

EVALUATION OF THE PRODUCT EFFICACY ON SKIN MELANIN LEVEL AND PIGMETATION SIGNS ON THE BASIS OF INSTRUMENTAL EVALUATION

1. GENERAL INFORMATION

STUDY SPONSOR	Skin Ingredients Pty, Cape Town, South Africa
STUDY CODE	C037/002
NAME AND ADDRESS OF THE ORGANIZATION IN CHARGE OF THE ASSESSMENT	Luamed, Tanja Židan s.p. Lukovica, Slovenia
TEST PRODUCT	Sk.in Flash 3
AUTHORIZED BY	Tanja Židan
ADDITIONAL INVESTIGATIONS INVOLVED	Sara Urbanija
REPORT DATE	1.2.2020

2. PURPOSE AND OBJECTIVE OF THE TEST

The object of this test was to define the direct influence of the tested product on the level of skin melanin content and pigmentation signs and to confirm the declared properties and efficacy of the product on the basis of instrumental methods.).

DESCRIPTION OF THE PRODUCT

INTENDED USE	Face care product
APPEARANCE	Cream
COLOR	Yellowish
FRAGRANCE	Characteristic
INSTRUCTIONS FOR USE	Use every 2nd night for 3 weeks then every night. all volunteers continue to use their normal basic skincare regime such as cleanser, moisturiser and SPF and to slot the serums in.
PRODUCT CLAIMS AS DECLARED BY CUSTOMER	Counteract the signs of UV sun damage and intrinsic skin ageing, improving skin texture, hydrates, minimising pore size, improving fine lines and wrinkles

INCI LIST (QUALITATIVE COMPOSITION) AS DECLARED BY CUSTOMER

The qualitative composition was delivered to the laboratory by the Sponsor, before the start of the study.

3. TEST SCHEDULE

STARTING DATE	6.12.2020
FINISHING DATE	31.1.2020

4. METHODOLOGY

PROTOCOL SUMMARY

Instrumental test using: Callegari 1930 Company – Soft Plus device (melanin probe and micro camera)

The aim of the test was to determine the direct influence of the tested product on skin melanin level and pigmentation signs. The test was conducted with a special measuring device manufactured by Callegari 1930 Company – Soft Plus.

The instrumental measurements were performed on forearm/arm/facial skin (depending of the pigmentation signs location). Tested and control zones of 5 cm x 5 cm area were indicated on the forearm/arm/face of 10 volunteers. The measurements were carried out for each zone in all tested and control places immediately prior to the application of the tested product. Subjects were told not to rinse off and to continue with their basic skincare regime one until the end of the study (8 weeks).

The measurement of skin melanin level was performed three times, at the beginning, after 4 weeks and at the end of the study (8 weeks). The arithmetic mean of the measurements of each of the 10 subjects is considered as each final result.

Evaluation of pigmentation signs was performed at the beginning and at the end of the study (8 weeks). Before and after fotos were recorded to evaluate the changes of the 10 subjects.

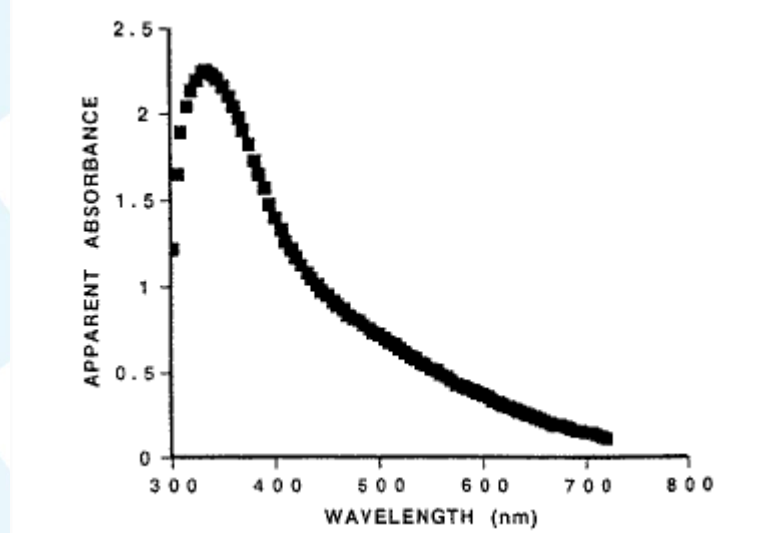
All measurements were carried out in a room with a temperature of $20 \pm 3^{\circ}\text{C}$ and a relative humidity of $50 \pm 10\%$. Directly before testing, the skin of the volunteers was gently wiped with warm water.

