M	icrobiological Services and Consulta		(2005)					
Title	Microbiological Analysis Quantitative suspension activity of chemical disi (Phase 1 / Step 1)	n test for the evalua	tion of ba	sic bacter	ricidal	UKAS TESTING 4393		
Product	CondenCide	MGS No	24136	SO No	5786			
a) <b>Identific</b>	ation of test laboratory:							
Test labora	itory	MGS Laboratories Unit 20 Hoeford P Barwell Lane Gosport Hampshire PO13 0AU						
b) <b>Identific</b>	ation of the Customer:							
Customer I	Name	Advanced Engine	ering Ltd					
Customer /	Address	Guardian House Stroudley Rd Basingstoke Hampshire RG24 8NL						
c) <b>Identific</b>	ation of the sample:							
Name of pr	roduct	CondenCide						
Batch num available)	ber (and expiry date if	N/A						
Manufactu	rer	Advanced Engine	ering Ltd					
Date of del	livery	01 Sep 16						
Storage co	onditions	Room temperatur	e and dark	ness				
Product dil manufactu	uent recommended by the rer for use	Not stated						
	stance(s) and their ion(s) (optional)	Didecyl dimethyl a (0.173mol/L).	ammonium	chloride -	Pre-diluted: 6.2	25g/100g		
Appearanc	e of the product	Clear pale blue lic	luid					
d) Test me	ethod and its validation:							
MGS proce	edure reference	WIN-1000.048-05						
Method		Dilution neutralisa	ition					
Neutraliser		Lecithin 3g/I, polysorbate 80 30g/I, sodium thiosulphate 5g/I, L- histidine1g/I, saponin 30g/I, phosphate buffer powder 0.35g/I						
Details of v	validation of the neutraliser	Neutraliser valida	tion perform	med accor	ding to 5.5.2 of	EN 1040: 2005		

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.

		C							
	LABORATORIE	ncy		Doc No.	TRB-2	016-122-02			
Title	Microbiological Analysis Quantitative suspension activity of chemical disin (Phase 1 / Step 1)	test for	the evalua	tion of bas	sic bacter	ricidal			
Product	CondenCide		MGS No	24136	SO No	5786			
e) Experime	ental conditions:								
Period of ana	alysis	05 Sep 16 to 12 Sep 16							
Product dilue	ent used during the test	Distille	d water						
Product test	concentrations	1:6 Dilu	ution (1 par	t product:6	parts wat	er)			
Appearance	of product dilutions	Clear p	ale blue liq	uid					
Contact time	ne en e	5 minu	tes ± 10s						
Test tempera	ature range	20°C ± 2°C							
Stability and	appearance of the mixture	Precipi	itate absent	throughou	t test				
Temperature	e of incubation	36°C ±	2°C						
Identification used	of the bacterial strains	Pseudomonas aeruginosa ATCC 15442 Staphylococcus aureus ATCC 6538							
f) Results:									
Test results		<ol> <li>Controls and validation</li> <li>Evaluation of bactericidal activity</li> </ol>							
g) <b>Conclusi</b>	on:	Based on EN 1040 (2005), the product CondenCide, when tested 1 part product: 6 parts water, possesses bactericidal activity in 5 minutes at 20°C for the referenced strains of <i>P. aeruginosa</i> and <i>S. aureus</i> .							
h) Deviation	ns:	None							
i) Comment	S:	This re	eport replac	es TRB-20	16-122-01				
Re-issued b	y: Kinda James	5	Ар	proved by:		252			
Name: Linda	a James	Name: Kim Morwood							
Position: La	aboratory Manager		Po	Position: Technical Director					
Date:	22 SEP 16	Date: 22 Sapile							

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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.

	LABORATORI		Doc No.	TRB-20	016-122-02	_
Title	Microbiological Analys Quantitative suspension activity of chemical dis (Phase 1 / Step 1)	on test for the evalua	tion of bas	sic bacter	ricidal	
Product	CondenCide	MGS No	24136	SO No	5786	+000

The MGS procedure WIN-1000.048 is a laboratory method based on the EN 1040 (2005) standard; the minor deviations from the standard, which do not affect the overall results, are detailed below:

- EN 1040 states an allowed tolerance of 36°C ±1°C or 37°C±1°C, MGS laboratories equipment is validated to ±2°C therefore MGS procedures state ±2°C.
- Organisms are prepared by swabbing plates and adding to 9ml diluent to form a suspension, rather than
  adding loopfuls of organism to 10ml diluent with beads, shaking for 3 minutes, aspirating and adding to a
  new container.
- All tests performed include validation of neutralisation; however, the neutraliser is not always pre-proved.
- The laboratory is regulated at 20°C; therefore for testing at 20°C a water bath is not used.
- Plates are incubated for ≥40 hours rather than 20-24 hours read followed by another 20-24 hours. The
  interim counting does not add value since plates are re-counted, extended incubation allows recovery of
  stressed organisms so they can be detected.
- Plates are incubated for the full time rather than performing an interim read; in addition the incubation
  period may be extended to a maximum of 4 due to business hours.
- Any part of the method may be altered to meet customer requirements; MGS does not insist on testing the standard conditions or three concentrations of product with replicates of the limiting organism

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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.

	crobiological Sei	RATORIES rvices and Consultancy		Doc No.	TRB-20	)16-122-02					
Title	Microbiological Analysis Based on EN 1040 (2005) Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics (Phase 1 / Step 1)										
Product	CondenC	ide	MGS No	24136	SO No	5786					
Actual test te Test organisr Incubation te Date of Test: Person respo Diluent used	ralisation met ates: 1 / ml ecithin 3g/l, p buffer pow mperature: 23 m: <i>P. aerugine</i> mperature: 36 05 Sep 16 onsible: La for product te	hod Pour pla polysorbate 80 30g/l, so vder 0.35g/l $3.5^{\circ}$ C osa ATCC 15442 $5^{\circ}$ C $\pm$ 2°C	تسسی odium thiosulp Signature: مر		L-histidine		30g/l, phosphate				
Validation a					(mail (D))	Mathad Val	idation (C)				
(Nv <sub>0</sub> )	suspension	Experimental Conditions Control		aliser Cor		Method Val					
(1440)			(*)		_	Prod conc: 1					
Vc1 104	x =100	Vc1 93 x =1	05 Vc1	96 X	=94	Vc1 87	χ =95				

Vc2

Nvo?

