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RESEARCH

DEVELOPMENT

TESTING

ANALYSIS

Sun Protection in Europe and China
Mentionable Remarks

Mathias Rohr

Su Ning, Cheng Yanzhang, Andreas Schrader

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SPF-Test Method

- Aim of SPF-Testing:
  Quantifying *in vivo* a value, which defines a protection level against an UV-induced Erythemal Reaction.

- By this the defined SPF (Sun Protection Factor) is the ratio of those Energies / UV-Doses,
  which are needed minimally to provoke an Erythemal Reaction (MED) with and without Product application.

$$SPF = \frac{\text{MED (protected skin)}}{\text{MED (unprotected skin)}}$$

SPF-Test Method

$$SPF = \frac{\text{MED (protected skin)}}{\text{MED (unprotected skin)}}$$

MED :

- minimal UV-Dose, that produces the first perceptible unambiguous erythema
- with defined borders appearing over most of the field of UV exposure
- 16-24 h after UV exposure

- The final SPF is the arithmetic mean of 10 subject in minimum linked to an 95%-CI of less than 17% of the mean

SPF-Testing / What is needed?

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SPF-Test-Method

Lab – Conditions

Product - Application

Irradiation
- Spectrum
- Energy
- Homogeneity

Reading - MED

Standards / Label – SPF

Subjects

Lab-Conditions

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Lab - Conditions

- Lab-Conditions

  - Stable / Constant Conditions

  - Temperature: 18 °C – 26 °C

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Lab - Conditions

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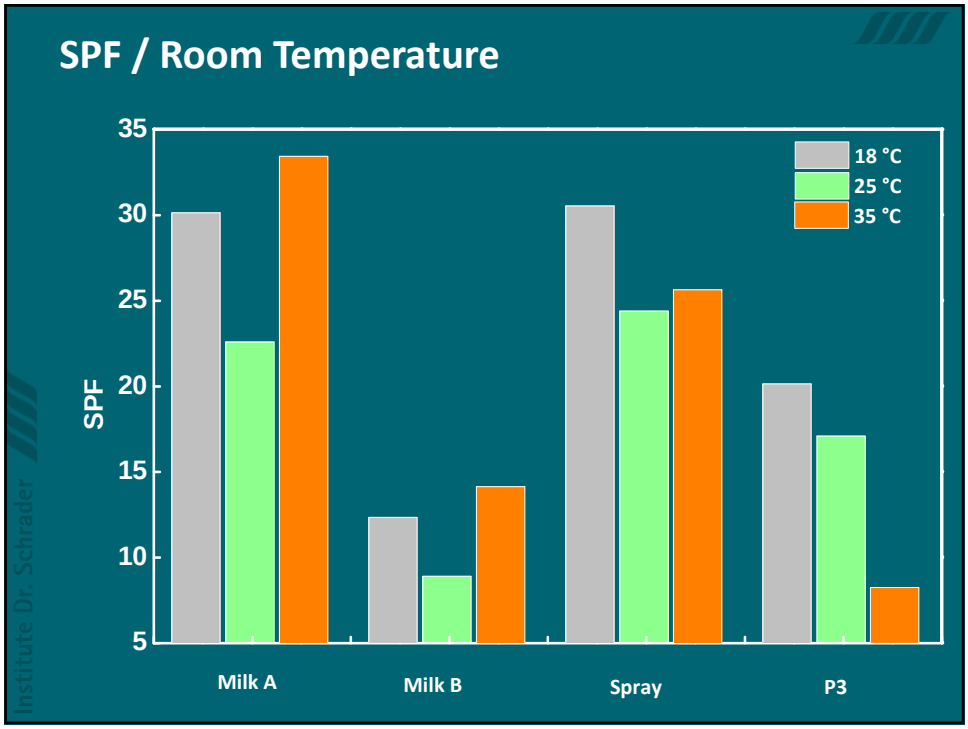
SPF / Room Temperature
SPF
35
30
25
20
15
10
5
18 °C
25 °C
35 °C
Milk A
Milk B
Spray
P3
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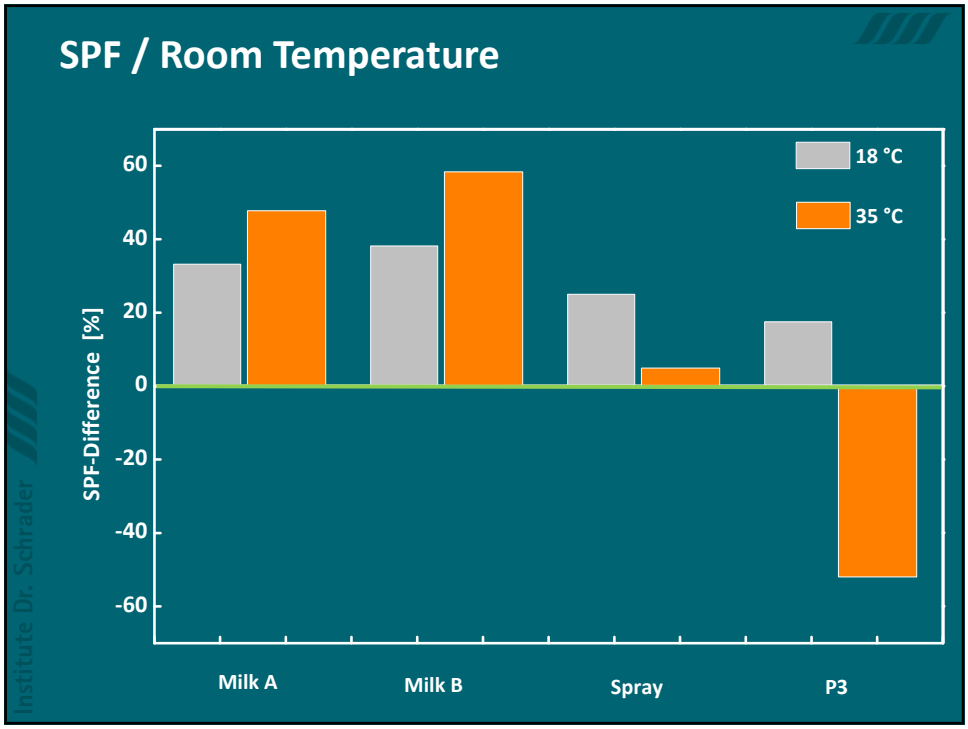
SPF / Room Temperature
SPF-Difference [%]
60
40
20
0
-20
-40
-60
18 °C
35 °C
Milk A
Milk B
Spray
P3
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SPF

