

1 rue de l'Espoir 59260 LEZENNES France Tel +33 3 20 67 67 67 Fax + 33 3 20 67 67 68 Email Vigilance@anios.com To Healthcare Organisation Name Address

URGENT FIELD SAFETY NOTICE

<u>Date</u>: 07/11/19

Object:

| | Batch recall

☐ Information and/or recommendations

Affected products:

Device Commercial Name	Packaging	Article Code
SURFA'SAFE PREMIUM contained in	12x750ML	2524326*
BACCIDE KIT PRO		
ECI MND PREMIUM	12x750ML	2722371
INSTRUNET SURFA'SAFE PREMIUM	12x750ML	2585544E2
SURFA'SAFE PREMIUM	12x750ML	2419326*, 2419326EZ*, 2419326HQ*,
		2419544, 2419544BA, 2419544BR,
		2419544D2, 2419544GA, 2419544HA,
		2419544HD, 2419544S6, 2419544T4,
		2419544UE, 2419544UO, 2419544UY,
		2419544UZ
	16X500ML	2419105
	1X500ML	2419982
	1X50ML	2419874
	1X5L	2419922
	1X750ML	2419890, 2419890UY, 2419892,
		2419892HQ
	4X5L	2419028, 2419028HR

^{*}diffused foam form products

Madam, Sir,

We have identified that you received products in the above table, and we are recalling all batches (Annex II) as they do not comply with our quality expectations. They may contain the opportunistic environmental microorganism Burkholderia Cepacia.

Burkholderia cepacia poses little medical risk to healthy people. However, it is a known cause of infections in hospitalized patients. Patients who have certain health problems like weakened immune systems, especially immunocompromised patients or in neonatal care, or chronic lung diseases, particularly those with cystic fibrosis, are at higher risk of infection.

The products are available in a variety of packaging: foam sprays, diffused foam sprays (see indication in the above table) and dropping bottles. Depending on the indicated application of the products, the

Customer n°:

FSN_ANIOS_SSP_DISTRIBUTORS_EN_EX EU



risks are different. When using a diffused foam form, the risk is higher for the at-risk population due to possible inhalation exposure. When using the product in a wiping action, the probability of the bacteria infecting the at-risk patient population is less important. Laboratory data indicates that in Surfa'Safe Premium the bacteria dies two and a half minutes after product use on surfaces (Annex III).

Corrective actions to eliminate the contamination source are being implemented. We have introduced additional hygiene security protocols which means that all our medical devices manufactured and delivered from our Sainghin-en-Mélantois plant will have successfully passed the test protocols.

For precautionary reasons, we ask that you stop immediately using the recalled products that you may have in stock, as there is a risk they may be contaminated.

We ask you to block and isolate these products. In addition, we need you to inform immediately your end customers and ask them to notify you of the quantities they have in stock. You will be required to collect the completed response form (Annex I) from your customers and share a consolidated form with us of all the products you have recalled to the following e-mail address: Vigilance@anios.com. Any quantity declared can be subject of verification.

Please acknowledge receipt of this communication by returning at your earliest convenience - but no later than 05/12/2019 - the completed and signed reply form.

Your Anios representative will contact you to discuss the return of the recalled product you have in stock. We remain at your entire disposal for any question or assistance that you may need.

The undersigns confirm that this notice has been reported to the appropriate Regulatory Agency.

Please accept our apologies for the inconvenience it may have caused.

Yours faithfully

Isabelle Prévost	Dr Monique Manche	Thomas Decoster
Quality Manager	Materiovigilance Contact Person	President
Luium!		- tu-

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

This means, if you are a distributor, that this information has to be forwarded to any customers which was delivered with one of the affected batches.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.



1 rue de l'Espoir 59260 LEZENNES - France Tel +33 3 20 67 67 67 Fax + 33 3 20 67 67 68 Email Vigilance@anios.com Healthcare Organisation Name Address

ANNEX I CUSTOMER REPLY FORM

1. Field Safety Notice (FSN)

FSN Reference:

FSN_ANIOS_SSP_DISTRIBUTORS_EN_EX EU

FSN Date: November 7, 2019

Affected products: Please refer to Annex II

2. Customer Details

Customer Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	
Print Name*	
Signature*	
Date*	

Mandatory fields are marked with *



3. Customer action undertaken on behalf of Healthcare Organisation

☐ I confirm	n receipt of the Field Safety No	otice (FSN) and	that I read and	understood its content.
□ I perform	med all actions requested by t	he FSN.		
☐ The info	ormation and required actions	have been brouç	to the attent	ion of all relevant users and
execute	ed, including end customers in	case of distribut	tion of those pro	oducts
□ I inform	ed the supplier of the stock I h	ave that is subje	ct of the recall	and needs to be returned
PE	ERSON OF CONTACT FOR R	ETURN OF GO	OD:	
EN	MAIL OF CONTACT:			
	HONE NUMBER OF CONTAC			
	Device Commercial Name	Article Code	Batch N°	Packages Quantity (units)
_				
_				
☐ No affec	cted devices are available for	return		
☐ Other A	ction (Define):			

