How to Avoid Fraud in Sun Protection Factor (SPF) Data

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Abstract

Sun Protection Factor (SPF) claims on marketed products were found to be incorrect, posing a potential risk to consumers. Incorrect claims may negatively impact manufacturers' public relations, legal exposure, and regulatory compliance. The authors discuss some of the most recent SPF incidents and their potential causes. As these causes are primarily linked to improper or fraudulent testing, the article describes approaches to prevent such outcomes.

INTRODUCTION

It is widely accepted that proper use of a topical sunscreen is an important part of a healthy skin care regimen [1,2]. It is well documented that prolonged exposure of the skin to ultraviolet B (UVB) and short-wavelength UVA 3 radiation (290-340 nm) may lead to accelerated signs of aging and common skin cancers such as basal and squamous cell carcinomas [3]. It is widely known that ultraviolet B (UVB) radiation (λ = 290-320 nm) and short-wavelength ultraviolet A (UVAII, λ = > 320-340 nm) can damage skin primarily through DNA photolesions, leading to erythema [30], whereas long wavelength Ultraviolet A (termed UVA1) damages skin through more subtle effects in the lower epidermis and dermis [31].

Application of effective over-the-counter (OTC) sunscreens has been shown to mitigate these conditions [4]. However, as discussed in this article, not all marketed sunscreen products are as effective as they claim. That may be due to improper or fraudulent testing or misleading labeling by the manufacturer or labeler. This article, after providing marketing background, reviewing recent testing incidents, and summarizing testing methods, describes how to identify potential sources of fraud and error.

Market background

According to the EWG (Environmental Working Group), thousands of products on the market carry SPF claims, and most of them also claim 'broad-spectrum' coverage [5]. According to Mintel's primary product collection database, GNPD (Global New Products Database), the total number of US and European UV exposure products has more than doubled from November 2015 to October 2025 (from 827 to 1699; see ***Figure 1a***). From this dataset, ***Figure 1b*** shows the relative number of products released by selected companies

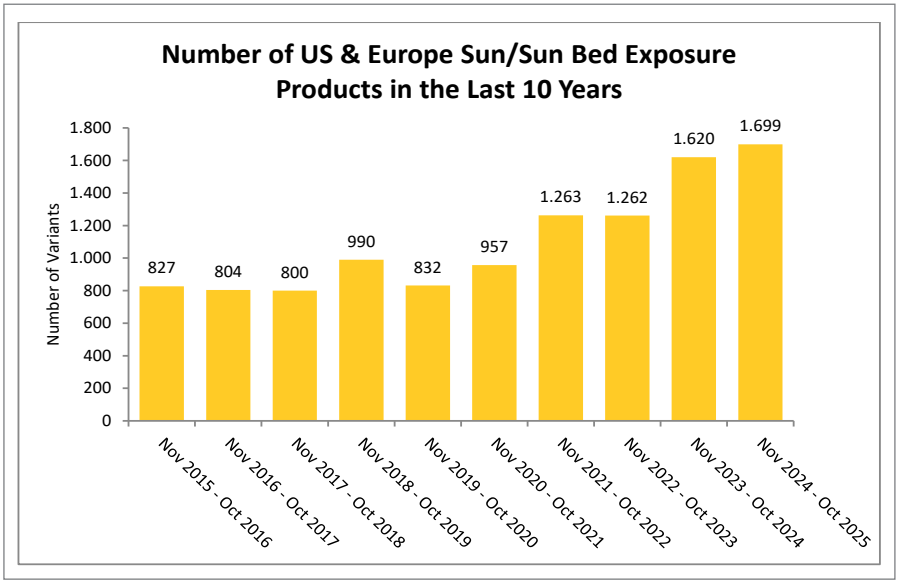


Figure 1a: *Number of U.S. and European Sun/Sun Bed Exposure Products in the Last 10 Years Includes products designed for use during exposure to UV rays, either in direct sunlight or through a sunbed. Excludes daily use cosmetic and skincare products with the additional benefit of sun protection, such as Daily UV lotions (i.e., primary sunscreens).*

