行政院及所屬各機關出國報告

(出國類別：開會及研習)

赴日參加第七次化粧品法規國際會議及研習UVA防護力測定法

服務機關：行政院衛生署藥物食品檢驗局

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出國地區：日本

出國期間：中華民國九十二年十月二十日至十月三十一日

報告日期：中華民國九十三年一月三十一日

系統識別號：C09204794

公 務 出 國 報 告 提 要

頁數：35　含附件：否

報告名稱：赴日參加第七屆化粧品法規國際會議及研習 UVA 防護力測定法

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出國類別：開會 研究 實習
出國地區：日本
出國期間：民國 92 年 10 月 20 日-民國 92 年 10 月 31 日
報告日期：民國 91 年 1 月 31 日
分類號/目：J0/綜合(醫藥類)
關鍵詞：化粧品法規，UVA 防護力測定法，國際調和

內容摘要：此次奉派出國赴日參加第七次化粧品法規國際會議，以瞭解國際間化粧品法規現狀與國際調和趨勢，供本局未來化粧品行政管理與檢驗規範之參考；另順道學習日本化粧品工業連合會 JCIA 之 UVA 防護力測定法，建立國內 UVA 測定法之檢驗規範。

此次化粧品國際會議主要精神為國際間之「相互瞭解」，訂有五個議題：①化粧品工業未來展望，②化粧品聯盟擴大國家之法規一致化機制，③化粧品及原料之安全性，④化粧品法規之改正，⑤化粧品之調和成果。主要內容為化粧品以區域性聯盟國一致化模式，進行法規改訂及國際間之調和為未來趨勢；歐聯積極進行第七次修正化粧品法規，改正內容主要以非動物模式試驗取代動物試驗與其產品與原料之各項執行時間表、增加產品安全標示項目及加強提供消費者使用安全訊息，日本修正藥事法加強化粧品上市後安全性之規範；目前國際間進行一致化議題有化粧品微生物方法指導方針、SPF 的國際調和與化粧品成分標示等。

在日本資生堂新橫濱研究中心，學習 UVA 防護力測定法，學習內容從理論說明比較 UVB 與 UVA 差異，受試者塗抹皮膚之技巧與光源儀器操作校正，黑化反應之判讀，PFA 值計算，及國際間常用之 UVA 防護力測定法介紹等。目前因 UVA 防護力測定法多達九種，且美國 FDA 正評估而尚未正式公告，故仍未達成國際調和結果，此行赴日研習之 UVA 防護力測定法，擬將整合 UVA 與其 UVB 方法，建立我國化粧品防曬劑之有效性試驗方法，並供我國未來制定 UVA 防護力測定法之參考依據。

摘　要

此次奉派出國赴日參加第七次化粧品法規國際會議，以瞭解國際間化粧品法規現狀與國際調和趨勢，供本局未來化粧品行政管理與檢驗規範之參考；另順道學習日本化粧品工業連合會 JCIA 之 UVA 防護力測定法，建立國內 UVA 測定法之檢驗規範。

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在日本資生堂新橫濱研究中心，學習 UVA 防護力測定法，學習內容從理論說明比較 UVB 與 UVA 差異，受試者塗抹皮膚之技巧與光源儀器操作校正，黑化反應之判讀，PFA 值計算，及國際間常用之 UVA 防護力測定法介紹等。目前因 UVA 防護力測定法多達九種，且美國 FDA 正評估而尚未正式公告，故仍未達成國際調和結果，此行赴日研習之 UVA 防護力測定法，擬將整合 UVA 與其 UVB 方法，建立我國化粧品防曬劑之有效性試驗方法，並供我國未來制定 UVA 防護力測定法之參考依據。

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壹、前言與目的

化粧品為國際化產品，各國間對化粧品之管理有明訂規章與檢驗規範；為了能促進化粧品產業經濟發展為目的及適應WTO開放市場後之壓力，近年來，世界三大化粧品主體歐、美、日積極進行法規修正與調和會議，並且每三年一次舉辦國際會議，說明各國間調和現況與成果，希望藉由國際間之交流與國際一致化結果，使化粧品產業流通世界化。為能與國際接軌，瞭解國際間化粧品法規現狀與國際調和趨勢，特參加在 2003 年 10 月，由日本化粧品工業連合會舉辦之第七次化粧品法規國際會議，會議中之一致化內容與結果，將供本局未來化粧品行政管理與檢驗規範之參考。

過度曝曬陽光會造成皮膚傷害及病變，民眾除了要加強防止受陽光照射及遵守 ABC 防曬防護措施外，塗抹防曬化粧品為目前最有效防曬方法之一。化粧品防曬劑之有效性試驗方法 UVB 防曬係數與 UVA 防護力測定法，為目前國際間進行一致化之主要議題；UVB 防曬係數測定法歐聯與日本均已達成調和，其測定方法亦經研習會推廣於國內化粧品業者。目前 UVA 防護力之表示法 PA^{+}、PA^{++}、PA^{+++}為日本制定並廣為化粧品產品採用之方法，為建立我國 UVA 防護力測定法，並整合我國化粧品防曬劑之有效性試驗規範，此行日本參加國際會議後，順道前往資生堂化粧品研究中心學習 UVA 防護力測定法，供我國未來制定 UVA 防護力測定法之參考依據。

貳、開會與研習行程

日期	行程內容
10 月 20 日	起程(台北至於東京)
10 月 21 日	參加第七回化粧品法規國際會議
10 月 22 日	參加第七回化粧品法規國際會議
10 月 23 日	佳麗寶化粧品工廠觀摩 UVA 防護力測定法
10 月 24 日	參觀 DHC 化粧品工廠
10 月 25 日	資料整理
10 月 26 日	資料整理
10 月 27 日	新橫濱資生堂研究中心
10 月 28 日	新橫濱資生堂研究中心
10 月 29 日	新橫濱資生堂研究中心
10 月 30 日	資料整理
10 月 31 日	返程(抵達台灣)

參、開會與研習內容

此行日本參加日本化粧品工業連合會在台場舉辦的第七回化粧品法規國際會議，會後，承蒙日本化粧品工業連合會與台灣資生堂安排，前往佳麗寶化粧品工廠觀摩 UVA 防護力測定法，及參觀 DHC 化粧品工廠。

