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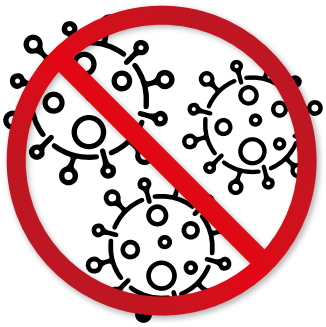

STOP
COVID-19

Il sistema che sanifica e deodorizza l'aria e le superfici
The system that sanitizes and deodorizes the air and the surfaces

Test contro il COVID-19

STAND ALONE

TECHNICAL REPORT

VIRUCIDAL ACTIVITY STUDY OF THE "MAIA" PRODUCT (UNI EN 16777:2019)

Technical Report N° D202101605

Customer: *SKILL GROUP S.r.l. - Società Unipersonale*
Via Lombardia, 2
37044 Cologna Veneta (VR) Italy

Testing Laboratory *LabAnalysis S.r.l.*
Via Europa 5,
27041 Casanova Lonati (PV) Italy

Sample Submitted: *Bioxigen Air Sanitizer "MAIA" (batch N° MAC1S 2012 5908)*

LabAnalysis code: *FD-21-000035-000058*

Report Editing by: *Fabio De Leonardis RALTBCF1*

Verified by: *Guido Premoli DTAM1*

IL RESPONSABILE D'AREA
TBCF
Fabio De Leonardis, PhD

ORDINE DEI CHIMICI DELLA PROVINCIA DI PAVIA
Dott. GUIDO PREMOLI CHIMICO N°439 A

1. SUMMARY

The virucidal activity of the product was assessed exposing a surface pre-treated with a viral test suspension to the test item, at the conditions defined by the customer and described below. After the prescribed incubation time, the viral suspension was inoculated in the appropriate cellular monolayer. At the end of the incubation period, cellular cultures were observed by microscopy for the detection of cytopathic effects (CPE) produced by viral multiplication.
The verification of the methodology was performed in compliance to the reference method.
All detailed results for each test performed are reported in the chapter 2.

1.1 PRODUCT IDENTIFICATION

This study was conducted on the test item Bioxigen Air Sanitizer "MAIA", a static unit with bipolar ionization technology. See Table 1 for sample identification:

Table 1: Sample identification

Test item	Active Ingredient	Storage conditions	Batch	Production date	Expiry date	LabAnalysis internal code
Bioxigen Air Sanitizer "MAIA"	negative oxygen ions	n.a.	MAC1S 2012 5908	12/2020	n.d.	FD-21-000035-000058

1.2 ASSAY SYSTEM

In order to evaluate the virucidal effectiveness the product was tested against the virus model inoculated in sensitive host cell line. See Table 2 for the biological system used for the tests of the study:

Table 2: Biological Assay System

Virus type	Host Cell Line
Vaccinia virus, strain Elstree, ATCC VR-1549	Vero cells, ATCC CCL-81

1.3 EXPERIMENTAL CONDITION

The test item was analysed at the following conditions summarized in Table 3:

Table 3: Virucidal Activity Assay Condition

Contact Temperature	20 ± 1 °C
Contact Time	15 / 30 / 45 / 60 minutes
Interfering Substance	0.3 g/L BSA (Clean conditions)
Sample concentrations	Saturated air condition by negative oxygen ions

Questa Relazione Tecnica riguarda solo i campioni sottoposti a prova. La Relazione non può essere riprodotta parzialmente salvo approvazione scritta da parte di LabAnalysis.

1.3.1 METHOD OF SUPPRESSION (FOR REFERENCE TEST)

To suppress the virucidal activity, the mixtures of interfering substance, Reference material and virus suspension recovered with ice-cold medium from inoculated surface, were kept in ice bath during the serial dilutions preparation.

1.4 PERIOD OF ANALYSIS

Tests started on: 11/01/2021
Tests completed on: 15/02/2021

2. RESULTS

All the raw data recorded for each test of this study are reported in validated data sheet used to perform the computation of the required parameters following the Spearman-Karber method.

2.1 VALIDATION OF THE ASSAY FOR VIRUCIDAL ACTIVITY

The results obtained to verify assay validity are reported in the Table 4 below. Due to the type of product under examination, some of the test recommended in the EN 16777 are not applicable.

