

7. Procedures

The back of each animal was clipped and freed of hair about 24 hours before the test, and the clipped area was divided into four sections (about 6 cm²). Two of the sections were abraded. Abrasion was made by epidermal incision through the stratum corneum; two incisions perpendicular to the other two were made in a manner resembling a "#" pattern by use of a sterile 18-gauge needle. The other two sections were left intact.

A 0.5-mL portion of the test sample was applied to each gauze patch (about 2 cm × 3 cm) and held in one intact and one abraded sections on each animal with MULTI FIX-ROLL (ALCARE Co., Ltd.). To ensure the contact of the test sample with skin, the patches were covered with KEEP SILK (NICHIBAN Co., Ltd.). The other intact and abraded sections served as controls.

After 24 hours of exposure, the patches were removed and the test sections were wiped with water for injection. The skin reactions were then read at 1, 24, 48 and 72 hours after removal of the patches according to the criteria shown in Table 1.

According to ISO 10993-10:2010, Biological evaluation of medical devices - Part 10, the scores of the readings at 24, 48 and 72 hours for each animal were added together and divided by six to obtain a mean for each animal. Next, a mean for all the animals was calculated and defined as the primary irritation index (P.I.I.). The primary skin irritation was evaluated by the P.I.I. based on ISO 10993-10 shown in Table 2.

The animals were weighed before treatment and on the last observation date.

8. Results (Tables 3 and 4)

1) Rabbit No. 1

Very slight erythema (score 1) was seen on the intact and abraded skin at 1 hour after removal of the test sample, but it had disappeared at the 24-hour observation. No further abnormalities were found during the subsequent period.

2) Rabbit No. 2

Very slight erythema (score 1) was seen on the intact skin at 1 hour after removal of the test sample, but it had disappeared at the 24-hour observation. No further abnormalities were found during the subsequent period.

No irritation response was observed on the abraded skin throughout the observation period.

3) Rabbit No. 3

Very slight erythema (score 1) was seen on the intact and abraded skin at 1 hour after removal of the test sample, but it had disappeared at the 24-hour observation. No further abnormalities were found during the subsequent period.

The P.I.I. was calculated to be 0.

At the non-treatment intact and abraded sections, no irritation response was observed in any of the animals throughout the observation period.