一、參加第七回化粧品法規國際會議 –10 月 21 日至 22 日

1. 議題一：化粧品工業未來發展

   日本代表以化粧品工業界今日與明日之任務為主題，柔性地說明日本化粧品產業是以共存共榮，相互和平，為調和作努力；歐盟與美國則分別以化粧品經濟發展為題，提出歐盟在改正法規環境下，化粧品產業市場的影響；美國以目前化粧品產業市場經濟效益狀況分析及對未來五來的市場預測，其中指出皮膚保養類(skin care)市場佔有率最大，P&G 公司銷售佔全美第一，未來五年化粧品市場將以皮膚保養與彩粧類為主流。

2. 議題二：化粧品聯盟擴大國家之法規一致化機制

   隨著 WTO 市場開放，除了歐、美、日三大主體佔有世界化粧品市場外，其他如拉丁美洲(巴西、阿根廷、烏拉圭、哥倫比亞、智利、厄瓜多爾、)、東南亞協國(印尼、馬來西亞、菲律賓、泰國、新加坡)，都採聯盟國方式進行化粧品法規一致化，再以這種區域性聯盟方式進行國際間調和會談。

拉丁美洲：在2003年由6國擴充至16國，主要調和目標有拉丁美洲國間之相互認可登記制度，包括化粧品色素劑、防腐劑、限量與禁用成分之一致化，安全性指導方針之一致化，使用 INCI 標示法，以及與國際進行一致化工作。

東南亞協：由原來5個增加至10個國家形成東南亞協國化粧品協會 ASEAN COSMETICS ASSOCIATION，第一階段主要工作為確保化粧品使用之安全與排除貿易障礙，進行產品相互認可程序，並訂定至 2008 年完成，第二階段進行法規鬆綁之改正，主要依據歐盟法規規定，將在 2008 年執行。未來更朝與國際法規系統一致化。

歐盟國家：歐聯國家現在共有15國，在2004年5月1日將有10個東歐國家加入，至2007年再增加羅馬尼亞與保佳利亞兩個國家後，將共有 27 個聯合歐盟組織。加入聯盟之東歐國家首要改正上市前產品查驗系統，訂定9年緩衝時間與歐聯之法規一致化，這些程序之執行與法規之一致化工作，全由歐洲化粧品香粧協會 COLIPA 主導。

3. 議題三：化粧品與原料之安全性

為保護消費者使用化粧品之安全性，歐美均有建立評估安全性機制之方式，會議中美國提出化粧品原料安全性評估，歐聯則以非動物模式試驗方法，建立化粧品之安全性。

美國：美國 FDA 對化粧品產品及成分之安全性評估方式，係先選擇經由報告對消費者人體有害成分，或已由 The Cosmetic Ingredient Review (CIR)學者檢閱上千種化粧品成分或產品，經評估需作安全性者，由聯邦政府和合約實驗室例如 National Toxicology Program Testing (NTP testing)，針對有害成分做：toxicology, carcinogenicity, photogenecity 等毒性試驗，報告結果會再經由科學會議討論(scientific meeting review)作成建議，若是對人體會產生致癌結果，FDA 持謹慎態度將再轉由屬於州政府之實驗室 California's Proposition 65，針對成分作各種化學成分試驗後，再作成最終結果與建議。以果酸 AHAs 舉例，美國 FDA 在 1998 先由 NTP testing，比較 10% 果酸與不含 10% 果酸(pH 3.5)對皮膚作用差異，兩者結果對 skin 都沒有傷害，但使用果酸後，反而會增加對紫外線的敏感性，所以 FDA 繼續在 California's Proposition 65 作紫外線光過敏性試驗 (sun-photosensitization test)，報告在 1999 年作出結論，並在 FDA/COSMETICS 網站上公布。其他 acrylamide、DEA 及 TEA、染髮劑、Licorice、奈米氧化鋅、paraben 類、phthalate、pyrocatechol、triclosan、zinc pyrithione 等成分也都列入安全性評估名單中。

歐聯：歐聯在第七次法規修正內容中，執行對於新成分化粧品及新新法之化粧品，其安全性要以非動物模式試驗取代動物試驗。早在 1992 年開始，COLIPA 即透過「動物試驗替代法指導委員會」(SCAAT)與歐洲化粧品業之科學家、學者、政府實驗室與合作，致力於動物試驗替代方法之研發，目前已有 4 種經確認作為安全性評估之動物試驗替代方法，包括皮膚腐蝕性(skin corrosion)、皮膚吸收性(skin absorption)、光毒性(phototoxicity)，以及光誘變性(photomutagenicity)等。同時 SCAAT 於 2001-2004 年期間的 R&D 計畫中，也針對眼睛刺激性(eye irritation)、皮膚敏感性(skin sensitisation)及皮膚刺激性(skin irritation)等，進行替代方法之研發，2004 年時這些方法將導向確效(validation)前之階段。研發之替代方法將由政府實驗室-歐洲替代方法確效中心(European Center for the Validation of Alternative Methods, ECVAM)進行確效試驗，是否使用替代方法採取減少(reduction)、改良(refinement)、取代(replacement)3R 法則，最後再由歐聯收載為指導方針。目前進行確效替代方法結果如下表所示：

The current regulatory testing status of alternative methods (based on the Three Rs – reduction, refinement, replacement) for key human health endpoints is summarised in the following table:

Type of test / endpoint	Status	Test Method / Guideline for alternative method*
Acute toxicity	reduction & refinement alternatives (FDP[1], ATC[1], UDP[1]) in use; ICCVAM - ECVAM validation study in progress (probable outcome – partial replacement); R&D[1] (basic research on *in vitro* systems)	B1bis, B1tris (EU) / TG 420, 423, 425 (OECD)
Skin irritation	R&D (basic research on *in vitro* systems); ECVAM validation study to start during 2004 (probable outcome – partial replacement)	
Skin corrosion	validated (ECVAM); accepted by OECD	B40 (EU) / TG 430, 431 (OECD)
Eye irritation	refinement alternative (rabbit LVET[1]) available but not widely used; existing *in vitro* methods not formally validated - used as in-house screens (partial replacement) and for identification of severe eye irritants; R&D (basic research on *in vitro* systems)	
Skin sensitisation	reduction & refinement alternative (mouse LLNA[1]) validated and accepted by OECD; R&D on-going for replacement alternative(s)	TG429 (OECD) / B42 (EU)
Phototoxicity	validated (ECVAM); accepted by OECD	B41 (EU) / TG432 (OECD)
Skin absorption	*in vitro* methods considered to be valid (no formal validation study conducted); R&D on-going (repeat exposure)	TG428 (OECD)
Sub-chronic toxicity (repeated dose)	R&D (basic research on target organ toxicity and repeat dosing *in vitro*)	
Mutagenicity	*in vitro* methods used routinely, but not specifically as alternatives to animal testing (part of accepted testing strategy); validity of *in vitro* micronucleus assay under review	
Photomutagenicity	no standard animal test protocol / guideline; *in vitro* assays considered to be valid and used when appropriate (hazard identification)	
Toxicokinetics	R&D (basic research on *in vitro* assays and kinetic modelling)	
Teratogenicity	*in vitro* screens (partial replacement) for embryotoxicity have been validated (ECVAM); R&D (basic research on *in vitro* systems)	
Reproductive toxicity	R&D (basic research on *in vitro* systems)	
Carcinogenicity	R&D (basic research on *in vitro* systems); validity of *in vitro* cell transformation assay under review, but would not replace rodent bioassays	

