

## WE CREATE YOUR BENEFIT

RESEARCH | DEVELOPMENT | TESTING | ANALYSIS



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### HDRS

Hybrid Diffuse Reflectance Spectroscopy

The first real change in SPF-testing since COLIPA 1994



Mathias Rohr

Institute Dr. Schrader

### HDRS – COLIPA-TF Sun Protection 1994 / Venice



Published May 1994



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### HDRS – The Future of SPF

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Albert Einstein (1879-1955)

Die Probleme dieser Welt lassen sich nicht mit den gleichen Denkweisen lösen,  
die sie erzeugt haben!

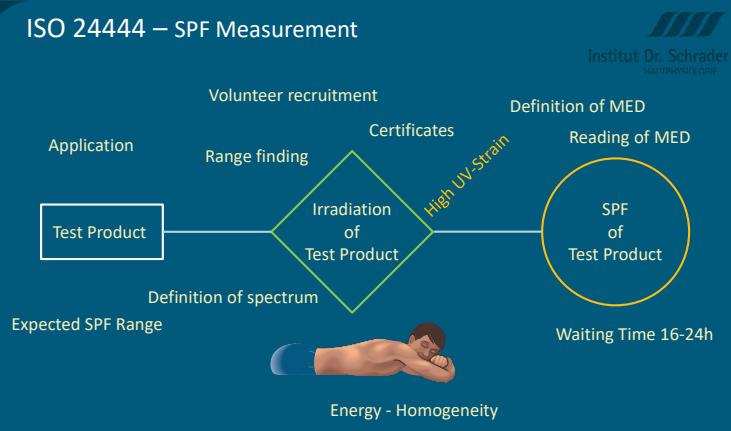
A whole new way of thinking is required for  
solving the problems we have created through our old way of thinking!

➤ Let's Start and Think  
E  
W  
HDR

➤ Let's talk about Hybrid Diffuse Reflectance Spectroscopy or ISO 23698

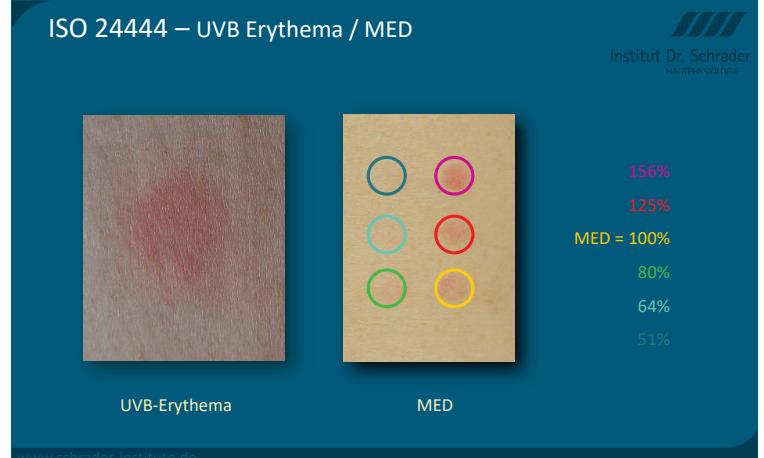
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## ISO 24444 – SPF Measurement



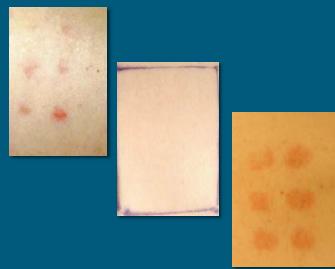
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## ISO 24444 – UVB Erythema / MED



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## ISO 24444 – UVB Erythema?



UVB-Erythema?

Beside any Ethical Concerns sometimes even the simple definition of the correct MED might be a challenge

In order to get rid of all these points Future SPF-Testing should be „free off“ any Erythema Testing



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## Basic Ideas of HDRS

- Technique
- Results / SPF / Photostability
- Results / UVA-PF
- Results / Water-Resistance
- Ongoing Statistics - ISO
- Summary

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## Basic Ideas of HDRS



## SPF<sub>HDRS</sub> – A combination of *in vivo* and *in vitro* calculations



### SPF-Calculation

$$\text{SPF}_{\text{calculated}} = \frac{\int_{\lambda=290}^{\lambda=400} E(\lambda) I(\lambda) d\lambda}{\int_{\lambda=290}^{\lambda=400} E(\lambda) I(\lambda) 10^{-A(\lambda)} d\lambda}$$

