

TOPLINE REPORT

A FOUR (4) WEEK PILOT EVALUATION OF THE SAFETY AND EFFICACY OF A FACIAL PEEL

**STUDY NO. 3239KMP0407
JULY 20, 2007**

The objective of this pilot study was to determine the relative safety and efficacy of **Vi Peel**. The study was initiated on May 16, 2007 and completed on June 13, 2007. Fifteen (15) subjects were enrolled and fourteen (14) completed the study. One (1) subject discontinued due to an adverse experience.

Results of evaluation of the relative safety and efficacy of **Vi Peel** are detailed in Tables 1 through 9B. Mean values for all evaluation parameters were calculated and analyzed for change as a function of treatment and time using the Paired Samples t-Test. Product-induced change was considered significant at the $p \leq 0.050$ level.

VISUAL/TACTILE EVALUATION

SIGNS OF IRRITATION (TABLE 1)

Signs of dryness statistically significantly improved (decreased) by the week 2 assessment interval and persisted through to week 4, study end. With respect to erythema, numerical improvement, relative to baseline values, was noted at week 2 and significant improvement at week 4. Based on these findings, **Vi Peel** appears safe within its intended use.

SIGNS OF SKIN AGING/PHOTOAGING (TABLES 2 THROUGH 6).

No significant changes were detected in any of the visual parameters as a function of treatment of time.

INSTRUMENTAL EVALUATION

COSMETRICS – HEMOGLOBIN, MELANIN AND COLLAGEN (TABLE 7)

No significant changes were detected in hemoglobin, melanin or collagen levels as a function of treatment or time. Numerically, values for hemoglobin, melanin and collagen were consistent throughout all assessment intervals.

ELASTICITY (TABLE 8)

A small numerical increase in skin elasticity, relative to baseline values, was detected at the week 4 interval. However, significant change was not observed. An overall improvement level of approximately 4% was noted.

COARSE LINES/WRINKLES -REPLICA ANALYSIS (TABLE 9A)

For coarse crow's feet lines, changes from baseline were statistically significant for the Spacing parameter, and trendwise (directionally) significant for five additional parameters. The significant changes were in the direction of rougher texture, i.e., increases from baseline for Rz, Ra, Shadows, and NumWr parameters, and a decrease for the spacing parameter.

FINE LINES/WRINKLES – REPLICA ANALYSIS (TABLE 9B)

For fine lines, changes from baseline for four (4) parameters were statistically significant. Overall, the changes were in the direction of smoother fine line texture, i.e., decreases from baseline for Rz, Ra, Shadows and NumWr.

Overall, the results are consistent with a significant decrease in the roughness of fine lines accompanied by a similar, but statistically less significant increase in roughness of the coarse crow's feet lines.

CONCLUSION

In conclusion, under the conditions employed in this study, following use of **Vi Peel** signs of irritation decreased, indicating safety within its intended use. No significant changes in visual signs of skin aging/photoaging were observed. Results of instrumental analysis indicated a significant decrease in the roughness of fine lines in the crow's feet area.

TABLE 1. Results of Evaluation of the Effects of **Vi Peel** on Skin Condition:
Visual Evaluation: Skin Irritation.

M	DRER_B	0.7	1.6	_W	0.1	1.4	_W	0.4	0.6
EA	YNYTAS	8±	4±	EE	4±	2±	EE	2±	4±
N	ESHEEL	0.4	0.6	K	0.3	0.7	K	0.5	0.7
SC	S MIN	2	3	2	6*	5	4	1*	4*
OR	A E				(82	(13		(46	(61
E ±))))
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*Significantly different than baseline value, $p \leq 0.050$.

TABLE 2. Results of Evaluation of the Effects of **Vi Peel** on Skin Condition:
Visual Evaluation: Uniformity of Pigmentation.

M	_B	6.2	_W	6.2	_W	6.7
EA	AS	7±	EE	6±	EE	4±
N	EL	1.1	K	1.0	K	0.7
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_[†]Trendwise significantly different than baseline value, p=0.015 - 0.051.

TABLE 3. Results of Evaluation of the Effects of **Vi Peel** on Skin Condition:
Visual Evaluation: Fine Lines/Wrinkles.

