S. M. T. L. Cover Sheet for Test Report

Title: **Antimicrobial Testing of Bandages**

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subject: **Antimicrobial Testing of Bandages**

date: **8 May 2006**

from: **Pamela Ashman**
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Report No: 06/1874/3

Test Report

06/1874/3

1. Name & Address of Client/Requesting Authority.

Urgo Limited
Sullington Road
Shepshed
Leicestershire
LE12 9JJ

2. Introduction

The report details the results of the antimicrobial activity of the bandages supplied by the client against selected microorganisms.

The ASTM dynamic contact method is designed to evaluate the resistance of non-leaching antimicrobial treated products to the growth of microorganisms under dynamic contact conditions. Therefore the products are first screened to rule out leaching of the antimicrobial using the zone of inhibition method (see section 5.1).

If there is no leaching, the product is then assessed using the dynamic test (see section 5.2), which determines the effectiveness of the product in eliminating the challenge bacteria.

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3. Test Product(s)/Sample(s)

TABLE 1. Test Product(s)/Sample(s) tested by SMTL.

Manufacturer	Item	Batch/Lot No	Quantity	Date Received
Parema	Bandage K-Band Treated	Not Stated	30	13/6/05
Parema	Bandage K-Band Un-Treated	Not Stated	2	13/6/05
Parema	Bandage K-Lite Treated	Not Stated	15	13/6/05
Parema	Bandage K-Lite Un-Treated	Not Stated	2	13/6/05

NOTE: The test results in this report relate only to the test sample(s) analysed.

3.1 Departures/Abnormalities of Sample Condition

None

4. Date of Testing

11th July - 25th August 2005

5. Testing Details

5.1 Zone of Inhibition

To check that there is no leaching of the active substance, a sample is placed onto an agar plate which has been inoculated with bacteria. The plate is incubated, and if the antimicrobial leaches from the sample there will be a zone of no growth around the sample. The larger the zone the more readily the active agent leaches from the sample.

A zone of inhibition investigation was carried out against 2 organisms, *Staphylococcus aureus ATCC 6538 & Escherichia coli ATCC 8739*.

A sample (2x2cm) of the product was placed onto a seeded agar plate and incubated for 24 hours. The control (untreated product) was tested in the same way to ensure that the bandage itself did not have any inherent antimicrobial effect. The plates were examined and zones measured. This was carried out in triplicate.

5.2 Antimicrobial Activity under Dynamic Conditions

The ASTM dynamic method ensures good contact between the bacteria and the treated product by constant agitation of the test specimen in a concentrated bacterial suspension. This is essential as the antimicrobial activity of immobilised agents is dependent upon the microorganisms coming into direct contact with the active agent.

An investigation of the dynamic activity in solution was carried out against 5 organisms - *Staphylococcus aureus ATCC 6538, Escherichia coli ATCC 8739, Klebsiella pneumoniae ATCC 4352, Pseudomonas aeruginosa ATCC 9027* & MRSA NCTC 12493. The product (1g ± 0.2g) was placed into a flask with 50ml of buffer containing a known number of organisms. The flask was incubated with shaking for 1 and 24 hours and at each time period a sample was removed and serially diluted to determine the count. The controls were a flask containing the inoculum only and a flask containing the non-treated product. The non-treated product was tested to ensure that the bandage itself did not have any inherent antimicrobial effect.

The percentage reduction is calculated as follows :-

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$$\% \text{ Reduction} = \frac{\text{treated}(T=0) - \text{treated}(T=1 \text{ or } 24 \text{ hours})}{\text{treated}(T=0)} \times 100$$

The counts for the inoculum only control after the specified contact time and the counts for the untreated control after the specified contact time should be within 15%. If they are not the percentage reduction for the treated sample is compared directly to the untreated control after the specified time.

5.3 Standards relevant to the test method.

— ASTM: E 2149-01[1]

5.4 Deviations/exclusions from, and additions to standard methods.

The initial concentration for *Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa and Klebsiella pneumoniae* was not between 1.5 -3.0x10 ^{5}cfu/ml as stated in the standard, due the unpredictability of the growth of the organisms.

5.5 Sampling Details

All samples were supplied by the client.

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6. Results

6.1 Zone of Inhibition against Staphylococcus aureus & Escherichia coli

The results for the zone of inhibition against *Staphylococcus aureus & Escherichia coli* are shown in Table 2.

TABLE 2. Zone of Inhibition Results *S.aureus & E.coli*

Product	*S. aureus* **Zone (mm)**	*E.Coli* **Zone (mm)**
K Lite (treated)	0	0
K Lite (un-treated)	0	0
K Band (treated)	0	0
K Band (un-treated)	0	0

6.2 Dynamic activity in solution

The results for antimicrobial activity against various micro-organisms are detailed in the following tables.

