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(Direttore: Prof. Plinio Richelmi)

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Preliminary in vivo determination of the sun protection factor (SPF) (ISO 24444:2010)

(Obtained results are considered as equivalent to results obtained in accordance to
International sun protection factor (SPF) test method - Colipa 2006)

Record No. 1401A31SP

BIOSELECT

BABY'S SUN CARE MILK BL1351

Place and date of issue: 12nd February 2014



PROCEDURE

RECEIVING AND CONTROL OF SAMPLE

Samples received from Bio Basic Europe S.r.l.

FAULTS DISCOVERED: nothing to report
Responsible for inspection: Dott.ssa Parmeggiani Katia

Samples delivered by DHL shipment to laboratory for test execution

FAULTS DISCOVERED: nothing to report
Responsible for inspection: Dott.ssa Evelyn Falconi Klein

PRODUCT NAME:

**BABY'S SUN CARE MILK
BL1351**

INCI

EXPERIMENTAL PROTOCOL

MATERIALS

Source of ultraviolet radiation
Xenon lamp, model Multiport Solar UV Simulator model 601 connected to energy source
model XPS400 (Solar Light Co. Inc. Philadelphia, USA)

Standard P3 (Enclosure 1)

SYSTEM CALIBRATION

Emission of UV solar simulator: complies with RCEE % limits
Control UV irradiation with calibrated radiometer: complies

METHOD*

Selection of 5 subjects to be tested according to the inclusion criteria (ISO 24444:2010)

Compilation and signing of the Informed Consent Form for each tested subject

Sample opening

The product was mixed to ensure homogeneity: **HOMOGENEOUS**

Sampling and sample application on the skin of the subjects to carry out the test in accordance
with Standard

In vivo determination of the sun protection factor (SPF) ISO 24444:2010

*Test performed by applying the Ethical Principles for Medical Research Involving Human Subject
HELSINKI DECLARATION

Responsible for experimentation:
Dermatologist: Dott.ssa Evelyn Falconi Klein

Quality control:
Dott. Claudio ANGELINETTA

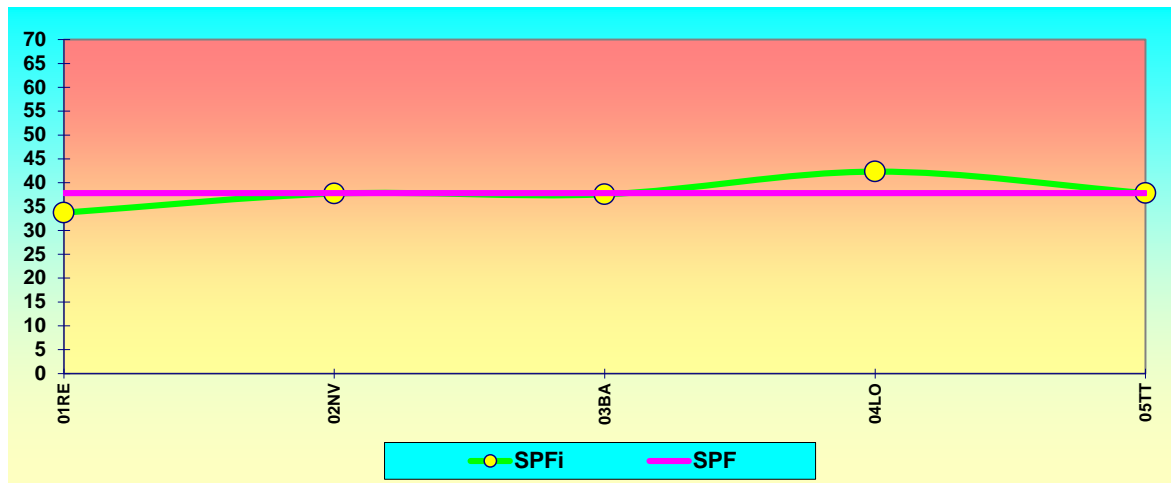
Monitor
Prof. Plinio Richelmi



RESULTS

GRAPH AND TABLES

reference	SEX	Phototype	MEDu sec.	MEDp sec.	SPFi	SPF	s	c	CL (0,17 SPF)
01RE	F	I	43	1450	33,7				
02NV	F	II	54	2037	37,7				
03BA	F	II	68	2555	37,6				
04LO	M	III	95	4021	42,3				
05TT	M	III	119	4503	37,8	37,8	3,0	3,1	6,4
Final result with variability							34,8	37,8	40,9





