TOXICOLOGY LABORATORY
National Poison Centre of Malaysia
Universiti Sains Malaysia, 11800 Penang, Malaysia
Tel: 04-6532171/011-20863130 Email: prnlab@usm.my

CERTIFICATE OF ANALYSIS (COA)

Analysis : Screening of Whitening Agent by HPLC
(Test Method: In-House Method USM/NPC/TM21)

Date : 15 February 2023 **Ref no.:** PRN2023 / 29 **Page :** 1 of 1

Client and Address:
ARMILA BERHAD
NO. 16, JALAN LINGGIS 15/24,
TAMAN PERINDUSTRIAN LINGGIS,
SEKSYEN 15,
40460, SHAH ALAM,
SELANGOR.

Sample Descriptions:
Name/ID : SUNSCREEN UV SHIELD KAK ELL
Received : Friday, February 3, 2023 at 3.30 pm
Registered : Tuesday, February 7, 2023 at 9.48 am
Type : Cream
Container : Plastic container
Mfg. Date : NA
Exp. Date : NA
Batch No. : NA
NOT No. : NOT220603501K
Test Performance Duration : 13 – 15 February 2023

Results:

No.	Test Parameter	LOD (ppm)	Result
1	Hydroquinone	3	ND
2	Tretinoin	3	ND

Opinions and interpretations: NA

Notes:
1. LOD: Limit of detection
2. ppm: part per million or µg/g or µg/mL
3. ND: Not detected
4. NA: Not Available
5. HPLC: High Performance Liquid Chromatography
6. KKM No.: MAL No. or NOT No.

ChM. NORJULIANA BINTI MOHD NOOR
(IKM No: M/2947/5743/10)
Approved Signatory/ Science Officer

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3. USM assumes no liability for any loss, expense or damage occasioned by use or interpretation of this test results.
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5. Full laboratory address: Toxicology Laboratory of National Poison Centre, Block JO6, National Poison Centre, Universiti Sains Malaysia, 11800 Penang.

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(Company No.: 199601037981 (410334-X))
No.1, Persiaran Dato' Menteri, P.O.BOX 7035, Section 2,
40700 Shah Alam, Selangor Darul Ehsan, Malaysia
Tel: 03-55446682
Fax: 03-55446688
www.sirim-qas.com.my

TEST REPORT

REPORT NO : 2022CE1721	PAGE : 1 OF 3

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THIS TEST REPORT IS ISSUED IN SECURED PDF SOFTCOPY

Applicant	: ARMILA BERHAD No.16, Jalan Linggis 15/24, Taman Perindustrian Linggis, Seksyen 15, 40460 Shah Alam, Selangor, Malaysia
Manufacturer	: ENSU LIFESCIENCES SDN. BHD 49, Jalan KP 3, Kawasan Perindustrian Kota Puteri, Kota Puteri, 48100 Batu Arang, Selangor, Malaysia
Product	: KAK ELL SUNSCREEN UV SHIELD WHITE
Reference Standard / Method of Test	: 1) Guidelines for Control of Cosmetic Products In Malaysia, 1st Revision – February 2017, National Pharmaceutical Regulatory Division Ministry Of Health, Malaysia. 2) CPCT/TP/MM/In-House 018 - Determination of Heavy Metals by Inductive Coupled Plasma Mass Spectrometry (ICP-MS).
Description of sample	: Received one (1) sample for testing which was identified on the next page.
Date Received of Complete Application	: 12 July 2022
Job No.	: J20223671450
Description of Test Results	: The test results of the submitted test samples are described on Page 2 of this test report.
Issued Date	: 20 July 2022

Approved Signatory;

L/3099/9189/21

(WAN MUHAMAD AFEEQ AFNANI BIN WAN ALI)
Testing Executive

SIRIM QAS International Sdn. Bhd. CHEMICAL, POLYMER AND COMPOSITE SECTION (CPCT)

(HAHNAS BINTI MAHBUT)
Head
Chemical, Polymer and Composite Section
Testing Services Department

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TEST RESULTS

Product Name : **KAK ELL SUNSCREEN UV SHIELD WHITE**
Brand : **KAK ELL**
Model : **ARMILA BERHAD**
Type : **CREAM**
Size : **30g**
Product Description : **KAK ELL SUNSCREEN UV SHIELD WHITE**

No.	Type of Tests	Testing Method	Requirements of Guidelines for Control of Cosmetic Products [a]	Results	Remarks
1.	Heavy Metals	CPCT/TP/MM/In - House 018 – based on AOAC 2015.01			
	a) Arsenic (As), mg/kg		5 max	< 0.03[b]	Pass
	b) Lead (Pb), mg/kg		20 max	0.07	Pass
	c) Cadmium (Cd), mg/kg		5 max	< 0.01[b]	Pass
	d) Mercury (Hg), mg/kg		1 max	< 0.01[b]	Pass

Note :
1) [a] Guidelines for Control of Cosmetic Products In Malaysia, 1st Revision – July 2017, National Pharmaceutical Regulatory Division Ministry Of Health, Malaysia.
[b] Limit of reporting.
2) Simple acceptance rule is used for the conformity statement. The level of risk regarding the probability of false accept is up to 50%.
3) Testing period – 14th to 15th July 2022.

SIRIM QAS International Sdn. Bhd.
CHEMICAL, POLYMER AND COMPOSITE SECTION (CPCT)
L/3099/189/21

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   b) Obtaining an injunction from Court (cost on a solicitor-client basis to be borne by the Applicant);
   c) Refusing to accept any further Product for Testing Services from the Applicant or whosoever related to the Applicant, whether subsidiary or otherwise;
   d) Instructing the Applicant to withdraw and recall the advertisement, statement or document in question and advertise a clarification and apology to SIRIM QAS International, SIRIM and/or other SIRIM's subsidiaries twice in a national publication of SIRIM QAS International's choice at the Applicant's sole cost; and
   e) Informing or lodging a report pertaining the Applicant's Test Report with the relevant authorities.