TABLE 3. Antimicrobial Activity against *Staphylococcus aureus* after 1 and 24 hour incubation

Test Product	**N.o. of cfu/ml Time 0**	**N.o. of cfu/ml Time 1 H**	**% Reduction 1 hour**	**N.o. of cfu/ml Time 24 H**	**% Reduction 24 hour**
K Lite (treated)	$1.05x10^5$	<5*	100	<5*	100
K Lite (un-treated)	$1.17x10^5$	$1.75x10^5$	-	$2.21x10^7$	-
K Band (treated)	$8.67x10^4$	<5*	100†	<5*	100†
K Band (un-treated)	$9.50x10^4$	$1.40x10^5$	-	$1.11x10^7$	-
Inoculum only	$1.21x10^5$	$2.05x10^5$	-	$2.65x10^7$	-

NOTE

i. † % Reduction compared to untreated product

ii. * Below level of detection

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TABLE 4. Antimicrobial Activity against *Escherichia coli* after 1 and 24 hour incubation

Test Product	N.o. of cfu/ml Time 0	N.o. of cfu/ml Time 1 H	% Reduction 1 hour	N.o. of cfu/ml Time 24 H	% Reduction 24 hour
K Lite (treated)	$8.31x10^4$	$9.0x10^1$	99.84†	<5*	100†
K Lite (un-treated)	$9.35x10^4$	$5.83x10^4$	-	$>1.50x10^7$	-
K Band (treated)	$7.77x10^4$	<5*	100†	<5*	100†
K Band (un-treated)	$7.65x10^4$	$6.33x10^4$	-	$1.59x10^7$	-
Inoculum only	$8.10x10^4$	$1.05x10^5$	-	$2.18x10^8$	-

NOTE

i. †% Reduction compared to untreated product

ii. * Below level of detection

TABLE 5. Antimicrobial Activity against *Pseudomonas aeruginosa* after 1 and 24 hour incubation

Test Product	N.o. of cfu/ml Time 0	N.o. of cfu/ml Time 1 H	% Reduction 1 hour	N.o. of cfu/ml Time 24 H	% Reduction 24 hour
K Lite (treated)	$1.02x10^5$	$1.82x10^2$	99.55†	<5	100†
K Lite (un-treated)	$9.17x10^4$	$4.0x10^4$	-	$1.28x10^7$	-
K Band (treated)	$1.05x10^5$	<5*	100†	<5*	100†
K Band (un-treated)	$1.15x10^5$	$3.08x10^4$	-	$2.18x10^7$	-
Inoculum only	$8.50x10^4$	$6.17x10^4$	-	$4.43x10^8$	

NOTE

i. †% Reduction compared to untreated product

ii. * Below level of detection

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TABLE 6. Antimicrobial Activity against *Klebsiella pneumoniae* after 1 and 24 hour incubation

Test Product	N.o. of cfu/ml Time 0	N.o. of cfu/ml Time 1 H	% Reduction 1 hour	N.o. of cfu/ml Time 24 H	% Reduction 24 hour
K Lite (treated)	$3.25x10^5$	<5*	100†	<5*	100†
K Lite (un-treated)	$8.73x10^5$	$4.42x10^5$	-	$1.92x10^6$	-
K Band (treated)	$9.40x10^5$	<5*	100†	<5*	100†
K Band (un-treated)	$8.55x10^5$	$2.58x10^5$	-	$2.18x10^6$	-
Inoculum only	$9.20x10^5$	$8.67x10^5$	-	$1.48x10^6$	-

NOTE

i. †% Reduction compared to untreated product

ii. * Below level of detection

TABLE 7. Antimicrobial Activity against MRSA after 1 and 24 hour incubation

Test Product	N.o. of cfu/ml Time 0	N.o. of cfu/ml Time 1 H	% Reduction 1 hour	N.o. of cfu/ml Time 24 H	% Reduction 24 hour
K Lite (treated)	$1.58x10^5$	$8.12x10^3$	94.86	<5*	100†
K Lite (un-treated)	$1.95x10^5$	$1.47x10^5$	-	$4.15x10^7$	-
K Band (treated)	$1.62x10^5$	$2.17x10^1$	99.98	<5*	100†
K Band (un-treated)	$1.82x10^5$	$1.22x10^5$	-	$4.03x10^6$	-
Inoculum only	$1.77x10^5$	$1.38x10^5$	-	$1.11x10^8$	-

NOTE

i. †% Reduction compared to untreated product

ii. * Below level of detection

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7. Summary

The zone of inhibition results showed no evidence of any leachable activity from the treated products against both organisms tested. This means that the active agent is bound in the bandage, as intended by the manufacturer.

The dynamic activity results show that the treated products were active against all five organisms. After 24 hours, no visible bacterial growth was detected.

Authorised by:

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Acting Director, SMTL
May 2006

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1. ASTM, "Standard Test Method for Determining the Antimicrobial Activity of Immobilized Antimicrobial Agents Under Dynamic Contact Conditions," *ASTM E2149 -01*, ().

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