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Controlled User Trial With
“Oops! Aloe Vera Balsam toilet paper”
(VTSZ: 4818109000)
(Cosmetic Study)

Summary

Study Sponsor: **Vajda Papír Kft.**
Ócsai u. 8.
1239 Budapest
Hungary

Date of Order.....: 25.06.2010

Performance of Test: Derma Consult GmbH
and Evaluation by Brunnenstrasse 61
53347 Alfter
Germany

Supervisor of Study: Dr. C. A. Schirren - gynaecologist

Test Product: The test product **“Oops! Aloe Vera Balsam toilet paper”**
(VTSZ: 4818109000) was provided by Vajda Papír Kft.

Subjects: Number of individuals.: 20 (+1 reserve subject)
Sex.....: female
Age range (completing) ..: 26-62 years (average: 44,1)

Test Area: Outer genital area

Application.....: Duration....: 14 days
Frequency.: by selection of subjects; min. once daily

Test Period: March / April 2010

Study Objective.....: Determination of skin compatibility in a gynecological
controlled user trial.

manager: Dr. H. P. Nissen B. R. Nissen-Zoufal district court Bonn HRB 5272 VAT-REG.No. DE 123369725
bank account: VR Bank Bonn account 6 106 665 018 BLZ 381 602 20 Tax No. 222/5703/0374
IBAN: DE38 3816 0220 6106 6650 18 BIC: GENO DE D1 HBO

Performance of Test

The subjects were informed about importance and meaning of the study. Written informed consent was obtained from all the subjects prior to entry into the trial. The following criteria were used for selection of subjects:

for inclusion in study:

- female (≥ 18 years of age)
- clinically healthy

for exclusion from study:

- skin diseases
- pregnancy

They could withdraw from the study at any time without giving any reason and were instructed not to use any topical preparations on the test areas starting from seven days prior to testing and until the end of the test. For cleansing during the preconditioning phase, water or a mild syndet (Eubos[®] flüssig – blau; manufacturer: Dr. Hobein, D-53340 Meckenheim-Merl, Germany) was allowed only. A reserve subject to replace potential drop-outs started the study at the same time.

On their visit to the test institute after the preconditioning phase, the subjects were questioned on their current medical condition; only subjects in good health fulfilling the criteria above were allowed to participate in the study. They then received the test product along with application instructions for regular use. After 14 days of home use (frequency at choice of subjects; minimum once daily), the subjects returned for questioning on skin compatibility of the test product. The questionnaire is included in paper form in the appendix (German); the subjects were presented this questionnaire using Keypoint 5.54 (MU + Data Entry, Cambridge Software Publishing, UK) on a touch sensitive computer terminal with on-screen keyboard for open questions.


Because of an unrelated medical condition, one subject (3) was unable to comply with the usage instructions, dropped out of the study and was replaced by the reserve subject. The twenty completing subjects of this study were between 26-62 years of age (average: 44,1).

Results

Eight subjects used the test product on average twice daily; all other subjects used the test product once daily. No incompatibilities, discomfort or any other problems with relation to the test product and its use were reported by any of the subjects.

On the basis of these results, the test product was found to be “harmless” with regard to its irritative potential and can be considered as “safe” for use in the outer genital area.

Signature:


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Dr. C. A. Schirren Gynaecologist

Enclosures: Questionnaire, tabulated questionnaire answers

Subject	Age	Usage Frequency	Stinging	Itching	Reddening	Scaling / Dryness	Rash	Other Problems	Other Type	Problem Description
1	39	once daily	-	-	-	-	-	-	-	-
2	34	once daily	-	-	-	-	-	-	-	-
3	42					drop-out				
4	54	once daily	-	-	-	-	-	-	-	-
5	35	twice daily	-	-	-	-	-	-	-	-
6	61	once daily	-	-	-	-	-	-	-	-
7	34	twice daily								
8	30	once daily	-	-	-	-	-	-	-	-
9	42	once daily	-	-	-	-	-	-	-	-
10	38	twice daily	-	-	-	-	-	-	-	-
11	27	twice daily	-	-	-	-	-	-	-	-
12	39	once daily	-	-	-	-	-	-	-	-
13	44	twice daily	-	-	-	-	-	-	-	-
14	43	once daily	-	-	-	-	-	-	-	-
15	56	once daily	-	-	-	-	-	-	-	-
16	39	once daily	-	-	-	-	-	-	-	-
17	40	twice daily	-	-	-	-	-	-	-	-
18	58	once daily	-	-	-	-	-	-	-	-
19	60	twice daily	-	-	-	-	-	-	-	-
20	52	twice daily	-	-	-	-	-	-	-	-
Reserve	56	once daily	-	-	-	-	-	-	-	-

Questionnaire - User Trial - Oops! Aloe Vera Balsam toilet paper

Thank you for your participation in this trial. After you had the chance to try out the Oops! Aloe Vera Balsam toilet paper, we now would like to ask you a few questions about the tolerance of the product:

Q1. How often did you use the "Oops! Aloe Vera Balsam toilet paper" on average?

<input type="checkbox"/> more than twice daily	<input type="checkbox"/> twice daily
<input type="checkbox"/> once daily	<input type="checkbox"/> less than once daily

Q2. Did you notice during or as a result of the application of the test product any problems? Please mark all that apply:

	Yes**	No
Stinging	<input type="checkbox"/>	<input type="checkbox"/>
Itching	<input type="checkbox"/>	<input type="checkbox"/>
Reddening	<input type="checkbox"/>	<input type="checkbox"/>
Scaling / dryness	<input type="checkbox"/>	<input type="checkbox"/>
Rash	<input type="checkbox"/>	<input type="checkbox"/>
Other problems: _____	<input type="checkbox"/>	<input type="checkbox"/>

**If yes, please describe the problems briefly. Please list the exact nature of the problems, the time of occurrence and the frequency of occurrence:

Thank you for your participation.

Fragebogen - Anwendungstest - Oops! Aloe Vera Balsam toilet paper

Vielen Dank für Ihre Teilnahme an dieser Studie. Nachdem Sie Gelegenheit hatten das Oops! Aloe Vera Balsam Toilettenpapier kennenzulernen, möchten wir Sie nun bitten uns einige Fragen zur Verträglichkeit des Produktes zu beantworten:

F1. Wie oft haben Sie das "Oops! Aloe Vera Balsam" Toilettenpapier durchschnittlich angewendet?

<input type="checkbox"/> mehr als 2* täglich	<input type="checkbox"/> 2* täglich
<input type="checkbox"/> 1* täglich	<input type="checkbox"/> seltener als täglich

F2. Traten während oder durch die Anwendung des Testproduktes irgendwelche Probleme auf? Bitte benennen Sie alle zutreffenden:

	<i>Ja**</i>	<i>Nein</i>
Brennen	<input type="checkbox"/>	<input type="checkbox"/>
Jucken	<input type="checkbox"/>	<input type="checkbox"/>
Rötung	<input type="checkbox"/>	<input type="checkbox"/>
Schuppung/Austrocknung	<input type="checkbox"/>	<input type="checkbox"/>
Ausschlag	<input type="checkbox"/>	<input type="checkbox"/>
Sonstige Probleme: _____	<input type="checkbox"/>	<input type="checkbox"/>

****Wenn ja, beschreiben Sie bitte die aufgetretenen Probleme in Stichworten. Bitte nennen Sie die genaue Art der Probleme, sowie den Zeitpunkt und die Häufigkeit des Auftretens:**

Vielen Dank für Ihre Mitarbeit.