



THE INSTITUTE FOR SKIN RESEARCH

Consumer Product Evaluation

**Prof. Sarah Brenner, Director
Specialist in Dermatology**

Safe Sea SPF 50 With Zinc Ox
Test No. 239

March 3, 2003

Sunscreen product testing procedures for waterproof determination.

Report no.: 239

Product : Safe Sea SPF 50 With Zinc Ox

Sponsor: Sponsor: NIDARIA TECHNOLOGY LTD.

Aim: To establish the sun protection factor (SPF) of sunscreens.

Method: According to COLIPA guidelines, ref. 94/289, October 1994.

The test will be performed on 10 healthy fair-skin volunteers, with skin types I, II or III.

Skin type will be determined on the basis of sunburn and tanning history, based on the first 30 to 45 minutes of sun exposure after a winter season of no sun exposure, as follows:

- I Always burn easily, never tans
- II Always burn easily, tans minimally
- III Burns moderately, tans gradually

The subjects will not use any medication, topical or systemic, that is known to produce abnormal sunlight responses. Pregnant or lactating women will not be included. Subjects with dermatological problems, subjects with a history of abnormal response to the sun, and subjects accustomed to using UVA sunbeds will not be included.

The subjects will sign an informed consent prior to SPF testing.

There will be a minimum rest period of 1 month before participation in a new SPF determination. Subjects will not be used more than 5 times in any 12-month period.

The test site will be the untanned lower back. Excess hair will be shaved.

For irradiation, a solar simulator will be used.

Minimal erythema dose (MED) is defined as the lowest dose of UVB resulting in a homogenous well-margined erythema read 24 hours later.

First day: For MED determination, a series of graded exposures will be administered to 5 sites, 1 cm in diameter, at 25% increments, and read 24 hours later (second day).



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Second day: Establishing the MED. The MED is the time of exposure that produces minimal perceptible erythema at 16 to 24 hours post exposure.

waterproof determination: the same procedures will be applied, except for the second day procedure that will be as follows:

- After establishing the MED value, application of 2 mg/cm² or 2 µl/cm² of sunscreen to 5 new sites.
- Following a waiting period of 15 to 20 minutes, a 20-minute period of moderate activity in the water in a swimming pool.
- A 20-minute rest period.
- A second 20-minute period of moderate activity in the water.
- A 20-minute rest period.
- A third 20-minute period of moderate activity in the water.
- A 20-minute rest period.
- A fourth 20-minute period of moderate activity in the water.
- A 10-minute period of air drying, without toweling.
- Sites will then be irradiated in a series of 25% increments of exposure. The exact series of exposures will be determined by the MED of the unprotected skin. The first site exposure time will be lower than the MED multiplied by the expected SPF value of the product. The aim is to achieve a series of exposures of the sites in which the lower exposure times produce no effect on the skin, and the longer exposure times produce light and moderately red reactions.

Third day: The time of exposure that produces minimal perceptible erythema is determined for each product.

A sun protection factor (WP - SPF) value is the UV energy required to produce a minimal erythema dose (MED) on protected skin divided by the UV energy required to produce a minimal erythema dose (MED) on unprotected skin. In other words:

Waterproof - SPF value = MED protected skin / MED unprotected skin (after the water exposure procedure).

Confidence limits for the mean SPF must be within $\pm 20\%$ of the mean. If this is not so, additional volunteers will be tested until this statistical criterion is met. The average SPF of a product will be calculated from the results of all volunteers in the test.



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The product:

Safe Sea SPF 50 With Zinc Ox

Volunteer	SPF - WATERPROOF
1	32.17
2	40.00
3	40.00
4	40.00
5	40.00
6	40.00
7	40.00
8	40.00
9	32.17
10	32.17
	376.52
SPF - WATERPROOF	37.65
Standard Deviation (SD)	3.78
Standard Error (SE)	1.20
calculated provisional 95% confidence interval for the mean SPF-WP	34.95-40.36

In summary:

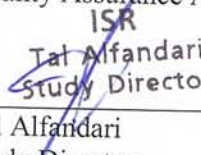
The product: Safe Sea SPF 50 With Zinc Ox	Sun protection factor (WP - SPF)
Expected WP(SPF 50)	37.65 (S.D3.78)

Signature:


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 Avigail Vainer
 Quality Assurance Auditor
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Date: 03/03/2003

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 Study Director
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