Yes

Vc2

Yes

Ν

10-6

10-7

Vc2

Yes

96

 $30 \leq \chi \text{ of } Nv_0 \leq 160?$ 

Х

(N and N<sub>0</sub>):

No

Test suspension and test

117

Vc1

>330

45

Х

 $\chi$  of A is  $\geq 0.5 \times \chi$  of Nvo?

No

Vc2

>330

39

92

Х

 $\chi$  of B is  $\geq$  0.5 x  $\chi$  of

No

 $\chi = 42 \times 10^7$ ; IgN= 8.63

 $N_0 = N/10$ ;  $IgN_0 = 7.63$ 

 $7.17 \le \log N_0 \le 7.70?$ 

Vc2

Nvo?

Yes

Yes

103

 $\chi$  of C is  $\geq$  0.5 x  $\chi$  of

Х

Х

No

No

Conc of the product	Vc1	Vc2	Na = χ x10	IgNa	lgR	Contact time
1:6	<14	<14	<140	<2.15	>5.48	5 minutes

Page 4 of 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.

	LABORATORIE	псу	Doc No. TRB-2016-122-02			
Title	Microbiological Analysis Quantitative suspension activity of chemical disi (Phase 1 / Step 1)	test for the evaluation	tion of bas	sic bacter	ricidal	UKAS 4393
Product	CondenCide	MGS No	24136	SO No	5786	
Dilution-neut Number of pl Neutraliser: I Actual test te Test organis Incubation te Date of Test Person respo Diluent used Appearance	lates: 1 / ml Lecithin 3g/l, polysorbate 80 3 buffer powder 0.35g/l emperature: 24.1°C m: <i>S. aureus</i> ATCC 6538 emperature: 36°C ± 2°C : 08 Sep 16 onsible: Edward Webber for product test solutions: Dis of product test solutions: Clea	Signa stilled water	Spread phate 5g/l, l ature:	L-histidine	] e1g/I, saponin	30g/l, phosphate
Validation a	nd Controls					

Valida (Nv <sub>0</sub> )	ation su	spension	Experi Condi		ontrol (A)	Neut	raliser	Control (B)		od Valid	l <b>ation (C)</b>
Vc1	44	χ =50	Vc1	62	χ =65	Vc1	62	χ =72	Vc1	97	χ =88
Vc2	55		Vc2	67		Vc2	82	_	Vc2	78	
VC255 $30 \le \chi$ of Nvo $\le 160$ ?Yes $\chi$ No				x χ of Nv₀? No	$\begin{array}{c c} \chi \text{ of } B \text{ is } \geq 0.5 \times \chi \text{ of} \\ Nv_0? \\ Yes \chi No \end{array}$			$\begin{array}{c c} \chi \text{ of } C \text{ is } \geq 0.5 \times \chi \text{ of} \\ Nv_0? \\ Yes  \chi  No  \end{array}$			

#### Test suspension and test

Test suspension	N	Vc1	Vc2	_ χ wm = 220 x 10 <sup>6</sup> ; IgN= 8.34
(N and N <sub>0</sub> ):	10-6	201	239	No = N/10; IgNo = 7.34
	10-7	21	22	7.17 $\leq$ lg N <sub>0</sub> $\leq$ 7.70? Yes X No

Conc of the product	Vc1	Vc2	Na = χ x10	IgNa	lgR	Contact time
1:6	<14	<14	<140	<2.15	>5.19	5 minutes

Page 5 of 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.

<b>Microbiological Services and Consultancy</b>			Doc No.			
Title	Microbiological Analysis Quantitative suspension activity of chemical disint (Phase 1 / Step 1)	test for the evalua	ation of ba	sic bacte	ricidal	UKAS TESTING 4393
Product	CondenCide	MGS No	24136	SO No	5786	4000

Explanations:

Vc = count per plate (one plate or more)

x = average of Vc1 and Vc2 (1. + 2. duplicate)

 $\chi$  wm = weighed mean of  $\chi$ 

R = reduction ( $IgR = IgN_0 - IgN_a$ )

Na = number of survivors in the test mixture

Nv = number of cells in the validation suspension

 $Nv_0 = Nv/10$ 

All test results have an associated uncertainty of measurement; for this test the expanded uncertainty is based on the estimated uncertainty multiplied by a coverage factor K=2 providing a level of confidence of approximately 95%. The uncertainty evaluation has been assessed in accordance with MGS laboratories' UKAS Accreditation and is available on request.

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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.

M	icrobiological Services and Consu		Doc No.	TRB-2016				
Title	Microbiological Analy Quantitative suspensi basic yeasticidal activ method and requireme	on test for the eval vity of chemical disi	uation of bas	ic fungicid d antiseptio	al or cs-Test	UKAS UKAS 4393		
Product	CondenCide	MGS No	24136	SO No	5786	4090		
a) <b>Identific</b>	ation of test laboratory:							
Test labora	tory	MGS Laboratories Unit 20 Hoeford Po Barwell Lane Gosport Hampshire PO13 0AU						
b) <b>Identific</b>	ation of the Customer:							
Customer N	lame	Advanced Enginee	ring Ltd					
Customer A	Address	Guardian House Stroudley Rd Basingstoke Hampshire RG24 8NL						
c) <b>Identific</b>	ation of the sample:	NO24 UNL						
Name of pro	oduct	CondenCide						
Batch numb available)	per (and expiry date if	N/A						
Manufactur	er (or supplier)	Advanced Enginee	ring Ltd					
Date of deli	very	01 Sep 16						
Storage cor	nditions	Room temperature	and darkness	5				
Product dilu manufactur	uent recommended by the er for use	Not stated						
	tance(s) and their on(s) (optional)	Didecyl dimethyl ar (0.173mol/L).	nmonium chlo	oride - Pre-d	iluted: 6.25g	/100g		
Appearance	e of the product	Clear pale blue liqu	iid					
d) Test me	thod and its validation:							
MGS proce	dure reference	WIN-1000.049-05						
Method		Dilution neutralisati	on					
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 va	alidation of the neutraliser	Neutraliser validation	on performed	according to	5.5.2 of EN	1275:2005.		

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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.

