FABRICATION FRANÇAISE

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Solution développée à partir de la technologie Coversafe™

FONdation pour le DEveloppement de la REcherche PHARmaceutique

Reference 16-1958 / 16-2064 / 17-2099

CERTIFICATE OF ANALYSIS

Society : PYLOTE
Address : 22 Avenue de la Mouyssaguèse
31280 Dremil-Lafage
FRANCE

To the attention of : LOIC MARCHIN

Test Evaluation of antimicrobial efficiency based on JIS Z2801 : 2010 for bacteria

Results: The results are given as log reduction R, corresponding to the value of antimicrobial activity

Customer Reference:	Pylote Technology
Fonderephar Sample Reference:	17-2099-1 / 17-2099-2
Date os sample receipt:	January 16th, 2017
Date of sample analysis:	January 2017
Date of certificate of analysis:	March 15th, 2017

Escherichia coli CIP 53.126	R = > 6,27 (reference)

Customer Reference:	Pylote Technology
Fonderephar Sample Reference:	16-2064-1 / 16-2064-2
Date os sample receipt:	October 10th, 2016
Date of sample analysis:	October 2016
Date of cetificate of analysis:	October 18th, 2016

Escherichia coli CIP 53.126	R = > 6,09 (after 6 months at 40°C/75% RH)

Customer Reference:	Pylote Technology
Fonderephar Sample Reference:	16-1958-1 / 16-1958-2
Date os sample receipt:	February 29th, 2016
Date of sample analysis:	March 2016
Date of certificate of analysis:	March 11th, 2016

Escherichia coli CIP 53.126	R = > 6,12 (after 50 months at room temperature)

Certified by Catherine FEUILLOLAY
Test Manager
June 26th, 2020

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PYLOTE regulatory compliance & strategy

European regulations on Biocidal products

ATOUT REACH is a service provider mandated by PYLOTE on regulatory compliance with the regulation of products EU biocides (BPR) n° 528/2012[1].

This communication from July 2nd ,2020 is based on the situation described by PYLOTE, and aims to support communication on their regulatory compliance and strategy to PYLOTE customers.

Biocidal products Regulation

BPR (PYLOTE and Customers)	The Antimicrobial technology developed by PYLOTE is subject to the obligations of the BPR as soon as allegations of the "disinfectant" or "antimicrobial" type are made. It relies on the use of a catalyst in order to generate hydroxyl free radicals. As a manufacturer, supplier and trader of these chemical, certain regulatory requirements apply.
Biocidal active substance and product (PYLOTE)	In accordance with article 3, PYLOTE technology can be considered as an In situ generation system[2] involving a biocidal product whose in situ generated active substance (hydroxyl radicals) is formally named "*free radicals generated in situ from ambient air or water*". Initial application for active substance approval under BPR is in progress. Biocidal product authorisation under BPR will be necessary afterwards.
Biocidal treated articles (PYLOTE and customers)	Mixtures and articles, as the **COVERSAFE** which are adhesive films activated by Pylote technology, can be considered as biocidal treated articles. These can be currently put in the market and details on PYLOTE compliance under BPR can be communicated upon request.

[1] https://echa.europa.eu/fr/regulations/biocidal-products-regulation/legislation

[2] Definition available in the CE note reference CA-Jul19-Doc 4.1_Clean

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FONdation pour le
DEveloppement de la
REcherche
PHARmaceutique

Système de management de la qualité
Certifié ISO 9001

Reference 20-2657/20-2658

CERTIFICATE OF ANALYSIS

Society : PYLOTE
Address : 22 Avenue de la Mouyssaguèse
31280 Dremil-Lafage
FRANCE

To the attention of : LOIC MARCHIN

Customer Reference:	Coversafe Film (Film Gerg. ADD)
Fonderephar Sample Reference:	20-2658-2 / 20-2657 - 2
Date os sample receipt:	May 25th, 2020
Date of sample analysis:	May - June 2020
Date of certificate of analysis:	June 8th, 2020

Test
Evaluation of antimicrobial efficiency based on JIS Z2801 : 2010 for bacteria

Results: The results are given as log reduction R, corresponding to the value of antimicrobial activity

Escherichia coli CIP 53.126 R = 5,75 (after a contact time 24H)

Test
Evaluation of antivirucidal activity according to the methodology based on ISO 21702 : 2019 for virus

Results: The results are given as log reduction R, corresponding to the value of antivirucidal activity