4. Return acknowledgement to sender

Email	Vigilance@anios.com
Postal Address	Laboratoires ANIOS
	Service qualité
	1, rue de l'Espoir
	59260 Lezennes - France
Fax	+33 3 20 67 67 68
Deadline for returning the customer reply form	05/12/2019

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



1 rue de l'Espoir 59260 LEZENNES France Tel +33 3 20 67 67 67 Fax + 33 3 20 67 67 68 E:mail vigilance@anios.com

ANNEX II AFFECTED PRODUCTS BATCHES

1. Field Safety Notice (FSN)

FSN Reference:

FSN_ANIOS_SSP_DISTRIBUTORS_EN_EX EU

FSN_ANIOS_SSP_DISTRIBUTORS_EN_EX NON EU

FSN Date: November 7, 2019

Reply form: Please refer to Annex I

2. Affected Products Batches

Device Commercial Name	Packaging	Article code	Batch number
SURFA'SAFE PREMIUM	12x750ML	2524326	A01510S
contained in			A13802S
BACCIDE KIT PRO			A26023S
			A34406S
			B17802S
ECI MND PREMIUM	12x750ML	2722371	A03211S
			A04305S
			A13618S
			A15503S
			A16218S
			A17927S
			A19214S
			A23419S
			A26405S
			A29904S
			A33705S
			A34426S
			A36127S
			B01906S
			B02902S
			B04605S
			B05712S
			B08702S
			B10629S
			B13323S
			B14414S
			B16327S
			B17802S



Device Commercial Name	Packaging	Article code	Batch number
ECI MND PREMIUM	12x750ML	2722371	B19604S
		2122311	B23213S
			B26920S
			W33210S
			W34906S
INTRUNET SURFA SAFE	12x750ML	2585544E2	A00807S
PREMIUM			A01510S
			A02505S
			A04322S
			A05308S
			A06406S
			A08805S
			A10013S
			A10123S
			A10303S
			A11002S
			A11204S
			A13713S
			A15503S
			A16218S
			A17106S
			A18508S
			A21915S
			A22213S
			A22907S
			A23419S
			A23703S
			A26803S
			A28403S
			A29211S
			A29904S
			A31018S
			A31309S
			A32204S
			A34106S
			B00406S
			B01405S
			B02902S
			B03721S
			B04807S
			B05712S
			B06909S
			B07719S
			B08702S
			B10101S
			B11318S
			B12808S
			B14828S
			B17118S
			B17803S
			B19126S
			B20807S
			B23213S
			B23907S
			B24304S



