REPORT No. 121350/17/JSHR/Z1

(Replaces the report no. 121350/17/JSHR made on 12.05.2017)

Client:		Sample (according to declaration of the Client)
BIOSELECT CHARMANI – CHRISTOULAKIS VAT: EL 099984857 4, PAPANIKOLAOU STR, RETHYMNO, CRETE, PO BOX 74100		**BIOSELECT BABY HAPPY HOUR SUN CARE MILK SPF 30**
Received on:	03.04.2017	
Analysis completed on:	11.05.2017	
Report date:	23.05.2017	

IN VIVO DETERMINATION OF THE SUN PROTECTION FACTOR (SPF)

FINAL REPORT

(COMPLEMENT OF PRELIMINARY ASSESSMENT NO. 121344/17/JSHR)

Authorised by: Marta Rosińska, Cosmetic Laboratory Manager
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SCOPE OF TEST COMPLIANT WITH:

- Regulation of the European Parliament and of the Council (EC) no. 1223/2009 of 30 November 2009 on cosmetic products.
- EN ISO 24444:2010/PN-EN ISO 24444:2011 - Cosmetics – Sun Protection test methods – In vivo determination of the sun protection factor (SPF).
- Recommendation No. 2006/647/EC on the efficacy of sunscreen products and the claims made relating thereto.

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CONTENT OF THE REPORT:

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1. THE BASIS OF THE STUDY

- Test samples delivered by the Client.
- The qualitative composition of the product delivered by the Client.
- Declaration of conformity composition of the product.
- The result of microbiology purity of the product declared by the Client.
- Negative test results dermatological of the product delivered by the Client (Report no.: SI.01.C_2014/654).
- Declared a sun protection factor: 30.
- Preliminary assessment in vivo determination of the Sun Protection Factor SPF (Report no.: 121344/17/JSHR).

2. SUBJECT OF TEST

No.	Parameter	Description
1.	Appearance	Emulsion
2.	Color	Pale yellow
3.	Fragrance	Characteristic for used fragrance composition
4.	Packaging	Repackaging covered with a label containing the name of the product

Picture 1: Sample no. 121350/17/JSHR - subject of study.

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3. QUALITATIVE COMPOSITION OF THE PRODUCT

Aqua (Water), Zinc Oxide, Pongamia Glabra (Karanja) Seed Oil, Olea Europaea (Olive) Fruit Oil, Polyglyceryl-3 Polyricinoleate, Helianthus Annuus (Sunflower) Seed Oil, Glycerin, Aloe Barbadensis Leaf Juice, Sorbitan Sesquioleate, Cetyl Ricinoleate, Cera Alba (Beeswax), Sodium Chloride, Glyceryl Caprate, Magnesium Stearate, Benzyl Alcohol, Parfum, Origanum Dictamnus Flower/Leaf/Stem Extract, Bisabolol, Aluminium Tristearate, Dehydroacetic Acid, Calendula Officinalis Flower Extract, Tocopherol.

The Client is responsible for compliance with the declared qualitative composition of the product and microbiological purity of sent samples for testing.

4. PURPOSE OF THE TEST

Confirmation / exclusion declared by the Manufacturer the Sun Protection Factor level.

5. SAMPLES AND TESTING CONDITIONS

Upon arrival, all products are registered on the HAMILTON LIMS System and kept at room temperature (unless otherwise requested). The test is performed in an air-conditioned room, with the room temperature maintained at 22 ± 4°C and the relative humidity 50 ± 10%.

6. INCLUSION CRITERIA

Healthy volunteers,
Subject having given her/his informed, written consent,
Subject that is willing to cooperate and aware of the necessity and duration of controls so that perfect adhesion to the protocol established by the clinical trial center could have been expected,
Age between 18 and 60,
Type: Caucasian,
Phototype: I to III,
Untanned skin on the test area.

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7. NON-INCLUSION CRITERIA

Children and persons below the age of consent or >60 years,
Pregnant or lactating women,
Persons using medication with photo-sensitizing potential,
Persons using anti-inflammatory medication,
Persons with dermatological conditions,
Persons with a history of abnormal response to the sun,
Persons accustomed to using tanning beds,
Persons having had sun exposure on the back area in the previous four weeks prior to SPF testing,
Persons having marks, blemishes or nevi or presenting existing sun damage in the test area,
Persons having excessive hair in the area of the test.

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8. TESTING EQUIPMENT

UV source:	Xenon lamp: Solar Light type Multiport 601
	Spectrum: 290 - 400 nm
	Power of the lamp: 300 W.
	Elimination of IR and visible radiation: UG11 (1mm) and dichroic mirror.
	Radiated surface: Six holes (diameter 8 mm).
UV Light Radiometer:	Solar Light Co. DCS 2.0.
Detector:	Solar Light Co. Erythema detector PMA2108.LLG.

9. LABORATOTY STAFF

The application of the product and visual skin assessment of the responses are made by technically qualified and trained persons.