Coronavirus Humain 229E R = 0,98 (after a contact time 1H)
R = 3,28 (after a contact time 24H)

Certified by Catherine FEUILLOLAY and Laila HADDIOUI
Test Managers

FONdation pour le
DEveloppement de la
REcherche
PHARmaceutique

Système de management de la qualité
Certifié ISO 9001

Reference 20-2663

CERTIFICATE OF ANALYSIS

Society : PYLOTE
Address : 22 Avenue de la Mouyssaguèse
31280 Dremil-Lafage
FRANCE

To the attention of : LOIC MARCHIN

Customer Reference:	Coversafe Film (Film Gerg. ADD)
Fonderephar Samples Reference:	20-2663-2/20-2663-3/20-2663-4/20-2663-5
Date os sample receipt:	June 2nd, 2020
Date of sample analysis:	June 2020
Date of certificate of analysis:	June 17th, 2020

Test
Evaluation of antimicrobial efficiency based on JIS Z2801 : 2010 for bacteria

Results: The results are given as log reduction R, corresponding to the value of antimicrobial activity after a contact time 24H

Escherichia coli CIP 53.126
R = 5,86 without wash
R = 5,86 after 100 washes with isopropilic alcohol
R = 5,86 after 100 washes with detergent with bleach
R = 5,86 after 100 washes with Surfanios Premium

Certified by Catherine FEUILLOLAY
Test Manager

FONdation pour le
DEveloppement de la
REcherche
PHARmaceutique

Système de management de la qualité
Certifié ISO 9001

Toulouse, June 4th 2020

STUDY 20-2657

EVALUATION OF THE VIRUCIDAL ACTIVITY OF NON-POROUS SURFACES AGAINST HUMAN CORONAVIRUS 229E ACCORDING TO THE METHODOLOGY OF STANDARD ISO 21702 MAY 2019

Client

PYLOTE SAS
22, Avenue de la Mouyssaguèse
31280 DREMIL LAFAGE

Test laboratory

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31062 TOULOUSE cedex 9
FRANCE

Dr Laïla HADDIOUI Assay Manager	Dr Jocelyne BACARIA Quality Manager

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I - IDENTIFICATION OF SAMPLE

- Product name:	Film Gerg. Standard
- Reference:	Film N°3 STD A.CO
- Batch:	Film N°3 du 20.05.2020
- Date of receipt :	05-25-2020
- Internal code :	20-2657-1

- Product name :	Coversafe Film (Film Ger. ADD)
- Reference:	Film N°1 A.CO ADD2
- Batch:	Film N°3 du 20.05.2020
- Date of receipt :	05-25-2020
- Internal code :	20-2657-2
- Promotor :	PYLOTE
- Period of testing :	May- June 2020

II -VIRUS TEST:

II-1 Human Coronavirus

Name:	Human Coronavirus 229E
Origin:	ATCC
Reference:	VR-740
Supplier batch number:	58505270
Internal batch number:	SS-2-081216 (Passage N°2)

II-2- Recipient cells

Name:	Vero Cells
Origin:	ATCC
Reference:	CCl-81
Supplier batch number:	3372621
Internal batch number:	WCB-090708 (Passages N°24)

III - EXPERIMENTAL CONDITIONS

- Contact times: 20 minutes, 60 minutes et 24 hours

- Test temperature: 36°C ± 1°C

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IV- IV- TEST METHOD

IV-1 Contact virus/Pieces

- Each sample (50mm/50mm) submitted to the test is placed in a sterile glass Petri dish.
- 400 µl of the previously adjusted viral film is added to the piece.
- The viral film is covered by a glass lamella

IV-2 Viral film recovery

After each incubation, the viral film is recovered by adding 2.6 ml of culture medium by gentle scraping with a cell scraper.
The titration of the residual viable viruses is then carried out immediately.

IV-3 Viral Load

The titration technique is the one indicated in standard NF EN 14476 + A2 (July 2019).
Dilutions of ratio 4 of the viral suspensions are carried out in the cell culture medium in neutral glass tubes in order to limit the phenomena of virus adsorption on the surfaces.
Titration is performed on 96-well microplates. Each dilution is performed 8 times.