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10. Issuance of Amendment Report due to the following reasons are chargeable to the Applicant :
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    b) Changes in details of the Manufacturer's name and/or address;
    c) Changes in details of the Factory location name and/or address;
    d) Changes in details of the model and/or type designation

11. However, issuance of Supplementary Report due to the following reasons are FOC :
    a) Misprints and typo errors;
    b) Missing technical information as agreed in PP1 form;
    c) Test data not reported;
    d) Mistake in reporting of test data

12. Corrections to report shall only be allowed if the date of issuance of the original report has not exceeded 6 months and shall be limited to a maximum 3 times, after either case whichever occurs earlier, an Amendment or a Supplementary Report shall not be issued.

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Tel : 603-5544 6400 Fax : 603-5544 6810
www.sirim-qas.com.my

SQAS/QOSHE/1/8

17hb November 2023

Ketua Pegawai Eksekutif
ARMILA BERHAD
Wisma Kak Ell, No. 16, Jalan Linggis 15/24,
Taman Perindustrian Linggis, Seksyen 15,
40460 Shah Alam, Selangor.

Dan
Kepada sesiapa yang berkenaan.

Tuan/Puan,

PENGESAHAN KESAHIHAN LAPORAN UJIAN MAKMAL SIRIM

Merujuk kepada perkara di atas dan senarai laporan ujian makmal berikut.

Bil	Laporan Ujian	Produk	Tarikh Laporan Ujian
1.	2021CE1595-S1	Tablet Kunyahan Prowhite Kak Ell	3/11/2021
2.	2022CE1721	Kak Ell Sunscreen UV Shield White	20/7/2022
3.	2022CE1724	Kak Ell Glow Day Cream	20/7/2022
4.	2022CE1786	Kak Ell Cleanser Cengkih + Madu	26/7/2022
5.	2022CE2605	Kak Ell Refreshing Spray Mist	21/10/2022
6.	2022CE2607	Kak Ell Fairy Glow	21/10/2022

Surat ini adalah untuk mengesahkan bahawa senarai laporan ujian tersebut telah dikeluarkan oleh SIRIM QAS International kepada syarikat **ARMILA BERHAD** dan merujuk kepada sampel yang diuji sahaja.

Berhubung kenyataan dan tuduhan terhadap produk Kak Ell yang mengaitkan SIRIM, ianya adalah diluar pengetahuan kami dan tiada sebarang bukti atau dokumen sokongan yang disertakan untuk semakan dan siasatan lanjut.

Diharapkan keterangan dan pengesahan di atas dapat membantu urusan pihak tuan/puan. Disertakan bersama adalah laporan ujian untuk rujukan lanjut.

Sekian, terima kasih.

Yang benar,

(FAUZIAH AHMAD)
Ketua
Seksyen QOSHE
SIRIM QAS International Sdn Bhd

ISO/IEC 17021-1:2015 QS 02121999 CB 01
ISO/IEC 17021-1:2015 EMS 17122002 CB 02
ISO/IEC 17065:2012 PC 05102004 CB 01
ISO/IEC 17021-1:2015 OSH 06122005 CB 01
ISO/IEC 17021-1:2015 HACCP 05052008 CB 03
ISO/TS 22003:2013 FSMS 23122008 CB 01
MS ISO/IEC 17021:2011 FMC 10122009 CB 02
MS ISO/IEC 27006:2011 ISMS 17022011 CB 01
ISO/IEC 17021-1:2015 EnMS 03012014 CB 01
ISO/IEC 17021-1:2015 MDQMS 30092015 CB 04
ISO/IEC 17021-1:2015 GMP 08102015 CB 04
ISO/IEC 17021-1:2015 MSPO 25072017 CB 05
ISO/IEC 17024:2012 PS 09032017 CB 03

MS ISO/IEC 17025
CALIBRATION /TESTING
SAMM NO.085 SAMM NO.086
SAMM NO.087 SAMM NO.219
SAMM NO.735 SAMM NO.240
SAMM NO.734 SAMM NO.377

MS ISO/IEC 17020
MIBAS NO. 003

074

MALAYSIAN PALM OIL BOARD
ADVANCED OLEOCHEMICAL TECHNOLOGY DIVISION
OLEO PRODUCT DEVELOPMENT UNIT
EFFICACY TEST LABORATORY

IN VITRO SUN PROTECTION FACTOR (SPF)

STUDY: **CPD/EFF/EXT/NAC/12-22**

APPLICANT: **Armila Berhad,**
24, Jln Linggis 15/24,
Seksyen 15,
40200 Shah Alam,
Selangor Darul Ehsan.
(Attn: Mrs. Sharmila Johan)

PRODUCT: **Kak Ell Sunscreen UV Shield**

STARTING DATE OF THE STUDY: 13/07/2022

COMPLETION DATE: 13/07/2022

"The data given in this report are exclusively referred to the samples tested. This report can only be reproduced in full. The data are not for product registration or claim purpose."