Lab – Conditions

Product - Application

Irradiation
- Spectrum
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Standards / Label – SPF

Subjects

Product-Application

Product - Application

- **Product Amount :** 2.00 mg/cm² +/- 2.5% (0.05 mg/cm²)
- **Product Distribution :** 20 – 50s
- **Balance :** min. 0.1 mg
- **Waiting Time :** 15 – 30 min
- **Test Area:** Back
  min. 30 cm²
  min. 1 cm distance

Product - Application

- **Product Application:**
  - approx. 1 Drop / 2 cm^2
  - Syringe / Pipette
  - Fingerstall
  - homogenous distribution with slight preasure

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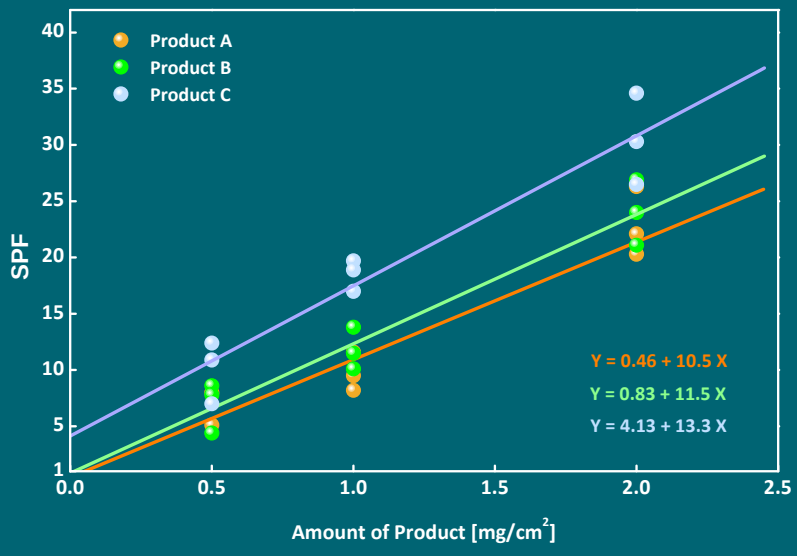
Product-Application / SPF and Amount of Product

Publication DGK-Working Group 2007



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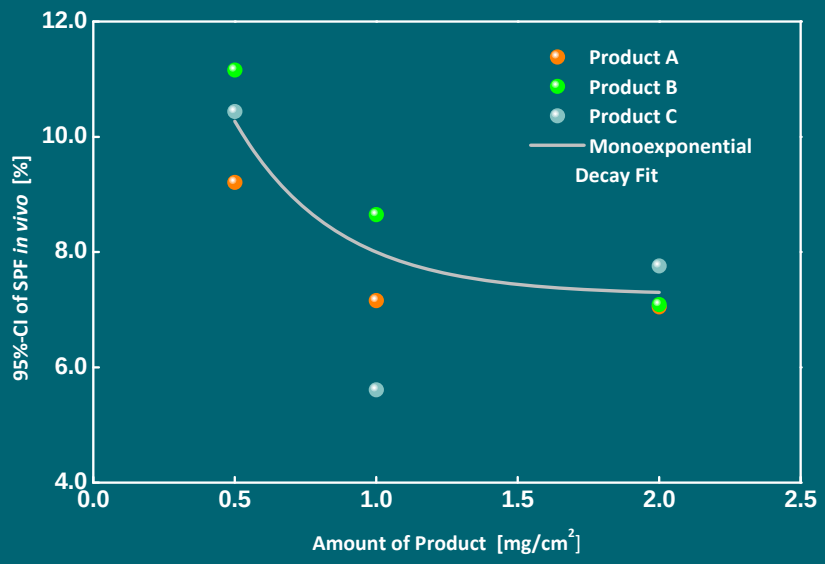
Product-Application / SPF and Amount of Product



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SPF

Lab – Conditions

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Irradiation
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Reading - MED

Standards / Label – SPF

Subjects

Irradiation

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Irradiation

- Sun Simulator : Xenon-Solar-Simulator
  Homogenous energy distribution
  Stabile energy over time
- Erythemal Balance: Ratio UVA I / UVA II

UVB	290 nm – 320 nm	→	100%
UVA	320 nm – 400 nm		
UVA II	320 nm – 340 nm	→	> 20%
UVA I	340 nm – 400 nm	→	> 60%

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Spectral Limits

- No pain during irradiation
- Maximal Spectral Energy of 120 mW/cm^2
- RCEE : Relative – Cumulative – Erythemal – Effectiveness
- Adjustment of %-RCEE to Standard Sun

