



LIST OF PROHIBITED AND RESTRICTED COSMETIC INGREDIENTS (THE COSMETIC INGREDIENT “HOTLIST”)

March, 2007

This March 2007 Cosmetic Ingredient “Hotlist” replaces the May 2005 version.

Section 16 of the *Food and Drugs Act* states that no person shall sell a cosmetic product that has in it any substance that may injure the health of the user when the cosmetic is used according to its customary method. To help cosmetic manufacturers satisfy this requirement, Health Canada has developed the Cosmetic Ingredient Hotlist - a list of substances which are restricted and prohibited in cosmetics.

The Cosmetic Ingredient Hotlist is a science-based document that is reviewed and updated a few times per year as new scientific data become available. In this way, the Hotlist serves to keep the cosmetic industry aware of new substances of concern. It is recommended to check the Cosmetics Program website regularly, or contact the Cosmetics Division directly to ensure the most accurate information.

If a cosmetic contains an ingredient which appears on the Hotlist, the manufacturer may be advised to:

- Remove the substance from the formulation;
- Reduce the concentration of the ingredient to an acceptable level;
- Consider marketing the product as a drug, with appropriate claims and apply for a Drug Identification Number (DIN);
- Provide evidence that the product is safe for its intended use;
- Confirm that the product is labelled as required;
- Confirm that the product is sold in a child-resistant package.

Depending on the response of the manufacturer, the cosmetic may be found to be unacceptable for sale in Canada. In such a case, the product would be:

- Referred to a regional Product Safety Officer for appropriate action;
- Referred to the Health Products and Food Branch (HPFB) Inspectorate.

The Hotlist appears below, listing ingredients in alphabetical order. Substances are designated as prohibited unless a specified restriction is stated. Caution statements and directions for safe use must appear on the label in English and French.

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NOTE:

- 1) If a cosmetic contains a restricted ingredient, the notifying company must indicate, in their cosmetic notification form, the **exact concentration** at which it is present in the product.
- 2) Unless otherwise stated, substances listed on the Cosmetic Ingredient Hotlist are prohibited in cosmetic products. Substances listed with specific condition(s) outlined are restricted in cosmetic products.

Example: 8 - Hydroxyquinoline and its sulfate

Permitted only as stabilizers for hydrogen peroxide in hair-care preparations, with a concentration equal to or less than

- a) 0.3% in rinse-off preparations
- b) 0.03% in leave-on preparations

This means that 8-Hydroxyquinoline and its sulfate are prohibited in cosmetics unless used as a stabilizer in a hair product at the indicated concentrations.

Please be aware of discrepancies between nomenclature, as one substance may have several synonyms. Whenever possible, ingredients on the Hotlist will appear under International Nomenclature of Cosmetic Ingredients (INCI) form, followed by a Chemical Abstracts Service number (CAS #). In the case that an INCI name or CAS # does not exist, ingredients may be listed by one of the following:

1. Latin name
2. International Non-Prioprietary Names (INN) recommended by the World Health Organization
3. European or U.S. Pharmacopoeia name
4. International Union of Pure and Applied Chemistry (IUPAC) name or Chemical Abstracts Service (CAS) name
5. Common name

Synonyms can be found by performing an internet search engine query. If in doubt, please contact the Cosmetics Division.

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Acenocoumarol (152-72-7)

Acetonitrile (75-05-8)

Acetylcholine (β -acetoxyethyl trimethyl ammonium hydroxide) (51-84-3)

Acetylsalicylic acid (50-78-2)

Aconitine (302-27-2) and its salts

***Aconitum napellus* L.** leaves, roots and galenical preparations

***Adonis vernalis* L.** and its preparations

Alkali earth metal sulfides (including, but not limited to barium sulfide (21109-95-5), calcium sulfide (20548-54-3), magnesium sulfide (12032-36-9), or strontium sulfide (1314-96-1))

Permitted at concentrations equal to or less than 6% sulfur in depilatories.

Alkali pentacyanonitrosylferrate (2-)

Alkali sulfides (including, but not limited to lithium sulfide (12136-58-2), potassium sulfide (1312-73-8), or sodium sulfide (1313-82-2))

Permitted at concentrations equal to or less than 2% sulfur in depilatories.

