Diphoterine® eye/skin chemical splash decontamination solution: An updated review of safety and efficacy data

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Innocity of Diphoterine® solution

<table>
<thead>
<tr>
<th>Task</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ocular irritation</td>
<td>Non irritant</td>
</tr>
<tr>
<td>In vitro Evaluation of the eye</td>
<td>No cytotoxic or irritant potential</td>
</tr>
<tr>
<td>Cutaneous irritation</td>
<td>Non irritant</td>
</tr>
<tr>
<td>Ocular irritation of a residue</td>
<td>Non irritant</td>
</tr>
<tr>
<td>Oral toxicity</td>
<td>Non toxic, LD₅₀ 2000 mg/kg</td>
</tr>
<tr>
<td>Acute dermal Toxicity</td>
<td>Non toxic, LD₅₀ 2000 mg/kg</td>
</tr>
<tr>
<td>Cytotoxicity</td>
<td>Non mutagenic</td>
</tr>
<tr>
<td>Anti-inflammatory potential</td>
<td>Non anti-inflammatory</td>
</tr>
<tr>
<td>Local irritation on damaged skin/healthy skin</td>
<td>Non irritant or toxic effects</td>
</tr>
<tr>
<td>Local skin tolerance</td>
<td>Non irritant</td>
</tr>
</tbody>
</table>

Formulation, classification of Diphoterine® solution

An aqueous saline solution containing Diphoterine®, amphoteric protein.

Medical device, Class IIa, CE 0459 can be used on healthy and damaged tissues

Limpid and colourless liquid

Osmotic pressure: 820 mosmoles/kg

Sterile solution (by autoclave)

In vivo study in the rabbit eye: Burn due to concentrated ammonia

No washing

Saline solution

Diphoterine® solution

No stromal edema and significant decrease of pH with an inflection of the curve when washing with Diphoterine® solution

An In Vivo cutaneous prospective, randomized, blinded study: Burn due to concentrated hydrochloric acid

Biomarkers

IL₅

Significantly decreased by the washing with Diphoterine® solution compared to other washing solutions at 48 hours and 7 days, 0.001 < p < 0.05

Substance P

Decreased and significantly different with Diphoterine® solution versus other groups at 6 and 48 hours, p < 0.05

B-Endorphin

Significantly increased when washing performed with Diphoterine® solution compared to no washing or other washing solutions after 7 days, p < 0.05

The differences in serum levels of biological markers and wound healing were likely due to the superior washing properties of Diphoterine® solution such that less HCl was left on the skin to produce injury (Cavallini, 2004).

Case Reports: Summary of observations when washing with Diphoterine® solution during an industrial chemical exposure (2014)

53 firms gave a testimony
64 victims of specified accidents
68 testimonies of = Everyday use without special accident stories
16 accidents involving Alkalis
25 accidents involving Ammonia
37 eye exposures
35 skin exposures
8 combined eye and skin splashes

Firms have described the following effects:

- Decrease in secondary care
- Improvement of the symptoms during washing
- Less pain
- Decrease in severity of the burn injuries
- Decrease in sequelae
- Decrease in last Time of Work

A retrospective comparative study at the hospital (Verbelven 2016): Rinsing with Diphoterine® or Hexafluorine® versus water

<table>
<thead>
<tr>
<th>Title / Author</th>
<th>Chemical</th>
<th>Experimental group</th>
<th>Ph scale (inside CS cloud)</th>
<th>Clinical</th>
<th>Radiological</th>
<th>Observations / Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verbelven</td>
<td>Dipho</td>
<td>Washed with Dipho</td>
<td>7.00 ± 0.25</td>
<td>0.00 ± 0.05</td>
<td>0.00 ± 0.05</td>
<td>No sequelae in any case</td>
</tr>
<tr>
<td></td>
<td>Hexa</td>
<td>Washed with Hexa</td>
<td>7.00 ± 0.25</td>
<td>0.00 ± 0.05</td>
<td>0.00 ± 0.05</td>
<td>No sequelae in any case</td>
</tr>
</tbody>
</table>

References:


