From the 1950’s

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Device Description

Trade/Proprietary Name:  Puremedy's Original Healing Salve
Common Name:     Dressing, wound, drug
Classification Regulations:  Unclassified
Product Code:     FRO
Classification Panel:    General & Plastic Surgery

Device description:  Topical wound healing salve

Puremedy Original Healing Salve is used for the management of wounds including:

- Pressure sores
- Diabetic ulcers
- Leg ulcers
- Donor sites and graft sites
- Surgical wounds
- Skin abrasions and lacerations
- 1st and 2nd degree burns
- Trauma wounds
- Minor cuts
- Minor scalds and 1st and 2nd degree burns
- Abrasions
- Lacerations
Today’s goals

To demonstrate that the Original Healing Salve would be appropriately categorized as a Class II device.

In addition I will demonstrate:
• Safety and Efficacy
• minimal to negligible public health risk
• evidence of indications for use
• antibacterial effectiveness
- Bactericidal

- Kills large spectrum of harmful bacteria including MRSA

- ~ 90% killed within the first 1 minute

- All microorganisms killed within 4 hours

### ANTIMICROBIAL EFFICACY / TIME-KILL ANALYSIS REPORT

<table>
<thead>
<tr>
<th>Microorganisms</th>
<th>Inoculum / Colony Forming Units (Viable Microbes) Recovered from Each Gram of Product</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Original Healing Salve</td>
</tr>
<tr>
<td>Staph. aureus (ATCC 6538)</td>
<td>$1.0 \times 10^8$</td>
</tr>
<tr>
<td>Methicillin Res. S. aureus (ATCC43300)</td>
<td>$1.2 \times 10^8$</td>
</tr>
<tr>
<td>Streptococcus pyogenes (ATCC 19615)</td>
<td>$1.1 \times 10^8$</td>
</tr>
<tr>
<td>Escherichia coli (ATCC 8739)</td>
<td>$1.0 \times 10^8$</td>
</tr>
<tr>
<td>Salmonella typhimurium (ATCC 14028)</td>
<td>$1.1 \times 10^8$</td>
</tr>
<tr>
<td>Enterobacter Cloacae (ATCC 13047)</td>
<td>$1.0 \times 10^8$</td>
</tr>
<tr>
<td>Klebsilla Pneumoniae (ATCC 13883)</td>
<td>$1.0 \times 10^8$</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa (ATCC 9027)</td>
<td>$1.1 \times 10^8$</td>
</tr>
<tr>
<td>Burkholderia cepacia (ATCC 25416)</td>
<td>$1.0 \times 10^8$</td>
</tr>
<tr>
<td>Candida albicans (ATCC 10231)</td>
<td>$1.1 \times 10^8$</td>
</tr>
<tr>
<td>Vegetative A. niger (ATCC 16404)</td>
<td>$2.2 \times 10^8$</td>
</tr>
</tbody>
</table>

*(ATCC = American Type Culture Collection; < 10 is the statistical expression of no microbial recovery for the plate count test method; NR = No Significant Reduction from the initial count)*

**CONCLUSION:** 99.9 percent of the inoculated microorganisms were killed within 4 hours of coming in contact with the product.

Approved By: [Signature]

Laboratory Director
Bacteriostatic

1. Bacteria cannot grow in the presence of the salve
2. Proves the device does not require a preservative

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**MICROBIOLOGICAL TEST REPORT**

