Abbott Analytical

Consulting Scientists to the Disinfectant Industry

Certificate of Analysis

Sample(s):	One sample of Virex		
Received from:	Kilco (International) Ltd. Broomhouses 2 Industrial Estate, Lockerbie, DG11 2SD		
Date received:	21 May 2012	**Date tested:**	30 May 2012
Certificate no:	12E.050VB.KIL	**Certificate date:**	1 June 2012
Sample ref:	12E/050	**Page:**	1 of 2
Analysis required:	EN 1656, Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area – Test method and requirements (phase 2, step 1)		

Product stored at:	Room temperature
Active substance:	Not declared
Test conditions:	Low-level soiling
Interfering substance:	3.0g/l bovine albumin
Product test concentration:	0.5% v/v
Product diluent used during test:	Sterile hard water 300mg/l $CaCO_3$
Contact time:	5 minutes
Test temperature:	10°C ± 0.5°C
Neutralising solution:	5% Sodium thiosulphate
Incubation temperature:	37°C ± 1°C
Identification of bacterial strain(s) used:	*Pseudomonas aeruginosa* NCIMB 10421 *Proteus vulgaris* NCTC 4175 *Staphylococcus aureus* NCTC 10788 *Enterococcus hirae* NCIMB 8192

D C Watson

D C Watson BSc, CBiol, MSB, MIFST, ACIEHO
PO Box 95, New Ferry, Wirral, CH62 6HA
Tel: 0151 637 3331 Mob: 07767 871275
email: abbottanalytical@hotmail.co.uk

Test results:

Test Organism	*Pseudomonas aeruginosa*		*Proteus vulgaris*		*Staphylococcus aureus*		*Enterococcus hirae*	
Validation Suspension	Vc1 210	Vc2 199	Vc1 244	Vc2 278	Vc1 200	Vc2 236	Vc1 302	Vc2 276
(Nv_o)	ẍ = 205		ẍ = 261		ẍ = 218		ẍ = 289	
Experimental Control	Vc1 204	Vc2 178	Vc1 232	Vc2 266	Vc1 186	Vc2 214	Vc1 288	Vc2 252
(A)	ẍ = 191	≥ 0.5Nv_o	ẍ = 249	≥ 0.5Nv_o	ẍ = 200	≥ 0.5Nv_o	ẍ = 270	≥ 0.5Nv_o
Neutraliser Control	Vc1 210	Vc2 184	Vc1 270	Vc2 246	Vc1 220	Vc2 192	Vc1 300	Vc2 264
(B)	ẍ = 197	≥ 0.5Nv_o	ẍ = 258	≥ 0.5Nv_o	ẍ = 206	≥ 0.5Nv_o	ẍ = 282	≥ 0.5Nv_o
Method Validation	Vc1 166	Vc2 192	Vc1 290	Vc2 232	Vc1 180	Vc2 214	Vc1 270	Vc2 294
(C)	ẍ = 179	≥ 0.5Nv_o	ẍ = 261	≥ 0.5Nv_o	ẍ = 197	≥ 0.5Nv_o	ẍ = 282	≥ 0.5Nv_o
Test Suspension 10^{-6}	Vc1 200	Vc2 214	Vc1 284	Vc2 310	Vc1 210	Vc2 222	Vc1 288	Vc2 312
10^{-7}	Vc1 23	Vc2 25	Vc1 34	Vc2 36	Vc1 30	Vc2 25	Vc1 35	Vc2 32
(N = ẅ)	lg N = 8.32		lg N = 8.48		lg N = 8.35		lg N = 8.48	
(N_o = 0.1N)	lg N_o = 7.32		lg N_o = 7.48		lg N_o = 7.35		lg N_o = 7.48	
Results	Vc1 0	Vc2 0	Vc1 5	Vc2 7	Vc1 25	Vc2 15	Vc1 13	Vc2 8
(Na = 10ẍ)	lg Na < 2.15		lg Na < 2.15		lg Na = 2.30		lg Na < 2.15	
(R)	lg R > 5.18		lg R > 5.33		lg R = 5.04		lg R > 5.34	
Pass: lg R ≥ 5	PASS		PASS		PASS		PASS	

Vc = plate count per ml

ẍ = average of Vc1 and Vc2

ẅ = weighted mean of ẍ

R = reduction (lg R = lg N_o – lg Na)

Requirements & Conclusion:

This batch of Virex, when diluted to 0.5% v/v, passes the requirements of EN 1656 for bactericidal activity in 5 minutes at 10°C under low-level soiling conditions against all of the reference organisms detailed.

D C Watson

D C Watson BSc, CBiol, MSB, MIFST, ACIEHO
PO Box 95, New Ferry, Wirral, CH62 6HA
Tel: 0151 637 3331 Mob: 07767 871275
email: abbottanalytical@hotmail.co.uk

mgsLABORATORIES Microbiological Services and Consultancy				Doc No.	TRA-2012-053-01
Title	**EN 14349 (2007) Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary area on non-porous surfaces without mechanical action (Phase 2 / Step 2)**				
Product	**Virex**	MGS No	02196	SO No	**3197**

a) **Identification of test laboratory:**	
Test laboratory	MGS Laboratories Ltd Unit 14, Newlands Drive Poyle 14 Horton Road Poyle Berkshire SL3 0DX
b) **Identification of the Customer:**	
Customer Name	Kilco (International) Limited
Customer Address	Broomhouses 2 Industrial Estate Old Glasgow Road Lockerbie Dumfriesshire DG11 2SD
c) **Identification of the sample:**	
Name of product	Virex
Batch number	B/N: 1213011; Expiry: Feb 14
Manufacturer	Kilco (International) Limited
Date of delivery	14 Feb 12
Storage conditions	Room temperature and darkness
Active substance(s) and their concentration(s) (optional)	Pentapotassium bis (peroxymonosulphate) Sulphamic acid Sodium dichloroisocyanurate
d) **Test method and its validation:**	
MGS procedure reference	WIN-1000.059-03
Neutraliser	Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine1g/l, saponin 30g/l, phosphate buffer powder 0.35g/l
Details of validation of the neutraliser	Neutraliser validation performed according to Annex A
e) **Experimental conditions:**	
Period of analysis	07 Mar 12 – 09 Mar 12
Product diluent used during the test	Standard hard water 300mg/kg $CaCO_3$

NOTE 1: The results relate only to the sample which was tested and cannot be guaranteed to represent the batch from which it was taken.

Title	**EN 14349 (2007) Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary area on non-porous surfaces without mechanical action (Phase 2 / Step 2)**				
Product	**Virex**	MGS No	02196	SO No	**3197**

Product test concentrations	1:100 (w/v)
Appearance of product dilutions	Pink solution
Contact time	30 minutes ± 10s
Test temperature	10°C ± 2°C
Interfering substance	3.0g/l Bovine albumin
Counting procedure	Pour plate
Stability of the mixture	Precipitate absent throughout test
Temperature of incubation	36°C ± 2°C
Identification of the bacterial strains used	*Staphylococcus aureus* ATCC 6538
Identification of the test surface	Stainless steel
f) **Results:**	
Test results	See table: 1
g) **Conclusion:**	Based on EN 14349 (2007), the batch 1213011of the product Virex, when diluted at 1:100 (w/v) in hard water, possesses bactericidal activity in 30 minutes at 10°C under clean conditions for the referenced strain of *S. aureus*
h) **Deviations:**	To comply with EN 14349, *Enterococcus hirae* NCIMB 8192, *Proteus vulgaris* ATCC 13315 and *Pseudomonas aeruginosa* NCIMB 10421 must also be tested.

Prepared By: Helen Duxbury

Name: Miss Helen Duxbury BSc (Hons)

Position: Laboratory Manager

Date: 13/Mar/12

Approved by:

Name: Mrs Kim Morwood BSc (Hons) CBiol MIBiol

Position: Technical Director

Date: 14 MAR 12

Table 1: Bacterial surface testing test results testing

Test organisms	Bacterial test suspension: N	Validation test:		Water control Nc	Test procedure at concentrations	
		NT	NC			1:100 (w/v)
Staphylococcus aureus ATCC 6538	10^{-7}: >300, >300 10^{-8}: 41, 32 N: 8.0	10^{-4}: >300, >300 10^{-5}: 112, 101 10^{-6}: 14, 12 NT: 8.0	10^{-4}: >300, >300 10^{-5}: 103, 102 10^{-6}: 12, 8 NC: 8.0	10^{-4}: >300, >300 10^{-5}: 104, 106 10^{-6}: 16, 12 Nc: 8.0	10^{-0}: 10^{-1}: 10^{-2}: Nd : Nts : ME :	<15, <15 <15, <15 <15, <15 <2.2 1 >5.8

N = $\log_{10}$ number of cfu applied to test surface;
NT = $\log_{10}$ number of cfu per test surface of the neutralisation test;
NC = $\log_{10}$ number of cfu per test surface of the neutralisation control;
Nc = $\log_{10}$ number of cfu per test surface of the water control;
Nd = $\log_{10}$ number of cfu per test surface of the disinfectant test;
Nts = number of residual colony forming units remaining on the test surface;
ME = microbicidal effect.

mgsLABORATORIES Microbiological Services and Consultancy				Doc No.	TRB-2010-024-01
Title	**EN 14349 (2007) Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary area on non-porous surfaces without mechanical action (Phase 2 / Step 2)**				
Product	**Virex**	MGS No	**19468**	SO No	**2315**

a) **Identification of test laboratory:**

Test laboratory	MGS Laboratories Ltd Unit 14, Newlands Drive Poyle 14 Horton Road Poyle Berkshire SL3 0DX

b) **Identification of the Customer:**

Customer Name	Kilco (International) Limited
Customer Address	Broomhouses 2 Industrial Estate Old Glasgow Road Lockerbie Dumfriesshire DG11 2SD

c) **Identification of the sample:**

Name of product	Virex
Batch number	1005046
Manufacturer	Kilco (International) Ltd
Date of delivery	24 May 10
Storage conditions	Room temperature and darkness
Active substance(s) and their concentration(s) (optional)	Pentapotassium bis (peroxymonosulphate) 50% Sulphamic acid <10% Sodium dichloroisocyanurate <5%

d) **Test method and its validation:**

MGS procedure reference	WIN-1000.059-01
Neutraliser	Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine1g/l, saponin 30g/l, phosphate buffer powder 0.35g/l
Details of validation of the neutraliser	Neutraliser validation performed according to Annex A

e) **Experimental conditions:**

Period of analysis	26 May 10 – 25 Jun 10
Product diluent used during the test	Standard hard water 300mg/kg $CaCO_3$

NOTE 1: The results relate only to the sample which was tested and cannot be guaranteed to represent the batch from which it was taken.

Product test concentrations	1:200 (v/v)
Appearance of product dilutions	Pale pink solution
Contact time	30 minutes ± 10s
Test temperature	10°C ± 2°C
Interfering substance	10.0g/l Yeast extract and 10g/l bovine albumin
Counting procedure	Pour plate
Stability of the mixture	Precipitate absent throughout test
Temperature of incubation	Bacteria: 37°C ± 2°C
Identification of the bacterial strain used	*Proteus vulgaris* NCTC 4175 *Enterococcus hirae* NCIMB 8192 *Staphylococcus aureus* ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442
Identification of the test surface	Stainless steel
f) **Results:**	
Test results	See tables: 1-2
g) **Conclusion:**	Based on EN 14349 (2007), the batch 1005046 of the product Virex, when diluted at 1:200 (v/v) in hard water, possesses bactericidal activity in 30 minutes at 10°C under dirty conditions for the referenced strain of *P. vulgaris*, *E. hirae*, and *P. aeruginosa*, but not *S. aureus*.
h) **Deviations:**	None

Prepared By: Newton

Name: Mrs Emma Newton BSc (Hons)

Position: Laboratory Manager

Date: 25 June 10

Approved by:

Name: Mrs Kim Morwood BSc (Hons) CBiol MiBiol

Position: Technical Director

Date: 25 June 10

NOTE 1: The results relate only to the sample which was tested and cannot be guaranteed to represent the batch from which it was taken.

Table 1: Bacterial surface testing results

Test organisms	Interfering substance	Bacterial test suspension: N	Validation test: NT	Validation test: NC	Water control Nc	Test procedure at concentrations 1:200 (v/v)	
Proteus vulgaris NCTC 4175	10.0g/l Yeast extract and 10g/l bovine albumin	10^{-6}:>300, >300 10^{-7}: 217; 255 10^{-8}: 25; 23 N: 7.8	10^{-3}:>300; >300 10^{-4}: 70; 60 10^{-5}: 7; 6 NT: 6.8	10^{-3}:>300; >300 10^{-4}: 34; 39 10^{-5}: 3; 11 NC: 6.6	10^{-3}: 216; 229 10^{-4}: 24; 12 10^{-5}: 2; 2 10^{-6}: <1, <1 Nc: 6.3	10^{-0}: 10^{-1}: 10^{-2}: Nd : Nts : ME :	<1, <1 <1, <1 <1, <1 <1.0 <1 >5.3
Enterococcus hirae NCIMB 8192	10.0g/l Yeast extract and 10g/l bovine albumin	10^{-6}:>300, >300 10^{-7}: 146; 169 10^{-8}: 17; 16 N: 7.6	10^{-3}:>300, >300 10^{-4}:>300, >300 10^{-5}: 59; 82 NT: 7.9	10^{-3}:>300, >300 10^{-4}:>300, >300 10^{-5}: 47; 38 NC: 7.6	10^{-3}: >300, >300 10^{-4}:>300, >300 10^{-5}: 44; 43 Nc: 7.6	10^{-0}: 10^{-1}: 10^{-2}: Nd : Nts : ME :	<1, <1 <1, <1 <1, <1 <1.0 <1 >6.6
Pseudomonas aeruginosa ATCC 15442	10.0g/l Yeast extract and 10g/l bovine albumin	10^{-6}:>300, >300 10^{-7}: 220; 211 10^{-8}: 12, 16 N: 7.7	10^{-3}:>300, >300 10^{-4}:>300, >300 10^{-5}: 31; 48 NT: 7.6	10^{-3}:>300, >300 10^{-4}:>300, >300 10^{-5}: 34; 53 NC: 7.6	10^{-3}: >300, >300 10^{-4}:>300, >300 10^{-5}: 44; 40 Nc: 7.6	10^{-0}: 10^{-1}: 10^{-2}: Nd : Nts : ME :	<1, <1 <1, <1 <1, <1 <1.0 <1 >6.6

NOTE 1: The results relate only to the sample which was tested and cannot be guaranteed to represent the batch from which it was taken.

mgsLABORATORIES Microbiological Services and Consultancy				Doc No.	TRB-2010-024-01
Title	**EN 14349 (2007) Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary area on non-porous surfaces without mechanical action (Phase 2 / Step 2)**				
Product	**Virex**	MGS No	**19468**	SO No	**2315**

Test organisms	Interfering substance	Bacterial test suspension: N	Validation test: NT	Validation test: NC	Water control Nc		Test procedure at concentrations 1:200 Replicate 1	Replicate 2	Replicate 3
S. aureus ATCC 6538	10.0g/l Yeast extract and 10g/l bovine albumin	10^{-6}:>300, >300 10^{-7}: 172; 176 10^{-8}: 20, 12 N: 7.6	10^{-3}:>300, >300 10^{-4}:>300, >300 10^{-5}: 48; 53 NT: 7.7	10^{-3}:>300, >300 10^{-4}:>300, >300 10^{-5}: 42; 55 NC: 7.7	10^{-3}:>300, >300 10^{-4}:>300, >300 10^{-5}: 49; 46 Nc: 7.7	10^{-0} 10^{-1} 10^{-2} Nd Nts ME	>300; >300 >300; >300 >300; >300 >5.5 >300 <2.2	>300; >300 >300; >300 >300; >300 >5.5 >300 <2.2	>300; >300 >300; >300 >300; >300 >5.5 >300 <2.2

N = $\log_{10}$ number of cfu applied to test surface;
NT = $\log_{10}$ number of cfu per test surface of the neutralisation test;
NC = $\log_{10}$ number of cfu per test surface of the neutralisation control;
Nc = $\log_{10}$ number of cfu per test surface of the water control;
Nd = $\log_{10}$ number of cfu per test surface of the disinfectant test;
Nts = number of residual colony forming units remaining on the test surface;
ME = microbicidal effect