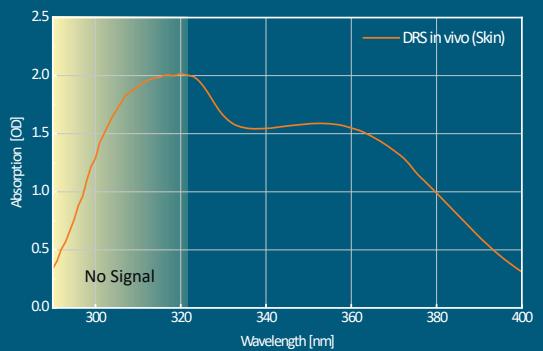
$E(\lambda)$  = Erythemal Action Spectrum  
 $I(\lambda)$  = Spectral Irradiance  
 $A(\lambda)$  = Absorbance

### Experimental Design HDRS:

Combination of ISO 24443 (*in vitro*) and Diffuse Reflectance Spectroscopy (DRS *in vivo*)

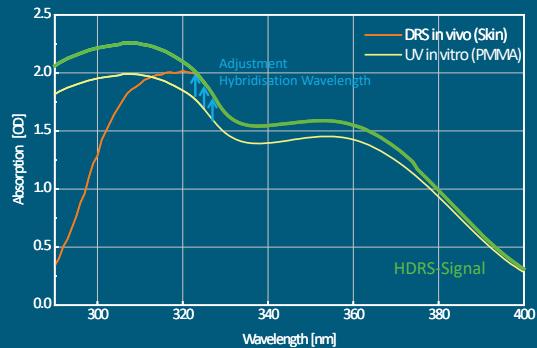
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## HDRS – DRS-Signal



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## SPF<sub>HDRS</sub> – Hybrid-Signals



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## SPF<sub>HDRS</sub> – A combination of *in vivo* and *in vitro* calculations



### SPF-Calculation HDRS

$$\text{SPF}_{\text{calculated}} = \frac{\int_{\lambda=290}^{\lambda=400} E(\lambda) I(\lambda) d\lambda}{\int_{\lambda=290}^{\lambda=400} E(\lambda) I(\lambda) 10^{-A(\lambda)} d\lambda}$$

$E(\lambda)$  = Erythemal Action Spectrum  
 $I(\lambda)$  = Spectral Irradiance  
 $A(\lambda)$  = Absorbance

SPF-Calculation based on  $A(\lambda)$  from HDRS-Data

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☰ Basic Ideas of HDRS

☰ Technique

- Results / SPF / Photostability
- Results / UVA-PF
- Results / Water-Resistance
- Ongoing Statistics - ISO
- Summary



## ☰ Technique

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### SPF<sub>HDRS</sub> – Technique

Hardware configuration



Signal analysis

UVB / UVA Detection

Emission monochromator

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### SPF<sub>HDRS</sub> – Technique



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System

6 OD

optically  
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☰ Basic Ideas of HDRS

☰ Technique

- Results / SPF / Photostability
- Results / UVA-PF
- Results / Water-Resistance
- Ongoing Statistics - ISO
- Summary



## ☰ Results / SPF / Photostability

## HDRS – Test-Design

- Study Objective: Quantification of SPF
- Experimental Design: Combination of ISO 24443 (*in vitro*) and Diffuse Reflectance Spectroscopy (DRS *in vivo*) ISO 24444 (SPF *in vivo*)
- Test Products : 250 Products (marked and specially designed)
- SPF-Range : SPF 4 - SPF 120
- Subjects: SPF<sub>24444</sub> (n=10) / SPF<sub>HDRS</sub> (n=10-15)
- Statistical Analysis: SPF<sub>24444</sub> and SPF<sub>HDRS</sub> / Regression Analysis.....



