

## **DGK Test Guideline**

### **1. DGK Test design: Comparative Patch Test with Surfactants**

**Test aim:** Determination of rank orders of surfactants and blends of surfactants with respect to the primary skin irritation properties after 24h full-occlusive treatment.  
The study design compares substances against a known positive-standard. Therefore it can also be used for the classification of products.

**Samples:** Standards are:  
Sodiumlaurylsulfate (SLS) in 0.5% concentration  
Sodiumlaurylethersulfate (NaLES) in 1% concentration  
Aqua bidestillata  
Surfactants should be diluted in aqua bidest.  
The dilution has to be adapted acc. to the aim of the study.  
Generally, a concentration of 1% active surfactant should not be exceeded.

**Design:** Randomized application of samples with fixed position of the controls  
Double-blinded  
Intra individual comparison of the samples against SLS resp. against the other standards, if appropriate

**Method:** 24h – application, full-occlusive ( Large-Finn-Chambers on Scanpor®) on the back (paravertebral area) with up to 2 x 8 (maximally 20) test areas.

**Reading:** Reading of erythema after 24,48, and 72hrs after removal of the chambers. Further dermal reactions may be noticed and described without invading the numerical score.

**Number of subjects:** at least 30

**Inclusion criteria:**

- a) Standard design  
Subjects aged 18 and above with healthy skin in the application area  
1/3 of the subjects having sensitive skin against surfactants
- b) Extra designs:  
Special inclusion of skin sensitivity, skin type, age etc. possible acc. to the respective aim of the study; reason should be indicated.

**Exclusion criteria:**

Gravidity, lactation, ingestion of medication effective on skin regulation, specific local treatment, in particular with corticosteroids, antihistaminica, immunosuppressiva, rube-faciencia, dyes, bleaches, etc; skin diseases with the danger of interaction or exacerbation, allergies against ingredients, hypothyreosis or hyperthyreosis, hyperpigmentation, extreme sun tan, skin types V and VI after Fitzpatrick, foreseeable non-compliance.

**Goal criteria:**

Erythema with or without associated reaction, scored as follows:

0	= no reaction, unchanged skin without erythema	(0)
±	= doubtful (minimal) erythema, loosely marked	(0,5)
+	= slight erythema, sharply marked, clearly visible	(1)
++	= clear to strong erythema, sharply marked	(2)
+++	= strong erythema plus follicular reaction and/or papules and /or edema and/or small vesicles and/or rhagades	(3)
++++	= strong erythema plus bulla or necrosis or incrustation	(4)

Other efflorescences:

(elevated) texture  
scaling  
fissures  
pigmentation  
de-pigmentation  
other effects

**Statistical methods:**

- equivalence test for the erythema sum score with  $\sigma/2$  as limit of equivalence
- test for monotone effects with linear contrasts in block variance analysis for the proof of an expected gradient
- test of monotony with Page test

**Ethics:** A written consent shall be given acc. to the current ICH/GCP Guidelines after information about products and method of treatment.

**Quality assurance:**

Reading shall be performed by trained personnel using standardized day-light sources. The readings are noticed in a documentation form sheet (or formatted EDV-mask) and signed by the reader. Any changes have to be documented and justified.

**Assessment:**

Equivalence or deviation of one or more substances from the positive standard SLS shall be evaluated. Products should reach a better compatibility than SLS. In case of equivalence testing of a known sample against one or more test samples, respectively, an expected or desired rank order has to be defined in advance. In accordance, the result will be "equivalent" or "better than...".

In tests for monotony expected rank orders will be confirmed or not confirmed. The assessment has to be argued in accordance with the aim of the study.

All participating laboratories in the DGK circle trial will continue to join a voluntary inter-laboratory control program of the standard values. That will ensure to recognize deviations in the inclusion criteria or skin sensitivity of subjects as well as in the evaluation of the results.

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DGK Working Group I "Safety and Compatibility"