....., 15/7/2022

DR. YUSRABBIL AMIYATI YUSOF
GROUP LEADER
SAFETY AND EFFICACY ASSESSMENT GROUP
OLEO PRODUCT DEVELOPMENT UNIT, AOTD
MALAYSIAN PALM OIL BOARD

MPOB - Advanced Oleochemical Technology Division (AOTD) No. 6, Persiaran Institusi, Bandar Baru Bangi, 43000, Kajang, Selangor, Malaysia Tel: 603-8769 4308/4293
E-mail: amiyati@mpob.gov.my or zuliana@mpob.gov.my

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E-mail: amiyati@mpob.gov.my or zuliana@mpob.gov.my

1. GENERAL INFORMATION

Study Title	*In Vitro* SPF
Test Facility Manager	Dr. Yusrabbil Amiyati Yusof Head of Safety & Efficacy Assessment Group, Oleo Product Development (OPD) Unit, Advanced Oleochemical Technology Division (AOTD), Malaysian Palm Oil Board (MPOB)
Study Director	Mrs. Nor Zuliana Yusof Senior Research Officer SEA Group, OPD Unit, AOTD.
Test Facility Name Address Tel Fax	Efficacy Test Laboratory, Advanced Oleochemical Technology Division, Malaysian Palm Oil Board, 6, Persiaran Institusi, Bandar Baru Bangi, 43000 Kajang, Selangor. 03-8769 4308 03-8925 6197
Time Study Duration	13/07/2022 1 day
Sponsor Company Name Company Address Tel	Mrs. Sharmila Johan Armila Berhad, 24, Jln Linggis 15/24, Seksyen 15, 40200 Shah Alam, Selangor Darul Ehsan. -

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E-mail: amiyati@mpob.gov.my or zuliana@mpob.gov.my

1.1 Sample Data Sheet

SAMPLE REFERENCE: Kak Ell Sunscreen UV Shield

REFERENCE CODE: -

SAMPLE NUMBER: 1

PRODUCT:

COLOUR: White

QUANTITY: 50 g

OTHER INFORMATION RELATED TO THE PRODUCT: NA

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2.0 PRINCIPLE OF METHOD

2.1 Introduction

Many regulatory bodies such as the US FDA and The European Cosmetic, Toiletry and Perfumery Association (COLIPA), mandate *in vivo* testing on human subjects using the erythemal endpoint to determine the Sun Protection Factor (SPF) of a topical sunscreen. However, the *in vivo* tests are costly and time-consuming and may not be practical for routine product evaluation. The Labsphere UV-2000S Ultraviolet Transmittance Analyzer is designed for predicting the SPF of cosmetic sun care products via *in vitro* technique and thus making routine product evaluation possible. The instrument operates by measuring the diffuse transmittance of a carefully prepared sample as a function of wavelength in the ultraviolet spectrum. Many sunscreens are translucent materials that diffuse incidence light. A ray of light incident onto a sunscreen sample will often be scattered. The light that is not transmitted is reflected or absorbed.

SPF by definition is determined *in vivo* as the increase in time required to induce erythema. However, the work by Diffey and Robson in 1989 on *in vitro* technique involves measuring the spectral transmittance at UV wavelengths from 280nm to 400nm and can be used to determine the SPF. Physical measurements have shown that the solar erythemal response is inversely proportional to the radiation wavelength. The shorter wavelength (UV-B) region at 280 – 315 nm can induce an erythemal reaction. No erythemal reaction is observed for the UV-A region at 315 – 400 nm.

The *in vitro* SPF is calculated as follows:

$$SPF = \frac{\int_{280nm}^{400nm} E_\lambda \cdot S_\lambda \cdot d\lambda}{\int_{280nm}^{400nm} E_\lambda \cdot S_\lambda \cdot T_\lambda \cdot d\lambda}$$

where,

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E_λ = CIE Erythemal Spectral Effectiveness

S_λ = Solar Spectral Irradiance

T_λ = Spectral Transmittance of the sample
(as measured on the UV-2000S)

The equation shows that the higher the amount of transmittance, the lower the SPF value. The transmittance spectrum of a sunscreen in either region is averaged in order to produce one value, which describes the amount of UV-A or UV-B blocking. The average transmittance in each region is given by:

$$T\,(UVA)_{av} = \frac{\sum_{315nm}^{400nm} T_\lambda \times \Delta\lambda}{\sum_{315nm}^{400nm} \Delta\lambda}$$

and,

$$T\,(UVB)_{av} = \frac{\sum_{280nm}^{315nm} T_\lambda \times \Delta\lambda}{\sum_{280nm}^{315nm} \Delta\lambda}$$

where, $\Delta\lambda$ = measured wavelength interval

Consequently, the percent blocking for UVA and UVB, respectively, is calculated as follows:

$= 100\% - T(UVA)_{av}$

$= 100\% - T(UVB)_{av}$

where, $T(UVA)_{av}$ or $T(UVB)_{av}$ is expressed as a percentage.

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The recommended SPF classifications are shown in the table below:

Classification	SPF level
Low	≥ 6 - < 15
Medium	≥ 15 - < 30
High	≥ 30 - < 50
Very High	≥ 50

Note: if the SPF level is more than 50, it may be labelled as SPF 50+

Ref: Guidelines for Control of Cosmetic Products in Malaysia (2017). https://www.npra.gov.my/index.php/en/cosmetics-guideline-annex-i-vii

2.2 UVA Effectiveness – The Boot Star System

In addition to its ability to determine the SPF of a sunscreen, the *in vitro* technique can also measure the UVA protection of the sunscreen. Boots the Chemist, the largest producer of sunscreens in the UK, has developed a label system that uses star rating based on spectrophotometric analysis. The labelling is already used within the UK.

The spectral transmittance values, T_λ, are converted to spectral absorbance values $A_\lambda = -\log(T_\lambda)$. A term called the *UVA ratio* is calculated, which is the ratio of the total absorption in the UVA to that in the UVB:

$$\frac{aUVA}{aUVB} = \frac{\int_{320nm}^{400nm} A_\lambda \cdot d\lambda}{\int_{290nm}^{320nm} A_\lambda \cdot d\lambda}$$

The star rating for UVA protection is determined from the measured UVA ratio as shown in the table below:

Mean UVA:UVB Ratio	Star Rating Category	Category Description
0.0 to 0.2	-	*Too Low/No Claim*
0.21 to 0.4	*	*MINIMUM*
0.41 to 0.6	**	*MODERATE*
0.61 to 0.8	***	*GOOD*
0.81 to 0.9	****	*SUPERIOR*
0.91 and above	*****	*ULTRA*

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2.3 Sample preparation

Sample preparation for *in vitro* SPF system is similar to the application technique used for *in vivo* testing. The recommended amount of sample to be applied based on COLIPA 2007 is 1.30 mg/cm^2. The area of application is 25cm^2 and 32.5 mg sample is applied on the PMMA plate.

