Analytical MicroLabs Industrial Microbiologists

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Derm-E-San shelf life and efficacy results

| Certificate number: | AML 030106 |
|----------------------------|-------------------|
| Batch number: | Derm-E-San |
| Production date: | June 2005 |
| Product tested: | Derm-E-San (gel) |
| Date or period of testing: | 11/01/06-31/01/06 |

Accelerated shelf life testing:

| Incubation temperature | Period of testing | Conversion details | Shelf life of the product | Comments |
|---------------------------|---------------------------|---|---------------------------|---|
| | | | | |
| 37°C incubator | 11/10/2005- 31/01/2006 | 1 week at 37°C equivalent to 8.5 weeks at room temperature | 136 weeks or 2.5 years | Shelf life testing will be continuos 'till 156 weeks or 3 years |

| Organism tested: | Staphylococcus aureus NCTC 4163 Escherichia coli NCTC 8196 | |
|-------------------------|---|--|
| Initial bacterial load: | Staphylococcus aureus Escherichia coli | 5.0 x 10 ⁹ orgs/ml 5.0 x 10 ⁹ orgs/ml |

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| Exposure time | 1 minute | 5 minutes | 10 minutes |
|---------------------------------------|---------------------------------|---------------------------------|---------------------------------|
| | | | |
| Staphylococcus aureus NCTC 4163 | No growth detected < 10 orgs/ml | No growth detected < 10 orgs/ml | No growth detected < 10 orgs/ml |
| Escherichia coli NCTC 8196 | No growth detected < 10 orgs/ml | No growth detected < 10 orgs/ml | No growth detected < 10 orgs/ml |

| Controls: | Recovery Broth contamination Disinfectant (Derm-E-San) contamination Fertility test | | No growth detected No growth detected Growth detected | |
|------------------|---|---|---|--|
| Number of chal | lenge: | One (1) | | |
| Brief descriptio | n of testing method: | 3 ml Derm-E-San challenged with 1 ml of bacterial suspensi Challenged at room temperature (22°C) for -5 and 10 minute 10 μ l transferred into 10 ml recovery broth Recovery broth incubated at 35°C for 48 hours and checked to bacterial growth. | | |
| Origin of Test (| Organisms: | The University of Queenslan | nd, Australia | |
| Enumeration of | f initial bacterial load: | HBA in duplicate-spread pla | ate technique | |
| Incubation tem | perature and time: | 35°C, 48 hrs | | |
| Medium for gro | owth of Test Organisms: | Wright- Mundy Dextrose me | edium (Difco) | |
| Recovery Media | um: | Nutrient Broth No. 2 (Oxoid |)) | |
| Diluent for Citr | ofresh: | Sterile Hard Water (Melbourne University) | | |

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