

# C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

March 14, 1995

John E. Bailey Ph.D. HFS-100  
Director  
Office of Cosmetics and Colors  
Food and Drug Administration  
200 C Street S.W.  
Washington, DC 20204

E. EDWARD KAVANAUGH  
P R E S I D E N T

Re: International Harmonization  
Cosmetic Ingredient Labeling Names

Dear Dr. Bailey:

The European Cosmetic Toiletry and Fragrance Association (COLIPA) recently informed the CTFA that the Legal Services of the EC Commission has accepted the names in CTFA's International Cosmetic Ingredient Dictionary (the Dictionary) without translation. These names, now identified as International Nomenclature Cosmetic Ingredient (INCI) names, will be used to identify ingredients in the EU Inventory of Cosmetic Ingredients and are expected to be the basis for ingredient labeling that will be required in the EU in 1997.

COLIPA submitted the first draft of the EU Inventory to the EU Commission in December 1994. In this draft COLIPA was required to modify selected groups of INCI names to comply with the EU Cosmetic Directive and to minimize the confusion from certain common names in the EU where nine different languages are spoken.

The purpose of this letter is to outline some future changes that must be made to achieve international harmonization of INCI names and to seek input from the FDA concerning these changes. In addition, the CTFA is seeking to obtain a letter from the FDA that will permit the interim use of the "harmonized" names until such time as the changes can be considered as part of a petition to adopt new names for ingredient labeling.

Below is a summary of the ingredient categories where changes were made in the INCI names in the EU inventory.

### **1. COLORANTS**

Annex IV of the EU Cosmetics Directive identifies all colorants (with a few exceptions) by their Color Index Number. The Color Index Number will be used in the EU for ingredient labeling.

**To achieve international harmonization for colorants CTFA proposes that colorants be permitted to use a dual declaration in the ingredient statement as shown in the following example:**

**Harmonized INCI Name: FD&C Green No. 3 (CI 42053)**

### **2. DENATURED ALCOHOL (Ethyl Alcohol)**

At the present time the term "Alcohol Denat." is the accepted term in the EU for ingredient labeling of alcohols that have been denatured in accordance with any of the national regulations of the nine countries of the EU.

In the US there are currently 26 SD Alcohols and 1 CD Alcohol listed in the Dictionary, with names established by the Bureau of Alcohol, Tobacco, and Firearms regulations 27 CFR 20.11 and 21.32 though 21.81. For any given SD or CD formulation there are a wide variety of substances that may be added to meet the criteria for denaturing the alcohol. For example, in reference to SD Alcohol 38B, this formula allows it to be denatured with one or more of over 40 different substances ranging from Anethole and Anise Oil to Turpentine or Wintergreen Oil.

Cosmetic firms doing business in international markets have stated that it is essential that a single labeling name be established for alcohols containing denaturing ingredients.

**To achieve international harmonization for alcohols CTFA proposes that the following single name be established to refer to all appropriately denatured alcohols.**

**Harmonized INCI Name: Alcohol Denat.**

### **3. PLANT EXTRACTS**

To achieve international harmonization for plant extracts and to minimize confusion from American common names for plant materials the EU Inventory identifies these material by their genus/species name using the Linné system.

To achieve international harmonization for Plant Extracts CTFA proposes that the genus/species names using the Linné system as shown in the following example be used for labeling:

Current US INCI Name -- Orange Peel Extract

Proposed Harmonized INCI Name -- Citrus Sinensis Peel Extract

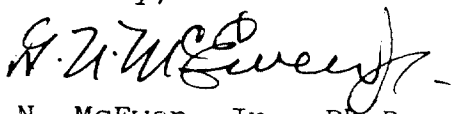
**ACTION REQUESTED**

The above are the categories of cosmetic ingredients that CTFA is seeking to revise to foster international harmonization.

CTFA is seeking a letter from the FDA stating the agency will not take action against labelers using such new harmonized INCI names after they suitably published.

We would like to discuss this matter with you in the near future since we are facing a short deadline for the preparation of the text for the next edition of the CTFA International Dictionary, which as noted above will be available for distribution October 1995.

Sincerely,



G.N. McEwen, Jr., Ph.D., J.D.  
Vice President - Science

cc: Linda R. Horton, Director, International Policy Staff, FDA