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DEONAT Deodorant Stick
DEONAT Deodorant Roll-on

Safety and efficacy assessment in healthy adult volunteers

Study report

Based on agreement for product safety test between

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Germany

and

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Summary

DEONAT Stick and DEONAT Roll-on are body deodorants made from natural alum crystal and intended for daily use.

To test the safety and efficacy profile of the two products a two-week, controlled in-use test in adults was performed. 24 healthy female volunteers aged 18-60 years took part in the study. After conditioning and baseline examination, the volunteers were instructed to use the deodorant stick and roll-on daily in a standardized fashion. The volunteers reported to the study center on three occasions: beginning of the study (day 0), day 7 and day 14 (study end) when safety evaluation was performed and additionally, a questionnaire regarding efficacy and satisfaction with the product use were filled out.

All volunteers completed the study, skin irritancy or contact sensitization to the products, necessitating withdrawal was not observed and the overall satisfaction with the products was good. The study results are herein presented in detail:

Study Design

Testproducts

DEONAT deodorant stick

DEONAT deodorant roll-on

The composition of the products (INCI) as provided by the manufacturer is enclosed to this report.

Inclusion criteria

Healthy female volunteers aged 18-60

Exclusion criteria

Visible dermatitis or other skin disease in the test area

Known or suspected contact sensitization to the product ingredients

Excessive sweating (axillary hyperhidrosis)

Participation in another study in the last 30 days

Serious systemic illness

Pregnancy or lactation

Test area

Left and right axilla (armpit)

Study population

24 volunteers

Beginning of the study: 25.03.2008

End of the study: 11.04.2008

Test period: 2 Weeks

A. Safety evaluation

1. Visual scoring according to Frosch and Kligmann on day 0, day 7 and day 14 as follows

- ✓ Erythema on a 0-4 point scale (0 = no visible erythema; 1 = slight redness, spotty or diffuse; 2 = moderate, uniform redness; 3 = intense redness; 4 = fiery red with edema)

- ✓ Scaling on a 0-3 point scale (0 = no visible scaling; 1 = fine scaling; 2 = moderate scaling; 3 = severe scaling with large flakes)
- ✓ Fissures on a 0-3 point scale (0 = no visible fissures; 1 = fine cracks; 2 = single or multiple broader fissures; 3 = wide cracks with hemorrhage or exsudation)

2. Registration of the subjective symptoms reported by the volunteers on day 7 and day 14 using a standardized questionnaire taking into account the presence/absence of the following symptoms:

- ✓ Erythema (Redness)
- ✓ Scaling
- ✓ Skin dryness
- ✓ Burning sensation
- ✓ Stinging
- ✓ Tension
- ✓ Itch
- ✓ Other

3. Daily registration of the presence/absence of the above mentioned symptoms by the volunteers using a diary

B. Efficacy

1. The deodorant and antiperspirant efficacy of the products was assessed by the means of a questionnaire and standardized 4 point-grading scale as follows:

- ✓ Very good
- ✓ Good
- ✓ Satisfactory
- ✓ Unsatisfactory

and additionally by subjective assessment of the efficacy using standardized formulations integrated in questionnaire on satisfaction with the product use.

C. Assessment of the overall satisfaction with the product use

1. The overall satisfaction with the product was assessed by the means of a standardized questionnaire at day 14 (end of the study)

Results

24 healthy adult female volunteers 18 to 60 years of age meeting the above mentioned inclusion and exclusion criteria were included in the study after signing written informed consent.

All volunteers completed the 2-week study period. There was no premature termination due to consent withdrawal or unwanted reaction to the products.

A. Safety evaluation

In the safety evaluation were included data from 24 volunteers (safety population).

At the baseline evaluation upon entering the study (day 0) performed by a certified dermatologist erythema, scaling or fissures in the test area were not observed in any of the volunteers.

On day 7, discrete erythema in the left axilla (where deodorant stick was applied) evaluated as 0.5 by the dermatologist was present in only one study participant. The symptom was reported by the volunteer and recorded on 2 consecutive days in the diary as "mild" along with the presence of skin dryness and tension. The symptom however was only transitory and no longer present on day 14.