## HDRS – Test-Products

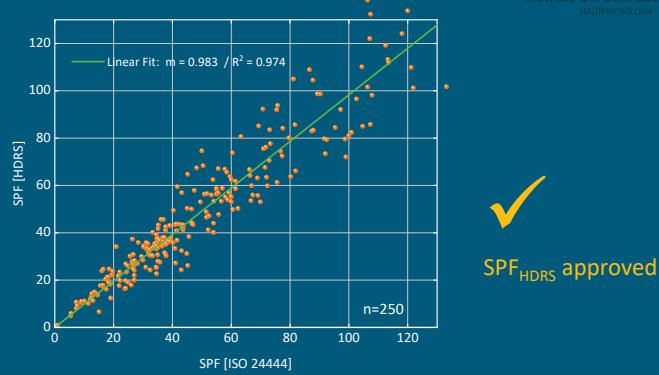
- Test Products: O/W-Lotion and Cream  
W/O-Lotion and Cream  
Cream Gel  
O/W-Spray  
Oil-Spray (with and without Alcohol)  
Stick  
Aerosol-Spray  
Powder  
Foam
- UV-Filter: A wide range of organic and inorganic UV-Filter  
With and without TiO<sub>2</sub> (Nano and Non-Nano)  
With and without ZnO
- Photostability: Photo-stable  
Photo-unstable (UVB and/or UVA)



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## HDRS – Results SPF<sub>24444</sub> / SPF<sub>HDRS</sub> / n=250



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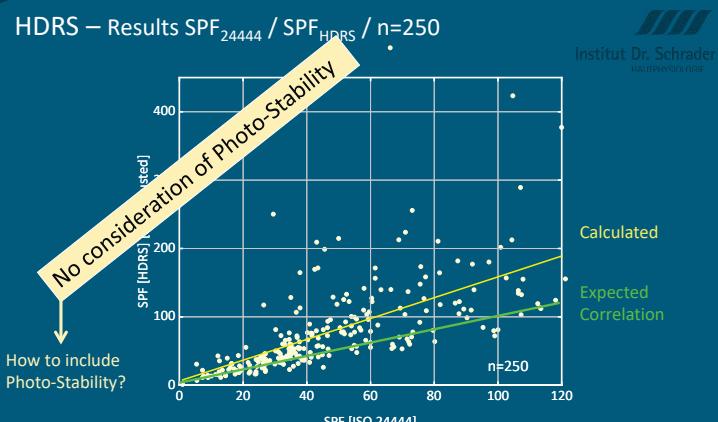
## SPF<sub>HDRS</sub> – approved

- Excellent Correlation of SPF<sub>24444</sub> and SPF<sub>HDRS</sub> up to SPF 120
- No limits concerning the type of formulation
- Photo-Stability adjusted



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## HDRS – Results $SPF_{24444} / SPF_{HDRS}$ / n=250



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## HDRS – Photo-Stability / Limits of pre-Irradiation Dose

How to include Photo-Stability

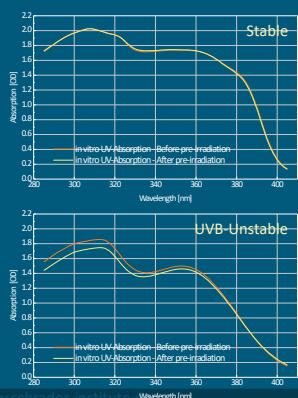
■■■ Using ISO 24443

■■■ Pre-Irradiation Dose according to ISO 24443 ( $1.2 \times UVA-PF_0 [\text{J}/\text{cm}^2]$ )

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## Absorption – Variation of UV-Stability (PMMA)

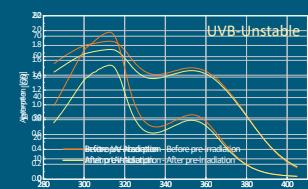


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$$SPF_{\text{calculated}} = \frac{\int_{\lambda=290}^{\lambda=400} E(\lambda) I(\lambda) d\lambda}{\int_{\lambda=290}^{\lambda=400} E(\lambda) I(\lambda) 10^{-A(\lambda)} d\lambda}$$

## SRPD – Spectral Ratio of Photo Degradation

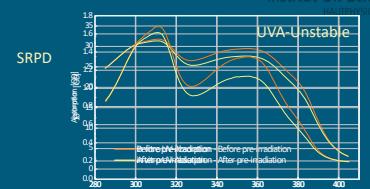


Ratio of Absorption Curves

$$SRPD_{\text{mean}} = \frac{1}{111} \sum_{\lambda=290}^{400} \frac{10^{-A(\lambda)}}{10^{-A_0(\lambda)}}$$

Photostability: Multiplication of  $SPF_{\text{HDRS}}$  with the defined SRPD wavelength by wavelength