The substrate for *in vitro* SPF needs to be transparent to the ultraviolet and simulate the porosity and texture of human skin as in *in-vivo* tests. Four readily available materials; 3M Transpore™ Tape, Vitro Skin™ , Polyvinyl Chloride Film and Poly Methyl Methacrylate (PMMA) can be used as substrates. Transpore Tape is used as the substrate as it is readily available and inexpensive. The other two substrates (Vitro Skin™ and Polyvinyl Chloride Film) are expensive and do not mimic human skin topography. However, PMMA is preferred as the measurement reproducibility is very good and comparable to that obtained during *in vivo* testing.

2.4 Poly Methyl Methacrylate (PMMA)

The product is applied to the PMMA plate by weight. The application rate is determined in such a way that the actual quantity of product left on the substrate is 1.30 mg/cm^2.

The amount of sample is applied by using a micropipette and distributed evenly over the whole roughened PMMA surface of the plate (50 x 50 mm).

Immediately after weighing, the sample is spread over the whole surface with a finger-cot (pre-saturated) with the product using light strokes. Spreading had to be completed as quickly as possible (less than 30 seconds). Then the sample was rubbed into the rough surface using stronger pressure. This also had to take 20 to 30 seconds. The sample thus obtained was allowed to settle for 15 minutes in the dark at room temperature to ensure self-levelling of the formula.

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3.0 RESULTS

The *in-vitro* SPF test on the sample was carried out using Labsphere Ultraviolet Transmittance Analyzer UV-2000S with triplicate plates and 9 scans per each plate. The sample with a total weight of 32.5 ± 0.5 mg was applied on 50 x 50 mm PMMA plate. The results are shown in the following table:

Sample Name	**Kak Ell Sunscreen UV Shield**			
Parameter	**SPF**	**% Transmittance UVA, T(UVA)**	**% Transmittance UVB, T(UVB)**	**Critical wavelength**
Mean	**50.79**	**12.26%**	**1.82%**	**375.93**
STD	4.68	0.60%	0.17%	0.13
COV	9.22%	4.88%	9.21%	0.03%
Number of Sets	3	3	3	3
UVA/UVB Ratio	**0.646**			

4.0 CONCLUSION

Sample Kak Ell Sunscreen UV Shield has a mean SPF of 50.79 with good protection against UVA.

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REPORTED BY

14/07/2022

NOR ZULIANA YUSOF
SENIOR RESEARCH OFFICER
SAFETY AND EFFICACY ASSESSMENT GROUP
OPD, AOTD, MPOB

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E-mail: amiyati@mpob.gov.my or zuliana@mpob.gov.my

Labsphere Transmittance Analyzer
SPF Report

Sample:	Kak Ell Sunscreen UV Shield
Description:	
Operator:	Rosmah
Client:	Armila Berhad
Comment:	
Date:	13/7/2022 11:08:42 AM
Unit serial number:	0521120855

Solar Irradiance Profile: COLIPA, 2009

UVA/UVB ratio calculation used: Boots Star Method

Study Statistics

	SPF	T(UVA)	T(UVB)	Lambda Critical
Number of Sets:	3	3	3	3
Mean:	50.79	12.26%	1.82%	375.93
STD:	4.68	0.60%	0.17%	0.13
COV:	9.22%	4.88%	9.21%	0.03%

UVA/UVB Ratio: 0.646

Kak Ell Sunscreen UV Shield-P1

	SPF	T(UVA)	T(UVB)	Lambda Critical
Number of Scans:	9	9	9	9
Mean:	55.65	11.68%	1.64%	376.00
STD:	6.52	0.53%	0.20%	0.00
COV:	11.71%	4.56%	12.22%	0.00%

UVA/UVB Ratio: 0.648

Scan	SPF	Critical Wavelength
Scan 1	52.24	376
Scan 2	53.69	376
Scan 3	53.29	376
Scan 4	45.83	376
Scan 5	52.43	376
Scan 6	62.65	376
Scan 7	68.36	376
Scan 8	55.50	376
Scan 9	56.83	376

Kak Ell Sunscreen UV Shield-P2

	SPF	T(UVA)	T(UVB)	Lambda Critical
Number of Scans:	9	9	9	9
Mean:	50.43	12.23%	1.83%	376.00
STD:	6.73	0.57%	0.29%	0.50
COV:	13.35%	4.65%	16.08%	0.13%