TEST REPORT

Determination of virucidal activity
Using British Standard prEN 14675

Department of Agriculture and Rural Development
www.dardni.gov.uk

a) Identification of the test Laboratory : **Virology Department, Veterinary Services Division, Stoney Road, Stormont, Belfast BT3 4SD, N. Ireland, U.K.**

b) Identification of the sample

Name of the product	:	Virex
Batch number	:	041050
Manufacturer	:	Kilco International, Broomhouses 2 Industrial Estate, Old Glasgow Road, Lockerbie, Dumfriesshire. UK
Date of delivery	:	21/10/04
Expiry date	:	21/10/06
Storage conditions	:	17-20°C out of direct sunlight
Active substance(s) and their concentrations	:	Potassium Peroxymonosulphate 50% [CAS 70693-62-8] Sodium Dichloroisocyanurate 2.5% [CAS 2893-78-9]

c) Experimental conditions

Period of analysis	:	03/03/05 – 14/03/05
Appearance of the product and its dilutions	:	Product - White powder with small purple particles. Dilutions – Clear solution (slightly cloudy at 2 %)
Product test concentrations	:	5 ml/l (0.5 %), 10 ml/l (1 %), 20ml/l (2 %)
Test temperature	:	10 °C ± 1 °C
Contact times	:	30 min ± 10 sec
Interfering substance	:	10g/l bovine albumin and 10g/l yeast extract
Product diluent	:	Hard water ($MgCl_2$, 19.48g/l; $CaCl_2$, 46.24g/l; $NaHCO_3$, 35.02g/l).
Stability of test mixture	:	Stable throughout
Temperature of incubation	:	15°C ± 1 °C
Viral strain used	:	**Bovine Enterovirus type 1 (strain VG/5/27)**

d) Test results

Titre of virus suspension	:	$10^{5.375}$ Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Maximum detectable virus inactivation	:	<10 Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Virus inactivation of the reference virus inactivation test after 30 minutes	:	Successful inactivation

e) Conclusion

According to prEN 14675 2003:E the sample of batch 041050 of the product VIREX possesses virucidal activity for the referenced strain of Bovine Enterovirus 1 (strain VG/5/27) virus at a concentration of 2.0 % (v/v) at 10 °C with a 30 minute contact time and under simulated high soiling conditions

f) Locality, date and identified signature

Location	:	Biocide Test Unit, Virology Department, Veterinary Sciences Division
Date	:	23/03/05

Test Personnel	Quality Control Manager	Test Director
Miss Marice Lunny	Mrs Mildred Wylie	Professor Brian Adair

INVESTOR IN PEOPLE

Department of Agriculture
Veterinary Sciences Division
Stoney Road, Stormont
Belfast BT4 3SD

TEST REPORT

Determination of virucidal activity
Using British Standard prEN 14675

Department of
Agriculture and
Rural Development
www.dardni.gov.uk

a) Identification of the test Laboratory : **Virology Department, Veterinary Services Division, Stoney Road, Stormont, Belfast BT3 4SD, N. Ireland, U.K.**

b) Identification of the sample

Name of the product	:	Virex
Batch number	:	041050
Manufacturer	:	Kilco International, Broomhouses 2 Industrial Estate, Old Glasgow Road, Lockerbie, Dumfriesshire. UK
Date of delivery	:	21/10/04
Expiry date	:	21/10/06
Storage conditions	:	17-20°C out of direct sunlight
Active substance(s) and their concentrations	:	Potassium Peroxymonosulphate 50% [CAS 70693-62-8] Sodium Dichloroisocyanurate 2.5% [CAS 2893-78-9]

c) Experimental conditions

Period of analysis	:	11/07/05-22/07/05
Appearance of the product and its dilutions	:	Product - White powder with small purple particles. Dilutions – Clear solution (slightly cloudy at 2 %)
Product test concentrations	:	5 ml/l (0.5 %), 10 ml/l (1 %), 20ml/l (2 %)
Test temperature	:	10 °C ± 1 °C
Contact times	:	30 min ± 10 sec
Interfering substance	:	10g/l bovine albumin and 10g/l yeast extract
Product diluent	:	Hard water ($MgCl_2$, 19.48g/l; $CaCl_2$, 46.24g/l; $NaHCO_3$, 35.02g/l).
Stability of test mixture	:	Stable throughout
Temperature of incubation	:	15°C ± 1 °C
Viral strain used	:	**Egg Drop Syndrome Virus (strain 127)**

d) Test results

Titre of virus suspension	:	$10^{7.25}$ Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Maximum detectable virus inactivation	:	<10 Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Virus inactivation of the reference virus inactivation test after 30 minutes	:	Successful inactivation

e) Conclusion

According to prEN 14675 2003:E the sample of batch 041050 of the product VIREX possesses virucidal activity for the referenced strain of Egg Drop Syndrome virus (strain 127) at a concentration of 1.0 % (v/v) at 10 °C with a 30 minute contact time and under simulated high soiling conditions

f) Locality, date and identified signature

Location	:	Biocide Test Unit, Virology Department, Veterinary Sciences Division
Date	:	03/08/05

Test Personnel	Quality Control Manager	Test Director
Miss Marice Lunny	Mrs Mildred Wylie	Professor Brian Adair

INVESTOR IN PEOPLE

Department of Agriculture
Veterinary Sciences Division
Stoney Road, Stormont
Belfast BT4 3SD

TEST REPORT

Determination of virucidal activity
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a) Identification of the test Laboratory : **Virology Department, Veterinary Services Division, Stoney Road, Stormont, Belfast BT3 4SD, N. Ireland, U.K.**

b) Identification of the sample

Name of the product	:	Virex
Batch number	:	041050
Manufacturer	:	Kilco International, Broomhouses 2 Industrial Estate, Old Glasgow Road, Lockerbie, Dumfriesshire. UK
Date of delivery	:	21/10/04
Expiry date	:	21/10/06
Storage conditions	:	17-20°C out of direct sunlight
Active substance(s) and their concentrations	:	Potassium Peroxymonosulphate 50% [CAS 70693-62-8] Sodium Dichloroisocyanurate 2.5% [CAS 2893-78-9]

c) Experimental conditions

Period of analysis	:	03/03/05 – 14/03/05
Appearance of the product and its dilutions	:	Product - White powder with small purple particles. Dilutions – Clear solution (slightly cloudy at 2 %)
Product test concentrations	:	5 ml/l (0.5 %), 10 ml/l (1 %), 20ml/l (2 %)
Test temperature	:	10 °C ± 1 °C
Contact times	:	30 min ± 10 sec
Interfering substance	:	10g/l bovine albumin and 10g/l yeast extract
Product diluent	:	Hard water ($MgCl_2$, 19.48g/l; $CaCl_2$, 46.24g/l; $NaHCO_3$, 35.02g/l).
Stability of test mixture	:	Stable throughout
Temperature of incubation	:	15°C ± 1 °C
Viral strain used	:	**Aujeszky's Disease Virus (strain NIA1)**

d) Test results

Titre of virus suspension	:	$10^{6.875}$ Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Maximum detectable virus inactivation	:	<10 Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Virus inactivation of the reference virus inactivation test after 30 minutes	:	Successful inactivation

e) Conclusion

According to prEN 14675 2003:E the sample of batch 041050 of the product VIREX possesses virucidal activity for the referenced strain of Aujeszky's Disease Virus (strain NIA1) at a concentration of 0.5 % (v/v) at 10 °C with a 30 minute contact time and under simulated high soiling conditions

f) Locality, date and identified signature

Location	:	Biocide Test Unit, Virology Department, Veterinary Sciences Division
Date	:	23/03/05

Test Personnel	Quality Control Manager	Test Director
Miss Marice Lunny	Mrs Mildred Wylie	Professor Brian Adair

INVESTOR IN PEOPLE

Department of Agriculture
Veterinary Sciences Division
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Belfast BT4 3SD

TEST REPORT

Determination of virucidal activity
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a) Identification of the test Laboratory : **Virology Department, Veterinary Services Division, Stoney Road, Stormont, Belfast BT3 4SD, N. Ireland, U.K.**

b) Identification of the sample

Name of the product	:	Virex
Batch number	:	041050
Manufacturer	:	Kilco International, Broomhouses 2 Industrial Estate, Old Glasgow Road, Lockerbie, Dumfriesshire. UK
Date of delivery	:	21/10/04
Expiry date	:	21/10/06
Storage conditions	:	17-20°C out of direct sunlight
Active substance(s) and their concentrations	:	Potassium Peroxymonosulphate 50% [CAS 70693-62-8] Sodium Dichloroisocyanurate 2.5% [CAS 2893-78-9]

c) Experimental conditions

Period of analysis	:	18/07/05 – 31/08/05
Appearance of the product and its dilutions	:	Product - White powder with small purple particles. Dilutions – Clear solution (slightly cloudy at 2 %)
Product test concentrations	:	5 ml/l (0.5 %), 10 ml/l (1 %), 20ml/l (2 %)
Test temperature	:	10 °C ± 1 °C
Contact times	:	30 min ± 10 sec
Interfering substance	:	10g/l bovine albumin and 10g/l yeast extract
Product diluent	:	Hard water ($MgCl_2$, 19.48g/l; $CaCl_2$, 46.24g/l; $NaHCO_3$, 35.02g/l).
Stability of test mixture	:	Stable throughout
Temperature of incubation	:	15°C ± 1 °C
Viral strain used	:	**Avian Influenza (A/Turkey/Eng/N28/73)(H5N1)**

d) Test results

Titre of virus suspension	:	$10^{4.5}$ Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Maximum detectable virus inactivation	:	<10 Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Virus inactivation of the reference virus inactivation test after 30 minutes	:	Successful inactivation

e) Conclusion

According to prEN 14675 2003:E the sample of batch 041050 of the product VIREX possesses virucidal activity for the referenced strain Avian Influenza virus (A/Turkey/Eng/N28/73)(H5 N1) at a concentration of 1% (v/v) at 10 °C with a 30 minute contact time and under simulated high soiling conditions.

f) Locality, date and identified signature

Location	:	Biocide Test Unit, Virology Department, Veterinary Sciences Division
Date	:	09/08/05

Test Personnel	Quality Control Manager	Test Director
Mr John Murphy	Mrs Mildred Wylie	Professor Brian Adair

INVESTOR IN PEOPLE

Department of Agriculture
Veterinary Sciences Division
Stoney Road Stormont
Belfast BT4 3SD

TEST REPORT

Determination of virucidal activity
Using British Standard prEN 14675

Department of
Agriculture and
Rural Development
www.dardni.gov.uk

a) Identification of the test Laboratory : **Virology Department, Veterinary Services Division, Stoney Road, Stormont, Belfast BT3 4SD, N. Ireland, U.K.**

b) Identification of the sample

Name of the product	:	Virex
Batch number	:	041050
Manufacturer	:	Kilco International, Broomhouses 2 Industrial Estate, Old Glasgow Road, Lockerbie, Dumfriesshire. UK
Date of delivery	:	21/10/04
Expiry date	:	21/10/06
Storage conditions	:	17-20°C out of direct sunlight
Active substance(s) and their concentrations	:	Potassium Peroxymonosulphate 50% [CAS 70693-62-8] Sodium Dichloroisocyanurate 2.5% [CAS 2893-78-9]

c) Experimental conditions

Period of analysis	:	01/12/05 – 12/12/05
Appearance of the product and its dilutions	:	Product - White powder with small purple particles. Dilutions – Clear solution (slightly cloudy at 2 %)
Product test concentrations	:	5 ml/l (0.5 %), 10 ml/l (1 %), 20ml/l (2 %)
Test temperature	:	10 °C ± 1 °C
Contact times	:	30 min ± 10 sec
Interfering substance	:	10g/l bovine albumin and 10g/l yeast extract
Product diluent	:	Hard water ($MgCl_2$, 19.48g/l; $CaCl_2$, 46.24g/l; $NaHCO_3$, 35.02g/l).
Stability of test mixture	:	Stable throughout
Temperature of incubation	:	15°C ± 1 °C
Viral strain used	:	**Avian Reovirus (Uchida strain)**

d) Test results

Titre of virus suspension	:	$10^{5.750}$ Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Maximum detectable virus inactivation	:	$10^{1.750}$ Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Virus inactivation of the reference virus inactivation test after 30 minutes	:	Successful inactivation

e) Conclusion

According to prEN 14675 2003:E the sample of batch 041050 of the product VIREX possesses virucidal activity for the referenced strain of Avian Reovirus at a concentration of 0.5 % (v/v) at 10 °C with a 30 minute contact time and under simulated high soiling conditions

f) Locality, date and identified signature

Location	:	Biocide Test Unit, Virology Department, Veterinary Sciences Division
Date	:	23/01/06

Test Personnel	Quality Control Manager	Test Director
A J Tanner	M Wylie	
Miss Arlene Tanner	Mrs Mildred Wylie	Professor Brian Adair

INVESTOR IN PEOPLE

Department of Agriculture
Veterinary Sciences Division
Stoney Road, Stormont
Belfast BT4 3SD

TEST REPORT

Determination of virucidal activity
Using British Standard prEN 14675

Department of
Agriculture and
Rural Development
www.dardni.gov.uk

a) Identification of the test Laboratory : **Virology Department, Veterinary Services Division, Stoney Road, Stormont, Belfast BT3 4SD, N. Ireland, U.K.**

b) Identification of the sample

Name of the product	:	Virex
Batch number	:	041050
Manufacturer	:	Kilco International, Broomhouses 2 Industrial Estate, Old Glasgow Road, Lockerbie, Dumfriesshire. UK
Date of delivery	:	21/10/04
Expiry date	:	21/10/06
Storage conditions	:	17-20°C out of direct sunlight
Active substance(s) and their concentrations	:	Potassium Peroxymonosulphate 50% [CAS 70693-62-8] Sodium Dichloroisocyanurate 2.5% [CAS 2893-78-9]

c) Experimental conditions

Period of analysis	:	03/03/05 – 14/03/05
Appearance of the product and its dilutions	:	Product - White powder with small purple particles. Dilutions – Clear solution (slightly cloudy at 2 %)
Product test concentrations	:	5 ml/l (0.5 %), 10 ml/l (1 %), 20ml/l (2 %)
Test temperature	:	10 °C ± 1 °C
Contact times	:	30 min ± 10 sec
Interfering substance	:	10g/l bovine albumin and 10g/l yeast extract
Product diluent	:	Hard water ($MgCl_2$, 19.48g/l; $CaCl_2$, 46.24g/l; $NaHCO_3$, 35.02g/l).
Stability of test mixture	:	Stable throughout
Temperature of incubation	:	15°C ± 1 °C
Viral strain used	:	**Bovine parainfluenza type 3 virus (strain 125)**

d) Test results

Titre of virus suspension	:	$10^{5.375}$ Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Maximum detectable virus inactivation	:	<10 Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Virus inactivation of the reference virus inactivation test after 30 minutes	:	Successful inactivation

e) Conclusion

According to prEN 14675 2003:E the sample of batch 041050 of the product VIREX possesses virucidal activity for the referenced strain of bovine parainfluenza type 3 virus (strain 125) at a concentration of 0.5 % (v/v) at 10 °C with a 30 minute contact time and under simulated high soiling conditions

f) Locality, date and identified signature

Location	:	Biocide Test Unit, Virology Department, Veterinary Sciences Division
Date	:	23/03/05

Test Personnel	Quality Control Manager	Test Director
Miss Marice Lunny	Mrs Mildred Wylie	Professor Brian Adair

INVESTOR IN PEOPLE

Department of Agriculture
Veterinary Sciences Division
Stoney Road, Stormont
Belfast BT4 3SD