INTRUNET SURFA SAFE PREMIUM 12x750ML 2585544E2 W3003S W33411S W36314S W36314S A01024S A01024S A01024S A01024S A01024S A01013S A05209S A05919S A08017S A08017S A11302S A11302S A11502S A11612S A1300S A14222S A15601S A16218S A1620S A16218S A1620S A16218S A1620S A17821S A18508S A17821S A18508S A19013S A2005S A21202S A22011S A2611S	Device Commercial Name	Packaging	Article code	Batch number
PREMIUM W31810S W35411S W35411S W36314S A01771S A0297S A01711S A0297S A04420S A0420S A05209S A086017S A086017S A086017S A11502S A11502S A11502S A11502S A11612S A1422S A15601S A15601S A16218S A16218S A16218S A16218S A16218S A16218S A16909S A17821S A18508S A19013S A20005S A22101S A2611S A26111S A26111S A26111S A26803S A27906 A33109S A32204S A31309S A32204S A31309S B00724S B01906S B03123S B07710S B06909S B0710S B0710S B06909S B0710S B0710S B0710S B0710S B08909S B0710S B08909S B0710S B08909S B0710S B18509S B18509S B18509S B18509S B18509S B18509S B18509S	INTRUNET SURFA SAFF	12x750ML	2585544E2	W30805S
W320235 W35411S W36314S SURFA'SAFE PREMIUM 12x750ML 2419326 A010246 A017113 A029078 A04209 A05209S A05209S A05209S A080178 A086018 A100133 A11313S A11502S A11502S A141612S A146218S A146218S A16228S A156015 A15803S A16228S A16526S A16909S A77821S A18508S A2006S A20011S A20011S A2011S A26111S A26111S A26803S A27906S A28910S A2916S A3103S A3103S A34406S A3103S A34406S B00724S B01906S B00724S B01906S B03721S B05114S B051908S B03721S B05196S B03721S B05196S B03721S B05196S B03721S B05196S B07908S B08908S B07908S B08908S B07908S B07908S B08908S B07908S B08908S B07908S B08908S B08908S B07908S B08908S				
SURFA'SAFE PREMIUM 12x750ML 2419326 A010245 A029078 A042098 A052098 A052098 A060178 A086018 A100138 A113133 A115028 A115028 A1416028 A1462188 A1622188 A162288 A162288 A162288 A162288 A162288 A162088 A162188 A200058 A210028 A220118 A261118 A261118 A261118 A261118 A26118 A26118 A296168 A31038 A31038 A31038 A344068 A331038 A344068 B007248 B019068 B037218 B007248 B019068 B037218 B061968 B037218 B061968 B037218 B061968 B037218 B061968 B037218 B061968 B07908 B07908 B07908 B07908 B07908 B07908 B07908 B07908 B089083 B07908 B089083 B079088 B079088 B089088 B116168 B135098	TALIMION			
SURFA'SAFE PREMIUM 12x750ML 2419326 A01024S A01711S A02907S A04420S A05209S A05919S A08017S A08017S A08017S A08017S A08018S A11513S A11502S A11502S A11612S A13803S A14222S A15801S A15803S A16218S A16228S A16228S A16218S A1628S A1628S A16298S A17821S A18508S A21002S A22011S A26111S A26111S A26811S A26803S A27906S A27906S A2291S A31309S A3204S A33103S A34406S A35220S B00724S B01906S B03123S B03721S B03721S B05014S B06909S B07909S B08906S B185509S B185509S				
A01711S A02907S A04420S A05209S A05919S A08017S A08601S A10013S A11313S A11313S A11502S A11612S A14601S A1502S A15601S A15601S A15803S A16218S A16218S A16826S A16909S A17821S A18508S A19013S A20005S A21202S A22011S A26803S A27906S A28910S A27906S A28910S A29616S A31309S A3204S A33103S A34406S A33103S A34406S A3406S A3406S B00724S B01906S B00724S B01906S B00724S B01906S B03123S B00724S B01906S B03123S B03721S B05014S B06909S B07108S B06909S B07108S B07909S B07909S B08906S B11616S B13509S B14828S B14509S				
A029078 A04420S A052098 A052098 A052098 A059198 A08017S A080018 A10013S A11313S A11313S A11502S A11612S A13908S A14222S A13908S A14222S A156018 A16503S A16218S A16526S A16909S A17821S A18508S A19013S A200055 A21202S A21018 A26111S A266118 A266118 A266118 A26603S A27906S A28910S A27906S A28910S A29016S A31309S A31309S A3204S A3103S A34406S A3520S B00724S B01906S B03123S B03721S B05014S B05014S B05014S B05090S B07108S B08906S B08906S B08906S B11616S B13509S B18508S B14828S B15509S B14828S	SURFA'SAFE PREMIUM	12x750ML	2419326	
A04420S A05209S A05919S A05919S A08017S A08601S A10013S A11013S A11502S A11502S A11612S A13908S A14222S A15601S A15803S A16218S A16526S A16909S A17821S A18508S A2005S A21202S A22011S A26803S A27906S A28910S A28910S A28910S A33103S A34406S A33103S A34204S A33103S A34204S A33103S A34204S A3103S A34204S B01906S B03123S B00724S B01906S B03123S B03721S B05014S B06909S B07108S B08906S B118168S B13509S B14828S B13509S B14828S B15509S				
A052095 A05919S A08017S A08001S A10013S A11013S A11313S A11313S A11502S A11602S A11602S A15601S A15601S A15601S A16208S A16218S A16226S A16909S A17821S A18508S A19013S A20005S A21202S A22011S A26111S A26813S A27906S A28910S A28910S A28910S A28910S A31309S B00724S B01906S B03123S B03721S B01906S B03123S B03123S B03123S B03123S B03123S B03121S B05014S B06909S B07909S B07909S B07909S B07909S B07909S B07909S B08906S				
A05919S A08017S A08601S A08017S A10013S A11302S A11502S A11502S A11612S A13908S A14222S A15601S A15803S A16218S A1628S A1628S A16909S A17821S A18508S A1909S A17821S A26005S A21202S A21202S A21202S A21202S A21202S A213S A26111S A26811S A26813S A27906S A28910S A28910S A28910S A28910S A33103S A33103S A3406S A33103S A3406S B00724S B00724S B00724S B007908S B00714S B06909S B07108S B07909S B08906S B07909S B08906S B07909S B08906S B07909S B08906S B07909S B08906S B13509S				
A08017S A08601S A10013S A11013S A11313S A11502S A11612S A13908S A14222S A15601S A15803S A16218S A1626S A1626S A16909S A17821S A18508S A20015S A22011S A22011S A26111S A26111S A26803S A27906S A27906S A28910S A31303S A3406S A31303S A34406S A34406S A35220A B00724S B001724S B001908S B00123S B003121S B005014S B00909S B00108S B00909S B0090S				A05209S
A08801S A10013S A10013S A11313S A11502S A11612S A13908S A14222S A15601S A15803S A16218S A16226S A16909S A17821S A18508S A19013S A20005S A21202S A22011S A22611S A26803S A27906S A28910S A27906S A29616S A31309S A3204S A33103S A34406S A35220S B00724S B01906S B03123S B03123S B03123S B03123S B03121S B05014S B06909S B07909S				A05919S
A10013S A11302S A11502S A11612S A11612S A11902S A11902S A15801S A15803S A16218S A16526S A16909S A17821S A18508S A19013S A20005S A21202S A22011S A26111S A26111S A26803S A27906S A28910S A27906S A28910S A29616S A31309S A3209S A33103S A3406S A3520S B00724S B001906S B03123S B03123S B03123S B03123S B03123S B03123S B03121S B05014S B06909S B07108S B07909S B07909S B07909S B08906S B11616S				A08017S
A11313S A115028 A116028 A11612S A13908S A14222S A15803S A16218S A16218S A1626S A16909S A17821S A18508S A18508S A20005S A21202S A21202S A21202S A22011S A26803S A27906S A28910S A28910S A28910S A28910S A31309S A33103S A34406S A33103S A34406S B00724S B01906S B03123S B03721S B05014S B05014S B06909S B07909S B08906S B07909S B08906S B07909S B08906S B11616S B13509S B145509S				A08601S
A11502S A11612S A113008S A14222S A13601S A15601S A15601S A15601S A15608S A16218S A16526S A16909S A118008S A19013S A2001S A2011S				A10013S