MELANIN MEASUREMENT

The melanin technology employed is based on the absorption/reflecting principle at two defined wavelengths (875 nm and 660 nm).

Melanin is the most important pigment in determining skin colour in humans. Other substances that mainly contribute to the colour of the skin are oxy- and deoxyhaemoglobin and carotenoids.

While oxy- and deoxyhaemoglobin and carotenoids have a peculiar absorbing spectrum in the visible range, melanin polymer is neither well characterized nor unique and it does not have a typical band in the visible range. As expected, it has a maximum of absorbance in the UV portion of the spectrum (according to its biological function) and its absorptive capacity decreases with increasing wavelength (see image below).



The sensor of the probe is constituted by two kinds of LEDs emitting in the visible (660 nm) and IR (875 nm) spectrum and by a photodetector. The chosen wavelengths correspond to the different absorption rates of the pigments of the skin.

Once the probe has been applied to the skin surface, the radiation emitted by the light sources is partially absorbed and partially reflected by the skin.

The radiation reflected by the skin reaches the photodetector that measures the amount of energy both at 660 nm and 880 nm. The effect of melanin is observed as the decrease of reflectance in all bands.

DESCRIPTION OF VOLUNTEERS

INCLUSION CRITERIA	GENERAL Skin without irritation and changes requiring pharmacological treatment	SPECIFIC Age: 30-65 Skin type: Normal skin Amount: 10
EXCLUSION CRITERIA	- Skin diseases or any other medical condition requiring systemic medical treatment or which may interfere with the objectives of the study.	

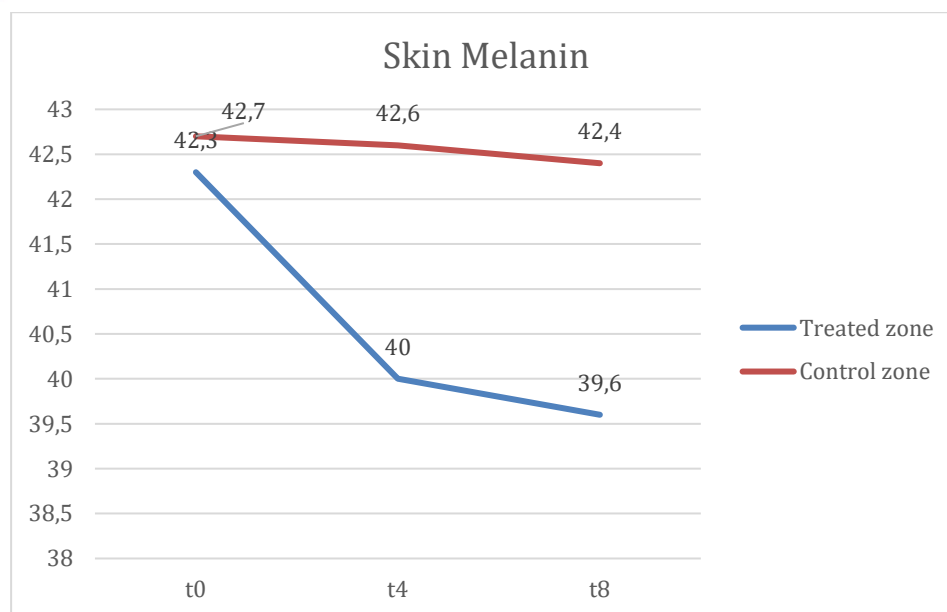
5. RESULTS

PRESENTATION OF RESULTS- MELANIN LEVEL

Table 1: The results of skin melanin measurement before application (t0), after 4 weeks (t4) and 8 weeks (t8) after the product application in arbitrary units. Each result is the average of 5 individual measurements

