MERIEUX NutriSciences

CHELAB S.R.L.

TEST REPORT N. 21/000128983

date of issue 25/03/2021

Customer ID 0084162

Messrs
AVS ELECTRONICS SPA
VIA VALSUGANA, 63
35010 CURTAROLO (PD)
IT

Sample information

Acceptance number 20.537120.0001

Delivered by The Customer on 12/11/2020

Receiving Date 12/11/2020

Place of origin AVS ELECTRONICS SPA VIA VALSUGANA, 63 35010 CURTAROLO (PD) IT

Sample Description SANY SAFE PLUS FLUID- EN 14476: Quantitative suspension test for the evaluation of virucidal activity in the medical area

Sampling information

Sampled by Customer

ANALYTICAL RESULTS

	Value/ Uncertainty	Unit of measure	LoQ	LoD	Start/end date of analysis	Op. units	Line
ON SAMPLE AS IT IS							1
VIRUCIDAL ACTIVITY:SUSPENSION TEST Met.: UNI EN 14476:2019	view attached file				16/11/2020- -24/03/2021	09	2
RESEARCH ANALYSIS Met.: .	see observations				16/11/2020- -24/03/2021	09	3

Operative units

Unit 09 : Via Fratta Resana PHARMA (TV)

Information provided by the client

Sampled by: Customer
Place of origin: AVS ELECTRONICS SPA VIA VALSUGANA, 63 35010 CURTAROLO (PD) IT
Description: SANY SAFE PLUS FLUID- EN 14476: Quantitative suspension test for the evaluation of virucidal activity in the medical area

Biologist responsible

Dott.ssa Federica Cattapan

Ordine nazionale dei biologi
Albo professionale n.045961 sez.A

Num. certificato 19693609 emesso dall'ente certificatore ArubaPEC S.p.A. NG CA 3, ArubaPEC S.p.A., IT

- If not otherwise specified, the uncertainty is extended and has been calculated with a coverage factor k=2 corresponding to a probability interval of about 95%. - LoD is the detection limit and identifies a confidence interval of zero with a probabilty interval of about 99%. - LoQ is the limit of quantification."n.d" is not detected and indicates a value inferior to the LoD. "traces (X)" means a value between LoD and LoQ, this value is indicative. "<x" or ">x" indicate inferior or superior to the measurement field of the test. - If not differently specified, the sums are calculated by lower bound criteria (L.B.). - In case of alteration of the sample the laboratory declines any responsibility on the results that can be influenced by the deviation in case the customer asks for the execution of the test anyway. - If the sampling is not carried out by the laboratory staff, the results obtained are considered referring to the sample as received and the laboratory declines its responsibility for the results calculated considering the sampling data provided by the Customer. The name and contact information of the Customer are always provided by the Customer.

END OF TEST REPORT

CHELAB S.r.l. Socio Unico, Company subject to the direction and coordination of M¶rieux NutriSciences Corporation

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Client

AVS ELECTRONICS SPA
VIA VALSUGANA, 63
35010 CURTAROLO (PD)
ITALY

SANY SAFE PLUS FLUID

Evaluation of virucidal activity according to UNI EN 14476:2019

Prepared by: Giorgio Libralesso

Date: 16/03/2021

1. Test Method:

UNI EN 14476:2019 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area – Test method and requirements (phase 2, step 1)

2. Product Identification:

Product name	SANY SAFE PLUS FLUID
Batch number	n.a.
Manufacturing date	n.a.
Expiry date	n.a.
Laboratory number	20.537120.0001
Receiving date	16/11/2020
Storage conditions	RT, darkness
Product appearance	liquid, clear, colourless
Active substances	hydrogen peroxide, ethanol, isopropanol