O-Alkyldithiocarbonic acids, salts of

Alkyne alcohols and their esters, ethers and salts

Alloclamide (5486-77-1) and its salts

Allyl isothiocyanate (57-06-7)

2-(4-Allyl-2-methoxyphenoxy)-N,N-diethylacetamide (305-13-5) and its salts

Alpha-hydroxy acids (including, but not limited to citric acid (77-92-9), glycolic acid (79-14-1), lactic acid (50-21-5), malic acid (6915-15-7), glycolic acid + ammonium glycolate, alpha-hydroxyethanoic acid + ammonium alpha-hydroxyethanoate, alpha-hydroxyoctanoic acid, alpha-hydroxycaprylic acid, hydroxycaprylic acid, mixed fruit acid, triple fruit acid, tri-alpha hydroxy fruit acids, alpha hydroxy and botanical complex, L-alpha hydroxy acid and glycomer in cross-linked fatty acids alpha nutrium)

Permitted at concentrations equal to or less than 10%, with a pH equal to or greater than 3.5.

Bath bombs may contain levels of citric acid exceeding 10%.

Preparations containing higher concentrations of AHAs may be permitted for use if the manufacturer provides Health Canada with evidence of their safety, pH levels, and the directions for use.

Cosmetics, with the exception of bath bombs, shall carry cautionary statements to the effect: "Use only as directed, avoid contact with the eyes, if irritation persists, discontinue use and consult a physician, it is recommended that prior to exposure to the sun, users cover areas to which AHAs have been applied, with sunscreen, contact of the product with the skin must be of limited frequency and duration."

Ambenonium salts

2-Amino-1,2-bis(4-methoxyphenol) ethanol (530-34-7) and its salts

Aminocaproic acid (1319-82-0) and its salts

2-Amino-4-nitrophenol (99-57-0)

2-Amino-5-nitrophenol (121-88-0)

4-Amino-2-nitrophenol (119-34-6)

Aminophylline (58-55-9, 317-34-0)

4-Aminosalicylic acid (65-49-6) and its salts

Amitriptyline (50-48-6) and its salts

Ammi majus and its galenical preparations

Amydracaine (alpine) (1,1-bis (dimethylaminomethyl) propyl benzoate) (963-07-5) and its salts

Amylocaine (644-26-8) and its salts

Anaesthetic effects, substances with

Analgesics

Anamirta cocculus L. fruit

Androgenic effects, substances with

Aniline (62-53-3), its salts and, its halogenated and sulfonated derivatives

Anthracene (120-12-7) oil

Antiandrogens with steroid structure

Antibiotics

Antihistamines

Antimony (7440-36-0) and its compounds

Apocynum cannabinum L. and its preparations

Apomorphine (58-00-4) and its salts

Apronalide (528-92-7)

Arecoline (63-75-2)

Aristolochic acid (313-67-7) and its salts

Arsenic (7440-38-2) and its compounds

Atropa belladonna L. and its preparations

Atropine (51-55-8), its salts and derivatives

Azacyclonol (115-46-8) and its salts

Azamethonium salts

Barbiturates

Barium salts

Permitted only as barium sulfate (7727-43-7), as a colouring agent or as a lake for preparation of other colouring agents and barium sulfide (21109-95-5).

Basic Violet 1 (CI 42535) (8004-87-3)

Basic Violet 3 (CI 42555, CI 42555:1, CI 42555:2) (548-62-9)

Basic Violet 10 (CI 45170) (81-88-9)

Bemegrade (64-65-3)

Benactyzine (302-40-9)

Bendroflumethiazide (73-48-3) and its derivatives

Benzadiazepines

Benzalkonium chloride (8001-54-5, 61789-71-7, 68391-01-5, 68424-85-1)

Permitted at concentrations equal to or less than 0.1% as a preservative (i.e. benzalkonium chloride with chain lengths ≥ 14 C) in all products.

Permitted at concentrations equal to or less than 3% as a conditioning agent (i.e. benzalkonium chloride with chain lengths ≥ 16 C) in rinse-off products.

Benzatropine (86-13-5) and its salts

Benzazepines

Benzene (71-43-2)

Benzethonium chloride (121-54-0)

Permitted at concentrations equal to or less than 0.2% in leave-on products and 0.3% in rinse-off products.