IV-4 viral load calculation

The assay was performed by the microplate method of suspension cells. The cytopathic effect was determined at least 4 days of culture.
The number of infectious units is estimated by the SPEARMAN-KÄRBER method by calculating the negative logarithm of the 50% limit point ($lgDICT_{50}$) using the following formula:
$lgDICT_{50}$ = Negative logarithm of the highest concentration of virus used - [(Sum of % assigned to each dilution/100 - 0.5) X (lg of dilution)]

V- RESULTS

V-1 Contact time 20 min

V-1-1 Test validation

Control T0 :

- Control 1: lg $DICT_{50}$ = 3.98
- Control 2 : lg $DICT_{50}$ = 4.20
- Control 3 : lg $DICT_{50}$ = 4.13

Average lg $DICT_{50}$ Control T0 = 4.10

$\frac{\text{Maximum viral load - Minimum viral load}}{\text{Average of the 3 viral loads.}}$ = 0.02

The loads (lg TCID50) of the 3 tests at T0 must be homogeneous.
Maximum viral load - Minimum viral load / Average of the 3 viral loads ≤ 0.2.

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Control T20 min :

- Control 1 : lg $DICT_{50}$ = 4.43
- Control 2 : lg $DICT_{50}$ = 4.35
- Control 3 : lg $DICT_{50}$ = 4.43

Average lg $DICT_{50}$ Control 20 min = 4.40

Maximum viral load - Minimum viral load = 0.05
Average of the 3 viral loads.

The loads (lg TCID50) of the 3 tests at T20 min must be homogeneous.
Maximum viral load - Minimum viral load / Average of the 3 viral loads ≤ 0.2.

V-1-2 Test

- Test 1 : lg $DICT_{50}$ = 4.35
- Test 2 : lg $DICT_{50}$ = 4.13
- Test 3 : lg $DICT_{50}$ = 3.83

Average lg $DICT_{50}$ test = 4.10

R = Average lg $DICT_{50}$ test 20 min – Average lg $DICT_{50}$ control 20 min = 0.30 lg

V-2 Contact time 60 min

V-2-1 Test validation

Control T0 :

- Control 1 : lg $DICT_{50}$ = 3.98
- Control 2 : lg $DICT_{50}$ = 4.20
- Control 3 : lg $DICT_{50}$ = 4.13

Average lg $DICT_{50}$ T0 = 4.10

Maximum viral load - Minimum viral load = 0.05
Average of the 3 viral loads.

The loads (lg TCID50) of the 3 tests at T0 min must be homogeneous.
Maximum viral load - Minimum viral load / Average of the 3 viral loads ≤ 0.2.

Control T60 min :

- Control 1 : lg $DICT_{50}$ = 4.43
- Control 2 : lg $DICT_{50}$ = 4.50
- Control 3 : lg $DICT_{50}$ = 4.50

Average lg $DICT_{50}$ Control 60 min = 4.48

Maximum viral load - Minimum viral load = 0.02
Average of the 3 viral loads.

The loads (lg TCID50) of the 3 tests at T60 min must be homogeneous.
Maximum viral load - Minimum viral load / Average of the 3 viral loads ≤ 0.2.

V-2-2 Test

- Test 1 : lg $DICT_{50}$ = 3.45
- Test 2 : lg $DICT_{50}$ = 3.45
- Test 3 : lg $DICT_{50}$ = 3.60

Average lg $DICT_{50}$ Test = 3.50

R = Average lg $DICT_{50}$ test 60 min – Average lg $DICT_{50}$ control 60 min = 0.98 lg

V-3 Contact time 24 hours

V-3-1 test validation

Control T0 :
- Control 1 : lg $DICT_{50}$ = 3.98
- Control 2 : lg $DICT_{50}$ = 4.20
- Control 3 : lg $DICT_{50}$ = 4.13

Average lg $DICT_{50}$ T0 = 4.10

Maximum viral load - Minimum viral load = 0.05
Average of the 3 viral loads.

The loads (lg TCID50) of the 3 tests at T0 must be homogeneous.
Maximum viral load - Minimum viral load / Average of the 3 viral loads ≤ 0.2.

Control T24 hours :
- Control 1 : lg $DICT_{50}$ = 4.35
- Control 2 : lg $DICT_{50}$ = 4.13
- Control 3 : lg $DICT_{50}$ = 4.05

Average lg $DICT_{50}$ Control 24 hours = 4.18

Maximum viral load - Minimum viral load = 0.07
Average of the 3 viral loads.

The loads (lg TCID50) of the 3 tests at T24 hours must be homogeneous.
Maximum viral load - Minimum viral load / Average of the 3 viral loads ≤ 0.2.