TEST REPORT

Determination of virucidal activity
Using British Standard prEN 14675

Department of
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a) Identification of the test Laboratory : **Virology Department, Veterinary Services Division, Stoney Road, Stormont, Belfast BT3 4SD, N. Ireland, U.K.**

b) Identification of the sample

Name of the product	:	Virex
Batch number	:	041050
Manufacturer	:	Kilco International, Broomhouses 2 Industrial Estate, Old Glasgow Road, Lockerbie, Dumfriesshire. UK
Date of delivery	:	21/10/04
Expiry date	:	21/10/06
Storage conditions	:	17-20°C out of direct sunlight
Active substance(s) and their concentrations	:	Potassium Peroxymonosulphate 50% [CAS 70693-62-8] Sodium Dichloroisocyanurate 2.5% [CAS 2893-78-9]

c) Experimental conditions

Period of analysis	:	03/03/05 – 14/03/05
Appearance of the product and its dilutions	:	Product - White powder with small purple particles. Dilutions – Clear solution (slightly cloudy at 2 %)
Product test concentrations	:	5 ml/l (0.5 %), 10 ml/l (1 %), 20ml/l (2 %)
Test temperature	:	10 °C ± 1 °C
Contact times	:	30 min ± 10 sec
Interfering substance	:	10g/l bovine albumin and 10g/l yeast extract
Product diluent	:	Hard water ($MgCl_2$, 19.48g/l; $CaCl_2$, 46.24g/l; $NaHCO_3$, 35.02g/l).
Stability of test mixture	:	Stable throughout
Temperature of incubation	:	15°C ± 1 °C
Viral strain used	:	**Bovine viral diarrhoea (BVD) virus (strain NADL)**

d) Test results

Titre of virus suspension	:	$10^{4.5}$ Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Maximum detectable virus inactivation	:	<10 Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Virus inactivation of the reference virus inactivation test after 30 minutes	:	Successful inactivation

e) Conclusion

According to prEN 14675 2003:E the sample of batch 041050 of the product VIREX possesses virucidal activity for the referenced strain of Bovine Viral Diarrhoea (BVD) virus (strain NADL) at a concentration of 0.5 % (v/v) at 10 °C with a 30 minute contact time and under simulated high soiling conditions

f) Locality, date and identified signature

Location	:	Biocide Test Unit, Virology Department, Veterinary Sciences Division
Date	:	23/03/05

Test Personnel	Quality Control Manager	Test Director
Miss Marice Lunny	Mrs Mildred Wylie	Professor Brian Adair

Department of Agriculture
Veterinary Sciences Division
Stoney Road, Stormont
Belfast BT4 3SD

INVESTOR IN PEOPLE

TEST REPORT

Determination of virucidal activity
Using British Standard prEN 14675

Department of
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a) Identification of the test Laboratory : **Virology Department, Veterinary Services Division, Stoney Road, Stormont, Belfast BT3 4SD, N. Ireland, U.K.**

b) Identification of the sample

Name of the product	:	**Virex**
Batch number	:	041050
Manufacturer	:	Kilco International, Broomhouses 2 Industrial Estate, Old Glasgow Road, Lockerbie, Dumfriesshire. UK
Date of delivery	:	21/10/04
Expiry date	:	21/10/06
Storage conditions	:	17-20°C out of direct sunlight
Active substance(s) and their concentrations	:	Potassium Peroxymonosulphate 50% [CAS 70693-62-8] Sodium Dichloroisocyanurate 2.5% [CAS 2893-78-9]

c) Experimental conditions

Period of analysis	:	01/08/06 – 31/08/06
Appearance of the product and its dilutions	:	Product - White powder with small purple particles. Dilutions – Clear solution (slightly cloudy at 2 %)
Product test concentrations	:	5 ml/l (0.5 %), 10 ml/l (1 %), 20ml/l (2 %)
Test temperature	:	10 °C ± 1 °C
Contact times	:	30 min ± 10 sec
Interfering substance	:	10g/l bovine albumin and 10g/l yeast extract
Product diluent	:	Hard water ($MgCl_2$, 19.48g/l; $CaCl_2$, 46.24g/l; $NaHCO_3$, 35.02g/l).
Stability of test mixture	:	Stable throughout
Temperature of incubation	:	15°C ± 1 °C
Viral strain used	:	**Chicken Anaemia Virus (strain Cux)**

d) Test results

Titre of virus suspension	:	$10^{6.000}$ Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Maximum detectable virus inactivation	:	<10 Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Virus inactivation of the reference virus inactivation test after 30 minutes	:	Successful inactivation

e) Conclusion

According to prEN 14675 2003:E the sample of batch 041050 of the product VIREX possesses virucidal activity for the referenced strain of Chicken Anaemia Virus at a concentration of 0.5% (v/v) at 10 °C with a 30 minute contact time and under simulated high soiling conditions

f) Locality, date and identified signature

Location	:	Biocide Test Unit, Virology Department, Veterinary Sciences Division
Date	:	01/09/06

Test Personnel	Quality Control Manager	Test Director
P.P. E. McNeilly		
Miss Arlene Tanner	Mrs Mildred Wylie	Professor Brian Adair

INVESTOR IN PEOPLE

Department of Agriculture
Veterinary Sciences Division
Stoney Road, Stormont
Belfast BT4 3SD

TEST REPORT

Determination of virucidal activity
Using British Standard prEN 14675

Department of
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a) Identification of the test Laboratory : **Virology Department, Veterinary Services Division, Stoney Road, Stormont, Belfast BT3 4SD, N. Ireland, U.K.**

b) Identification of the sample

Name of the product	:	Virex
Batch number	:	041050
Manufacturer	:	Kilco International, Broomhouses 2 Industrial Estate, Old Glasgow Road, Lockerbie, Dumfriesshire. UK
Date of delivery	:	21/10/04
Expiry date	:	21/10/06
Storage conditions	:	17-20°C out of direct sunlight
Active substance(s) and their concentrations	:	Potassium Peroxymonosulphate 50% [CAS 70693-62-8] Sodium Dichloroisocyanurate 2.5% [CAS 2893-78-9]

c) Experimental conditions

Period of analysis	:	03/03/05 – 14/03/05
Appearance of the product and its dilutions	:	Product - White powder with small purple particles. Dilutions – Clear solution (slightly cloudy at 2 %)
Product test concentrations	:	5 ml/l (0.5 %), 10 ml/l (1 %), 20ml/l (2 %)
Test temperature	:	10 °C ± 1 °C
Contact times	:	30 min ± 10 sec
Interfering substance	:	10g/l bovine albumin and 10g/l yeast extract
Product diluent	:	Hard water ($MgCl_2$, 19.48g/l; $CaCl_2$, 46.24g/l; $NaHCO_3$, 35.02g/l).
Stability of test mixture	:	Stable throughout
Temperature of incubation	:	15°C ± 1 °C
Viral strain used	:	**Feline Calicivirus (FeCV) strain F9**

d) Test results

Titre of virus suspension	:	$10^{5.125}$ Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Maximum detectable virus inactivation	:	$10^{1.625}$ Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Virus inactivation of the reference virus inactivation test after 30 minutes	:	Successful inactivation

e) Conclusion

According to prEN 14675 2003:E the sample of batch 041050 of the product VIREX possesses virucidal activity for the referenced strain of Feline Calicivirus (FeCV) strain F9 at a concentration of 0.5 % (v/v) at 10 °C with a 30 minute contact time and under simulated high soiling conditions

f) Locality, date and identified signature

Location	:	Biocide Test Unit, Virology Department, Veterinary Sciences Division
Date	:	23/03/05

Test Personnel	Quality Control Manager	Test Director
Miss Marice Lunny	Mrs Mildred Wylie	Professor Brian Adair

INVESTOR IN PEOPLE

Department of Agriculture
Veterinary Sciences Division
Stoney Road, Stormont
Belfast BT4 3SD

TEST REPORT

Determination of virucidal activity
Using British Standard prEN 14675

Department of
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Rural Development
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a) Identification of the test Laboratory : **Virology Department, Veterinary Services Division, Stoney Road, Stormont, Belfast BT3 4SD, N. Ireland, U.K.**

b) Identification of the sample

Name of the product	:	Virex
Batch number	:	041050
Manufacturer	:	Kilco International, Broomhouses 2 Industrial Estate, Old Glasgow Road, Lockerbie, Dumfriesshire. UK
Date of delivery	:	21/10/04
Expiry date	:	21/10/06
Storage conditions	:	17-20°C out of direct sunlight
Active substance(s) and their concentrations	:	Potassium Peroxymonosulphate 50% [CAS 70693-62-8] Sodium Dichloroisocyanurate 2.5% [CAS 2893-78-9]

c) Experimental conditions

Period of analysis	:	03/03/05 – 14/03/05
Appearance of the product and its dilutions	:	Product - White powder with small purple particles. Dilutions – Clear solution (slightly cloudy at 2 %)
Product test concentrations	:	5 ml/l (0.5 %), 10 ml/l (1 %), 20ml/l (2 %)
Test temperature	:	10 °C ± 1 °C
Contact times	:	30 min ± 10 sec
Interfering substance	:	10g/l bovine albumin and 10g/l yeast extract
Product diluent	:	Hard water ($MgCl_2$, 19.48g/l; $CaCl_2$, 46.24g/l; $NaHCO_3$, 35.02g/l).
Stability of test mixture	:	Stable throughout
Temperature of incubation	:	15°C ± 1 °C
Viral strain used	:	**Infectious Bursal Disease Virus (IBDV) (strain G13)**

d) Test results

Titre of virus suspension	:	10^{635} Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Maximum detectable virus inactivation	:	$10^{1.625}$ Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Virus inactivation of the reference virus inactivation test after 30 minutes	:	Successful inactivation

e) Conclusion

According to prEN 14675 2003:E the sample of batch 041050 of the product VIREX possesses virucidal activity for the referenced strain of Infectious Bursal Disease Virus (IBDV) virus (strain G13) at a concentration of 0.5 % (v/v) at 10 °C with a 30 minute contact time and under simulated high soiling conditions

f) Locality, date and identified signature

Location	:	Biocide Test Unit, Virology Department, Veterinary Sciences Division
Date	:	21/04/05

Test Personnel	Quality Control Manager	Test Director
Miss Marice Lunny	Mrs Mildred Wylie	Professor Brian Adair

INVESTOR IN PEOPLE

Department of Agriculture
Veterinary Sciences Division
Stoney Road, Stormont
Belfast BT4 3SD

TEST REPORT

Determination of virucidal activity
Using British Standard prEN 14675

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a) Identification of the test Laboratory : **Virology Department, Veterinary Services Division, Stoney Road, Stormont, Belfast BT3 4SD, N. Ireland, U.K.**

b) Identification of the sample

Name of the product	:	Virex
Batch number	:	041050
Manufacturer	:	Kilco International, Broomhouses 2 Industrial Estate, Old Glasgow Road, Lockerbie, Dumfriesshire. UK
Date of delivery	:	21/10/04
Expiry date	:	21/10/06
Storage conditions	:	17-20°C out of direct sunlight
Active substance(s) and their concentrations	:	Potassium Peroxymonosulphate 50% [CAS 70693-62-8] Sodium Dichloroisocyanurate 2.5% [CAS 2893-78-9]

c) Experimental conditions

Period of analysis	:	03/03/05 – 14/03/05
Appearance of the product and its dilutions	:	Product - White powder with small purple particles. Dilutions – Clear solution (slightly cloudy at 2 %)
Product test concentrations	:	5 ml/l (0.5 %), 10 ml/l (1 %), 20ml/l (2 %)
Test temperature	:	10 °C ± 1 °C
Contact times	:	30 min ± 10 sec
Interfering substance	:	10g/l bovine albumin and 10g/l yeast extract
Product diluent	:	Hard water ($MgCl_2$, 19.48g/l; $CaCl_2$, 46.24g/l; $NaHCO_3$, 35.02g/l).
Stability of test mixture	:	Stable throughout
Temperature of incubation	:	15°C ± 1 °C
Viral strain used	:	**Infectious Bovine Rhinotracheitis (IBR) virus (JCF strain)**

d) Test results

Titre of virus suspension	:	$10^{7.0}$ Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Maximum detectable virus inactivation	:	$10^{1.625}$ Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Virus inactivation of the reference virus inactivation test after 30 minutes	:	Successful inactivation

e) Conclusion

According to prEN 14675 2003:E the sample of batch 041050 of the product VIREX possesses virucidal activity for the referenced strain of Infectious Bovine Rhinotracheitis (IBR) virus (JCF strain) at a concentration of 0.5 % (v/v) at 10 °C with a 30 minute contact time and under simulated high soiling conditions

f) Locality, date and identified signature

Location	:	Biocide Test Unit, Virology Department, Veterinary Sciences Division
Date	:	23/03/05

Test Personnel	Quality Control Manager	Test Director
Miss Marice Lunny	Mrs Mildred Wylie	Professor Brian Adair

INVESTOR IN PEOPLE

Department of Agriculture
Veterinary Sciences Division
Stoney Road, Stormont
Belfast BT4 3SD

TEST REPORT

Determination of virucidal activity
Using British Standard prEN 14675

Department of
Agriculture and
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a) Identification of the test Laboratory	:	**Virology Department, Veterinary Services Division, Stoney Road, Stormont, Belfast BT3 4SD, N. Ireland, U.K.**

b) Identification of the sample

Name of the product	:	Virex
Batch number	:	041050
Manufacturer	:	Kilco International, Broomhouses 2 Industrial Estate, Old Glasgow Road, Lockerbie, Dumfriesshire. UK
Date of delivery	:	21/10/04
Expiry date	:	21/10/06
Storage conditions	:	17-20°C out of direct sunlight
Active substance(s) and their concentrations	:	Potassium Peroxymonosulphate 50% [CAS 70693-62-8] Sodium Dichloroisocyanurate 2.5% [CAS 2893-78-9]

c) Experimental conditions

Period of analysis	:	03/03/05 – 14/03/05
Appearance of the product and its dilutions	:	Product - White powder with small purple particles. Dilutions – Clear solution (slightly cloudy at 2 %)
Product test concentrations	:	5 ml/l (0.5 %), 10 ml/l (1 %), 20ml/l (2 %)
Test temperature	:	4 °C ± 1 °C
Contact times	:	30 min ± 10 sec
Interfering substance	:	10g/l bovine albumin and 10g/l yeast extract
Product diluent	:	Hard water ($MgCl_2$, 19.48g/l; $CaCl_2$, 46.24g/l; $NaHCO_3$, 35.02g/l).
Stability of test mixture	:	Stable throughout
Temperature of incubation	:	4°C ± 1 °C
Viral strain used	:	**Infectious Pancreatic Necrosis (IPN) virus (strain A2, Sp)**

d) Test results

Titre of virus suspension	:	$10^{6.875}$ Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Maximum detectable virus inactivation	:	$10^{2.5}$ Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Virus inactivation of the reference virus inactivation test after 30 minutes	:	Successful inactivation

e) Conclusion

According to prEN 14675 2003:E the sample of batch 041050 of the product VIREX possesses virucidal activity for the referenced strain of Infectious Pancreatic Necrosis (IPN) virus (strain A2, Sp)at a concentration of 0.5% (v/v) at 10 °C with a 30 minute contact time and under simulated high soiling conditions

f) Locality, date and identified signature

Location	:	Biocide Test Unit, Virology Department, Veterinary Sciences Division
Date	:	21/04/05

Test Personnel	Quality Control Manager	Test Director
Miss Marice Lunny	Mrs Mildred Wylie	Professor Brian Adair

INVESTOR IN PEOPLE

Department of Agriculture
Veterinary Sciences Division
Stoney Road, Stormont
Belfast BT4 3SD

TEST REPORT

Determination of virucidal activity
Using British Standard prEN 14675

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Agriculture and
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a) Identification of the test Laboratory : **Virology Department, Veterinary Services Division, Stoney Road, Stormont, Belfast BT3 4SD, N. Ireland, U.K.**

b) Identification of the sample

Name of the product	:	Virex
Batch number	:	041050
Manufacturer	:	Kilco International, Broomhouses 2 Industrial Estate, Old Glasgow Road, Lockerbie, Dumfriesshire. UK
Date of delivery	:	21/10/04
Expiry date	:	21/10/06
Storage conditions	:	17-20°C out of direct sunlight
Active substance(s) and their concentrations	:	Potassium Peroxymonosulphate 50% [CAS 70693-62-8] Sodium Dichloroisocyanurate 2.5% [CAS 2893-78-9]

c) Experimental conditions

Period of analysis	:	03/03/05 – 14/03/05
Appearance of the product and its dilutions	:	Product - White powder with small purple particles. Dilutions – Clear solution (slightly cloudy at 2 %)
Product test concentrations	:	5 ml/l (0.5 %), 10 ml/l (1 %), 20ml/l (2 %)
Test temperature	:	10 °C ± 1 °C
Contact times	:	30 min ± 10 sec
Interfering substance	:	10g/l bovine albumin and 10g/l yeast extract
Product diluent	:	Hard water ($MgCl_2$, 19.48g/l; $CaCl_2$, 46.24g/l; $NaHCO_3$, 35.02g/l).
Stability of test mixture	:	Stable throughout
Temperature of incubation	:	15°C ± 1 °C
Viral strain used	:	**Infectious Pancreatic Necrosis (IPN) virus (strain A2, Sp)**

d) Test results

Titre of virus suspension	:	$10^{6.875}$ Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Maximum detectable virus inactivation	:	$10^{2.5}$ Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Virus inactivation of the reference virus inactivation test after 30 minutes	:	Successful inactivation

e) Conclusion

According to prEN 14675 2003:E the sample of batch 041050 of the product VIREX possesses virucidal activity for the referenced strain of Infectious Pancreatic Necrosis (IPN) virus (strain A2, Sp)at a concentration of 0.5% (v/v) at 10 °C with a 30 minute contact time and under simulated high soiling conditions

f) Locality, date and identified signature

Location	:	Biocide Test Unit, Virology Department, Veterinary Sciences Division
Date	:	21/04/05