	ABORATOR obiological Services and Cons			Doc No.	TRB-2016	6-123-02				
Title	Microbiological Analy Quantitative suspens basic yeasticidal activ method and requirem	ion test vity of cl	for the evalu hemical disi	uation of bas						
Product	CondenCide		MGS No	24136	SO No	5786	4393			
e) Experimer	tal conditions:	-l		1						
Period of ana		09 Sep	09 Sep 16 to 13 Sep 16							
Product diluer	nt used during the test	Distille	d water							
Product test o	oncentrations	1:6 Dil	ution (1 part	product:6 part	ts water)					
Appearance of	of product dilutions	Clear	bale blue liqu	id						
Contact time		15 min	utes ± 10s							
Test temperat	ture range	20°C ± 2°C								
Stability and a mixture	appearance of the	Precip	itate absent t	hroughout tes	st					
Temperature	of incubation	30°C ±	2°C							
Identification of used	of the fungal strains	Aspergillus brasiliensis ATCC 16404 Candida albicans ATCC 10231								
f) Results:										
Test results		1) 2)		ntrols and validation aluation of fungicidal or yeasticidal activity						
g) Conclusio	n:	Based on EN 1275 (2005), the product CondenCide, when tested 1 part product:6 parts water, possesses fungicidal activity in 15 minutes at 20°C for the referenced strains of <i>A. brasiliensis and C. albicans.</i>								
h) <b>Deviations</b>	:	None								
i) Comments:		This re	port replaces	TRB-2016-1	23-01					
De issued by										
Re-issued by	what our	29		proved by:		25				
Name: Linda	Name: Linda James				Name: Kim Morwood					
Position: Lab	oratory Manager		Po	Position: Technical Director						
Date:	22 SEP16		Da	Date: 22 Sapil						

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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.

	LABORATOR		Doc No.	TRB-201	6-123-02	
Title	Microbiological Analy Quantitative suspens basic yeasticidal activ method and requirem	ion test for the eval /ity of chemical dis	uation of bas			
Product	CondenCide	MGS No	24136	SO No	5786	4393

The MGS procedure WIN-1000.049 is a laboratory method based on the EN 1275 (2005) standard; the minor deviations from the standard, which do not affect the overall results, are detailed below:

- Temperature tolerance of ±2°C rather than ±1°C. Validations are performed in tandem with the test, if the temperature has an adverse effect this would be reflected in the validations and the test would be invalid.
- Since the laboratory is maintained at 20°C a water bath is not used for testing at this temperature
- MGS Laboratories use Pro-Lab Microbank<sup>™</sup> cryovials according to the manufacture instructions.
- For mould a cryovial bead is added to broth and stored at 2-8°C for a maximum of 7 days; streaks are
  made from that broth, rather than streaking from stored slopes for 6-9 weeks.
- EN 12353 states mould for cryovials should be filter through a fritted filter and centrifuge at 2000 g<sub>N</sub> for 20 min, MGS laboratories centrifuge step only.
- Organisms are prepared by swabbing plates and adding to diluent which gives a homogenous suspension; rather than adding loopfuls to diluent with beads and vortexing to get a homogenous suspension
- Mould spores have been prepared based on the most recently issued EN method (EN 1650:2008 +A1:2013)
- Mould spores have been validated for storage at 2-8°C beyond the date of preparation
- The incubation period may be extended to a maximum of 4 days (6 for mould) due to business hours
- All tests performed include validation of neutralisation; however the neutraliser is not always pre-proved
- Preparation of hard water is based on the most recently issued standard rather than taking into account minor sterilisation differences between different EN methods
- Any part of the method may be altered to meet customer requirements; MGS does not insist on testing the standard conditions or three concentrations of product with replicates of the limiting organism

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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.

	LABORATORI		Doc No.	TRB-2010	6-123-02	
Title	Microbiological Analy Quantitative suspensi basic yeasticidal activ method and requireme	on test for the evaluation test for the evaluation of chemical disi	uation of bas			
Product	CondenCide	MGS No	24136	SO No	5786	4393
Dilution-r Number	patch number: N/A neutralisation method of plates: 1 / ml er: Lecithin 3g/l, polysorbate	Pour plate e 80 30g/l, sodium thi		Spread plate	L	in 30g/l,

phosphate buffer powder 0.35g/l

Actual test temperature: 23.2°C

Test organism: A. brasiliensis ATCC 16404

Incubation temperature:  $30^{\circ}C \pm 2^{\circ}C$ 

Date of Test: 09 Sep 16

Signature: E. Wer Person responsible: Edward Webber

Diluent used for product test solutions: Distilled water

Appearance of product test solutions: Clear pale blue liquid

#### Validation and Controls

Validation suspension (Nv <sub>0</sub> )		Experimental Conditions Control (A)			Neutraliser Control (B)			Method Validation (C)			
								N	Prod c	onc: 1:6	6
Vc1	41	χ =45	Vc1	39	χ =46	Vc1	42	x =42	Vc1	50	χ =49
Vc2	49		Vc2	52	1	Vc2	42		Vc2	47	
_	χ of Nv	₀ ≤ 160?	χ of A i	is ≥ 0.5	x χ of Nv₀?	χc	of B is ≥ Nv	0.5 x χ of 	χof	C is ≥ ( Nv₀	0.5 x χ of ?
Yes	X	10	Yes )	x	No	Yes	X	No	Yes	Х	No

#### Test suspension and test

Test suspension	N	Vc1	Vc2	$\chi = 29 \times 10^6$ ; IgN= 7.46	
(N and N₀):	10-5	>165	>165	No = N/10; IgNo = 6.46	
	10-6	31	26	$6.17 \le \log N_0 \le 6.70?$	Yes X No

Conc of the product	Vc1	Vc2	Na = χ x10	lgNa	lgR	Contact time
1:6	<14	<14	<140	<2.15	>4.31	15 minutes

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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.

