

# INCI Nomenclature and the INCI Application Process

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# Presentation Overview

- **U.S. Regulatory Framework for Labeling**
- **INCI Nomenclature - Background**
- **The International Cosmetic Ingredient Nomenclature Committee**
- **INCI Goals and Naming Principles**
- **INCI Application Process**
- **INCI Nomenclature Publication**

## Cosmetic Labeling - U.S. Regulatory Framework

- Two laws govern the labeling of cosmetics:
  - Federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C. section 301
  - Fair Packaging and Labeling Act (FPLA), 15 U.S.C. section 1451
- Regulations issued by FDA pursuant to these laws are contained in the Code of Federal Regulations (CFR) Title 21, Parts 700 to 740.
- Personal Care Product Council's Labeling Manual provides a comprehensive overview of U.S. labeling requirements.

## Cosmetic Labeling - U.S. Regulatory Framework

- FPLA requires ingredient declaration by common or usual name in descending order of predominance (21 CFR 701.3(a)).
- 21 CFR 701.3(c) sets out sources for ingredient nomenclature.
  - Names established by the Commissioner.
  - CTFA Cosmetic Ingredient Dictionary and Handbook (21 CFR section 701.3(c)(2)(i)) for International Nomenclature Cosmetic Ingredient (INCI) names.
  - Alternate compendia are listed in the order of preference at 21 CFR 701.3(c)(2).
  - In the absence of a listing, use the name generally recognized by consumers.
  - In the absence of that name, use the chemical or technical name.
- For a cosmetic/OTC drug, follow 21 CFR sections 201.66(c)(2), (c)(8), and (d). OTC ingredients must be labeled according to the applicable OTC monograph.

## Cosmetic Labeling - U.S. Regulatory Framework

### Colors:

- All color additives used in cosmetics marketed in the U.S. (with the exception of coal-tar hair dyes) must be approved by FDA.
- In addition to approval, synthetic organic color additives must be batch certified by FDA.
- All color additives must meet the requirements for identity and specifications stated in the CFR.
- Color additives may be used only for the intended uses and concentrations stated in the regulations.
- FDA currently does not object to dual declaration as long as the official FDA name comes first, e.g. Green 3 (CI 42053).
- <http://www.fda.gov/ForIndustry/ColorAdditives/ColorAdditiveInventories/ucm115641.htm#table3A>

## INCI Nomenclature – Background

- Initiated by consumer movement during 1960s
- Industry survey
- Committee formed to review survey
- Proposal to FDA for uniform system for names
- CTFA Adopted Names - created and published in Dictionary, 1973
- FDA recognizes Dictionary by regulation

## INCI Nomenclature – Background

- 1993 CTFA Adopted Names changed to INCI (International Nomenclature Cosmetic Ingredient)
- INCI names formally recognized by regulation in many countries for ingredient labeling
- Benefits of international harmonization:
  - Uniformity
  - Transparency
  - Global Trade

## INCI Nomenclature – Background

International status brings about change:

- International Nomenclature Committee expanded to include representatives from the EU, Canada, and Japan
- The Committee worked closely with COLIPA during the 1990s to codify botanical and colorant nomenclature
- Colorant names specific to the EU and Japan are published in the Dictionary

## INCI Nomenclature – Background

International status brings about change:

- Trivial Names published for ingredients specific to the EU and Japan
- Ingredients are translated into Japanese and Chinese during the 1990s; Korean translations were recently added (2015).

## INCI Nomenclature – Background

International status brings about change:

- INCI data base updated to cross-reference Canadian Hot List, Japan Index, EU Annexes, REACH, CLP Index, INN Names, UNII Codes
- Specific monograph written for [Nano] in accordance with the EU regulation, EC Regulation No. 1223/2009.

