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FINAL STUDY REPORT

MICROBIOLOGICAL EVALUATION OF "VALIDATE" HEALTHCARE FACILITY LAUNDRY PRODUCT

Sponsor:

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EXECUTIVE SUMMARY

The study provides evidence that the improved formula "Validate" product meets the performance criterion for chemical disinfection in laundry processes as defined in ASINZS 4146:2000, Laundry Practice, Section 3.5.3, Chemical Disinfection.

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INTRODUCTION

2.1 A study was required by Cleveland Cleaning Supplies to evaluate an improved laundry detergent for use in healthcare facilities.

2.2 The experimental work was conducted by AMS laboratories Pty Ltd, 118 Hattersley Street, Rockdale, NSW 2216. AMS laboratories Pty Ltd are licensed for analysis and testing by the Australian Therapeutic Goods Administration (License No. 118118), National Registration Authority for Agricultural & Veterinary Chemicals (License No. 6057) and certified by Standards Australia (SAI Global) to ISO9002-1994 / ISO 17025 (License No. QEC14256).

2.3 In-use testing was conducted in an accredited healthcare facility using their normal laundry equipment. The identity has been kept confidential for privacy reasons.

OBJECTIVES

3.1 To microbiologically evaluate the new formulation product "Validate" in an in-use situation with respect to the performance criterion in AS/NZS 4146:2000, Laundry Practice, Section 3.5.3, Chemical Disinfection.

SAMPLE MATERIALS

4.1 "Validate" laundry product, Batch No. "improved formula" - 23/1/2003 was supplied On site by Mr John Lipovic, Cleveland Cleaning Products on 20/3/03.

4.2 Product was added as 50 or 100g amounts. These were delivered using a pre-calibrated measuring container.

4.3 Laundry samples were normal patient wash loads. They comprised of personal clothing item, such as underwear, nightwear and daywear. No pre-selection process was used.

5 MATERIALS AND METHODS

4r5.1 On Site Equipment Used

5.1.1 The washing machine used was a Kleenmaid Commercial Heavy Duty Washer. Machine identity tag was 998812.

5.1.2 Settings were varied to examine warm and cold cycles. These were done by selecting either "warm/warm" or "cold/cold" for the wash/rinse temperatures respectively.

5.1.3 Thermometer to record machine wash temperatures, Number 25812.

5.1.4 Timer to record wash cycle length, Number T4.6.

5.1.5 Esky with cooler bricks for transport of samples to laboratory.

5.1.6 Sterile sample jars.

5.1.7 Sterile contact plates containing Tryptone Soya Agar (TSA) for sampling clothing.

5.2 Laboratory Procedures

5.2.1 Contact Plates

5.2.1.1 Plates were incubated at 30°C for 3 days.

5.2.1.2 Colony forming units (CFU) were counted and recorded on worksheets.

5.2.2 Water Testing

5.2.2.1 Testing was done using a pour plate method. This was judged to give sufficient sensitivity for the required purpose.

5.2.2.2 One mL was transferred to duplicate petri plates which were then filled with 15 - 20 ml of R2A medium and incubated at 30 degrees C for 3 days.

5.2.2.3 CFU were then counted and recorded on worksheets.

5.3 Laundry Procedures

5.3.1 Water Supply Sample

A sample of the Towns water at the 1aW1 dry tap was collected to verify input water quality.

5.3.2 Wash and Rinse Water Samples

Samples were taken of wash and rinse cycle waters from the machine drain pipe after allowing a volume of the water to pass to ensure samples were representative of the cycle.

5.3.3 Cloth Sampling

One location from 5 representative articles of clothing was taken, before and after the wash cycle. The agar surface was pressed against the flat clothing surface and held for approximately 10 seconds. The post-cleaning were not collected from the same locations as the pre-wash samples.

6. ASINZS 4146:2000, SECTION 3.5.3 REQUIREMENTS

6.1 Using an "aerobic bacterial plate count, there should be less than 1 microorganism per cm², by the contact plate method", on post-wash sampled clothing. Since it is not possible to guarantee that each colony results from a single organism it is standard microbiological practice to express results as CFU.

7. RESULTS

7.1 Laundry Procedures

The timer extended beyond 10 minutes during cycle 1 and the cycle was manually stopped at 11 minutes. During cycle 2, the timer was adjusted to give a shorter cycle time, but *stopped* at 7 minutes and emptied the wash water before a sample could be collected. It was decided to run cycle 3 for 7 minutes (stopped manually) to be able to compare more closely with cycle 2 which only varied by the amount of product used.

7.2 Supply Water

The Towns water supplying the laundry facility was shown to be of good quality with a result of less than 1 CFU per ml (Table 1).

7.3 Wash and Rinse Water

Low numbers of bacteria were found in the wash waters (2 CFU per rml) and no bacteria were found in the rinse waters (Table 1). No results were available for Wash Cycle 2 as described in section 7.1.

7.4 Contact Plates

Results for the contact plates before and after laundering are given in Table 2. Amongst the pre-wash samples there were two exhibiting very high bacterial counts. Post-wash samples were uniformly low.

Table 1.

Results for Supply, Wash and Rinse Waters for Cycles 1 to 3.

Sample TVDe	Plate 1	Plate 2	Mean CFU Der ml
Cycle 1, WASH water	2	2	2
Cycle 1, RINSE water	1	0	Less than 1
Cycle 2, WASH water	N/A	N/A	N/A
Cycle 2, RINSE water	0	0	Less than 1
Cycle 3, WASH water	2	1	2
Cycle 3, RINSE water	0	0	Less than 1
			Mean CFU per 100ml
Towns water (laundry input water)	0	0	Less than 1

Table 2. Results for Contact Plates Before and After Wash Cycles

Pre- / Post-samples	Individual Plate Counts (Colony Fomling Units)					Average Counts / Plate	Average Counts / Cm2 NOTE 1
	1	2	3	4	5		
Cycle 1							
PRE-	51	256 *	27	70	51	91	4
POST-	2	4	0	0	3	2	Less than 1
Cycle 2							
PRE-	208*	79	73	80	145	117	5
POST -	2	0	3	8	2	3	Less than 1
Cycle 3							
PRE-	68	43	45	42	21	44	2
POST.	2	1	1	2	2	2	Less than 1

Note 1: Divide average count by 23.8 to get count per cm2. * estimated due to large numbers present.

8. CONCLUSIONS AND DISCUSSION

The study demonstrated that the improved formula «Validate" product fully met the performance criterion set out in ASINZS 4146:2000, Section 3.5.3, for microbiological efficacy of chemical disinfection laundry products.

An in-use study such as this one makes the assumption that any microorganisms present on the study clothing will be evenly distributed over the material surface and be recovered with equal efficiency by the analytical procedures employed. In fact, it is impossible to get in-use clothing samples that have uniformly distributed bacteria on them. This limitation is overcome to a large extent by increasing the number of samples taken from the study garments. In the present study 5 samples were collected randomly from the test garments both before and after laundering. Thus the mean counts represent an averaging of the numbers present on the garments.

Although not called for in ASINZS 4146:2000, this study also examined the wash and rinse waters during the laundry cycles. In earlier studies with a less potent product it was found that wash and rinse water mean bacterial counts were 147 and 96 per ml respectively. Although the wash loads were not strictly comparable, being done on different loads at a different facility, it is clear that there was a marked improvement in these parameters in the present study, namely 2 and less than 1 per ml respectively. These results would support the contention that the product has a bactericidal (killing) effect rather than simply removing organisms from the surface of the garments by detergent action.

Signed _____.

Paul Priscott, PhD

Study Director