	LABORATORIES crobiological Services and Consultancy		Doc No.	TRB-2016	6-123-02	
Title	Microbiological Analysis B Quantitative suspension to basic yeasticidal activity o method and requirements	est for the evalu f chemical disi	uation of bas			
Product	CondenCide	MGS No	24136	SO No	5786	4393
Dilution-no Number o Neutralise phosphate Actual tes Test organ Incubation Date of Te	atch number: N/A eutralisation method f plates: 1 / ml er: Lecithin 3g/l, polysorbate 80 3 e buffer powder 0.35g/l t temperature: 23.2°C nism: <i>C. albicans</i> ATCC 10231 n temperature: 30°C $\pm$ 2°C est: 09 Sep 16 sponsible: Edward Webber					nin 30g/I,
	ed for product test solutions: Dis	stilled water	Eil	m		
٨			5 A			

Appearance of product test solutions: Clear pale blue liquid

#### Validation and Controls

Validation suspension (Nv₀)		Experimental Conditions Control (A)			Neut	Neutraliser Control (B)			Method Validation (C)		
									Prod o	conc: 1:6	5
Vc1	70	χ =71	Vc1	73	χ =73	Vc1	74	χ =78	Vc1	71	χ =71
Vc2	71		Vc2	73		Vc2	81		Vc2	71	1
$30 \le \chi \text{ of } Nv_0 \le 160?$ $\chi \text{ of } A \text{ is } \ge 0.5 \times \chi \text{ of } Nv_0?$		χ of E Nvo?	8 is ≥ 0.:	5 x χ of	χ of C Nvo?	is ≥ 0.5	x χ of				
Yes	XN	lo	Yes	X	No	Yes	Х	No	Yes	Х	No

#### Test suspension and test

Test suspension	N	Vc1	Vc2	χ = 274 x 10 <sup>5</sup> ; IgN= 7.44
(N and N₀):	10 <sup>-5</sup>	275	282	No = N/10; IgNo = 6.44
	10-6	24	21	$6.17 \le \log N_0 \le 6.70?$ Yes X No

Conc of the product	Vc1	Vc2	Na = χ x10	lgNa	lgR	Contact time
1:6	<14	<14	<140	<2.15	>4.29	15 minutes

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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.

mgs	LABORATOR	Itancy	Doc No.	TRB-2010	6-123-02	
Title	Microbiological Analy Quantitative suspensi basic yeasticidal activ method and requirem	on test for the eval vity of chemical dis	uation of bas	tic fungicid d antiseptio	al or cs-Test	
Product	CondenCide	MGS No	24136	SO No	5786	4393

Explanations:

Vc = count per plate (one plate or more)

χ = average of Vc1 and Vc2 (1. + 2. duplicate)

R = reduction ( $IgR = IgN_0 - IgNa$ )

Na = number of survivors in the test mixture

Nv = number of cells in the validation suspension

 $Nv_0 = Nv/10$ 

All test results have an associated uncertainty of measurement; for this test the expanded uncertainty is based on the estimated uncertainty multiplied by a coverage factor K=2 providing a level of confidence of approximately 95%. The uncertainty evaluation has been assessed in accordance with MGS laboratories' UKAS Accreditation and is available on request.

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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.

	LABORATORIES		Doc No.	TRB-20	016-124-02	_ 👳		
le	Microbiological Analysis Quantitative suspension chemical disinfectants an (Phase 2 / Step 1)	test for the evalua	(2009) tion of bac	ctericidal	activity of			
oduct	CondenCide	MGS No	224136	SO No	5786	4393		
a) Ident	ification of test laboratory:							
		MGS Laboratories	s Ltd					
Test lab	ooratory	Unit 20 Hoeford F Barwell Lane Gosport Hampshire PO13 0AU	Point					
b) <b>Ident</b>	ification of the Customer:							
Custom	er Name	Advanced Engine	ering Ltd					
Custom	er Address	Guardian House Stroudley Rd Basingstoke Hampshire						
c) <b>Ident</b>	ification of the sample:	RG24 8NL						
Name o	f product	CondenCide						
Batch n availabl	umber (and expiry date if e)	N/A						
Manufa	cturer (or supplier)	Advanced Engine	ering Ltd					
Date of	delivery	01 Sep 16						
Storage	conditions	Room temperatur	e and dark	ness				
	diluent recommended by the cturer for use	Not stated						
	ubstance(s) and their tration(s) (optional)	Didecyl dimethyl a (0.173mol/L).	ammonium	chloride -	Pre-diluted: 6.	.25g/100g		
Appeara	ance of the product	Clear pale blue lic	luid					
d) Test	method and its validation:							
MGS pr	ocedure reference	WIN-1000.050-07						
Method		Dilution neutralisa	ition					
Neutrali	ser	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 5.5.2 of EN 1276:2009.						

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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.

	ABORATORIE			Doc No.	TRB-20	)16-124-02			
tle	Microbiological Analysis Quantitative suspension chemical disinfectants a (Phase 2 / Step 1)	test for	the evaluation	(2009) tion of bac	ctericidal	activity of			
oduct	CondenCide		MGS No	224136	SO No	5786	4393		
e) Experir	mental conditions:								
Period of a	analysis	05 Se	p 16 to 12 S	Sep 16					
Product di	luent used during the test	Stand	ard Hardnes	ss Water					
Product te	st concentrations	1:6 Di	lution (1-pai	t product:6	6 parts wat	ter)			
Appearan	ce of product dilutions	Clear	pale blue lic	luid					
Contact tir	ne	5 mini	utes ± 10s						
Test temp	erature range	20°C :	± 2°C						
Interfering	substance	3g/l B	ovine album	in					
Stability of	f the mixture	Precipitate absent throughout test							
Temperati	ure of incubation	36°C ± 2°C							
Identificati used	on of the bacterial strains	Pseudomonas aeruginosaATCC 15442Escherichia coliNCTC 10418Staphylococcus aureusATCC 6538Enterococcus hiraeATCC 10541				C 10418 C 6538			
f) Results									
Test result	ts	1) 2)		and validat n of bacter		vity			
g) <b>Conclu</b>	sion:	1 part minute	product: 6 p	oarts water nder dirty	, possesse conditions	es bactericida for the refere			
h) Deviati	ons:	None							
i) Special	remarks:	All controls and validations were within basic limits No precipitate was formed during the test							
J) Comme	ents:	This re	eport replac	es TRB-20	16-124-01				
Re-issued	Iby: Unda Jan	NOS	A	pproved	by:				
Name: Lin		_	P	lame: Kim	Morwood				
Position:	Laboratory Manager		F	Position: Technical Director					
Date:			г	)ate:	0 0				
	22 SEPID			-2	2 526	di	Page 2 of 8		

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.

mgs	LABORATORI	ES	Doc No.			
Title	itle Microbiological Analysis Based on E Quantitative suspension test for the chemical disinfectants and antiseptio (Phase 2 / Step 1)		(2009) tion of bac	tericidal	activity of	
Product	CondenCide	MGS No	224136	SO No	5786	4393

