



MICRO REPORT ADDENDUM

Swift Silliker (Pty) Ltd
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FULVIMED SA (PTY) Ltd
AGRI PARK
BADEN POWELL DRIVE
LYNDOCH
STELLENBOSCH
7603

ATTENTION: IMELDA JORDAAN

DATE: 15/06/15
DATE RECEIVED: 11/05/15
DATE TESTED: 13/05-15/06/15

REQ NO: CT 131735/15-01
ORDER NO: 3055
PAGE 1 OF 4

SAMPLE TYPE: CHD-FD 2% 2738
METHOD NO: SWJM 25

The following Preservative Efficacy analysis is tested over a 28 day period

Product challenged with inoculum of

<i>Escherichia coli</i>	ATCC 8739	<i>Pseudomonas aeruginosa</i>	ATCC 9027
<i>Staphylococcus aureus</i>	ATCC 6538	<i>Candida albicans</i>	ATCC 10231
<i>Aspergillus brasiliensis</i>	ATCC 16404		

SAMPLE TYPE	TEST TYPE	BACT.COUNT CFU/gram
Product: CHD-FD 2% 2738		
<i>Escherichia coli</i> ATCC 8739		
<u>Day 0 (13/05/15)</u>		
Positive control	TMA	230 000
Test	TMA	400
<u>Day 7 (20/05/15)</u>		
Test	TMA	No Growth
<u>Day 14 (27/05/15)</u>		
Test	TMA	No Growth
<u>Day 28 (10/06/15)</u>		
Test	TMA	No Growth

Directors: V. Stewart (Managing), A. Lambrechts, P. Sans (France), S. Schneider (France), J-F. Billet (France) / Reg. No 2000/025067/07

- TMA = Total Microbial Activity/Total Viable Plate Count.
- Limit of detection of Conventional Plate Count Methods = 10 CFU, unless otherwise specified.
- A test report relates only to the specific item submitted for testing. It furnishes or implies no guarantee whatsoever, in respect of a similar item that has not been tested.
- Method numbers refer to in-house methods. Standard test method references available on request.
- Detection times only relevant to certain test methods, where Malthus Systems are applicable.
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Pseudomonas aeruginosa* ATCC 9027*Day 0 (13/05/15)**

Positive control	TMA	300 000
Test	TMA	10

Day 7 (20/05/15)

Test	TMA	No Growth
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Day 14 (27/05/15)

Test	TMA	No Growth
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Day 28 (10/06/15)

Test	TMA	No Growth
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Staphylococcus aureus* ATCC 6538*Day 0 (13/05/15)**

Positive control	TMA	250 000
Test	TMA	10

Day 7 (20/05/15)

Test	TMA	No Growth
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Day 14 (27/05/15)

Test	TMA	No Growth
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Day 28 (10/06/15)

Test	TMA	No Growth
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Aspergillus brasiliensis* ATCC 16404*Day 0 (13/05/15)**

Positive control	Mould	300 000
Test	Mould	310 000

Day 7 (20/05/15)

Test	Mould	40 000
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Day 14 (27/05/15)

Test	Mould	4 900
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Day 28 (10/06/15)

Test	Mould	48 000
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Candida albicans* ATCC 10231*Day 0 (13/05/15)**

Positive control	Yeast	470 000
Test	Yeast	520 000

Day 7 (20/05/15)

Test	Yeast	No Growth
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Day 14 (27/05/15)

Test	Yeast	No Growth
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Day 28 (10/06/15)

Test	Yeast	No Growth
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Criteria for Antimicrobial effectiveness (Ref. USP 30 Section 51)

The requirements for antimicrobial effectiveness are met if the criteria specified in the table below are met.