3. Evaluation of virucidal activity according to UNI EN 14476:2019

3.1 Test Method: Neutralization filtration method

3.2 Product test concentrations

dilution	preparation	appearance
80%	product as it is	liquid, clear, colourless
25%	solution 31.25% (v/v) in distilled water	liquid, clear, colourless
1%	solution 1.25% (v/v) in distilled water	liquid, clear, colourless

3.3 Test conditions

Test strain (standard)	/	/
Test strain (additional)	Bovine Coronavirus (BCoV), Frierich Loeffler Institute S379 Riems	(passage n° 2)
Cell lines for test strains propagation	MDBK, BS CL 63-127 for the propagation of Bovine Coronavirus (BCoV)	(passage n° 23+8)
Contact time	60 min ± 10 sec (standard)	
Test temperature	25 °C ± 1 °C (standard)	
Interfering substance	Bovine albumin 0.3 g/l (clean conditions)	
Incubation conditions	37 °C ± 1 °C, 5 % CO_2	

3.4 Materials and reagents

Growth medium	MEM 10% FCS
Maintenance medium	MEM 2% FCS

3.5 Remarks

Stability and appearance of the test mixture during the procedure	stable, without precipitate
All controls and acceptance criteria resulted satisfied	
The test is valid if at least one concentration of the product demonstrates a log R ≥ 4 (active concentration)	At least one concentration of the product demonstrated a log R ≥ 4
The test is valid if at least one concentration of the product demonstrates a log R < 4 (non active concentration)	At least one concentration of the product demonstrated a log R < 4
"Virucidal activity" can be claimed when the test product is ACTIVE against Adenovirus, Murine Norovirus and Poliovirus	
"Limited spectrum virucidal activity" can be claimed when the test product is ACTIVE against Adenovirus and Murine Norovirus. "Limited virucidal activity" covers all envelope viruses, norovirus, rotavirus and adenovirus.	
"Virucidal activity against enveloped viruses" can be claimed when the test product is ACTIVE against Vaccinia virus. "Virucidal activity against enveloped viruses" covers all enveloped viruses only.	

3.6 Results: see tables 1-3

3.7 Testing period: 16/12/2020 – 12/03/2021

4. Conclusions

According to UNI EN 14476:2019, the test product SANY SAFE PLUS FLUID, does have virucidal activity (log $R \geq 4$) when used at concentrations

- 80% (product as it is)

under the following test conditions

- Contact time: 60 min ± 10 sec (standard)
- Temperature: 25 °C ± 1 °C (standard)
- Interfering substance: bovine albumin 0.3 g/l (clean conditions)
- Test strain: Bovine Coronavirus (BCoV)

Table 1: Results of the test UNI EN 14476+A2:2019 on Bovine Coronavirus (BCoV)

BCoV							
Test	**Contact time**	**Interfering substance**	**Concentration**	**Virus titration (Log TCID50)**	**Reduction**	**Acceptance criteria**	**Result**
Susceptibility (Control)	60 min	PBS	/	5,75 (CI95% = 0,328 → PASS)	/	/	/
Susceptibility (Test substance)	60 min	PBS	0,0008%*	5,625 (CI95% = 0,25 → PASS)	0,125 (CI95% = 0,412)	R < 1	PASS
Virus Titration	0 min	0,3 g/l bovine albumin	/	5,875 (CI95% = 0,366 → PASS)	/	/	/
	60 min		/	5,75 (CI95% = 0,328 → PASS)	0,125 (CI95% = 0,491)	R < 1	PASS
Reference Virus Inactivation	30 min	PBS	0,7%	≤ 1,5 (CI95% = 0 → PASS)	≥ 4,25 (CI95% = 0,328)	n.a.	/
	60 min		0,7%	≤ 1,5 (CI95% = 0 → PASS)	≥ 4,25 (CI95% = 0,328)	n.a.	/
Virucidal Activity	60 min	0,3 g/l bovine albumin	80 %	≤ 4,5 (CI95% = 0 → PASS)	≥ 1,25 (CI95% = 0,328)	ACTIVE if R ≥ 4	NOT DETERMINABLE
			80 % (LVP method)	≤ 0,99 (CI95% = n.c.)	≥ 5,01 (CI95% = 0,378)	ACTIVE if R ≥ 4	ACTIVE
			25 %	≤ 3,5 (CI95% = 0 → PASS)	≥ 2,25 (CI95% = 0,328)	ACTIVE if R ≥ 4	NOT DETERMINABLE
			1 %	4,625 (CI95% = 0,25 → PASS)	1,125 (CI95% = 0,412)	ACTIVE if R ≥ 4	NOT ACTIVE
Efficency of Product's Activity Suppression	30 min	0,3 g/l bovine albumin	80 %	5,75 (CI95% = 0,328 → PASS)	0 (CI95% = 0,464)	R ≤ 0,5	PASS
			25 %	5,5 (CI95% = 0 → PASS)	0,25 (CI95% = 0,328)	R ≤ 0,5	PASS
			1 %	5,875 (CI95% = 0,366 → PASS)	0,125 (CI95% = 0,491)	R ≤ 0,5	PASS