A11612S A13908S A14202S A15601S A15803S A16218S A16526S A16909S A17821S A18508S A19013S A20005S A22011S A22011S A26111S A2683S A27906S A28910S A29616S A33103S A33103S A3406S A34204S A33103S A3408S A3520S B00724S B01906S B03123S B03123S B03121S B05014S B06909S B06909S B08906S B07909S B08906S B09306S B11616S B13509S B14828S B15509S				A11313S
A13908S A14222S A15601S A15803S A16218S A16526S A16909S A17821S A18508S A19013S A20005S A21202S A22011S A26803S A27906S A27906S A28910S A29616S A31309S A3406S A3406S A3406S B00724S B00724S B00724S B003721S B05014S B05014S B05014S B06909S B07909S B08906S B07909S B08906S B11616S B13509S B13509S B13509S B13509S B13509S B13509S B13509S B13509S B13509S				A11502S
A14222S A15601S A15803S A16218S A1626S A16909S A17821S A18508S A19013S A20005S A21202S A22011S A26111S A26803S A27906S A28910S A29616S A31303S A3204S A33103S A34406S A35220S B00724S B01906S B03123S B03721S B03721S B03721S B05014S B06909S B07108S B07909S B08906S B09306S B11616S B13628S B15509S				A11612S
A14222S A15601S A15803S A16218S A1626S A16909S A17821S A18508S A19013S A20005S A21202S A22011S A26111S A26803S A27906S A28910S A29616S A31303S A3204S A33103S A34406S A35220S B00724S B01906S B03123S B03721S B03721S B05014S B06909S B07108S B07909S B08906S B09306S B11616S B13628S B14828S B15509S				A13908S
A15601S A15803S A16218S A16526S A16909S A177821S A18508S A19013S A20005S A21202S A22011S A26111S A26803S A27906S A28910S A29616S A31309S A3204S A33103S A34406S A35220S B00724S B01906S B03123S B03721S B05014S B06909S B07108S B07108S B07108S B07909S B08906S B09306S B11616S B13509S B14828S B15509S				
A15803S A16218S A16526S A16909S A17821S A18508S A19013S A20005S A21202S A2211S A26803S A27906S A28910S A29616S A31309S A32204S A33103S A34406S A35220S B00724S B01906S B03123S B03721S B05014S B05014S B06909S B07108S B07908S B07908S B07908S B07908S B07908S B07908S B07908S B07908S B07908S B08906S B08906S B08906S B09306S B11616S B13509S B14828S B14828S B14828S B14828S				
A16218S A16526S A16909S A17821S A18508S A19013S A20005S A21202S A22011S A26111S A26803S A27906S A28910S A29916S A33109S A32204S A33109S A34406S A35220S B00724S B01906S B03123S B03721S B05014S B06909S B07909S B07909S B08906S B11616S B11616S B13509S B14828S B15509S				
A16526S A16909S A17821S A18508S A19013S A20005S A21020S A2102S A22011S A26111S A26803S A27906S A28910S A29616S A31309S A32204S A33103S A34406S A35220S B00724S B01906S B03123S B03721S B05014S B06909S B07108S B07909S				
A16909S A17821S A18508S A19013S A20005S A21202S A22011S A26111S A26803S A27906S A28910S A29616S A31309S A32204S A33103S A34406S A34406S A35220S B00724S B01906S B03123S B03123S B03721S B05014S B06909S B07909S B07909S B08906S B09306S B116168 B13509S B118569S				
A17821S A18508S A19013S A20005S A21202S A22011S A2611S A26803S A27906S A28910S A29616S A31309S A33103S A33103S A34406S A35220S B00724S B01906S B03123S B03721S B05014S B06909S B07108S B07909S B08906S B09306S B11616S B13509S B14828S B13509S B14828S B14828S B14828S B15509S				
A18508S A19013S A20005S A21202S A21202S A22011S A26111S A26803S A27906S A28910S A28910S A31309S A33103S A34406S A35220S B00724S B01906S B03123S B03721S B05014S B06909S B07108S B07909S B08906S B09306S B11616S B13509S B14828S B15509S				
A19013S A20005S A21202S A21202S A22011S A26111S A26803S A27906S A28910S A29616S A31309S A32204S A33103S A34406S A35220S B00724S B01906S B03123S B03721S B05014S B06909S B07108S B07909S B08906S B11616S B13509S B14828S B15509S				
A20005S A21202S A21202S A22011S A26810S A27906S A28910S A29616S A31309S A32204S A33103S A34406S A35220S B00724S B01906S B03123S B03721S B05014S B06909S B07108S B07909S B08906S B09306S B11616S B13509S B14828S B15509S				
A21202S A22011S A26111S A26803S A27906S A28910S A28910S A29616S A31309S A32204S A33103S A34406S A35220S B00724S B01906S B03123S B03721S B05014S B06909S B07108S B07909S B07909S B08906S B11616S B13509S B14828S B15509S				
A22011S A26111S A26803S A27906S A28910S A28910S A29616S A31309S A32204S A33103S A34406S A35220S B00724S B01906S B03123S B03721S B05014S B06909S B07108S B07909S B07909S B08906S B11616S B13509S B14828S B15509S				
A26111S A26803S A27906S A28910S A29616S A31309S A32204S A33103S A34406S A35220S B00724S B01906S B03123S B03721S B05014S B06909S B07108S B07909S B07909S B08906S B09306S B11616S B13509S B14828S B15509S				
A26803S A27906S A28910S A29616S A31309S A32204S A33103S A34406S A35220S B00724S B01906S B03123S B03721S B05014S B06909S B07108S B07909S B07909S B08906S B09306S B11616S B13509S B14828S B15509S				
A27906S A28910S A29616S A31309S A32204S A33103S A34406S A35220S B00724S B01906S B03123S B03721S B05014S B06909S B07108S B07909S B07909S B08906S B11616S B118509S				
A28910S A29616S A31309S A32204S A33103S A34406S A35220S B00724S B01906S B03123S B03721S B05014S B06909S B07108S B07909S B08906S B11616S B13509S B14828S B15509S				
A29616S A31309S A32204S A33103S A34406S A35220S B00724S B01906S B03123S B03721S B05014S B06909S B07108S B07909S B08906S B08906S B11616S B13509S B14828S B15509S				
A31309S A32204S A33103S A34406S A35220S B00724S B01906S B03123S B03721S B05014S B06909S B07108S B07909S B08906S B08906S B11616S B13509S B14828S B15509S				
A32204S A33103S A34406S A35220S B00724S B01906S B03123S B03721S B05014S B06909S B07108S B07909S B08906S B09306S B11616S B13509S B14828S B15509S				
A33103S A34406S A35220S B00724S B01906S B03123S B03721S B05014S B06909S B07108S B07909S B08906S B08906S B11616S B11616S B13509S B14828S B15509S				
A34406S A35220S B00724S B01906S B03123S B03721S B05014S B06909S B07108S B07909S B08906S B09306S B11616S B13509S B14828S B15509S				
A35220S B00724S B01906S B03123S B03721S B05014S B06909S B07108S B07909S B08906S B09306S B11616S B115509S				
B0724S B01906S B03123S B03721S B05014S B06909S B07108S B07909S B08906S B09306S B11616S B115509S B14828S B15509S				
B01906S B03123S B03721S B05014S B06909S B07108S B07909S B08906S B09306S B11616S B13509S B14828S B15509S				
B03123S B03721S B05014S B06909S B07108S B07909S B08906S B09306S B11616S B13509S B14828S B15509S				
B03721S B05014S B06909S B07108S B07909S B08906S B09306S B11616S B13509S B14828S B15509S				
B05014S B06909S B07108S B07909S B08906S B09306S B11616S B13509S B14828S B15509S				
B06909S B07108S B07909S B08906S B09306S B11616S B13509S B14828S B15509S				
B07108S B07909S B08906S B09306S B11616S B13509S B14828S B15509S				
B07909S B08906S B09306S B11616S B13509S B14828S B15509S				
B08906S B09306S B11616S B13509S B14828S B15509S				
B09306S B11616S B13509S B14828S B15509S				
B11616S B13509S B14828S B15509S				
B13509S B14828S B15509S				
B14828S B15509S				
B15509S				
B17511S				
				B17511S