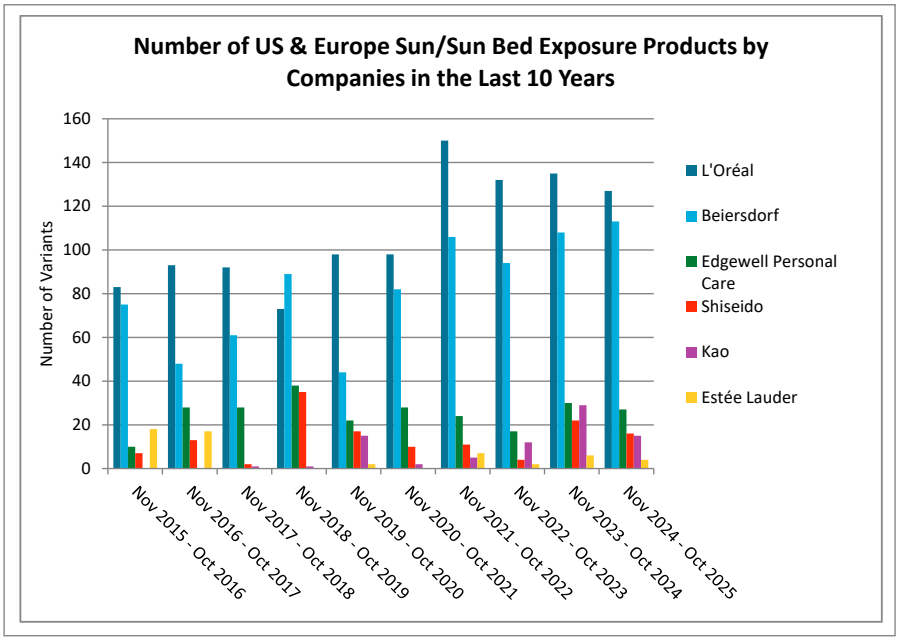


Figure 1b: *Number of U.S. and European Sun/Sun Bed Exposure Products by Companies in the Last 10 Years*

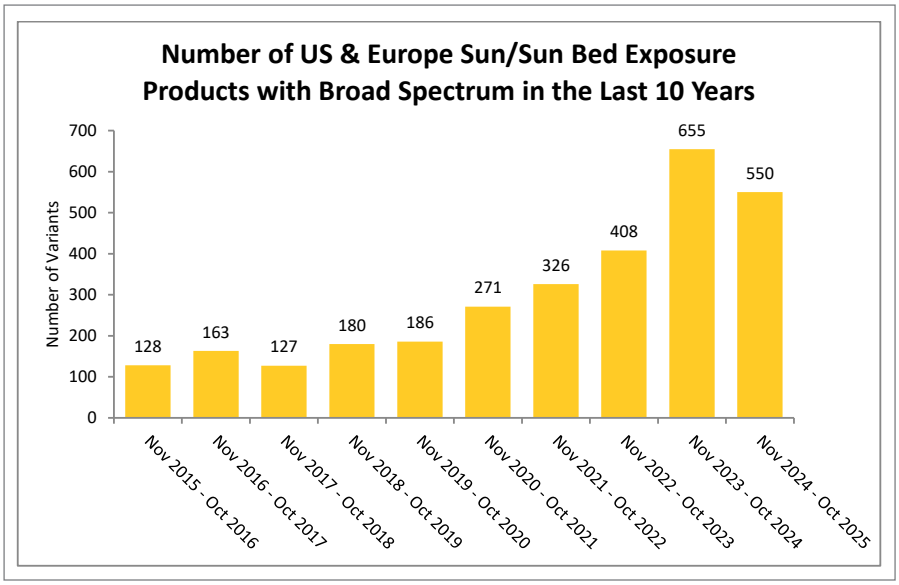


Figure 2: *Number of U.S. and European Sun/Sun Bed Exposure Products with Broad Spectrum in the Last 10 Years*

(as shown) active in this space. Of these, the number claiming 'broad-spectrum' coverage, as shown in ***Figure 2***, more than doubled over the same period (from 15.5% to approximately 36%), indicating the growing importance of delivering broad-spectrum coverage and rising consumer demand.