UVA/UVB Ratio: 0.647

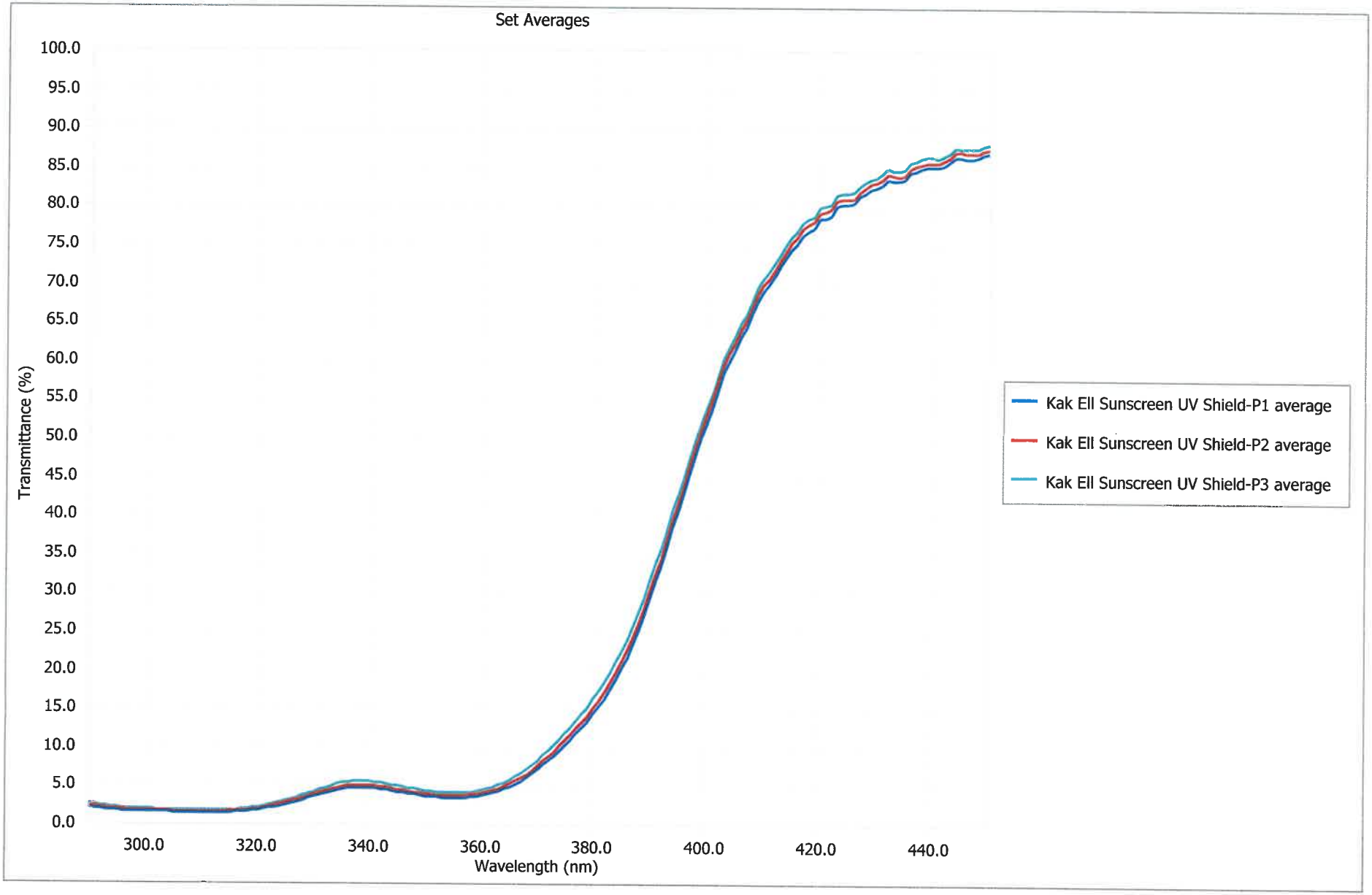
Scan	SPF	Critical Wavelength
Scan 1	50.56	376
Scan 2	38.68	376
Scan 3	54.01	377
Scan 4	49.79	376
Scan 5	51.86	376
Scan 6	59.84	375
Scan 7	56.99	376
Scan 8	50.48	376
Scan 9	41.63	376

Kak Ell Sunscreen UV Shield-P3

	SPF	T(UVA)	T(UVB)	Lambda Critical
Number of Scans:	9	9	9	9
Mean:	46.31	12.87%	1.98%	375.78
STD:	3.78	0.61%	0.17%	0.44
COV:	8.15%	4.77%	8.60%	0.12%

UVA/UVB Ratio: 0.642

Scan	SPF	Critical Wavelength
Scan 1	52.51	376
Scan 2	43.55	376
Scan 3	49.34	376
Scan 4	43.56	376
Scan 5	42.60	376
Scan 6	50.13	375
Scan 7	47.94	375
Scan 8	45.18	376
Scan 9	41.97	376


Set Averages
100.0
95.0
90.0
85.0
80.0
75.0
70.0
65.0
60.0
55.0
50.0
45.0
40.0
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0.0
Transmittance (%)
300.0
320.0
340.0
360.0
380.0
400.0
420.0
440.0
Wavelength (nm)
Kak Ell Sunscreen UV Shield-P1 average
Kak Ell Sunscreen UV Shield-P2 average
Kak Ell Sunscreen UV Shield-P3 average

Labsphere Ultraviolet Transmittance Analyzer
UV-2000 Validation Report

Operator:	Rosmah
Date:	Wednesday, 15 June, 2022
Time:	1:47:15 PM
Comment:	Instrument validation Jun 2022
Unit serial number:	0521120855
Validation kit serial number:	0517120754
Description:	

Test	Specification	Measured	Criteria	Result
Wavelength Peak 1	289.4	290.0	+/- 1nm	passed
Wavelength Peak 2	335.9	336.0	+/- 1nm	passed
Wavelength Peak 3	349.1	349.0	+/- 1nm	passed
Wavelength Peak 4	362.1	363.0	+/- 1nm	passed
Wavelength Peak 5	387.2	388.0	+/- 1nm	passed
Wavelength Peak 6	415.9	416.0	+/- 1nm	passed
0.3% Transmittance	0.33%	0.28%	+/- 0.1% of nominal	passed
3% Transmittance	5.3%	5.1%	+/- 0.5% of nominal	passed
10% Transmittance	11.2%	10.7%	+/- 1.0% of nominal	passed
20% Transmittance	23.7%	23.8%	+/- 1.5% of nominal	passed
SPF	60.00	91.89	> 60 SPF	passed
Baseline Average	100.00%	99.98%	+/- 1.00%	passed
Baseline RMS Deviation	100.00%	0.17%	< 1.50%	passed

MALAYSIAN PALM OIL BOARD
ADVANCED OLEOCHEMICAL TECHNOLOGY DIVISION
OLEO PRODUCT DEVELOPMENT UNIT
EFFICACY TEST LABORATORY

IN VITRO SUN PROTECTION FACTOR (SPF)

STUDY: **CPD/EFF/EXT/NAC/12-22**

APPLICANT: **Armila Berhad,**
24, Jln Linggis 15/24,
Seksyen 15,
40200 Shah Alam,
Selangor Darul Ehsan.
(Attn: Mrs. Sharmila Johan)

PRODUCT: **Kak Ell Sunscreen UV Shield**

STARTING DATE OF THE STUDY: 13/07/2022

COMPLETION DATE: 13/07/2022

"The data given in this report are exclusively referred to the samples tested. This report can only be reproduced in full. The data are not for product registration or claim purpose."

