



Institut Fresenius - Postfach 12 61 - 65220 Taunusstein

Carl Freudenberg
Analyt. Labor, Bau 32c
Mr. Böhm
Postfach 10 03 63

69443 Weinheim

May 02, 1994

Mrs. G. Götttsch/Hc6589
Phone: 06128/744-154
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Pr.Nr. 93TC101590 - 101597
Unsere Auftrags-Nr. 93/20678-00

Test of plastic samples including a dermatic tolerance test according to
your order

Dear Mr. Böhm,

referring to your order we tested the following samples - received on
December 02, 1993.

Sample No.	designation of sample
93TC101590	Nora Lunairflex 1 mm, color 07
93TC101591	Nora Lunairmed 1 mm, color 07
93TC101592	Nora Lunalastik 1 mm, color 07
93TC101593	Nora Lunacell-A 1 mm, color 07
93TC101594	Nora Lunalight-A 1 mm, color 07
93TC101595	Nora Lunasoft-A 1 mm, color 07
93TC101596	Nora Lunasoft-SL 1 mm, color 07
93TC101597	Nora Lunasoft-SLW 1 mm, color 07

The samples were tested for:

1. migration into synthetic sweat solution
2. qualitative test for heavy metals
3. pH-value of migrate
4. dermatic tolerance test (epicutane test)



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Page 2 of the letter dated May 02, 1994
to Carl Freudenberg, Weinheim

Sample No. 93TC101590 - 101597

Test results

1. Migration test with synthetic sweat-solution

The samples were stored for 24 hours at room temperature in synthetic sweat solution. The ratio of surface to volume was 1:1, i.e. 100 cm² in 100 ml.

The sweat migrate was visually checked for colour release. The residue of the migrate dried at 105 °C was classified semiquantitative.

Sample No. 93TC-	101590	101591	101592	101593
color release	no	no	no	no
residue	minor amount	minor amount	minor amount	minor amount

Sample No. 93TC-	101594	101595	101596	101597
color release	no	no	no	no
residue	minor amount	minor amount	minor amount	minor amount

Page 3 of the letter dated May 02, 1994
to Carl Freudenberg, Weinheim

Sample No. 93TC101590 - 101597

2. Qualitative spectral analysis of the dry residue

The evaporation residue of the sweat migrate was submitted to a qualitative emission spectral analysis in order to test whether heavy metals had passed into the migrate.

In comparison to the sweat solution without contact to the sample only the amount of calcium in the migrate is slightly more.

3. pH-value

The samples were stored for 24 hours at room temperature in demineralized water, which was adjusted at a pH of 7,0. The ratio of surface of the sample to volume of test liquid was 1:1, i.e. 100 cm² in 100 ml.

Sample No. 93TC-	101590	101591	101592	101593
pH of blank	7.0	7.0	7.0	7.0
pH of migrate	8.3	7.9	8.7	8.6
difference	+1.3	+0.9	+1.7	+1.6

Sample No. 93TC-	101594	101595	101596	101597
pH of blank	7.0	7.0	7.0	7.0
pH of migrate	8.6	8.5	8.4	8.8
difference	+1.6	+1.5	+1.4	+1.8



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Page 4 of the letter dated May 02, 1994
to Carl Freudenberg, Weinheim

Sample No. 93TC101590 - 101597

4. Dermatic tolerance test (epicutane test)

The epicutane test was run with a panel of 50 persons (males and females).

The samples were cut into small patches of about 1 cm², put into the chambers of a special epicutane test plaster and fixed to the skin on the outside of the upper arms.

After 48 hours the plasters were removed and then two hours later the upper arms were checked for skin reactions. Further checks took place after 72 and 96 hours.

Epicutane test plasters: FINN CHAMBERS on SCANPORE,
Hermal-Chemie Kurt Herrmann,
Reinbek bei Hamburg

Key:

- no irritation
- (+) slight or questionable irritation
- + distinct irritation
- ++ strong erythema and/or papules
- +++ papules standing close together and/or vesicles
- ++++ blisters or necroses



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Page 5 of the letter dated May 02, 1994
to Carl Freudenberg, Weinheim

Sample No. 93TC101590 - 101597

Result:

Three of the test person told they had shown allergic reaction earlier from time to time. None of them had a reaction during this test.

Sample No.	designation of sample	assessment of the dermatic tolerance
93TC101590	Nora Lunairflex 1 mm, Farbe 07	very good (1 person showed a reaction after 48 hours)
93TC101591	Nora Lunairmed 1 mm, Farbe 07	very good
93TC101592	Nora Lunalastik 1 mm, Farbe 07	very good (1 person showed a reaction after 48 hours)
93TC101593	Nora Lunacell-A 1 mm, Farbe 07	very good (1 person showed a reaction after 72 and 96 hours)
93TC101594	Nora Lunalight-A 1 mm, Farbe 07	very good
93TC101595	Nora Lunasoft-A 1 mm, Farbe 07	very good
93TC101596	Nora Lunasoft-SL 1 mm, Farbe 07	very good
93TC101597	Nora Lunasoft-SLW 1 mm, Farbe 07	very good

All the samples (substitutes for leather) have as a result of this patch test a very good dermatic tolerance.

Sincerley
INSTITUT FRESENIUS GMBH



(J. Schütte)



(G. Götsch)

Enclosure: epicutane test