Briefly, broad-spectrum coverage can be defined as the relative amount of UVA protection, as measured by either a laboratory method (critical wavelength), which measures the breadth of UV absorption, or a clinical method that shows a reduction in tanning following UVA exposure (*i.e.,* persistent pigment darkening). The application of broad-spectrum claims varies worldwide [32]. In the EU, for example, sunscreens do not specifically claim 'broad-spectrum' on their labels or in advertising. Still, UVA protection must be at least 1/3 of UVB protection (UVA/UVB ratio). Many countries in Asia rely on an *in vivo* method (ISO 24442) for demonstrating UVA coverage. Using this method, the level of UVA protection is defined by the Protection Grade of UVA (PA) scale [33].

Figure 3 shows the number of products that claim an SPF higher than 30 among the total number of US and European UV exposure products shown in ***Figure 1***. From the same period, products claiming SPF greater than 30 went from approximately 40% to more than 70%. Again, indicating the importance of delivering higher UV/sun protection and consumer demand for it. The demand for high SPF values leads to competition among manufacturers and among the limited test facilities to attract manufacturers, and to difficulty in formulating high SPF values, which may enable fraudulent practices.

While the testing and labeling requirements vary by country/region, nearly every jurisdiction mandates an *in vivo* SPF test on humans that conforms to either the US FDA or ISO standards [7].

The clinical testing of sunscreens is a highly specialized field, and in the United States, labs conducting such testing are subject to FDA audits because sunscreens are classified as drugs. Sunscreens are also classified as drugs in Canada and in Australia [8, 9]. With a few exceptions (*e.g.,* quasi-drug classification in Japan), most of the world classifies sunscreens as cosmetics. However, regardless of their classification, every jurisdiction has laws requiring that marketed claims be truthful. In the case of sunscreen claims, this means that they qualify their products using either FDA or ISO sunscreen testing standards [7].

Testing of sunscreens requires expertise in calibrating and maintaining delicate xenon-arc lamps, consistent application of test products, expert evaluation of UV-induced erythema, and adherence to GCP standards. It was shown through 'round robin' tests between labs that there is often wide variability with respect to accuracy and precision – that is, the SPF value may vary depending on who is testing [10]. Because of this, manufacturers should take an active role in auditing and monitoring sunscreen labs to ensure their

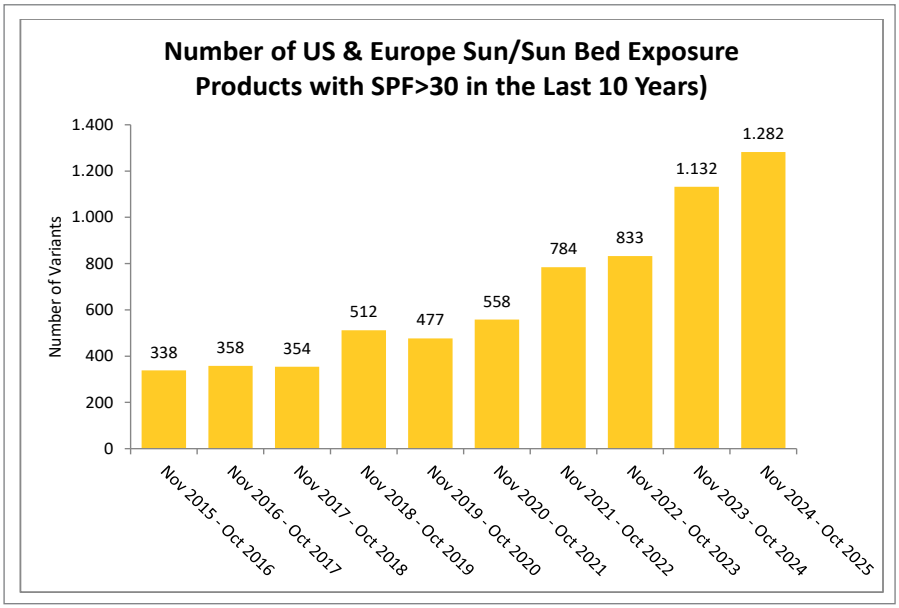


Figure 3: Number of U.S. and European Sun/Sun Bed Exposure Products with SPF>30 in the Last 10 Years

products are properly tested and comply with relevant regulatory standards. While it is true that current regulations are vague with respect to assigning blame for sub-standard SPF products, class-action law firms almost always target the brand/label making the claim.