Test Personnel	Quality Control Manager	Test Director
Miss Marice Lundy	Mrs Mildred Wylie	Professor Brian Adair

INVESTOR IN PEOPLE

Department of Agriculture
Veterinary Sciences Division
Stoney Road, Stormont
Belfast BT4 3SD

TEST REPORT

Determination of virucidal activity
Using British Standard prEN 14675

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a) Identification of the test Laboratory : **Virology Department, Veterinary Services Division, Stoney Road, Stormont, Belfast BT3 4SD, N. Ireland, U.K.**

b) Identification of the sample

Name of the product	:	Virex
Batch number	:	041050
Manufacturer	:	Kilco International, Broomhouses 2 Industrial Estate, Old Glasgow Road, Lockerbie, Dumfriesshire. UK
Date of delivery	:	21/10/04
Expiry date	:	21/10/06
Storage conditions	:	17-20°C out of direct sunlight
Active substance(s) and their concentrations	:	Potassium Peroxymonosulphate 50% [CAS 70693-62-8] Sodium Dichloroisocyanurate 2.5% [CAS 2893-78-9]

c) Experimental conditions

Period of analysis	:	18/07/05 – 05/08/05
Appearance of the product and its dilutions	:	Product - White powder with small purple particles. Dilutions – Clear solution (slightly cloudy at 2 %)
Product test concentrations	:	5 ml/l (0.5 %), 10 ml/l (1 %), 20ml/l (2 %)
Test temperature	:	10 °C ± 1 °C
Contact times	:	30 min ± 10 sec
Interfering substance	:	10g/l bovine albumin and 10g/l yeast extract
Product diluent	:	Hard water ($MgCl_2$, 19.48g/l; $CaCl_2$, 46.24g/l; $NaHCO_3$, 35.02g/l).
Stability of test mixture	:	Stable throughout
Temperature of incubation	:	15°C ± 1 °C
Viral strain used	:	**Porcine circovirus type 2 (strain 1010)**

d) Test results

Titre of virus suspension	:	$10^{5.5}$ Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Maximum detectable virus inactivation	:	<10 Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Virus inactivation of the reference virus inactivation test after 30 minutes	:	Successful inactivation

e) Conclusion

According to prEN 14675 2003:E the sample of batch 041050 of the product VIREX possesses virucidal activity for the referenced strain Porcine Circovirus type 2 (strain 1010) at a concentration of 1% (v/v) at 10 °C with a 30 minute contact time and under simulated high soiling conditions.

f) Locality, date and identified signature

Location	:	Biocide Test Unit, Virology Department, Veterinary Sciences Division
Date	:	09/08/05

Test Personnel
Miss Marice Lunny

Quality Control Manager
Mrs Mildred Wylie

Test Director
Professor Brian Adair

INVESTOR IN PEOPLE

Department of Agriculture
Veterinary Sciences Division
Stoney Road, Stormont
Belfast BT4 3SD

TEST REPORT

Determination of virucidal activity
Using British Standard prEN 14675

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a) Identification of the test Laboratory : **Virology Department, Veterinary Services Division, Stoney Road, Stormont, Belfast BT3 4SD, N. Ireland, U.K.**

b) Identification of the sample

Name of the product	:	Virex
Batch number	:	041050
Manufacturer	:	Kilco International, Broomhouses 2 Industrial Estate, Old Glasgow Road, Lockerbie, Dumfriesshire. UK
Date of delivery	:	21/10/04
Expiry date	:	21/10/06
Storage conditions	:	17-20°C out of direct sunlight
Active substance(s) and their concentrations	:	Potassium Peroxymonosulphate 50% [CAS 70693-62-8] Sodium Dichloroisocyanurate 2.5% [CAS 2893-78-9]

c) Experimental conditions

Period of analysis	:	01/12/05 – 12/12/05
Appearance of the product and its dilutions	:	Product - White powder with small purple particles. Dilutions – Clear solution (slightly cloudy at 2 %)
Product test concentrations	:	5 ml/l (0.5 %), 10 ml/l (1 %), 20ml/l (2 %)
Test temperature	:	10 °C ± 1 °C
Contact times	:	30 min ± 10 sec
Interfering substance	:	10g/l bovine albumin and 10g/l yeast extract
Product diluent	:	Hard water ($MgCl_2$, 19.48g/l; $CaCl_2$, 46.24g/l; $NaHCO_3$, 35.02g/l).
Stability of test mixture	:	Stable throughout
Temperature of incubation	:	15°C ± 1 °C
Viral strain used	:	**Porcine Parvovirus (strain 59E)**

d) Test results

Titre of virus suspension	:	$10^{6.250}$ Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Maximum detectable virus inactivation	:	<10 Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Virus inactivation of the reference virus inactivation test after 30 minutes	:	Successful inactivation

e) Conclusion

According to prEN 14675 2003:E the sample of batch 041050 of the product VIREX possesses virucidal activity for the referenced strain of Porcine Parvovirus at a concentration of 0.5 % (v/v) at 10 °C with a 30 minute contact time and under simulated high soiling conditions

f) Locality, date and identified signature

Location	:	Biocide Test Unit, Virology Department, Veterinary Sciences Division
Date	:	23/01/06

Test Personnel	Quality Control Manager	Test Director
A J Tanner	M Wylie	
Miss Arlene Tanner	Mrs Mildred Wylie	Professor Brian Adair

INVESTOR IN PEOPLE

Department of Agriculture
Veterinary Sciences Division
Stoney Road, Stormont
Belfast BT4 3SD

TEST REPORT

Determination of virucidal activity
Using British Standard prEN 14675

Department of
Agriculture and
Rural Development
www.dardni.gov.uk

a) Identification of the test Laboratory : **Virology Department, Veterinary Services Division, Stoney Road, Stormont, Belfast BT3 4SD, N. Ireland, U.K.**

b) Identification of the sample

Name of the product	:	Virex
Batch number	:	041050
Manufacturer	:	Kilco International, Broomhouses 2 Industrial Estate, Old Glasgow Road, Lockerbie, Dumfriesshire. UK
Date of delivery	:	21/10/04
Expiry date	:	21/10/06
Storage conditions	:	17-20°C out of direct sunlight
Active substance(s) and their concentrations	:	Potassium Peroxymonosulphate 50% [CAS 70693-62-8] Sodium Dichloroisocyanurate 2.5% [CAS 2893-78-9]

c) Experimental conditions

Period of analysis	:	03/03/05 – 14/03/05
Appearance of the product and its dilutions	:	Product - White powder with small purple particles. Dilutions – Clear solution (slightly cloudy at 2 %)
Product test concentrations	:	5 ml/l (0.5 %), 10 ml/l (1 %), 20ml/l (2 %)
Test temperature	:	10 °C ± 1 °C
Contact times	:	30 min ± 10 sec
Interfering substance	:	10g/l bovine albumin and 10g/l yeast extract
Product diluent	:	Hard water ($MgCl_2$, 19.48g/l; $CaCl_2$, 46.24g/l; $NaHCO_3$, 35.02g/l).
Stability of test mixture	:	Stable throughout
Temperature of incubation	:	15°C ± 1 °C
Viral strain used	:	**Porcine Respiratory & Reproductive Syndrome (PRRS) virus (Lleystad strain)**

d) Test results

Titre of virus suspension	:	$10^{6.375}$ Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Maximum detectable virus inactivation	:	<10 Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Virus inactivation of the reference virus inactivation test after 30 minutes	:	Successful inactivation

e) Conclusion

According to prEN 14675 2003:E the sample of batch 041050 of the product VIREX possesses virucidal activity for the referenced strain of Porcine Respiratory & Reproductive Syndrome (PRRS) virus (Lelystad strain) at a concentration of 0.2 % (v/v) at 10 °C with a 30 minute contact time and under simulated high soiling conditions

f) Locality, date and identified signature

Location : Biocide Test Unit, Virology Department, Veterinary Sciences Division

Date :

Test Personnel	Quality Control Manager	Test Director
Miss Marice Lunny	Mrs Mildred Wylie	Professor Brian Adair

INVESTOR IN PEOPLE

Department of Agriculture
Veterinary Sciences Division
Stoney Road, Stormont
Belfast BT4 3SD

TEST REPORT

Determination of virucidal activity
Using British Standard prEN 14675

Department of
Agriculture and
Rural Development
www.dardni.gov.uk

a) Identification of the test Laboratory : **Virology Department, Veterinary Services Division, Stoney Road, Stormont, Belfast BT3 4SD, N. Ireland, U.K.**

b) Identification of the sample

Name of the product	:	**Virex**
Batch number	:	041050
Manufacturer	:	Kilco International, Broomhouses 2 Industrial Estate, Old Glasgow Road, Lockerbie, Dumfriesshire. UK
Date of delivery	:	21/10/04
Expiry date	:	21/10/06
Storage conditions	:	17-20°C out of direct sunlight
Active substance(s) and their concentrations	:	Potassium Peroxymonosulphate 50% [CAS 70693-62-8] Sodium Dichloroisocyanurate 2.5% [CAS 2893-78-9]

c) Experimental conditions

Period of analysis	:	01/07/06 – 28/07/06
Appearance of the product and its dilutions	:	Product - White powder with small purple particles. Dilutions – Clear solution (slightly cloudy at 2 %)
Product test concentrations	:	5 ml/l (0.5 %), 10 ml/l (1 %), 20ml/l (2 %)
Test temperature	:	10 °C ± 1 °C
Contact times	:	30 min ± 10 sec
Interfering substance	:	10g/l bovine albumin and 10g/l yeast extract
Product diluent	:	Hard water ($MgCl_2$, 19.48g/l; $CaCl_2$, 46.24g/l; $NaHCO_3$, 35.02g/l).
Stability of test mixture	:	Stable throughout
Temperature of incubation	:	15°C ± 1 °C
Viral strain used	:	**Teschen virus (strain F65)**

d) Test results

Titre of virus suspension	:	$10^{6.500}$ Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Maximum detectable virus inactivation	:	<10 Tissue Culture Infectious Doses 50% ($TCID_{50}$)
Virus inactivation of the reference virus inactivation test after 30 minutes	:	Successful inactivation

e) Conclusion

According to prEN 14675 2003:E the sample of batch 041050 of the product VIREX possesses virucidal activity for the referenced strain of Teschen virus at a concentration of 2.0% (v/v) at 10 °C with a 30 minute contact time and under simulated high soiling conditions

f) Locality, date and identified signature

Location	:	Biocide Test Unit, Virology Department, Veterinary Sciences Division
Date	:	02/08/06

Test Personnel	Quality Control Manager	Test Director
A B J Tanner	M Wylie	
Miss Arlene Tanner	Mrs Mildred Wylie	Professor Brian Adair

Department of Agriculture
Veterinary Sciences Division
Stoney Road, Stormont
Belfast BT4 3SD

INVESTOR IN PEOPLE

Sponsor : HYPRED

TEST REPORT

DETERMINATION OF THE VIRUCIDAL ACTIVTY OF THE VIREX PRODUCT ACCORDING TO THE EN 14675 STANDARD

Delivered to : **Ms BOISUMEAU**

For : **HYPRED SAS**
55 BD JULES VERGER
35 800 DINARD

Date of request: 03/12/2020

Study references: n°064D15-2020-01 / order n°CF-171499

VIRUCIDAL TESTS:

According to the NF EN 14675 standard (May 2015) – Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the veterinary area — Test method and requirements (Phase 2, step 1)

Tests using the VIREX product batch n°20020117 against the enteric cytopathogenic bovine orphan virus (ECBO virus).

This test report included 11 pages.

Study completion date: 06/18/2020

Stephanie MOROT-BIZOT
PhD in microbiology
Study director

SUMMARY

Rédacteur	Superviseur
Mme Emilie CANTREL, technicienne de laboratoire	Mme Stephanie MOROT-BIZOT, directrice
	

1. PERFORMING LABORATORY

APEX BIOSOLUTIONS
4, rue des Grandes Pièces
Zone EURESPACE
25 770 SERRE LES SAPINS
FRANCE

2. PRODUCT IDENTITY

Reference	Batch N°
VIREX	20020117

- Expiration date: non communicated
- Owner: KERSIA
- Date of manufacture: 03/06/2020
- Storage conditions: according to the sponsor recommendations
- Active substances: 30% ≤ bis peroxymonosulfate bis sulfate of pentapotassium < 50% (CAS 70693-62-8); 1% ≤ troclosene sodium < 5% (CAS 2893-78-9)
- Appearance of the product: pink powder
- Product diluent: tap water
- Date of delivery of the product: 03/30/2020
- Date of tests: from 03/30/2020 to 04/24/2020

3. EXPERIMENTAL CONDITIONS

- Final concentrations: 0,1% - 0,5% - 1,0% - 1,5% - 2,0%
- Temperature used during the assays: 10°C ± 1°C
- Titration unit: log $TCID_{50}$
- Exposure Time: 30 minutes
- Diluent used for the product: hard water
- Viral strain: Enteric cytopathogenic bovine orphan ATCC VR-248 (ECBO), grown on VERO cells, under 5% CO2 atmosphere
- Organic soil load: BSA 3 g/L (low dirty conditions)
- Product stability: stable
- Stop solution: cold shock

Rédacteur	**Superviseur**
Mme Emilie CANTREL, technicienne de laboratoire	Mme Stephanie MOROT-BIZOT, directrice
	

- **Viral titer:**

Viral titers are expressed in $TCID_{50}$, according to the Spearman-Kärber method = 7,00 log $TCID_{50}$.

4. VALIDATIONS

a) Cytotoxicity

The VIREX product (2.0%) has been tested on the VERO cells and a weak toxicity was observed (10^{-1}).

b) Cells sensitivity to the virus

For each viral suspension, comparative titers of the virus were performed on cells treated or untreated with the product.

	Viral titer (log $TCID_{50}$)		
Product dilution	Viral suspension on untreated cells	Viral suspension on treated cells	**Viral titer difference (log $TCID_{50}$)**
VIREX 10^{-2}	7,00	6,50	**0,50**

The VIREX product do not affect the infectious capacity of the virus: the differences in viral titers between the virus inoculated on VERO cells and the virus inoculated on the VERO cells treated with the VIREX product was ≤ 1,0 log.

c) Inactivation of the virus

	Viral titer (log $TCID_{50}$)	**Viral titer reduction (log TCID50)**
Viral suspension - Formaldehyde 0,7%	7,000	
Inactivation after 5 min	6,500	**0,500**
Inactivation after 15 min	6,000	**1,000**
Inactivation after 30 min	5,500	**1,500**

The virus is inactivated with the control solution of 0,7 % formaldehyde after 30 min of exposure if the reduction is comprised between |-0,5| and |-2,5| log. The reduction observed was of 1,500 log for the ECBO virus.

Rédacteur	**Superviseur**
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5. VIRUCIDAL ASSAYS

TRIAL 1

Viral suspension: 7,000 log $TCID_{50}$.

PRODUCT	Final concentration (v/v)	Exposure time	Temperature	Titer after trial (log $TCID_{50}$)	Viral titer reduction
VIREX	**2,0%**	30 min	10°C	2,000	**5,000**
	1,5%			2,500	**4,500**
	1,0%			2,625	**4,375**
	0,5%			3,250	3,750
	0,1%			4,000	3,000

TRIAL 2

Viral suspension: 7,000 log $TCID_{50}$.

PRODUCT	Final concentration (v/v)	Exposure time	Temperature	Titer after trial (log $TCID_{50}$)	Viral titer reduction
VIREX	**2,0%**	30 min	10°C	2,125	**4,875**
	1,5%			2,500	**4,500**
	1,0%			2,750	**4,250**
	0,5%			3,375	3,625
	0,1%			4,125	2,875

The product has a virucidal effect if the viral titer reduction is ≥ 4,0 log.