V-2-2 Test

- Test 1 : lg $DICT_{50}$ = 0.90
- Test 2 : lg $DICT_{50}$ = 0.90
- Test 3 : lg $DICT_{50}$ = 0.90

Average lg $DICT_{50}$ test = 0.90

R = Average lg $DICT_{50}$ test 24 hours – Average lg $DICT_{50}$ control 24 hours = 3.28 log

VI-CONCLUSION

According to the methodology of the ISO 21702 standard (May 2019), the contact of the Coversafe Film (Film Ger. ADD) with the strain of human Coronavirus 229E Batch N°3 of 20/05/2020 induced:

- **A reduction of the log viral load of 0.30 lg at 20 min contact time.**
- **A reduction of the viral load 0.98 lg at contact time 60 min.**
- **A viral load reduction of 3.28 lg at 24 hours contact time.**

FONdation pour le
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PHARmaceutique

Système de management de la qualité
Certifié ISO 9001

Toulouse, June 16th 2020

STUDY 20 - 2658M

This report supersedes the precedent one (June 2nd 2020)

ANTIBACTERIAL PRODUCTS
TEST FOR ANTIBACTERIAL ACTIVITY AND EFFICACY
***Escherichia coli* CIP 53.126**
According to the methodology of standard JIS Z 2801: 2010

Client

PYLOTE
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31280 Dremil-Lafage
FRANCE

Test laboratory

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Faculté des Sciences Pharmaceutiques
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Dr Catherine FEUILLOLAY Assay Manager	**Dr Jocelyne BACARIA** Quality Manager

JIS Z 2801 : 2010. Antimicrobial products - Test for antimicrobial activity and efficacy.

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1. Laboratory Test

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Faculté des Sciences Pharmaceutiques
35 chemin des Maraîchers
31062 Toulouse cedex 9
France

2. Identification of samples

Product's name :	**Untreated test pieces – Film Gerg. Standard**
Reference :	FILM N°3 STD A.CO
Batch:	FILM N°3 - 20.05.2020
Date of receipt :	May/25/2020
Internal code :	**20-2658-1**

Product's name :	**Treated test pieces – Coversafe Film (Film Gerg. ADD)**
Reference :	FILM N°1 A.CO ADD
Batch:	FILM N°3 - 20.05.2020
Date of receipt :	May/25/2020
Internal code :	**20-2658-2**

Promotor : PYLOTE

Period of testing : May 2020

3. Experimental Conditions

*** Test Microorganism :**

Escherichia coli CIP 53.126

*** Preparation of test pieces :**

Test pieces (untreated and treated) were firstly treated with ethanol, rinsed with distilled sterile water, and then dried under microbiological safety cabinet before the test.
During the test, the inoculum was covered by a film (hydrophobic character of pieces)

0,4 mL of test inoculum have been put onto each test piece (= final concentration 10^5 CFU/piece).

*** Culture medium :**

The inoculum was prepared in 1/500 Nutrient Broth (Internal preparation – Batch 9409 Exp. June/02/2020).
The recovery solution used was SCDLP (Internal preparation - Batch 9364 Exp. June/04/2020).
The dilutions have been performed in PBS (SIGMA - Batch RNBJ0743 Exp. Dec/2021).

*** Agar Medium**

Tryptic-soy agar (Biomérieux – Batch 1007893660 Exp. Aug/15/2021).

*** Microorganism recovery**

- **Untreated and Treated pieces**: deposition of each piece in a sterile flask + 10mL SCDLP + sterile glass beads. Manual mix for 1 minute.

*** Conditions of the test**

- Temperature during the contact : 36 ± 1°C
- Relative humidity : > 90%
- Contact time : 24 hours

The test has been performed three times.

4. Results

- **Untreated pieces** (Area : 16 cm^2)

Inoculum/piece : $1{,}56.10^5$ CFU = $0{,}98.10^4$ CFU/cm^2

Untreated pieces	CFU	CFU/cm2	log CFU	log CFU/cm2
T0 - 1	$1{,}39.10^5$	$8{,}69.10^3$	5,14	3,94
T0 - 2	$1{,}52.10^5$	$9{,}50.10^3$	5,18	3,98
T0 - 3	$1{,}38.10^5$	$8{,}63.10^3$	5,14	3,94
Mean (U0=CFU/cm2)			5,15	3,95

Test validation :
(Lmax - Lmin)/(Lmean) ≤ 0,2
Number of viable bacteria shall be within the range $1{,}0 \times 10^5$ et $4{,}0 \times 10^5$ CFU / 16 cm^2