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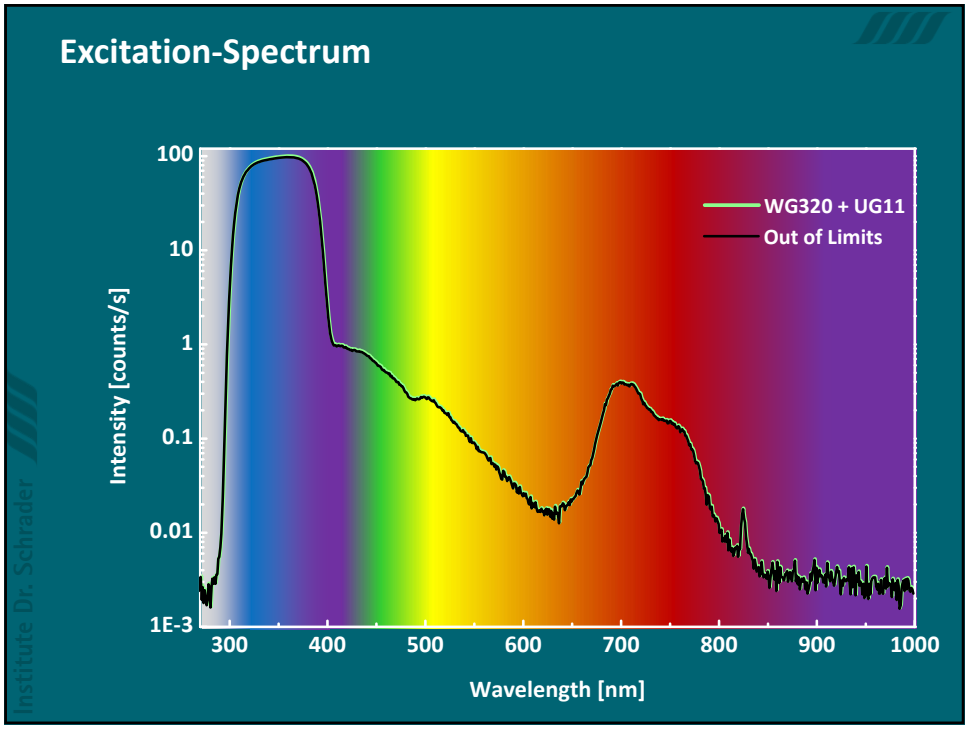
Excitation-Spectrum
Intensity [counts/s]
100
10
1
0.1
0.01
1E-3
300
400
500
600
700
800
900
1000
Wavelength [nm]
WG320 + UG11
Out of Limits
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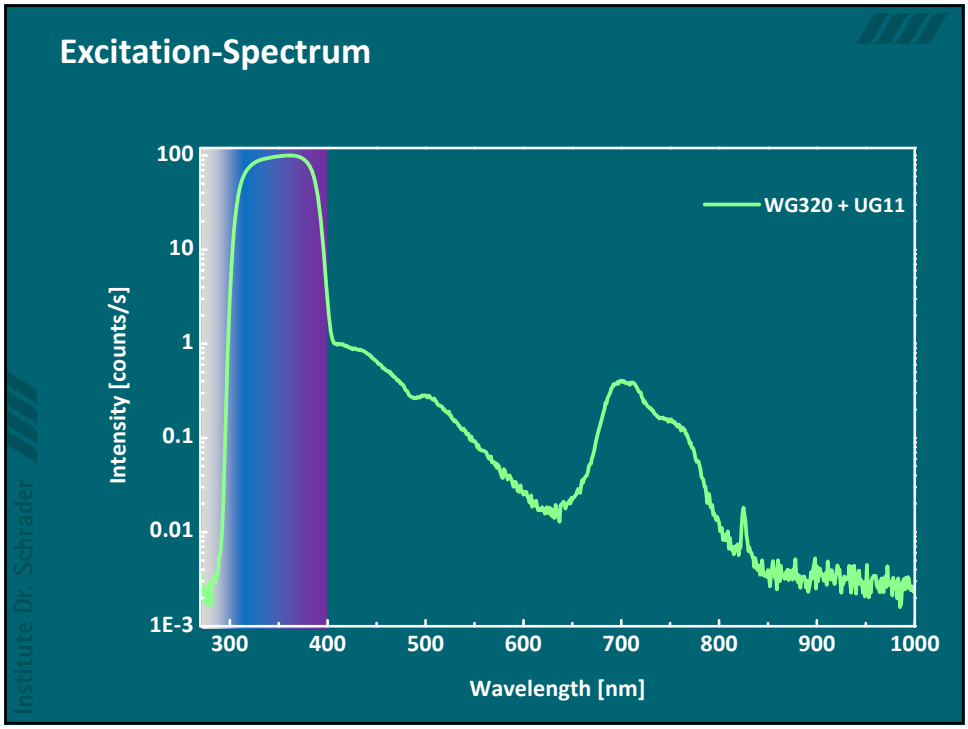
Excitation-Spectrum
Intensity [counts/s]
100
10
1
0.1
0.01
1E-3
300
400
500
600
700
800
900
1000
Wavelength [nm]
WG320 + UG11
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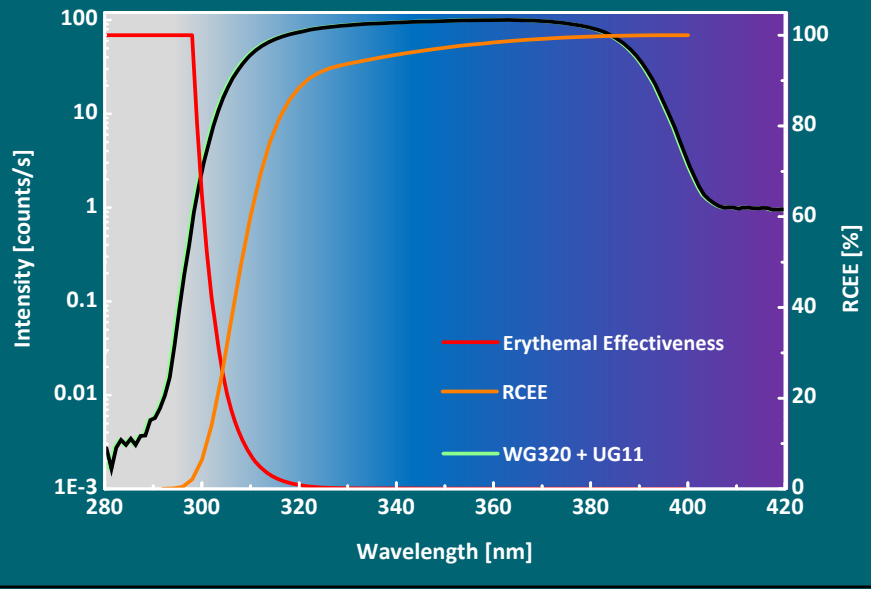
Excitation-Spectrum



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RCEE-Values

Spectrum	COLIPA 94	
	% RCEE Lower Limit	% RCEE Upper Limit
< 290		< 1.0
290 - 300		
290 - 310	46.0	67.0
290 - 320	80.0	91.0
290 - 330	86.5	95.0
290 - 340	90.5	97.0
290 - 350	93.5	99.0
290 – 400	100.0	100.0

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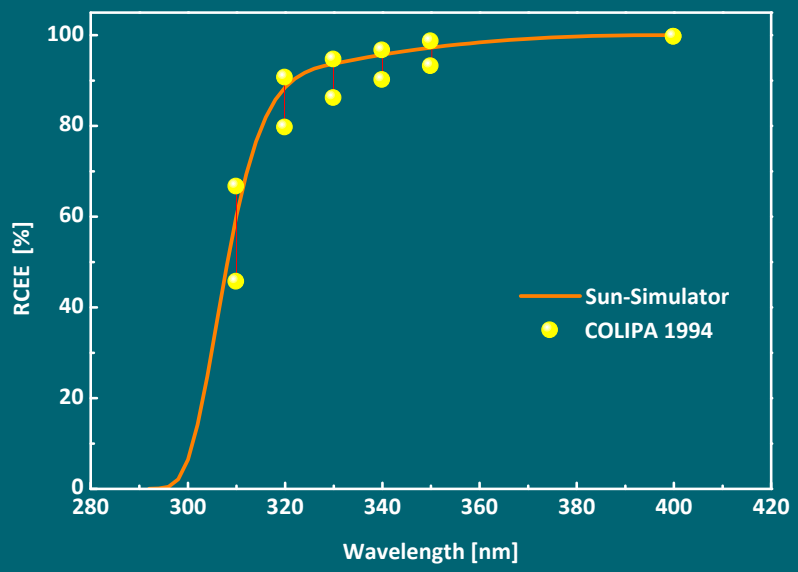
RCEE-Values



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Spectral Limits / Definition of RCEE-Values

Spectrum	COLIPA 94		IM 2006 / ISO 2011	
	% RCEE Lower Limit	% RCEE Upper Limit	% RCEE Lower Limit	% RCEE Upper Limit
< 290		< 1.0		< 0.1
290 - 300			2.0	8.0
290 - 310	46.0	67.0	49.0	65.0
290 - 320	80.0	91.0	85.0	90.0
290 - 330	86.5	95.0		
290 - 340	90.5	97.0		
290 - 350	93.5	99.0		
290 - 400	100.0	100.0	100.0	100.0

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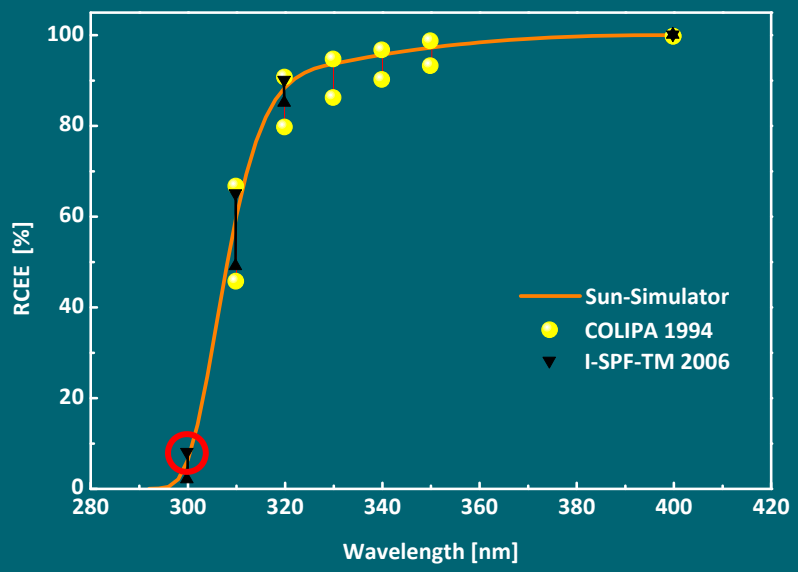
RCEE-Values



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External Certification

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SPF

Lab – Conditions

Product - Application

Irradiation
- Spectrum
- Energy
- Homogeneity

Reading - MED

Standards / Label – SPF

Subjects

Reading - MED

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MED Reading

- Minimal UV-Dose, that produces the first perceptible unambiguous erythema
- with defined borders appearing over most of the field of UV exposure
- 16-24 h after UV exposure
- MED-Reading has to be carried out 16-24h after irradiation
- MEDu and MEDp Reading has to be carried out on the same day
- Product application and MED reading has to be carried out from 2 different technicians