*Three Rs definition of alternatives

[1]LVET = low volume eye test; R&D = research & development; LLNA = local lymph node assay; FDP = fixed dose procedure; ATC = acute toxic class method; UDP = up and down procedure

4. 議題四：化粧品法規之改正

日本為因應未來國際一致化趨勢，及為達全球化化粧品市場與排除非貿易障礙的前提下，對化粧品管理政策做了修正，包括免除上市前查驗登記系統、成分之表示法以及產品實施全成分標示；2002 年 7 月所公佈之藥事法修正內容當中針對化粧品上市後安全性之規範，包括將製造販賣行為從現行製造業中加以分離，亦即由現行製造業中分離製造販賣行為及引進製造販賣承認制度之架構。化粧品製造販賣業者需確保製品之品質，並符合製造販賣品質保証基準(GQP) 之規範。另外，製造販賣業者亦必須進行製造販賣後之安全管理，並符合製造販賣後安全管理基準(GVP) 之規範。並為使化粧品製造販賣業者進行品質管理以及製造販賣後之安全管理，必須令其設置符合所訂立資格要件之製造販賣總括負責人，該總括負責人必須負責品質保証責任者及安全管理責任者之指揮、市售商品之品質保證、安全管理之業務等責任。

歐盟對歐聯化粧品法規及化學製品之規範(Registration, Evaluation and Authorization of Chemicals; REACH)，決定做第七回修正，其內容包括禁止成分及最終產品之動物試驗、自發性聲明“非經由動物試驗”、香精過敏原之標示及開封後之保存時間等，其中，自2004

年9月11日起，全面禁止最終產品及樣品之動物試驗，自2009年3月11日起，禁止成分之動物試驗，但重複劑量毒性、生殖系統毒性及毒性動力學等三類動物試驗，可延至2013年3月。

5. 議題五：化粧品國際調和成果

目前進行化粧品國際一致化內容有：①化粧品微生物方法指導方針，②SPF 的國際調和，③化粧品成分標示，其結果分述如下：

1. 化粧品微生物方法指導方針

美國 CTFA、歐聯 COLIPA 與日本 JCIA 對化粧品產品均各有建立微生物方法指導針，其微生物限量規定比較如下表所示：

國家	微生物限量	調合現況
美國	1.嬰兒及眼睛區域用產品： 不可多於 100cfu/g(mL)~500 cfu/g(mL) 2.其他產品： 不可多於 1000cfu/g(mL)~5000 cfu/g(mL) 3.無任何微生物含量被確認為有害	美國鼓勵 ISO 將 CTFA 方法列為規範。ISO 正進行建立 ISO TC 217 微生物方法供各國採用
歐聯	1.嬰兒及眼睛區域用產品： 不可多於 100cfu/g(mL) 2.其他產品： 不可多於 1000cfu/g(mL) 3.無任何 S. aureus、P. aeruginosa、	微生物限量調和與 CTFA 一致

	C. ablicans 被確認為病原菌 4.含 aerobic mesophilic 微生物之限量 嬰兒及眼睛區域用產品： 不可多於 100cfu/g(mL)~500 cfu/g(mL) 其他產品： 不可多於 1000cfu/g(mL)~5000 cfu/g(mL)	
日本	1.Viable count method： 確認 bacteria 及 eumycetes 數量， 方法採 pour plate, spread plate, membrance filter method 2.Specified microorganism method 確認特殊細菌包括：E. coli、P. aeruginosa、S. aureus、Salmonella、Enterococcus	現行之化粧品產品進行 bacteria 及 fungi 兩項微生物限量測定

另外，未來仍需繼續進行調和內容包括防腐劑有效性測試之必要性及其準則、微生物限制之必要性及其準則及在無微生物限制之前提下是否能達成微生物之管控等。

2. SPF的國際調和

關於國際間SPF測試標準之一致化方面，自1990年起即陸續被提出，並開始進行國際間之調和會議，目前包括日本、歐聯與南非已於2002年10月已達成一致化成果；美國FDA目前因正針對各種UVA防護力檢測方法進行評估，預計在2005年初將UVA與UVB檢測方法一併公布，故目前仍採1999年5月21日所公布之防曬產品最終規範。

3.化粧品成分標示

實施產品全成分標示，使成分命名一致化，有助於化粧品在各國間流通，一般均採INCI命名法。我國已於2001年11月5日公告化粧品產品需以全成分標示，並於2002年5月5日實施。下表列出各國實施成分標示比較：

Cosmetic Ingredient-Labeling Status in the World		
cosmetic ingredient-labeling method	Number of countries	Representative countries
all-ingredient labeling with INCI nomenclature	32	USA, EU, Astralia, Brazil, Taiwan, etc.
all-ingredient labeling with INCI nomenclature translated into own language	5	Japan, Mexico, Russia etc.
all-ingredient labeling in own language	4	Columbia, Honduras, Nigeria, etc.
Labeling of specific ingredients	13	China, Korea, Peru, Vietnam, etc.
no obligation to label ingredients	18	Canada, Egypt, India, Panama, etc.

