

INCI Application – Complete Instructions

One ingredient (or commercial product) per application can be submitted for an INCI name assignment. All required fields on the application must be filled in. Additional information can be submitted as an attachment. Maximum file size per attachment is 25 MB, and recommended file formats include *.pdf, .xlsx, .doc or .docx, .jpg or .jpeg, .gif, .zip*. Applications can be saved in progress; however, after an application is submitted, changes cannot not be made other than to upload attachments when requested by PCPC. A non-refundable payment by credit card of \$400 per application is made upon submission.

The first screen in the application process instructs the applicant to select a category for their ingredient (listed below).

- Biotechnology/Animal Cell Culture (including defined media)
- Biotechnology/Fermentation Processes
- Biotechnology/Peptides (recombinant; solid and liquid phase)
- Biotechnology/Plant Cell Culture (including defined media)
- Biotechnology/Biologicals, Botanicals, Misc.
- General Chemistry/Inorganic
- General Chemistry/Organic
- Polymers/Silicones

Each category corresponds to a specific application which contains required fields about the ingredient's identity and composition. Details about these fields are described as follows:

Trade Name

A trade name or commercial name for the ingredient should be provided. Applicants that do not want their trade name or company name published in the subscription INCI data bases, *w/INCI* and the *InfoBase*, should check “no” where it asks: “Publish Tradename”?

Requested Nomenclature

Applicants may recommend an INCI name. Requested names should be based on the guiding principles outline in the INCI Conventions. If you are submitting an ingredient that is similar to an existing INCI name or relates to a trade name previously submitted by your company, be sure to provide this information.

Chemical Structure

Where applicable, structures should be submitted as attachments to the application. Descriptions for R groupings, (e.g., alkyl groups), or repeating units (e.g., moles ethylene oxide or propylene oxide) must be provided. All features of the structure must be clearly defined (i.e., without ambiguity).

Empirical Formula

Provide where applicable.

CAS Number

Provide if available. On General Chemistry and Polymer applications, a field is included for the CAS numbers for both the starting materials and final product.

EC Number

Provide if available. On General Chemistry and Polymer applications, a field is included for the CAS numbers for both the starting materials and final product.

Chemical Synonyms

Provide related chemical, technical or common names.

Composition Statement

Provide a brief statement about the general composition of the product. If the final product is a **blended mixture**, identify the components in an organized list in descending order of predominance. Technical data sheets or CoAs are required for purchased components. Manufacturer name can be blocked out if needed. Indicate approximate percentages of each component when possible. If the product is not a mixture, this field may be used to provide additional compositional information.

Manufacturing Method

A detailed, step-by-step manufacturing method **must be provided**, including complete identification of all starting materials. **An INCI monograph definition does not constitute a manufacturing method.** In some cases, technical data sheets or CoAs for starting materials may be requested. Patents or literature references can be uploaded as an attachment for documentation **but should not be included in place of a detailed method.** Reaction schemes, flow charts, reaction process diagrams should be included where appropriate and uploaded as attachments to the application. Preservatives used to protect the raw material are not typically included in the INCI name unless requested by the applicant. ***Note, proprietary information cannot be accepted. If your application or any attachment is marked "confidential", it will not be reviewed.***

Diluents

List the name and relative percentage of any solvents or diluents present in the final preparation as it is sold for use in finished products. This field is not intended to describe solvents or diluents that are used in the process and removed, nor is it intended to describe solvents that can solubilize the final preparation.

Botanicals

For this category, applicants must provide the genus, species, and plant part for each botanical material in the product, and manufacturing process information. If a specific component is isolated, the manufacturing information should clearly describe the isolation technique, the relative % purity of the isolated fraction based on dry weight, the chemical identity of the fraction and method used to characterize its identity and purity. Corresponding analytical data should be uploaded as an attachment.

If the product consists of several plant materials (e.g., more than 4), applicants should attach an Excel spreadsheet which identifies each plant source in the format depicted below. Note, if more than one

plant part is used for a given genus/species, list each part separated by a comma; state “whole” where entire plant is used.

Genus	Species	Plant Part
Daucus	sativa	root
Camellia	japonica	seed
Saliva	Officinalis	whole

For botanical ingredients prepared through tissue culture, process details are very important with clear identification of callus formation, and a description of the final preparation that identifies whether the product is the media, the cells, or both. If plant vesicles are isolated, indicate whether the vesicles are isolated from the cells or the media, and provide the % purity for the isolated vesicles. If diluted in the final product, indicate the % purity of the vesicles prior to dilution.

Animal-Derived Ingredients

For this category, applicants must include the identity of the animal and its genus/species, part of animal material is derived from, and step-by-step details for the manufacturing method. If a specific component is isolated, the % purity of the isolated fraction based on dry weight must be provided, its chemical identity and method used to characterize the identity and purity, along with supporting data.

For specific cells, the species, source tissue, complete method details, flow cytometry data with appropriate markers and gating strategy must be provided. A description of the final preparation that clearly identifies whether the product is the media, the cells, or both is necessary. For exosomes, include FACS data with gating using both positive and negative cell surface makers. The % purity of the isolated exosomes must be included.

Minerals and Inorganics

Mineral composition information must be provided, along with manufacturing details. For mined materials, describe mining process and particle size of final product. Include X-ray diffraction scan of product, synthesized and natural, in addition to a Bureau Standard.

Polymers

The manufacturing details must list all starting monomers, all cross-linking agents, and a reaction scheme that describes step-wise process. For monomers that are alkoxyated, the degree of alkoxylation must be indicated (moles EO, PO, etc.) The degree of polymerization of any polyether must be provided. All R groups, (e.g., alkyl groups) must be disclosed.

Ferments

Complete step-by-step details of the fermentation method should be provided in addition to a description of any downstream processing. Products derived by spontaneous fermentation or co-fermentation should be specified. The identity of the genus and species of all microorganisms must be provided, in addition to all materials added to the fermentation process. If more than four plant materials are used in the fermentation process, applicants should attach an Excel spread sheet in the format noted below. Note, if more than one plant part is used for a given genus/species, list each part separated by a comma; state “whole” where entire plant is used.

Microorganism	Plant Genus	Plant Species	Plant Part
Bacillus subtilis	Camellia	sinensis	leaf
	Malus	domestica	whole

Peptides

Applications for all peptides must include the total number of amino acids, the sequence in single letter code, purity information, and complete manufacturing information. For biologically-inspired peptides, describe whether the protein originates from a gene directly isolated from a human cell; or is a chemically synthesized copy of a human gene or gene fragment produced in a gene synthesizer. If the peptide is derived from other organisms, provide the common name and genus/species for the organism. Provide the protein name and the Uniprot number and NCBI Gene ID number for the parent protein. If the peptide is a fusion peptide, provide the sequence for each fragment along with each corresponding protein name and Uniprot and Gene ID numbers. If the final product is a blended mixture, identify the components in an organized list in descending order of predominance. Peptide modifications need to be described with complete manufacturing details, e.g., modifications on the 5' and/or 3' end of the peptide.