Research on Toxicological Characteristics of Antibacterial Composite Materials

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Abstract: Experiments were carried out for determining the acute dermal toxicity, dermal irritation and skin abnormality of antibacterial composite materials, according to the testing methods of technical specifications of toxic chemicals (2005’Version). The medium lethal dose in the group of acute dermal toxicity was greater than 2000 mg/kg, and the mean value of rabbit's dermal irritation was 1.67. The skin of guinea pigs appeared erythema in the group of skin sensitization, and the integral in each time of skin sensitization reached two. The results indicated that the acute dermal toxicity of antibacterial composite materials towards big mice belonged to low toxicity or actual non-toxic. The single intensity of irritation towards rabbit as well as the sensitized strength was slight.

Key words: antibacterial composite materials; toxicological characteristics; footwear

1 Introduction

Many kinds of antimicrobial agents and technique are used on footwear. The toxicological characteristics of antibacterial agent, however, affect the safety of products. In addition, the market of antibacterial materials in China is still in transition period from chaos to norms, unified evaluation standards for testing of antibacterial toxicology are still needed. In this research a new detecting method of antibacterial toxicological performance was designed and the toxicological characteristics of antibacterial agent made by ourselves were tested.

2 Experimental

2.1 Experimental Animals

1) Healthy adult male and female rats, 200 g~300 g in weight, ten in each group.
2) Four healthy adult male rabbits, with intact skin.
3) Fifteen nulliparous and non-pregnant healthy adult female guinea pigs.

2.2 Experimental Antibacterial Agents

In this research, the applied antibacterial agents include organic, inorganic and composite antibacterial agent which is compounded by above two.

2.3 Acute Dermal Toxicity Test of Antibacterial Agents

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Testing rats have been shaved the hair and divided into four groups. The composite antibacterial agents are applied with 1000mg / kg, 1500mg / kg, 2000mg / kg and 2500mg / kg respectively. Then observe the toxic reaction and mortality of rates.

2.4 Dermal Irritation Test of Antibacterial Agents

The skin of testing rabbit is coated with composite antibacterial agent, about 0.5ml each time. Observe the testing parts and to assess the irritation degree after 1 hour, 24 hours and 48 hours respectively.

2.5 Skin Abnormality Test of Antibacterial Agents

After 10 to 14 days of induction phase, i.e. coating or injecting intradermally several times on the testing guinea pigs, the organic antibacterial agents with irritating does are coated and then observe the intensity of skin reaction, compare with non-coated ones[1].

3 Results and discussion

3.1 Acute Dermal Toxicity of Antibacterial Agents

![Fig.1 Survived numbers after coating the antibacterial composite agents](image)

By observing the rats' death situation (as shown in Fig. 3-1), it is clear that during the observation period, the survival rate of rats is a hundred percent, no death.

According to the data between the dermal toxicity grade (Tab. 1) and the experimental results (Tab. 2), we found that the acute dermal toxicity LD₃₀ is greater than 2000mg/kg, which means the toxicity of antibacterial agents is low or actually nontoxic.

<table>
<thead>
<tr>
<th>Tab.1 Dermal toxicity grading</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD₃₀(mg / kg)</td>
</tr>
<tr>
<td>≤200</td>
</tr>
<tr>
<td>&gt; 200 ~ 2000</td>
</tr>
<tr>
<td>&gt; 2000 ~ 5000</td>
</tr>
<tr>
<td>&gt; 5000</td>
</tr>
</tbody>
</table>

<p>| Tab.2 Test results of acute dermal toxicity |</p>
<table>
<thead>
<tr>
<th>S. e Group (mg/kg)</th>
<th>Does</th>
<th>Weight (x±SD) (g)</th>
<th>The number of animal died in 1-14 days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ID</td>
<td>After zero day</td>
<td>After seven days</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F 1000</td>
<td>1</td>
<td>185.84</td>
<td>186.23</td>
</tr>
<tr>
<td>F 1000</td>
<td>2</td>
<td>187.82</td>
<td>172.81</td>
</tr>
<tr>
<td>E 1500</td>
<td>3</td>
<td>191.12</td>
<td>190.25</td>
</tr>
<tr>
<td>M 2000</td>
<td>3</td>
<td>213.38</td>
<td>213.56</td>
</tr>
<tr>
<td>M 2500</td>
<td>4</td>
<td>217.72</td>
<td>219.54</td>
</tr>
<tr>
<td>M 2500</td>
<td>5</td>
<td>222.28</td>
<td>223.41</td>
</tr>
</tbody>
</table>