茲將我國目前法規現狀與歐美日國調和比較如下表所示：

	我國	美國	歐聯	日本
製造與輸入上市前查驗登記	含藥化粧品上市前查驗登記	取消查驗登記(自由報備)	取消查驗登記(收載製造廠)	取消查驗登記(銷售商品報備)
微生物試驗方法指導方針	尚未建立	有指導方針	有指導方針	有指導方針
UVA 防護力測定法	尚未建立	預定2005年公告	未公告	有公告基準(1996)
UVB 防曬係數測定法	有建立未公告	預定2005年公告	已與日本達成調和	已與歐聯達成調和
安全性試驗	動物試驗	動物試驗	非動物模式	動物試驗
產品全成分標示	全成分標示(2002.5.5)	全成分標示	全成分標示	全成分標示(2002.9)

二、佳麗寶化粧品工廠觀摩 UVA 防護力測定法– 10 月 23 日

佳麗寶化粧品工廠位於神奈川縣內小田原，從東京搭新幹線約 1 時 20 分鐘車程，由佳麗寶化粧品事業本部部長增田和久先生帶領我們觀摩 UVA 防護力試驗。佳麗寶化粧品研究中心分有 6 個研究部門：①企劃部門②安全性評估部門③分析部門④產品評估部門⑤開發部門⑥基礎研究部門。由研究所領導人四宮達郎先生，帶領我們在基礎研究部門的模擬天氣溫度的房間內，觀摩 UVA 防護力試驗操作過程；從產品取樣、塗抹受試者、照設 UVA 紫外線、照射後之黑化反應觀察與判定。佳麗寶研究中心對防曬試驗人體之姿勢，採背躺非坐式，讓受試者與操作試驗者免於等待照射時間而感到疲倦，非常體貼的改良，值得我們學習。

三、參觀 DHC 化粧品工廠 – 10 月 24 日

DHC 化粧品公司之「DHC」源自於日本「大學翻譯中心」(DAIGAKU HONYAKU CENTER)，1972 年最初以從事翻譯事業為主，擴展事業做更多元化的延伸後，有化粧品事業部門；DHC 在日本有七家工廠，銷售主要走天然化粧品，透過通信販賣管道，在日本業績急速成長，1999 年台灣分公司成立，採郵購方式購買，佔化粧品郵購市場首位。此行日本順道參觀 DHC 位於東京本社及横濱區的工廠，DHC 公司發展之化粧品全由該社隆夫博士負責，我們除了參觀本社區新穎的實驗室設備外，與隆夫博士進行製造與檢驗的經驗交流，對該公司以天然化粧品生產走向，有更深一層的瞭解。下午，驅

車費時約 1 小時前往橫濱市的兵庫工廠，該工廠相當新且有 GMP 工廠規模與規範，參觀現場正在製造皮膚保養、睫毛膏、面霜、手霜等半成品，工廠線上採一貫作業自動充填，人工包裝後再送物流中心，相當有規模。

四、新橫濱資生堂研究中心研習 －10 月 27 日至 29 日

(一).日本 UVA 防護力測定法簡介 -- 10 月 27 日

日本 UVA 防護力測定法，從 1986 年資生堂化粧品公司開始標示 3A「A, AA, AAA」，表示對抗 UVA 紫外線之能力，從此後，日本國內其他公司競相出現不同 UVA 表示法，致當時無法統合 UVA 防護力之標示法；日本化粧品工業連合會紫外線專門委員會，於 1992 年 UVB 防曬係數基準法正式定案後，即開始檢討 UVA 防護力測定法及其標示法之一致性，經過幾年努力與研究，終於整合方法與其標示法，在 1995 年 11 月 15 日訂定基準並編印成冊發行，1996 年 UVA 防護力測定法之基準正式生效，茲將內容摘取見**附錄一**。

(二).日本 UVA 防護力測定法內容：

1. 試驗前試驗者之質問書。
2. UVA 標準試料。
3. 防曬產品之人體試驗。
4. 人體試驗結果判讀。
5. UVA 表示法之統計運算。

(三).UVA 標準試料

日本測定 UVA 防護力之標準試料係自行製作，其使用之處方原料與製作步驟如下所示：

Standard Sample

		Wt%
A1	Purified Water	57.13
A2	Dipropylene Glycol	5.00
A3	Potassium Hydroxide	0.12
A4	Trisodium Edetate	0.05
A5	Phenoxyethanol	0.3
B1	Stearic Acid	3.0
B2	Glyceryl Monostearate, Selfemulsifying	3.0
B3	Cetostearyl Alcohol	5.0
B4	Petrolatum	3.0
B5	Glyceryl Tri-2-ethylhexanoate	15.0
B6	2-Ethylhexyl p-Methoxycinnamate	3.0
B7	4-tert-Butyl 4'-Methoxydibenzoylmethane	5.0
B8	Ethyl Parahydroxybenzoate	0.2
B9	Methyl Parahydroxybenzoate	0.2
	Total	100.00

製造步驟：

精確稱取 A1~A5 之成分，溶於純水中，加熱至 70°C。再精確稱取 B1~B9 之成分，溶於純水中，加熱至 70°C 使完全溶解。再於乳化機下將 B 部份加入 A 中，使乳化完成，冷卻即得標準試料。

(四).人體試驗前之準備

1. 人體試驗前試驗者之質問書

參加 UVA 試驗之受試者要先進行問卷調查，查詢是否對光、藥物過敏等，另外，問卷決定皮膚型態，UVA 試驗之受試者為 II、III、IV 三種型態，最後，參加之受試者需簽署同意書。

2. 太陽光模擬裝置與其光源校正

太陽光模擬裝置應符合 UVA 吸收波長範圍，UVA I (340-400nm)與 UVA II (320-340nm)比例應接近於太陽光, UVA II/ UVA I = 8-20%；濾光鏡採 335nm, 光源定期每年以 spectrometer 校正一次。

3. 塗抹皮膚技術與投予量

至少 20cm^2(5cm x 4cm)以上的皮膚面積，均勻塗抹 2mg/ cm^2 防曬產品，塗抹後等待 15 分鐘，以太陽光模擬器照射塗抹處；未塗抹處以太陽光模擬器照射，得到之最小持續型黑化劑量值(Minimal Persistent Pigment Darkening Dose, MPPD)。

(五).人體試驗實作 －10 月 28 日

今天有一位男性受試者進行人體試驗，標準試料 PFA 3.75，未知防曬產品兩種 PFA 範圍約 3~4、8~10，以機械照射強度範圍 5.4~1.78J/cm^2/min 調整六種強度，每個強度間以 1.25%比例增加，未塗抹皮膚處照射時間設定為 4 分 21 秒 (依經驗決定，可能因人而改變)，故塗抹產品之六個皮膚處之照射量為照射強度乘上 4.21 (J/cm^2)。實驗開始前，先在受試者背部畫出 6cm x 5cm 之區域，共四區域供作 MPPD、標準試料、產品 1、產品 2 試驗用；除 MPPD 測定處外，每固定區域塗抹 60mg 之標準試料與防曬產品，塗完 15 分鐘後，即刻進行紫外線照射。照射完後即刻觀察「即時黑化」並記錄 0 時間之黑化落點；接著，每間隔 1 個小時觀察持續型黑化變化及黑化陽性落點，記錄至 4 小時為止。

