

ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 148835/20/CGDA

A) IDENTIFICATION OF THE SAMPLE:	
Name of the product	Hygiene of Sweden screen & handspray 1:15 Batch/lot: BN005 Production date: 23-03-2020 Expiry date: 23-03-2025
The active substance	Not indicated
Aspect of the dilutions of the product	Transparent
B) TEST METHOD :	
Performed in accredited subcontracted partner laboratory: Scope of Accreditation Nr 648/LE1286	UNE- EN-14476:2014+A2:2019 Guideline- Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine. Test method and requirements (phase 2, step 1)
Testing method	Procedure DESIN-6225
C) EXPERIMENTAL CONDITIONS:	
Product test concentrations (%V/V)	80%, 50%, 0,1%
Assay period	09/04/2020 – 21/04/2020
Assay temperature	37°C ± 1°C
Contact time	1 minute
Contact temperature	20°C ± 1°C
Titration method	TCID ₅₀ (Tissue Culture Infective Dose 50%).
Solvent of the product used in the assay	Sterile distilled water.
Procedure to stop product cytotoxicity	Molecular sieving
Procedure to stop product activity	Cooling with ice
Interfering substance	Clean conditions in the presence of bovine serum albumin 0,3 g/L
Identification of the origin of viral strains and number of passes	Coronavirus 229E (ATCC VR-740) aliquot: 2019/03/04 passage 2
Cell lines (name, origin, number of passes)	MRC-5 ref. FTMR, working aliquot 3, passages 17, working aliquot 4, passages 9 and 10

Date:

25.05.2020

Authorized by: Agnieszka Erber, Expert Analyst, Microbiology Laboratory

Approved by: Hanna Wachowska, Laboratory Director (*Approved with qualified electronic signature*)

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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 148835/20/CGDA**Validation of assay results****Coronavirus 229E (ATCC VR-740)**

Titre of the viral suspension for the virus control (1 minute):

- Clean conditions.....log 10^{-6.32}
- Cytotoxicity level (80%).....log 10
- ^{-0.5}

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

- Clean conditions.....log 10^{-5.82}

Reference test (formaldehyde 1.4%)Cytotoxicity level of formaldehyde 0.7%.....log 10^{-0.5}

Viral quantification in the reference test (formaldehyde) after 15 minutes and with

Coronavirus 229E.....log10^{-2.74}**Confidence interval**

Titre of virus with 95% confidence interval with Coronavirus 229E (1 minute)

- Clean conditionslog 10^{-6.32 ± 0.36}

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

Sensitivity of cells to virus

- Viral quantification of Coronavirus 229E with cells not treated with “Hygiene of Sweden Screen & Handspray” disinfectantlog10^{-6.25}
- Viral quantification of Coronavirus 229E with cells treated with the “Hygiene of Sweden Screen & Handspray” disinfectant.....log10^{-5.74}

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 titre of the virus <1log10.

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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 148835/20/CGDA**Control of the effectivity of the disinfectant detection activity**

- Viral quantification of Coronavirus 229E after 30 minutes on bath ice without exposing the virus to the “Hygiene of Sweden Screen & Handspray” disinfectant.....log10^{-6.16}
- Viral quantification of Coronavirus 229E exposing the virus to “Hygiene of Sweden Screen & Handspray” disinfectant and incubated 30 minutes on ice bath.....log10^{-5.82}

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

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 higher than ≥ 4 log.

Assay results**Description**

The disinfectant product, “**Hygiene of Sweden Screen & Handspray**”, batch **BN10**, under clean conditions, diluted at 80% and 50% and during 1 minute of exposure, **shows** virucidal activity against Human Coronavirus 229E (ATCC VR-740), with a reduction $\geq 5.82 \pm 0.36$ TCID₅₀, for both concentrations, when the activity is assayed according with the internal procedure DESIN-6255 based on the NF EN 14476: 2013 + A2: 2019 guideline.

The disinfectant product, “**Hygiene of Sweden Screen & Handspray**”, batch **BN10**, under clean conditions, diluted at 0.1% and during 1 minute of exposure, **does not show** virucidal activity against Human Coronavirus 229E (ATCC VR-740), with a reduction 0.16 ± 0.50 TCID₅₀, when the activity is assayed according with the internal procedure DESIN-6255 based on the NF EN 14476: 2013 + A2: 2019 guideline.