Not permitted in products to be applied to mucous membranes.

Benzidine (92-87-5)

Benzilium bromide (1050-48-2)

Benzimidazol-2(3H)-one

Benzoyl peroxide (94-36-0)

Permitted at concentrations equal to or less than 10% for use only as a catalyst in products to be applied to the fingernails or in hair dyes.

Not permitted in products to be applied to the skin.

Benzyl cyanide (140-29-4)

Benzylidene acetone (122-57-6)

4-Benzyloxyphenol (monobenzene) (103-16-2)

Beryllium (7440-41-7) and its compounds

Betoxycaine (3818-62-0) and its salts

Bietamiverine (479-81-2)

Biphenamine (3572-52-9) and its salts

Bispyrithione (3696-28-4)

Bithionol (97-18-7)

Boric acid (10043-35-3, 11113-50-1) and its salts

Permitted at concentrations equal to or less than 5%.

The label of the cosmetic shall carry cautionary statements to the effect: "Do not use on broken or abraded skin, not to be used by children under three years of age." Warning is not required when boric acid is used as a pH adjuster and the concentration is equal to or less than 0.1%.

Bovine tissues and ingredients derived from the skull, brain, trigeminal ganglia, eyes, spinal cord, and dorsal root ganglia of cattle aged 30 months or older and the small intestine and tonsils of cattle of all ages

This prohibition does not apply to tallow derivatives, or to gelatin, collagen and hydrolyzed proteins prepared from bovine hides and skins.

Bretylium tosilate (61-75-6)

Bromine (7726-95-6), elemental

Bromisoval (496-67-3)

2-Bromo-2-nitropropane-1,3-diol (52-51-7)

Permitted at concentrations equal to or less than 0.1%.

Not permitted in formulations that contain amines or amides.

5-Bromo-5-nitro-1,3-dioxane (30007-47-7)

Permitted at concentrations equal to or less than 0.1%.

Not permitted in formulations that contain amines or amides.

Brompheniramine (86-22-6) and its salts

Brucine (357-57-3)

Permitted at concentrations equal to or less than 0.1%

Butanilcaine (3785-21-5) and its salts

Butopiprine (55837-15-5) and its salts

Butoxyethanol (111-76-2)

Permitted at concentrations equal to or less than 10% in hair dyes and nail products.

1-Butyl-3-(N-crotonoylsulfanilyl) urea (52964-42-8)

4-tert-Butylphenol (98-54-4)

4-tert-Butylpyrocatechol (98-29-3)

Cadmium (7440-43-9) and its compounds

Calcium peroxide (calcium dioxide) (1305-79-9) (see peroxide and peroxide generating compounds).

Camphor (76-22-2)

Permitted at concentrations equal to or less than 3%.

Cannabis sativa seed oil (Hemp seed oil) (8016-24-8, 68956-68-3)

Permitted at concentrations less than 10 µg/g THC (delta-9-tetrahydrocannabinol), as per the *Industrial Hemp Regulations*.

Cantharides

Cantharidin (56-25-7)

Cantharis vesicatoria

Captan (N-(trichloromethylthiol)-4-cyclohexene-1,2-dicarboximide) (133-06-2)

Captodiame (486-17-9)

Caramiphen (77-22-5, 125-85-9) and its salts

Carbamide (urea) peroxide (124-43-6) (see peroxide and peroxide generating compounds).

Carbazol (86-74-8), nitroderivatives of

Carbon disulfide (75-15-0)

Carbon tetrachloride (56-23-5)

Carbromal (77-65-6)

Carbutamide (339-43-5)

Carisoprodol (78-44-4)

Catalase (9001-05-2)

The inner label and the outer label of the cosmetic shall carry a cautionary statement to the effect:
"This product is not intended for use on broken or abraded skin."

