HAMILTON

REPORT OF ANALYSIS No. 213653/20/JSHR

Client	Sample description *(according to declaration of Client)*
PROMEDIVET SRL STR. LUNGĂ 46/G - SOVATA 545500 SOVATA	**PROCID** **Lot: 9** **Cantitatea: 500 ml** **Data exprarii: 25.02.2022** **Data prelevarii: 30.04.2020** **Sample without any visible damages**
Sample received: **2020-05-08**	
Analysis completed: **2020-08-09**	**Order of 2020-05-07**
Report dated: **2020-08-09**	The samples were delivered by Client

Test	Method	Unit	Result
# * Virucidal activity in veterinary area. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and anti septics used in the veterinary area. Test method and requirements (phase 2, step 1).[1)]	UNE-EN 14675:2015		1)

[1)] The results of the analysis in attachment No 1 to the report of analysis.

THE END OF THE REPORT

Authorized by: Agnieszka Erber, Cosmetics Microbiology Laboratory Manager
Approved by: Hanna Wachowska, Laboratory Director *(Approved with electronic signature)*

Laboratory: Tychy 43-100, Goździków 1

* Test method accredited; # Test performed by external provider

J.S. HAMILTON POLAND Sp. z o.o.
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A) IDENTYFICATION OF THE SAMPLE:	
Name of the product	**PROCID** Batch number: Not indicated
Expiration date	Not indicated
The active substance	Glutaral CAS: 111-30-8 and CE: 203-856-5 concentration of active substance 10% (10g active substance at 100g product); active compound : Didecyldimethylammonium chloride CAS: 7173-51-5 and CE 230-525-2 concentration of active substance (3.75 g active substance at 100g product)
B) TEST METHOD :	
Performed in accredited subcontracted partner laboratory: Scope of Accreditacion Nr 648/LE1286	**UNE-EN 14675: 2015 guideline. Chemical IsInfectant and antiseptics. Quantitative suspension test for the evaluation of virucidal activity of chemical disinfectant and antiseptics used in the veterinary area. Test method and requirements (phase 2, step 1). AFNOR.**
Testing method	Procedure **DESIN-1077**
C) EXPERIMENTAL CONDITIONS:	
Assay period	23/06/2020 –10/07/2020
Product test concentrations (%V/V)	5%, 0,3%, 0,01%
Contact time	30 minutes
Assay temperature	37ºC ± 1ºC
Titration method	$TCID_{50}$ (Tissue culture infective dose 50%)
Solvent of the product used in the assay	Hard water
Aspect of the dilutions of the product	Colourless
Contact temperature	10°C ± 1°C
Procedure to stop product cytotoxicity	Molecular sieving
Procedure to stop product activity	Cooling with ice
Interfering substance	Low dirty conditions in the presence of 3 g/L serum albumin
Identification of the origin of viral strains and number of passes	Bovine Enterovirus type 1 (ATCC VR-248) aliquot: 2017/05/16 passage 2
Cell lines (name, origin, number of passes and culture medium)	MDBK, ref: FTMB; working aliquot 2, passages 17, 19 and 20

Date: 09.08.2020

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Validation of assay results

Bovine Enterovirus type 1 (ATCC VR-248)

Title of the viral suspension for the virus control (30 minutes):

- Low dirty conditions……log $10^{-6.15}$

Cytotoxicity level (5%)……log $10^{-0.5}$

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

- Low dirty conditions……log $10^{-5.65}$

Reference test (formaldehyde 1.4%)

Cytotoxicity level of formaldehyde 0.7%……log $10^{-0.5}$

Viral quantification in the reference test (formaldehyde) after 30 minutes and with Bovine Enterovirus type 1……log$10^{-3.49}$

Confidence interval

Title of virus with 95% confidence interval with Bovine Enterovirus type 1 (ATCC VR-248) (30 minutes):

- Low dirty conditions ……log $10^{-6.15 \pm 0.43}$

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

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Sensitivity of cells to virus

- Viral quantification of Bovine Enterovirus type 1 with cells not treated with "PROCID" disinfectant .....$log10^{-6.24}$
- Viral quantification of Bovine Enterovirus type 1 with cells treated with the "PROCID" disinfectant.....$log10^{-5.66}$

