



216 Congers Road, Bldg. 1
New City, NY 10956-6261 USA
(845) 634-4330
Fax: (845) 634-5565
www.amalabs.com

**EVALUATION OF SUN PROTECTION
BY SPF DETERMINATION (FDA) – WATER RESISTANT**

AMA Ref. No.: MS11.SPF.M0355.DPS.WR20

Date: May 9, 2011

Sponsor: Deutsche Pharma S.A.
Avd. La Concepcion #56
Office 307-308-309
Providencia Santiago De Chile

1.0 Objective:

This panel has been convened to evaluate the effectiveness of a test material as a sunscreen product by determining the Sun Protection Factor (SPF) on human skin as defined by the Final Monograph; "Sunscreen Drug Products For Over-The-Counter Human Use", Final Rule, 21 CFR Part 352, Subpart D (Federal Register / Vol. 64, No. 98 / Friday May 21, 1999, Proposed Amendment; Docket number 78N-0038/CP12, June 21, 1999) using a Xenon arc solar simulator as the UV source. This test was conducted prior to and immediately following a water immersion experiment which was carried out under controlled conditions (Water Resistant Testing) as described in the above mentioned FDA monograph and Section 6.0 herein.

2.0 Sample Description:

On April 28, 2011 one test sample labeled SUNWORK Gel 191041M was received from Deutsche Pharma S.A. and assigned AMA Lab No.: M-0355.

3.0 Test Material Handling:

Upon arrival at AMA Laboratories, Inc., the test material was assigned a unique laboratory code number and entered into a daily log identifying the lot number, sample description, sponsor, date received and tests requested.

Samples are retained for a period of three months beyond submission of final report unless otherwise specified by the sponsor or if sample is known to be in support of governmental applications, in which case retained samples are kept two years beyond final report submission.

Sample disposition is conducted in compliance with appropriate federal, state and local ordinances.

14.0 Conclusions:

The Sun Protection Factor (SPF) of the above test material (AMA Lab No.: M-0355; Client No.: SUNWORK Gel 191041M) when tested on twenty subjects as described herein under static and water resistant conditions yielded the mean SPF values of 55.70 and 53.03 respectively, and the label SPF's of 54 (Static) and 52 (Water Resistant), which can be assigned a Products Category Designation (PCD) of High, according to the reference.

The mean SPF of the 8% homosalate standard on the same panel was 4.30 and the label SPF was 4. The mean water resistant SPF of 15/15 water resistant in house control on the same panel was 15.68 and the label SPF was 15.

Donna Muratschew, MD

Donna Muratschew, M.D.
Study Director

Kaitlyn Callaghan

Kaitlyn Callaghan, B.S. (Candidate)
Technician

Jayne M. Reidy

Jayne M. Reidy, A.A.
Technician

Erica Tavormina

Erica Tavormina, B.S.
Technician

David R. Winne

David R. Winne, B.S.
Technical Director

5/9/11

Date

