> <tbody> <tr> <td>ANIOSYME XL3- 2381</td> <td>Refer to appendix A attached below</td> <td>Refer to appendix A attached below</td> </tr> <tr> <td>ANIOS CLEAN EXCEL D-2416</td> <td>Same as above</td> <td>Same as above</td> </tr> </tbody> </table>	Product	SKU	Batch Numbers	ANIOSYME XL3- 2381	Refer to appendix A attached below	Refer to appendix A attached below	ANIOS CLEAN EXCEL D-2416	Same as above	Same as above
Product	SKU	Batch Numbers								
ANIOSYME XL3- 2381	Refer to appendix A attached below	Refer to appendix A attached below								
ANIOS CLEAN EXCEL D-2416	Same as above	Same as above								

2. Reason for Field Safety Corrective Action (FSCA)							
2.	<p>1. Description of the product problem</p> <ul style="list-style-type: none"> • There is incorrect information on the label of the transport packaging or secondary packaging of the products. • Product shipped with incorrect secondary packaging label that is not compliant with the CLP regulations: products are labelled as “not classified” while they should be labelled with the corresponding CLP classification (see Table 1 in page 1). 						
2.	<p>2. Hazard giving rise to the FSCA</p> <p>Hazard is associated with the use of inadequate or insufficient personal protective equipment when handling the products as distributor or in warehouses. In case of insufficient protective equipment, user might get exposed to chemicals causing skin irritation, eye irritation and eye damage. The skin and eye irritation are transient effects with no lasting damage. The probability of injury to the user is negligible and only in case of leakage. Without leakage, there is no immediate patient/user risk.</p>						
3. Type of Action to mitigate the risk							
3.	<p>1. Action To Be Taken by the User</p> <p>Not applicable</p>						
3.	<p>2. Action To Be Taken by the Distributor</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Handle device according to Safety Data Sheet <input checked="" type="checkbox"/> Inform all users within your facility 						
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 40%;">3. By when should the action be completed?</td> <td>Immediately</td> </tr> </table>	3. By when should the action be completed?	Immediately				
3. By when should the action be completed?	Immediately						
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 70%;">4. Is customer Reply Required? (If yes, form attached specifying deadline for return)</td> <td style="text-align: center;">Yes 15 January 2025</td> </tr> </table>	4. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes 15 January 2025				
4. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes 15 January 2025						
3.	<p>5. Action Being Taken by the Manufacturer</p> <table style="width: 100%;"> <tr> <td><input type="checkbox"/> Product Removal</td> <td><input type="checkbox"/> On-site device modification/inspection</td> </tr> <tr> <td><input type="checkbox"/> Software upgrade</td> <td><input checked="" type="checkbox"/> IFU or labelling change</td> </tr> <tr> <td><input type="checkbox"/> Other</td> <td><input type="checkbox"/> None</td> </tr> </table> <p>All new batches have been produced with new labels.</p>	<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
<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	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:	Appendix A for product information, Customer Reply Form
4.	6. Name/Signature	Director, Quality, Quality & Process Engineering EU
		Senior Regulatory Affairs Manager

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>

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Appendix A

SKU	Product name and format	BATCH
23810956F	ANIOSYME XL3	H27407S
2416036A1	ANIOS CLEAN EXCEL D	G29807S