研究报告编号：H-HSIT-28-08
研究完成日期：6 月 20 日 2009 年
标题：人体皮肤刺激试验

4.5.6
Data
Data, including results with positive and negative control materials,is summarized in tabular form, showing for each individual the irritation grading at 24 hours and 72 hours after patch removal and any other effects observed.
数据
数据显示了受试者在凉贴移除 24 小时和 72 小时之后的刺激等级以及其他反应，以表格方式给出，包括了阳性对照组与阴性对照组。

4.5.7
Data evaluation/interpretation
The aim of this test is to determine whether a material presents as a significant skin irritation potential hazard following acute exposure. Thus, if the material produces a frequency of skin irritation in the test subjects which is similar to or greater than, the positive control, it shall be regarded as a significant skin irritant. On the other band, if it produces a frequency of skin irritation in the test subjects, which is substantially and significantly less than the positive control, then it is not be regarded as a significant skin irritant.
数据评估/解释
该测试的目的是评判这种材料在人体急性接触后是否具有潜在显著的皮肤刺激。因此，如果这种材料在测试过程中产生频繁的皮肤刺激，这种刺激频度与阳性对照组相似或者高于阳性对照组，那么它将被认为具有显著的皮肤刺激。反之，如果刺激的频度基本上或者明显低于阳性对照组，那么将被认为不具有显著的皮肤刺激性。
Interpretation of results
the irritant potential of the product is expressed as percentage and is evaluated as follows:
1. the number of reactions caused by the product to the total number of subjects.
2. The severity of the irritant reactions.
结果的解释
该产品的潜在刺激程度用百分比来表示，评判的依据如下：
1.引起受试者皮肤刺激的产品数量与产品总数量；
2.刺激性反应的严重程度。

The reaction of grade 1 （weakly positive reaction -usually characterized by mild erythema and/or dryness across most of the treatment sites）, disappearing within 25 hours after the product has been removed,are not considered.
The reaction of grade 3 （Strongly positive reaction -strong and often spreading erythema with oedema and/or eschar formation）are counted twice.
Irritant potential was calculated as the percentage of subjects that showed the described degrees of irritant phenomena to the total number of subjects at different time interval
1 级反应（弱阳性反应 - 通常特征在于在大多数的治疗点轻度红斑、干燥），在产品移除后的 25 小时之内消失的，不被考虑在内。
3 级（强阳性反应-强大并传播的伴随着水肿的红斑、焦痂的形成），这种反应计算两次。
在不同的时间段计算存在潜在刺激反应的受试者与总的受试者之比。

Results

Test Group
A total of 107 subjects completed the study, 73 females and 34 males；age range was between 20 to 49 years, mean age was 30.17

Highest Irritant potential for 1% sodium dodecyl sulfate was 87.8%
（material is considered to be maximum irritant）

Highest Irritant Potential for 0.9% sodium chloride was 0.9%
（material is considered to be non irritant）
Highest irritant potential for test sample： natural sago hydrogel（H_2O） was 1.8%
（material is considered to be non irritant）
结果

测试组
共有 107 受试者完成了研究，73 名女性和 34 男性；年龄范围 20～49 岁之间，平均年龄为 30.17 岁。
浓度 1%的十二烷基硫酸钠的最大潜在刺激为 87.8%（该材料被认为是最大的刺激物）
0.9%的生理盐水的最大潜在刺激胃 0.9%（该材料被认为是无刺激性）
测试样品的最高潜在刺激为：天然西米凝胶（H_2O）为 1.8％

（材料被认为是无刺激性）

Conclusion

The application of the tested samples Natural sago hydrogel for 48 hours on 107 healthy subjects result in non irritant reaction

结论
107 名健康受试者使用测样品天然西米水凝胶 48 小时，不产生刺激反应。