15/7/2022

DR. YUSRABBIL AMIYATI YUSOF
GROUP LEADER
SAFETY AND EFFICACY ASSESSMENT GROUP
OLEO PRODUCT DEVELOPMENT UNIT, AOTD
MALAYSIAN PALM OIL BOARD

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1. GENERAL INFORMATION

Study Title	*In Vitro* SPF
Test Facility Manager	Dr. Yusrabbil Amiyati Yusof Head of Safety & Efficacy Assessment Group, Oleo Product Development (OPD) Unit, Advanced Oleochemical Technology Division (AOTD), Malaysian Palm Oil Board (MPOB)
Study Director	Mrs. Nor Zuliana Yusof Senior Research Officer SEA Group, OPD Unit, AOTD.
Test Facility Name Address Tel Fax	Efficacy Test Laboratory, Advanced Oleochemical Technology Division, Malaysian Palm Oil Board, 6, Persiaran Institusi, Bandar Baru Bangi, 43000 Kajang, Selangor. 03-8769 4308 03-8925 6197
Time Study Duration	13/07/2022 1 day
Sponsor Company Name Company Address Tel	Mrs. Sharmila Johan Armila Berhad, 24, Jln Linggis 15/24, Seksyen 15, 40200 Shah Alam, Selangor Darul Ehsan. -

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1.1 Sample Data Sheet

SAMPLE REFERENCE: Kak Ell Sunscreen UV Shield

REFERENCE CODE: -

SAMPLE NUMBER: 1

PRODUCT:

COLOUR: White

QUANTITY: 50 g

OTHER INFORMATION RELATED TO THE PRODUCT: NA

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2.0 PRINCIPLE OF METHOD

2.1 Introduction

Many regulatory bodies such as the US FDA and The European Cosmetic, Toiletry and Perfumery Association (COLIPA), mandate *in vivo* testing on human subjects using the erythemal endpoint to determine the Sun Protection Factor (SPF) of a topical sunscreen. However, the *in vivo* tests are costly and time-consuming and may not be practical for routine product evaluation. The Labsphere UV-2000S Ultraviolet Transmittance Analyzer is designed for predicting the SPF of cosmetic sun care products via *in vitro* technique and thus making routine product evaluation possible. The instrument operates by measuring the diffuse transmittance of a carefully prepared sample as a function of wavelength in the ultraviolet spectrum. Many sunscreens are translucent materials that diffuse incidence light. A ray of light incident onto a sunscreen sample will often be scattered. The light that is not transmitted is reflected or absorbed.

SPF by definition is determined *in vivo* as the increase in time required to induce erythema. However, the work by Diffey and Robson in 1989 on *in vitro* technique involves measuring the spectral transmittance at UV wavelengths from 280nm to 400nm and can be used to determine the SPF. Physical measurements have shown that the solar erythemal response is inversely proportional to the radiation wavelength. The shorter wavelength (UV-B) region at 280 – 315 nm can induce an erythemal reaction. No erythemal reaction is observed for the UV-A region at 315 – 400 nm.

The *in vitro* SPF is calculated as follows:

$$SPF = \frac{\int_{280nm}^{400nm} E_\lambda \cdot S_\lambda \cdot d\lambda}{\int_{280nm}^{400nm} E_\lambda \cdot S_\lambda \cdot T_\lambda \cdot d\lambda}$$

where,

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E_λ = CIE Erythemal Spectral Effectiveness

S_λ = Solar Spectral Irradiance

T_λ = Spectral Transmittance of the sample
(as measured on the UV-2000S)

The equation shows that the higher the amount of transmittance, the lower the SPF value. The transmittance spectrum of a sunscreen in either region is averaged in order to produce one value, which describes the amount of UV-A or UV-B blocking. The average transmittance in each region is given by:

$$T\,(UVA)_{av} = \frac{\sum_{315nm}^{400nm} T_\lambda \times \Delta\lambda}{\sum_{315nm}^{400nm} \Delta\lambda}$$

and,

$$T\,(UVB)_{av} = \frac{\sum_{280nm}^{315nm} T_\lambda \times \Delta\lambda}{\sum_{280nm}^{315nm} \Delta\lambda}$$

where, $\Delta\lambda$ = measured wavelength interval

Consequently, the percent blocking for UVA and UVB, respectively, is calculated as follows:

= 100% - $T(UVA)_{av}$

= 100% - $T(UVB)_{av}$

where, $T(UVA)_{av}$ or $T(UVB)_{av}$ is expressed as a percentage.

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The recommended SPF classifications are shown in the table below:

Classification	SPF level
Low	≥ 6 - < 15
Medium	≥ 15 - < 30
High	≥ 30 - < 50
Very High	≥ 50

Note: if the SPF level is more than 50, it may be labelled as SPF 50+

Ref: Guidelines for Control of Cosmetic Products in Malaysia (2017). https://www.npra.gov.my/index.php/en/cosmetics-guideline-annex-i-vii

2.2 UVA Effectiveness – The Boot Star System

In addition to its ability to determine the SPF of a sunscreen, the *in vitro* technique can also measure the UVA protection of the sunscreen. Boots the Chemist, the largest producer of sunscreens in the UK, has developed a label system that uses star rating based on spectrophotometric analysis. The labelling is already used within the UK.