Recently, the spotlight shone on products that were allegedly mislabeled, in some cases by orders of magnitude. The most prominent incidents that galvanized us to write this guide to avoiding fraud in SPF data are discussed.

Recent Testing Incidents

The US FDA 2019 monograph proposed rule [11] is almost certainly considered a major Federal fraud case in which a US-based testing laboratory, AMA, Congers, NY, was convicted of defrauding many companies by reporting fictitious SPF results [12]. Among many changes in the proposal aimed at ensuring data integrity and ethics, the FDA proposed designating manufacturers as the 'responsible persons' who must ensure that testing and labeling were conducted in accordance with the proposed rule.

In 2025, as of this writing, class action lawsuits have recently been filed against 4 prominent US brands, namely Super-Goop! [13] as well as La Roche Posay, Sun Bum, and Hawaiian Tropic, alleging that the 'true' SPF of their formulas was far below the SPF label claim.

In Australia, the consumer advocacy group CHOICE reported that 16 of 20 sunscreens marketed there were mislabeled. [14] CHOICE focused on high-SPF (>30) primary sunscreens, and while 4 products met their label claims, 16 did not. Amongst the group that failed, many were shown to provide SPF of about 20-30, but one product, Ultra Violette Lean Screen SPF 50, retested as low as 4! Following the publication of that data, the Therapeutic Goods Administration (TGA) announced it would investigate those products to determine whether they were compliant [15].

The lawsuits and regulatory actions mentioned above show that the credibility of sunscreen testing is not just an 'intramural' struggle.

After an overview of the two recognized *in vivo* testing methods, we discuss measures to ensure one's SPF claim is accurate and truthful.

Overview of FDA and ISO SPF Methods

Overall, the US FDA Monograph proposal [11] and the ISO 24444:2019 SPF methods [16] are very similar. They both rely on a solar simulator (Solar Light Inc.) for UV exposures. Both determine SPF by measuring the relative amount of UVB (and short-wavelength UVA) required to produce a visible burn, comparing treated and untreated sites (mid- to lower back, either side of the midline). Both methods typically yield similar SPF mean values [17,18]. A noteworthy difference is that the FDA's method requires only a single control standard to check data consistency and accuracy. In contrast, the ISO method recommends different control standards depending on the target SPF. The FDA is also less restrictive regarding UV beam uniformity. There is also some difference in exposure increments among the major compendial methods, but this would tend to affect precision more than accuracy. Finally, methods vary in how they handle outlier data. The ISO method allows up to 20 subjects to be tested and permits the rejection of up to 5 subjects' data as outliers. In contrast, the FDA method allows up to 13 subjects and rejects only 3 outliers. There are a few other minor technical differences among the major compendial methods, but they have little impact on the data in practice.

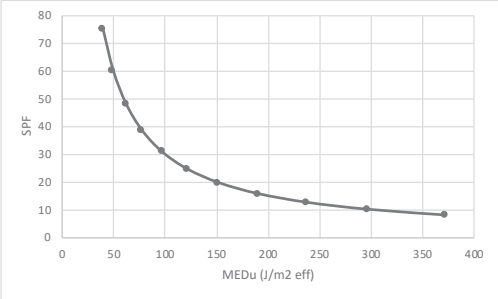
Beyond the methods themselves, each local/regional jurisdiction has its own rules for converting test data to SPF label claims. For example, as per Pirotta [19], the FDA requires that a correction factor (A) be subtracted from the average SPF value. The correction factor 'A' is essentially the standard deviation corrected for a small sample size. Alternatively, most countries rely on a combination of the ISO 24444 [16] criteria (mean SPF with an acceptable 95% confidence interval (CI) within 17% of the mean) and local regulations for assigning label values.