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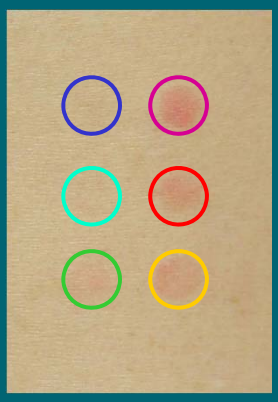
UVB Erythema



156%

125%

MEDu = 100%

80%

64%

51%

UVB-Erythema MED

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SPF / Increasing Dose

- Increments 12% or 25% geometric progression
- For SPF > 25 - 12% have to be used!
- ISO 24444 - 15% are accepted as well

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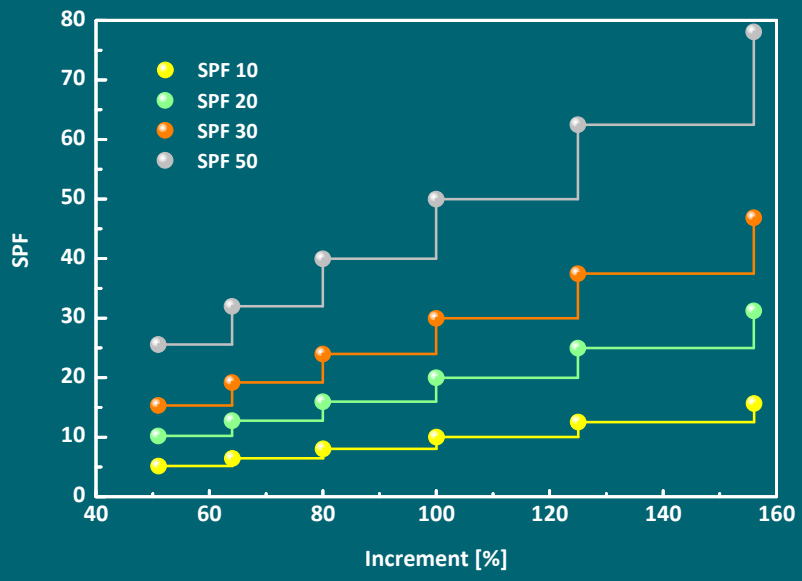
Increasing Dose / 12% or 25%



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Increasing Dose / 25% oder 12%

25 %	I-SPF-TM 2006				I-SPF-TM 2006				12 %
	SPF 10	SPF 20	SPF 30	SPF 50	SPF 10	SPF 20	SPF 30	SPF 50	
156%	16	31	47	78	13	25	38	63	125%
125%	12	25	38	63	11	22	34	56	112%
100%	10	20	30	50	10	20	30	50	100%
80%	8	16	24	40	9	18	27	45	90%
64%	6	13	19	32	8	16	24	40	80%
51%	5	10	15	26	7	14	21	36	71%

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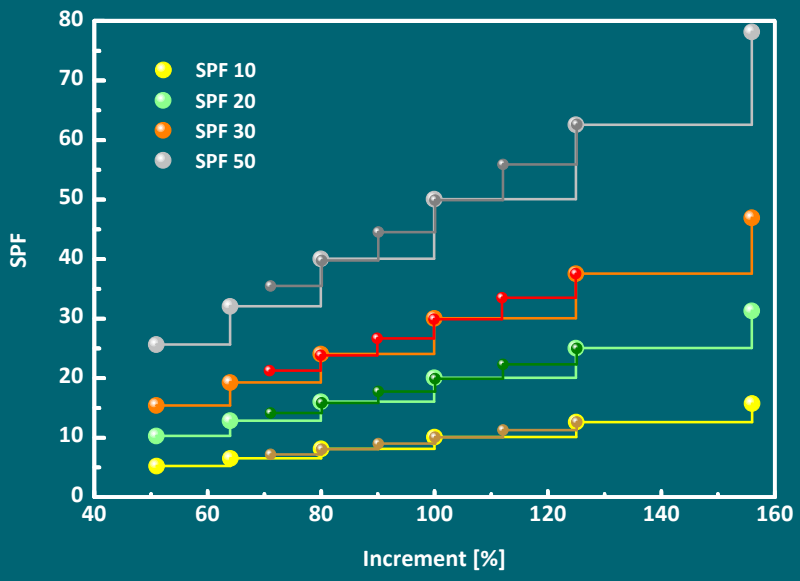
Increasing Dose / 12% oder 25%



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Increasing Dose / IM-2006

- Inkrements 12% or 25% geometric progression
- For SPF > 25 - 12% have to be used!
- SPF-Testing only can produce defenite SPF-Values
- SPF und Absorption are not linked linear!