Mortality are zero

**3.2 Dermal Irritation of Antimicrobial Agents**

By observing the skin changes of rabbits' (as shown in Fig. 2), we saw erythema and eschar after coating antimicrobial composite agents.

![Skin changes on testing parts of rabbits](image)

**Fig.2 Skin changes on testing parts of rabbits**

According to the data of dermal toxicity grade (Tab. 3) and the experimental results (Tab. 4), we can get the conclusion: in the dermal irritation test, the mean value of rabbit's dermal irritation is 1.67, which means the irritation of antimicrobial agents is light.
Tab.3 Grading standard on the intensity of dermal irritation

<table>
<thead>
<tr>
<th>Mean Value</th>
<th>Intensity of Irritation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0~0.5</td>
<td>Non-irritation</td>
</tr>
<tr>
<td>0.5~2.0</td>
<td>Light</td>
</tr>
<tr>
<td>2.0~6.0</td>
<td>Middle</td>
</tr>
<tr>
<td>6.0~8.0</td>
<td>High</td>
</tr>
</tbody>
</table>

Tab.4 Test results of acute dermal irritation

<table>
<thead>
<tr>
<th>Sample</th>
<th>Reference</th>
<th>Sample</th>
<th>Reference</th>
<th>Sample</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>After 1 hr</td>
<td></td>
<td>After 24 hrs</td>
<td></td>
<td>After 48 hrs</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>I D</th>
<th>Sex</th>
<th>Weight (g)</th>
<th>Ery the me a</th>
<th>Ery the me a</th>
<th>Ery the me a</th>
<th>Ery the me a</th>
<th>Ery the me a</th>
<th>Ery the me a</th>
<th>Ery the me a</th>
<th>Ery the me a</th>
<th>Ery the me a</th>
<th>Ery the me a</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Male</td>
<td>2118</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>Male</td>
<td>1962</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>Male</td>
<td>1871</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>Male</td>
<td>2084</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total score</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.67</td>
<td></td>
<td></td>
<td></td>
<td>Light</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3.3 Skin Abnormality of Antibacterial Agents

In the tentative tests the induced concentration and inspired concentration of organic antibacterial agent were set to 1% and 0.5% respectively. By observing the skin changes (as shown in Fig. 3), we saw light erythema on the skin.

Negative groups ➔
Positive groups ➔
Testing groups ➔
Shaving just 24h induced excitation 48h induced excitation

Fig.3 Skin changes on testing parts of guinea pigs

According to the data of intensity of irritation (Tab. 5) and the experimental results (Tab. 6), we can get the conclusion: in the test of skin abnormality, there is no guinea pig which the total score of skin abnormality is above two. The test results of skin abnormality are negative, anaphylactic rate is 25%, which means the skin abnormality is slight.

Tab.5 Grading standard on intensity of irritation

<table>
<thead>
<tr>
<th>Sensitization rate (%)</th>
<th>Intensity of irritation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Group</td>
<td>Numbers</td>
</tr>
<tr>
<td>---------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Negative control group</td>
<td>4</td>
</tr>
<tr>
<td>The testing group</td>
<td>4</td>
</tr>
<tr>
<td>Positive control group</td>
<td>4</td>
</tr>
</tbody>
</table>

4 Conclusions

1) The acute dermal toxicity LD_{50} > 2000mg/kg, which means the toxicity of antibacterial agents, is low or actually nontoxic.

2) The mean value of rabbit's dermal irritation is 1.67, means the irritation of composite antibacterial agents is light.

3) In the test of skin abnormality, there is no guinea pig which the total score of skin abnormality is above two. The test results of skin abnormality are negative, anaphylactic rate is 25%, which means the skin abnormality of organic antibacterial agent is slight.

Reference