How to spot likely sources of fraud and errors

Qualifying a Testing Lab

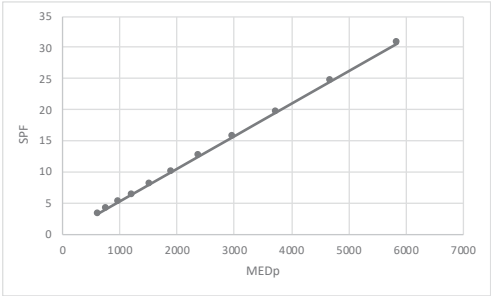
While the number of accredited/licensed sunscreen testing labs worldwide is limited (as of this writing, 8 or fewer in the US), that is no excuse for not choosing the right one. Accreditation and a long history of testing do not prevent a facility from conducting fraud or falsifying data. Therefore, the first step towards achieving credible data is to choose a labora-

4a) MEDu (Not Linear)



Relationship between SPF and MED_u showing that for a constant MED_p the MED_u yields a disproportionate rise in SPF as the MED_u value decreases.

4b) MEDp (Linear)



Relationship between SPF and MED_u showing that for a constant MED_u, the MED_p yields a linear drop in SPF as the MED_p value decreases.

Figure 4: *Untreated ('u') vs Treated/protected ('p') MED across the Fitzpatrick range*

tory with the infrastructure, equipment, staff/training, and experience to deliver reliable results. It is the responsibility of the study Sponsor (*i.e.,* manufacturer) to conduct a thorough audit of any prospective SPF testing laboratory before initiating any work, AND to regularly monitor (at least yearly) the laboratory's projects to ensure that protocols are followed. Standards are maintained (ICH Guideline for Good Clinical Practice E6(R3). [20] For example, the laboratory space should be equipped with sufficient solar simulators and staff to conduct the claimed volume of work, and the rooms where work is performed should be properly lit to enable precise product application and visual assessment of erythema. In addition, there should be appropriate standard operating procedures (SOP's) and training records to show that the lab staff is properly trained and that equipment is clean, maintained in proper working order, and, most importantly, calibrated regularly. Finally, the lab should be able to provide procedures for troubleshooting out-of-spec (OOS) results.

Any testing lab that performs work subject to regulatory oversight should be fully transparent to its clients about its operations. The study sponsor should have full access to the facility, the staff, and all relevant documentation. Labs that evaluate sunscreens should follow the latest Good Clinical Practice guidelines (ICH Guideline for Good Clinical Practice E6(R3), [20] as well as the requirements of the FDA (11) and ISO (16) methods. Any reputable laboratory should allow its clients to visit at any time without even an appointment – *i.e.,* a surprise visit. After all, government agencies such as the FDA do not warn labs before they audit a facility, and most credible labs are in a perpetual state of readiness for unannounced 'visitors'.

It should be stated here that many companies have rigorous programs for auditing and proactively monitoring studies through their Regulatory Affairs Divisions. This is especially true for large multinational companies that market a wide array of regulated products. In addition, many commercial laboratories participate in proficiency testing programs (*e.g.,* BIPEA) to confirm their compliance with compendial methods [34].

Baseline Minimal Erythema Dose (MED)

Both the FDA and ISO methods begin with determining the subject's minimal erythemal dose (MED). This is the dose of simulated sunlight (UVR) that is required to produce a well-delineated burn response. This response is expressed in J/m^2 (Joules/meter squared). Normally, this first involved assigning each subject to a Fitzpatrick Skin Type category. Depending on one's Fitzpatrick Skin Type (I through VI), there will be a different tendency to burn *vs* tan [21]. Therefore, assigning a subject a Fitzpatrick Skin Type determines the UVR dose to be applied to that person. For example, a typical UV dose for a Fitzpatrick Type I would be in the 150-300 J/m^2 range, whereas Fitzpatrick Type III would be in the 300-500 J/m^2 range. Neither the FDA nor the ISO methods allow for dark-skinned panelists, as is the case with Fitzpatrick Types IV-VI.

