


<b>mgsLABORATORIES</b> Microbiological Services and Consultancy		Doc No.		TRB-2016-122-02	
					
Title	<b>Microbiological Analysis Based on EN 1040 (2005)</b> <b>Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics (Phase 1 / Step 1)</b>				
Product	CondensCide	MGS No	24136	SO No	5786

**a) Identification of test laboratory:**

Test laboratory	MGS Laboratories Ltd Unit 20 Hoeford Point Barwell Lane Gosport Hampshire PO13 0AU
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**b) Identification of the Customer:**

Customer Name	Advanced Engineering Ltd
Customer Address	Guardian House Stroudley Rd Basingstoke Hampshire RG24 8NL

**c) Identification of the sample:**


Name of product	CondensCide
Batch number (and expiry date if available)	N/A
Manufacturer	Advanced Engineering Ltd
Date of delivery	01 Sep 16
Storage conditions	Room temperature and darkness
Product diluent recommended by the manufacturer for use	Not stated
Active substance(s) and their concentration(s) (optional)	Didecyl dimethyl ammonium chloride - Pre-diluted: 6.25g/100g (0.173mol/L).
Appearance of the product	Clear pale blue liquid

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

MGS procedure reference	WIN-1000.048-05
Method	Dilution neutralisation
Neutraliser	Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine 1g/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 1040: 2005.

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Title	<b>Microbiological Analysis Based on EN 1040 (2005)</b> <b>Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics (Phase 1 / Step 1)</b>				
Product	Condencide	MGS No	24136	SO No	5786

**e) Experimental conditions:**

Period of analysis	05 Sep 16 to 12 Sep 16
Product diluent used during the test	Distilled water
Product test concentrations	1:6 Dilution (1 part product:6 parts water)
Appearance of product dilutions	Clear pale blue liquid
Contact time	5 minutes $\pm$ 10s
Test temperature range	20°C $\pm$ 2°C
Stability and appearance of the mixture	Precipitate absent throughout test
Temperature of incubation	36°C $\pm$ 2°C
Identification of the bacterial strains used	<i>Pseudomonas aeruginosa</i> ATCC 15442 <i>Staphylococcus aureus</i> ATCC 6538

**f) Results:**

Test results	1) Controls and validation 2) Evaluation of bactericidal activity
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**g) Conclusion:**

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 *P. aeruginosa* and *S. aureus*.

**h) Deviations:**

None

**i) Comments:**

This report replaces TRB-2016-122-01

**Re-issued by:** Linda James

**Approved by:**

**Name:** Linda James

**Name:** Kim Morwood

**Position:** Laboratory Manager

**Position:** Technical Director


**Date:** 22 SEP 16

**Date:** 22 SEP 16

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<b>mgs</b> LABORATORIES Microbiological Services and Consultancy					
			Doc No.	TRB-2016-122-02	
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	Condencide	MGS No	24136	SO No	5786




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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<b>mgs</b> LABORATORIES Microbiological Services and Consultancy				Doc No.		TRB-2016-122-02
Title		<b>Microbiological Analysis Based on EN 1040 (2005)</b> <b>Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics</b> <b>(Phase 1 / Step 1)</b>				
Product	Condencide	MGS No	24136	SO No	5786	

Product batch number: N/A  
 Dilution-neutralisation method      Pour plate ☒      Spread plate ☐  
 Number of plates: 1 / ml  
 Neutraliser: Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine 1g/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  
 Date of Test: 05 Sep 16  
 Person responsible: Laura Taylor      Signature: *pr Ewen*  
 Diluent used for product test solutions: Distilled water  
 Appearance of product test solutions: Clear pale blue liquid