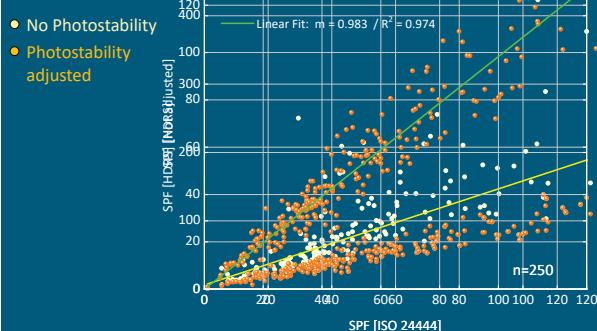
Calculation of  $SPF_{\text{HDRS}}$



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## HDRS – Results SPF<sub>24444</sub> / SPF<sub>HDRS</sub> / n=250



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## HDRS – Photo-Stability / Limits of pre-Irradiation Dose

How to include Photo-Stability

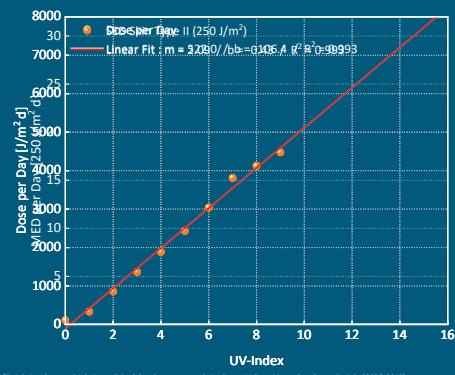
■■■ Using ISO 24443

■■■ Pre-Irradiation Dose according to ISO 24443 ( $1.2 \times \text{UVA-PF}_0 [\text{J/cm}^2]$ )

■■■ Is there a reason to define a maximum pre-Irradiation Dose?

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## HDRS – Limits of pre-Irradiation Dose

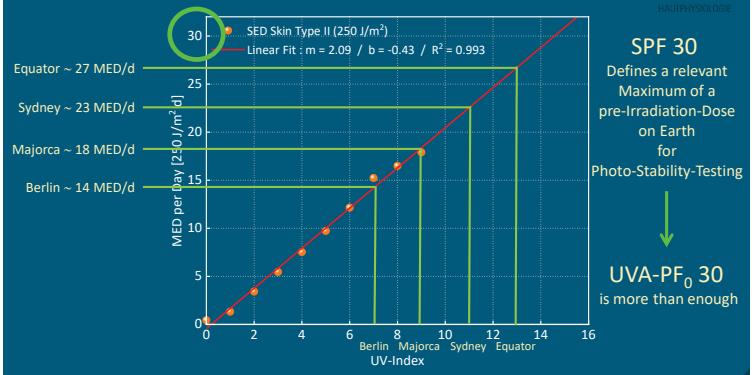


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(Data from: Knuscke et. al., Bundesamt für Arbeitsschutz und Arbeitsmedizin, Schutzkomponenten bei solarer UV-Exposition – Forschungsprojekt F2036, 2015)

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## HDRS – Limits of pre-Irradiation Dose



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## HDRS – Photo-Stability / Limits of pre-Irradiation Dose



### How to include Photo-Stability

■■■ Using ISO 24443

■■■ Pre-Irradiation Dose according to ISO 24443 ( $1.2 \times \text{UVA-PF}_0 [\text{J}/\text{cm}^2]$ )

■■■ Is there a reason to define a maximum pre-Irradiation Dose?

■■■ Proposal:

If the calculated  $\text{UVA-PF}_{0-\text{HDRS}} > 30$

This value should be limited to  $\text{UVA-PF}_0 = 30$   
to calculate the pre-Irradiation Dose according to ISO 24443 ( $1.2 \times \text{UVA-PF}_0 [\text{J}/\text{cm}^2]$ )

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## SPF<sub>HDRS</sub> – approved



■■■ Excellent Correlation of SPF<sub>24444</sub> and SPF<sub>HDRS</sub> up to SPF 120

■■■ No limits concerning the type of formulation

■■■ Photo-Stability adjusted (and should be limited, correlated to UVA-PF<sub>0</sub> 30) ✓

■■■ No Irradiation of Skin

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## HDRS – Really non-invasive?



### Irradiation during measurement

■■■ Is there a relevant irradiation dose during the measurement process?