Table 4: Assay Validation Results - Vaccinia virus, strain Elstree

Assay Performed	Results (with 95% confidence interval)	Assay Validity
Sample cytotoxicity	CPE < 1 (< 25 % of cell monolayer destruction)	Not Applied
Virus stock solution titration	Virus Titre (-log $TCID_{50}$/mL) = 7.33 ± 0.34	VALID
Cell susceptibility to virus	Not Applied	Not Applied
Suppression of virucidal activity	Not Applied	Not Applied
Reference test for virus inactivation	$TCID_{50}$ reduction after 5 min: 1.00 ± 0.63	VALID

The assay validity criteria for all the performed controls were satisfied.

2.2 VIRUCIDAL ACTIVITY ASSAY

The results obtained for the reduction of virus infectivity expressed as logarithm values, at the different incubation time points and conditions applied in the test are reported table **5.**

Questa Relazione Tecnica riguarda solo i campioni sottoposti a prova. La Relazione non può essere riprodotta parzialmente salvo approvazione scritta da parte di LabAnalysis.

Table 5: Results - Vaccinia virus, strain Elstree

Product Code/Name	Experimental Conditions		Control / Sample Virus Titre (-log TCID50/mL) with 95% confidence interval after contact time	Reduction with 95% confidence interval
	Incubation Time point (min)	Interfering Substance		
FD-21-000035-000058 "MAIA"	15	0.3 g/L BSA (Clean)	6.83 ± 0.56 / 6.33 ± 0.34	0.50 ± 0.65
FD-21-000035-000058 "MAIA"	30	0.3 g/L BSA (Clean)	7.00 ± 0.45 / 5.33 ± 0.34	1.67 ± 0.56
FD-21-000035-000058 "MAIA"	45	0.3 g/L BSA (Clean)	7.17 ± 0.42 / 4.17 ± 0.42	3.00 ± 0.59
FD-21-000035-000058 "MAIA"	60	0.3 g/L BSA (Clean)	7.50 ± 0.00 / 3.50 ± 0.00	4.00 ± 0.00

2.3 INTERPRETATION OF RESULTS

In agreement to the UNI EN 16777:2019 the product shall demonstrate a titre reduction of 4 log or more compared to the virus control titration ("PASS"), not considering the 95% confidential interval. Therefore, the results obtained in the present study can be summarized in the following Table 6:

Table 6: Assay Outcome

Product Code/Name	Experimental Conditions		Reduction with 95% confidence interval	Assay Outcome
	Incubation Time point (min)	Virus model		
FD-21-000035-000058 "MAIA"	15	Vaccinia virus, strain Elstree	0.50 ± 0.65	NOT PASS
FD-21-000035-000058 "MAIA"	30	Vaccinia virus, strain Elstree	1.67 ± 0.56	NOT PASS
FD-21-000035-000058 "MAIA"	45	Vaccinia virus, strain Elstree	3.00 ± 0.59	NOT PASS
FD-21-000035-000058 "MAIA"	60	Vaccinia virus, strain Elstree	4.00 ± 0.00	**PASS**

3. CONCLUSION

On the basis of the obtained results, operating following the indications of the UNI EN 16777, the device Bioxigen Air Sanitizer "MAIA" tested in clean conditions, at 20 °C proves virucidal activity against Vaccinia virus, after exposure of 60 minutes.

Therefore, the product can be considered effective against all enveloped viruses (including the coronaviruses such as SARS-Cov-2), as defined in the Annex A of the standard EN 16777:2019.

Questa Relazione Tecnica riguarda solo i campioni sottoposti a prova. La Relazione non può essere riprodotta parzialmente salvo approvazione scritta da parte di LabAnalysis.

Annex A
(informative)

Examples of viruses sorted according to their presence in the human body in case of virus infection

These viruses may contaminate hands, instruments, other surfaces and textiles.

NOTE 1 This list is not exhaustive.

NOTE 2 Enveloped viruses are in bold

Blood

Enterovirus
Filoviridae
Flavivirus
Herpesviridae
Hepatitis A Virus (HAV)
Hepatitis B virus (HBV)
Hepatitis C virus (HCV)
Hepatitis Delta virus (HDV)
Human Immunodeficiency Virus (HIV)
Human T-Cell Leukaemia Virus (HTLV)
Parvovirus B 19

Respiratory tract

Adenovirus (Mast-)
Coronavirus
Enterovirus
Herpesviridae
Influenza Virus
Paramyxoviridae
Rhinovirus
Rubella Virus