M_B	6.5	_W	6.3	_W	6.8
EAAS	5±	EE	7±	EE	3±
N EL	0.9K	0.6K	0.8		
FI IN	1 2	1 4	7 (-		
NEE		(3)	4)		
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TABLE 4. Results of Evaluation of the Effects of **Vi Peel** on Skin Condition:
Visual Evaluation: Skin Tone.

M_B	6.0	_W	6.3	_W	6.1
EAAS	3±	EE	4±	EE	8±
N EL	1.3K	0.8K	0.9		
SKIN	2 2	4 (-4	4 (-		

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TABLE 5. Results of Evaluation of the Effects of **Vi Peel** on Skin Condition:
 Visual Evaluation: Suppleness/Texture.

M_B 5.5_W5.9_W5.7
 EAAS 8± EE 5± EE 5±
 NEL 1.2K 0.8K 0.7
 SUIN 0 2 5 (-4 4 (-
 PPE 7) 3)
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TABLE 6. Results of Evaluation of the Effects of **Vi Peel** on Skin Condition:
Visual Evaluation: Elasticity/Firmness/Resiliency.

M_B	5.6	_W	6.1	_W	5.6
EAAS	2±	EE	4±	EE	2±
N EL	1.2	K	0.8	K	1.2
ELIN	3	2	1	(-4	3
ASE			9)		(0)
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_*Significantly different than baseline value, $p \leq 0.050$.

TABLE 7. Results of Evaluation of the Effects of **Vi Peel** on Skin Condition:
Instrumental Evaluation: Cosmetics – Hemoglobin, Melanin and Collagen.

M_	HE M CO_B	85.155187_	W	92.155185_	W	87.158186						
EA	M EL LLAS	11	.37	.69	EE	91	.05	.91	EE	10	.42	.32
N	O ANAGEL	±1	±1	±1	K	±2	±1	±1	K	±2	±9.	±1
CO	GL IN ENIN	9.2	1.4	8.4	2	4.8	2.6	9.3	4	0.2	33	7.1
SM	OB	E	1	6	9	2 ^T	4	7	(-	8	(2)	8
ET	IN					(9)	(0)	1)		(2)		1)
RI												
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[†]Trendwise significantly different than baseline value, p=0.015 - 0.051.

TABLE 8. Results of Evaluation of the Effects of **Vi Peel** on Skin Condition:
Instrumental Evaluation: Elasticity.

M_B 15. W 16.
EAAS 70 EE 27
N EL ±6. K ±8.
ELIN 91 4 91
ASE (4)
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^{*}Significantly different than baseline value, p≤0.050.

TABLE 9A. Results of Evaluation of the Effects of **Vi Peel** on Skin Condition:
Instrumental Evaluation: Replica Analysis – Coarse Wrinkles.

M pV_R 23.0.0_R 5.5.0.0_Fs - 0.8_F 0.0.0.5_S - 0.0_B 0.0.0.0_S 3.0.0.0_N 22.0.0
EAALz 2± 53^Ta ±9.55^Tpac0.0 58 NU 1± 29 pac0.321*rea 3± 84^Tha ±6.80^Tum 4± 71^T

N UE	40.	8	e	2±	M	0.0	ing	8±	dth	0.0	do	0	Wr	42.
CH	8			0.4		8		0.5		6	ws			7
AN				5				4						
GE														
±														
S.														
D.														

*Significantly different than baseline value, p≤0.050.

Trendwise significantly different than baseline value, p=0.015 - 0.051.

TABLE 9B. Results of Evaluation of the Effects of **Vi Peel** on Skin Condition:
Instrumental Evaluation: Replica Analysis – Fine Lines.

M pV_R - 0.0_R - 0.0_Fs - 0.3_F 0.0 0.4_S 0.2 0.5_B 0.0 0.2_S - 0.0_N - 0.0	EAALz	22.02*	a	3.7	15*	pac	0.0	72	NU	2±	85	pac	4±	83	rea	1±	82	ha	1.7	22*	um	29.24*
N UE	4±			±4.		e	8±	M	0.1	ing	1.6	dth	0.0	do	±2.	Wr	9±					
CH	22.			9		0.3		0		5		3	ws	4								44.
AN	5					2																1
GE																						
±																						
S.																						
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*Significantly different than baseline value, p≤0.050.