Oral Irritation
Dental Material Testing

Model: SkinEthic™ HOE, SkinEthic™ HGE

DESCRIPTION

Evaluation of cell viability

For each of the tested products or controls, at the end of the incubation period, two cultures are rinsed and placed on 300 µl of 0.5 mg/ml MTT

After 3 hours of incubation at 37°C, 5% CO₂, cultures are placed in 1.5 ml of isopropanol

Extraction is performed at room temperature, for a minimum of 1.5 hour at room temperature

Optical density is measured on 200 µl of extracts at 570 nm (reference filter: 690 nm)

Results are expressed as percentage of viability compared to negative control (mean +/- SD of duplicate cultures).

% of viability = [OD(570 nm - 690 nm) test product / OD(570 nm - 690 nm) negative control] x 100.

Histo-pathologic interpretation:

Negative control cultures: The epithelial tissues must have a constant thickness (corresponding to the internal control sections), devoid of terminally differentiated cells, and a regular and compact shape. Cells are attached to the others via multiple desmosomes.

Positive control cultures: Most of the upper cell-layers of the epithelial tissues must be disintegrated, and the remaining basal cells loosely attached to the polycarbonate substratum

TESTED PRODUCTS

- Adhesive gel
- 15 µl and 30 µl
- Exposure time: 1 hour, 3 hours, 24 hours

RESULTS

<table>
<thead>
<tr>
<th>Tested Product</th>
<th>Percentage of viability compared to negative control (mean +/- SD of duplicate cultures)</th>
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<tbody>
<tr>
<td></td>
<td>1 hour</td>
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<tr>
<td>Negative control (Non treated)</td>
<td>100% +/- 0.35</td>
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<tr>
<td>15 µl</td>
<td>104.86% +/- 4.96</td>
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<tr>
<td>30 µl</td>
<td>103.21% +/- 2.34</td>
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