The MGS procedure WIN-1000.050 is a laboratory method based on the EN 1276 (2009) standard; the minor deviations from the standard, which do not affect the overall results, are detailed below:

- EN 1276 states an allowed tolerance of 36°C ±1°C or 37°C±1°C, MGS laboratories equipment is validated to ±2°C therefore MGS procedures state ±2°C. The tests are self validating so any stress caused to the organism will be reflected in the validations.
- Organisms are prepared by swabbing plates and adding to 9ml diluent to form a suspension, rather than adding loopfuls of organism to 10ml diluent with beads, shaking for 3 minutes, aspirating and adding to a new container. Swabbing forms a smooth suspension removing the need to shake with beads.
- The laboratory is regulated at 20°C; therefore for testing at 20°C a water bath is not used.
- Plates are incubated for the full time rather than performing an interim read; in addition the incubation period may be extended to a maximum of 4 due to business hours
- All tests performed include validation of neutralisation, but the neutraliser is not always pre-proved.
- Any part of the method may be altered to meet customer requirements; MGS does not insist on testing the standard conditions or three concentrations of product with replicates of the limiting organism

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.

	LABORATORIE		Doc No.	TRB-20	016-124-02	
Title	Title Microbiological Analysis Based on E Quantitative suspension test for the chemical disinfectants and antiseption (Phase 2 / Step 1)	n test for the evaluation	6 (2009) tion of bac	ctericidal	activity of	
Product	CondenCide	MGS No	224136	SO No	5786	4393

Product batch number: N/A	
Dilution-neutralisation method Pour plate	C Spread plate
Number of plates: 1 / ml	
Neutraliser: Lecithin 3g/l, polysorbate 80 30g/l, sodium t	hiosulphate 5g/l, L-histidine1g/l, saponin 30g/l,
phosphate buffer powder 0.35g/l	
Actual test temperature: 23.5°C	
Test organism: P. aeruginosa ATCC 15442	
Incubation temperature: 36°C ± 2°C	
Interfering substances: 3g/I Bovine albumin	
Date of Test: 05 Sep 16	
Person responsible: Laura Taylor Signate	ure: prene
Diluent used for product test solutions: Standard Hardne	ess Water

Appearance of product test solutions: Clear pale blue liquid

#### Validation and Controls

Validation suspension (Nv <sub>0</sub> )		[3] [3] [3] [3] [4] [4] [4] [4] [4] [4] [4] [4] [4] [4	imental tions C	ontrol (A)	Neutraliser Control (B)			Method Validation (C Prod conc: 1:6		53	
Vc1	104	x =100	Vc1	90	x =87	Vc1	96	χ =94	Vc1	129	x =127
Vc2	96		Vc2	84		Vc2	92		Vc2		
$VC2$ 96 $VC2$ 64 $30 \le \chi$ of Nv <sub>0</sub> $\le 160$ ? $\chi$ of A is $\ge 0.5 \times \chi$ of Nv <sub>0</sub> ?Yes $\chi$ No		χ of B Nv₀? Yes	is ≥ 0. X	5 x χ of No	$\begin{array}{c c} \chi \text{ of } C \text{ is } \geq 0.5 \text{ x } \chi \text{ of} \\ Nv_0? \\ Yes  \chi \qquad No  \end{array}$						

### Test suspension and test

Test suspension	Ν	Vc1	Vc2	$\chi = 42 \times 10^7$ ; IgN= 8.63	and an	
(N and N <sub>0</sub> ):	10-6	>330	>330	N <sub>0</sub> = N/10; IgN <sub>0</sub> = 7.63	[]	[]
	10-7	45	39	7.17 ≤ lg N₀ ≤ 7.70?	Yes X	No

Conc of the product	Vc1	Vc2	Na = x x10	lgNa	lgR	Contact time
1:6	<14	<14	<140	<2.15	>5.48	5 minutes

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.

	LABORATORI		Doc No.	TRB-2	016-124-02	
Title	Microbiological Analys Quantitative suspension chemical disinfectants (Phase 2 / Step 1)	on test for the evaluat		ctericidal	activity of	
Product	oduct CondenCide		224136	SO No	5786	4393
Dilution-r Number of Neutralise Actual tes Test orga Incubatio Interfering Date of T Person re Diluent us	oatch number: N/A neutralisation method of plates: 1 / ml er: Lecithin 3g/l, polysorbate phosphate buffer pow st temperature: 23.5°C anism: <i>E. coli</i> NCTC 10418 n temperature: 36°C ± 2°C g substances: 3g/l Bovine al est: 05 Sep 16 esponsible: Laura Taylor sed for product test solutions:	vder 0.35g/l bumin Sig s: Standard Hardness \	sulphate 5g gnature: <i>ρ</i> ι			onin 30g/I,

#### Validation and Controls

Valida (Nv <sub>0</sub> )	ation su	spension	Experimental Conditions Control (A)		Neut	Neutraliser Control (B)			Method Validation (C)		
									Prod o	conc: 1:0	6
Vc1	87	χ =82	Vc1	67	χ =61	Vc1	89	χ =80	Vc1	57	x =54
Vc2	76		Vc2	54		Vc2	70		Vc2	51	
$30 \le \chi \text{ of } Nv_0 \le 160?$ $\chi \text{ of } A \text{ is } \ge 0.5 \text{ x } \chi \text{ of } Nv_0?$		χ of B is ≥ 0.5 x χ of Nv₀?			χ of C is ≥ 0.5 x χ of Nv₀?						
Yes	X	No	Yes X No		Yes	Х	No	Yes	X	No	

#### Test suspension and test

Test suspension	Ν	Vc1	Vc2	χ wm = 285 x 10 <sup>6</sup> ; IgN= 8.45
(N and N₀):	10 <sup>-6</sup>	284	281	No = N/10; IgNo = 7.45
	10 <sup>-7</sup>	32	29	$7.17 \le \log N_0 \le 7.70?$ Yes X No

Conc of the product	Vc1	Vc2	Na = χ x10	lgNa	lgR	Contact time
1:6	<14	<14	<140	<2.15	>5.30	5 minutes

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.

