REPORT OF ANALYSIS No. 82025/20/ROBCH

Client **KYNITA SRL** SAT RACOVITA, NR. 145, STR. ISLAZ BARZA 247055 BUDESTI	Sample number: **82025/20/ROBCH** Sample description *(according to declaration of Client)* **K-SEPT GEL DEZINFECTANT DE MAINI** **Lot/Batch: 1** **Expiration date: 30.11.2022** **Sampling date: 01.12.2020** **Sampling quantity: 1 x 500 ml** **Sample temperature: 15°C** **Reception hour: 14:51** **Responsible for sampling: Nita Ion**
Sample received: **05.01.2021** Tests performed: **06.01.2021** Tests completed: **07.04.2021** Report dated: **07.04.2021**	**Sample condition with no objections** **Order of 17.12.2020** Sampling and delivery were carried out by client.

Test	Method	Unit	Result
# * Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine. Test method and requirements (Phase 2/Step1).AFNOR	NF EN 14476:2013+A2:2019	-	Test method performed by the subcontractor; the results are taken in full from the test report No D/20/1831, issued by the subcontractor. The results of the analysis are listed starting with enclosure No1 to report of analysis.

Elaborated by: Mariana Ilinca, Manager of Microbiological Laboratory
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Laboratory: Bucuresti 041914, sos. Berceni nr.8

* Test method accredited # Test performed by external provider
ø Non accredited methods

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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 82025/20/ROBCH

A) IDENTYFICATION OF THE SAMPLE	
Name of the product/Details about the product	**K-SEPT Gel dezinfectant de maini.** Batch number: 1 Expiration date: 31.11.2021 Keeping conditions – Dry, without sun, 5-25 Celsius degree Condition of use – Not indicated.
The active substance	Ethanol CAS 64-17-5; CONCENTRATIE 73,6%; propan-2-ol CAS 67-63-0; concentratie, 1.4%
Concentration ordered for the assay	(80%)
B) TEST METHOD	
Performed in accredited subcontracted partner laboratory: Scope of Accreditation Nr. 648/LE1286	UNE-EN 13624:2014 Quantitative suspension test for the evaluation of fungicidal or yeastcidal activity of chemical disinfectants and antiseptics.
Testing method	Procedure DESIN-1078-b
C) INFORMATION ABOUT SAMPLE RECEPTION	
Date of reception of order with test conditions	21.12.2021
Date of reception of the product	21.12.2021
Aspect of the received product	Transparent gel in blue plastic container.
D) EXPERIMENTAL CONDITIONS	
Assay period	January 05.2021 to January 22.2021
Solvent of the product used in the assay	Sterile distilated water
Product concentrations for the assay	80%;50%;0.1%.
Aspect of the dilutions of the product	Transparent
Contact time	60 seconds
Contact temperature	20°C ± 1°C
Procedure to stop product cytotoxcicity	Molecular sieving (3 MicroSpin columns)
Procedure to stop product activity	Cooling with ice
Assay temperature	37°C ± 1°C(Vaccinia) 35°C ± 1°C(Coronoavirus)
Titration method	$TCID_{50}$
Interfering substance	-Clean conditions in the presence of bovine serum albumin 0.3 g/L
Stability of the mixture (interfering substance and product diluted in sterile distilled water)	Stable
Identification of the strains used	Vaccinia virus strain modified Vaccinia Ankara (MVA) (ATCC VR-1508),aliquot: 22.01.2018. Coronavirus 229E (ATCC VR-740) aliquot 03.03.2021.
Cell lines (name,origin,number of passes)	BHK-21,ref:FTBH,working aliquot 9, passage 21,

	and working aliquot 10, passage 9 and 12. MRC-5 ref.FTMR, working aliquot 9, passage 21, and working aliquot 10, passage 9 and 13.

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7. Validation of assay results

Vaccinia virus strain modified Vaccinia Ankara (MVA)

Titre of the viral suspension for the virus control (at the requested test time):

- Clean conditions..... $\log 10^{-6.25}$

Cytotoxicity level (80%)..... $\log 10^{-0.50}$

Maximum level of virus inactivation detectable (difference between the titre of the viral suspension and the cytotoxicity level):

- Clean conditions.....$\log 10^{-5.57}$

Coronavirus 229E (ATCC VR-740)

Titre of the viral suspension for the virus control (at the requested test time):

- Clean conditions..... $\log 10^{-6.25}$

Cytotoxicity level (80%)..... $\log 10^{-0.50}$

Maximum level of virus inactivation detectable (difference between the titre of the viral suspension and the cytotoxicity level):

- Clean conditions.....$\log 10^{-5.75}$

Reference test (formaldehyde 1.4%)

Cytotoxicity level of formaldehyde 0.7%..... $\log 10^{-0.50}$

Viral quantification in the reference test (formaldehyde) after 15 minutes and with Vaccinia virus strain modified Vaccinia Ankara (MVA) .....$\log 10^{-2.49}$

Viral quantification in the reference test (formaldehyde) after 15 minutes and with Coronavirus 229E.....$\log 10^{-2.49}$

Confidence interval

Titre of virus with 95% confidence interval with Vaccinia virus strain modified Vaccinia Ankara (MVA) (at the requested test time):

- Clean conditions .....$\log 10^{-6.25 \pm 0.40}$

Titre of virus with 95% confidence interval with Coronavirus 229E (at the requested test time):

- Clean conditions .....$\log 10^{-6.25 \pm 0.40}$

Reduction with the confidence interval of 95 % .....See table 1.