#### Validation and Controls

Validation suspension (N <sub>v0</sub> )			Experimental Conditions Control (A)			Neutraliser Control (B)			Method Validation (C)		
Vc1	104	χ = 100	Vc1	93	χ = 105	Vc1	96	χ = 94	Vc1	87	χ = 95
Vc2	96		Vc2	117		Vc2	92		Vc2	103	
30 ≤ χ of N <sub>v0</sub> ≤ 160?			χ of A is ≥ 0.5 x χ of N <sub>v0</sub> ?			χ of B is ≥ 0.5 x χ of N <sub>v0</sub> ?			χ of C is ≥ 0.5 x χ of N <sub>v0</sub> ?		
Yes	<input checked="" type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>	No	<input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>	No	<input type="checkbox"/>


#### Test suspension and test


Test suspension (N and N <sub>0</sub> ):	N	Vc1	Vc2	χ = 42 x 10 <sup>7</sup> ; lgN= 8.63			
	10 <sup>-6</sup>	>330	>330	N <sub>0</sub> = N/10; lgN <sub>0</sub> = 7.63			
	10 <sup>-7</sup>	45	39	7.17 ≤ lg N <sub>0</sub> ≤ 7.70?			
				Yes	<input checked="" type="checkbox"/>	No	<input type="checkbox"/>

Conc of the product	Vc1	Vc2	Na = χ x 10	lgNa	lgR	Contact time
1:6	<14	<14	<140	<2.15	>5.48	5 minutes

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<b>Title</b> 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)					
<b>Product</b> Condencide	<b>MGS No</b> 24136	<b>SO No</b> 5786			

Product batch number: N/A  
 Dilution-neutralisation method      Pour plate ☒      Spread plate ☐  
 Number of plates: 1 / ml  
 Neutraliser: Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine 1g/l, saponin 30g/l, phosphate buffer powder 0.35g/l  
 Actual test temperature: 24.1°C  
 Test organism: *S. aureus* ATCC 6538  
 Incubation temperature: 36°C ± 2°C  
 Date of Test: 08 Sep 16  
 Person responsible: Edward Webber      Signature:   
 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)		
									Prod conc: 1:6		
Vc1	44	χ =50	Vc1	62	χ =65	Vc1	62	χ =72	Vc1	97	χ =88
Vc2	55		Vc2	67		Vc2	82		Vc2	78	
30 ≤ χ of Nv <sub>0</sub> ≤ 160?			χ of A is ≥ 0.5 x χ of Nv <sub>0</sub> ?			χ of B is ≥ 0.5 x χ of Nv <sub>0</sub> ?			χ of C is ≥ 0.5 x χ of Nv <sub>0</sub> ?		
Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>

#### Test suspension and test


Test suspension (N and N <sub>0</sub> ):	N	Vc1	Vc2	χ <sub>wm</sub> = 220 x 10 <sup>6</sup> ; lgN = 8.34 N <sub>0</sub> = N/10; lgN <sub>0</sub> = 7.34 7.17 ≤ lg N <sub>0</sub> ≤ 7.70?      Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
	10 <sup>-6</sup>	201	239	
	10 <sup>-7</sup>	21	22	

Conc of the product	Vc1	Vc2	Na = χ x 10	lgNa	lgR	Contact time
1:6	<14	<14	<140	<2.15	>5.19	5 minutes

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				Doc No.	TRB-2016-122-02
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	CondensCide	MGS No	24136	SO No	5786



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Explanations:


Vc = count per plate (one plate or more)  
 $\bar{x}$  = average of Vc1 and Vc2 (1. + 2. duplicate)  
 $\bar{x}_{wm}$  = weighed mean of  $\bar{x}$   
R = reduction ( $\lg R = \lg N_0 - \lg N_a$ )  
Na = number of survivors in the test mixture  
Nv = number of cells in the validation suspension  
Nv<sub>0</sub> = 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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<b>mgsLABORATORIES</b> Microbiological Services and Consultancy			Doc No. <b>TRB-2016-123-02</b>		
Title	<b>Microbiological Analysis Based on EN 1275 (2005)</b> <b>Quantitative suspension test for the evaluation of basic fungicidal or basic yeasticidal activity of chemical disinfectants and antiseptics-Test method and requirements (phase 1)</b>				
Product	Condencide	MGS No	24136	SO No	