	LABORATORI		Doc No.			
Title	le Microbiological Analysis Based on E Quantitative suspension test for the chemical disinfectants and antiseption (Phase 2 / Step 1)			ctericidal	activity of	
Product	CondenCide	MGS No	224136	SO No	5786	4393
Product I	patch number: N/A					

Pour plate X Spread plate

Number of plates: 1 / ml
Neutraliser: Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine1g/l, saponin 30g/l,
phosphate buffer powder 0.35g/l
Actual test temperature: 24.1°C
Test smeniers & surrous ATCC 6520

Test organism: S. aureus ATCC 6538

Incubation temperature: 36°C ± 2°C

Dilution-neutralisation method

Interfering substances: 3g/I Bovine albumin

Date of Test: 08 Sep 16

Person responsible: Edward Webber

Signature: E Work Diluent used for product test solutions: Standard Hardness Water Appearance of product test solutions: Clear pale blue liquid

## Validation and Controls

		uspension Experimental Conditions Control (A)		Neut	Neutraliser Control (B)		Method Validation (C)				
						1			Prod o	conc: 1:0	6
Vc1	44	χ =5	Vc1	72	χ =67	Vc1	62	χ =72	Vc1	58	χ =59
Vc2	55		Vc2	62		Vc2	82	1	Vc2	59	
30 ≤ ) Yes [	(of Nv₀ ≤ X	≤ 160? No			x χ of Nv₀? No	χ of B Nv₀? Yes	3 is ≥ 0.	5 x χ of No	χ of C Nv₀? Yes	is ≥ 0.5 X	x χ of No

#### Test suspension and test

Test suspension	N	Vc1	Vc2	χ wm = 220 x 10 <sup>6</sup> ; IgN= 8.34
(N and N <sub>0</sub> ):	10-6	201	239	$N_0 = N/10; IgN_0 = 7.34$
	10 <sup>-7</sup>	21	22	7.17 ≤ lg N₀ ≤ 7.70? Yes X No

Conc of the product	Vc1	Vc2	Na = χ x10	lgNa	lgR	Contact time
1:6	<14	<14	<140	<2.15	>5.19	5 minutes

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.

	LABORATORIE		Doc No.	TRB-20	016-124-02	
Title	Microbiological Analysi Quantitative suspension chemical disinfectants a (Phase 2 / Step 1)	n test for the evalua	6 (2009) tion of bac	ctericidal	activity of	
Product	CondenCide	MGS No	224136	SO No	5786	4393

Pour plate X Spread plate Dilution-neutralisation method Number of plates: 1 / ml Neutraliser: Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine1g/l, saponin 30g/l, phosphate buffer powder 0.35g/l Actual test temperature: 24.1°C Test organism: E. hirae ATCC 10541 Incubation temperature: 36°C ± 2°C Interfering substances: 3g/l Bovine albumin Date of Test: 08 Sep 16 Signature: K. WON Edward Webber Person responsible: Diluent used for product test solutions: Standard Hardness Water

Appearance of product test solutions: Clear pale blue liquid

#### Validation and Controls

Validation suspension (Nv <sub>0</sub> )	Experimental Conditions Control (A)	Neutraliser Control (B)	Method Validation (C) Prod conc: 1:6
Vc1 71 χ =69	Vc1 67 χ=65	Vc1 74 χ =71	Vc1 45 χ =57
Vc2 67	Vc2 62	Vc2 67	Vc2 68
$30 \le \chi \text{ of } Nv_0 \le 160?$ Yes $\chi$ No	$\chi$ of A is ≥ 0.5 x $\chi$ of Nv <sub>0</sub> ? Yes $\chi$ No	$\chi$ of B is $\geq 0.5 \times \chi$ of Nv <sub>0</sub> ? Yes $\chi$ No	$\chi$ of C is $\geq 0.5 \times \chi$ of Nv <sub>0</sub> ? Yes $\chi$ No

#### Test suspension and test

Test suspension	N	Vc1	Vc2	χ wm = 245 x 10 <sup>6</sup> ; IgN= 8.39
(N and N <sub>0</sub> ):	10-6	261	223	$N_0 = N/10; IgN_0 = 7.39$
	10-7	30	25	7.17 ≤ lg N₀ ≤ 7.70? Yes X No

Conc of the product	Vc1	Vc2	Na = χ x10	lgNa	lgR	Contact time
1:6	<14	<14	<140	<2.15	>5.24	5 minutes

#### Page 7 of 8

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.

	<b>Microbiological Services and Consultancy</b>		Doc No.	TRB-2	016-124-02	
Title	Microbiological Analysis Quantitative suspension chemical disinfectants a (Phase 2 / Step 1)	test for the evaluation	(2009) tion of bac	ctericidal	activity of	
Product	CondenCide	MGS No	224136	SO No	5786	4393

Explanations:

- Vc = count per plate (one plate or more)
- χ = average of Vc1 and Vc2 (1. + 2. duplicate)
- $\chi$  wm = weighed mean of  $\chi$
- $R = reduction (IgR = IgN_0 IgNa)$
- Na = number of survivors in the test mixture
- N = number of cells in the test suspension
- No =N/10
- Nv = number of cells in the validation suspension
- $Nv_0 = Nv/10$

All test results have an associated uncertainty of measurement; for this test the expanded uncertainty is based on the estimated uncertainty multiplied by a coverage factor K=2 providing a level of confidence of approximately 95%. The uncertainty evaluation has been assessed in accordance with MGS laboratories' UKAS Accreditation and is available on request.

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.



BS EN 14476:2013+A2:2019

# Study Title: Quantitative suspension test for evaluation of virucidal activity in the medical area (Phase 2 Step1)

Microbiological Solutions Limited (MSL) Gollinrod, Walmersley, Bury, BL9 5NB, UK

Angela Davies, CEO

Customer: Advanced Engineering Ltd Contact name: Kajally Jobe Email: Address: Guaridian House, Stroudley Road, Basingstoke, RG24 8NL PO/Quote number: Q003251 Report date: 25/08/2020 Issue number: 1

Megan Barrett Laboratory Manager

Peter Thistlethwaite Technical Projects Manager

The test results on this report refer only to the items tested as supplied by the customer. This report shall not be reproduced except in full and with written approval of Microbiological Solutions Ltd. All reports are archived for a minimum of 2 years. The sample will be retained for 1 month unless otherwise requested in writing.