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## HDRS – Erythema weighted Irradiation Dose



UV-Range [nm]	Mean Irradiation Dose (n=10) [mJ/cm <sup>2</sup> ]	Relative to Reference MEDu (Skin Type II, 21 J/cm <sup>2</sup> ) [%]
280 – 405	$0.377 \pm 0.029$	1.79
290 – 405	$0.336 \pm 0.011$	1.60
300 – 405	$0.155 \pm 0.009$	0.74
310 - 405	$0.036 \pm 0.002$	0.17

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## SPF<sub>HDRS</sub> – approved

- Excellent Correlation of SPF<sub>24444</sub> and SPF<sub>HDRS</sub> up to SPF 120
- No limits concerning the type of formulation
- Photo-Stability adjusted (and should be limited, correlated to UVA-PF<sub>0</sub> 30) ✓
- No Irradiation of Skin (Absolute no relevant UV-Irradiation of Skin) ✓

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- Basic Ideas of HDRS
- Technique
- Results / SPF / Photostability
- Results / UVA-PF
  - Results / Water-Resistance
  - Ongoing Statistics - ISO
  - Summary



## ■■■ Results / UVA-PF

## HDRS – Test-Design / UVA-PF

- Experimental Design : Diffuse Reflectance Spectroscopy (DRS *in vivo*)

ISO 24442 (UVA-PF *in vivo*)

42 Products

UVA-PF 2 - UVA-PF 30



ISO 24443 (UVA-PF *in vitro*)

210 Products

UVA-PF 2 - UVA-PF 50

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## HDRS – UVA-PF

- Study Objective: Quantification of UVA-PF

$$\text{UVA-PF} = \frac{\int_{\lambda=320}^{\lambda=400} P(\lambda_i) I(\lambda_i) d\lambda}{\int_{\lambda=320}^{\lambda=400} P(\lambda_i) I(\lambda_i) 10^{-A(\lambda_i)} d\lambda}$$

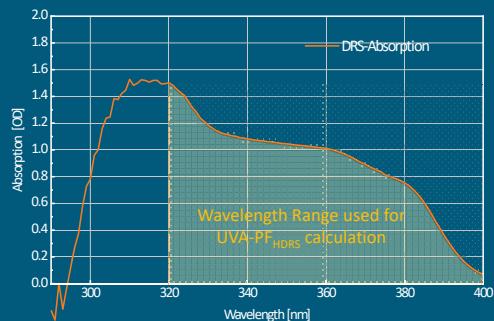
P(λ<sub>i</sub>) = PPD Action Spectrum  
I(λ<sub>i</sub>) = Spectral Irradiance (UVA)  
A(λ<sub>i</sub>) = Absorbance

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## HDRS – Spectrum of UVA-PF<sub>HDRS</sub>

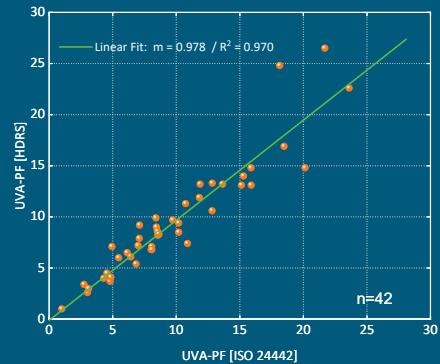


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$$\text{UVA-PF} = \frac{\int_{\lambda=320}^{\lambda=400} P(\lambda) I(\lambda) d\lambda}{\int_{\lambda=320}^{\lambda=400} P(\lambda) I(\lambda) 10^{-A(\lambda)} d\lambda}$$

Direct calculation based on *in vivo* DRS-Absorbance  $A(\lambda)$

## HDRS – Results UVA-PF<sub>24442</sub> / UVA-PF<sub>HDRS</sub>



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## SPF<sub>HDRS</sub> – approved / UVA-PF<sub>HDRS</sub> – approved

### SPF

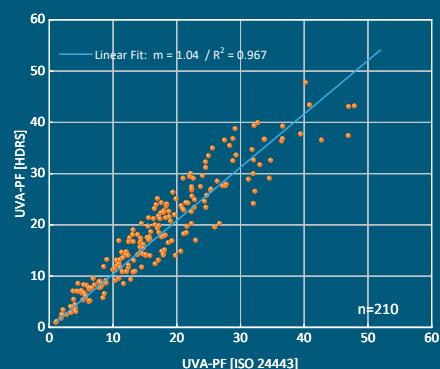
- Excellent Correlation of SPF<sub>24444</sub> and SPF<sub>HDRS</sub> up to SPF 120
- No limits concerning the type of formulation
- Photo-Stability adjusted (and should be limited, correlated to UVA-PF<sub>0</sub> 30)
- No Irradiation of Skin (Absolute no relevant UV-Irradiation of Skin)

### UVA-PF

- All comments can be adapted to UVA-PF
- Does it work in correlation to ISO 24443 UVA *in vitro*?