Studies have suggested that relying on subjects' recall of their personal experience with sun exposure is not a reliable means for assigning skin types [22, 23]. Therefore, a testing facility should not rely on a subject's personal experience with sun exposure. An experienced technician should determine the subject's skin type. For repeat subjects, the technician may rely on the subject's recorded history. As an alternative to the subjective Fitzpatrick Skin Type determination, labs are starting to use the Individual Typology Angle (ITA) method, which is an ISO 24444 (2019) requirement. ITA objectively assigns subjects a skin color typology [24,25]. The advantage of this method is the strong correlation between the objective ITA score and burn/suntanning potential [26,27].

The ISO method requires that the average ITA score of each sunscreen panel lie between 41 and 55, which roughly corresponds to a Fitzpatrick II phenotype. This is important because the risk of unprotected skin burning is not linearly proportional to the ITA score, as shown in ***Figures 4a*** and ***4b***.

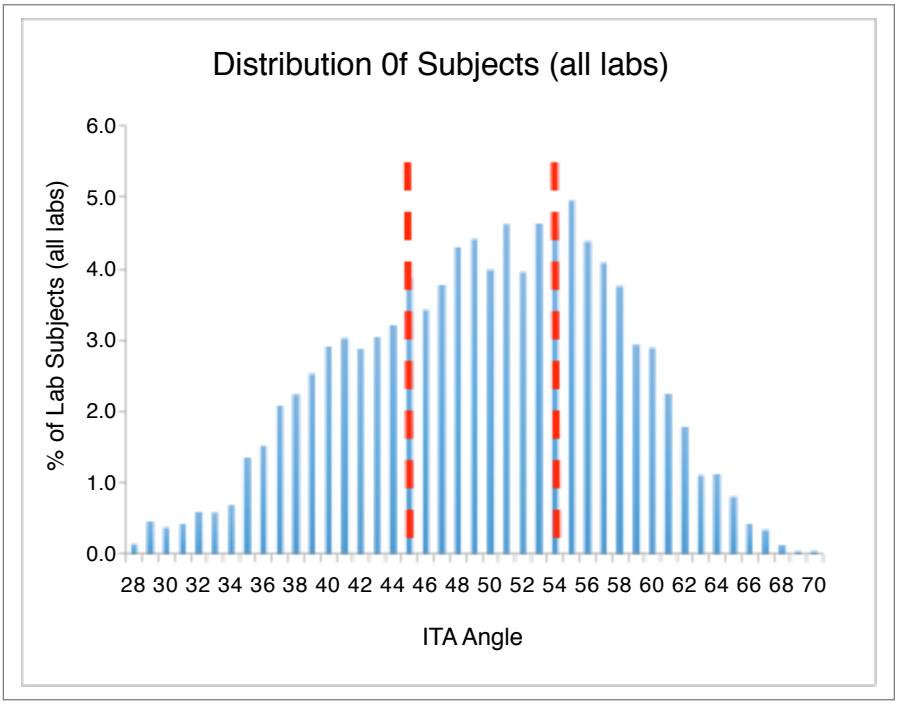


Figure 5: *Distribution of Individual Typology Angle (ITA) Scores, n=9931*

The fact that the potential for protected (*i.e.*, with sunscreen) skin to burn is linearly proportional points to the crucial need for the baseline MED to be as accurate as possible. In other words, the baseline MED is the primary driver of SPF. It should be noted here that while the FDA method still relies on Fitzpatrick self-reporting to recruit subjects, adherence to that standard also results in the acceptance of subjects with an average Fitzpatrick II score.

In his 2020 study (26), Curt Cole analyzed nearly 10,000 baseline MED's from 12 testing labs around the world and showed that most subjects fell in the mid-30s to the low 60s ITA range ***(Figure 5)***.