## International Cosmetic Ingredient Nomenclature Committee (INC)

The International Cosmetic Ingredient Nomenclature Committee (INC), sponsored by the Personal Care Products Council, is charged with the responsibility of designating INCI names. The INC is comprised of dedicated scientists from industry, academia, regulatory authorities and sister associations who volunteer their time to serve the global cosmetic industry community. Scientists on the INC have backgrounds in various disciplines, e.g., biochemistry, polymer chemistry, organic and inorganic chemistry, as well as botany and biotechnology.. The INC oversees the continued development of the INCI nomenclature system, and assures the integrity of the information related to INCI names that is published in the *International Cosmetic Ingredient Dictionary and Handbook*.

# International Cosmetic Ingredient Nomenclature Committee (INC)

## International Nomenclature Committee

John Sanzone, Chairman, Estée Lauder Companies

Eric Abrutyn, Consultant

Patricia Aikens, Ph.D., BASF

James Anderson, Consultant

Karolina Brzuska, Cosmetics Europe

Gaetano Castaldo, Ph.D., European Commission

Federica DeGaetano, Ph.D., European Commission

Michael J. Fevola, Ph.D., Johnson & Johnson Consumer and  
Personal Products

John Gardlik, Ph.D., The Procter & Gamble Company

Mindy Goldstein, Ph.D., Atlantic Coast Media Group

Bart Heldreth, Ph.D., Cosmetic Ingredient Review

Laurie Joseph, Ph.D., Rutgers, The State University of New  
Jersey

Peter Kaufmann, Consultant

Akihiro Kinoshita, Ph.D., Shiseido America, Inc.,

Robert Y. Lochhead, Ph.D., University of Southern  
Mississippi

Khalid Mahmood, Ph.D., Johnson & Johnson Consumer and  
Personal Products

Stanley Milstein, Ph.D., U.S. Food and Drug Administration

Joanne Nikitakis, Personal Care Products Council

Claude Salilou, PharmD., Ph.D., Estee Lauder Companies

Katrika Shaw, Personal Care Products Council

Mike Starch, Consultant

David Story, Kao Brands Company

Colleen Sutton, Ph.D., Health Canada

Ryuji Sugai, Kanebo Cosmetics, Inc., J CIA Liaison

Krishnan Tamaraselvey, Lubrizol

Miao Wang, L'Oreal USA, Inc.

Willem van der Wilden, Ph.D., Life Sciences

Shontell Wright, U.S. Food and Drug Administration

Chao Zhu, L'Oréal USA, Inc.

## INCI Goals and Key Points

- INCI provides a uniform, standardized system for the global identification of cosmetic ingredients
- Harmonization is essential to the free movement of goods on a global basis.
- INCI is not an endorsement of safety or acceptability for use in a cosmetic.
- It is the responsibility of the finished product manufacturer to substantiate safety and to comply with current regulatory requirements for the intended market.

## INCI Naming Principles

- Names are assigned through an application process
- Names are created by the INC on a consensus basis
- Success of INCI system is based on sound-science
- Conventions published in the Introduction to the Dictionary outline INCI naming principles
- Conventions are continually reviewed and updated to reflect current technology
- Names are essentially based on the composition of the final product

## INCI Naming Principles

- Depending on final product, raw material source has traditionally been used as part of name
- Consideration is given to existing terminology from related industries
- Every effort is made to be consistent with existing INCI names
- Changes to INCI names are avoided whenever possible
- There is a petition process for name changes

## INCI Naming Principles

### Botanicals:

- INCI names for plants are based on the Linnaean binomial system which uses a scientific genus and species name to identify an organism.
- Plant parts are included in the INCI name
- Some common names are included in the INCI name (i.e., where the plant was originally identified by its common name)

**Rosmarinus Officinalis (Rosemary) Flower Extract**

**Rosmarinus Officinalis (Rosemary) Flower/Leaf/Stem Extract**

**Pinus Pinaster Bark Extract**

## INCI Naming Principles

### Botanicals:

- To facilitate ease for creating product labels, special punctuation, formatting, and rules called for in the taxonomic codes are omitted in INCI names, e.g., italics are not utilized, species is not in lower casing, varieties and subspecies are not included, and “x” for hybrids is not utilized.
- Due to the dynamic nature of plant classification, the scientific nomenclature for plants is continually being updated based on new research results. INCI names are not readily updated to minimize economic impact of name changes.
- Monograph definitions include the full scientific name where possible.