Device Commercial Name	Packaging	Article code	Batch number
SURFA'SAFE PREMIUM	12x750ML	2419326	B17826S
			B19126S
			B20510S
			B23213S
			B23424S
			B24716S
			B25008S
			B26920S
			B27424S
			W31203S
			W32206S
			W33925S
			W34906S
		0.44000055	W35411S
		2419326EZ	A02505S
			A08017S
			A08601S
			A11313S
			A11502S
			A13908S
			A14911S
			A18508S
			A22011S
			A28227S
			A32320S
			A34106S
			B01906S
			B06323S
			B06909S
			B10724S
			B12606S
			B14414S
			B15509S
			B18102S
			B19718S
			B22416S
		2419326HQ	B25008S
			W32206S
			W34809S
			W34906S
			A05209S
			A08017S
			A13802S
			A18401S
			A21202S
			A28227S
			A28910S
			A31309S
			B00406S
			B02902S
			B04605S
			B06909S
			B08906S
			B14414S
			B19604S



Device Commercial Name	Packaging	Article code	Batch number
SURFA'SAFE PREMIUM	12x750ML	2419326HQ	B22416S
	TEXTOONIE	2110020119	B26920S
			W31203S
			W36314S
		2419544	A00408S
			A00807S
			A00928S
			A01024S
			A01510S
			A01711S
			A02404S
			A02505S
			A02907S
			A03613S
			A04322S
			A04420S
			A04606S
			A05209S
			A05308S
			A05720S A05919S
			A06406S
			A06816S
			A000103 A07424S
			A08017S
			A08210S
			A08601S
			A08805S
			A09420S
			A09520S
			A10013S
			A10123S
			A10303S
			A11002S
			A11204S
			A11313S
			A11612S
			A13202S
			A13417S
			A13618S
			A13713S
			A13802S
			A14222S
			A15211S
			A15503S
			A15601S
			A15703S
			A15803S
			A16909S
			A17106S
			A17404S
			A17613S
			A17715S
			A17821S
			A17927S