Cephaeline (483-17-0) and its salts

Cephaelis ipecacuanha Brot. and related species roots, powder, and galenical preparations

Chenopodium ambrosioides essential oil (8006-99-3)

Chloral hydrate (302-17-0)

Chloramine T (127-65-1)

Chlorhexidine (55-56-1) and its salts

Permitted at concentrations equal to or less than 0.14%, calculated as chlorhexidine (55-56-1) free base; 0.19%, calculated as chlorhexidine diacetate (56-95-1); 0.20%, calculated as chlorhexidine digluconate (18472-51-0); and 0.16%, calculated as chlorhexidine dihydrochloride (3697-42-5)

Chlorine (7782-50-5)

Chlormethine (51-75-2) and its salts

Chlormezanone (80-77-3)

Chloroacetamide (79-07-2)

N-5-Chlorobenzoxazol-2-ylacetamide and its salts

Chloroethane (75-00-3)

N,N-bis(2-Chloroethyl)methylamine N-oxide and its salts

Chloroform (67-66-3)

Chlorophacinone (2-(2-(4-chlorophenyl)-2-phenylacetyl indan-1,3-dione) (3691-35-8)

Chlorphenoxamine (77-38-3)

Chlorpropamide (94-20-2)

Chlorprothixene (113-59-7) and its salts

Chlortalidone (77-36-1)

Chlorzoxazone (95-25-0)

Cholecalciferol (67-97-0)

Average daily absorption must be equal to or less than 25 µg per day.

Choline (62-49-7) salts and their esters

Chromic acid (1308-14-1, 7738-94-5, 13530-68-2) and its salts

Chromium (7440-47-2)

Chrysoidine citrate hydrochloride

CI 12140 (3118-97-6)

CI 13065 (587-98-4)

CI 42640 (1694-09-3)

Cinchocaine (85-79-0) and its salts

Cinchophen (132-60-5), its salts, derivatives and salts of these derivatives

Citrus reticulata leaf oil (8014-17-3)

Permitted at concentrations equal to or less than 0.1% in leave-on products.

Claviceps purpurea Tul., its alkaloids and galenical preparations

Clobetasone (54063-32-0)

Clofenamide (671-95-4)

Clofenotane (50-29-3)

Clostridium botulinum

Coal tar dye, coal tar dye base or coal tar dye intermediate

According to section 14 of the *Cosmetic Regulations*, "no person shall sell a cosmetic for use in the area of the eye that contains any coal tar dye, coal tar dye base or coal tar dye intermediate." "Area of the eye" is defined by the area bound by the supraorbital and infraorbital ridges and includes the eyebrows, the skin underlying the eyebrows, the eyelids, and eyelashes, the conjunctival sac of the eye, the eyeball and the soft tissue that lies below the eye and within the infraorbital ridge.

The following coal tar dyes are permitted in the area of the eye: Blue 1 (3844-45-9) and lake, Green 5 (4403-90-1), Red 40 (25956-17-6) and lake, Yellow 5 (1934-21-0) and lake.

Permitted in hair dye provided:

(a) the inner label and the outer label of the cosmetic shall carry statements to the effect:

“CAUTION: this product contains ingredients that may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows. To do so, may cause blindness.”

"MISE EN GARDE: Ce produit contient des ingrédients qui peuvent causer de l'irritation cutanée chez certaines personnes: il faut donc d'abord effectuer une épreuve préliminaire selon les directives ci-jointes. Ce produit ne doit pas servir à teindre les sourcils ni les cils: en ce faisant, on pourrait provoquer la cécité.”; and

(b) instructions to the following effect accompany each package of hair dye:

(i) the preparation may cause serious inflammation of the skin in some persons and a preliminary test should always be carried out to determine whether or not special sensitivity exists; and

(ii) to make the test, a small area of skin behind the ear or on the inner surface of the forearm should be cleansed, using either soap and water or alcohol, and a small quantity of the hair dye as prepared for use should be applied to the area and allowed to dry. After 24 hours, the area should be washed gently with soap and water. If no irritation or inflammation is apparent, it is usually assumed that no hypersensitivity to the dye exists. The test should, however, be carried out before each application. On no account should the hair dye be used for dyeing eyebrows or eyelashes as severe inflammation of the eye or even blindness may result.

Coal tars (crude and refined) (8007-45-2)

Cobalt benzenesulfonate

Colchicine (64-86-8), its salts and derivatives

Colchicoside (477-29-2) and its derivatives

***Colchicum autumnale* L.** and its galenical preparations

Coniferyl alcohol (4-hydroxy-3-methoxycinnamyl alcohol) (458-35-5), except for naturally occurring in plant extracts.