6. VALIDATION OF THE METHODOLOGY

The assays were validated as required by the European standard EN 14675:2015:

- The viral titers of the suspension tests were sufficient in order to observe a reduction of 4 log after time exposure with the product. The viral titer of the ECBO virus was 7,000 log $TCID_{50}$.
- The virus was inactivated with the control solution of 0,7 % formaldehyde after 30 min of exposure: the reduction observed was of 1,500 log for the ECBO virus.
- The VIREX product has a weak cytotoxic effect on the VERO cells, after microspin column treatment.
- The VIREX product do not affect the infectious capacity of the virus: the differences in viral titers between the virus inoculated on VERO cells and the virus inoculated on the VERO cells treated with the VIREX product was ≤ 1,0 log (0,50 log).

Rédacteur	**Superviseur**
Mme Emilie CANTREL, technicienne de laboratoire	Mme Stephanie MOROT-BIZOT, directrice
	

7. CONCLUSION

The assays performed with the VIREX batch n° 20020117 product demonstrated that:

- **The product VIREX demonstrated a virucidal activity against the ECBO virus from the concentration 1,0%, according to the European standard EN 14675:2015, following a 30 minutes exposure period, at 10°C, in low dirty conditions.**

8. TECHNICAL APPENDIX 1

Cell line for ECBO virus: VERO cells (R&D Biotech**,** ref. 84009, batch n°110118-110V)
Viral strain: Enteric cytopathogenic bovine orphan ATCC VR-248 (batch n° 58087749)

Buffer and reagents:

- Buffer PBS: sodium chloride, Dominique DUTSCHER, ref. 836751; sodium phosphate dibasic, Sigma Aldrich, ref. S5136, batch n° BCBC7067V; sodium phosphate monobasic, Sigma Aldrich, ref. S5011, batch n° 1019K01021V
- MEM media, PAN Biotech, ref. P04-03590, batch n°9420112
- Horse serum, Sigma Aldrich, ref. H1270, batch n° 12J395

Organic soil load:

- Bovine Sera Albumin, Sigma Aldrich, ref. A5479, batch n° STBB7838V

Inactivation solution:

- Formaldehyde, Sigma Aldrich, ref. F-1635, batch n° BCBB3510

Rédacteur	**Superviseur**
Mme Emilie CANTREL, technicienne de laboratoire	Mme Stephanie MOROT-BIZOT, directrice
	

9. TECHNICAL APPENDIX 2

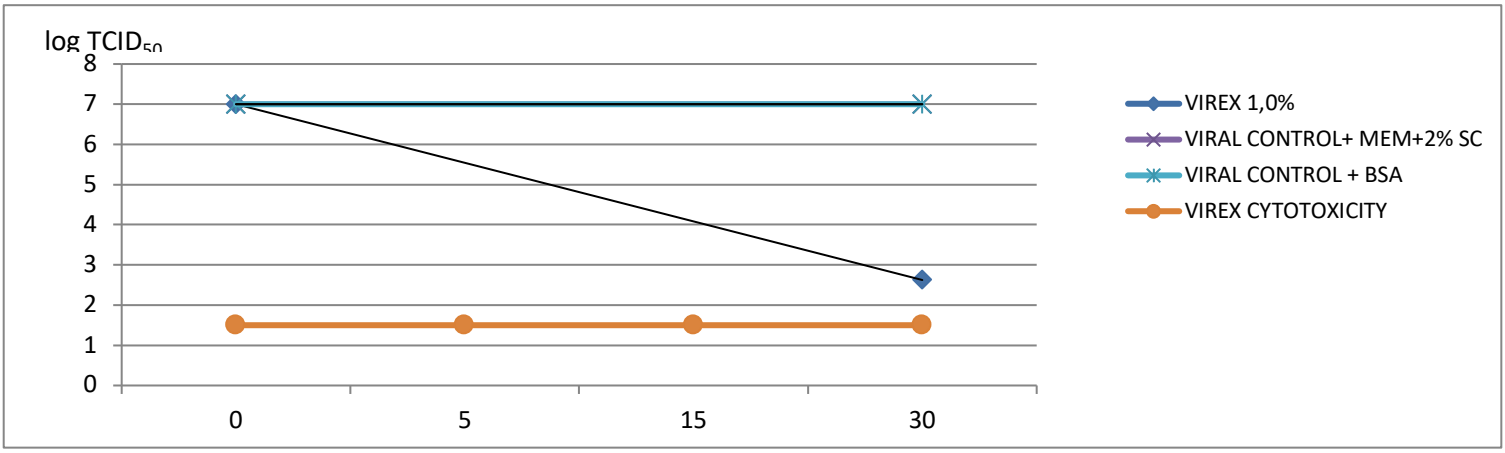
Table A1 – Viral titer of ECBO virus calculated with the Spaerman-Kärber (cytopathic effect method):

log $TCID_{50}$ = 7,000

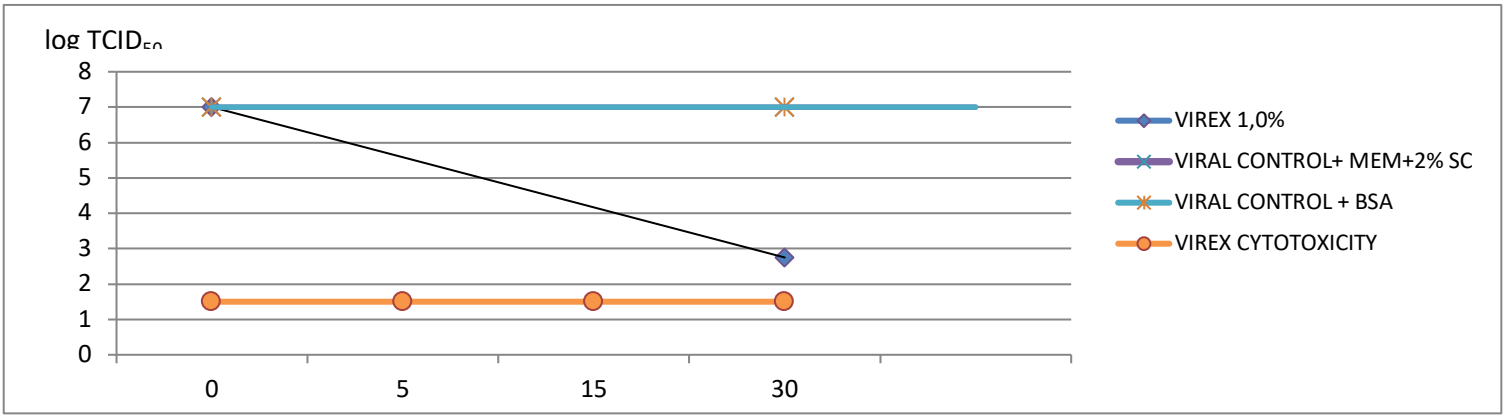
Dilution (- log)	Result	% positive results
-3	44444444	100
-4	44444444	100
-5	44444444	100
-6	44444444	100
-7	44440000	50
-8	00000000	0
-9	00000000	0
Sum of the % of the positive wells		450,0

Chart 1 –graphical chart of the results:

Trial 1



Trial 2



Rédacteur	**Superviseur**
Mme Emilie CANTREL, technicienne de laboratoire	Mme Stephanie MOROT-BIZOT, directrice

Table A2 — results with the VIREX product against the ECBO virus in low dirty conditions

Product	Concentration	Organic soil load	Cytotoxicity	Lg $TCID_{50}$				Reduction
				0	5 min	15 min	30 min	
VIREX TRIAL 1	1,00%	3 g/L BSA	1,500	7,000	N.T.	N.T.	2,625	R= 4,375
VIREX TRIAL 2	1,00%		1,500	7,000	N.T.	N.T.	2,750	R= 4,250
Formaldehyde	0,70%	MEM+2% SC	2,250	7,000	6,500	6,000	5,500	
Viral control of infectivity TRIAL 1	N.A.	MEM+2% SC	N.A	7,000	N.T.	N.T.	N.T.	
	N.A.	3 g/L BSA	N.A	7,000	N.T.	N.T.	N.T.	
Viral control of infectivity TRIAL 2	N.A.	MEM+2% SC	N.A	6,625	N.T.	N.T.	N.T.	
	N.A.	3 g/L BSA	N.A	7,000	N.T.	N.T.	N.T.	
Cells sensitivity	VIREX	N.A.	Untreated cells	7,000	N.T.	N.T.	N.T.	
	10^{-2}	N.A.	Treated cells	6,500	N.T.	N.T.	N.T.	

CS : Calf Serum YE : Yeast Extract

Other concentrations tested :

	Concentration	Organic soil load	Time exposure	dilutions									
				-1	-2	-3	-4	-5	-6	-7	-8	-9	-10
VIREX	2,00%	3 g/L BSA	30 min	4444	4444	0000	0000	00000	0000	0000	0000	0000	0000
				4444	0000	0000	0000	0000	0000	0000	0000	0000	0000
	1,50%			4444	4444	0000	0000	00000	0000	0000	0000	0000	0000
				4444	4444	0000	0000	0000	0000	0000	0000	0000	0000
	0,50%			4444	4444	4444	0000	00000	0000	0000	0000	0000	0000
				4444	4444	4400	0000	0000	0000	0000	0000	0000	0000
	0,10%			4444	4444	4444	4444	0000	0000	0000	0000	0000	0000
				4444	4444	4444	0000	0000	0000	0000	0000	0000	0000

	Concentration	Organic soil load	Time exposure	Log $DICT_{50}$		Reduction	
				0	30 min		
VIREX	2,00%	3 g/L BSA	30 min	7,000	2,000	**5,000**	active
	1,50%			7,000	2,500	**4,500**	active
	0,50%			7,000	3,250	3,750	inactive
	0,10%			7,000	4,000	3,000	inactive

Rédacteur	**Superviseur**
Mme Emilie CANTREL, technicienne de laboratoire	Mme Stephanie MOROT-BIZOT, directrice
	

Table A3 — Raw data for the VIREX product against the ECBO virus, in low dirty conditions (cytopathic effect; 8 wells)

Trial 1

	Concentration	Organic soil load	Exposure time	Dilutions									
				-1	-2	-3	-4	-5	-6	-7	-8	-9	-10
VIREX TRIAL 1	1,00%	3 g/L BSA	30 min	4444	4444	4000	0000	0000	0000	0000	0000	0000	0000
				4444	4444	0000	0000	0000	0000	0000	0000	0000	0000
			Viral control	4444	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
VIREX TRIAL 1 cytotoxicity	2,00%	3 g/L BSA	N.A.	4444	0000	0000	0000	0000	0000	0000	0000	0000	N.T.
				4444	0000	0000	0000	0000	0000	0000	0000	0000	N.T.
Viral control of infectivity	N.A.	MEM+2% SC	0	4444	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
			30	4444	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
	N.A.	3 g/L BSA	0	4444	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
			30	4444	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
Formaldehyde	0,70%	MEM+2% SC	5	4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
			15	4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
				4444	4444	4444	4444	4444	0000	0000	0000	0000	0000
			30	4444	4444	4444	4444	4444	0000	0000	0000	0000	0000
				4444	4444	4444	4444	4444	0000	0000	0000	0000	0000
Formaldehyde (cytotoxicity)	0,70%	MEM+2% SC	N.A.	4444	4444	0000	0000	N.T.	N.T.	N.T.	N.T.	N.T.	N.T.
				4444	4400	0000	0000						

Rédacteur	**Superviseur**
Mme Emilie CANTREL, technicienne de laboratoire	Mme Stephanie MOROT-BIZOT, directrice
	

Trial 2

	Concentration	Organic soil load	Time exposure	Dilutions									
				-1	-2	-3	-4	-5	-6	-7	-8	-9	-10
VIREX TRIAL 2	1,00%	3 g/L BSA	30 min	4444	4444	4400	0000	0000	0000	0000	0000	0000	0000
				4444	4444	0000	0000	0000	0000	0000	0000	0000	0000
			Viral control	4444	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
VIREX TRIAL 2 cytotoxicity	2,00%	3 g/L BSA	N.A.	4444	0000	0000	0000	0000	0000	0000	0000	0000	N.T.
				4444	0000	0000	0000	0000	0000	0000	0000	0000	N.T.
Viral control of infectivity	N.A.	MEM+2% SC	0	4444	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
			30	4444	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
	N.A.	3 g/L BSA	0	4444	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
			30	4444	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
Formaldehyde	0,70%	MEM+2% SC	5	4444	4444	4444	4444	4444	4444	4000	0000	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
			15	4444	4444	4444	4444	4444	0000	0000	0000	0000	0000
				4444	4444	4444	4444	4444	0000	0000	0000	0000	0000
			30	4444	4444	4444	4444	4444	0000	0000	0000	0000	0000
				4444	4444	4444	4444	4000	0000	0000	0000	0000	0000
Formaldehyde (cytotoxicity)	0,70%	MEM+2% SC	N.A.	4444	4444	0000	0000	N.T.	N.T.	N.T.	N.T.	N.T.	N.T.
				4444	4444	0000	0000						

Rédacteur	**Superviseur**
Mme Emilie CANTREL, technicienne de laboratoire	Mme Stephanie MOROT-BIZOT, directrice

Sensitivity of the cells to the virus

Trial 1

Product	Dilution	Organic soil load		Dilutions								
				-2	-3	-4	-5	-6	-7	-8	-9	-10
VIREX	10^{-2}	3 g/L BSA	Untreated cells	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	0000	0000	0000	0000
			Treated cells	4444	4444	4444	4 444	4444	0000	0000	0000	0000
				4444	4444	4444	4444	4444	0000	0000	0000	0000

Trial 2

Product	Dilution	Organic soil load		Dilutions								
				-2	-3	-4	-5	-6	-7	-8	-9	-10
VIREX	10^{-2}	3 g/L BSA	Untreated cells	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	0000	0000	0000	0000
			Treated cells	4444	4444	4444	4444	4444	0000	0000	0000	0000
				4444	4444	4444	4444	4440	0000	0000	0000	0000

Validation of the stop method (microspin filtration and cold shock)

Product	dilution	organic soil load		Dilutions								
				-2	-3	-4	-5	-6	-7	-8	-9	-10
VIREX 2.0%	10^{-2}	MEM+2% CS	Cold dilution	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	0000	0000	0000	0000
			Viral control	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	0000	0000	0000	0000

Cold dilution : viral titer = 7,000 R = 0

Viral control : viral titer = 7,000 The stop method is validated (R ≤ 0,5 log)

Rédacteur	**Superviseur**
Mme Emilie CANTREL, technicienne de laboratoire	Mme Stephanie MOROT-BIZOT, directrice

Sponsor : HYPRED

TEST REPORT

DETERMINATION OF THE VIRUCIDAL ACTIVTY OF THE VIREX PRODUCT ACCORDING TO THE EN 14675 STANDARD

Delivered to : **Ms BOISUMEAU**

For : **HYPRED SAS**
55 BD JULES VERGER
35 800 DINARD

Date of request: 03/12/2020

Study references: n°064D15-2020-02 / order n°CF-171499

VIRUCIDAL TESTS:

According to the NF EN 14675 standard (May 2015) – Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the veterinary area — Test method and requirements (Phase 2, step 1)

Tests using the VIREX product batch n°20020117 against the enteric cytopathogenic bovine orphan virus (ECBO virus).

This test report included 11 pages.

Study completion date: 06/18/2020

Stephanie MOROT-BIZOT
PhD in microbiology
Study director

SUMMARY

Rédacteur	Superviseur
Mme Emilie CANTREL, technicienne de laboratoire	Mme Stephanie MOROT-BIZOT, directrice
	

1. PERFORMING LABORATORY

APEX BIOSOLUTIONS
4, rue des Grandes Pièces
Zone EURESPACE
25 770 SERRE LES SAPINS
FRANCE

2. PRODUCT IDENTITY

Reference	Batch N°
VIREX	20020117

- Expiration date: non communicated
- Owner: KERSIA
- Date of manufacture: 03/06/2020
- Storage conditions: according to the sponsor recommendations
- Active substances: 30% ≤ bis peroxymonosulfate bis sulfate of pentapotassium < 50% (CAS 70693-62-8); 1% ≤ troclosene sodium < 5% (CAS 2893-78-9)
- Appearance of the product: pink powder
- Product diluent: tap water
- Date of delivery of the product: 03/30/2020
- Date of tests: from 03/30/2020 to 04/24/2020

3. EXPERIMENTAL CONDITIONS

- Final concentrations: 0,5% - 1,0% - 1,5% - 2,0% - 3,0%
- Temperature used during the assays: 4°C ± 1°C
- Titration unit: log $TCID_{50}$
- Exposure Time: 30 minutes
- Diluent used for the product: hard water
- Viral strain: Enteric cytopathogenic bovine orphan ATCC VR-248 (ECBO), grown on VERO cells, under 5% CO2 atmosphere
- Organic soil load: BSA 3 g/L (low dirty conditions)
- Product stability: stable
- Stop solution: cold shock

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- **Viral titer:**

Viral titers are expressed in $TCID_{50}$, according to the Spearman-Kärber method = 7,00 log $TCID_{50}$.