On day 14, slight erythema in the right armpit where the roll-on was applied, was observed in only one volunteer. The intensity was evaluated as 1.0 (slight redness, spotty or diffuse) as described. The symptom was not reported or recorded by the volunteer.

The presence of scaling or fissures was not observed by the dermatologist throughout the study.

The subjective symptoms reported by the patients on day 7 and day 14 are presented in Table 1a-1b. The symptoms recorded in the diary are summarized in Table 2a-2b.

Table 1a. Safety evaluation: subjective symptoms reported by the study participants on day 7 (n=24)

Erythema	Scaling	Dryness	Burning	Stinging	Tension	Itch	Other
0 (0%)	0 (0%)	1 (4.2%)	2 (8.3%)	0 (0%)	1 (4.2%)	0 (0%)	0 (0%)

Table 1b. Safety evaluation: subjective symptoms reported by the study participants on day 14 (n=24)

Erythema	Scaling	Dryness	Burning	Stinging	Tension	Itch	Other
2 (8.3%)	0 (0%)	1 (4.2%)	2 (8.3%)	0 (0%)	3 (12.5%)	0 (0%)	0 (0%)

Table 2a. Deodorant stick safety evaluation: symptoms recorded by the study participants over the test period using a diary (n=24)

Erythema	Scaling	Dryness	Burning	Stinging	Tension	Itch	Other
1 (4.2%)	0 (0%)	3 (12.5%)	1 (8.3%)	0 (0%)	3 (12.5%)	0 (0%)	0 (0%)

Table 2b. Deodorant roll-on safety evaluation: symptoms recorded by the study participants over the test period using a diary (n=24)

Erythema	Scaling	Dryness	Burning	Stinging	Tension	Itch	Other
0 (0%)	0 (0%)	0 (0%)	3 (12.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Most of the reported or recorded symptoms occurred as isolated events with the exception of one case, in which the participant recorded tension associated with the use of the deodorant stick throughout the entire test period as well as skin dryness and tension on more than two occasions. While the symptoms were clearly related to the product use, improper application of the deodorant stick as a reason for the reported subjective symptoms cannot be completely excluded.

The overall judgement of the safety of the test products by the investigator and the study participants is presented in tables 3-6.

Table 3. Deodorant stick: overall safety assessment by the investigator based on data from 24 volunteers

Very good	Good	Satisfactory	Unsatisfactory
83,3% (20/24)	12,5% (3/24)	4,2% (1/24)	0% (0/24)

Table 4. Deodorant stick: overall safety assessment by the volunteers (n=24)

Very good	Good	Satisfactory	Unsatisfactory
83,3% (20/24)	12,5% (3/24)	4,2% (1/24)	0% (0/24)

Table 5. Deodorant roll-on: overall safety assessment by the investigator based on data from 24 volunteers

Very good	Good	Satisfactory	Unsatisfactory
91,7% (22/24)	0% (0/24)	8,3% (2/24)	0% (0/24)

Table 6. Deodorant Roll-on: overall safety assessment by the volunteers (n=24)

Very good	Good	Satisfactory	Unsatisfactory
79,2% (19/24)	20,8% (5/24)	0% (0/24)	0% (0/24)

B. Efficacy assessment

The assessment of the efficacy of DEONAT deodorant stick and roll-on based on standardized 4 point-scale by the volunteers is presented in Tables 7-10. In the evaluation were included data from 24 volunteers (efficacy population).

Table 7. DEONAT stick deodorant efficacy (prevention of unpleasant body odour) assessment by the volunteers (n=24)

Very good	Good	Satisfactory	Unsatisfactory
83,3% (20/24)	8,3% (2/24)	4,2% (1/24)	4,2% (1/24)

Table 8. DEONAT stick anti-perspirant efficacy assessment (n=24)

Very good	Good	Satisfactory	Unsatisfactory
75% (18/24)	16,7% (4/24)	4,2% (1/24)	4,2% (1/24)

Table 9. DEONAT roll-on deodorant efficacy assessment (n=24)

Very good	Good	Satisfactory	Unsatisfactory
41,7% (10/24)	41,7% (10/24)	12,5% (3)	4,2% (1/24)

Table 10. DEONAT roll-on anti-perspirant efficacy assessment (n=24)

Very good	Good	Satisfactory	Unsatisfactory
33,3% (8/24)	33,3% (8/24)	25% (6/24)	8,3% (2/24)

91,7% (22/24) of the volunteers share the opinion that the deodorant stick provides all day long protection against perspiration and 95,8% (23/24) think the test product prevents efficiently unpleasant body odour.