# INCI Naming Principles

## Example monographs:

### **CARUM PETROSELINUM (PARSLEY) EXTRACT**

**INCI Monograph ID:** 8598

**Definition:** *Carum Petroselinum* (Parsley) Extract is the extract of the herb, *Carum petroselinum*. The accepted scientific name for *Carum petroselinum* is *Petroselinum crispum*. For further information about botanical nomenclature, consult the Introduction, Part A, No. 6, Botanicals. See Sections 20 to 22 for the Japanese, Chinese, and Korean translations of this INCI Name.

**Information Sources:** 21CFR182.20, FCC, JCLS, JSQI, UNII: 1WZA4Y92EX

**Chemical Class:** Botanical Products and Botanical Derivatives

**Reported Function:** Skin-Conditioning Agent - Miscellaneous

**Ingredient Source:** Plant

**Technical/Other Names:**  
Parsley Extract  
*Petroselinum Sativum* Extract

**Trade Name Mixtures:**  
Actiphyte of Parsley BG50 (Active Organics)  
Actiphyte of Parsley GI 50 (Active Organics)

### **PLUMBAGO ROSEA ROOT EXTRACT**

**INCI Monograph ID:** 22044

**Definition:** *Plumbago Rosea* Root Extract is the extract of the roots of *Plumbago rosea*. The accepted scientific name for *Plumbago rosea* is *Plumbago indica*. For further information about botanical nomenclature, consult the Introduction, Part A, No. 6, Botanicals. See Section 21 for the Chinese translation of this INCI Name.

**Information Source:** UNII: 9NSO691EBH

**Chemical Class:** Botanical Products and Botanical Derivatives

**Reported Function:** Skin-Conditioning Agent - Miscellaneous

**Ingredient Source:** Plant

**Trade Name Mixture:**  
Medimix 18 (Cholayil)

# INCI Naming Principles

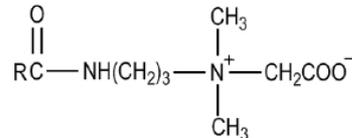
## Example monographs:

### COCAMIDOPROPYL BETAINE

INCI Monograph ID: 555

CAS Nos.	EINECS/ELINCS
61789-40-0	263-058-8 (I)
70851-07-9	274-923-4 (I)
83138-08-3	
97862-59-4 (generic)	

**Definition:** Cocamidopropyl Betaine is the zwitterion (inner salt) that conforms generally to the formula:



where RCO- represents the fatty acids derived from coconut oil.

See Sections 20 to 22 for the Japanese, Chinese, and Korean translations of this INCI Name.

**Information Sources:** CIR: [SQ] IJT-31 (SUPPL. 1)2012, CIR: [SQ] JACT-10(1)-1991, CTFA S, JCIC, JCLS, JSQI, TSCA, UNII: 5OCF3O11KX

**Reported Functions:** Antistatic Agent; Hair Conditioning Agent; Skin-Conditioning Agent - Miscellaneous; Surfactant - Cleansing Agent; Surfactant - Foam Booster; Viscosity Increasing Agent - Aqueous

**Ingredient Sources:** Plant; Synthetic

#### Technical/Other Names:

CADG  
N-(Carboxymethyl)-N,N-Dimethyl-3-[(1-Oxococonut)Amino]-1-Propanaminium Hydroxide, Inner Salt  
Cocamido Betaine  
Cocamidopropyl Dimethyl Glycine  
Cocoyl Amide Propylbetaine  
Cocoyl Amide Propyldimethyl Glycine  
Cocoyl Amide Propyldimethyl Glycine Solution  
1-Propanaminium, N-(Carboxymethyl)-N,N-Dimethyl-3-[(1-Oxococonut)Amino]-, Hydroxide, Inner Salt  
Quaternary Ammonium Compounds, (Carboxymethyl)(3-Cocoamidopropyl)-Dimethyl, Hydroxides, Inner Salts