(六).人體試驗結果判讀

判讀受試者黑化反應落點，需要至少 2 位以上有經驗者判讀，判讀之技巧在於觀察背部照射處產生黑化之

面積為總面積之 2/3 以上即是陽性。一般以「－」、「±」、「＋」、「++」、「+++」分級，「－」為陰性，其餘為陽性，「±」為陽性起點值。將黑化反應陽性之落點劑量記錄，以供計算產品之 PFA 值。

(七).PFA 統計運算 －10 月 29 日

計算 PFA 值之規定：

1. 在試驗部位決定未塗抹處之 MPPD、標準試料及未知防曬產品之 MPPD。
2. 判斷數據是否可取用。
3. 依公式計算個人之 PFA 值：

   $PFA_I = MPPD_I$ treated / $MPPD_I$ untreated
4. 判斷標準試料之PFA是否在規定範圍內(3.75±1.01)。
5. 計算平均值、標準偏差、95% C.I.統計量

   $PFA=PFA_1+PFA_2+PFA_3+.....PFA_n/n$(n=10 或以上)
6. 標準偏差應落在於 10%之內，若超過則試驗人數需增加或重新再試驗。

利用觀察之MPPD值計算防曬產品之PFA值，一般PFA值之規定為：PFA 2 至 4 但小於 4 者，標示 PA^+，

PFA 4 至 8 但小於 8 者，標示 PA^{++}，

PFA 大於 8 者，標示 PA^{+++} 。

將人體試驗結果紀錄如下表：

	照射強度	5.4	4.32	3.46	2.77	2.22	1.78
未塗抹結果	照射量(4'21")	23.49	18.8	15.0	12.0	9.66	7.74
	照射後黑化反應	++	++	++	++	++	++
	照射 2.5 小時後之黑化反應	±	±	± MPPD	−	−	−
產品1	照射量(13'03")	70.5	56.4	45.0	36.0	29.0	23.2
	照射後黑化反應	++	++	++	+	+	+
	照射 2 小時後之黑化反應	±	±	±	±	−	−
	照射 3 小時後之黑化反應	±	±	±	± MPPD	−	−
					PFA= 2.4 PA^+		
產品2	照射量(26'06")	141	112	90	72	58	46.4
	照射後黑化反應	++	++	++	++	++	++
	照射 1.5 小時後之黑化反應	±	±	±	±	±	±
	照射 2.5 小時後之黑化反應	+	+	±	±	± MPPD	−
						PFA= 3.9 PA^+	

肆、心得

(1).日本民間組織化粧品工業連合會JCIA承辦此次化粧品法規國際會議，國際間化粧品業務交流主要亦經由非政府機構推動，例如，美國化粧品香粧學會CTFA、歐聯的化粧品香粧學會COLIPA。除配合政府執行化粧品法令與協助檢驗研究外，能有效地協調化粧品業者間意見與國際間情報訊息交換，為政府機關推動政策之好伙伴。

(2).化粧品為國際化產品，以區域性聯盟國一致化之模式進行國際間調和為未來趨勢。目前除美國、歐聯及日本三大主體外，歐盟在2007年將由現有的15國擴增至27國，另外，拉丁美洲(CASIC) 6國、東南亞協(ASEAN) 5國，也將形成聯盟國之方式進行國際間調和會談。

(3).以保護消費者使用化粧品安全為目的，歐聯排除萬難地進行第七次修正化粧品法規，改正內容主要以非動物模式試驗取代動物試驗與其產品與原料之各項執行時間表、增加產品安全標示項目及加強提供消費者使用安全訊息。

(4).第二次前往日本資生堂新橫濱研究中心，學習UVA防護力測定法，承蒙日本化粧品工業連合會紫外線專門委員長福田 實博士親自指導，並由人體試驗經驗豐富之長沼雅子部長實際演練，從理論說明比較UVB與UVA差異，受試者塗抹皮膚之技巧與光源儀器操作校正，黑化反應之判讀，PFA 值計算與其每一步驟之應注意點，都非常仔細指導，除了互相討論交流經驗與技術外，更能體會他們在化粧品領域研究上之用心，值得我們學習。

(5).UVA 防護力檢測方法以體外及體內區分共多達九種，各國採認方法不同，體外方法快速又便宜，但與體內結果無法關聯；體內方法花費高、曝露高劑量 UVA，且因不易判讀反應終點或可能引發皮膚癌之慮，故目前 UVA 防護力測定法尚無法進行國際一致化，美國 FDA 亦正針對各種 UVA 防護力檢測方法進行評估，預計在 2005 年初將 UVA 與 UVB 檢測方法一併公布。

伍、建議

(1).為與國際化接軌，除熟稔並掌握各國間化粧品法規外，應主動積極參與國際會議或調和會議，瞭解國際一致化發展趨勢，作為未來我國化粧品管理參考。

(2).歐聯為加強消費者使用化粧品之安全，積極進行非動物模式試驗方法之建立，其先循在國會立法下，訂定漸進式時間表，與學者、業界及政府合作模式合力要完成這艱巨任務；美國 FDA 對化粧品產品或成分之安全性評估，亦採與民間實驗室與政府雙重軌道下進行，歐美等國評估安全性機制之方式，可供我國未來建立安全性風險評估管理之導向。

(3).目前國際間進行化粧品微生物方法指導方針、SPF 的國際調和與化粧品成分標示等之一致化內容結果，我國除了 SPF 的國際調和與化粧品成分標示要求尚能符合調和趨勢外，化粧品微生物方法尚未建立，為因應未來國際間一致化結果，應及早彙整並規劃制定指導方針。

(4).化粧品防曬劑之有效性試驗方法-UVB 防曬係數與 UVA 防護力測定法，為目前國際間進行一致化之主要議題；UVB 防曬係數測定法歐聯與日本均已達成調和，其測定方法亦經研習會推廣於國內化粧品業者。此次赴日研習 UVA 防護力測定法，將整合並建立我國化粧品防曬劑之有效性試驗方法，並供我國未來制定 UVA 防護力測定法之參考依據。

(5).各國間以非政府機構成立之粧品協會模式，推動進行化粧品法規一致化或擴展進入國際間互動的方式，使政府在推動政策執行面有實質幫助，對國內化粧品業者應予鼓勵，以結合民間力量參與國際會議進行國際交流，有助於我國未來化粧品業務推展與政策推動。

附錄一

日本 UVA 防護力測定法

Japan Cosmetic Industry Association

Measurement Standards for UVA Protection Efficacy

Nov. 15, 1995

Japan Cosmetic Industry Association

Introduction

The damaging effects of UV rays on the skin have become widely recognized by consumers, and there have been reports in the media warning of increases in the level of UV rays due to environmental pollution. This has resulted in the appearance of many "Cosmetics with UV Protection" on the market. These products protect the skin by reducing or blocking the effects of UV rays.