4. VALIDATIONS

a) Cytotoxicity

The VIREX product (3.0%) has been tested on the VERO cells and a weak toxicity was observed (10^{-2}).

b) Cells sensitivity to the virus

For each viral suspension, comparative titers of the virus were performed on cells treated or untreated with the product.

	Viral titer (log $TCID_{50}$)		
Product dilution	Viral suspension on untreated cells	Viral suspension on treated cells	**Viral titer difference (log $TCID_{50}$)**
VIREX 10^{-3}	7,00	6,375	**0,625**

The VIREX product do not affect the infectious capacity of the virus: the differences in viral titers between the virus inoculated on VERO cells and the virus inoculated on the VERO cells treated with the VIREX product was ≤ 1,0 log.

c) Inactivation of the virus

	Viral titer (log $TCID_{50}$)	**Viral titer reduction (log TCID50)**
Viral suspension - Formaldehyde 0,7%	7,000	
Inactivation after 5 min	6,500	**0,500**
Inactivation after 15 min	6,000	**1,000**
Inactivation after 30 min	5,500	**1,500**

The virus is inactivated with the control solution of 0,7 % formaldehyde after 30 min of exposure if the reduction is comprised between |-0,5| and |-2,5| log. The reduction observed was of 1,500 log for the ECBO virus.

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5. VIRUCIDAL ASSAYS

TRIAL 1

Viral suspension: 7,000 log $TCID_{50}$.

PRODUCT	Final concentration (v/v)	Exposure time	Temperature	Titer after trial (log $TCID_{50}$)	Viral titer reduction
VIREX	**3,0%**	30 min	4°C	2,000	**5,000**
	2,0%			2,500	**4,500**
	1,5%			2,625	**4,375**
	1,0%			3,250	3,750
	0,5%			4,000	3,000

TRIAL 2

Viral suspension: 7,000 log $TCID_{50}$.

PRODUCT	Final concentration (v/v)	Exposure time	Temperature	Titer after trial (log $TCID_{50}$)	Viral titer reduction
VIREX	**3,0%**	30 min	4°C	2,125	**4,875**
	2,0%			2,500	**4,500**
	1,5%			2,750	**4,250**
	1,0%			3,375	3,625
	0,5%			4,125	2,875

The product has a virucidal effect if the viral titer reduction is ≥ 4,0 log.

6. VALIDATION OF THE METHODOLOGY

The assays were validated as required by the European standard EN 14675:2015:

- The viral titers of the suspension tests were sufficient in order to observe a reduction of 4 log after time exposure with the product. The viral titer of the ECBO virus was 7,000 log $TCID_{50}$.
- The virus was inactivated with the control solution of 0,7 % formaldehyde after 30 min of exposure: the reduction observed was of 1,500 log for the ECBO virus.
- The VIREX product has a weak cytotoxic effect on the VERO cells, after microspin column treatment.
- The VIREX product do not affect the infectious capacity of the virus: the differences in viral titers between the virus inoculated on VERO cells and the virus inoculated on the VERO cells treated with the VIREX product was ≤ 1,0 log (0,625 log).

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Mme Emilie CANTREL, technicienne de laboratoire	Mme Stephanie MOROT-BIZOT, directrice
	

7. CONCLUSION

The assays performed with the VIREX batch n° 20020117 product demonstrated that:

- **The product VIREX demonstrated a virucidal activity against the ECBO virus from the concentration 1,5%, according to the European standard EN 14675:2015, following a 30 minutes exposure period, at 4°C, in low dirty conditions.**

8. TECHNICAL APPENDIX 1

Cell line for ECBO virus: VERO cells (R&D Biotech**,** ref. 84009, batch n°110118-110V)
Viral strain: Enteric cytopathogenic bovine orphan ATCC VR-248 (batch n° 58087749)

Buffer and reagents:

- Buffer PBS: sodium chloride, Dominique DUTSCHER, ref. 836751; sodium phosphate dibasic, Sigma Aldrich, ref. S5136, batch n° BCBC7067V; sodium phosphate monobasic, Sigma Aldrich, ref. S5011, batch n° 1019K01021V
- MEM media, PAN Biotech, ref. P04-03590, batch n°9420112
- Horse serum, Sigma Aldrich, ref. H1270, batch n° 12J395

Organic soil load:

- Bovine Sera Albumin, Sigma Aldrich, ref. A5479, batch n° STBB7838V

Inactivation solution:

- Formaldehyde, Sigma Aldrich, ref. F-1635, batch n° BCBB3510

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9. TECHNICAL APPENDIX 2

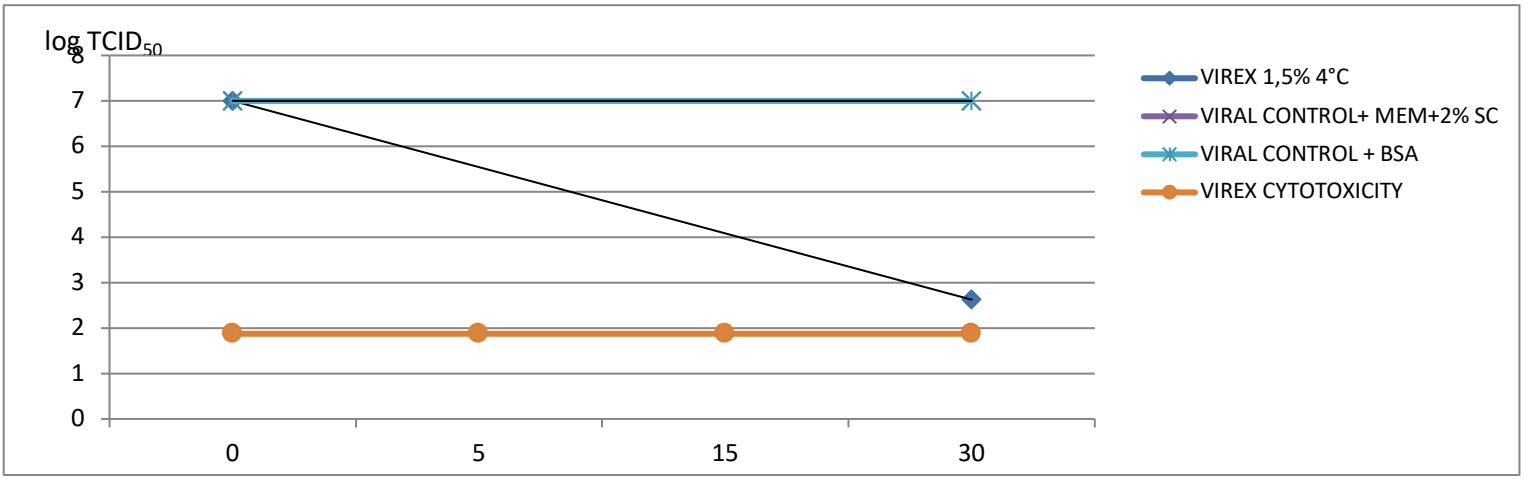
Table A1 – Viral titer of ECBO virus calculated with the Spaerman-Kärber (cytopathic effect method):

log $TCID_{50}$ = 7,000

Dilution (- log)	Result	% positive results
-3	44444444	100
-4	44444444	100
-5	44444444	100
-6	44444444	100
-7	44440000	50
-8	00000000	0
-9	00000000	0
Sum of the % of the positive wells		450,0

Chart 1 –graphical chart of the results:

Trial 1



Trial 2

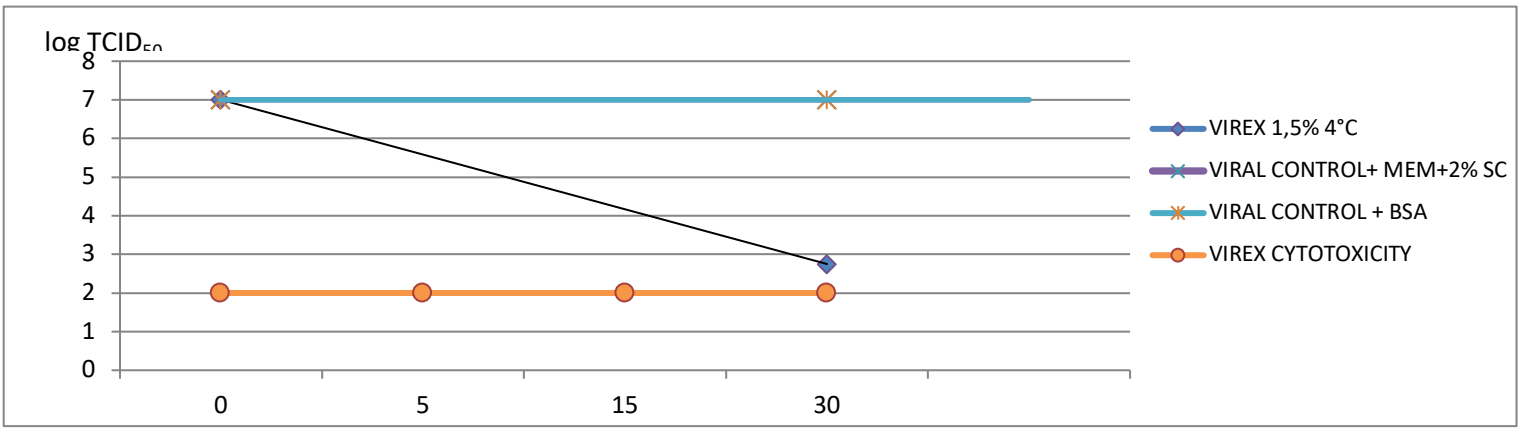


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Table A2 — results with the VIREX product against the ECBO virus in low dirty conditions

Product	Concentration	Organic soil load	Cytotoxicity	Lg $TCID_{50}$				Reduction
				0	5 min	15 min	30 min	
VIREX TRIAL 1	1,50%	3 g/L BSA	1,875	7,000	N.T.	N.T.	2,625	R= 4,375
VIREX TRIAL 2	1,50%		2,000	7,000	N.T.	N.T.	2,750	R= 4,250
Formaldehyde	0,70%	MEM+2% SC	2,250	7,000	6,500	6,000	5,500	
Viral control of infectivity TRIAL 1	N.A.	MEM+2% SC	N.A	7,000	N.T.	N.T.	N.T.	
	N.A.	3 g/L BSA	N.A	7,000	N.T.	N.T.	N.T.	
Viral control of infectivity TRIAL 2	N.A.	MEM+2% SC	N.A	6,625	N.T.	N.T.	N.T.	
	N.A.	3 g/L BSA	N.A	7,000	N.T.	N.T.	N.T.	
Cells sensitivity	VIREX	N.A.	Untreated cells	7,000	N.T.	N.T.	N.T.	
	10^{-3}	N.A.	Treated cells	6,375	N.T.	N.T.	N.T.	

CS : Calf Serum YE : Yeast Extract

Other concentrations tested :

	Concentration	Organic soil load	Time exposure	dilutions									
				-1	-2	-3	-4	-5	-6	-7	-8	-9	-10
VIREX	3,00%	3 g/L BSA	30 min	4444	4444	0000	0000	00000	0000	0000	0000	0000	0000
				4444	0000	0000	0000	0000	0000	0000	0000	0000	0000
	2,00%			4444	4444	0000	0000	00000	0000	0000	0000	0000	0000
				4444	4444	0000	0000	0000	0000	0000	0000	0000	0000
	1,00%			4444	4444	4444	0000	00000	0000	0000	0000	0000	0000
				4444	4444	4400	0000	0000	0000	0000	0000	0000	0000
	0,50%			4444	4444	4444	4444	0000	0000	0000	0000	0000	0000
				4444	4444	4444	0000	0000	0000	0000	0000	0000	0000

	Concentration	Organic soil load	Time exposure	Log $DICT_{50}$		Reduction	
				0	30 min		
VIREX	3,00%	3 g/L BSA	30 min	7,000	2,000	**5,000**	active
	2,00%			7,000	2,500	**4,500**	active
	1,00%			7,000	3,250	3,750	inactive
	0,50%			7,000	4,000	3,000	inactive

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Table A3 — Raw data for the VIREX product against the ECBO virus, in low dirty conditions (cytopathic effect; 8 wells)

Trial 1

	Concentration	Organic soil load	Exposure time	Dilutions									
				-1	-2	-3	-4	-5	-6	-7	-8	-9	-10
VIREX TRIAL 1	1,50%	3 g/L BSA	30 min	4444	4444	4000	0000	0000	0000	0000	0000	0000	0000
				4444	4444	0000	0000	0000	0000	0000	0000	0000	0000
			Viral control	4444	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
VIREX TRIAL 1 cytotoxicity	3,00%	3 g/L BSA	N.A.	4444	4440	0000	0000	0000	0000	0000	0000	0000	N.T.
				4444	0000	0000	0000	0000	0000	0000	0000	0000	N.T.
Viral control of infectivity	N.A.	MEM+2% SC	0	4444	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
			30	4444	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
	N.A.	3 g/L BSA	0	4444	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
			30	4444	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
Formaldehyde	0,70%	MEM+2% SC	5	4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
			15	4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
				4444	4444	4444	4444	4444	0000	0000	0000	0000	0000
			30	4444	4444	4444	4444	4444	0000	0000	0000	0000	0000
				4444	4444	4444	4444	4444	0000	0000	0000	0000	0000
Formaldehyde (cytotoxicity)	0,70%	MEM+2% SC	N.A.	4444	4444	0000	0000	N.T.	N.T.	N.T.	N.T.	N.T.	N.T.
				4444	4400	0000	0000						

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Trial 2

	Concentration	Organic soil load	Time exposure	Dilutions									
				-1	-2	-3	-4	-5	-6	-7	-8	-9	-10
VIREX TRIAL 2	1,50%	3 g/L BSA	30 min	4444	4444	4400	0000	0000	0000	0000	0000	0000	0000
				4444	4440	0000	0000	0000	0000	0000	0000	0000	0000
			Viral	4444	4444	4444	4444	4444	4444	4444	0000	0000	0000
			control	4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
VIREX TRIAL 2 cytotoxicity	3,00%	3 g/L BSA	N.A.	4444	4444	0000	0000	0000	0000	0000	0000	0000	N.T.
				4444	0000	0000	0000	0000	0000	0000	0000	0000	N.T.
Viral control of infectivity	N.A.	MEM+2% SC	0	4444	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
			30	4444	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
	N.A.	3 g/L BSA	0	4444	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
			30	4444	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
Formaldehyde	0,70%	MEM+2% SC	5	4444	4444	4444	4444	4444	4444	4000	0000	0000	0000
				4444	4444	4444	4444	4444	4444	0000	0000	0000	0000
			15	4444	4444	4444	4444	4444	0000	0000	0000	0000	0000
				4444	4444	4444	4444	4444	0000	0000	0000	0000	0000
			30	4444	4444	4444	4444	4444	0000	0000	0000	0000	0000
				4444	4444	4444	4444	4000	0000	0000	0000	0000	0000
Formaldehyde (cytotoxicity)	0,70%	MEM+2% SC	N.A.	4444	4444	0000	0000	N.T.	N.T.	N.T.	N.T.	N.T.	N.T.
				4444	4444	0000	0000						

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Mme Emilie CANTREL, technicienne de laboratoire	Mme Stephanie MOROT-BIZOT, directrice

Sensitivity of the cells to the virus

Trial 1

Product	Dilution	Organic soil load		Dilutions								
				-2	-3	-4	-5	-6	-7	-8	-9	-10
VIREX	10^{-3}	3 g/L BSA	Untreated cells	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	0000	0000	0000	0000
			Treated cells	4444	4444	4444	4 444	4444	0000	0000	0000	0000
				4444	4444	4444	4444	4440	0000	0000	0000	0000

Trial 2

Product	Dilution	Organic soil load		Dilutions								
				-2	-3	-4	-5	-6	-7	-8	-9	-10
VIREX	10^{-3}	3 g/L BSA	Untreated cells	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	0000	0000	0000	0000
			Treated cells	4444	4444	4444	4444	4444	0000	0000	0000	0000
				4444	4444	4444	4444	4400	0000	0000	0000	0000

Validation of the stop method (microspin filtration and cold shock)

Product	dilution	organic soil load		Dilutions								
				-2	-3	-4	-5	-6	-7	-8	-9	-10
VIREX 3.0%	10^{-3}	MEM+2% CS	Cold dilution	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	0000	0000	0000	0000
			Viral control	4444	4444	4444	4444	4444	4444	0000	0000	0000
				4444	4444	4444	4444	4444	0000	0000	0000	0000

Cold dilution : viral titer = 7,000 R = 0

Viral control : viral titer = 7,000 The stop method is validated (R ≤ 0,5 log)

Rédacteur	**Superviseur**
Mme Emilie CANTREL, technicienne de laboratoire	Mme Stephanie MOROT-BIZOT, directrice

Testing the efficacy of a disinfectant against African swine fever virus (ASFV)

VIREX

Report: 1845223-VIREX-1% 5 min 4°C low
Project: 1600001932

This study was organized and financed by HYPRED S.A.S. (KERSIA Group)

Michiel Kroese, Wageningen Bioveterinary Research (WBVR), August 2019

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General information

Study title:	Testing the efficacy of disinfectants against African swine fever virus (ASFV)
Desinfectant(s):	VIREX, batch 19010134 (cat AF9523), Manufacturer: KILCO (KERSIA Group)
Study organized by:	Ms. Isabelle Le Dreau and Mr. Patrick Arnould LCB food safety (KERSIA Group) PAE ACTIPARC Rue des Acacias 01190 BOZ France
Test directed by:	Mr. Michiel Kroese Wageningen Bioveterinary Research P.O. Box 65 8200 AB Lelystad The Netherlands
Sponsor:	HYPRED S.A.S. (KERSIA Group)
Test facility:	Wageningen Bioveterinary Research Animal Biosafety Level 4 Laboratory Facilities P.O. Box 65 8200 AB Lelystad The Netherlands

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Introduction

Disinfection of materials contaminated with ASFV is an essential aspect in the process of prevention and control of ASFV outbreaks. Before routine use of the disinfectant, it should be tested for the efficacy against ASF virus in a quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants.