Neuronal tissue, ear and nose, eye

Adenovirus (Mast-)
Enterovirus
Herpesviridae
Measles Virus
Human Immunodeficiency Virus (HIV)
Polyomavirus
Rabies Virus
Rubella Virus

Gastro-intestinal

Adenovirus(Mast-)
Caliciviridae
Coronavirus
Astrovirus
Enterovirus
Hepatitis A Virus (HAV)
Hepatitis E Virus (HEV)
Rotavirus

Skin, breast and/or milk

Enterovirus
Herpesviridae
Human Immunodeficiency Virus (HIV)
Human T-Cell Leukaemia Virus (HTLV)
Papillomavirus
Poxviridae

Questa Relazione Tecnica riguarda solo i campioni sottoposti a prova. La Relazione non può essere riprodotta parzialmente salvo approvazione scritta da parte di LabAnalysis.

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Cap. Soc. €103.000,00 int. vers. Registro Imprese di Pavia C.F. / P.I. 02235450182 R.E.A. CCIAA di Pavia n. 257033

Spleen and lymph nodes (see also „Blood")

Human T-Cell Leukaemia Virus (HTLV)

Human Immunodeficiency Virus (HIV)

Dental procedure

Adenovirus(Mast-)

Enterovirus

Herpesviridae

Hepatitis B virus (HBV)

Hepatitis C Virus (HCV)

Hepatitis Delta Virus (HDV)

Human Immunodeficiency Virus (HIV)

Urogenital tract

Hepatitis B Virus (HBV)

Herpesviridae

Human Immunodeficiency Virus (HIV)

Human T-Cell Leukaemia Virus (HTLV)

Papillomavirus

Polyomavirus

Reference:

Van Regenmortel MHV et al.,Eds.: Virus Taxonomy, Classification and Nomenclature of Viruses, seventh report of the international committee on taxonomy of viruses.

Academic Press, San Diego, 2000

End Technical Report

Questa Relazione Tecnica riguarda solo i campioni sottoposti a prova. La Relazione non può essere riprodotta parzialmente salvo approvazione scritta da parte di LabAnalysis.

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TECHNICAL REPORT

VIRUCIDAL ACTIVITY STUDY OF THE "MAIA" PRODUCT (UNI EN 16777:2019)

Technical Report N° D202101670

Customer: *SKILL GROUP S.r.l. - Società Unipersonale*
Via Lombardia, 2
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Testing Laboratory *LabAnalysis S.r.l.*
Via Europa 5,
27041 Casanova Lonati (PV) Italy

Sample Submitted: *Bioxigen Air Sanitizer "MAIA"*
(batch N° MAC1S 2012 5908)

LabAnalysis code: *FD-21-000035-000058*

Report Editing by: *Fabio De Leonardis RALTBCF1*

Verified by: *Guido Premoli DTAM*

IL RESPONSABILE D'AREA
TBCF
Fabio De Leonardis, PhD

ORDINE DEI CHIMICI DELLA PROVINCIA DI PAVIA
Dott.
GUIDO
PREMOLI
CHIMICO
N°439 A

1. SUMMARY

The virucidal activity of the product was assessed exposing a surface pre-treated with a viral test suspension to the test item, at the conditions defined by the customer and described below. After the prescribed incubation time, the viral suspension was inoculated in the appropriate cellular monolayer. At the end of the incubation period, cellular cultures were observed by microscopy for the detection of cytopathic effects (CPE) produced by viral multiplication.
The verification of the methodology was performed in compliance to the reference method.
All detailed results for each test performed are reported in the chapter 2.

1.1 PRODUCT IDENTIFICATION

This study was conducted on the test item Bioxigen Air Sanitizer "MAIA", a static unit with bipolar ionization technology. See Table 1 for sample identification:

Table 1: Sample identification

Test item	Active Ingredient	Storage conditions	Batch	Production date	Expiry date	LabAnalysis internal code
Bioxigen Air Sanitizer "MAIA"	negative oxygen ions	n.a.	MAC1S 2012 5908	12/2020	n.d.	FD-21-000035-000058

1.2 ASSAY SYSTEM

In order to evaluate the virucidal effectiveness the product was tested against the virus model inoculated in sensitive host cell line. See Table 2 for the biological system used for the tests of the study:

Table 2: Biological Assay System

Virus type	Host Cell Line
Adenovirus type 5, strain Adenoid 75, ATCC-VR-5	HeLa ATCC CCL-2

1.3 EXPERIMENTAL CONDITION

The test item was analysed at the following conditions summarized in Table 3:

Table 3: Virucidal Activity Assay Condition

Contact Temperature	20 ± 1 °C
Contact Time	15 / 30 / 45 minutes
Interfering Substance	0.3 g/L BSA (Clean conditions)
Sample concentrations	Saturated air condition by negative oxygen ions

Questa Relazione Tecnica riguarda solo i campioni sottoposti a prova. La Relazione non può essere riprodotta parzialmente salvo approvazione scritta da parte di LabAnalysis.