Cosmetics with UV Protection can be roughly divided into two groups. One is "Suntan Cosmetics" which are used for the purpose of obtaining a beautifully suntanned complexion while limiting the effects of UV rays on the skin to a minimum, the other is "Sunscreen Cosmetics" which are used for the purpose of preventing Sunburn and Suntan.

UV rays that reach the surface of the earth can be divided into the A region of UV light (UVA: 320-400 nm) and the B region of UV light (UVB: 280-320 nm), and these two types of UV rays have different effects on the skin. UVB causes erythema of the skin several hours after exposure, and several days after exposure to UVB may lead to increased pigmentation, dryness and scale. UVA causes darkening of the skin immediately after exposure (immediate pigment darkening) and in the event of exposure to large amounts of UVA, this darkening appears to be transformed to delayed pigment darkening. There are also reports that UVA increases sensitivity of the skin to UVB. In addition to these acute responses, UV rays contribute to skin cancer and to aging of the skin typified by blotches and wrinkles. The relative contributions of UVB and UVA to these various reactions are not known, but the effects of the deep penetration of UVA rays cannot be ignored.

Under these circumstances, the expression "UV Protection" (in product claims) is not always adequate, so there is a need to clarify whether a product protects against UVA or UVB, and to what extent it protects against each.

At present, Sun Protection Factor (SPF) is recognized throughout the world as an index of the protection against UVB provided by Cosmetics with UV Protection. The SPF value is determined in accordance with the Japan Cosmetic Industry Association SPF Measurement Standards (Effective from January 1992) in Japan, in accordance with COLIPA regulations (October 1994) in Europe, and in accordance with FDA regulations (Tentative Final Monograph, May 1993) in the U.S.. Because these methods are quite similar, their SPF values are roughly comparable even though a uniform method is not employed worldwide. Throughout the world the SPF value acts as an index that consumers use in product selection.

With respect to an index or measurement methods for UVA protection, however, a uniform measurement method has not yet been established on a national or industry-wide level although several papers on the subject have been published, and studies are underway in various countries. Throughout the world there are products displaying numerical values, etc., for UVA protection, but because there is particular concern that a uniform measurement method has not been established in

Japan and these numerical values may cause confusion among consumers in their product selection, it has been decided not to employ some types of index to list the level of UVA protection on cosmetic products.

Therefore, for the purpose of establishing a method for measuring UVA protection, the Technical Committee of the Japan Cosmetic Industry Association reorganized its previous SPF task force in November 1992 and established the Ultra Violet task force. This task force has handled the basic research project on UV protection approved and sponsored by the Japan Human Sciences Foundation and has compiled its results in this document.

The fundamental principles toward the standard are described below:

(1) The standard is intended to provide uniform measurement method of PFA (Protection Factor of UVA) values and labeling method for the grade of UVA protection on sunscreen and suntan cosmetics enable consumers to select products which meet consumers' desired UV light protection efficacy.

(2) The standard shall go into effect on January 1, 1996.

(3) The standard shall be reviewed when new technological findings warrant it.

The standard consist of "I. Measurement Method of UVA Protection efficacy," listing itemized measurement conditions and "II. Annotation " providing practical points carry out tests using this method.

I. PFA Measurement Method

1. Selection of Test Subjects and Test Sites (Annotation 1)

(1) Subjects must be healthy males and females at least 18 years old and belong to Skin Type II, III or IV mentioned below.

Subjects must be asked of their physical conditions and must be excluded if they have photodermatitis or take medicine (such as anti-inflammative agent, antihypertensive agent etc.) relating to skin's photosensitivity.

Skin Type:	I	Always burns easily; never tans
	II	Always burns easily; tans minimally
	III	Burns moderately; tans gradually
	IV	Burns minimally; always tans well
	V	Rarely burns; tans profusely
	VI	Never burns; deeply pigmented

The skin types are classified based on the typical skin reactions to 30 to 45 minutes sun bathing after a winter season of no sun exposure.

(2) Test site is the back, and the skin must have almost uniform color without pigmentation, nevus and so forth.

2. Number of Subjects (Annotation 2)

Each test must be performed with at least 10 subjects and the starndard error for measuring PFA shall not exceed 10% of obtained PFA value.

3. Standard Sample (Annotation 3)

The standard sample shall be prepared according to the formula described below. Measurement of the standard sample shall be performed concurrently with the measurement of the test sample.

Formula and Preparation method of the Standard sample (a cream containing 5% 4 -tert-Butyl-4'-Methoxydibenzoylmethane and 3% 2-Ethylhexyl p-Methoxycinnamate).

		% by Weight
A1	Purified Water	57.13
A2	Dipropylene Glycol	5.00
A3	Potassium Hydroxide	0.12
A4	Trisodium Edetate	0.05
A5	Phenoxyethanol	0.3
B1	Stearic Acid	3.0
B2	Glyceryl Monostearate, Selfemulsifying	3.0
B3	Cetostearyl Alcohol	5.0
B4	Petrolatum	3.0
B5	Glyceryl Tri-2-ethylhexanoate	15.0
B6	2-Ethylhexyl p-Methoxycinnamate	3.0
B7	4-tert-Butyl-4'-Methoxydibenzoylmethane	5.0
B8	Ethyl Parahydroxybenzoate	0.2
B9	Methyl Parahydroxybenzoate	0.2

Weigh out each of the ingredients in A, dissolve them in the purified water, and heat the solution to 70℃.

Weigh out each of the ingredients in B and heat them to 70℃ so that they dissolve completely.

Add B to A, emulsify the mixture, and adjust the size of the emulsified particles with a homogenizer, etc.

Cool the emulsion to obtain the standard sample.

4. Amount of the Samples to be Applied (Annotation 4)

The amount of the samples to be applied shall be 2 mg/cm² or 2 μ L/cm² each.

5. Area of the Samples to be Applied (Annotation 5)

The area (for applying samples) shall be at least 20 cm².

6. Time from Application to Exposure

Radiation exposure shall begin at least 15 minutes after the samples are applied.

7. Light Source (Annotation 6)

An artificial light shall be used as a source of light, which must satisfy following conditions.