This study is performed to test the efficacy of various disinfectants against ASFV and to examine the effective dilution of the disinfectants. A method designed by the ISO 9001 accredited facilities at Wageningen Bioveterinary Research is based on the European Standard EN 14675: chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (Phase 2, step 1), 2015

In the current study, 1 product of Kilco was tested: VIREX.

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Materials and methods

Materials (as described in the test protocol)

1) Test virus: The Netherlands '86 ASFV isolate grown on Porcine Alveolar Macrophages (PAMs)
2) Test cell: PAMs
3) Test medium for cell culture: RPMI supplemented with FCS and antibiotics
4) The diluent for disinfectants and virus: hard water according to NEN-EN 14675
5) Soiling solutions: according to NEN-EN 14675
6) Medium for neutralizing disinfectant: DMEM supplemented with 10% FBS and 2% antibiotics

Methods (as described in the test protocol)

1) Preparation of virus
   a. The virus titer used is about 10^7 $TCID_{50}$/ml (+/- 0.2 log) being able to determine a 4 log_{10} reduction
2) Preparation of the disinfectants dilution
   a. Prepare the disinfectant to 1.25 concentrated dilutions of the requested dilution rates that need to be tested
   b. The disinfectants shall be diluted with hard water, and the concentrations of the individual disinfectants including the various test conditions used, are summarized in Table 1
   c. Cytotoxic effects will be evaluated in the IPMA assay

Temp	4°C						10°C					
Soiling	low			high			low			high		
Time	1'	5'	30'	1'	5'	30'	1'	5'	30'	1'	5'	30'
Disinfectant(s)												
1% VIREX		x										

Table 1: Concentrations of disinfectant(s) and corresponding test conditions

3) Preparation of cells for IPMA assay
   a. Primary cells are prepared from porcine lungs and stored in liquid nitrogen. When needed, cells are thawed and seeded in 96-well plates. These plates are used in the IPMA assay
4) Test procedure
   a. A sample of the product diluted with hard water is added to a test suspension of virus. The mixture is maintained in a water bath at 4°C at ± 1°C for 5 min ± 10 s (Table 1)
   b. One part of virus suspension is mixed with one part of hard water containing soiling agent. Eight parts of disinfectant dilution (1.25x the requested dilution to give the correct final concentration) is added and is placed in a water bath and the incubation time is started.
   c. At the end of the contact time, 0.5 ml mixture is taken and diluted in 4.5 ml ice-cold medium to overcome the virucidal activity. These samples are directly diluted in six serial tenfold dilutions in cold medium (so the 6 dilutions to be tested are 10^{-2} up to 10^{-7}). The dilutions are tested immediately or stored at -70°C.

5) IPMA assay (end point titration)
   a. (After thawing) 100 µl of each dilution is inoculated (in 8-fold) into separate wells of a 96-well plate and 100µl PAM cells are added. The plates are incubated at 37°C in a humidified incubator with 5% CO_2 for four days. After four days of incubation, the plates are washed, dried and frozen. Subsequently, the cells are fixed, plates are washed again and stained using ASF-HIS, Mouse-anti-Swine IgG/HRPO conjugate and AEC (IPMA protocol).
   b. Plates are read microscopically and judged for the presence of virus. Titers are calculated according to Spearman-Kärber.

Test Evaluation

1) To test the titre of the virus used, a hard water control is included, which means that hard water is used instead of a disinfectant.
2) Two positive controls as disinfectants, NaOH 1% and 2%, are included in the test. The reduction after 5 minutes of the positive controls should be within +/- 3 sd of the mean valid for these controls for a valid test. Our passed experience showed that formaldehyde 0.7% was toxic for PAMs and was therefore replaced by NaOH 1% and 2%.
3) The reduction in ASFV titre, induced by each dilution of the disinfectant, is calculated by subtracting the ASF virus titre, measured in the mix with disinfectant, from the titre measured in the water control.
4) A minimum of a 4 $\log_{10}$ reduction reduction after 30 minutes at 10°C is needed for a disinfectant to pass the test. In the current study, these conditions were not included.

Test validation

1) According to the NEN-EN 14675 norm, the validation of the used method regarding the control of efficiency for suppression of disinfectant activity require that the difference with the viral suspension assay does not exceed 0.5 $\log_{10}$. It is impracticable to test as there is no suspension test available for ASFV either with or without primary macrophages.

Note: this effectivity test is built upon a biological system containing living cells and challenging virus. The outcome of the test is therefore dependent on the effect of the disinfectant(s) on the virus as well as on the cells. The difference between the viral titer obtained from cells exposed to the disinfectant at a non-cytotoxic concentration and the viral titer obtained from cells non-exposed to the disinfectant should be lower than 1 $\log_{10}$ according to the NEN EN 14675 norm. It is our view that a treatment of cells at a non-cytotoxic concentration of the disinfectant should by definition yield the same titer as at non-exposed cells, otherwise it is toxic. Therefore, it does not make any sense scientifically to test this issue. Unquestionably, we are aware of the possible effect of the disinfectant on either cells or virus. In case the cells are affected by the disinfectants tested, no conclusive data can be generated relating to the effect of the disinfectant on the virus applied according to the NEN-EN 14675 norm. The NEN EN 14675 norm does not define a differentiation between these two effects.

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Results

Controls

The hard water control in low soiling conditions at 4°C showed a titre (log_{10}: 6.88) with a value satisfactory for the test. The reduction observed with the two positive controls were within reach of validity of the test performed. See table 2 for the log_{10} values of all controls included.

Temp	4°C						10°C					
Soiling	low			high			low			high		
Time	1'	5'	30'	1'	5'	30'	1'	5'	30'	1'	5'	30'
Controls												
Water		6.88										
1% NaOH		3.13										
2% NaOH		3.00										

Table 2: log_{10} values of controls

Disinfectant(s)

The result of the effect of the 1% VIREX disinfectant on ASFV in low soiling conditions was 2.75 log_{10} at 5 min. incubation at 4°C, see Table 3. No cytotoxicity was observed in PAMs using VIREX.

Temp	4°C						10°C					
Soiling	low			high			low			high		
Time	1'	5'	30'	1'	5'	30'	1'	5'	30'	1'	5'	30'
Disinfectant(s)												
1% VIREX		2.75										

Table 3: log_{10} values of disinfectant(s)

Conclusions

In order to pass the test, a disinfectant should show a minimum of a 4 log_{10} reduction in titre after 30 min at 10°C.

The disinfectant VIREX (1%) showed a reduction of 4.13 after 5 min. at 4°C in low soiling conditions.

Wageningen Bioveterinary Research
Postbus 65
8200 AB Lelystad
T 0320 23 82 38
info.bvr@wur.nl
www.wur.nl/bioveterinary-research

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Rapportnummer:

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Appendix 1: Raw data

Order: 2018 ASFV LCB food safety-1													
Water							**1% VIREX**						
Temp: 4°C Soiling: low Time (min): 5 TCID50/ml: 6.88							Temp: 4°C Soiling: low Time (min): 5 TCID50/ml: 2.75						
	1	2	3	4	5	6	7	8	9	10	11	12	
A	pos	pos	pos	pos	pos	neg	neg	neg	neg	neg	neg	neg	A
B	pos	pos	pos	neg	neg	pos	neg	neg	neg	neg	neg	neg	B
C	pos	pos	pos	pos	neg	neg	neg	neg	neg	neg	neg	neg	C
D	pos	pos	pos	neg	neg	neg	pos	neg	neg	neg	neg	neg	D
E	pos	pos	pos	pos	neg	neg	pos	neg	neg	neg	neg	neg	E
F	pos	pos	pos	pos	pos	neg	neg	neg	neg	neg	neg	neg	F
G	pos	pos	pos	pos	pos	neg	neg	neg	neg	neg	neg	neg	G
H	pos	pos	pos	neg	pos	neg	neg	neg	neg	neg	neg	neg	H

Order: 2018 ASFV LCB food safety-1													
1% NaOH							**2% NaOH**						
Temp: 4°C Soiling: low Time (min): 5 TCID50/ml: 3.13							Temp: 4°C Soiling: low Time (min): 5 TCID50/ml: 3.00						
	1	2	3	4	5	6	7	8	9	10	11	12	
A	pos	pos	neg	neg	neg	neg	pos	neg	neg	neg	neg	neg	A
B	neg	neg	neg	neg	neg	neg	pos	neg	neg	neg	neg	neg	B
C	pos	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	C
D	pos	neg	neg	neg	neg	neg	pos	neg	neg	neg	neg	neg	D
E	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	E
F	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	F
G	neg	pos	neg	neg	neg	neg	pos	neg	neg	neg	neg	neg	G
H	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	H

Testing the efficacy of a disinfectant against African Swine Fever Virus ASFV

VIREX

Report: 1845223-VIREX-1% 30 min 10°C low
Project: 1600001932

This study was organized and financed by HYPRED S.A.S. (KERSIA Group)

Michiel Kroese, Wageningen Bioveterinary Research (WBVR), November 2019

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General information

Study title:	Testing the efficacy of disinfectants against African Swine Fever Virus (ASFV)
Disinfectant(s):	VIREX, batch 19010134 (cat AF9523), Manufacturer: KILCO (KERSIA Group)
Study organized by:	Ms. Isabelle Le Dreau and Mr. Patrick Arnould LCB food safety (KERSIA Group) PAE ACTIPARC Rue des Acacias 01190 BOZ France
Test directed by:	Mr. Michiel Kroese Wageningen Bioveterinary Research P.O. Box 65 8200 AB Lelystad The Netherlands
Sponsor:	HYPRED S.A.S. (KERSIA Group)
Test facility:	Wageningen Bioveterinary Research Animal Biosafety Level 4 Laboratory Facilities P.O. Box 65 8200 AB Lelystad The Netherlands

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Introduction

Disinfection of materials contaminated with ASFV is an essential aspect in the process of prevention and control of ASFV outbreaks. Before routine use of the disinfectant, it should be tested for the efficacy against ASF virus in a quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants.

This study is performed to test the efficacy of various disinfectants against ASFV and to examine the effective dilution of the disinfectants. A method designed by the ISO 9001 accredited facilities at Wageningen Bioveterinary Research is based on the European Standard EN 14675: chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (Phase 2, step 1), 2015

In the current study, one product of KILCO (KERSIA Group) was tested: VIREX in a 1% dilution.

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Materials and methods

Materials (as described in the test protocol)

1) Test virus: The Netherlands '86 ASFV isolate grown on Porcine Alveolar Macrophages (PAMs)
2) Test cell: PAMs
3) Test medium for cell culture: RPMI supplemented with FCS and antibiotics
4) The diluent for disinfectants and virus: hard water according to NEN-EN 14675
5) Soiling solutions: according to NEN-EN 14675
6) Medium for neutralizing disinfectant: DMEM supplemented with 10% FBS and 2% antibiotics

Methods (as described in the test protocol)

1) Preparation of virus
   a. The virus titre used is about 10^7 $TCID_{50}$/ml (+/- 0.2 log) being able to determine a 4 log_{10} reduction
2) Preparation of the disinfectants dilution
   a. Prepare the disinfectant to 1.25 concentrated dilutions of the requested dilution rates that need to be tested
   b. The disinfectants shall be diluted with hard water, and the concentrations of the individual disinfectants including the various test conditions used, are summarized in Table 1
   c. Cytotoxic effects will be evaluated in the IPMA assay

Temp	4°C						10°C					
Soiling	low			high			low			high		
Time	1'	5'	30'	1'	5'	30'	1'	5'	30'	1'	5'	30'
Controls												
Water									x			
1% NaOH									x			
2% NaOH									x			
Disinfectant(s)												
1% VIREX									x			

Table 1: Concentrations of disinfectant(s) and corresponding test conditions

3) Preparation of cells for IPMA assay
   a. Primary cells are prepared from porcine lungs and stored in liquid nitrogen. When needed, cells are thawed and seeded in 96-well plates. These plates are used in the IPMA assay
4) Test procedure
   a. A sample of the product diluted with hard water is added to a test suspension of virus. The mixture is maintained in a water bath at 10°C ± 1°C for 30 min ± 10 s (Table 1)
   b. One part of virus suspension is mixed with one part of hard water containing soiling agent. Eight parts of disinfectant dilution (1.25x the requested dilution to give the correct final concentration) is added and is placed in a water bath and the incubation time is started.
   c. At the end of the contact time, 0.5 ml mixture is taken and diluted in 4.5 ml ice-cold medium to overcome the virucidal activity. These samples are directly diluted in six serial tenfold dilutions in cold medium (so the 6 dilutions to be tested are 10^{-2} up to 10^{-7}). The dilutions are tested immediately or stored at -70°C.

5) IPMA assay (end point titration)
   a. (After thawing) 100 µl of each dilution is inoculated (in 8-fold) into separate wells of a 96-well plate and 100µl PAM cells are added. The plates are incubated at 37°C in a humidified incubator with 5% CO_2 for four days. After four days of incubation, the plates are washed, dried and frozen. Subsequently, the cells are fixed, plates are washed again and stained using ASF-HIS, Mouse-anti-Swine IgG/HRPO conjugate and AEC (IPMA protocol).
   b. Plates are read microscopically and judged for the presence of virus. Titres are calculated according to Spearman-Kärber.

Test Evaluation

1) To test the titre of the virus used, a hard water control is included, which means that hard water is used instead of a disinfectant.
2) Two positive controls as disinfectants, NaOH 1% and 2%, are included in the test. The reduction after 30 minutes of the positive controls should be within +/- 3 sd of the mean valid for these controls for a valid test. Our passed experience showed that formaldehyde 0.7% was toxic for PAMs and was therefore replaced by NaOH 1% and 2%.
3) The reduction in ASFV titre, induced by each dilution of the disinfectant, is calculated by subtracting the ASF virus titre, measured in the mix with disinfectant, from the titre measured in the water control.
4) A minimum of a 4 $\log_{10}$ reduction reduction after 30 minutes at 10°C is needed for a disinfectant to pass the test. In the current study, these conditions were applied.

Test validation

1) According to the NEN-EN 14675 norm, the validation of the used method regarding the control of efficiency for suppression of disinfectant activity require that the difference with the viral suspension assay does not exceed 0.5 $\log_{10}$. It is impracticable to test as there is no suspension test available for ASFV either with or without primary macrophages.