#### Trade Names:

Amido Betaine C (Zohar)

# INCI Naming Principles

## Example monographs:

### ETHYLHEXYL DIMETHYL PABA

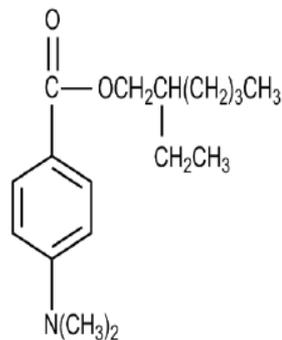
**INCI Monograph ID:** 1782

**CAS Nos.**            **EINECS/ELINCS**  
21245-02-3        244-289-3 (I)  
58817-05-3

**Empirical Formula:**

$C_{17}H_{27}NO_2$

**Definition:** Ethylhexyl Dimethyl PABA is the ester of 2-ethylhexyl alcohol and dimethyl p-aminobenzoic acid. It conforms generally to the formula:



In the United States, Ethylhexyl Dimethyl PABA may be used as an active ingredient in OTC drug products. When used as an active drug ingredient, the established drug name is *Padimate O*. See "Regulatory and Ingredient Use Information" regarding the labeling names for U.S. OTC Drug Ingredients in Volume 1, Introduction, Part A, No. 10. For products marketed outside of the United States, readers are reminded to consult the appropriate laws and regulations for the countries in which the product is marketed.

See Sections 20 to 22 for the Japanese, Chinese, and Korean translations of this INCI Name.

**Information Sources:** BAN, 21CFR352.10, CTFA S, EC(VI-21), JCLS, JSCI, JSQI, MHLW-331/4, MI, OTC-I-SU, TSCA, UNII: Z11006CMUZ, USAN, USP

**Chemical Class:** PABA Derivatives

**Reported Functions:** Light Stabilizer;  
Sunscreen Agent

**Ingredient Source:** Synthetic

**Technical/Other Names:**

Benzoic Acid, 4-(Dimethylamino)-, 2-Ethylhexyl Ester  
Benzoic Acid, 4-(Dimethylamino)- Octyl

# INCI Naming Principles

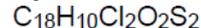
## Example monographs:

### RED 30

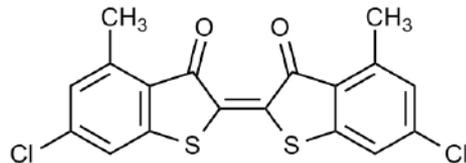
**INCI Monograph ID:** 698

**CAS No.:** 2379-74-0

**Empirical Formula:**



**Definition:** Red 30 is classed chemically as an indigoid color. It conforms to the formula:



*To identify the certified colorant for labeling purposes in the US, the INCI Name Red 30 must be used. The INCI Name for batches of this colorant that have not been certified is Vat Red 1. To identify the colorant allowed for use in the European Union (EU), the INCI Name CI 73360 must be used. To identify the colorant allowed for use in Japan, the INCI name Aka226 must be used. See "Regulatory and Ingredient Use*

Information" for colorants in Volume 1, Introduction, Part A, Nos., 1, 2, 3, and 4. See Sections 20 and 21 for the Japanese and Chinese translations of this INCI Name.

