

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                |

<sup>\*</sup>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: <a href="Vigilance@anios.com">Vigilance@anios.com</a>. 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!           |                                 | wo 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.



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# 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 confi | rm receipt of the Field Safety N  | otice (FSN) and    | that I read and   | understood its content.       |
|-----------|-----------------------------------|--------------------|-------------------|-------------------------------|
| □ I perfo | ormed all actions requested by t  | he FSN.            |                   |                               |
| ☐ The in  | formation and required actions    | have been broug    | ght to the attent | ion of all relevant users and |
| execu     | uted, including end customers in  | n case of distribu | tion of those pr  | oducts                        |
| ☐ I infor | med the supplier of the stock I h | nave that is subje | ect of the recall | and needs to be returned      |
| F         | PERSON OF CONTACT FOR F           | RETURN OF GO       | OD:               |                               |
| E         | EMAIL OF CONTACT:                 |                    |                   | <del></del>                   |
| F         | PHONE NUMBER OF CONTAC            | CT:                |                   |                               |
|           |                                   |                    |                   |                               |
|           | Device Commercial Name            | Article Code       | Batch N°          | Packages Quantity (units)     |
|           |                                   |                    |                   |                               |
|           |                                   |                    |                   |                               |
|           |                                   |                    |                   |                               |
|           |                                   |                    |                   |                               |
|           |                                   |                    |                   |                               |
|           |                                   |                    |                   |                               |
|           |                                   |                    |                   |                               |
|           |                                   |                    |                   |                               |
|           |                                   |                    |                   |                               |
|           |                                   |                    |                   |                               |
| □ No aff  | ected devices are available for   | return             |                   |                               |
|           | Action (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   | SURFA'SAFE PREMIUM     | FA'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 B11616S   |                        |                          |              |              |
| 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<br>B09306S<br>B11616S<br>B13509S<br>B14828S<br>B15509S  |                        |                          |              |              |
| B09306S<br>B11616S<br>B13509S<br>B14828S<br>B15509S   |                        |                          |              |              |
| B11616S B13509S B14828S B15509S   |                        |                          |              |              |
| B13509S<br>B14828S<br>B15509S   |                        |                          |              |              |
| B14828S<br>B15509S  |                        |                          |              |              |
| B15509S   |                        |                          |              |              |
|   |                        |                          |              |              |
| B17511S   |                        |                          |              |              |
|   |                        |                          |              | B17511S      |



| <b>Device Commercial Name</b> | 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      |
|                               |           | 2419326HQ    | B22416S      |
|                               |           |              | 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<br>A05919S |
|                        |           |              | A06406S            |
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|                        |           |              | A000103<br>A07424S |
|                        |           |              | A08017S            |
|                        |           |              | A08210S            |
|                        |           |              | A08601S            |
|                        |           |              | A08805S            |
|                        |           |              | A09420S            |
|                        |           |              | A09520S            |
|                        | [         |              | A10013S            |
|                        |           |              | A10123S            |
|                        |           |              | A10303S            |
|                        |           |              | A11002S            |
|                        |           |              | A11204S            |
|                        |           |              | A11313S            |
|                        |           |              | A11612S            |
|                        |           |              | A13202S            |
|                        |           |              | A13417S            |
|                        |           |              | A13618S            |
|                        |           |              | A13713S            |
|                        |           |              | A13802S            |
|                        |           |              | A14222S            |
|                        |           |              | A15211S            |
|                        |           |              | A15503S            |
|                        |           |              | A15601S            |
|                        |           |              | A15703S            |
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|                        |           |              | 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     |
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|                        |           |              | A28314S     |
|                        |           |              | A28403S     |
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|                        |           |              | A29904S     |
|                        |           |              | A31018S     |
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|                        |           |              | A31706S     |
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|                        |           |              | A32905S     |
|                        |           |              | A33103S     |
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|                        |           |              | 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            |
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|                        |           |              | B11616S            |
|                        |           |              | B12312S            |
|                        |           |              | B12606S            |
|                        |           |              | B12808S            |
|                        |           |              | B12919S            |
|                        |           |              | B13323S            |
|                        |           |              | B13509S            |
|                        |           |              | B14716S            |
|                        |           |              | B15102S            |
|                        |           |              | B15102S<br>B15509S |
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|                        |           |              | 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            |