Device Commercial Name	Packaging	Article code	Batch numbe
SURFA'SAFE PREMIUM	12x750ML	2419544	A18401S
		2110011	A18601S
			A19013S
			A19214S
			A19408S
			A20005S
			A20615S
			A21202S
			A21403S
			A21915S
			A22213S
			A22613S
			A22907S
			A23419S
			A23703S
			A24309S
			A24610S
			A26405S
			A26803S
			A26827S
			A27906S
			A28227S
			A28314S
			A28403S
			A28417S
			A28910S
			A29211S
			A29616S
			A29810S
			A29904S
			A31018S
			A31309S
			A31412S
			A31706S
			A31819S
			A32204S
			A32320S
			A32501S
			A32620S
			A32905S
			A33103S
			A34106S
			A34406S
			A34426S
			A34619S
			A34722S
			A34905S
			A35220S
			A35324S
			B00406S
			B00724S
			B00827S
			B01016S
			B01714S
	1	I	B01906S



Device Commercial Name	Packaging	Article code	Batch number
SURFA'SAFE PREMIUM	12x750ML	2419544	B02902S
		2413044	B03123S
			B03721S
			B04605S
			B04807S
			B05014S
			B05301S
			B05507S
			B05712S
			B07318S
			B07719S
			B07909S
			B08016S
			B08702S
			B08906S
			B09306S
			B10101S
			B10521S
			B10724S
			B11208S
			B11318S
			B11616S
			B12312S
			B12606S
			B12808S
			B12919S
			B13323S
			B13509S
			B14716S
			B15102S
			B15102S B15509S
			B15701S
			B16427S
			B17118S
			B17511S
			B17803S
			B17826S
			B18102S
			B18604S
			B19032S
			B19126S
			B19916S
			B20310S
			B20529S
			B20807S
			B21121S
			B21228S
			B21403S
			B21924S
			B23907S
			B24118S
			B24304S
			B24716S
			DZ-77 100
			B25008S



8/14

Device Commercial Name	Packaging	Article code	Batch number
SURFA'SAFE PREMIUM	12x750ML	2419544	B25609S
		2413344	B26109S
			B27424S
			B28014S
			B28203S
			W30618S
			W30805S
			W31105S
			W31203S
			W31810S
			W32023S
			W32206S
			W32510S
			W32810S
			W33422S
			W33925S
			W34701S
			W34809S
			W34906S
			W35309S
			W35612S
		0440544DA	W36314S
		2419544BA	A04305S
			A08017S
			A13802S
			A17927S
			A21202S
			A22613S
		2419544BR	A10123S
			A14222S
			A16909S
			A17927S
			A31004S
			A31018S
			A31309S
			B04605S
			B07108S
			B08702S
			B10629S
			B20807S
			B23907S
			B25609S
			W31810S
		2419544D2	A05308S
		241304402	A06816S
			A11204S
			A12712S
			A13802S
			A20005S
			A22213S
			A26803S
			A28314S
			A31819S
			A32501S
			B10521S



Device Commercial Name	Packaging	Article code	Batch number
SURFA'SAFE PREMIUM	12x750ML	2419544D2	B12312S
	12/1/00/11/2		W36314S
		2419544GA	A00807S
			A18601S
			B15505S
		2419544HA	A15503S
			A21202S
			B17802S
		2419544HD	A01024S
			A05209S
			A05308S
			A05919S
			A06406S
			A09420S
			A09520S
			A11204S
			A13618S
			A13802S
			A15803S
			A17927S
			A18601S
			A21915S
			A26111S
			A28403S
			A29616S
			A29810S A31819S
			A32501S
			A33705S
			A34619S
			B00406S
			B004003
			B00909S
			B01405S
			B04105S
			B05712S
			B06909S
			B07909S
			B08702S
			B10724S
			B12919S
			B15509S
			B16327S
			B16906S
			B17802S
			B19126S
			B19206S
			B19604S
			B19916S
			B20529S
			B21924S
			B23424S
			B24716S
			B26109S
		İ	W31203S



Device Commercial Name	Packaging	Article code	Batch number
SURFA'SAFE PREMIUM	12x750ML	2419544HD	W33210S
	12X1 OOIVIL		W35612S
		2419544S6	A05209S
			A12712S
			A15503S
			A19013S
			A22907S
			A29211S
			A31018S
			A34106S
			B04105S
			B04605S
			B10724S
			B11616S
			B15102S
			B16327S B19206S
			B22416S
			W31810S
			W316103 W33210S
			W34701S
		2419544T4	A05919S
		241304414	A26111S
			A28314S
			B01714S
			B19126S
		2419544UE	A01711S
			A06406S
			A19214S
			A22213S
			A34619S
			B01906S
			B02902S
			B04605S
			B07108S
			B10724S
			B15102S
			B19126S
			B21924S
			W31810S
		0440544110	W36314S
		2419544UO	A04322S
			A13202S
			A19214S
			A23419S A34722S
			B07318S
			B15102S
			B19206S
			B23424S
			W30805S
			W32023S
		2419544UY	B11616S
		211001101	B23907S
			B24304S
I	ı	1	DZ-100+0