Coniine (458-88-8)

***Conium maculatum* L.** fruit, powder and galenical preparations

Convallatoxin (508-75-8)

Coumetarol (4366-18-1)

Creosote (coal tar creosote (8001-58-9), wood creosote (8029-39-4))

Crimidine (2-chloro-6-methylpyrimidin-4-yl dimethylamine) (535-89-7)

Croton tiglium oil (8001-28-3)

Curare (8063-06-7, 2251-14-9)

Curarine (22260-42-0)

Curarizants, synthetic

Cyclarbamate (5779-54-4)

Cyclizine (82-92-8) and its salts

Cyclocoumarol (518-20-7)

Cyclomenol (5591-47-9) and its salts

Cyclophosphamide (50-18-0) and its salts

***Datura stramonium* L.** and its galenical preparations

Deanol aceglumate (3342-61-8)

Decamethylenebis (trimethylammonium) salts

Dextromethorphan (125-71-3) and its salts
Dextropropoxyphene (469-62-5)
O,O'-Diacetyl-N-allyl-N-normorphine
Dialkanolamines, secondary
2,4-Diaminophenylethanol and its salts
5-(α , β -Dibromophenethyl)-5-methylhydantoin (511-75-1)
Dibromosalicylanilides
Dichloroethanes (ethylene chlorides)
Dichloroethylenes (acetylene chlorides)
2,3-Dichloro-2-methylbutane (507-45-9)
Dichlorosalicylanilides
Dicoumarol (66-76-2)
3-Diethylaminopropyl cinnamate
Diethyl maleate (141-05-9)
Diethyl 4-nitrophenyl phosphate (311-45-5)
Diethyl toluamide (DEET) (134-62-3)
Difenclozazine (5617-26-5)
Digitaline (71-63-6)
Digitalis purpurea L., all heterosides of
Dihydrocoumarin (119-84-6)
Dihydrotachysterol (67-96-9)
2,4-Dihydroxy-3-methylbenzaldehyde (6248-20-0)
4,4'-Dihydroxy-3,3'-(3-methylthiopropylidene) dicoumarin
5,5'-Diisopropyl-2,2'-dimethylbiphenyl-4,4'-diyl dihyppiodite
Dimethoxane (2,6-dimethyl-1,3-dioxan-4-yl acetate) (828-00-2)
Dimethylamine (124-40-3)
4,6-Dimethyl-8-*tert*-butylcoumarin (17874-34-9)
Dimethyl citraconate (617-54-9)
7,11-Dimethyl-4,6,10-dodecatrien-3-one (26651-96-7)
Permitted at concentrations equal to or less than 2% only as an impurity in methylionones.
Dimethylformamide (68-12-2)
1,3-Dimethylpentylamine (105-41-9) and its salts
Dimethyl sulfoxide (DMSO) (67-68-5)
6,10-Dimethyl-3,5,9-undecatrien-2-one (141-10-6)
Dimevamide (60-46-8) and its salts
Dinitrophenol isomers (25550-58-7)
Dioxane (1,4-dioxane) (123-91-1)
Dioxethedrin (497-75-6) and its salts
Diphenhydramine (58-73-1) and its salts
Diphenoxylate hydrochloride (3810-80-8)

Diphenylamine (122-39-4)
5,5-Diphenyl-4-imidazolidone (3254-93-1)
Diphenylpyraline (147-20-6) and its salts
Disulfiram (97-77-8)
Doxylamine (469-21-6) and its salts
Emetine (483-18-1), its salts and derivatives
Endrin (72-20-8)
Ephedrine (299-42-3) and its salts
Epinephrine (51-43-4)
1,2-Epoxybutane (106-88-7)
Ergocalciferol (50-14-6)

Average daily absorption should be equal to or less than 25 µg per day.

Eserine (57-47-6) and its salts
Estil (305-13-5) and its salts
Estradiol (50-28-2)
Estrogens
Estrone (53-16-7)
Ethinylestradiol (57-63-6)
Ethionamide (536-33-4)
Ethoheptazine (77-15-6) and its salts
Ethoxyethanol (110-80-5)
Ethoxyethanol acetate (111-15-9)
4-Ethoxyphenol (622-62-8)
4-Ethoxy-m-phenylenediamine (5862-77-1) and its salts
Ethyl biscoumacetate (548-00-5) and salts of the acid
Ethylenediamine (107-15-3)
Ethylene oxide (75-21-8)
Ethyl methacrylate (97-63-2)

The label of the cosmetic shall carry a cautionary statement to the effect: "Avoid skin contact".