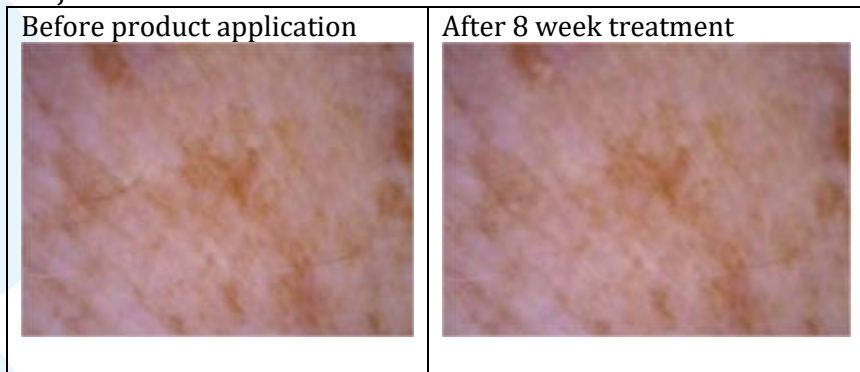
SUBJECT CODE	Treated zone			Control zone		
	t0	t4	t8	t0	t4	t8
001	22	19	18	24	22	24
002	35	33	30	34	36	35
003	34	28	27	32	34	31
004	27	24	24	28	28	29
005	49	42	40	47	49	50
006	30	27	26	29	31	30
007	70	72	71	72	69	70
008	66	68	66	66	64	68
009	35	33	38	38	35	34
010	55	54	56	57	58	53
MEAN	42,3	40	39,6	42,7	42,6	42,4
MIN	22	19	18	24	22	24
MAX	70	72	71	72	69	70
MEDIAN	35	33	34	36	35,5	34,5
SD	16,7	18,6	18,6	17,0	16,3	16,7

Graph I: The average results of skin melanin measurement before application (t0), after 4 weeks (t4) and 8 weeks (t8) after the product application in arbitrary units.