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| <b>Device Commercial Name</b> | 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      |
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|                               |           | 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      |



| <b>Device Commercial Name</b> | 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            |
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|                               |              |              | A18601S            |
|                               |              |              | A21915S            |
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|                               |              |              | A28403S            |
|                               |              |              | A29616S            |
|                               |              |              | A29810S<br>A31819S |
|                               |              |              | A32501S            |
|                               |              |              | A33705S            |
|                               |              |              | A34619S            |
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|                               |              |              | B004003            |
|                               |              |              | B00909S            |
|                               |              |              | B01405S            |
|                               |              |              | B04105S            |
|                               |              |              | B05712S            |
|                               |              |              | B06909S            |
|                               |              |              | B07909S            |
|                               |              |              | B08702S            |
|                               |              |              | B10724S            |
|                               |              |              | B12919S            |
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|                               |              |              | B16327S            |
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|                               |              |              | 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<br>B19206S |
|                        |             |              | B22416S            |
|                        |             |              | W31810S            |
|                        |             |              | W316103<br>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<br>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<br>B00406S |
|                        |             |              | B00406S<br>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            |
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|                        |             |              | A17106S<br>A17927S |
|                        |             |              | A17927S<br>A18508S |
|                        |             |              | A20005S            |
|                        |             |              | A20003S<br>A21212S |
|                        |             |              | A21502S            |
|                        |             |              | A21302S<br>A23320S |
|                        |             |              | A23703S            |
|                        |             |              | A26503S            |
|                        |             |              | A28314S            |
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| Device Commercial Name | Packaging | Article code | Batch number   |
|------------------------|-----------|--------------|--|
| SURFA'SAFE PREMIUM     | 16X500ML  | 2419105      | A31004S  |
|                        | TOTOGOME  | 2413103      | A31309S  |
|                        |           |              | A33103S  |
|                        |           |              | A34106S  |
|                        |           |              | A35513S  |
|                        |           |              | A36127S  |
|                        |           |              | B00827S  |
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|                        |           |              | B02207S  |
|                        |           |              | B03028S  |
|                        |           |              | B05121S  |
|                        |           |              | B06323S  |
|                        |           |              | B07318S  |
|                        |           |              | B08421S  |
|                        |           |              | B10629S  |
|                        |           |              | B12312S  |
|                        |           |              | B13509S  |
|                        |           |              | B14414S  |
|                        |           |              | B15505S  |
|                        |           |              | B16327S  |
|                        |           |              | B19206S  |
|                        |           |              | B19718S  |
|                        |           |              | B20510S  |
|                        |           |              | B21121S  |
|                        |           |              | B23213S  |
|                        |           |              | B25326S  |
|                        |           |              | B25915S  |
|                        |           |              | W31810S  |
|                        |           |              | W32206S<br>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  |              | A01510S  |
|                        |           |              | A01711S  |
|                        |           |              |  |
|                        |           |              |  |
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|                        |           |              |  |
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|                        |           |              |  |
|                        |           |              |  |
|                        |           |              |  |
|                        |           |              | A02907S<br>A06406S<br>A08805S<br>A10013S<br>A10303S<br>A11002S<br>A13202S<br>A13618S<br>A14222S<br>A15503S |



| <b>Device Commercial Name</b> | Packaging | Article code | Batch number       |
|-------------------------------|-----------|--------------|--------------------|
| SURFA'SAFE PREMIUM            | 1X750ML   | 2419890      | A18601S            |
|                               |           |              | A21403S            |
|                               |           |              | A22213S            |
|                               |           |              | A24309S            |
|                               |           |              | A26405S            |
|                               |           |              | A27906S            |
|                               |           |              | A28227S            |
|                               |           |              | A28403S            |
|                               |           |              | A31018S            |
|                               |           |              | A33103S            |
|                               |           |              | B03721S            |
|                               |           |              | B07719S            |
|                               |           |              | B09306S            |
|                               |           |              | B12808S<br>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 NEIMION  | 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 :

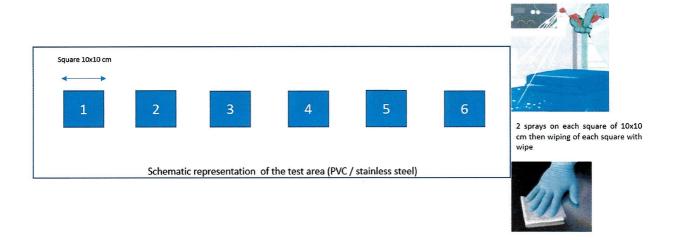
Two sprays of SURFA'SAFE PREMIUM (Batch B 274.24S) are applied to one wipe and then wiping of each test area of each surface (stainless steel / PVC) is carried out using this wipe (1 go- return).

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

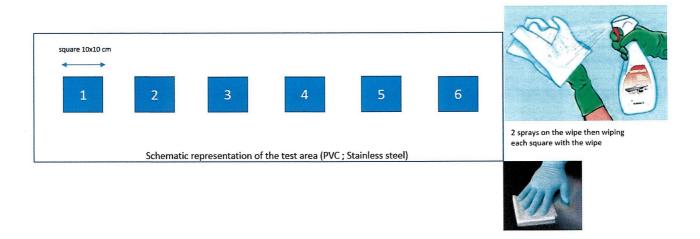
Zone 6: Contact time of 3 min

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.