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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 148835/20/CGDA**Tables of results and graphics**

See tables 1 and 2 and figure 1.

Conclusion

The disinfectant product “**Hygiene of Sweden Screen & Handspray**”, batch **BN10**, under clean conditions (bovine serum albumin 0.3 g/L), diluted at **80%**, requested by the customer, and during 1 minute of exposure, **shows** virucidal activity against Human Coronavirus 229E (ATCC VR-740), when the activity is assayed according with the internal procedure DESIN-6255 based on the NF EN 14476: 2013 + A2: 2019 guideline.

Tests performed only with Coronavirus strain 229E, **does not allow to conclude that the product tested shows a general virucidal activity**, but only that it shows activity against Coronaviruses.

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 provided".

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Table 1. Results of activity of the product “Hygiene of Sweden Screen & Handspray”, batch **BN10**, with Coronavirus 229E (ATCC VR-740) under clean conditions.

Product	Concentration*	Interfering substance	Cytotoxicity level	log ₁₀ TCID ₅₀ after.....				Reduction with the confidence interval of 95 % after 1 minute
				0 min	1 min	5 min	15 min	
Hygiene of Sweden Screen & Handspray	80%	0.3 g/L BSA	0.5	-	0.50	-	-	≥ 5.82 ± 0.36
	50%		0.5	-	0.50	-	-	≥ 5.82 ± 0.36
	0.1%		0.5	-	6.16	-	-	0.16 ± 0.50
Formaldehyde	0.7% (w:v)	NA	0.5	NR	NR	3.82	2.74	NA
Virus control	NA	0.3 g/L BSA	NA	6.07	6.32	NR	NR	NA
Virus control Formaldehyde	0.7% (w:v)	NA	0.5	5.91	NR	NR	5.83	NA

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Control of sensitivity of cells to virus (difference between decimal logarithm of titre using treated and untreated cells)log10^{-0.51}
Control of the effectiveness of the disinfectant detection activity (difference between decimal logarithm of titre without exposing the virus to the product and of the test suspension).....log10^{-0.34}

NA: not applicable; NR: not realized

Times recommended by Guideline for surfaces: maximum 5 or 5 minutes

Times recommended by Guideline for instruments: maximum 5 minutes

Times recommended by Guideline for Hygienic treatment of hands by friction and hygienic handwashing: between 30 or 120 minutes

PBS: phosphate buffered saline; BSA: bovine serum albumin.

Virucidal activity exists when the titre of virus shows a reduction ≥ 4 log.

*: see Special remarks to understand the values of these concentrations.

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Table 2. Results of the activity of the product “Hygiene of Sweden Screen & Handspray”, batch BN10, with Coronavirus 229E (ATCC VR-740) (Assay of titration with 12 wells), under clean conditions.

Product	Concentration *	Interfering substance	Time of contact (min)	Dilutions (log10) ^{a,b}							
				1	2	3	4	5	6	7	8
Hygiene of Sweden Screen & Handspray	80%	0.3 g/L BSA	1	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR
	50%		1	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR
	0.1%		1	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0003 2202 2220	0000 0001 0000	0000 0000 0000
Cytotoxicity	80%	0.3 g/L BSA	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR
Virus control	NA	0.3 g/L BSA	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0032 0220 2000	0000 0000 1100	0000 0000 0000
			1	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0032 2222 2020	0000 0011 0000	0000 0000 0000
Formaldehyde	0.7 (w/v)	NA	5	4444 4444 4444	4444 4444 4444	2322 2320 2332	0102 2200 0010	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR
			15	4444 4444 4444	2322 2223 2023	0021 0102 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR
Control of formaldehyde cytotoxicity	0.7 (w/v)	0.3 g/L BSA	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR
Virus control formaldehyde	0.7 (w/v)	NA	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	2332 0232 3322	0100 0021 1012	0000 0000 0000	NR
			15	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	2322 0302 3222	0212 0002 0110	0000 0000 0000	NR