CONCLUSIONS

From the table and the chart listed above we can maintain that the tested product

BABY'S SUN CARE MILK BL1351

tested according to the standard

In vivo determination of the sun protection factor (SPF) ISO 24444:2010

has got the following in vivo SPF :

37.8 ± 3.1

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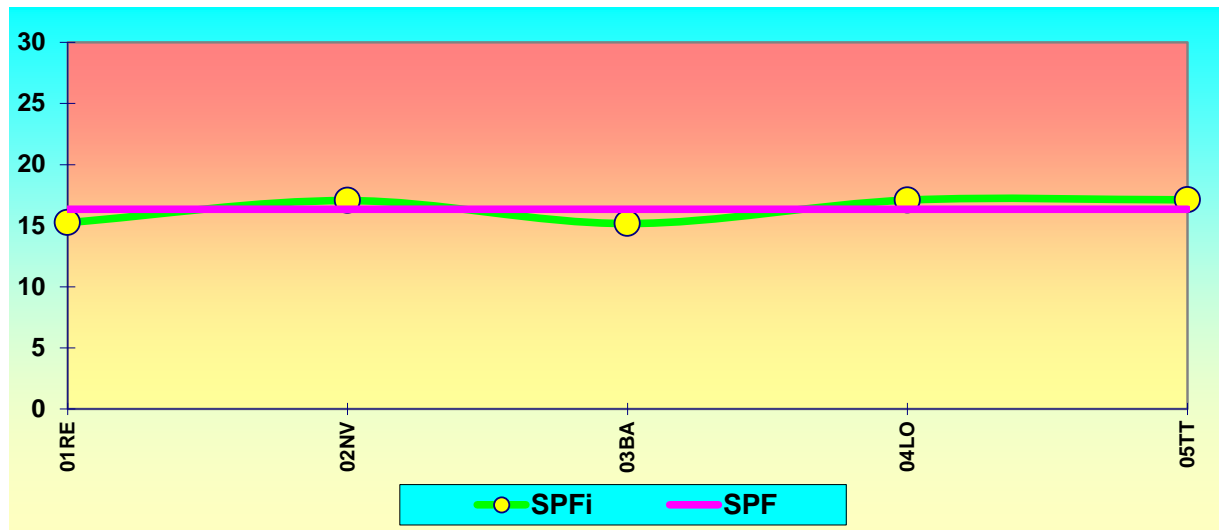
Quality Control

Dr. Claudio ANGELINETTA

Enclosure 1

Standard P3

reference	SEX	Phototype	MEDu sec.	MEDp sec.	SPFi	SPF	s	c	CL (0,17 SPF)
01RE	F	I	43	656	15,3				
02NV	F	II	54	921	17,1				
03BA	F	II	68	1032	15,2				
04LO	M	III	95	1624	17,1				
05TT	M	III	119	2037	17,1	16,3	1,0	1,0	2,8
Final result with variability							15,3	16,3	17,4





BIBLIOGRAPHY

- AS/NZS 2604:1998 Sunscreen products - Evaluation and classification
International sun protection factor (SPF) test method CFFA SA, Colipa, JCIA, CTFA, 2006, (a CD-ROM showing products application procedure is included in the guidelines)
- Department of health and human services, FDA, USA: Sunscreen drug products for over-the-counter human use; Final monograph, Federal Register. 64/98, 27686-27693, May, 21,1999
- ISO/TR 26369 Cosmetics - Sun protection test methods - Review and evaluation of methods to assess the photoprotection of sun protection products
- ICH Guidelines for Good Clinical Practice
- CIE Publication 15.2, CIE 1976 uniform colour spaces. Colorimetry, pp. 29-32, 1986.
- FITZPATRICK, T.B., The validity and practicability of sun-reactive skin types I through VI. *Arch. Dermatol.* **124**, pp. 869-871, 1988
- Declaration of Helsinki, adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975, the 35th World Medical Assembly, Venice, Italy, October 1983 and by the 41th World Medical Assembly, Hong Kong, September 1989
- Guidelines for monitoring UV radiation sources Colipa, March 2007
- CHARDON, A., CRETOIS, I., HOURSEAU, C. Skin color typology and suntanning pathways. *Int. J. Cosmet. Sci.*, **13**, pp. 191-208, 1991

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According to our experience we advice to check every 3 years its compliance with the guidelines in force.