The spectral transmittance values, T_λ, are converted to spectral absorbance values $A_\lambda = -\log(T_\lambda)$. A term called the *UVA ratio* is calculated, which is the ratio of the total absorption in the UVA to that in the UVB:

$$\frac{\text{aUVA}}{\text{aUVB}} = \frac{\int_{320nm}^{400nm} A_\lambda \cdot d\lambda}{\int_{290nm}^{320nm} A_\lambda \cdot d\lambda}$$

The star rating for UVA protection is determined from the measured UVA ratio as shown in the table below:

Mean UVA:UVB Ratio	Star Rating Category	Category Description
0.0 to 0.2	-	*Too Low/No Claim*
0.21 to 0.4	*	*MINIMUM*
0.41 to 0.6	**	*MODERATE*
0.61 to 0.8	***	*GOOD*
0.81 to 0.9	****	*SUPERIOR*
0.91 and above	*****	*ULTRA*

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2.3 Sample preparation

Sample preparation for *in vitro* SPF system is similar to the application technique used for *in vivo* testing. The recommended amount of sample to be applied based on COLIPA 2007 is 1.30 mg/cm^2. The area of application is 25cm^2 and 32.5 mg sample is applied on the PMMA plate.

The substrate for *in vitro* SPF needs to be transparent to the ultraviolet and simulate the porosity and texture of human skin as in *in-vivo* tests. Four readily available materials; 3M Transpore™ Tape, Vitro Skin™ , Polyvinyl Chloride Film and Poly Methyl Methacrylate (PMMA) can be used as substrates. Transpore Tape is used as the substrate as it is readily available and inexpensive. The other two substrates (Vitro Skin™ and Polyvinyl Chloride Film) are expensive and do not mimic human skin topography. However, PMMA is preferred as the measurement reproducibility is very good and comparable to that obtained during *in vivo* testing.

2.4 Poly Methyl Methacrylate (PMMA)

The product is applied to the PMMA plate by weight. The application rate is determined in such a way that the actual quantity of product left on the substrate is 1.30 mg/cm^2.

The amount of sample is applied by using a micropipette and distributed evenly over the whole roughened PMMA surface of the plate (50 x 50 mm).

Immediately after weighing, the sample is spread over the whole surface with a finger-cot (pre-saturated) with the product using light strokes. Spreading had to be completed as quickly as possible (less than 30 seconds). Then the sample was rubbed into the rough surface using stronger pressure. This also had to take 20 to 30 seconds. The sample thus obtained was allowed to settle for 15 minutes in the dark at room temperature to ensure self-levelling of the formula.

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3.0 RESULTS

The *in-vitro* SPF test on the sample was carried out using Labsphere Ultraviolet Transmittance Analyzer UV-2000S with triplicate plates and 9 scans per each plate. The sample with a total weight of 32.5 ± 0.5 mg was applied on 50 x 50 mm PMMA plate. The results are shown in the following table:

Sample Name	**Kak Ell Sunscreen UV Shield**			
Parameter	**SPF**	**% Transmittance UVA, T(UVA)**	**% Transmittance UVB, T(UVB)**	**Critical wavelength**
Mean	**50.79**	**12.26%**	**1.82%**	**375.93**
STD	4.68	0.60%	0.17%	0.13
COV	9.22%	4.88%	9.21%	0.03%
Number of Sets	3	3	3	3
UVA/UVB Ratio	**0.646**			

4.0 CONCLUSION

Sample Kak Ell Sunscreen UV Shield has a mean SPF of 50.79 with good protection against UVA.

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REPORTED BY

14/07/2022

NOR ZULIANA YUSOF
SENIOR RESEARCH OFFICER
SAFETY AND EFFICACY ASSESSMENT GROUP
OPD, AOTD, MPOB

MPOB - Advanced Oleochemical Technology Division (AOTD) No. 6, Persiaran Institusi, Bandar Baru Bangi, 43000, Kajang, Selangor, Malaysia Tel: 603-8769 4308/4293
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Labsphere Transmittance Analyzer
SPF Report

Sample:	Kak Ell Sunscreen UV Shield
Description:	
Operator:	Rosmah
Client:	Armila Berhad
Comment:	
Date:	13/7/2022 11:08:42 AM
Unit serial number:	0521120855

Solar Irradiance Profile: COLIPA, 2009

UVA/UVB ratio calculation used: Boots Star Method

Study Statistics

	SPF	T(UVA)	T(UVB)	Lambda Critical
Number of Sets:	3	3	3	3
Mean:	50.79	12.26%	1.82%	375.93
STD:	4.68	0.60%	0.17%	0.13
COV:	9.22%	4.88%	9.21%	0.03%

UVA/UVB Ratio: 0.646

Kak Ell Sunscreen UV Shield-P1

	SPF	T(UVA)	T(UVB)	Lambda Critical
Number of Scans:	9	9	9	9
Mean:	55.65	11.68%	1.64%	376.00
STD:	6.52	0.53%	0.20%	0.00
COV:	11.71%	4.56%	12.22%	0.00%

UVA/UVB Ratio: 0.648

Scan	SPF	Critical Wavelength
Scan 1	52.24	376
Scan 2	53.69	376
Scan 3	53.29	376
Scan 4	45.83	376
Scan 5	52.43	376
Scan 6	62.65	376
Scan 7	68.36	376
Scan 8	55.50	376
Scan 9	56.83	376

Kak Ell Sunscreen UV Shield-P2

	SPF	T(UVA)	T(UVB)	Lambda Critical
Number of Scans:	9	9	9	9
Mean:	50.43	12.23%	1.83%	376.00
STD:	6.73	0.57%	0.29%	0.50
COV:	13.35%	4.65%	16.08%	0.13%