Microbiological Solutions Ltd Gollinrod Walmersley Bury, BL9 5NB



#### <u>Scope</u>

The standard method BS EN 14476 describes a test method and the minimum requirements for virucidal activity of a chemical disinfectant and antiseptic products that form a homogenous physically stable preparation when diluted with hard water – or in the case of ready to use products that are not diluted when applied, - with water. Products can only be tested at a concentration of 80% (97% with a modified method for special cases) as some dilution is always produced by adding the test organisms and interfering substances. This European Standard applies to products that are used in the medical area in the fields of hygienic handrub, hygienic handwash, instrument disinfection by immersion, surface disinfection by wiping, spraying, flooding or other means and textile disinfection.

This European standard applies to areas and situations where disinfection is medically indicated. Such indication occurs in patient care, for example: In hospitals, in community medical facilities and in dental institutions or in clinics of schools, of kindergartens and of nursing homes, and may occur in the workplace and in the home. It may also include services such as laundries and kitchens supplying products directly for patients.

#### **Outline of Test Method (Obligatory Test Conditions)**

A sample of the test product is diluted in synthetic hard water in products diluted at point of use or water in the case of ready to use products is added to a test suspension of viruses in a solution of interfering substance. The mixture is maintained at one of the temperatures and contact times specified in the standard. At the end of this contact time, an aliquot is taken; the virucidal action in this portion is immediately suppressed by a validated method (dilutions of the sample in ice-cold cell maintenance medium). The dilutions are transferred into cell culture units either using monolayer or cell suspension. Infectivity tests are done either by plaque test or quantal tests. After incubation, the titres of infectivity are calculated according to Spearman and Käber or by plaque counting. Reduction of virus infectivity is calculated from differences of Ig virus titres before (virus control) and after treatment with the product. The standard minimum spectrum of test organisms is Poliovirus, Adenovirus and Murine Norovirus.

#### Acceptance Criteria

The product when tested as above shall demonstrate at least a 4 log<sub>10</sub> reduction against the test virus. The test is deemed valid where all control requirements are met.

Microbiological Solutions Ltd Gollinrod Walmersley Bury, BL9 5NB



#### BS EN 14476:2013+A2:2019

	Test information	Deviation
Name of Product	CondenCide	
Batch Number & Expiry Date	29/06/2025 0082906	
Date of Delivery	13/07/2020	
Period of Analysis	28/07/2020-	
Manufacturer / Supplier	Advanced Engineering Ltd	
Storage Conditions	Ambient	
Appearance of the Product	Pale blue liquid	
Neutralisation Method	Dilution	
Product Diluent	Synthetic hard water	
Test Concentrations	Neat (56700ppm), 1:6 (8110ppm), 1:13 (4050ppm)	
Experimental Conditions	Clean	
Interfering Substance	Clean 0.3g/l Bovine Albumin	
Test Temperature	20°C ± 1°C	
Temperature of Incubation	37°C ±1°C	
Identification of the Viral Strains:	Modified vaccinia virus Ankara (MVA), ATCC VR-1508	
Contact Times	15 minutes <u>+</u> 10s	
Stability and Appearance During Test	No Change Observed (Homogenous)	

#### **Deviations from Standard Method**

There were no deviations from the standard method

#### **Test Result Summary**

The test product received has achieved to achieve a 4-log reduction against Vaccinia virus, when tested under the condition stipulated in this report.

See page 2 for acceptance criteria and raw data tables below for complete test results.



#### BS EN 14476:2013+A2:2019

#### Summary

Controls					
MSL					
Conditions SOLUTION PROVIDERS	Concentration	Contact time	log TCID50	log reduction	Control validation
Virus control (water)	N/A	15 minutes	7.71	N/A	Validated
Cytotoxicity (product)	Neat	N/A	3.00	N/A	Validated
Product supression control	Neat	Neat	7.38	0.33	Validated
Reference virus inactivation (formaldyehyde)	1.4%	5 minutes	4.46	3.25	Validated
Reference virus inactivation (formaldyehyde)	1.4%	15 minutes	3.75	3.96	Validated
Cytotoxicity (formaldehyde)	1.4%	N/A	2.50	N/A	Validated

Interference controls	SOLUTION PROVIDERS					
Condition		Concentration	Contact time	log TCID50	Log difference	Control validation
Interference control (unt	reated)	N/A	N/A	8.58	N/A	N/A
Interference control (trea	ated)	Neat	N/A	8.50	0.08	Validated



Test Results	SOLUTION PROVIDERS					
Condition		Concentration	Contact time	log TCID50	log reduction	Pass/Fail
Test product		Neat	15 minutes	3.58	>4	Pass
Test product		1 in 6	15 minutes	3.50	>4	Pass
Test product		1 in 13	15 minutes	3.50	>4	Pass

Bury, BL9 5NB



#### Raw data

Virus cont	trol (water)			Contact ti	me	15 minutes		
Dilution	Counts						% CPE	p(1-p)
-2	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	1	0
-6	4	4	4	4	4	4	1	0
-7	4	4	4	4	4	2	0.91666667	0.076389
-8	2	2	1	0	1	1	0.29166667	0.206597
-9	0	0	0	0	0	0	0	0

Organism	Vacciniavirus					
	ATTC VR-1508					
d	1					
sum px	2.21					
n	8					
SD50	-7.71					
SE	0.20					
хр	-6					

Cytotoxic	Cytotoxicity (product) Product concentration					Neat		
Dilution	Counts						% CPE	p(1-p)
-2	4	4	4	4	4	4	1	0
-3	2	2	2	2	2	2	0.5	0.25
-4	0	0	0	0	0	0	0	0
-5	0	0	0	0	0	0	0	0
-6	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0

Product concentration

Neat

% CPE

p(1-p)

Vacciniavirus	
ATTC VR-1508	
1	
1.50	
8	
-3.00	
0.19	
-2	
	ATTC VR-1508 1 1.50 8 -3.00 0.19

Organism	Vacciniavirus	
	ATTC VR-1508	
d	1	
sum px	1.88	
n	8	
SD50	-7.38	
SE	0.21	
хр	-6	

Organism	Vacciniavirus				
	ATTC VR-1508				
d	1				
sum px	2.0833				
n	10				
SD50	-8.583				
SE	0.1746				
хр	-7				

-2	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	1	0
-6	4	4	4	4	4	4	1	0
-7	2	2	3	3	4	4	0.75	0.1875
-8	1	1	1	0	0	0	0.125	0.109375
-9	0	0	0	0	0	0	0	0
Interferer	nce control	(untreated	d)	Product co	oncentratio	on	Neat	
Dilution	Counts						% CPE	p(1-p)
								•