As for the deodorant roll-on 66,7% (16/24) of the study participants think it provides all day long protection against perspiration and 91,7% (22/24) share the opinion that the product prevents efficiently the unpleasant body odour.

C. Overall satisfaction with the product use

The overall satisfaction with the product use was evaluated by the means of a standardized questionnaire.

The results concerning DEONAT deodorant stick are presented in table 11.

Table 11. Overall satisfaction with the use of DEONAT deodorant stick by the study participants (n=24)

Very satisfied	Satisfied	Less satisfied	Unsatisfied
79,2% (19/24)	12,5% (3/24)	8,3% (2/24)	0% (0/24)

The results showing the percentage (number) of volunteers who answered positively to the questions included in the overall evaluation of DEONAT deodorant stick are summarized below:

1. The deodorant stick provides **anti-perspirant protection all day long**

91,7% (22/24) Yes

2. The deodorant stick **eliminates body odour** efficiently
95,8% (23/24) Yes
3. The deodorant stick leaves a **comfortable fresh body feeling**
87,5% (21/24) Yes
4. The deodorant stick leaves **no white residue on the skin or clothes**
100% (24/24) Yes
5. I like it. It is **nice, handy and suitable for travel**
70,8% (17/24) Yes
6. It looks **nice but is not comfortable to use**
29,2% (7/24) Yes

91,7% (22/24) of the volunteers would like to continue using DEONAT deodorant stick after the end of the study.

The data concerning the overall satisfaction with DEONAT deodorant roll-on are presented in Table 12.

Table 12. Overall satisfaction with the use of DEONAT roll-on by the volunteers (n=24)

Very satisfied	Satisfied	Less satisfied	Unsatisfied
25% (6/24)	50% (12/24)	25% (6/24)	0% (0/24)

58,3% (14/24) of the study participants would like to continue using the product after the end of the study. 50% (12/24) liked the fragrance of the roll-on.

The data regarding the percentage (number) of volunteers who answered positively to the questions included in the overall evaluation of DEONAT roll-on are summarized below:

1. The roll-on provides **anti-perspirant protection all day long**
66,7% (16/24) Yes
2. The roll-on **eliminates body odour** efficiently
91,7% (22/24) Yes
3. The roll-on leaves a **comfortable fresh body feeling**
75% (18/24) Yes
4. The roll-on leaves **no white residue on the skin as well as on the clothes**
91,7% (22/24) Yes
5. The roll-on leaves a **pleasant fresh fragrance**
70,8% (17/24) Yes

Discussion


The aim of the present study was to test the safety and efficacy of DEONAT stick and DEONAT roll-on as body deodorants intended for daily use. For the purpose a two-week in-use test in adult healthy female volunteers was performed. DEONAT stick and DEONAT roll-on were applied daily to the armpits while the use of other body deodorants or perfumes throughout the study was excluded.

As shown in the "Result" section of the report, the safety profile of both products throughout the study period was very good based on independent assessment by the investigator and the volunteers. Irritant or allergic reaction to the products was not observed or reported and all recruited volunteers completed the study. Subjective symptoms like burning sensation or feeling of tension and dryness in the test area were infrequently reported and with the exception of one case, occurred as isolated events. There was very good correlation in the overall assessment of the safety profile of the products by the investigator and the volunteers, supporting the consistency of the results.


The efficacy of the products concerning the prevention of unpleasant body odour and reduction of transpiration assessed by the volunteers was good. The products provided a fresh and clean body feeling without leaving white stains on the skin or clothes and were well accepted by the study participants. There was a preference for the deodorant stick compared to the roll-on based on preference for the fragrance (or its lack) as the fragrance of the roll-on was perceived as "intense" by the majority of volunteers.

Taken together, the results of the study provide evidence for a good safety profile of DEONAT stick and DEONAT roll-on when used daily, along with reasonably good deodorant and anti-perspirant efficacy assessed by the volunteers on the background of positive feedback concerning the overall satisfaction with the products.

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