**a) Identification of test laboratory:**

Test laboratory

MGS Laboratories Ltd  
 Unit 20 Hoeford Point  
 Barwell Lane  
 Gosport  
 Hampshire  
 PO13 0AU

**b) Identification of the Customer:**

Customer Name

Advanced Engineering Ltd

Customer Address

Guardian House  
 Stroudley Rd  
 Basingstoke  
 Hampshire  
 RG24 8NL

**c) Identification of the sample:**

Name of product

Condencide

Batch number (and expiry date if available)

N/A

Manufacturer (or supplier)

Advanced Engineering Ltd

Date of delivery

01 Sep 16

Storage conditions

Room temperature and darkness

Product diluent recommended by the manufacturer for use

Not stated

Active substance(s) and their concentration(s) (optional)

Didecyl dimethyl ammonium chloride - Pre-diluted: 6.25g/100g (0.173mol/L).

Appearance of the product

Clear pale blue liquid

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

MGS procedure reference

WIN-1000.049-05

Method

Dilution neutralisation

Neutraliser


Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine 1g/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 1275:2005.

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<b>Title</b> <b>Microbiological Analysis Based on EN 1275 (2005)</b> <b>Quantitative suspension test for the evaluation of basic fungicidal or basic yeasticidal activity of chemical disinfectants and antiseptics-Test method and requirements (phase 1)</b>					
<b>Product</b> <b>Condencide</b>	<b>MGS No</b> <b>24136</b>	<b>SO No</b> <b>5786</b>			

**e) Experimental conditions:**

Period of analysis	09 Sep 16 to 13 Sep 16
Product diluent used during the test	Distilled water
Product test concentrations	1:6 Dilution (1 part product:6 parts water)
Appearance of product dilutions	Clear pale blue liquid
Contact time	15 minutes $\pm$ 10s
Test temperature range	20°C $\pm$ 2°C
Stability and appearance of the mixture	Precipitate absent throughout test
Temperature of incubation	30°C $\pm$ 2°C
Identification of the fungal strains used	<i>Aspergillus brasiliensis</i> ATCC 16404 <i>Candida albicans</i> ATCC 10231

**f) Results:**

Test results	1) Controls and validation 2) Evaluation of fungicidal or yeasticidal activity
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**g) Conclusion:**

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 *A. brasiliensis* and *C. albicans*.

**h) Deviations:**

None

**i) Comments:**

This report replaces TRB-2016-123-01

**Re-issued by:** *Linda James*

**Name:** Linda James

**Position:** Laboratory Manager

**Date:** 22 SEP 16

**Approved by:** *[Signature]*

**Name:** Kim Morwood

**Position:** Technical Director


**Date:** 22 SEP 16

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Microbiological Services and Consultancy			Doc No.	TRB-2016-123-02	
Title	<b>Microbiological Analysis Based on EN 1275 (2005)</b> <b>Quantitative suspension test for the evaluation of basic fungicidal or basic yeasticidal activity of chemical disinfectants and antiseptics-Test method and requirements (phase 1)</b>				
Product	Condencide	MGS No	24136	SO No	5786


  
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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  $\pm 2^{\circ}\text{C}$  rather than  $\pm 1^{\circ}\text{C}$ . 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  $20^{\circ}\text{C}$  a water bath is not used for testing at this temperature
- MGS Laboratories use Pro-Lab Microbank™ cryovials according to the manufacture instructions.
- For mould a cryovial bead is added to broth and stored at  $2-8^{\circ}\text{C}$  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  $2000\text{ g}_N$  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  $2-8^{\circ}\text{C}$  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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<b>Product</b> <b>Condencide</b>		<b>MGS No</b> <b>24136</b>	<b>SO No</b> <b>5786</b>			

Product batch number: N/A  
 Dilution-neutralisation method      Pour plate ☒      Spread plate ☐  
 Number of plates: 1 / ml  
 Neutraliser: Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine 1g/l, saponin 30g/l, phosphate buffer powder 0.35g/l  
 Actual test temperature: 23.2°C  
 Test organism: *A. brasiliensis* ATCC 16404  
 Incubation temperature: 30°C ± 2°C  
 Date of Test: 09 Sep 16  
 Person responsible: Edward Webber      Signature: *E. Webber*  
 Diluent used for product test solutions: Distilled water  
 Appearance of product test solutions: Clear pale blue liquid