Untreated pieces	CFU	CFU/cm2	log CFU	log CFU/cm2
T24h - 1	$1{,}01.10^7$	$6{,}31.10^5$	7,00	5,80
T24h - 2	$7{,}80.10^6$	$4{,}88.10^5$	6,89	5,69
T24h - 3	$9{,}50.10^6$	$5{,}94.10^5$	6,98	5,77
Mean (Ut=CFU/cm^2)			6,96	5,75

Control / Petri dish	CFU	CFU/cm2	log CFU	log CFU/cm2
T24h	$8{,}90.10^6$	$5{,}56.10^5$	6,95	5,75

- **Treated pieces** (Area : 16 cm^2)

Treated pieces	CFU	CFU/cm2	log CFU	log CFU/cm2
E24h - 1	< 10	< 1	< 1,00	0
E24h - 2	< 10	< 1	< 1,00	0
E24h - 3	< 10	< 1	< 1,00	0
Mean (At=CFU/cm^2)			< 1,00	0

5. Conclusion

The antibacterial activity (R) is based on logarithmic reduction/cm^2 of *E. coli* CIP 53.126 strain between standard and antimicrobial surfaces after 24H of contact according to the following matrix:

$$R = (Ut - U0) - (At - U0) = Ut - At$$

Antimicrobial activity	Result (log CFU/cm^2)	Specifications (log CFU/cm^2) JIS Z2801 :2010
Coversafe Film (FILM Gerg. ADD)	5,75	> 2

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FONdation pour le
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REcherche
PHARmaceutique

Système de management de la qualité
Certifié ISO 9001

Toulouse, June 16th 2020

STUDY 20 - 2663 - A

ANTIBACTERIAL PRODUCTS
TEST FOR ANTIBACTERIAL ACTIVITY AND EFFICACY
Escherichia coli CIP 53.126
According to the methodology of standard JIS Z 2801: 2010

Client

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Test laboratory

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FRANCE

Dr Catherine FEUILLOLAY Assay Manager	Dr Jocelyne BACARIA Quality Manager

JIS Z 2801 : 2010. Antimicrobial products - Test for antimicrobial activity and efficacy.

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1. Laboratory Test

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France

2. Identification of samples

Product's name :	**Untreated test pieces - Film Gerg. Standard**
Reference :	FILM N°3 STD A.CO
Batch:	FILM N°3 - 20.05.2020
Date of receipt :	May/25/2020
Internal code :	**20-2663-1**
Product's name :	**Treated test pieces - Coversafe Film (Film Gerg. ADD) without wash**
Reference :	2000521/1
Batch:	Not indicated
Date of receipt :	June/02/2020
Internal code :	**20-2663-2**
Product's name :	**Treated test pieces Coversafe Film (Film Gerg. ADD) Isopropilic alcohol washes (100 times)**
Reference :	2000521/1 + 100 washes
Batch:	Not indicated
Date of receipt :	June/02/2020
Internal code :	**20-2663-3**
Product's name :	**Treated test pieces Coversafe Film (Film Gerg. ADD) detergent with bleach washes (100 times)**
Reference :	2000521/1 + 100 washes
Batch:	Not indicated
Date of receipt :	June/02/2020
Internal code :	**20-2663-4**
Product's name :	**Treated test pieces Coversafe Film (Film Gerg. ADD) Surfanios Premium washes (100 times)**
Reference :	2000521/1 + 100 washes
Batch:	Not indicated
Date of receipt :	June/02/2020
Internal code :	**20-2663-5**
Promotor :	PYLOTE
Period of testing :	June 2020

3. Experimental Conditions

*** Test Microorganism :**

Escherichia coli CIP 53.126

*** Preparation of test pieces :**

Test pieces (untreated and treated) were firstly treated with ethanol, rinsed with distilled sterile water, and then dried under microbiological safety cabinet before the test.
During the test, the inoculum was covered by a film (hydrophobic character of pieces)

0,4 mL of test inoculum have been put onto each test piece (= final concentration 10^5 CFU/piece).

*** Culture medium :**

The inoculum was prepared in 1/500 Nutrient Broth (Internal preparation - Batch 9436 Exp. June/10/2020).
The recovery solution used was SCDLP (Internal preparation - Batch 9434 Exp. July/03/2020).
The dilutions have been performed in PBS (SIGMA - Batch RNBJ0743 Exp. Dec/2021).