10. DESCRIPTION OF METHODOLOGY

The SPF test method is a laboratory method that utilizes a xenon arc lamp solar simulator of defined and known output to determine the protection provided by sunscreen products on human skin against erythema induced by solar ultraviolet rays. The test is restricted to the area of the back of selected human volunteers. A section of each volunteer's skin is exposed to ultraviolet light without any protection and another section is exposed after application of the sunscreen product under test. One further section is exposed after application of an SPF reference sunscreen formulation which is used for validation of the procedure.
To determine the sun protection factor, incremental series of delayed erythemal responses are induced on a number of small sub-sites on the skin. These responses are visually assessed for the presence of redness 16 to 24 hours after UV radiation, by the judgment for a trained evaluator. The Minimal Erythema Dose (MED) for unprotected skin (MEDu) and the MED obtained after application of a sunscreen product (MED for product protected skin MEDp) shall be determined on the same volunteer on the same day. An individual sun protection factor (SPFi) for each volunteer tested is calculated as the ratio of individual MED on product protected skin divided by the individual MED on unprotected skin MEDp / MEDu. The sun protection factor

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for the product (SPF) is the arithmetic mean of all valid SPFi results from each volunteer in the test. The minimum area for a product application site shall be 30 cm^2 and the maximum shall be 60 cm^2. The position of the products must be random distributed on the back over the whole test group of volunteers in order to reduce systematic error to anatomical differences in skin. The samples have been distributed in a quantity equal to 2,00 ± 0,05 mg/cm^2. After product is applied to the skin, exposure of the test site begins after a waiting period of 15-30 minutes. Lotions, liquids, milks, creams and sprays: To aid uniform coverage, droplets (approximately 15 per 30 cm^2 , 30 per 60 cm^2) of the product are deposited within the site using a syringe/pipette, then spread over the whole test site using light pressure. Drying time between application and UV exposure: exposure of the test site to the sequence of UV doses shall start 15 min to 30 min after the application of the products. Any extraneous exposure of the test sites to UV light (artificial or natural) shall be avoided during this period and for a period of 24 h after exposure. For the unprotected site, the center of the total UV dose range is established using the volunteer's provisional MEDu or estimated MEDu. 6 sub-sites centered on the provisional/estimated MEDu shall be exposed with incremental UV doses using a geometric progression of 1.25. Other geometric progression of less than 1.25 may be used but should be consistent throughout the test. For the product-protected site, the UV doses delivered are defined by the expected MEDp which is the multiple of the expected SPF of the test product and the provisional MEDu for the volunteer. 6 sub-sites centered on the provisional/estimated MEDu shall be exposed with incremental UV doses using a recommended geometric progression of 1.25. Other geometric progression may be used (e.g. 1.2, 1.15, 1.12). A maximum geometric progression of 1.15 shall be used for expected SPF >25. Smaller geometric progression (e.g. 1.12) may be used but should be consistent throughout the test.

11. SPF REFERENCE STANDARD

The method is controlled by the use of one of three reference sunscreen formulations to verify the test procedure (P2, P3, P7). At least one standard product must be used per test. The mean SPF and the acceptance limits for the used reference sunscreen formulations are:

Reference Sunscreen Formulation	Mean SPF	Range (±SD)	Acceptance limits (mean + 2SD)	
			Lower limit	Upper limit
P3	15,7	1,0	13,7	17,7

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12. PRODUCT LABELING METHOD

The following range of sun protection factors for each category and the respective labeling is recommended (in accordance with 2006/647/CE):

Labelled category	Labelled sun protection factor	Measured sun protection factor
"Low protection"	"6"	6-9,9
	"10"	10-14,9
"Medium protection"	"15"	15-19-9
	"20"	20-24,9
	"25"	25-29,9
"High protection"	"30"	30-49,9
	"50"	50-59,9
"Very high protection"	"50+"	60≤

13. DATE OF PERFORMANCE OF THE STUDY

121344/17/JSHR: 24.04.2017-28.04.2017
121350/17/JSHR: 08.05.2017-11.05.2017

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14.TEST RESULTS

VOLUNTEERS					RESULTS				
No.	Volunteer code	Age	Sex	Phototype	MEDu	MEDs	MEDp	SPFs	SPFi p
					mJ/cm^2				
1	17/SPF	34	M	II	28,00	470,40	940,80	16,80	33,60
2	15/SPF	25	M	II	40,00	618,24	1200,00	15,46	30,00
3	18/SPF	55	W	I	28,00	463,68	868,00	16,56	31,00
4	8/SPF	19	W	I	42,00	705,60	1260,00	16,80	30,00
5	9/SPF	19	M	I	30,00	470,40	930,00	15,68	31,00
6	5/SPF	46	W	I	28,00	439,04	840,00	15,68	30,00
7	20/SPF	23	M	II	44,00	608,00	1320,00	13,82	30,00
8	7/SPF	49	W	II	26,00	364,00	873,60	14,00	33,60
9	12/SPF	46	W	I	26,00	364,00	873,60	14,00	33,60
10	4/SPF	56	W	II	38,00	532,00	1140,00	14,00	30,00
Average value								15,28	31,28
Standard deviation								1,23	1,65
cn								0,88	1,18
Cln(100%)								5,77	3,77

15.CONCLUSION

Product **« BIOSELECT BABY HAPPY HOUR SUN CARE MILK SPF 30 »**

a. mean SPF value: **31,28.**
b. standard deviation: 1,65.
c. 95%CI confidence interval: from 30,00 to 33,60.
d. SPF value to be used in labelling (according to 2006/647/CE): **30. (high protection).**

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16.SIGNATURES

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