(1) The UV light emission in UVA range shall have a continuous spectrum similar to sun light. Moreover, the ratio of UVA I (340-400 nm) and UVA II (320-340 nm) shall be close to that of sunlight (UVA II/UVA=8-20%).

(2) To avoid extreme sunburn, UV ray shorter than 320 nm shall be excluded through the use of an appropriate filter.

Monitoring and maintenance shall be performed to insure that the above conditions are always maintained.

8. Radiation Field (Annotation 7)

A single radiation field shall be at least 0.5 cm^2 The radiation fields of the untreated area shall be equivalent to the radiation field of the treated area.

9. Progression of UV Dose (Annotation 8)

A UV dose progresses geometrically and the increment shall be 25% maximum.

10. MPPD (Minimal Persistent Pigment Darkening Dose) (Annotation 9)

The MPPD is defined as the minimum dose of UV rays that produces slight darkening over essentially the whole radiation field within 2 to 4 hours after exposure. Determination of MPPD shall be conducted in a room with sufficient lighting at a fixed time within 2 to 4 hours after the end of exposure. At least two trained evaluators are desired to read MPPD.

11. Calculation Method of the PFA Value (Annotation 10)

PFA value Shall be obtained from the following equation by using MPPDs at sites untreated and treated by a test sample.

PFA value = MPPD in protected skin/MPPD in unprotected skin

PFA value of a test sample is defined as the arithmetic mean of each subject's PFA values obtained from the above equation.

12. Method for Expressing UVA Protection (Annotation 11)

For labeling PFA values in UV protecting products, the figures to the right of the decimal point shall be discarded from the PFA value of the sample that has been calculated according to the above method to make it an integer. Then, when the value is not less than 2, it shall be classified according to the following PA (Protection grade of UVA), and this classification shall be expressed on the label.

PA shall be placed together with the SPF value.

PFA Value	PA (Protection grade of UVA)
2 or more but less than 4	PA+
4 or more but less than 8	PA++
8 or more	PA+++

II. Annotations

(Annotation 1) Selection of Subjects and Test Sites

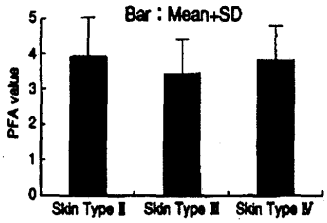
For the PFA value measurement to be an index of the persistent pigment darkening induced by UVA, it must be assumed that a stable darkening occurs from exposure to UV rays. If the skin color is dark, the determination of this reaction is very difficult. Moreover, as shown in Figure 1, no significant differences were found between PFA values obtained from skin types II, III , and IV. Therefore, skin types II, III, and IV have been stipulated. Results of a skin type survey of Japanese people conducted by the Japan Cosmetic Industry Association show that approximately 74% of Japanese belong to skin types II, III and IV.

The subjects shall be selected from applicants who understand the objective of the test by interview questions in the "Questionnaire for Subject Selection". Examples of drugs that contribute to photosensitivity include the following:

Hypotensive agents, psychotropic agents,
tranquilizers, antihistamines, oral hypoglycemic agents,
and tetracycline antibiotics.

Because it is necessary for the test subjects to evaluate their own skin types and agree to being a test subject, the minimum age for test subjects was set at 18 and above.
It is also recommended that subjects not be older than 60 year old.

Figure 1 Relationship Between Skin Type and PFA Values of Standard Sample



(Annotation 2) Number of Subjects

In determining the PFA value, the larger the number of subjects tested, the higher the reliability of the value obtained. However, it was decided that the PFA value may be determined from a minimum of 10 subjects, as long as the variation of results lie within a specified range.

With respect to variation, it was decided that the mean PFA value is valid if the standard error is kept within 10% of the measured PFA value. If, however the standard error exceeds 10% of the measured PFA value, the number of subjects shall be supplemented so that the standard error falls within 10% and a highly reliable PFA value may be determined.

(Annotation 3) Standard Sample

The reason for taking a measurement of the standard sample is to confirm that the PFA values are measured consistently in accordance with the Measurement Standards for UVA Protection. The mean PFA value of the standard preparation shall be 3.75 (standard deviation 1.01).

(Annotation 4) Amount to the Samples to be Applied

The applied amount of the samples shall be $2mg/cm^2$ or $2\mu L/cm^2$. From a practical standpoint, measurements shall be made in accordance with product form by weighing it on a balance or by measuring volume in a syringe, etc.

An area on the skin shall be marked with a marker, and the samples shall be deposited throughout the area and applied uniformly with the fingertips, etc.. For testing purposes, the condition of the sample application must be as close as possible to the form it will have in actual use.

For example, if a $20cm^2$ area is selected for sample application, 0.04ml of an emulsified test product may be measured in a syringe and dropped onto the surface of the skin. It is then applied with the fingertips so that it will be uniform within the specified surface area delineated by the marker. In a similar manner, 40mg of solid test product such as an oil-based stick or lip coloring may be weighed, dropped onto the surface of the skin and applied by spreading with the fingertips in a uniform manner, or it may be heated to a fluid state and then applied. Powdered solids such as face powder should be applied with the tip or puff that will actually be used for the product. The amount of sample adhering to the tip or puff should be measured, and then it should be applied so that 40mg of sample remains on the surface of the skin. As an alternative, 40mg of sample may be weighed out and then applied using purified water to increase its dispersion and adherence.

(Annotation 5) Area Applied by Samples

In order to minimize the weighing error of the sample, the area of application was made at least 20 cm^2. Of course, the larger the area of application is, the error which may take place during the weighing operation etc. becomes smaller.

In case when several different preparations are to be tested on one subject, the distance between application sites of the samples shall be at least 1cm to prevent samples from spreading over and

influencing neighboring sites.

(Annotation 6) Light Source

(1) Conditions Required for the Light Source

The light source for the PFA value measurement test must emit a continuous spectrum of UV rays in the range of 320-400 nm to enable testing of the level of protection for the skins against the effects of UVA, which is a component of UV rays in sunlight. The ratio of UVA I to UVA II in the final beam will depend on the strength of the lamp, the optics, etc., of the system, but it must not be far removed from the UVA I to UVA II ratio in sunlight. Therefore, the ratio of emitted UVA II was set at 8% to 20% of the total UVA. Moreover, it is important to consider the exclusion of UV light shorter than 320 nm, which is a strong cause of erythema, by using various types of filters. Visible and infrared light must also be excluded to avoid the darkening effects of visible light and the effect of heat.