Ethyl PABA (benzocaine) (94-09-7)
Ethylphenacemide (90-49-3)
β-Eucaine (500-34-5)
Eucalyptus oil (8000-48-4)

Permitted at concentrations equal to or less than 25%.

Fenadiazole (1008-65-7)
Fenozolone (15302-16-6)
Fenyramidol (553-69-5)
Ficus carica leaf absolute (68916-52-9)
Fluanisone (1480-19-9)
Fluoresone (2924-67-6)

Fluoride (16984-48-8) containing substances (including, but not limited to sodium fluoride (1333-83-1, 7681-49-4), calcium fluoride (7789-75-5), stannous fluoride (7783-47-3) and sodium monofluorophosphate (10163-15-2))

Not permitted in dentifrices, mouthwashes or breath drops.

Fluorouracil (51-21-8)

Formaldehyde (50-00-0)

Permitted at concentrations equal to or less than 0.2% as the minimum concentration to provide effective antimicrobial preservation, except in nail hardeners where the concentration can be equal to or less than 5% and in oral care products where concentrations are equal to or less than 0.1%.

Nail hardeners containing formaldehyde must be sold with nail shields, directions for use, and a cautionary statement to the effect: "This product contains formaldehyde which has the potential to cause skin sensitivity".

Not permitted in aerosol cosmetics.

Furazolidone (67-45-8)

Furfuryltrimethylammonium salts

Furocoumarins (66-97-7), except for naturally occurring in plant extracts

Permitted at concentrations less than 1 mg/kg in sun tanning products.

Galantamine (357-70-0)

Gallamine triethiodide (65-29-2)

Glucocorticoids (1524-88-5)

Glutarimide (1121-89-7) and its salts

Glutethimide (77-21-4) and its salts

Glycyclamide (664-95-9)

Gold salts

Guaifenesin (93-14-1)

Guanethidine (55-65-2) and its salts

Haloperidol (52-86-8)

trans-2-Heptenal (18829-55-5)

Hexachloroethane (67-72-1)

Hexachlorophene (2,2'-dihydroxy-3,3',5,5',6,6'-hexachlorodiphenylmethane) (70-30-4)

Hexaethyl tetraphosphate (757-58-4)

Hexamethonium salts

Hexapropymate (358-52-1)

Human origin, substance of (including, but not limited to human placental extracts, human placental enzymes, human placental lipids, human placental protein, human umbilical extract, hydrolyzed human placental protein (73049-73-7), hydrolyzed keratin from human hair, lyophilized human placental extract)

Manufacturers using substances of human origin must provide the following information to the Cosmetics Division of the Consumer Product Safety Bureau:

- 1) source of the substance;
- 2) a description of the method of production;
- 3) quality control data, particularly those relating to microbial limits (including viruses) and the absence of estrogenic substances;
- 4) product labelling.

Hydrastine (118-08-1) and their salts

Hydrastinine (6592-85-4) and their salts

Hydrazides and their salts

Hydrazine (302-01-2), its derivatives and their salts

Hydroabietyl alcohol (13393-93-6)

Hydrofluoric acid (7664-39-3), its normal salts, its complexes and hydrofluorides

Hydrogen cyanide (74-90-8) and its salts

Hydrogen peroxide (7722-84-1) (see peroxide and peroxide generating compounds).

Hydrolyzed Hemp seed protein

Permitted at concentrations less than 10 µg/g THC (delta-9-tetrahydrocannabinol), as per the *Industrial Hemp Regulations*.

Hydroquinone (123-31-9)

Not permitted in products to be applied on the skin or mucous membranes.

p-Hydroxyanisole (4-methoxyphenol) (150-76-5)

Permitted at concentrations equal to or less than 0.02% (after mixing), for professional use only, in artificial nail systems.

The inner label and the outer label of the cosmetic shall carry statements to the effect: "For professional use only, avoid skin contact, read use directions carefully".

11- α -Hydroxypregn-4-ene-3,20-dione (80-75-1) and its esters

8-Hydroxyquinoline (148-24-3) and its sulfate (134-31-6)

Permitted at concentrations equal to or less than 0.3% as stabilizers for hydrogen peroxide in rinse-off hair-care preparations, and 0.03% in leave-on preparations.