#### Validation and Controls

Validation suspension (N <sub>v0</sub> )			Experimental Conditions Control (A)			Neutraliser Control (B)			Method Validation (C)		
Vc1	41	χ = 45	Vc1	39	χ = 46	Vc1	42	χ = 42	Prod conc: 1:6		
Vc2	49		Vc2	52		Vc2	42		Vc1	50	χ = 49
30 ≤ χ of N <sub>v0</sub> ≤ 160?			χ of A is ≥ 0.5 x χ of N <sub>v0</sub> ?			χ of B is ≥ 0.5 x χ of N <sub>v0</sub> ?			χ of C is ≥ 0.5 x χ of N <sub>v0</sub> ?		
Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>

#### Test suspension and test


Test suspension (N and N <sub>0</sub> ):	N	Vc1	Vc2	χ = 29 x 10 <sup>6</sup> ; lgN = 7.46 N <sub>0</sub> = N/10; lgN <sub>0</sub> = 6.46 6.17 ≤ lg N <sub>0</sub> ≤ 6.70?
	10 <sup>-5</sup>	>165	>165	
	10 <sup>-6</sup>	31	26	
				Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>


Conc of the product	Vc1	Vc2	Na = χ x 10	lgNa	lgR	Contact time
1:6	<14	<14	<140	<2.15	>4.31	15 minutes

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Product		Condencide	MGS No	24136	SO No	5786	

Product batch number: N/A  
 Dilution-neutralisation method      Pour plate ☒      Spread plate ☐  
 Number of plates: 1 / ml  
 Neutraliser: Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine 1g/l, saponin 30g/l,  
 phosphate buffer powder 0.35g/l  
 Actual test temperature: 23.2°C  
 Test organism: *C. albicans* ATCC 10231  
 Incubation temperature: 30°C ± 2°C  
 Date of Test: 09 Sep 16  
 Person responsible: Edward Webber      Signature:   
 Diluent used for product test solutions: Distilled water  
 Appearance of product test solutions: Clear pale blue liquid

#### Validation and Controls

Validation suspension (N <sub>v0</sub> )			Experimental Conditions Control (A)			Neutraliser Control (B)			Method Validation (C)		
									Prod conc: 1:6		
Vc1	70	χ =71	Vc1	73	χ =73	Vc1	74	χ =78	Vc1	71	χ =71
Vc2	71		Vc2	73		Vc2	81		Vc2	71	
30 ≤ χ of N <sub>v0</sub> ≤ 160?			χ of A is ≥ 0.5 x χ of N <sub>v0</sub> ?			χ of B is ≥ 0.5 x χ of N <sub>v0</sub> ?			χ of C is ≥ 0.5 x χ of N <sub>v0</sub> ?		
Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>

#### Test suspension and test

Test suspension (N and N <sub>0</sub> ):	N	Vc1	Vc2	$\chi = 274 \times 10^5$ ; $\lg N = 7.44$ $N_0 = N/10$ ; $\lg N_0 = 6.44$ $6.17 \leq \lg N_0 \leq 6.70?$	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
	10 <sup>-5</sup>	275	282		
	10 <sup>-6</sup>	24	21		


Conc of the product	Vc1	Vc2	Na = χ x 10	lgNa	lgR	Contact time
1:6	<14	<14	<140	<2.15	>4.29	15 minutes

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Product	CondensCide	MGS No	24136	SO No	5786	



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Explanations:

Vc = count per plate (one plate or more)  
 $\bar{x}$  = average of Vc1 and Vc2 (1. + 2. duplicate)  
R = reduction ( $\lg R = \lg N_0 - \lg N_a$ )  
Na = number of survivors in the test mixture  
Nv = number of cells in the validation suspension  
 $N_{v0} = N_v/10$

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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