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Sensitivity of cells to virus

- Viral quantification of Vaccinia virus strain modified Vaccinia Ankara (MVA) with cells not treated by the test solution with the test product ……..log10$^{-6.33}$
- Viral quantification of Vaccinia virus strain modified Vaccinia Ankara (MVA) with cells treated by the test solution with the test product ……...log10$^{-5.91}$

- Viral quantification of Coronavirus 229E with cells not treated by the test solution with the test product ……..log10$^{-6.58}$
- Viral quantification of Coronavirus 229E with cells treated by the test solution with the test product ……..log10$^{-6.08}$

Note: only can be used to determine the infectivity of cells, those dilutions which: a) show a low degree of cellular destruction (< 25% of cell monolayer) and b) produce a reduction of the title of the virus < 1 $\log_{10}$.

Control of the effectivity of the disinfectant detection activity

- Viral quantification of Vaccinia virus strain modified Vaccinia Ankara (MVA) after 30 minutes on bath ice without exposing the virus to the test product ……..log10$^{-6.16}$
- Viral quantification of Vaccinia virus strain modified Vaccinia Ankara (MVA) exposing the virus to the test product and incubated 30 minutes on ice bath.....log10$^{-5.91}$

- Viral quantification of Coronavirus 229E after 30 minutes on bath ice without exposing the virus to the test product ……..log10$^{-6.15}$
- Viral quantification of Coronavirus 229E exposing the virus to the test product and incubated 30 minutes on ice bath.....log10$^{-5.75}$

Note: The difference between decimal logarithm of titre without exposing the virus to the product and of the test suspension should be ≤ 0.5

8. Special remarks

- The product is tested at 80%; 50% and 0.1%. The highest concentration that can be tested in the test is 80%, because of the mixtures made during the test.

- All controls and validation were between the basic limits.
- One concentration at least showed a log reduction less than 4 log.
- One concentration at least showed a log reduction equal or higher than 4 log.

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9. Assay results

9.1 Description of the results under the requested test conditions:

Virus of assay	Test concentrations, reduction obtained with the confidence interval of 95 % and virucidal activity		
	80%	50%	0.1%
Virus Vaccinia Ankara (MVA)	$\geq 5.75 \pm 0.40$ $TCID_{50}$ Shows	$\geq 5.75 \pm 0.40$ $TCID_{50}$ Shows	0.34 ± 0.50 $TCID_{50}$ Does not show
Coronavirus 229E	$\geq 5.75 \pm 0.40$ $TCID_{50}$ Shows	$\geq 5.75 \pm 0.40$ $TCID_{50}$ Shows	0.34 ± 0.50 $TCID_{50}$ Does not show

Virucidal activity exists when the titre of virus shows a reduction ≥ 4 log.
$TCID_{50}$: Tissue Culture Infectious Dose 50%.

9.2 Tables of results and graphics

See tables 1 to 4 and figure 1 to 2.

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Authorized by: Mariana Ilinca, Manager of Microbiological laboratory
Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

10. Conclusion

The disinfectant product **"K-SEPT Gel dezifectant de mani",** batch 1, under clean conditions (bovine serum albumin 0.3 g/L), diluted at **80%**, requested by the customer and during 60 seconds of contact time and 20ºC of temperature, **shows** virucidal activity against Vaccinia virus strain modified Vaccinia Ankara (MVA) (ATCC VR-1508) when the activity is assayed according with the NF EN 14476: 2013 + A2: 2019 guideline. It also **shows** virucidal activity against Coronavirus 229E (ATCC VR-740) when the activity is assayed according with the internal procedure DESIN-6225 based on NF EN 14476: 2013 + A2: 2019 guideline.

Virucidal activity of the disinfectant " **K-SEPT Gel dezifectant de mani** ", batch 1, against Vaccinia virus strain modified Vaccinia Ankara (MVA) (ATCC VR-1508), **does not mean that the product has general virucidal activity, but only that the product shows activity against the enveloped virus** presented in annex A, when tested according to NF EN 14476: 2013 + A2: 2019 guideline. It also **shows** virucidal activity against Coronavirus.

Note 1: The results obtained correspond to the product received in this laboratory.
Note 2: The information that depend on the information received from the client and are not facilitated by the same one, shown as "not indicated".

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