Interferer	ice control	(untreated	d)	Product co	oncentratio	on	Neat	
Dilution	Counts						% CPE	p(1-p)
-1	4	4	4	4	4	4	1	0
-2	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	1	0
-6	4	4	4	4	4	4	1	0
-7	4	4	4	4	4	4	1	0
-8	4	4	3	4	3	3	0.875	0.109375
-9	1	1	2	1	0	0	0.20833333	0.164931
-10	0	0	0	0	0	0	0	0

#### Microbiological Solutions Ltd

Gollinrod Walmersley Bury, BL9 5NB

Product supression control

Dilution Counts

Tel: 0844 824 6003 Email: info@mls.io Web: www.msl.io Company number: 4218514

#### BS EN 14476:2013+A2:2019

#### Raw data

Interferer	nce control	(treated)		Product co	Product concentration			
Dilution	Counts						% CPE	p(1-p)
-1	4	4	4	4	4	4	1	0
-2	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	1	0
-6	4	4	4	4	4	4	1	0
-7	4	4	4	4	4	4	1	0
-8	3	3	3	4	4	4	0.875	0.109375
-9	2	1	0	0	0	0	0.125	0.109375
-10	0	0	0	0	0	0	0	0

Organism	Vacciniavirus	
	ATTC VR-1508	
d	1	
sum px	2	
n	10	
SD50	-8.5	
SE	0.1559	
хр	-7	

Reference	Reference virus inactivation (formaldyehyde)					me	5 minutes	
Dilution	Counts						% CPE	p(1-p)
-2	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	1	0
-4	3	3	3	3	3	3	0.75	0.1875
-5	2	2	1	0	0	0	0.20833333	0.164931
-6	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0

Reference	e virus inac	tivation (fo	ormaldyeh	yde)	Contact ti	me	15 minutes	
Dilution	Counts						% CPE	p(1-p)
-2	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	1	0
-4	2	2	1	0	1	0	0.25	0.1875
-5	0	0	0	0	0	0	0	0
-6	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0

Organism	Vacciniavirus	
	ATTC VR-1508	
d	1	
sum px	1.96	
n	8	
SD50	-4.46	
SE	0.22	
хр	-3	

Organism	Vacciniavirus	
	ATTC VR-1508	
d	1	
sum px	1.25	
n	8	
SD50	-3.75	
SE	0.16	
хр	-3	

Organism Vacciniavirus			
	ATTC VR-1508		
d	1		
sum px	1.00		
n	8		
SD50	-2.50		
SE	0.00		
хр	-2		

#### Cytotoxicity (formaldehyde) Dilution Counts 4 -2 4 4 4 4 -3 0 0 0 0 0

-2	4	4	4	4	4	4	1	0
-3	0	0	0	0	0	0	0	0
-4	0	0	0	0	0	0	0	0
-5	0	0	0	0	0	0	0	0
-6	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0

#### **Microbiological Solutions Ltd**

Gollinrod Walmersley Bury, BL9 5NB Tel: 0844 824 6003 Email: info@mls.io Web: www.msl.io Company number: 4218514 % CPE

p(1-p)

#### BS EN 14476:2013+A2:2019



#### BS EN 14476:2013+A2:2019

#### Raw data

Test prod	uct	Product concentration		Neat	Contact time		15 minutes	
Dilution	Counts						% CPE	p(1-p)
-2	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	1	0
-4	1	1	0	0	0	0	0.08333333	0.076389
-5	0	0	0	0	0	0	0	0
-6	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0

Organism	Vacciniavirus		
	ATTC VR-1508		
d	1		
sum px	1.08		
n	8		
SD50	-3.58		
SE	0.10		
хр	-3		

Test prod	est product		Product concentration			Contact time		15 minute
Dilution	Counts						% CPE	p(1-p)
-2	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	1	0
-4	0	0	0	0	0	0	0	0
-5	0	0	0	0	0	0	0	0
-6	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0

Vacciniavirus	
ATTC VR-1508	
1	
1.00	
8	
-3.50	
0.00	
-3	
	1 1.00 8 -3.50 0.00

Test produ	duct Product concentration 1 in 13 Contact time 2				15 minutes			
Dilution	Counts						% CPE	p(1-p)
-2	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	1	0
-4	0	0	0	0	0	0	0	0
-5	0	0	0	0	0	0	0	0
-6	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0

Organism	Vacciniavirus		
Organisin			
	ATTC VR-1508		
d	1		
sum px	1.00		
n	8		
SD50	-3.50		
SE	0.00		
хр	-3		

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#### BS EN 14476:2013+A2:2019

#### <u>KEY</u>

CPE Counts	Cytopathic effect 0-4 indicating degree of cytopathic effect									
counts		0 = No effect, 1 = 25% CPE, 2 = 50% CPE, 3 = 75% CPE, 4 = 100% CPE								
d		Dilution factor (log)								
Sum px	Sum of 9	Sum of % CPE from the highest dilution showing 100% CPE to the lowest dilution assessed.								
n	Number of dilutions									
SD50	Dilution showing 50% of the end point according to Spearman-Kärber method									
SE	Standard error									
хр	Lowest o	dilution showing 100% CPE								
TCID50	Titre causing 50% of the end point according to Spearman-Kärber									
PASS	=	lg R greater than or equal to 4								
FAIL	=	lg R less than 4								
>	greater	than	≥	equal to or greater than						
<	less thar	1	≤	equal to or less than						

#### Calculation notes

In cases where the highest dilution assessed has not shown 100% CPE, the value has been calculated assuming the dilution above this would give 100% CPE and the corresponding value has been assigned as <x.

The standard requires the product suppression control to show a <0.5 log reduction in viral titre. In cases where the product has failed to achieve the required 4 log reduction, but the product suppression control shows a >0.5 log reduction the result has been deemed as valid for fail as the consequence of inadequate suppression would be a partially extended contact time which would generate false positives, but not false negatives.

A similar approach has been taken in regards to the cytotoxicity controls. The standard requires a 4-log difference between the cytotoxicity level and the viral titre. In cases where this is not obtained, but the log reduction observed by the product is within the difference between the cytotoxicity levels and the viral titre the result is deemed acceptable for a fail as there will be no impact on the determination of efficacy.

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