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 effectiveness of the disinfectant detection activity

- Viral quantification of Bovine Enterovirus type 1 after 30 minutes on bath ice without exposing the virus to the "PROCID" disinfectant .....$log10^{-6.16}$
- Viral quantification of Bovine Enterovirus type 1 exposing the virus to "PROCID" disinfectant and incubated 30 minutes on ice bath .....$log10^{-5.90}$

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

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

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Assay results

Description

The disinfectant product **PROCID,** batch not indicated, under low dirty conditions (3 g/L serum albumin), diluted to 5% during 30 minutes of exposure, **shows** virucidal activity against Bovine Enterovirus type 1 with a reduction $\geq 5.65 \pm 0.43$ $TCID_{50}$, when the activity is assayed according with the UNE-EN 14675: 2015 guideline.

The disinfectant product **PROCID,** batch not indicated, under low dirty conditions (3 g/L serum albumin), diluted to 0.3% and 0.01% and during 30 minutes of exposure, **does not show** virucidal activity against Bovine Enterovirus type 1, with a reduction 1.25 ± 0.57 $TCID_{50}$ when diluted at 3% and with a reduction 0.16 ± 0.54 $TCID_{50}$ when diluted at 0.01% when the activity is assayed according with the UNE-EN 14675: 2015 guideline.

Tables of results and graphics

See tables 1 to 2 and figure 1.

Conclusion

The disinfectant product **PROCID,** batch not indicated, under low dirty conditions (3 g/L serum albumin), diluted at **0.3%,** requested by the customer, and during 30 minutes of exposure **does not show** virucidal activity against Bovine Enterovirus type 1, according with the UNE-EN 14675: 2015 guideline.

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Table 1. Results of activity of the product **PROCID,** batch not indicated, with Bovine Enterovirus type 1 (ATCC VR-248) under low dirty conditions:

Product	Concen-tration*	Interfering substance	Cytoto-xicity level	log_{10} $TCID_{50}$ after…..			Reduction with the confidence interval of 95 % after 30 min
				0 min	15 min	30 min	
PROCID	5%	3 g/L BSA	0.5	-	-	0.50	≥5.65 ± 0.43
	0.3%		0.5	-	-	4.90	1.25 ± 0.57
	0.01%		0.5	-	-	5.99	0.16 ± 0.54
Virus control	NA	3 g/L BSA	NA	6.33	NR	6.15	NA
Formaldehyde	0.7% (p:v)	NA	0.5	-	-	3.49	NA
Virus control Formaldehyde	0.7% (p:v)	NA	0.5	6.16	NR	5.99	NA

Control of sensitivity of cells to virus (difference between decimal logarithm of titre using treated and untreated cells) ……..$log10^{-0.58}$

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)……..$log10^{-0.26}$

NA: not applicable; NR: not realized
Times recommended by Guideline for veterinary area: 30 minutes (optionals 1, 5 and 60 min).
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 **PROCID**, batch not indicated, with Bovine Enterovirus type 1 (ATCC VR-248) under low dirty conditions.

Product	Concen-tration *	Interfering substance	Time of contact (min)	Dilutions (log10)[a,b]							
				1	2	3	4	5	6	7	8
PROCID	5%	3 g/L BSA	30	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR
	0.3%		30	4444 4444 4444	4444 4444 4444	4444 4444 4444	0434 4342 4434	2020 2300 0020	0000 0000 2000	0000 0000 0000	NR
	0.01%		30	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4434 4442 3414	0203 2020 0002	0000 0000 0200	0000 0000 0000
Cytotoxicity	5%	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	3 g/L BSA	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0203 2040 3200	0020 0002 3002	0000 0000 0000
			30	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3220 3404 2344	0222 0320 2302	0002 0000 0020	0000 0000 0000
Formaldehyde	0.7 (p/v)	NA	30	4444 4444 4444	4444 4444 4444	2303 4020 3420	0020 0203 0020	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR
Control of folmaldehyde cytotoxicity	0.7 (p/v)	NA	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 folmaldehyde	0.7 (p/v)	NA	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3023 0323 0202	0000 0000 0000	0000 0000 0000
			30	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	2322 3024 3442	2040 0203 2002	0000 2000 0000	0000 0000 0000
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 CCC0C	C0C0 0CC0 0CCC	00C0 000C C000	0000 0000 0000
			Cells treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC C0C0 CCCC	0000 CC0C 0000	00C0 0000 0000	0000 0000 0000
Effectivity control of the disinfectant detection activity	NA	3 g/L BSA	Without **PROCID**	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	0C0C CC0C 0CCC	0000 0C0C C000	0000 0000 0000
			With **PROCID**	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	C0CC 0CCC CCCC	0C0C C0C0 000C	0000 000C 0C00	0000 0000 0000