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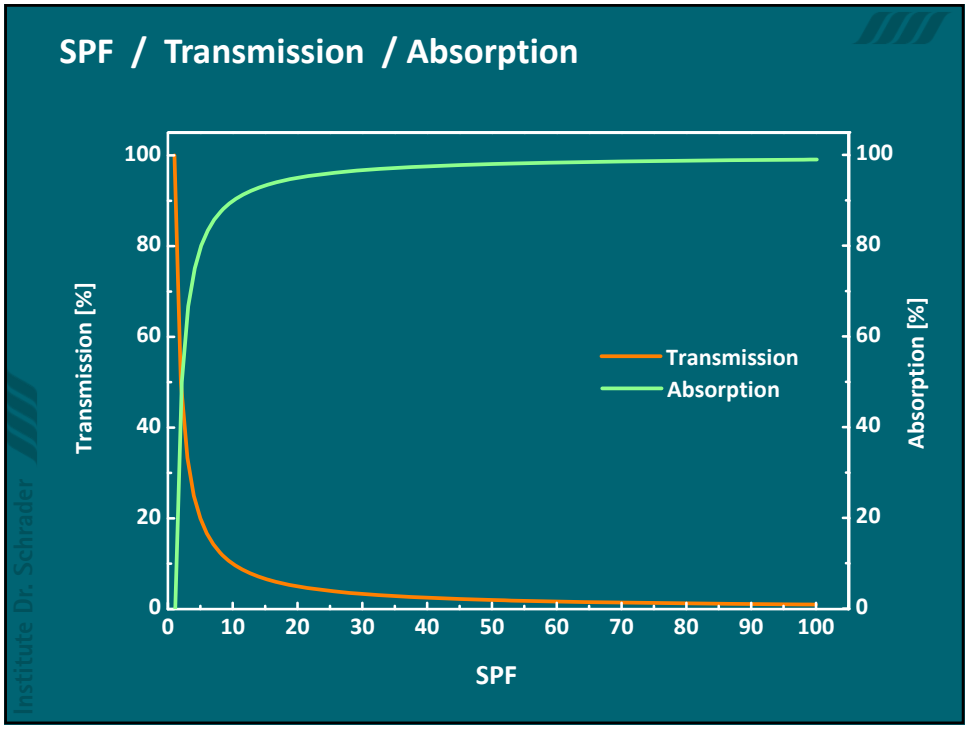
SPF / Transmission / Absorption
Transmission [%]
Absorption [%]
SPF
Transmission
Absorption
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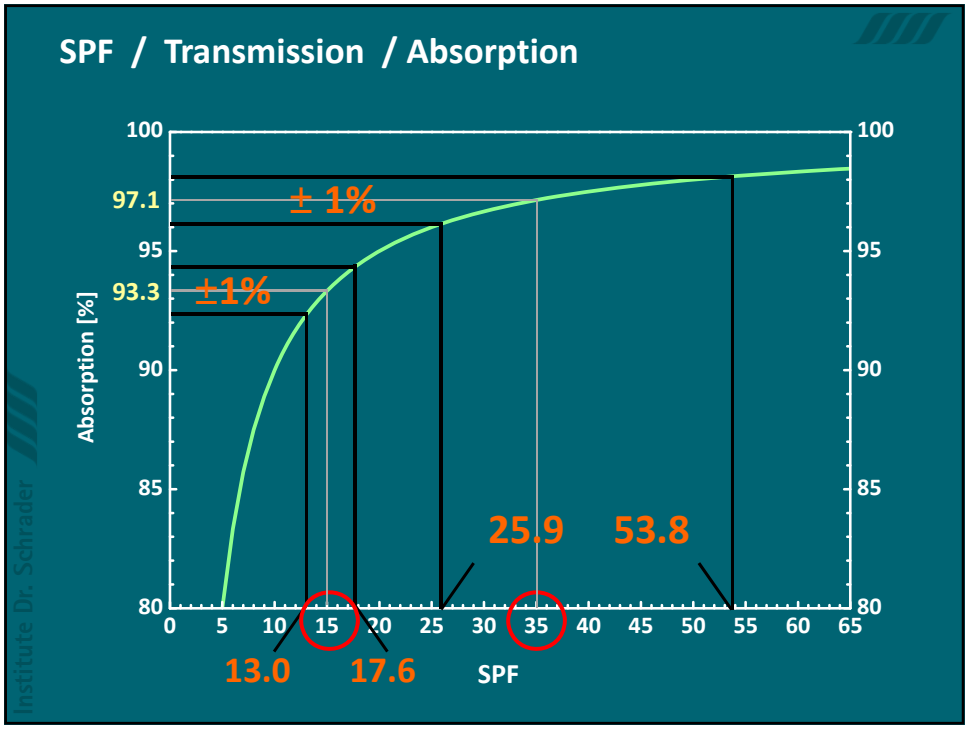
SPF / Transmission / Absorption
Absorption [%]
SPF
± 1%
±1%
97.1
93.3
25.9
53.8
13.0
17.6
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SPF

Lab – Conditions

Product - Application

Irradiation
- Spectrum
- Energy
- Homogeneity

Reading - MED

Standards / Label – SPF

Subjects

Standards / Label-SPF

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Standard Products

	3 Standard Products			
	IM-2006		ISO 24444	
P2	16.6	(14.2 - 19.0)	16.1	(13.7 - 18.5)
P3	16.2	(13.8 - 18.7)	15.7	(13.7 - 17.7)
P7	5.1	(4.4 – 5.9)	4.4	(4.01 – 4.8)

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Label-SPF

- A Label-SPF is not defined by the IM-2006 or the ISO 24444!
- EU - Commission Recommendation
  (22. September 2006)

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Label-SPF

• LOW	6	(6.0 – 9.9)
	10	(10.0 – 14.9)
• MEDIUM	15	(15.0 – 19.9)
	20	(20.0 – 24.9)
	25	(25.0 – 29.9)
• High	30	(30.0 – 49.9)
	50	(50.0 – 59.9)
• Very High	50+	(>= 60.0)

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SPF

Lab – Conditions

Product - Application

Irradiation
- Spectrum
- Energy
- Homogeneity

Reading - MED

Standards / Label – SPF

Subjects

Subjects

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SPF / Phototype

- Phototype I, II, III (Fitzpatrick)
  Typ I : always burns easily, never tans
  Typ II : always burns easily, tans minimally
  Typ III : burns moderately, tans gradually
- ITA° > 28

ITA° > 55°	very light
ITA° von > 41° bis 55°	light
ITA° von > 28° bis 41°	intermediate