Device Commercial Name	Packaging	Article code	Batch number
SURFA'SAFE PREMIUM	12x750ML	2419544UY	B26920S
	12X1 OOIVIL	2419544UZ	A02907S
			A05919S
			A08805S
			A11002S
			A15503S
			A15803S
			A18401S
			A21403S
			A22907S
			A26111S
			A28403S
			A28417S
			A31018S
			A33705S
			A34619S B00406S
			B00406S B00909S
			B03123S
			B04105S
			B08421S
			B08702S
			B10101S
			B10724S
			B12919S
			B16906S
			B18102S
			B20807S
			B28014S
			W33210S
			W33422S
			W33925S
			W36314S
	16X500ML	2419105	A00415
			A01911
			A03613S
			A05380S
			A06816S
			A08210S
			A11502S
			A12712S
			A14911S
			A15803S
			A16307S
			A16526S
			A17106S A17927S
			A17927S A18508S
			A20005S
			A20003S A21212S
			A21502S
			A21302S A23320S
			A23703S
			A26503S
			A28314S
I	I	ı	71200140



Device Commercial Name	Packaging	Article code	Batch number
SURFA'SAFE PREMIUM	16X500ML	2419105	A31004S
	TOTOGOME	2413103	A31309S
			A33103S
			A34106S
			A35513S
			A36127S
			B00827S
			B01714S
			B02207S
			B03028S
			B05121S
			B06323S
			B07318S
			B08421S
			B10629S
			B12312S
			B13509S
			B14414S
			B15505S
			B16327S
			B19206S
			B19718S
			B20510S
			B21121S
			B23213S
			B25326S
			B25915S
			W31810S
			W32206S W33210S
			W34906S
			W35411S
	1X500ML	2419982	A00415
	IXJUUIVIL	2419902	A06816S
			A23320S
			B01714S
			B15505S
			B16327S
			B23213S
	1X50ML	2419874	A03613S
	IXOUNE	211007-1	W34906S
	1X5L	2419922	W31810S
	1X750ML	2419890	A01024S
	I TOONIE	2110000	A01510S
			A01711S
			A02907S A06406S A08805S A10013S A10303S A11002S A13202S A13618S A14222S A15503S



Device Commercial Name	Packaging	Article code	Batch number
SURFA'SAFE PREMIUM	1X750ML	2419890	A18601S
			A21403S
			A22213S
			A24309S
			A26405S
			A27906S
			A28227S
			A28403S
			A31018S
			A33103S
			B03721S
			B07719S
			B09306S
			B12808S B14716S
			B15701S
			B18604S
			B21403S
			B25609S
			W30618S
			W30805S
			W31105S
			W33925S
			W34809S
		2419890UY	W34809S
		2419892	A00928S
		2410002	A01024S
			A01711S
			A02907S
			A05919S
			A08805S
			A15601S
			A26111S
			A31309S
			B06909S
			B08906S
			B17511S
			W30618S
			W30805S
			W31105S
			W33925S
			W34809S
		2419892HQ	A01711S
			W30618S
			W31203S
			W36314S
	4X5L	2419028	A03211S
			A10815S
			A16307S
			A19408S
			A21502S
			A30910S
			A34406S
			B02207S
			B09202S



Device Commercial Name	Packaging	Article code	Batch number
SURFA'SAFE PREMIUM	47/51	0.440000	B10629S
JOIN A SAI ET NEWIOW	4X5L	2419028	B12606S
			B17826S
			B19718S
			B24304S
			W31810S
		2419028HR	A23320S
			B02207S
			B24304S



Numéros de demande : 38 515

Sainghin-en-Mélantois, on the October 31th 2019

Responsibles:

Dr LOEFFERT FREMIOT Sophie PLUCHART Chrystèle

Study followed by:

LAURENT Meghan

PURPOSE OF THE STUDY:

Study of the survival of the bacteria *Burkholderia cepacia* contained in the disinfectant detergent SURFA'SAFE PREMIUM after application on two types of surface

In charge of the study:

Chrystèle PLUCHART

Microbiology Laboratory Manager

Sophie LOEFFERT FREMIOT

Microbiology Manager

This document has 5 numbered pages including 0 appendix



PROTOCOL

The tests described below were carried out based on the standard NF EN 16615 (May 2015) "Chemical disinfectants and antiseptics - Quantitative test for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces, with mechanical action using wipes in the medical field (Phase 2 / Step 2) ".

Principle:

The disinfectant detergent SURFA'SAFE PREMIUM (lot B 274.24S) contaminated with the bacteria *Burkholderia cepacia* is applied on two types of surfaces according to the protocols described below.

Tested surfaces: Stainless steel and PVC.