Note: this effectivity test is built upon a biological system containing living cells and challenging virus. The outcome of the test is therefore dependent on the effect of the disinfectant(s) on the virus as well as on the cells. The difference between the viral titre obtained from cells exposed to the disinfectant at a non-cytotoxic concentration and the viral titre obtained from cells non-exposed to the disinfectant should be lower than 1 $\log_{10}$ according to the NEN EN 14675 norm. It is our view that a treatment of cells at a non-cytotoxic concentration of the disinfectant should by definition yield the same titre as at non-exposed cells, otherwise it is toxic. Therefore, it does not make any sense scientifically to test this issue. Unquestionably, we are aware of the possible effect of the disinfectant on either cells or virus. In case the cells are affected by the disinfectants tested, no conclusive data can be generated relating to the effect of the disinfectant on the virus applied according to the NEN-EN 14675 norm. The NEN EN 14675 norm does not define a differentiation between these two effects.

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Results

Controls

The hard water control in low soiling conditions at 10°C showed a titre (log_{10}: 6.63) with a value satisfactory for the test. The reduction observed with the two positive controls were within reach of validity of the test performed. See table 2 for the log_{10} values of all controls included.

Temp	4°C						10°C					
Soiling	low			high			low			high		
Time	1'	5'	30'	1'	5'	30'	1'	5'	30'	1'	5'	30'
Controls												
Water									6.63			
1% NaOH									≤2.50			
2% NaOH									2.63			

Table 2: log_{10} values of controls

Disinfectant(s)

The result of the effect of the disinfectant VIREX (1%) on ASFV in low soiling conditions was ≤2.50 log_{10} at 30 min. incubation at 10°C, see Table 3. No cytotoxicity was observed in PAMs using VIREX.

Temp	4°C						10°C					
Soiling	low			high			low			high		
Time	1'	5'	30'	1'	5'	30'	1'	5'	30'	1'	5'	30'
Disinfectant(s)												
1% VIREX									≤2.50			

Table 3: log_{10} values of disinfectant(s)

Conclusions

In order to pass the test, a disinfectant should show a minimum of a 4 log_{10} reduction in titre after 30 min at 10°C (obligatory test conditions).

The disinfectant VIREX (1%) showed a reduction of a minimum of 4 log_{10} after 30 min. at 10°C in low soiling conditions, therefore passing the test based on the European Standard EN 14675.

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Appendix 1: Raw data

Order: 2018 ASFV LCB food safety-1													
water							**1% NaOH**						
Temp: 10°C Soiling: low Time (min): 30 TCID50/ml: 6.63							Temp: 10°C Soiling: low Time (min): 30 TCID50/ml: ≤2.50						
	1	2	3	4	5	6	7	8	9	10	11	12	
A	pos	pos	pos	pos	neg	neg	neg	neg	neg	neg	neg	neg	A
B	pos	pos	pos	pos	pos	neg	neg	neg	neg	neg	neg	neg	B
C	pos	pos	pos	pos	neg	neg	neg	neg	neg	neg	neg	neg	C
D	pos	pos	pos	pos	neg	neg	neg	neg	neg	neg	neg	neg	D
E	pos	pos	pos	pos	neg	neg	neg	neg	neg	neg	neg	neg	E
F	pos	pos	pos	pos	neg	neg	neg	neg	neg	neg	neg	neg	F
G	pos	pos	pos	pos	neg	neg	neg	neg	neg	neg	neg	neg	G
H	pos	pos	pos	pos	neg	neg	neg	neg	neg	neg	neg	neg	H

Order: 2018 ASFV LCB food safety-1													
2% NaOH							**1% VIREX**						
Temp: 10°C Soiling: low Time (min): 30 TCID50/ml: 2.63							Temp: 10°C Soiling: low Time (min): 30 TCID50/ml: ≤2.50						
	1	2	3	4	5	6	7	8	9	10	11	12	
A	pos	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	A
B	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	B
C	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	C
D	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	D
E	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	E
F	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	F
G	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	G
H	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	H

Abbott Analytical

Consulting Scientists to the Disinfectant Industry

Certificate of Analysis

Sample(s):	One sample of Virex		
Received from:	Kilco (International) Ltd. Broomhouses 2 Industrial Estate, Lockerbie, DG11 2SD		
Date received:	21 May 2012	**Date tested:**	1 June 2012
Certificate no:	12E.050VF.KIL	**Certificate date:**	6 June 2012
Sample ref:	12E/050	**Page:**	1 of 2
Analysis required:	EN 1657, Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area – Test method and requirements (phase 2, step 1)		

Product stored at:	Room temperature	
Active substance:	Not declared	
Test conditions:	Low-level soiling	
Interfering substance:	3.0g/l bovine albumin	
Product test concentration:	1.0% v/v	
Product diluent used during test:	Sterile hard water 300mg/l $CaCO_3$	
Contact time:	5 minutes	
Test temperature:	10°C ± 0.5°C	
Neutralising solution:	5% Sodium thiosulphate	
Incubation temperature:	30°C ± 1°C	
Identification of fungal/yeast strain(s) used:	*Aspergillus niger* *Candida albicans*	NCPF 2275 NCPF 3179

D C Watson

D C Watson BSc, CBiol, MSB, MIFST, ACIEHO
PO Box 95, New Ferry, Wirral, CH62 6HA
Tel: 0151 637 3331 Mob: 07767 871275
email: abbottanalytical@hotmail.co.uk

Test results:

Test Organism	*Aspergillus niger*		*Candida albicans*	
Validation Suspension	Vc1 206	Vc2 174	Vc1 324	Vc2 308
(Nv$_o$)	ẍ = 190		ẍ = 316	
Experimental Control	Vc1 200	Vc2 158	Vc1 300	Vc2 278
(A)	ẍ = 179	≥ 0.5Nv$_o$	ẍ = 289	≥ 0.5Nv$_o$
Neutraliser Control	Vc1 234	Vc2 216	Vc1 314	Vc2 330
(B)	ẍ = 225	≥ 0.5Nv$_o$	ẍ = 322	≥ 0.5Nv$_o$
Method Validation	Vc1 220	Vc2 204	Vc1 292	Vc2 280
(C)	ẍ = 212	≥ 0.5Nv$_o$	ẍ = 286	≥ 0.5Nv$_o$
Test Suspension 10^{-5}	Vc1 252	Vc2 188	Vc1 238	Vc2 274
10^{-6}	Vc1 18	Vc2 30	Vc1 27	Vc2 32
(N = ẅ)	lg N = 7.35		lg N = 7.41	
(N$_o$ = 0.1N)	lg N$_o$ = 6.35		lg N$_o$ = 6.41	
Results	Vc1 0	Vc2 0	Vc1 0	Vc2 0
(Na = 10ẍ)	lg Na < 2.15		lg Na < 2.15	
(R)	lg R > 4.20		lg R > 4.27	
Pass: lg R ≥ 4	PASS		PASS	

Vc = plate count per ml

ẍ = average of Vc1 and Vc2

ẅ = weighted mean of ẍ

R = reduction (lg R = lg N$_o$ – lg Na)

Requirements & Conclusion:

This batch of Virex, when diluted to 1.0% v/v, passes the requirements of EN 1657 for fungicidal activity in 5 minutes at 10°C under low-level soiling conditions against both of the reference organisms detailed.

D C Watson

D C Watson BSc, CBiol, MSB, MIFST, ACIEHO
PO Box 95, New Ferry, Wirral, CH62 6HA
Tel: 0151 637 3331 Mob: 07767 871275
email: abbottanalytical@hotmail.co.uk

Nom du produit (Name of the product) **: VIREX**
Produit en poudre (Powdered product)

Test d'efficacité levuricide selon la norme NF EN 16438 – Mars 2014

Efficacy test *yeasticidal*
according to the standard *NF EN 16438-March 2014*

Rapport d'essai n°2020/112

Date : 24/04/2020

DEMANDEUR : **HYPRED S.A.S.**
Applicant

ESSAI RÉALISÉ PAR : **LCB Food Safety (*)**
Test performed by: **P.A.E. Actiparc- Rue des acacias – 01190 BOZ (France)**

(*) système de management de la qualité certifié par AFNOR-AFAQ selon la norme ISO 9001 :2015
quality management system certified by AFNOR-AFAQ in compliance with standard ISO 9001: 2015

ESSAI : Essai quantitatif pour l'évaluation de l'activité fongicide et/ou levuricide d'un désinfectant liquide utilisé dans le domaine vétérinaire selon la norme NF EN 16438 – Mars 2014 (phase 2, étape 2)
Test : Quantitative test for the evaluation of fungicidal and/or yesticidal activity of liquid disinfectant used in veterinary area according to the standard NF EN 16438-March 2014 (phase 2, step 2)

IDENTIFICATION DU PRODUIT TESTÉ :

Identification of the tested disinfectant

Nom du désinfectant : VIREX
Disinfectant Name

Numéro de lot : 13110300
Batch number

Fabricant : HYPRED S.A.S.
Manufacturer

Date de réception : 18/12/19
Date of receipt

Date de fabrication : /
Manufacture date

Date de péremption : /
Expiration date

Aspect du produit : Poudre rose, hétérogène avec granulations blanches
Product appearance *Pink, heterogeneous powder with white granulations*

Conditions de stockage : Température ambiante, à l'abri de la lumière
Storage conditions: *Ambient temperature, protected from light*

Substance(s) active(s) : Pentapotassium bis(peroxymonosulphate) bis(sulphate) + Troclosene sodique
Active(s) substance(s): *Pentapotassium bis(peroxymonosulphate) bis(sulphate) + Sodium troclosene*

Diluant du produit dont l'utilisation est recommandée par le fabricant : /
Diluent of the product whose use is recommended by the manufacturer:

DONNÉES RELATIVES A L'ESSAI :
Test data

Essai n°: VIREX-23
Test n°

Date de l'essai : 22/04/2020
Test date

Opérateur : C. Chicard
Operator

CONDITIONS EXPÉRIMENTALES DE L'ESSAI :
Experimental conditions of the test

Concentrations testées du liquide désinfectant : 3%, 2%, 1%, 0,5%, 0,1% (p/v)
Tested concentrations of the liquid disinfectant

Diluant utilisé : Eau dure
Diluent used:

Aspect des dilutions d'essai du produit : Homogène, physiquement stable, absence de précipité
Appearance of product dilutions: *Homogeneous, physically stable, absence of precipitate*

MÉTHODE UTILISÉE :
Method used

Par dilution – neutralisation :
Dilution neutralization method

Dénombrement en profondeur ☒
Enumeration in depth

Dénombrement en surface ☐
Enumeration in surface

Nombre de boîtes : 1/ml
Nomber of dish

Neutralisant utilisé : *Tween 80 : 3% (p/v) ; Lecithine d'oeufs : 0,3% (p/v)* **;** *Thiosulfate de sodium : 5% (p/v) ; Histidine : 0,1% (p/v) ;* Na_2HO_4 *: 2% (p/v)*
Neutralizer used: Tween 80: 3% (w/v) ; Eggs lecithin: 0.3% (w/v) ; Histidine: 0.1% (w/v) ; Sodium thiosulfate: 5% (w/v) ; Sodium hydrogene phosphate: 2% (w/v)

Conditions de l'essai :
Conditions test

Microorganisme(s) d'essai : *Test microorganisme(s)*	*Candida albicans* ATCC 10231 Souche de référence *Reference stain*
Temps de contact : *Contact time*	30 minutes
Température d'essai : *Test temperature*	10 °C
Substance interférente : *Interfering substance*	3,0g/L d'albumine bovine = Conditions de saleté de bas niveau *Bovine serum albumin 3.0g/L = Low dirty level conditions*
Température d'incubation : *Incubation temperature*	30 °C
Temps de séchage du support *Drying time of the support*	≤ 60 minutes

L'essai a été réalisé dans les conditions obligatoires décrites par la norme NF EN 16438 – Mars 2014.
The test was performed under the mandatory conditions described by the standard NF EN 16438–March 2014.

Oui / *yes* ☐ Non / *no* ☒

Pour *Aspergillus brasiliensis* ATCC 16404, le pourcentage de spores échinulées est > à 75%
For Aspergillus brasiliensis ATCC 16404, the percentage echinulate spores> 75%

Oui / *yes* ☐ Non / *no* ☐

ECART PAR RAPPORT A LA NORME :
Deviation from the norm

L'essai présente un écart par rapport à la norme NF EN 16438 – Mars 2014.
L'écart observé est le temps de contact de 30 minutes.

The test shows deviation from the standard NF EN 16438–March 2014.
The observed deviation is the contact time of 30 minutes.

CONCLUSION
Conclusion

Selon la norme NF EN 16438 – Mars 2014 en présence de 3,0g/L d'albumine bovine (conditions de saleté de bas niveau), à la température de 10°C et avec un temps de contact de 30 minutes, le désinfectant VIREX lot 19110300 présente une activité levuricide à la concentration de 3% (p/v) sur la souche de référence *Candida albicans* ATCC 10231.
La souche est conservée et contrôlée selon la norme NF EN 12353.

According to the standard NF EN 16438 – March 2014, with bovine serum albumin 3.0g/L (low dirty level conditions), at the temperature 10°C and with a 30 minutes contact time, the disinfectant VIREX batch 19110300 is yeasticide at the concentration 3% (w/v) on the reference strain Candida albicans ATCC 10231.
The strain is conserved and controlled according to standard NF EN 12353.

Caroline Chicard
Microbiologiste
Microbiologist

Patrick Arnould
Responsable Réglementation & Laboratoire
Regulatory & Laboratory Manager

Vérifié par / *Verified by* :

Kathleen Ferrand
Microbiologiste / *Microbiologist*

RÉSULTATS DES ESSAIS :
Test results

1/ Essais de validation :
Validation test

Suspension d'essai (N) *Test suspension*			**Validation du neutralisant (B)** *Validation of neutralizer*				**Validation de la méthode (C) Conc. du produit : 3 %** *Validation de method Conc. of product: 3 %*			
	10^{-6}	10^{-7}		10^{-3}	10^{-4}	10^{-5}		10^{-3}	10^{-4}	10^{-5}
Vc1	265	31	Vc1	>330	48	1	Vc1	162	17	3
Vc2	247	26	Vc2	>330	52	4	Vc2	183	27	2
$\bar{x} = 6{,}47.10^6$			$\bar{x} = 5{,}00.10^6$				$\bar{x} = 1{,}77.10^6$			
$3{,}75.10^6 \leq N \leq 1{,}25.10^7$ ($6{,}57 \leq \lg N \leq 7{,}10$)			B ≥ 0,5 × Nw				C ≥ 0,5 × Nw			

Le coefficient des moyennes pondérées est compris entre 5,0 et 15,0.
The weighted average coefficient is between 5.0 and 15.0.

2/ Témoin eau
Water control

Témoin eau (Nw) *Water control*		10^{-3}	10^{-4}	10^{-5}	Nw = lg ($\bar{x}$ x 10/d) = 6,40 lg Nw ≥ 5,27
	Vc1	240	26	3	
	Vc2	258	24	1	

L'essai est-il validé ? Oui / yes ☒ Non / no ☐
Is the test valid?

3/ Résultats d'essai
Test results

Conc. du produit (%) *Conc. of product*		10^{-0}	10^{-1}	10^{-2}	lg Na = lg ($\bar{x}$ ou/or $\bar{x}$ wn)	lg R = (lg Nw – lg Na)
3%	Vc1	63	2	0	2,82	3,58
	Vc2	69	5	3		
2%	Vc1	>330	132	13	4,12	2,28
	Vc2	>330	133	11		
1%	Vc1	>330	>330	81	4,86	1,54
	Vc2	>330	>330	65		
0,5%	Vc1	>330	>330	>330	>5,52	<0,88
	Vc2	>330	>330	>330		
0,1%	Vc1	>330	>330	>330	>5,52	<0,88
	Vc2	>330	>330	>330		

Explications :
Explanations

N : nombre d'UFC/0,025ml dans la suspension d'essai
B, C et Nw : Nombre d'UFC/surface d'essai de validation
Na : Nombre d'UFC/surface d'essai
Vc : dénombrement par ml et par boîte
$\bar{x}$: moyenne de Vc1 et Vc2
$\bar{x}$ wn = moyenne pondérée de $\bar{x}$
R = réduction (lg R = lg Nw – lg Na)

N: cfu/0.025ml in the test suspension
B, C et Nw: cfu/validation test surface
Na: cfu/test surface
Vc: *enumeration by ml and by dish*
$\bar{x}$: *average of Vc1 and Vc2*
$\bar{x}$ wn = *weighted average of* $\bar{x}$
R = reduction (lg R = lg Nw – lg Na)