*** Agar Medium**

Tryptic-soy agar (Biomérieux - Batch 1007893660 Exp. Aug/15/2021).

*** Microorganism recovery**

- **Untreated and Treated pieces**: deposition of each piece in a sterile flask + 10mL SCDLP + sterile glass beads. Manual mix for 1 minute.

*** Conditions of the test**

- Temperature during the contact : 36 ± 1°C
- Relative humidity : > 90%
- Contact time : 24 hours

The test has been performed three times.

4. Results

- **Untreated pieces** (Area : 16 cm^2)

Inoculum/piece : $2,63.10^5$ CFU = $1,64.10^5$ CFU/cm^2

Untreated pieces	CFU	CFU/cm2	log CFU	log CFU/cm2
T0 - 1	$1,89.10^5$	$1,18.10^4$	5,28	4,07
T0 - 2	$1,79.10^5$	$1,12.10^4$	5,25	4,05
T0 - 3	$1,79.10^5$	$1,12.10^4$	5,25	4,05
Mean (U0=CFU/cm2)			5,26	4,06

Test validation :
(Lmax - Lmin)/(Lmean) ≤ 0,2
Number of viable bacteria shall be within the range $1,0 \times 10^5$ et $4,0 \times 10^5$ CFU / 16 cm^2

Untreated pieces	CFU	CFU/cm2	log CFU	log CFU/cm2
T24h - 1	$1,00.10^7$	$6,25.10^5$	7,00	5,80
T24h - 2	$1,42.10^7$	$8,88.10^5$	7,15	5,95
T24h - 3	$1,12.10^7$	$7,00.10^5$	7,05	5,85
Mean (Ut=CFU/cm^2)			7,07	5,86

- **Treated pieces - Coversafe Film (Film Gerg. ADD) without wash** (Area : 16 cm^2)

Treated pieces	CFU	CFU/cm2	log CFU	log CFU/cm2
E24h - 1	< 10	< 1	< 1,00	0
E24h - 2	10	< 1	1,00	0
E24h - 3	< 10	< 1	< 1,00	0
Mean (At=CFU/cm^2)			< 1,00	0

- **Treated pieces - Coversafe Film (Film Gerg. ADD) Isopropilic alcohol washes** (Area : 16 cm^2)

Treated pieces	CFU	CFU/cm2	log CFU	log CFU/cm2
E24h - 1	< 10	< 1	< 1,00	0
E24h - 2	< 10	< 1	< 1,00	0
E24h - 3	< 10	< 1	< 1,00	0
Mean (At=CFU/cm^2)			< 1,00	0

- **Treated pieces - Coversafe Film (Film Gerg. ADD) detergent with bleach washes** (Area : 16 cm^2)

Treated pieces	CFU	CFU/cm2	log CFU	log CFU/cm2
E24h - 1	< 10	< 1	< 1,00	0
E24h - 2	< 10	< 1	< 1,00	0
E24h - 3	< 10	< 1	< 1,00	0
Mean (At=CFU/cm^2)			< 1,00	0

- **Treated pieces - Coversafe Film (Film Gerg. ADD) Surfanios Premium washes** (Area : 16 cm^2)

Treated pieces	CFU	CFU/cm2	log CFU	log CFU/cm2
E24h - 1	< 10	< 1	< 1,00	0
E24h - 2	< 10	< 1	< 1,00	0
E24h - 3	< 10	< 1	< 1,00	0
Mean (At=CFU/cm^2)			< 1,00	0

5. Conclusion

The antibacterial activity (R) is based on logarithmic reduction/cm^2 of *E. coli* CIP 53.126 strain between standard and antimicrobial surfaces after 24H of contact according to the following matrix:

$$R = (Ut - U0) - (At - U0) = Ut - At$$

Antimicrobial activity	Result (log CFU/cm^2)	Specifications (log CFU/cm^2) JIS Z2801 :2010
Coversafe Film (Film Gerg. ADD) without wash	5,86	> 2
Coversafe Film (Film Gerg. ADD) Isopropilic alcohol washes	5,86	> 2
Coversafe Film (Film Gerg. ADD) detergent with bleach washes	5,86	> 2
Coversafe Film (Film Gerg. ADD) Surfanios Premium washes	5,86	> 2

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FONdation pour le DEveloppement de la RECherche PHARmaceutique