Test areas are plotted 10/10 cm square on each surface

Six zones 10/10 cm are identified: 1, 2, 3, 4, 5, 6

♦ Protocol 1 :

Two sprays of SURFA'SAFE PREMIUM (Batch B 274.24S) are applied to each test area of each surfaces (stainless steel / PVC) and wiping of each zone is carried out using a wipe (1 go- return).

♦ Protocol 2 :

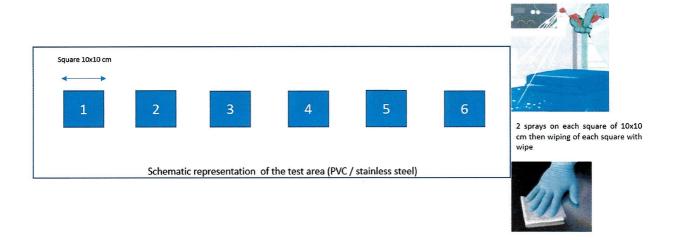
Two sprays of SURFA'SAFE PREMIUM (Batch B 274.24S) are applied to one wipe and then wiping of each test area of each surface (stainless steel / PVC) is carried out using this wipe (1 go- return).

Each operation is performed in duplicate.



Below the diagram of the tests.

Protocol 1: On PVC and stainless-steal surface.



After the implementation of the protocol, a contact time is respected before proceeding to the sampling of residual germs on the surfaces.

The experimental plan (zone/contact ime) is as follows:

Zone 1: T0: immediate

Zone 2: Contact time of 1 min

Zone 3: Contact time of 1 min 30

Zone 4: Contact time of 2 min

Zone 5: Contact time of 2 min 30

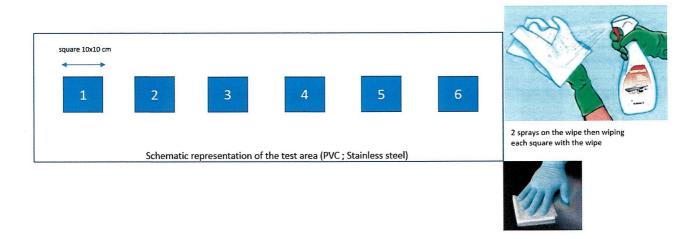
Zone 6: Contact time of 3 min

The *Burkholderia cepacia* strain is recovered by applying a Count tact box for 10 seconds on each defined area.

The Petri dishes are then incubated for 48H at 30°C ± 1°C



Protocol 2: On PVC and stainless-steel surface.



After the implementation of the protocol, a contact time is respected before proceeding to the sampling of residual germs on the surfaces.

The experimental plan (zone/contact ime) is as follows:

Zone 1: T0: immediate

Zone 2: Contact time of 1 min

Zone 3: Contact time of 1 min 30

Zone 4: Contact time of 2 min

Zone 5: Contact time of 2 min 30

Zone 6: Contact time of 3 min

The *Burkholderia cepacia* strain is recovered by applying a Count tact box for 10 seconds on each defined area.

The Petri dishes are then incubated for 48H at 30°C ± 1°C



Résults : Protocol 1

Surface PVC

	Zone 1 : T0	Zone 2: T1min	Zone 3: T1min30	Zone 4: T2min	Zone 5: T2min30	Zone 6: T3min
Contact time	CFU/25 cm2	CFU/25 cm2	CFU/25 cm2	CFU/25 cm2	CFU/25 cm2	CFU/25 cm2
Test Result	+	+	231	32	0	0
DVC	+	+	243	41	0	0
PVC	+	+	217	25	0	0

Surface Stainless steal

	Zone 1 : TO	Zone 2: T1min	Zone 3: T1min30	Zone 4: T2min	Zone 5: T2min30	Zone 6: T3min
Contact time	CFU/25 cm2	CFU/25 cm2	CFU/25 cm2	CFU/25 cm2	CFU/25 cm2	CFU/25 cm2
Test Result	+	+	144	15	0	0
La sau	+	+	130	17	0	0
Inox	+	+	127	19	0	0

Résults : Protocol 2

Surface PVC

Contact time	Zone 1 : T0	Zone 2: T1min	Zone 3: T1min30		Zone 5: T2min30	Zone 6: T3min
Contact time	CFU/25 cm2	CFU/25 cm2	CFU/25 cm2	CFU/25 cm2	CFU/25 cm2	CFU/25 cm2
Test Result	+	+	202	32	0	0
DV C	+	+	213	27	0	0
PVC	+	+	227	39	0	0

Surface Stainless steal

	Zone 1 : TO	Zone 2: T1min	Zone 3: T1min30	Zone 4: T2min	Zone 5: T2min30	Zone 6: T3min
Contact time	CFU/25 cm2	CFU/25 cm2	CFU/25 cm2	CFU/25 cm2	CFU/25 cm2	CFU/25 cm2
Test Result	+	+	151	22	0	0
	+	+	163	20	0	0
lnox	+	+	140	17	0	0

Conclusion:

Regardless of the protocol and the surface, the results of the tests demonstrate that the *Burkholderia cepacia* strain contained in SURFA'SAFE PREMIUM (Batch B 274.24S) is no longer present after 2 minutes 30.