

March 6,7 2018

Continued on next  
page

5. Results

The results of the test are shown in Table 1.

Table 1 Change in concentration of nitrogen oxide (ppm) over time for each specimen

	Supplied concentration	Immediately after gas introduction	2 h	4 h	24 h
(1) ORGALOS-ZERO/eco FRESH (LIQUID)	600	330	100	30	0
(2) ORGALOS GEL/eco FRESH (GEL)	600	570	400	350	280

END

Food

Research

Laboratories

No. 104062007-001

The exposure time was 4 hours, after which the patches were removed, and the exposed surface cleaned with pure water. Observations were made at 1, 24, 48 and 72 hours after removal, and the stimulation reaction was scored according to Table 1. Also, in accordance with Federal Register (1972), the scoring values for 1, 24 and 48 hours after patch removal were totaled, divided by 6, and the mean of each test animal was calculated to obtain the primary irritation index (PII), and the irritation of the specimen was evaluated based on the standard of ISO 10993-10 shown in Table 2.

The body weight of the test animals was measured at the start of the test and at the end of the test.

#### 5 Test Results (Tables 3 and 4)

Very mild erythema (score 1) was seen at all applied sites at 1 hour after removal but disappeared at 24 hours, and thereafter no irritation reaction was observed.

The PII calculated from the scoring result was 0.3.

#### 6 Evaluation

A primary skin irritation test for the specimen using rabbits was conducted according to OECD Guidelines for the Testing of Chemicals 404 (1992).

As a result, extremely mild erythema was observed in all cases 1 hour after removal but disappeared in 24 hours.

Primary irritation index (PII) obtained in accordance with Federal Register (1972) was 0.3, and in the primary skin irritation test using rabbits, the specimen was evaluated as falling within the category of "nonirritating."

#### 7 References

- Federal Register ( § 191, December, 1972).
- ISO 10993-10 Biological Evaluation of Medical Devices-Part 10: Tests for irritation and delayed-type hypersensitivity 6.3 Animal skin irritation test (2002).