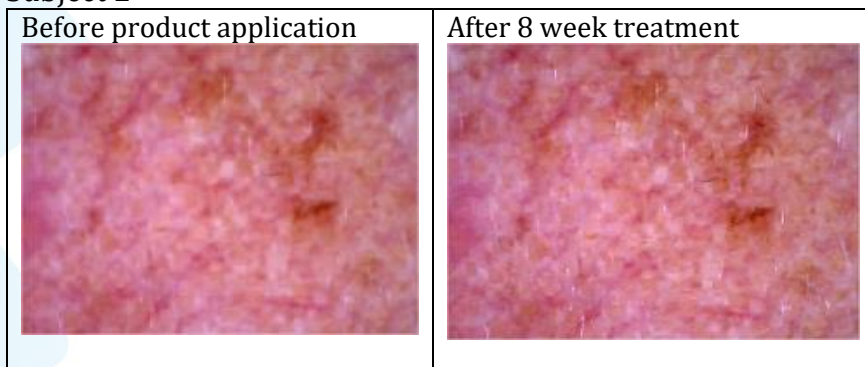


PRESENTATION OF RESULTS- PIGMENTATION SIGNS

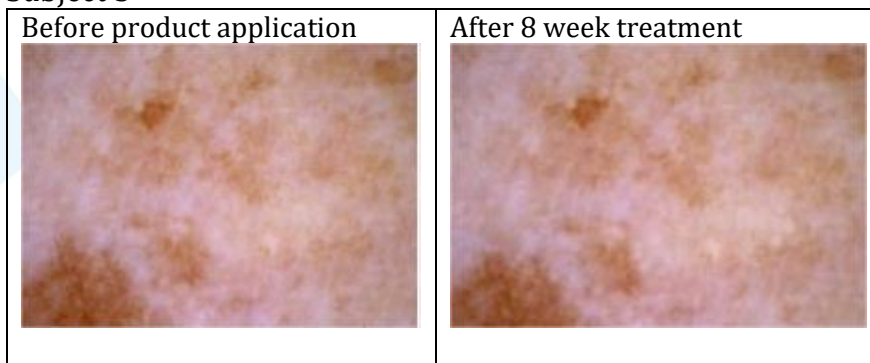
Subject 1



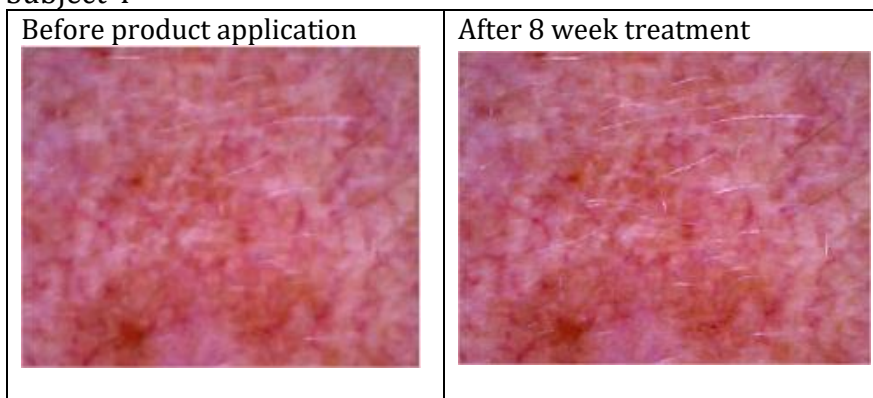
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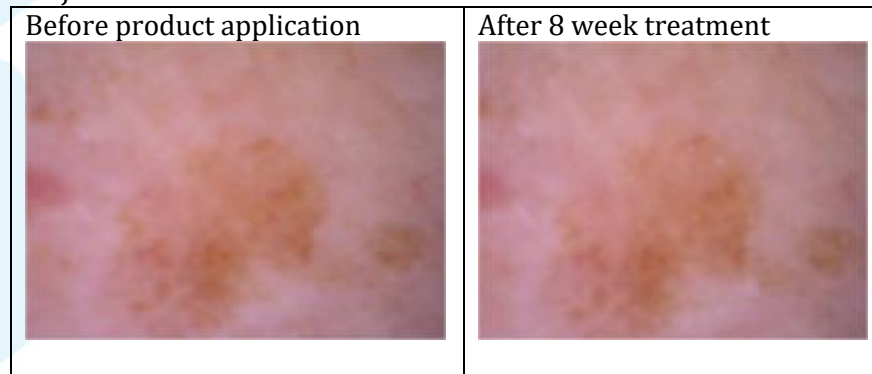
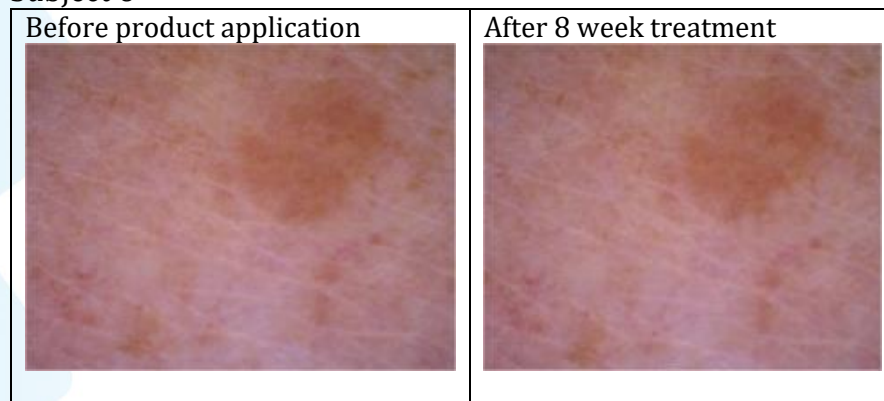
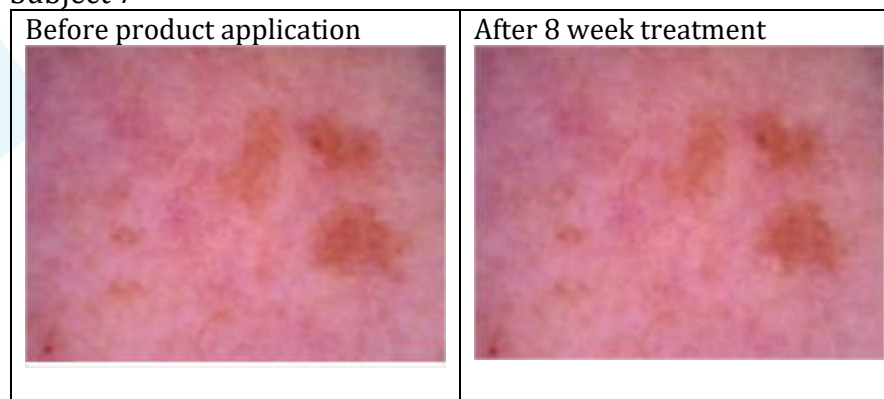
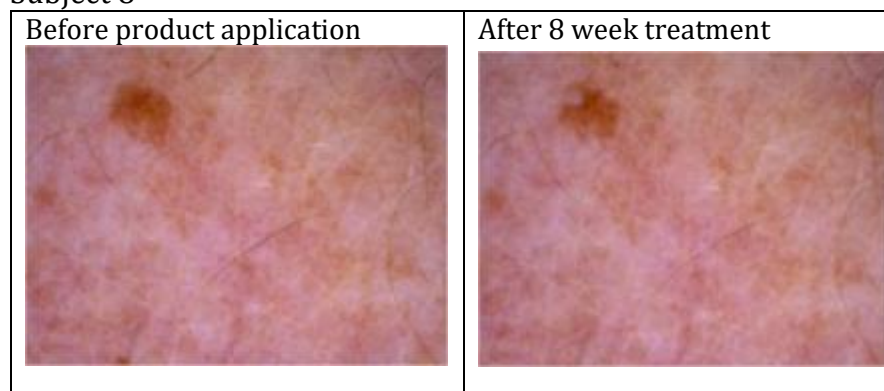