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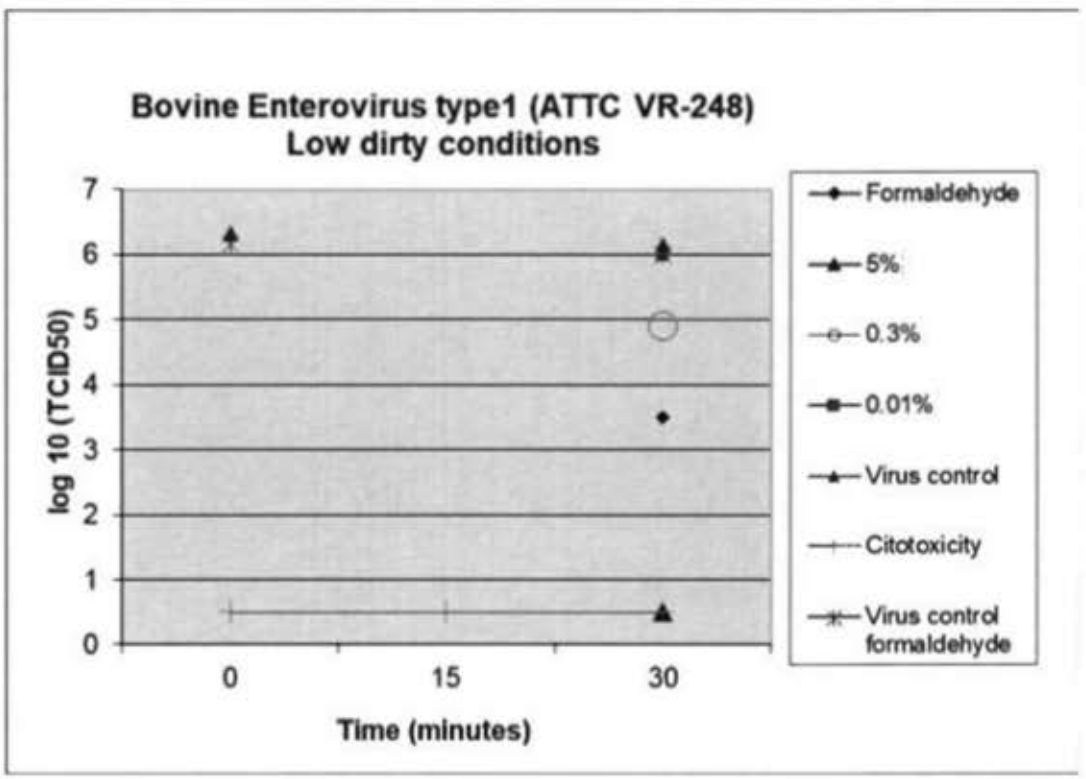
a): 1 to 4, virus present and grade of cytopathic effect in 12 units of cellular culture, or grade of cellular lesions in the cytotoxicity assay.
C = cytopathic effect with presence of virus (in this case and according to guideline does not take into account the degree of cytopathic effect only, the 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: seconds; min: minutes.
*: see Special remarks to understand the values of these concentrations.

Figure 1. Results of the activity of the **PROCID,** batch not indicated at different concentrations (5%, 0.3% and 0.01%) under low dirty conditions with Bovine Enterovirus type 1 (ATCC VR-248), and for the time of contact indicated.



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