Sensitivity control of cells to virus	NA	NA	Cells not treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	00CC C0CC C000	0000 0C0C C000	0000 0000 0000
			Cells treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	00C0 C0C0 C000	0000 0000 0000	0000 0000 0000
Effectiveness control of the disinfectant detection activity	NA	0.3 g/L BSA	Without PRODUCT	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	000C CC0C C0C0	0000 000C C000	0000 0000 0000
			With PRODUCT	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	000C C0CC 0C00	0000 0000 0000	0000 0000 0000

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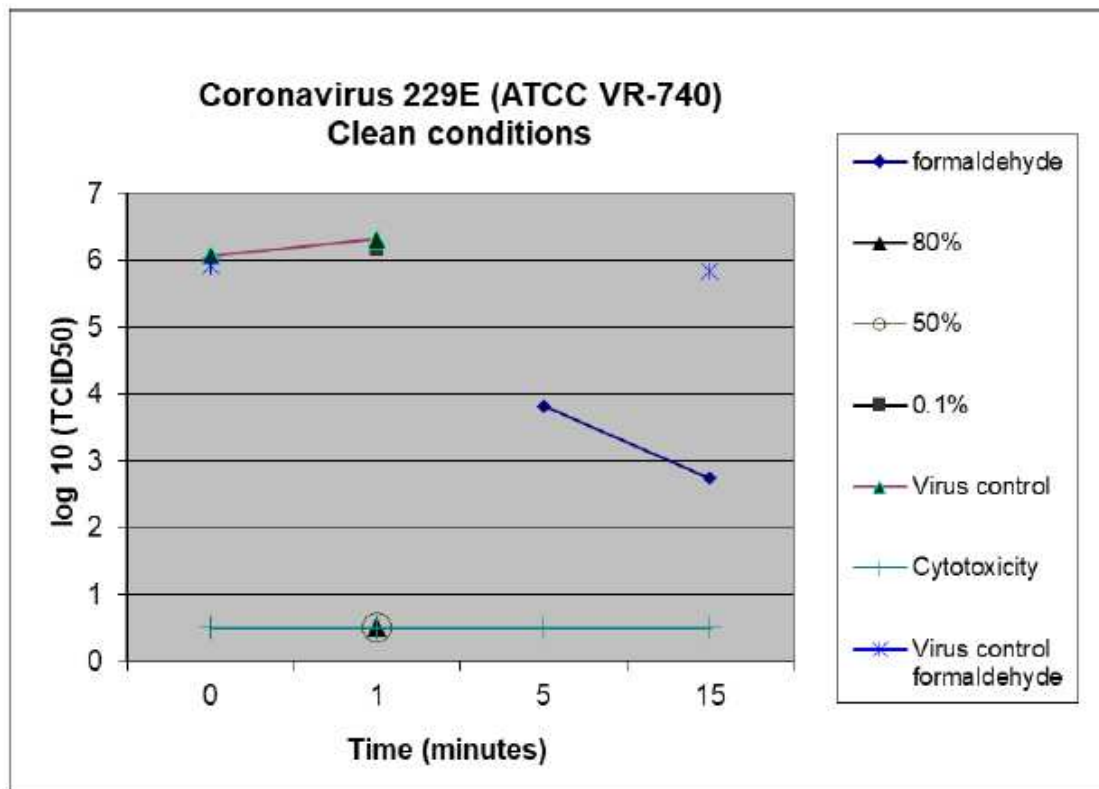
a): 1 to 4, virus present and grade of cytopathic effect in 12 units of cellular culture, or grade of cellular lesions in the cytotoxicity assay.

C = cytopathic effect with presence of virus (in this case and according to guideline does not take into account the degree of cytopathic effect only, the presence or absence of the same).

0 = no virus present or absence of cellular lesions in the cytotoxicity assay; NA: not applicable; NR: not realized; BSA: Bovine serum albumin; PBS: phosphate buffered saline. sec: minutes; min: minutes.

*: see Special remarks to understand the values of these concentrations.

Figure 1. Results of the activity of the product “Hygiene of Sweden Screen & Handspray”, batch **BN10**, at 80%, 50% and 0.1% concentration under clean conditions with Coronavirus 229E (ATCC VR-740).



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