1.3.1 METHOD OF SUPPRESSION (FOR REFERENCE TEST)

To suppress the virucidal activity, the mixtures of interfering substance, Reference material and virus suspension recovered with ice-cold medium from inoculated surface, were kept in ice bath during the serial dilutions preparation.

1.4 PERIOD OF ANALYSIS

Tests started on: 11/01/2021
Tests completed on: 15/02/2021

2. RESULTS

All the raw data recorded for each test of this study are reported in validated data sheet used to perform the computation of the required parameters following the Spearman-Karber method.

2.1 VALIDATION OF THE ASSAY FOR VIRUCIDAL ACTIVITY

The results obtained to verify assay validity are reported in Table 4. Due to the type of product under examination, some of the test recommended in the EN 16777 are not applicable.

Table 4: Assay Validation Results - Adenovirus type 5, strain Adenoid 75

Assay Performed	Results (with 95% confidence interval)	Assay Validity
Sample cytotoxicity	Not Applied	Not Applied
Virus stock solution titration	Virus Titre (-log $TCID_{50}$/mL) = 7.83 ± 0.42	VALID
Cell susceptibility to virus	Not Applied	Not Applied
Suppression of virucidal activity	Not Applied	Not Applied
Reference test for virus inactivation	$TCID_{50}$ reduction after 5 min: 3.17 ± 0.34	VALID

The assay validity criteria for all the performed controls were satisfied.

Questa Relazione Tecnica riguarda solo i campioni sottoposti a prova. La Relazione non può essere riprodotta parzialmente salvo approvazione scritta da parte di LabAnalysis.

2.2 VIRUCIDAL ACTIVITY ASSAY

The results obtained for the reduction of virus infectivity expressed as logarithm values, at the different incubation time points and conditions applied in the test are reported in Table 5.

Table 5: Results - Adenovirus type 5, strain Adenoid 75

Product Code/Name	Experimental Conditions		Control / Sample Virus Titre (-log TCID50/mL) with 95% confidence interval after contact time	Reduction with 95% confidence interval
	Incubation Time point (min)	Interfering Substance		
FD-21-000035-000058 "MAIA"	15	0.3 g/L BSA (Clean)	7.00 ± 0.45 / 4.00 ± 0.45	3.00 ± 0.63
FD-21-000035-000058 "MAIA"	30	0.3 g/L BSA (Clean)	7.50 ± 0.00 / 3.50 ± 0.00	4.00 ± 0.00
FD-21-000035-000058 "MAIA"	45	0.3 g/L BSA (Clean)	7.67 ± 0.34 / 3.50 ± 0.00	4.17 ± 0.34

2.3 INTERPRETATION OF RESULTS

In agreement to the UNI EN 16777:2019 the product shall demonstrate a titre reduction of 4 log or more compared to the virus control titration ("PASS"), not considering the 95% confidential interval. Therefore, the results obtained in the present study for the reliable time point, can be summarized in the following Table 6:

Table 6: Assay Outcome

Product Code/Name	Experimental Conditions		Reduction with 95% confidence interval	Assay Outcome
	Incubation Time point (min)	Virus model		
FD-21-000035-000058 "MAIA"	15	Adenovirus type 5, strain Adenoid 75	3.00 ± 0.63	NOT PASS
FD-21-000035-000058 "MAIA"	30	Adenovirus type 5, strain Adenoid 75	4.00 ± 0.00	**PASS**
FD-21-000035-000058 "MAIA"	45	Adenovirus type 5, strain Adenoid 75	4.17 ± 0.34	**PASS**

3. CONCLUSION

On the basis of the obtained results, operating following the indications of the UNI EN 16777, the device Bioxigen Air Sanitizer "MAIA" tested in clean conditions, at 20 °C proves virucidal activity against the Adenovirus after incubation of 30 and 45 minutes.

End Technical Report

Questa Relazione Tecnica riguarda solo i campioni sottoposti a prova. La Relazione non può essere riprodotta parzialmente salvo approvazione scritta da parte di LabAnalysis.

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