UVA/UVB Ratio: 0.647

Scan	SPF	Critical Wavelength
Scan 1	50.56	376
Scan 2	38.68	376
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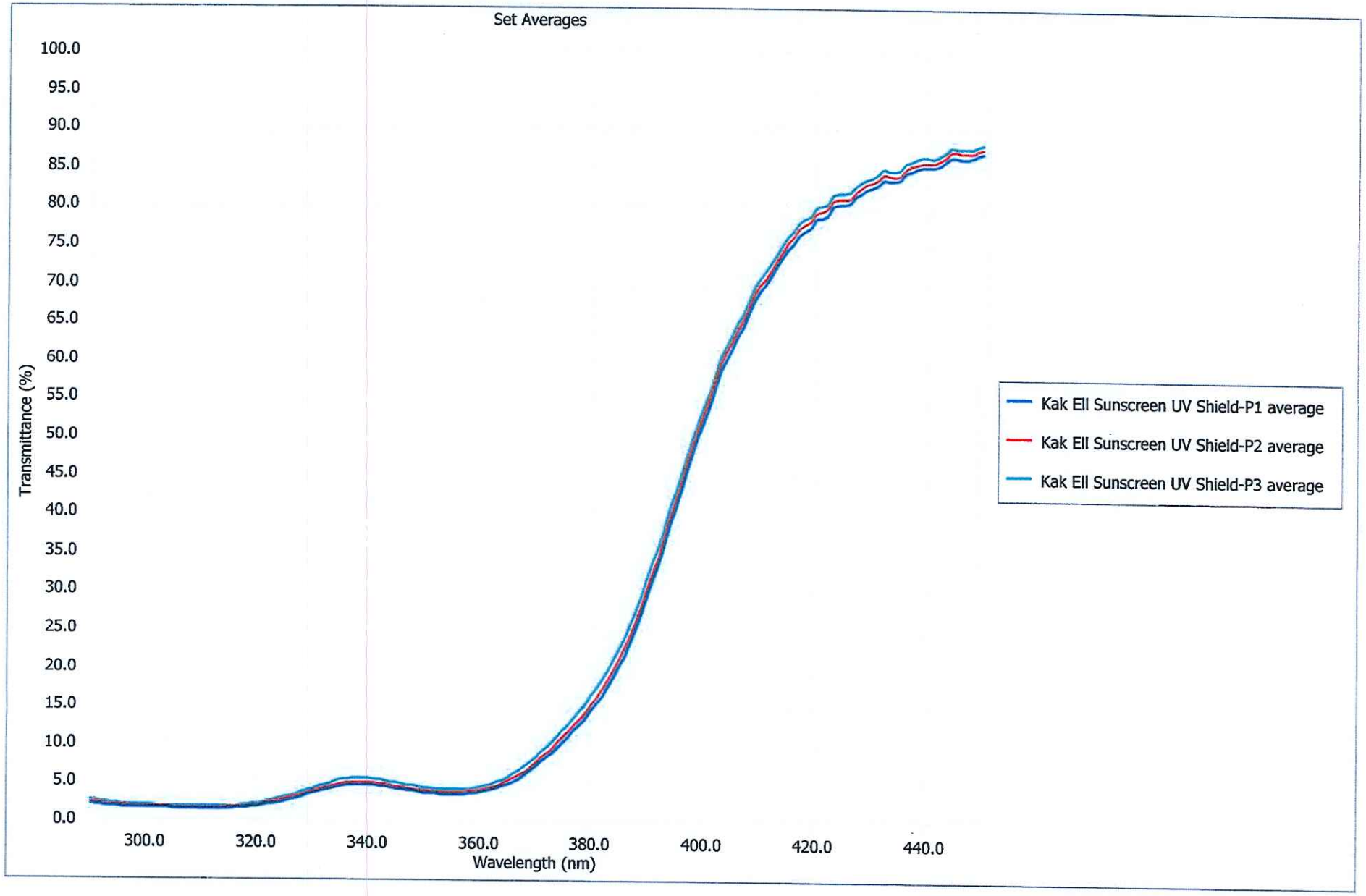
Scan 4	49.79	376
Scan 5	51.86	376
Scan 6	59.84	375
Scan 7	56.99	376
Scan 8	50.48	376
Scan 9	41.63	376

Kak Ell Sunscreen UV Shield-P3

	SPF	T(UVA)	T(UVB)	Lambda Critical
Number of Scans:	9	9	9	9
Mean:	46.31	12.87%	1.98%	375.78
STD:	3.78	0.61%	0.17%	0.44
COV:	8.15%	4.77%	8.60%	0.12%

UVA/UVB Ratio: 0.642

Scan	SPF	Critical Wavelength
Scan 1	52.51	376
Scan 2	43.55	376
Scan 3	49.34	376
Scan 4	43.56	376
Scan 5	42.60	376
Scan 6	50.13	375
Scan 7	47.94	375
Scan 8	45.18	376
Scan 9	41.97	376


Set Averages
100.0
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35.0
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20.0
15.0
10.0
5.0
0.0
Transmittance (%)
300.0
320.0
340.0
360.0
380.0
400.0
420.0
440.0
Wavelength (nm)
Kak Ell Sunscreen UV Shield-P1 average
Kak Ell Sunscreen UV Shield-P2 average
Kak Ell Sunscreen UV Shield-P3 average

Labsphere Ultraviolet Transmittance Analyzer
UV-2000 Validation Report

Operator:	Rosmah
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10% Transmittance	11.2%	10.7%	+/- 1.0% of nominal	passed
20% Transmittance	23.7%	23.8%	+/- 1.5% of nominal	passed
SPF	60.00	91.89	> 60 SPF	passed
Baseline Average	100.00%	99.98%	+/- 1.00%	passed
Baseline RMS Deviation	100.00%	0.17%	< 1.50%	passed