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## HDRS – Results UVA-PF<sub>24443</sub> / UVA-PF<sub>HDRS</sub>



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$\text{SPF}_{\text{HDRS}}$  – approved /  $\text{UVA-PF}_{\text{HDRS}}$  – approved

### SPF

- Excellent Correlation of  $\text{SPF}_{24444}$  and  $\text{SPF}_{\text{HDRS}}$  up to SPF 120
- No limits concerning the type of formulation
- Photo-Stability adjusted (and should be limited, correlated to  $\text{UVA-PF}_0$  30)
- No Irradiation of Skin (Absolute no relevant UV-Irradiation of Skin)

### UVA-PF

- All comments can be adapted to UVA-PF
- Correlation of  $\text{UVA-PF}_{\text{HDRS}}$  to ISO 24442 (*in vivo*) and ISO 24443 (*in vitro*)

  
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■■■ Basic Ideas of HDRS

■■■ Technique

■■■ Results / SPF / Photostability

■■■ Results / UVA-PF

■■■ Results / Water-Resistance

Ongoing Statistics - ISO

Summary

■■■ Results / Water-Resistance

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### HDRS – Water-Resistance-Testing

  
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- The actual method in Europe is still the COLIPA method from 2005 (2x20min Spa Pool, static and wet SPF, calculation of WR)

- Are there any experimental differences for HDRS?

### HDRS – Water-Resistance-Testing

Water-Resistance-Testing		
Product application	$2.0 \pm 0.05 \text{ mg/cm}^2$	Movement of water by jet impact, no air bubbles
Waiting Time	15 min	Test area has to be totally covered with water / no contact to pool
1. Spa Pool Time	20 min	Controlled water quality EC Council Directive 98/83 EC
Drying Time at air	15 min	Mg and Ca 50 mg/ml - 500 mg/ml
1. Spa Pool Time	20 min	Hygienic control by Cl
Drying Time at air	15 min / or until the test area is totally dry	Water Temperature $29 \pm 2^\circ\text{C}$ .

Test of SPF on static and wet test areas

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## HDRS – Water-Resistance-Testing / Spa Pool



  
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## HDRS – Water-Resistance-Testing

  
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■■■ The actual method in Europe is still the COLIPA method from 2005  
(2x20min Spa Pool, static and wet SPF, calculation of WR)

■■■ Are there any experimental differences for HDRS? → No!

■■■ Are there any calculation differences for HDRS?

## HDRS – Water-Resistance-Testing / Calculation

### WR-Classic:

$$\%WR_i = \frac{SPF_w^i - 1}{SPF_s^i - 1} \times 100$$

$$\text{mean \%WR} = \frac{\sum_{i=1}^n \%WR_i}{n}$$

$$WRR = \text{mean \%WR} - d$$

$SPF_w^i$	= individual SPF-static
$SPF_s^i$	= individual SPF-wet
$\%WR$	= individual Water-Resistance in %
$\text{mean \%WR}$	= Mean Water-Resistance in %
$d$	= 90% CI

### WR-HDRS:

$$\text{mean \%WR} = \frac{\text{mean } SPF_w - 1}{\text{mean } SPF_s - 1} \times 100$$

$\text{mean } SPF_w$	= mean SPF-static
$\text{mean } SPF_s$	= mean SPF-wet
$\text{mean \%WR}$	= Mean Water-Resistance in %

  
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## HDRS – Water-Resistance-Testing

  
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■■■ The actual method in Europe is still the COLIPA method from 2005  
(2x20min Spa Pool, static and wet SPF, calculation of WR)

■■■ Are there any experimental differences for HDRS? → No!

■■■ Are there any calculation differences for HDRS? → Yes!

■■■ Are there any differences in the resulting WR for HDRS?