Reference 13-1508 / 15-1928 / 17-2224 / 19-2436 / 20-2598

CERTIFICATE OF ANALYSIS

Society : PYLOTE
Address : 22 Avenue de la Mouyssaguèse
31280 Dremil-Lafage
FRANCE

To the attention of : LOIC MARCHIN

Test
Evaluation of antimicrobial efficiency based on JIS Z2801 : 2010 for bacteria

Results: The results are given as log reduction R, corresponding to the value of antimicrobial activity

Customer Reference:	Pylote Technology
Fonderephar Sample Reference:	15-1928/1-2 / 15-1928/1-1
Date os sample receipt:	December 21st, 2015
Date of sample analysis:	December 2015
Date of certificate of analysis:	January 6th, 2016
Escherichia coli BLSE (Fonderephar strain ref. B1023)	R = 3,83 (after a contact time 24H)
Staphylococcus aureus metiR ATCC 33591	R = > 3,01 (after a contact time 24H)

Customer Reference:	Pylote Technology
Fonderephar Sample Reference:	13-1508-1 / 13-1508-2
Date os sample receipt:	February 25th, 2013
Date of sample analysis:	March 2013
Date of certificate of analysis:	March 25th, 2013
Salmonella enterica CIP 60.62T	R = > 5,84 (after a contact time 24H)

Customer Reference:	Pylote Technology
Fonderephar Sample Reference:	19-2436-1 / 19-2436-2
Date os sample receipt:	February 15th, 2019
Date of sample analysis:	February 2019
Date of certificate of analysis:	February 22th, 2019
Pseudomonas aeruginosa CIP 82118	R = 4,07 (after a contact time 24H)

Test
Evaluation of antivirucidal activity according to the methodology based on JIS Z2801 : 2010 for virus

Results: The results are given as log reduction R, corresponding to the value of antivirucidal activity

Customer Reference:	Pylote Technology
Fonderephar Sample Reference:	15-1928/2-2 / 19-1928/2-1
Date os sample receipt:	December 21st, 2015 and December 31st, 2015
Date of sample analysis:	January 2016
Date of certificate of analysis:	January 22th, 2016

Influenzavirus A (H1N1) ATCC-VR-1520 — R = 2,60 (after a contact time 24H)

Customer Reference:	Pylote Technology
Fonderephar Sample Reference:	20-2598-1 / 20-2598-2
Date os sample receipt:	January 27th, 2020
Date of sample analysis:	January - February 2020
Date of certificate of analysis:	February 5th, 2020

Human Rotavirus ATCC-VR-2272 — R = 2,26 (after a contact time 24H)

Customer Reference:	Pylote Technology
Fonderephar Sample Reference:	15-1928/2-2 / 19-1928/2-1
Date os sample receipt:	December 21st, 2015 and December 31st, 2015
Date of sample analysis:	January 2016
Date of certificate of analysis:	January 22th, 2016

Herpes virus type 1 (HSV-A) ATCC-VR-1383 — R = 2,20 (after a contact time 24H)

Customer Reference:	Pylote Technology
Fonderephar Sample Reference:	17-2224-1 / 17-2224-2
Date os sample receipt:	December 4th, 2017
Date of sample analysis:	December 2017
Date of certificate of analysis:	December 12th, 2017

Adenovirus type 3 ATCC-VR-847 — R = 2,40 (after a contact time 24H)

Certified by Catherine FEUILLOLAY and Laila HADDIOUI
Test Managers
June 23th, 2020

TESTS FOR IN VITRO CYTOTOXICITY

Test Substance

01 CSAFE01 XX COVERSAFE™

Test Report N°20-0754-01

Test performed for

GERGONNE INDUSTRIE
ZI Nord - Rue de Tamas - CS 70204
01117 OYONNAX CEDEX - FRANCE

by
BIOCHEM S.r.l.
Via Benini 13
40069 ZOLA PREDOSA BO

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www.biochem-bcm.com E-mail: info@biochem-bcm.com - C.F. e P.IVA IT 03531810376 – R.E.A. BO-297535

QUALITY ASSURANCE

Quality Assurance Manager: Alessandra Marchesi, PhD

TEST DIRECTOR

Giovanni Bassini, Ch.Eng.

TIME SCHEDULE OF TEST

The test was started on 16/06/2020 and was completed on 18/06/2020.

