
 Microbiological Services and Consultancy		Doc No.		TRA-2011-212-01		
		Title Microbiological Analysis Based on EN 1276 (2009) Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics (Phase 2 / Step 1)				 4393
Product		Goldshield 24	MGS No	01388	SO No	

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	Goldshield Industries (Europe) Ltd
Customer Address	2 Victoria Square Victoria Street St Albans AL1 3TF
c) Identification of the sample:	
Name of product	Goldshield 24
Batch number (and expiry date if available)	Not stated
Manufacturer (or supplier)	Goldshield Industries (Europe) Ltd
Date of delivery	22 Nov 11
Storage conditions	Room temperature and darkness
Product diluent recommended by the manufacturer for use	Not stated
Active substance(s) and their concentration(s) (optional)	0.1% BAC
Appearance of the product	
d) Test method and its validation:	
MGS procedure reference	WIN-1000.050-05
Method	Dilution neutralisation / Membrane filtration
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
Rinsing Liquid	Sterile distilled water
Details of validation of the neutraliser	Neutraliser validation performed according to 5.5.2 of EN 1276:2009, no neutraliser could be determined for tests with <i>Staphylococcus aureus</i> or <i>Enterococcus hirae</i> , therefore

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Product	Goldshield 24	MGS No	01388	SO No	3082

membrane filtration was used in these instances.

e) Experimental conditions:

Period of analysis	25 Nov 11 – 05 Dec 11
Product test concentrations	Ready to Use (RTU)
Appearance of product dilutions	Cloudy colourless solution
Contact time	5 minutes ± 10s
Test temperature range	20°C ± 2°C
Interfering substance	0.3g/l Bovine albumin
Stability of the mixture	Precipitate absent throughout test
Temperature of incubation	36°C ± 2°C

Identification of the bacterial strains used	<i>Escherichia coli</i>	NCTC 10418
	<i>Enterococcus hirae</i>	NCIMB 8192
	<i>Staphylococcus aureus</i>	ATCC 6538
	<i>Pseudomonas aeruginosa</i>	ATCC 15442

f) Results:

Test results	1) Controls and validation 2) Evaluation of bactericidal activity
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g) Conclusion: Based on EN 1276 (2009), the product Goldshield 24, when tested at RTU, possesses bactericidal activity in 5 minutes at 20°C under clean conditions for the referenced strains of *E. coli*, *E. hirae*, *S. aureus* and *P. aeruginosa*.

h) Deviations: None

i) Special remarks All controls and validations were within basic limits
No precipitate was formed during the test

Prepared By: *Helen Duxbury*

Name: Miss Helen Duxbury BSc (Hons)

Position: Laboratory Manager

Date: 05 Dec 11

Approved by: *Kim Morwood*

Name: Mrs Kim Morwood BSc (Hons) CBiol MiBiol


Position: Technical Director

Date: 05 Dec 11

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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.
- A cryovial bead is added to broth and stored at 2-8°C for a maximum of 7 days; streaks are made from these broths, rather than streaking from stored slopes for 6-9 weeks.
- 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.
- Neutraliser is prepared at 8ml and 9ml taking into account required concentrations so that water does not have to be added to 8ml for Test and NTV aliquots.
- 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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Product Goldshield 24		MGS No 01388	SO No 3082			

Product batch number: Not stated
 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: 20°C
 Test organism: *P. aeruginosa* ATCC 15442
 Incubation temperature: 36°C ± 2°C
 Interfering substances: 0.3g/l Bovine albumin
 Date of Test: 30 Nov 11
 Person responsible: M. Matynia Signature: *Matynia Michal*
 Appearance of product test solutions: Cloudy colourless solution

Validation and Controls

Validation suspension (N _{v0})			Experimental Conditions Control (A)			Neutraliser Control (B)			Method Validation (C)		
Vc1	44	χ = 53	Vc1	54	χ = 58	Vc1	42	χ = 50	Prod conc: RTU		
Vc2	62		Vc2	62		Vc2	57		Vc1	54	χ = 55
30 ≤ χ of N _{v0} ≤ 160?			χ of A is ≥ 0.5 x χ of N _{v0} ?			χ of B is ≥ 0.5 x χ of N _{v0} ?			χ of C is ≥ 0.5 x χ of N _{v0} ?		
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 ₀):	N	Vc1	Vc2	$\chi_{wm} = 152 \times 10^6$; $\lg N = 8.18$ $N_0 = N/10$; $\lg N_0 = 7.18$ $7.17 \leq \lg N_0 \leq 7.70$?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
	10 ⁻⁶	151	153		
	10 ⁻⁷	16	11		

Conc of the product	Vc1	Vc2	Na = χ x 10	lgNa	lgR	Contact time
RTU	<14	<14	<140	<2.15	>5.03	5 min

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				Title		
Product		MGS No	01388	SO No	3082	