(2) Monitoring and Maintenance of the Light Source

The energy emitted by the light source must be constant and relatively uniform through the cross section of the beam. Changes in the voltage supply to the lamp, lamp life (hours of use) and accumulation of dust in the optical system alter the emission of the lamp and affect the spectral distribution. To protect against these problems and obtain reliable, reproducible results, conventional monitoring and maintenance of the light source are important. The light source should be monitored and maintained in the following manner.

1) The UV light emission intensity of a lamp shall be confirmed by using a UV light radio meter.

2) When periodic monitoring and maintenance are performed, the information shall be recorded together with the measured values.

UV light radio meters are not sensitive enough to detect changes in the light spectrum due to aging of the lamps and filters, so early replacement of lamps and filters shall be performed, and these operations shall be recorded, Moreover, it is possible that the MPPDs of subjects will change with changes in the intensity and spectrum of light.

Therefore, changes in the MPPD can indicate degradation of the light source, and they shall be carefully watched.

(3) Maintenance and Inspection of UV Light Radio Meter

Sometimes accurate readings with the UV light radio meter cannot be obtained because of filters that become dirty or degraded. Therefore, the meter shall receive periodic calibration by the meter manufacturer at least once a year,

(Annotation 7) Radiation Field

The minimum radiation field (ϕ 8mm) is 0.5cm^2, when using a solar simulator used at various Laboratories or sold in the market.

(Annotation 8) Progression of UV Dose

A radiation increment is 25%, that is, the radiated energy amount (exposure time) at each radiation field is calculated as geometric progression of minimum radiation dose (minimum radiation dose $\times$ 1.25^{n}) When the exposure time is held constant and the radiation intensity is varied, the radiation intensity shall be calculated as a geometric
progression of the minimum light intensity. The amount of increase should be smaller, however, if PFA values of higher accuracy are sought.

(Annotation 9) Minimal Persistent Pigment Darkening Dose (MPPD)

Immediate Pigment Darkening (IPD) is a temporary brown-gray to brown-black reaction observed in human skin immediately after exposure to UVA. This reaction was originally reported by Hausser1). Thereafter, it was discovered that IPD is due to a photo-oxidation reaction in which a colorless melanin precursor is oxidized to become pigmented melanin [2].

It was further discovered that IPD occurs with exposure to visible light[3,4] and that this response is an effective index for measuring the UVA protection in healthy human skin[5]. Because it occurs with a relatively small dose of UVA and fades quickly, it is believed that IPD is suitable as a response index for measuring UVA protection in Japanese subjects. However, the following problems were found in our results.

(1) Because it fades so rapidly, the darkening response immediately after UVA exposure varies widely among individuals, and stable PFA values are difficult to obtain[6].

(2) When tests are performed on cosmetics, especially makeup products, 2 or 3 minutes elapse after UVA exposure while the skin is wiped with skin cleanser, and from a practical standpoint, observation immediately after exposure is impossible.

(3) Determination should be performed by several experienced observers, but in the period of time required for 2 to 3 observers to make observations one after the other, the darkening response is changing, which creates a vicious circle.

Therefore, when time course observations of IPD were made in an attempt to overcome these problems, it was discovered that 2 hours or more after exposure the rate of fading slows and becomes stable[6]. It was then determined that stable values could be obtained when PFA values were sought by using the response 2 to 4 hours after exposure as an index6).

It is believed that the measurement of UVA protection by using the IPD response 2 to 4 hours after exposure as an index is the most suitable method.

It is not appropriate to designate this response that occurs 2 to 4 hours after exposure as IPD because it is different from the immediate response after exposure. Therefore, after considerable discussion it was decided that from the standpoint of a response that ultimately persists, this response should be called Persistent Pigment Darkening (PPD), and the minimum dose of UVA necessary for inducing this response should be called Minimal Persistent Pigment Darkening Dose (MPPD).

(Annotation 10) Calculation of the PFA Value

There is no uniform method for expressing UVA protection, and various researchers use different expressions[7][8][9][10]. Therefore, in this standard Protection Factor of UVA shall be expressed as a PFA value.

In calculating the PFA value, data shall be excluded from subjects in which the MPPD can not be determined from the area to which the samples were applied or from the area to which no sample was applied. After the PFA value for each individual is calculated, the arithmetic mean of the PFA values from all the subjects shall be used as the PFA value for that sample.

The standard error will be calculated to confirm the reliability of the measured values. The standard error must lie within 10% of the measured values. Calculation of the standard error shall be performed in accordance with the SPF Measurement Standard (Published on November, 1991, Effective from January 1, 1992).

(Annotation 11) Method for Expressing UVA Protection

The PFA value is a value that measures UVA protection as the index of darkening 2 to 4 hours after exposure. The SPF value uses the response (erythema) itself as the index of protection, and in that respect it is quite different from the PFA value. More specifically, because SPF is an index of the extent that reddening can be controlled, it can be used as a general approximation in actual situations. In the case of UVA, however, even when we use darkening as an index, it is impossible to prevent darkening through UVA protection alone, and it is difficult to link the response of the skin to a protective effect that can actually be felt by consumers. Moreover, the values differ if the index is changed[10]. For example, when the immediate darkening, which occurs directly after UVA exposure, is used as index rather than PPD, different PFA values are obtained. Although the values themselves may vary, it is believed that they all yield the same results concerning the relative strength or weakness of the protection.

Therefore, a classification scheme rather than numerical values was adopted for expressing UVA protection.

The method of classification was based on the following reasons:

(1) The difference in UVA protection must be clear from the measured values. For expressing the effectiveness we chose cutoff points of 2, 4, and 8 based on the fact that the value "2 or more" differs by at least 3 geometric progression increments ($1.25 \times 1.25 \times 1.25 = 1.95$) from the value of "1" given for no effect, and in the same manner each class differs from the next by at least 3 geometric progression increments.

(2) The meaning of the classification must be clear. The protection doubles for each step of increase in the classification.

In recognition of the fact that the labels must be simple, clear, and easy for consumers to understand, PA (Protection grade of UVA) was selected as the expression for UVA protection, and the classes of protection on products will be expressed by +, ++, and+++.

"PA+" will indicate that the product offers protection against UVA, "PA++" will indicate that the product offers considerable protection against UVA, and "PA+ + + " will indicate that the product offers the greatest protection against UVA.

However, a product that offers protection against UVA alone but not against UVB cannot be called a cosmetic with UV protection. Therefore, a restriction has been imposed such that the labeling of the level of UVA protection shall be combined with SPF values. Labeling examples are as follows:

Labeling Examples: SPF10 · PA+ or SPF10
PA+

III . References

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