While there was some variability with respect to data distribution between sites (data not shown), you can clearly see that very few subjects fell into the extremely light range (ITA of > 60), meaning that all these labs should be able to efficiently recruit panels with light to light-moderate basal skin pigmentation (see ***Figure 6***) that fall within the 41-55 ITA range. Cole also showed that the average amount of UVR energy (in J/m^2) for the group with ITA scores of 41-55 is roughly 200. Finally, in that same study, he showed that 100 J/m^2 represents the typical 'low point' for a burn potential. The number of subjects with an MED below 100 J/m^2 is so low that it can be considered rare.

This information may be used as a tool to identify data fraud or errors. If the average baseline MED score in your study, regardless of the method, is significantly less than 150-200 J/m^2, then one needs to question the data! As stated previously, the baseline (untreated) MED is the primary driver of the data, so the most effective way to generate 'good numbers' is to start with very low baseline scores. Most laboratories provide this data with their reports, and it should be the first thing one should check when reviewing SPF data.

Other statistical anomalies

As stated, sunscreen tests are notoriously difficult to master, involving a unique combination of 'high tech' (lamp calibration and maintenance) and 'low tech' (product application, scoring erythema) elements.

As regards product application, most laboratories do not allow staff members to apply sunscreen until they have passed a rigorous qualification program demonstrating the ability to apply products evenly across the treatment area. This process should take several weeks of training and be investigated during a lab audit. Although technicians may be properly trained and have extensive experience, quality-conscious labs may still use UV photography to assess evenness. This is another audit checkpoint. Another 'manual' challenge is scoring erythema. Both the ISO and FDA guidelines dictate how scoring should be conducted. Still, there is inherent variability because

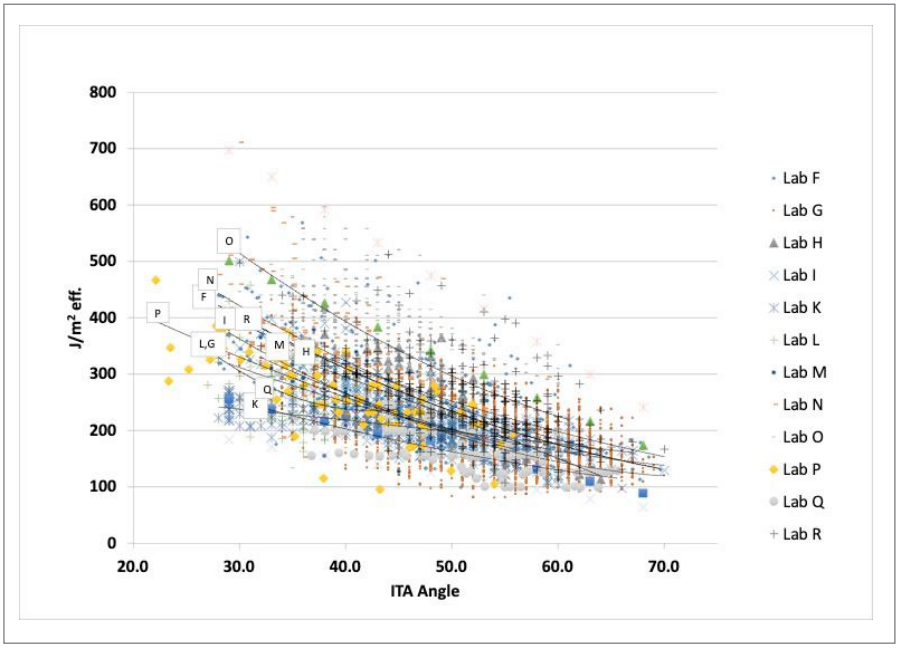


Figure 4: *Individual Typology Angle (ITA) Score Cluster Graph (Cole, 2020)*

both methods rely on human eyesight to make a scoring judgment and are therefore somewhat subjective. Credible labs minimize grading variability by establishing clear, consistent grading criteria and ensuring that all staff strictly follow these standards. From a practical standpoint, this involves both rigorous training of new graders and re-qualification of trained graders if there is evidence of 'drift'. The use of multiple trained graders is also a reasonable option for minimizing grader variability.