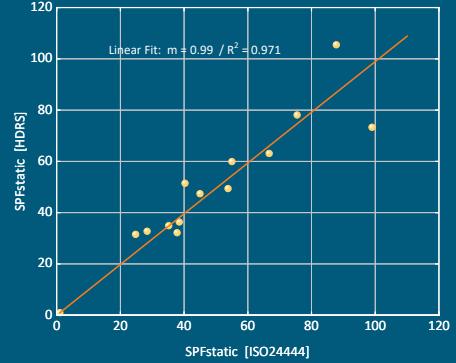
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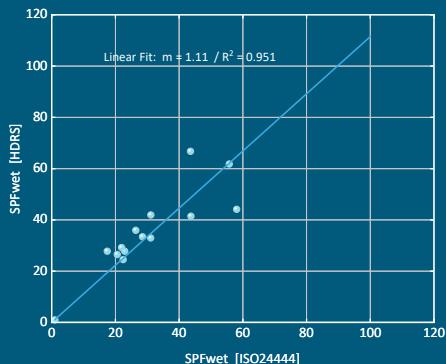
## HDRS – Test-Design / Water-Resistance

- Study Objective: Quantification of Water Resistance (WR)
- Experimental Design: WR-Classic and WR-HDRS
- Water Resistance: 2x20 min Spa Pool / WR: 30%-90% (classic)
- Test Products : 15 Products
- Measurements: DRS-static and DRS-wet
- Analysis: Calculation of SPF<sub>HDRS</sub> / Calculation of WR<sub>HDRS</sub>

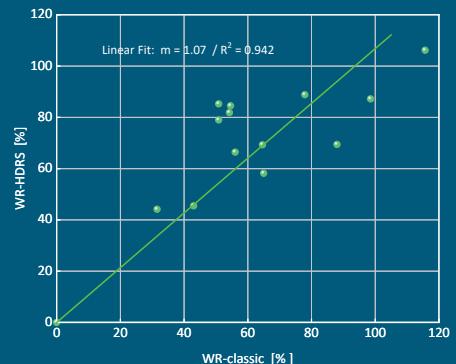
## HDRS – Water-Resistance / Static Results



## HDRS – Water-Resistance / Wet Results



## HDRS – Water-Resistance / %-Results



## HDRS – Water-Resistance-Testing



■■■ The actual method in Europe is still the COLIPA method from 2005  
(2x20min Spa Pool, static and wet SPF, calculation of WR)

■■■ Are there any experimental differences for HDRS? → No!

■■■ Are there any calculation differences for HDRS? → Yes!

■■■ Are there any differences in the resulting WR for HDRS? → No!

■■■ Again -  
For the first time we have an alternative method which can handle WR-Testing!

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■■■ Basic Ideas of HDRS

■■■ Technique

■■■ Results / SPF / Photostability

■■■ Results / UVA-PF

■■■ Results / Water-Resistance

■■■ Ongoing Statistics - ISO

Summary

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■■■ Ongoing Statistics - ISO

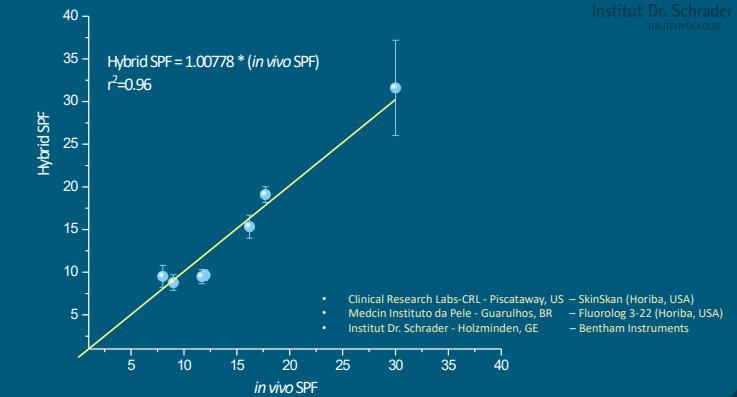
## HDRS – Ring-Test / 3 Countries



■■■ 1. Ringtest (2017):  
1 Lab  $\text{SPF}_{\text{ISO}} 24444$   
3 Labs  $\text{SPF}_{\text{HDRS}}$   
7 Products  
 $\text{SPF} 5 – 30$

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## HDRS – Ring-Test Results of 3 Labs / 7 Products (2017)



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## HDRS – Ring-Test / 3 Countries