$ITA° = [\arctan((L^*-50)/b^*)] 180 / 3.1416$

(ITA° : Individual Typology Angle)

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Subjects

- No ab-normal reaction to sun
- No sun bath within the last 4 weeks
- Homogenous skin colour in the test area (Back between Skapula und waist)
- In minimum 2 months break since last test and no visible tanning
- Exclusion Criteria
  - Subjects below the age of consent
  - Pregnant or lactating women
  - Photosensitising medication
  - Anti-inflammatory medication
  - Dermatological problems
  - Accustomed to using tanning beds

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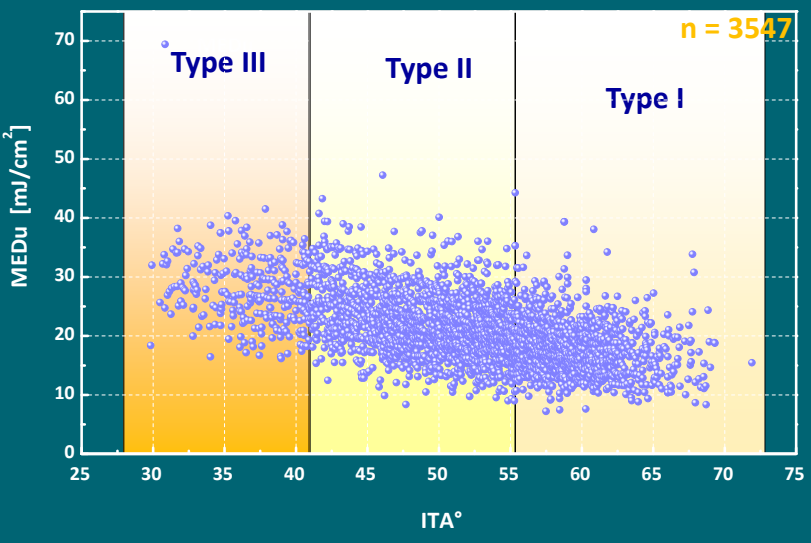
Correlation ITA° and MEDu / Europe

ITA° = [arc tg ((L*-50)/b*)]180/π



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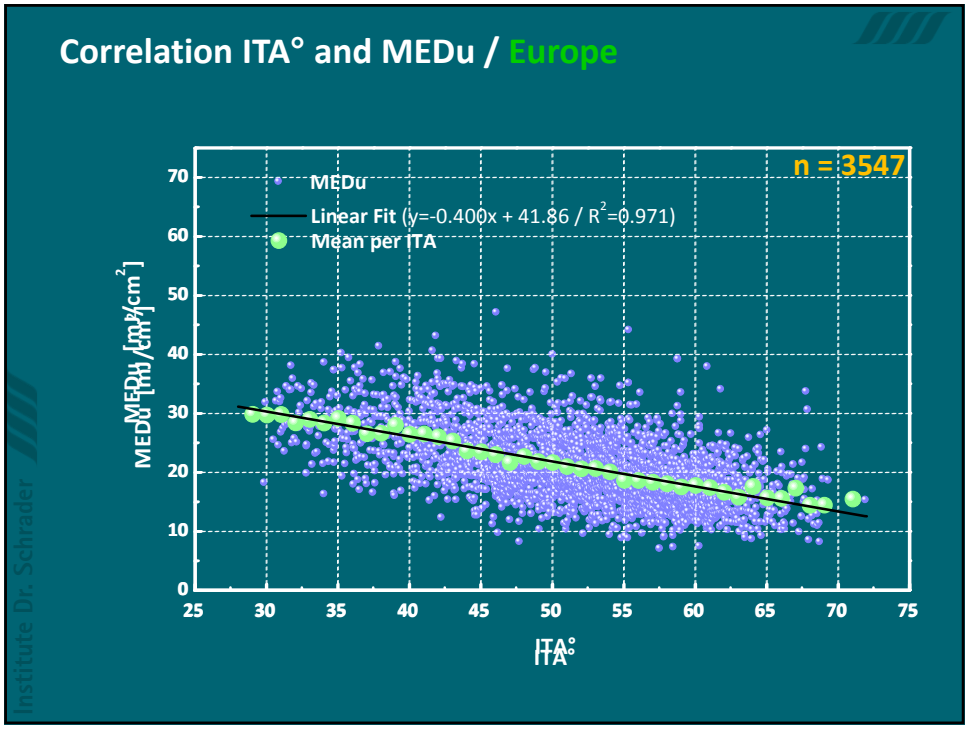
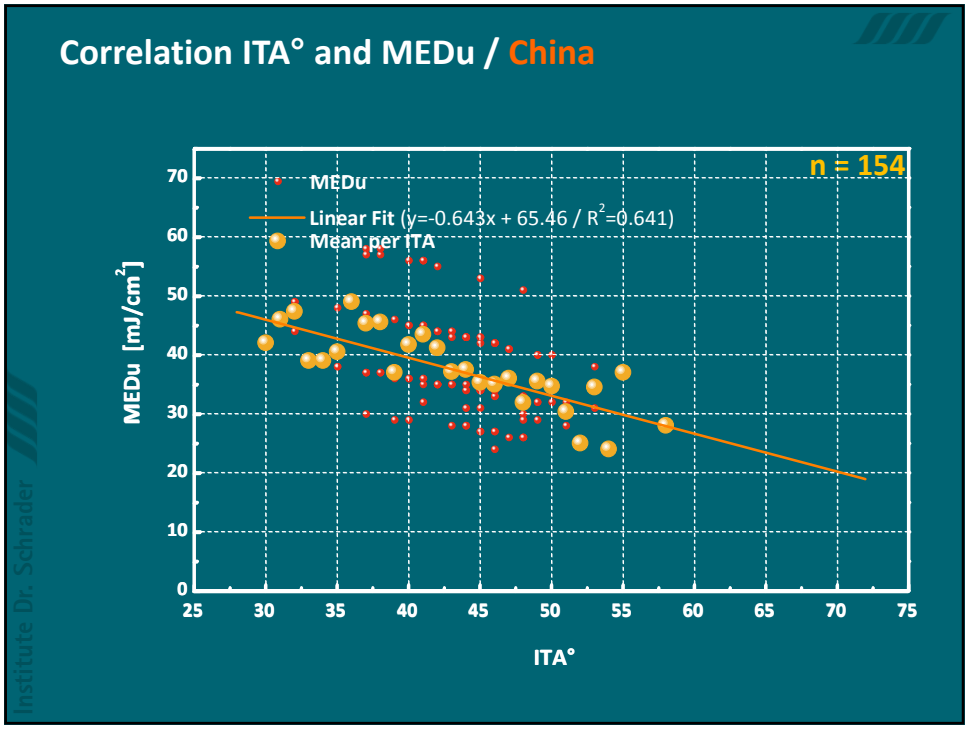
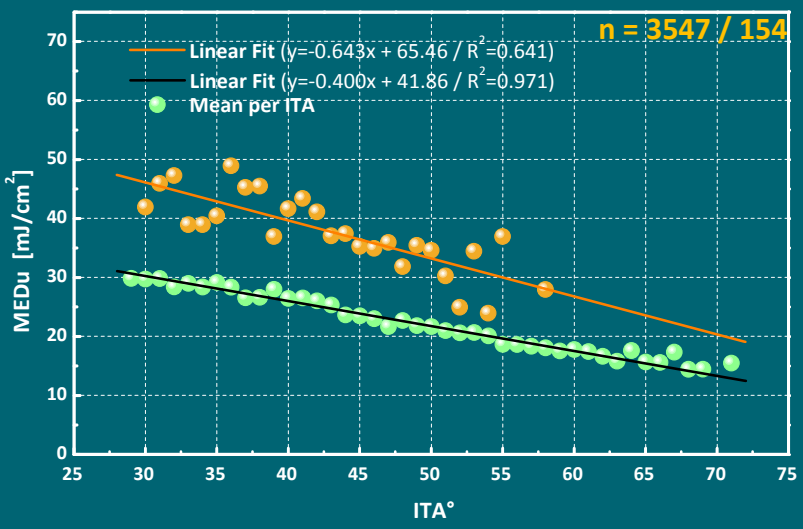
Correlation ITA° and MEDu / Europe