Product batch number: Not stated
 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: 20°C
 Test organism: *E. coli* NCTC 10418
 Incubation temperature: 36°C ± 2°C
 Interfering substances: 0.3g/l Bovine albumin
 Date of Test: 25 Nov 11
 Person responsible: M. Matynia Signature: *Not in Michael*
 Appearance of product test solutions: Cloudy colourless solution

Validation and Controls

Validation suspension (N _{v0})			Experimental Conditions Control (A)			Neutraliser Control (B)			Method Validation (C)		
Vc1	70	χ = 66	Vc1	75	χ = 68	Vc1	76	χ = 77	Prod conc: RTU		
Vc2	61		Vc2	61		Vc2	77		Vc1	43	χ = 43
30 ≤ χ of N _{v0} ≤ 160?			χ of A is ≥ 0.5 x χ of N _{v0} ?			χ of B is ≥ 0.5 x χ of N _{v0} ?			χ of C is ≥ 0.5 x χ of N _{v0} ?		
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 ₀):	N	Vc1	Vc2	χ _{wm} = 268 x 10 ⁶ ; lgN = 8.43 N ₀ = N/10; lgN ₀ = 7.43 7.17 ≤ lg N ₀ ≤ 7.70?	
10 ⁻⁶	285	252	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
10 ⁻⁷	29	24			

Conc of the product	Vc1	Vc2	Na = χ x 10	lgNa	lgR	Contact time
RTU	24	25	250	2.40	5.03	5 min

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Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics (Phase 2 / Step 1)

Product **Goldshield 24** MGS No 01388 SO No 3082

Product batch number: Not stated
 Membrane filtration method
 Number of plates: 1 / 0.1ml
 Rinsing liquid: Sterile distilled water
 Actual test temperature: 20°C
 Test organism: *S. aureus* ATCC 6538
 Incubation temperature: 36°C ± 2°C
 Interfering substances: 0.3g/l Bovine albumin
 Date of Test: 02 Dec 11
 Person responsible: E. Brzosko
 Appearance of product test solutions: Cloudy colourless solution

Signature: *PP Oleszczak*

Validation and Controls

Validation suspension (N _{v0})			Experimental Conditions Control (A)			Filtration Control (B)			Method Validation (C)		
Vc1	60	χ = 57	Vc1	45	χ = 49	Vc1	50	χ = 50	Prod conc: RTU		
Vc2	53		Vc2	53		Vc2	49		Vc1	32	χ = 30
30 ≤ χ of N _{v0} ≤ 160?			χ of A is ≥ 0.5 x χ of N _{v0} ?			χ of B is ≥ 0.5 x χ of N _{v0} ?			χ of C is ≥ 0.5 x χ of N _{v0} ?		
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 ₀):	N	Vc1	Vc2	χ _{wm} = 180 x 10 ⁶ ; lgN = 8.26 N ₀ = N/10; lgN ₀ = 7.24 7.17 ≤ lg N ₀ ≤ 7.70?	
	10 ⁻⁶	177	182		Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
	10 ⁻⁷	<14	19		

Conc of the product	Vc1	Vc2	Na = χ x 10	IgNa	IgR	Contact time
RTU	<14	<14	<140	<2.15	>5.11	5 min

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Product batch number: Not stated
 Membrane filtration method
 Number of plates: 1 / 0.1 ml
 Rinsing liquid: Sterile distilled water
 Actual test temperature: 20°C
 Test organism: *E. hirae* NCIMB 8192
 Incubation temperature: 36°C ± 2°C
 Interfering substances: 0.3g/l Bovine albumin
 Date of Test: 02 Dec 11
 Person responsible: E. Brzosko
 Appearance of product test solutions: Cloudy colourless solution

Signature: *[Handwritten Signature]*

Validation and Controls

Validation suspension (Nv ₀)			Experimental Conditions Control (A)			Filtration Control (B)			Method Validation (C)		
Vc1	65	χ = 72	Vc1	51	χ = 49	Vc1	36	χ = 45	Prod conc: RTU		
Vc2	78		Vc2	46		Vc2	53		Vc1	56	χ = 52
30 ≤ χ of Nv ₀ ≤ 160?			χ of A is ≥ 0.5 x χ of Nv ₀ ?			χ of B is ≥ 0.5 x χ of Nv ₀ ?			χ of C is ≥ 0.5 x χ of Nv ₀ ?		
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 ₀):	N	Vc1	Vc2	χ _{wm} = 252 x 10 ⁶ ; lgN = 8.40
	10 ⁻⁶	261	245	N ₀ = N/10; lgN ₀ = 7.40
	10 ⁻⁷	23	26	7.17 ≤ lg N ₀ ≤ 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
RTU	<14	<14	<140	<2.15	>5.25	5 min

Explanations:

- Vc = count per plate (one plate or more)
- χ = average of Vc1 and Vc2 (1. + 2. duplicate)
- χ_{wm} = weighed mean of χ
- R = reduction (lgR = lgN₀ - lgNa)
- Na = number of survivors in the test mixture
- N = number of cells in the test suspension
- N₀ = N/10
- Nv = number of cells in the validation suspension
- Nv₀ = Nv/10

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