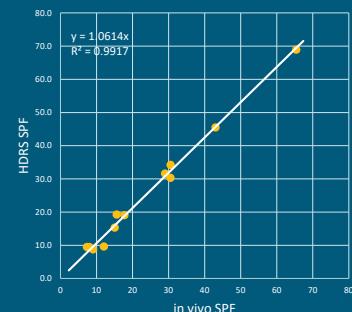
- 1. Ringtest (2017):      1 Lab SPF<sub>ISO</sub> 24444  
3 Labs SPF<sub>HDRS</sub>  
7 Products  
SPF 5 – 30
- 2. Ringtest (2018):      3 Labs SPF<sub>ISO</sub> 24444  
3 Labs SPF<sub>HDRS</sub>  
12 Products  
SPF 5 – 60

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## HDRS – Ring-Test Results of 3 Labs / 12 Products (2018)

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- 12 Products
- 3 Labs / in vivo and HDRS
- 3 different Countries
- Excellent Correlation

## HDRS – Ring-Test / 3 Countries

- 1. Ringtest (2017):      1 Lab SPF<sub>ISO</sub> 24444  
3 Labs SPF<sub>HDRS</sub>  
7 Products  
SPF 5 – 30
- 2. Ringtest (2018):      3 Labs SPF<sub>ISO</sub> 24444  
3 Labs SPF<sub>HDRS</sub>  
12 Products  
SPF 5 – 60
- 3. Ringtest (2019):      3 Labs SPF<sub>ISO</sub> 24444  
3 Labs SPF<sub>HDRS</sub>  
25 Products  
SPF 5 – 60

Results ready for presentation on  
the next ISO-Meeting / June 2019  
→ ISO Acceptance Criteria ✓

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■■■ Basic Ideas of HDRS

■■■ Technique

■■■ Results / SPF / Photostability

■■■ Results / UVA-PF

■■■ Results / Water-Resistance

■■■ Ongoing Statistics - ISO

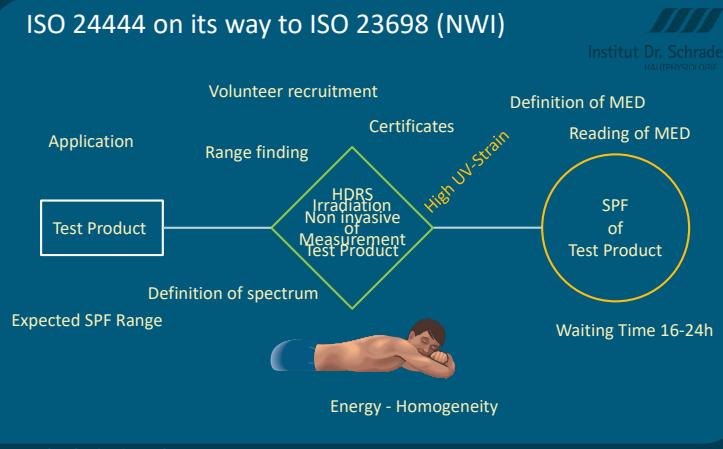
■■■ Summary

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■■■ Summary



## ISO 24444 on its way to ISO 23698 (NWI)



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SPF<sub>HDRS</sub> – The NEW alternative non erythema SPF – *in vivo*

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### Not needed:

- Irradiation of Skin
- Definition of MED
- Training of MED reading
- Information of expected SPF
- Irradiation Spectrum
- Separate testing of SPF and UVA-PF



Let's start and go this new way in SPF testing

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### Excellent:

- No Ethical Concerns
- Correlation of SPF<sub>24444</sub> and SPF<sub>HDRS</sub>
- Correlation of UVA-PF<sub>24442/3</sub> and UVA-PF<sub>HDRS</sub>
- Photostability linked to ISO 24443
- SPF-Range covered up to SPF 120
- UVA-PF-Range covered up to UVA-PF 30
- No limits concerning the type of formulation
- Water-Resistance Testing included

## HDRS – ISO 23698

HDRS the first real change in SPF *in vivo* since 25 years!

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ISO/TC217/WG7 Sun Protection test methods 2018 / Monaco

COLIPA-TF Sun Protection 1994 / Venice



ISO 23698 / HDRS  
Coming soon!



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## Headquarters - Holzminden

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Vielen Dank für Ihre Aufmerksamkeit



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