Correlation ITA° and MEDu / China



Correlation ITA° and MEDu / Europe and China



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Subjects – Europe and China

- Different distribution of Phototypes
- Different correlation of Phototype and resulting MEDu
- Different correlation of Phototype and resulting MEDp

→ Further studies have to be carried out in order to clarify if these differences might lead to differences in SPF determination if results in Europe and China will be compared!

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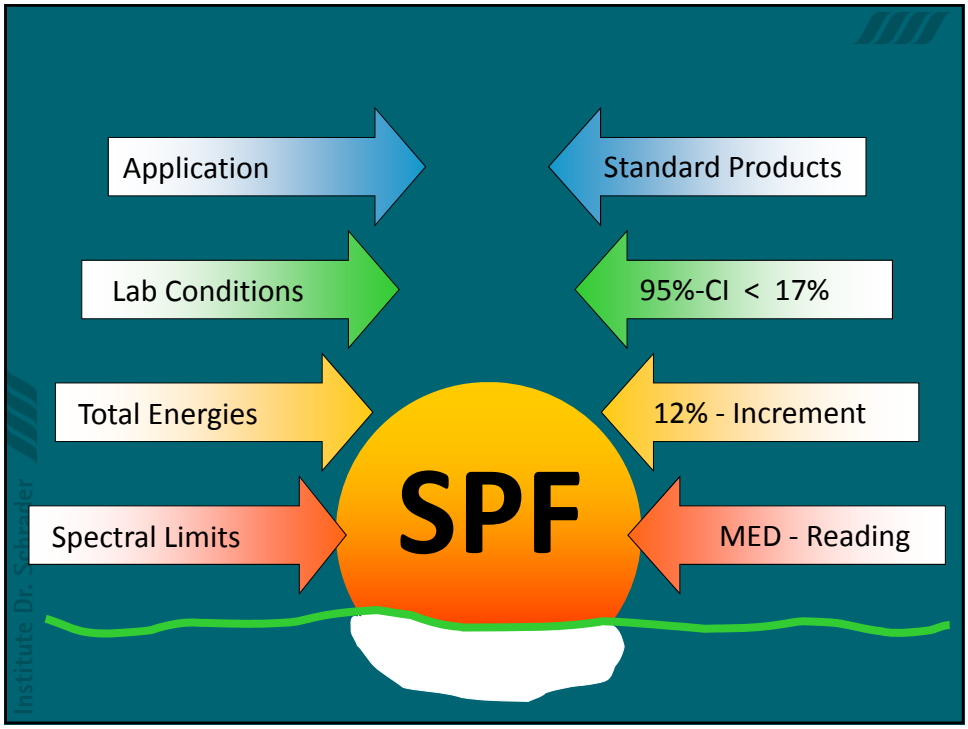
Application
Standard Products
Lab Conditions
95%-CI < 17%
Total Energies
12% - Increment
SPF
Spectral Limits
MED - Reading
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Headquarters - Holzminden
Vielen Dank für Ihre Aufmerksamkeit
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QUALITY THROUGH EXPERIENCE

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44 100 070914

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