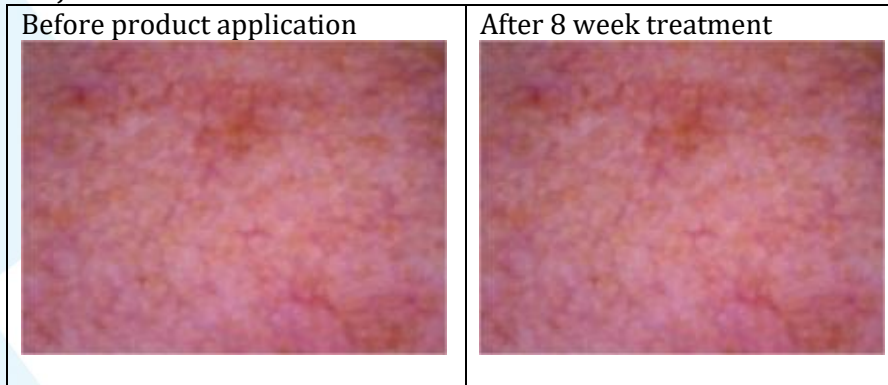
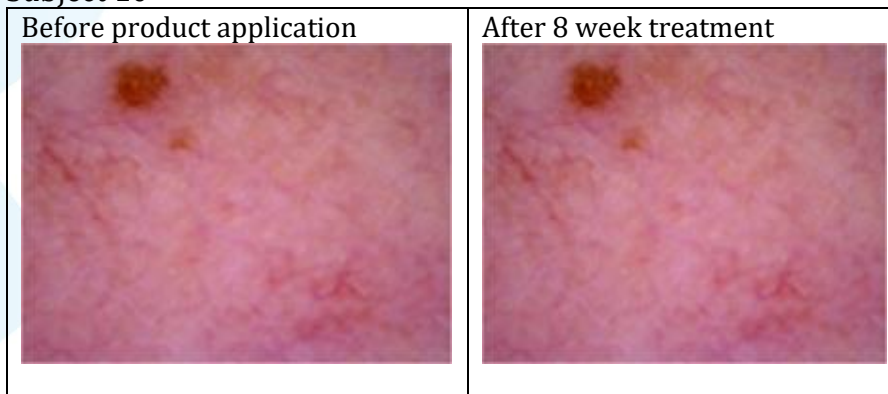
Subject 3



Subject 4



Subject 5**Subject 6****Subject 7****Subject 8**

Subject 9

Subject 10

Table 4: Assessment of product pigmentation improvement effect:

The product improves overall appearance of the skin	65% positive responses
The product reduces the appearance of pigmentation signs	65% positive responses

6. CONCLUSION

SKIN MELANIN LEVEL EVALUATION

Assumption:

The product decreases melanin level of the skin, if the parameter value decreases over time.

Conclusion:

The product was found to decrease skin melanin level within 8 weeks after application.

EFFECT ON PIGMENTATION SIGNS

Assumption:

The product visibly reduces pigmentation signs if that is visible from foto evaluation with micro camera.

Conclusion:

The product was found to slightly reduce the visibility of pigmentation signs after 8 weeks of usage, based on the measurements and consumer evaluation of the product.

7. SUMMARY OF THE REPORT

SKIN ELASTICITY

Under the study conditions, after continuous daily application of the product, can be concluded that the tested product reduces melanin level of the skin.

Table 3: Values of skin melanin level before application (t0), 4weeks (t4) and 8 weeks (t8) after the product application in arbitrary units in comparison to the control zone.

TIME	$\Delta t4$	$\Delta t8$
AVERAGE	-2,2	-2,4

PRESENCE OF PIGMENTATION SIGNS

Under the study conditions and continuous daily application of the product on 10 subjects it can be concluded that the tested product decreases the visibility of pigmentation signs.

Product Sk.in Flash 3 confirmed to reduce skin melanin level and pigmentation signs.

8. REFERENCES

- Regulation of the European Parliament and of the Council (EC) No. 1223/2009 of 30 November 2009 on cosmetic products.
- Cosmetics Europe – The Personal Care Association (previously COLIPA) Guidelines "Product Test Guidelines for the Assessment of Human Skin Compatibility 1997."
- Cosmetics Europe – The Personal Care Association (previously COLIPA) Guidelines for the Evaluation of the Efficacy of Cosmetic Products 2008.
- SOP 014 at Luamed company
- Joachim W. Fluhr. Practical Aspects of Cosmetic Testing. ISBN 978-3-642-05067-1