**Information Sources:** 21CFR74.1330, 21CFR74.2330, 21CFR82.1330, CI 73360, EC(II-1365), M3, TSCA, UNII: 2S42T2808B

**Chemical Class:** Color Additives - Batch Certified by the U.S. Food and Drug Administration

**Reported Function:** Colorant

**Ingredient Source:** Synthetic

**Technical/Other Name:**

D&C Red No. 30

**Trade Names:**

A505.10 Tudor Geranium (Kingfisher Colours)  
Calisha Art Red 30 Toner (BASF Corporation)  
Puricolor Red VRE1 (BASF Corporation)  
Ultrapearl Red 30 Pink Luster (Ultra Chemical)

**Trade Name Mixtures:**

Hot Dots - Red (Charm Girl)  
Lipobead Violet (Lipo)

## INCI Application Process

Visit the Council's Quick Links box located in the on our home page:

<http://www.personalcarecouncil.org/>

### Quick Links

- [CosmeticsInfo.org](#)
- [Cosmetic Ingredient Review](#)
- [Careers](#)
- [Look Good...Feel Better®](#)
- [On-line INFOBASE – the ultimate ingredient resource](#)
- [International Cosmetic Legal & Regulatory Database](#)
- [INCI FAQs](#)
- [INCI Application](#)
- [Ingredient Buyers Guide](#)
- [PCMAP - Personal Care Manufacturing Assessment Program](#)
- [Personal Care Suppliers Directory](#)
- [wINCI - Web Based Ingredient Dictionary](#)

<https://inci.personalcarecouncil.org/inci-app>



**Notice: The Personal Care Products Council is charging an application fee for the processing of INCI applications. These charges will be applied to the processing of all applications for this program. You will be asked to enter payment information during the application process.**

The INCI Application website has been redesigned. Security has changed. Click [here](#) to create your new User ID/Password. IT IS IMPORTANT YOU REMEMBER YOUR OLD USER ID/PASSWORD! You will be asked to use the Old User ID to link your new User ID to INCI Applications currently in the review process.

**First time user? Click [here](#) to create your INCI Application User ID and Password.**

**You must allow popup windows and accept cookies to be able to use this site.**

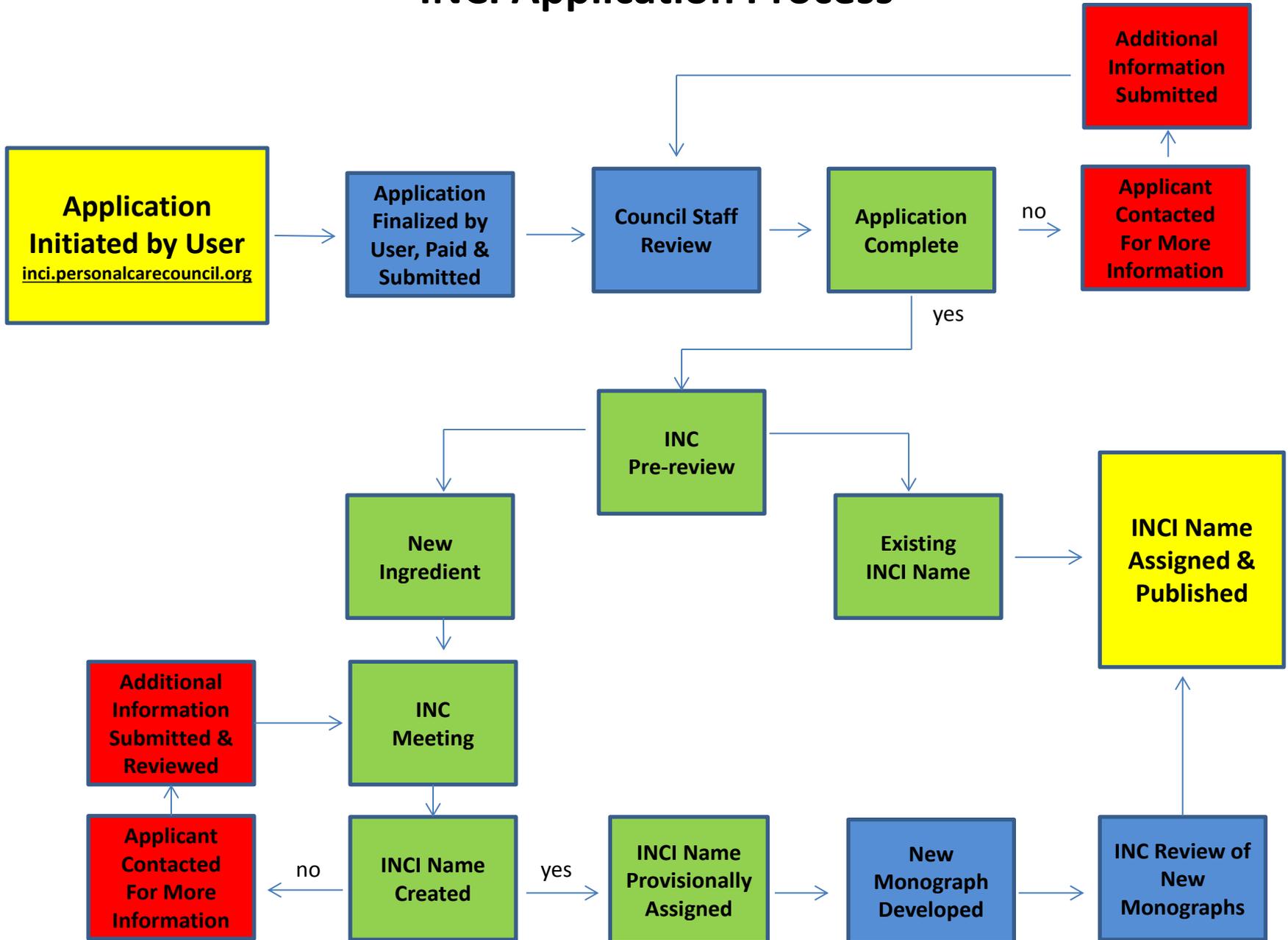
User ID:

Password:

Logon

**Forgot your password? Click [here](#).**

# INCI Application Process



## INCI Application Process

### INCI Application/Name Assignment Timetable:

- INC meets generally during the months of February, April, June, September and November
- Files are compiled in chronological order and distributed to the INC 4-6 weeks prior to the scheduled meeting date
- Name assignments are released approximately one month post-meeting
- In general, application process takes 3-6 months

## INCI Application Process

### Application Reminders:

- If ingredient utilizes a material with an existing INCI name as a starting material, include this on the application
- If ingredient is similar to a material previously named, include this on the application
- Genus/species must be included for all organisms; botanicals also require plant part
- If a question is posted after the application is reviewed, respond promptly and place answer in the application Comments Box

## INCI Application Process

### Application Reminders:

- Identify all starting materials completely
- Provide a detailed manufacturing method, even for materials which have an existing INCI Name
- Include a reaction scheme with chemical notation whenever possible
- Provide purity information if isolating a specific component from a natural source; describe how material is characterized; include technique for separation

## INCI Application Process

### INCI Name Change Procedure:

- There is no form or fee for a name change.
- Petitions for an INCI name change should include:
  - Current INCI Name
  - Trade Name
  - Application number, if applicable
  - Requested revision
  - Technical rationale to support the petition
  - Supporting composition information and/or manufacturing details
  - Analytical data where appropriate
- Petitions for a name change can be sent via email to:  
Joanne Nikitakis, [nikitakisj@personalcarecouncil.org](mailto:nikitakisj@personalcarecouncil.org)

## INCI Nomenclature Publication

- INCI names and related information are published in the *International Cosmetic Ingredient Dictionary and Handbook*, available on the Council's website in the eBookstore:  
<https://access.personalcarecouncil.org/eweb/DynamicPage.aspx?Site=pcpc&WebKey=4513b14e-2f75-4857-85b4-b3697be5d5d9>
- Electronic Dictionary subscriptions available through *wINCI*, and the Council's *InfoBase*. Data is updated nightly.
- New 16<sup>th</sup> edition available first quarter 2016.
- Ingredient Buyers' Guide available on Council's homepage is free of charge and provides an easy quick check for INCI names:  
<http://buyers.personalcarecouncil.org/jsp/BGSearchPage.jsp>

# Thank You!

# Questions?

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