Product Category	Measurand	Criteria
Category 1: Injections, other parenterals including emulsions, otic products, sterile nasal products, and ophthalmic products made with aqueous bases or vehicles.	Bacteria	Not less than 1.0 log reduction from the initial calculated count at 7 days, not less than 3.0 log reduction from the initial count at 14 days, and no increase from the 14 day's count at 28 days
	Yeast & Moulds	No increase from the initial calculated count at 7, 14 and 28 days
Category 2: Topically used products made with aqueous bases or vehicles, non sterile nasal products, and emulsions, including those applied to mucous membranes.	Bacteria	Not less than 2.0 log reduction from the initial count at 14 days, and no increase from the 14 day's count at 28 days.
	Yeast & Moulds	No increase from the initial calculated count at 7, 14 and 28 days

Category 3: Oral products other than antacids, made with aqueous bases or vehicles	Bacteria	Not less than 1.0 log reduction from the initial count at 14 days, and no increase from the 14 day's count at 28 days.
	Yeast & Moulds	No increase from the initial calculated count at 7, 14 and 28 days
Category 4: Antacids made with an aqueous base	Bacteria, Yeast and Moulds	No increase from the initial calculated count at 7, 14 and 28 days



**FAHIEMA PALEKER
SENIOR MICROBIOLOGIST**



**TASMIN WAKEFIELD
MICROBIOLOGIST**



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SAMPLE TYPE: CHD-FA 4% 2739
METHOD NO: SWJM 25

The following Preservative Efficacy analysis is tested over a 28 day period

Product challenged with inoculum of

<i>Escherichia coli</i>	ATCC 8739	<i>Pseudomonas aeruginosa</i>	ATCC 9027
<i>Staphylococcus aureus</i>	ATCC 6538	<i>Candida albicans</i>	ATCC 10231
<i>Aspergillus brasiliensis</i>	ATCC 16404		

SAMPLE TYPE	TEST TYPE	BACT.COUNT CFU/gram
Product: CHD-FA 4% 27398		
<i>Escherichia coli</i> ATCC 8739		
<u>Day 0 (13/05/15)</u>		
Positive control	TMA	230 000
Test	TMA	No Growth
<u>Day 7 (20/05/15)</u>		
Test	TMA	No Growth
<u>Day 14 (27/05/15)</u>		
Test	TMA	No Growth
<u>Day 28 (10/06/15)</u>		
Test	TMA	No Growth

Directors: V. Stewart (Managing), A. Lambrechts, P. Sans (France), S. Schneider (France), J-F. Billet (France) / Reg. No 2000/025067/07

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Pseudomonas aeruginosa* ATCC 9027*Day 0 (13/05/15)**

Positive control	TMA	300 000
Test	TMA	No Growth

Day 7 (20/05/15)

Test	TMA	No Growth
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Day 14 (27/05/15)

Test	TMA	No Growth
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Day 28 (10/06/15)

Test	TMA	No Growth
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Staphylococcus aureus* ATCC 6538*Day 0 (13/05/15)**

Positive control	TMA	250 000
Test	TMA	5 000

Day 7 (20/05/15)

Test	TMA	No Growth
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Day 14 (27/05/15)

Test	TMA	No Growth
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Day 28 (10/06/15)

Test	TMA	No Growth
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Aspergillus brasiliensis* ATCC 16404*Day 0 (13/05/15)**

Positive control	Mould	300 000
Test	Mould	420 000

Day 7 (20/05/15)

Test	Mould	2 400
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Day 14 (27/05/15)

Test	Mould	180
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Day 28 (10/06/15)

Test	Mould	5 000
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Candida albicans* ATCC 10231*Day 0 (13/05/15)**

Positive control	Yeast	470 000
Test	Yeast	560 000

Day 7 (20/05/15)

Test	Yeast	No Growth
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Day 14 (27/05/15)

Test	Yeast	No Growth
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Day 28 (10/06/15)

Test	Yeast	No Growth
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	Yeast & Moulds	No increase from the initial calculated count at 7, 14 and 28 days

Category 3: Oral products other than antacids, made with aqueous bases or vehicles	Bacteria	Not less than 1.0 log reduction from the initial count at 14 days, and no increase from the 14 day's count at 28 days.
	Yeast & Moulds	No increase from the initial calculated count at 7, 14 and 28 days
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