**PRESERVATIVE EFFICACY TEST**

<table>
<thead>
<tr>
<th>Microorganisms</th>
<th>Inoculum / g</th>
<th>Colony Forming Units / gram</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Time 0</td>
<td>Day 7</td>
</tr>
<tr>
<td>E. coli</td>
<td>$1.0 \times 10^6$</td>
<td>TNTC</td>
</tr>
<tr>
<td>S. aureus</td>
<td>$1.0 \times 10^6$</td>
<td>TNTC</td>
</tr>
<tr>
<td>Ent. cloacae</td>
<td>$1.05 \times 10^6$</td>
<td>TNTC</td>
</tr>
<tr>
<td>Kl. pneumoniae</td>
<td>$1.1 \times 10^6$</td>
<td>TNTC</td>
</tr>
<tr>
<td>Ps. aeruginosa</td>
<td>$1.05 \times 10^6$</td>
<td>TNTC</td>
</tr>
<tr>
<td>B. cepacia</td>
<td>$1.0 \times 10^6$</td>
<td>TNTC</td>
</tr>
<tr>
<td>Ps. fluorescens</td>
<td>$1.0 \times 10^6$</td>
<td>TNTC</td>
</tr>
<tr>
<td>Ps. putida</td>
<td>$1.05 \times 10^6$</td>
<td>TNTC</td>
</tr>
<tr>
<td>C. albicans</td>
<td>$1.0 \times 10^6$</td>
<td>TNTC</td>
</tr>
<tr>
<td>A. niger</td>
<td>$1.0 \times 10^7$</td>
<td>TNTC</td>
</tr>
</tbody>
</table>

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**REPORT**

**Report No.:** PM060810-01  
**Report Date:** July 12, 2010  
**Page:** 1 of 1
Method: Using a subcutaneous oxygen monitor from Radiometer, we conducted a randomized, controlled, crossover, triple-masked clinical trial to measure the effects of Original Healing Salve (OHS) on the TcPO2 in the skin of the lower extremity in sixteen (n=16) generally healthy adults with type 2 diabetes without peripheral artery disease.

Conclusion: The Puremedy® Original Healing Salve increased TcPO2 after 30 minutes in people with type 2 diabetes, (between 4% and 13%) however the contributions of the herbal and homeopathic ingredients remain unclear.
Autolytic Debridement

- An embedded sliver
- 3 mls of salve applied at night with a bandaid
- The next morning the splinter appears on the bandaid, drawn out from skin overnight
Tested and Potential Mechanisms of Puremedy’s Original Healing Salve for Wound Care

Mechanisms:

- “Drawing” action - autolytic debridement
- Increase blood circulation and oxygen
- Bacteriostatic and Bactericidal
- Provides moist wound healing environment
- Protects wound bed

Observed Mechanisms
Dr. Matt Montee of Advantage Wound Care in El Segundo, CA

- Stimulates Microphages and Fibroblasts
- Reduces colonization count
- Improve wound bed moisture retention
- Improve wound collagen matrix
- Speeds up epithelialization phase and formation of granulation tissue
- Anti-inflammatory action

Hypothesized Mechanism of action - Antibacterial properties (requires further study)

- It is proposed that the ointment fundamentally traps the bacteria in a water free air free environment and interfering with the. Additionally, because of the thick viscosity of the tree extracts, the device appears to be interfering somehow with communication between bacteria.
“Dudley” was rescued by The Gentle Barn. He had a severed foot and now successfully wears a prosthetic, thanks to Puremedy’s Original Healing Salve.
“Dudley” the cow: Wound healing progression

Wounds from prosthetic
wounds on his stump; necrotic and damaged tissue

After 5 days
wound, necrotic and damaged tissue resolved

After 10 days
Dudley’s stump is growing hair back on apparently new fully functioning skin
“Little Bear” dog wound healing progression over 4 weeks

1 day

1 week

2 weeks

3 weeks

4 weeks
Dog bite - wound healing progression

Only treated with Original Healing Salve

After 15 minutes

Day 4

Day 12

Day 22

Today
SAFETY: Based on the indications for use, I believe there is a minimal to risk to health from this product.

- Over 1 million users and 150 years - no adverse events reported
- Minimal side effects, <1% allergic or sensitive
- 100% food grade ingredients, all GRASE

EFFICACY: Puremedy’s Original Healing Salve salve provides:

- antibacterial action
- a moist wound healing environment
- autolytic debridement
- increased circulation and oxygen
- protection for the wound bed
- anti-inflammatory action
- resolution of chronic wounds in case studies
- antimicrobial power that should not contribute to the formation of new “superbugs”. More research is necessary

1960 - This salve saved my Mom’s life from a nearly fatal hospital acquired infection following a severe allergic reaction to penicillin
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