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LAB N° 0283 L
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Ref. Your Order PO193228 of 11/06/2020

Sample description

Denomination: 01 CSAFE01 XX COVERSAFE™
Code: /
Lot: /
Sterilization: No
Receipt number: 16556
Receipt date: 15/06/2020
Sampling carried out by: GERGONNE INDUSTRIE

Part of the sample to be tested: The whole sample
Pretreatment: /

Test Method

ISO 10993-5: 2009
ISO 10993-12: 2012

Other references

Cytotoxicity Test Protocol - /

Summary of practice

Cell cultures are grown to a near-confluent monolayer in cultures dishes. Three dishes for each sample are prepared. Moreover, three dishes are prepared for the Negative control, three for the Positive control and three for the Cell Culture Medium (MEM control). A portion/aliquot of the test sample, of the negative control and of the positive control are placed on the cell layer in the centre of each of the replicate dishes. Cell cultures are examined through microscope after 24 and 48h of incubation to assess the presence or absence of cytotoxic effects due to the sample.

Target cells: BSCL 56 /L 929 (Mouse connective tissue)

Culture medium: Minimum Essential Medium (MEM) with Earle's salts added with 5 % of foetal bovine serum, 1 % of L-glutamine, 0,6 % of penicillin/streptomycin and 0,3 % of fungizone (complete MEM).

Sample preparation: A portion of the sample that covers approximately one-tenth of the cell layer surface is placed in direct contact with the cell cultures.

Positive control: A portion of latex of natural rubber that covers approximately one-tenth of the cell layer surface.

Negative control: A portion of silicone rubber that covers approximately one tenth of the cell layer surface.

Vehicle control: Complete Cell Culture Medium MEM.

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Incubation: The dishes treated with the test specimen, with the Positive and Negative controls and with the Cell Culture Medium control are incubated for 48 h at 37 ± 1 °C in a 5% CO_2 atmosphere.

Apparatus

Incubator, which maintains the cultures at 37°C, 5% CO_2;
Microscope, with inverted phase contrast optics;
Laminar Flow Cabinet;
Sterile Disposable;
Tissue Culture Dishes.

Interpretation of Results: The determination of the cytotoxicity is performed after a 24 and 48 h incubation period examining the cells under the microscope to assess general morphology, vacuolation, detachment, cell lysis, membrane integrity.
The change from normal morphology of the Negative control is rated on a reactivity grade from 0 to 4 (see Grading system). Moreover, for the dishes treated with the Test specimen the confluence of the monolayer is evaluated and the color of test medium is compared to the negative control

Grading system:

Grade	Reactivity	Description of Reactivity Zone
0	None	No detectable zone around or under specimen
1	Slight	Some malformed or degenerated cells under specimen
2	Mild	Zone limited to area under specimen
3	Moderate	Zone extending specimen size up to 1,0 cm
4	Severe	Zone extending farther than 1,0 cm beyond specimen

Considering the employed test method in performing cytotoxicity test and the sample characteristics, eventual absence of cells under the negative control and the specimen should be ascribed to physical or mechanical trauma and not to a cytotoxic effect of the negative control and of the sample. Consequently a cytotoxic score is assigned exclusively evaluating the cells around the specimen.

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Results after 24 h incubation	**Score**
Positive control	4
Positive control	4
Positive control	4
Negative control	0
Negative control	0
Negative control	0
MEM control	0
MEM control	0
MEM control	0
Test specimen	0
Test specimen	0
Test specimen	0
Confluency of the monolayer	Confluent
Color of test medium	Comparable to the negative control

Results after 48 h incubation	**Score**
Positive control	4
Positive control	4
Positive control	4
Negative control	0
Negative control	0
Negative control	0
MEM control	0
MEM control	0
MEM control	0
Test specimen	0
Test specimen	0
Test specimen	0
Confluency of the monolayer	Confluent
Color of test medium	Comparable to the negative control

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OPINIONS AND INTERPRETATIONS – Not included in ACCREDIA accreditation

The cells treated with the Test sample after 24 and 48 hours of incubation do not show any changes from normal morphology of the Negative control. The Test sample does not show any reactivity.

The present test report exclusively refers to the referenced test sample.
If the sample has been sampled by the Customer, the results are referred to the sample as received.
The present test report may not be partially reproduced without Biochem authorization.

(#) Data provided by the Customer. The laboratory declines responsibility for such data.

Test verified by: Buriani Giampaolo, PhD.

Issue authorized by:
Test Director Giovanni Bassini, Ch.Eng.

Zola Predosa, 18/06/2020

END OF TEST REPORT

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