* lowest apparently non cytotoxic dilution

Table 2: Raw data UNI EN 14476+A2:2019 on Bovine Coronavirus (BCoV)

BCoV												
Test	**Contact time**	**Interfering substance**	**Concentration**	**Virus dilution (Log_{10})**										
				-1	**-2**	**-3**	**-4**	**-5**	**-6**	**-7**	**-8**	**-9**	**-10**	**-11**
Susceptibility (Control)	60 min	PBS	/	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	0000 0044	0000 0000	0000 0000	0000 0000	0000 0000	/
Susceptibility (Test substance)	60 min	PBS	0,0008%	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4000 0000	0000 0000	0000 0000	0000 0000	0000 0000	/
Virus Titration	0 min	0,3 g/l bovine albumin	/	/	4444 4444	4444 4444	4444 4444	4444 4444	0000 0444	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000
Virus Titration	60 min		/	/	4444 4444	4444 4444	4444 4444	4444 4444	0000 0044	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000
Reference Virus Inactivation	30 min	PBS	0,7%	/	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000
Reference Virus Inactivation	60 min		0,7%	/	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000
Virucidal Activity	60 min	0,3 g/l bovine albumin	80 %	/	CCCC CCCC	CCCC CCCC	CCCC CCCC	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000
			25 %	/	CCCC CCCC	CCCC CCCC	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000
			1 %	/	CCCC CCCC	4444 4444	4444 4444	0400 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000
Efficency of Product's Activity Suppression	30 min	0,3 g/l bovine albumin	80 %	CCCC CCCC	CCCC CCCC	CCCC CCCC	4444 4444	4444 4444	4000 4000	0000 0000	0000 0000	0000 0000	0000 0000	/
			25 %	CCCC CCCC	CCCC CCCC	4444 4444	4444 4444	4444 4444	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	/
			1 %	CCCC CCCC	4444 4444	4444 4444	4444 4444	4444 4444	4440 0000	0000 0000	0000 0000	0000 0000	0000 0000	/

1 to 4 = virus detectable / 0 = no virus

Table 3: Raw data UNI EN 14476+A2:2019 on Bovine Coronavirus (BCoV), LVP method

BCoV – LVP method							
Test	**Contact time**	**Interfering substance**	**Concentration**	**Non-Cytotoxic Dilution**	**Wells seeded/plate**	**Total Plated Volume**	**Plates seeded N°**
Virucidal Activity	60 min	0,3 g/l bovine albumin	80 % (LVP method)	1:10000*	88	88 ml	10

Infected wells/plate									
Plate 1	**Plate 2**	**Plate 3**	**Plate 4**	**Plate 5**	**Plate 6**	**Plate 7**	**Plate 8**	**Plate 9**	**Plate 10**
0	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

* Filtered