One of the reasons the FDA has repeatedly recommended placing upper limits on SPF labeling (*e.g.,* Proposed Rule; Testing and Labeling [11]) is the variability in SPF data. This variability is directly proportional to the target SPF. From a practical standpoint, as the Sponsor, you can leverage this knowledge by examining the variability (or lack thereof) of an SPF data table. As an example, for an SPF target of 50, you would expect a minimum standard deviation of the baseline to be at least 6-10%, and it is not unusual to see higher variability for high-performance products (SPFs ≥ 30). This is not to say that for a particular study, you might not be 'lucky' to have a lower standard deviation, but it would not be a typical result and should be questioned. This is especially true if an individual lab provides multiple studies exhibiting the same lack of typical variability.

However, it is not uncommon to see results from different labs that are notably different from one another. In fact, it is common to see ≥ 20% variability between labs. At least two studies have suggested that inter-lab variability can be even higher (≤ 50%) [28,10]. This fact can lead to an SPF label claim being challenged using data from another lab. There is no easy solution for such an outcome. However, risk can be managed to some extent by more conservative labeling (i.e., not applying the maximum possible number based on a single test) and/or by conducting multiple SPF assessments.

Any inter-lab variability exceeding 50% should be closely examined, as it is not readily explained by known factors (grading, subject, etc.), especially if one lab indicates the product achieved the target value while the other is far lower. Currently, most companies submit for SPF testing and provide a 'Target SPF' as a guide. The ONLY way to remove this confirmation bias is to submit samples for testing without a declared target SPF.

Every Sponsor should also be on alert for any data tables where there are an 'unusual' number of repeating scores (*e.g.,* 4+ subjects with the same baseline MED or post-Treatment values) and for post-treatment scores where every subject exceeds the target SPF. Again, it is within the realm of probability that, in a given study, unusual data distributions may be observed. Still, the likelihood that most subjects achieve identical baseline and/or post-treatment MEDs is remote at best and becomes even more so when observed across multiple studies.

Logistical and financial realities

Commercial laboratories that conduct sunscreen studies generally use a 'rolling' approach, in which subjects are recruited on a near-continuous basis, and products from multiple sponsors/clients are applied as shared panels. This approach means that it generally takes 2+ weeks to generate data for 5 subjects (i.e., preliminary screen), and this does not include any delays in the planning stage. The obvious takeaway is that every Sponsor should be suspicious of any lab that can turn around 5-subject data in a week or less, unless said Sponsor is paying extra for expedited results (*i.e.,* contractual terms). This is especially true during the late winter-early spring timeframe when many companies are developing their sunscreen for the following summer.

Sunscreen studies involve a cross-functional team (recruitment, lab techs, Principal Investigator, technical writers, and QA/QC), adequate infrastructure to conduct GCP projects, and costs for UV lamps, consumables, and test-subject remuneration. While the total cost for completing a 10-subject panel varies depending on several factors, every Sponsor should be suspicious of any laboratory that is markedly cheaper and/or provides a much quicker turnaround than comparable labs.

CONCLUSION

The cosmetic and personal product industries are highly competitive, and in recent years, this has led to an emphasis on speed-to-market while minimizing high costs. There was a time, not too long ago, when companies accepted the fact that it often took a few iterations before they achieved their target SPF label claims. This process can take several weeks and often becomes the primary factor affecting the product's release to the marketplace.

While that era has passed, every Sponsor company should still take ownership of its label claims, regardless of where tests are conducted. This is not only the right thing to do, but also the law. We hope that the reader leaves with an understanding of the challenge before us and commits to providing the most accurate SPF data possible.

Having incidents like those described above does a disservice to the industry by fostering mistrust. With special interest groups scrutinizing such products, a manufacturer cannot afford to be caught in an incident, as it may lead to public relations nightmares such as recalls, negative publicity, and legal action.

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Conflict Of Interest Statement

The viewpoints expressed in this paper are solely those of the authors and do not necessarily reflect those of any competent authority, industry organization, or our respective companies. The purpose of this article is to guide and inform the reader. The reader is encouraged to verify any opinions and facts the authors present.

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