

INTERNATIONAL NOMENCLATURE COSMETIC INGREDIENT (INCI) LABELLING COMPLIANCE AND ENFORCEMENT POLICY

This Policy serves to provide a common point of reference to facilitate uniform enforcement of section 21 of the *Cosmetic Regulations* pertaining to mandatory ingredient labelling of cosmetic products, which comes into force on November 16th, 2006.

BACKGROUND

It has been estimated that the typical Canadian adult uses on average seven different cosmetics or personal care products on a daily basis. The health risk for cosmetic products are relatively minor, however, a small percentage of Canadians experience severe or life threatening reactions to such products.

The Cosmetic Ingredient Hotlist serves to minimize risks based on the inherent nature of ingredients in cosmetic products, however it cannot entirely address sensitivities experienced by a small proportion of the population. Therefore, mandatory ingredient labelling on cosmetic products is expected to reduce reactions to cosmetic products by allowing consumers to make informed choices, and avoid products to which they may be sensitive.

Amendments to the *Cosmetic Regulations* were published in *Canada Gazette*, Part II in December 2004. The primary change was to have mandatory ingredient listing using International Nomenclature of Cosmetic Ingredient (INCI) for cosmetic products, which will come into force on November 16th, 2006. Therefore, by November 16th, 2006 all cosmetics and personal care products sold to retailers in Canada must contain a list of ingredients on the label using the INCI system.

This policy pertains to the enforcement of sections 21.2 to 21.5 of the *Cosmetic Regulations* as published in *Canada Gazette*, Part II on December 1st, 2004.

This policy is an interpretive tool. To the extent there is an inconsistency between the policy and the law, the law governs over this administrative policy.

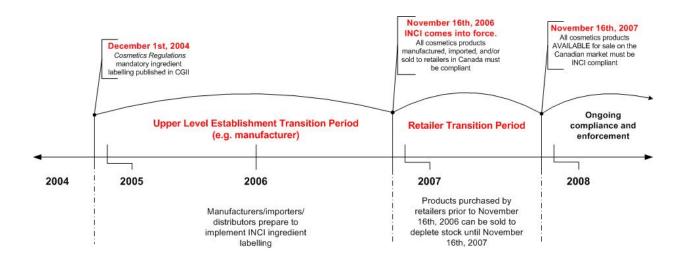
POLICY STATEMENT

All cosmetic products as of November 16th, 2006 must be in full compliance with the new requirements of the *Cosmetic Regulations* (mandatory ingredient labelling using the INCI system). This policy applies to all cosmetic products sold in Canada. It does not apply to products destined for export only.

An additional one year transition period for retailers will be provided to deplete inventory purchased prior to November 16th, 2006. During the transition period, consumers may request a list of ingredients from the manufacturer or importer.



As of November 16th, 2007, all cosmetic products available on the Canadian market including on retail shelves, must be in compliance with the *Cosmetic Regulations*.



RESPONSIBILITIES

It is the responsibility of the establishment to ensure that cosmetic products marketed for sale in Canada comply with the *Food and Drugs Act* and *Cosmetic Regulations*, including labelling of ingredients. The implementation of this policy is the responsibility of Health Canada. It is the responsibility of the consumer to read all product labelling. It is the responsibility of manufacturers to provide a list of ingredients to consumers upon request.

COMPLIANCE APPROACH

Compliance and enforcement efforts are focussed on areas where activities will have the greatest impact on the health and safety of consumers. The determination of enforcement action will depend upon the risk posed to the public, extent and quality of labelling, level of infraction, and the level of trade at which the product is observed. Enforcement actions may include the following: trader commitment, recall, removal of product, seizure, and/or prosecution.

This policy takes effect on November 16th, 2006. Health Canada may take action at any time in response to non-compliance.

DEFINITIONS

Cosmetic includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes.

Establishment - for the purposes of this policy, establishments are categorized into the following types: Manufacturer, Importer, Distributor, Wholesaler, Head Office of a Retain Chain, Retailer. The term *establishment* includes the person, business, or corporation responsible for the importation, manufacture, advertisement or sale of a product in Canada. The term includes an individual, sole proprietorship, unincorporated association, unincorporated syndicate, unincorporated organization, trust, body, corporate, and an individual in his or her capacity as trustee, executor, administrator or other legal representative.

ICI Dictionary means the *International Cosmetic Ingredient Dictionary and Handbook*, 10th Edition (2004), published in Washington, D.C., U.S.A., by The Cosmetic, Toiletry, and Fragrance Association Inc., as amended from time to time.

INCI name means the International Nomenclature Cosmetic Ingredient (INCI) name assigned to an ingredient in the ICI Dictionary.

Sell includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration.

ASSOCIATED DOCUMENTS

Other documents pertaining to compliance and enforcement aspects of labelling of cosmetic products are available on the Health Canada web site, and include:

- Information Pamphlet for Industry: Mandatory Ingredient Labelling for Cosmetics in Canada www.hc-sc.gc.ca/cps-spc/person/cosmet/label-ingredient-etiquet_e.html
- Cosmetic Regulations, Canada Gazette, Part II. December 1, 2004 www.hc-sc.gc.ca/cps-spc/alt_formats/hecs-sesc/pdf/person/cosmet/cosmetics_re gulations_e.pdf
- Frequently Asked Questions

 www.hc-sc.gc.ca/cps-spc/person/cosmet/faq_industry_e.html
 www.hc-sc.gc.ca/cps-spc/person/cosmet/faq_health_e.html
 www.hc-sc.gc.ca/cps-spc/person/cosmet/faq_consumers_e.html
- Healthy Environments and Consumer Safety Branch Compliance & Enforcement Policy (*Available upon request*)