Hydroxyzine (68-88-2)

Hyoscine (51-34-3), its salts and derivatives

Hyoscyamine (101-31-5), its salts and derivatives

***Hyoscyamus niger* L.** leaves, seeds, powder, and galenical preparations

3-Imidazol-4-ylacrylic acid (104-98-3) and its ethyl ester (urocanic acid (108-98-3))

Imperatorin (482-44-0)

Indanedioxa

Permitted as a fragrance ingredient, as per the *Canadian Environmental Protection Act's* Ministerial Condition No. 13052, September 4, 2004.

Inproquone (436-40-8)

Inula helenium oil (97676-35-2)

Iodine (7553-56-2)

Isocarboxazide (59-63-2)

Isodrin (465-73-6)

Isomethoptene (503-01-5) and its salts

Isophorone (78-59-1)

Isoprenaline (7683-59-2)

Isopropamide (N-(3-carbamoyl-3,3-diphenylpropyl)-N,N-diisopropylmethylammonium) salts

6-Isopropyl-2-decahydronaphthalenol (34131-99-2)

Isosorbide dinitrate (87-33-2)

***Juniperus sabina* L.** leaves, essential oil (68916-94-9) and galenical preparations

Keratin (see Human origin, substances of and/or Bovine tissues and ingredients)

***Laurus nobilis* L.**, oil (8007-48-5) from the seeds of

Lead (7439-92-1) and its compounds

Lead acetate (301-04-2)

Levopropacetoperane (24558-01-8) and its salts

Lidocaine (137-58-6)

Lindane (58-89-9)

***Lobelia inflata* L.** and its galenical preparations

Lobeline (90-69-7) and its salts

Lysergide (50-37-3) and its salts

Magnesium peroxide (1335-26-8) (see peroxide and peroxide generating compounds).

Malononitrile (109-77-3)

Mannomustine (576-68-1) and its salts

Mecamylamine (60-40-2)

Mefeclozazine (1243-33-0) and its salts

Mephesisin (59-47-2) and its esters

Meproamate (57-53-4)

Mercury (7439-97-6) and its compounds (including, but not limited to mercuric oxide (21908-53-2), phenyl mercuric acetate (62-38-4), phenyl mercuric benzoate (94-43-9), phenyl mercuric borate (102-98-7, 6273-99-0) and thimerosal (54-64-8))

Mescaline (3,4,5-trimethoxyphenethylamine) (54-04-6) and its salts

Metaldehyde (9002-91-9)

Metamfepramone (15351-09-4) and its salts

Metethoheptazine (509-84-2) and its salts

Metformin (657-24-9) and its salts

Methacrylic acid (79-41-4)

The inner label and the outer label of a cosmetic that contains more than 5% methacrylic acid shall carry a cautionary statement to the effect: "This product contains methacrylic acid, is poisonous, is to be kept out of reach of children and, in the case of accidental ingestion, a Poison Control Centre or physician is to be contacted immediately".

Methapyrilene (91-80-5) and its salts

Metheptazine (469-78-3) and its salts

Methocarbamol (532-03-6)

Methotrexate (59-05-2)

2-(4-Methoxybenzyl-N-(2-pyridyl)amino) ethyldimethylamine maleate

7-Methoxycoumarin (531-59-9)

1-Methoxy-2,4-diaminobenzene (2,4-diaminoanisole, CI 76050) (615-05-4) and their salts

1-Methoxy-2,5-diaminobenzene (2,5-diaminoanisole) (1244-42-1) and their salts

Methoxyethanol (109-86-4)

4-(4-Methoxyphenyl)-3-butene-2-one (943-88-4)

4-Methoxy-m-phenylenediamine (615-05-4) and its sulfate salts

4-Methoxy-m-phenylenediamine-HCl

Methyl alcohol (67-56-1)

The principal display panel of the inner label and the outer label of the container of a cosmetic, other than a disposal metal container designed to release pressurized contents by the use of a manually operated valve that forms an integral part of the container, that contains an amount of methyl alcohol equal or greater than 5 mL, shall display:

(a) the hazard symbol set out in column II of item 1 of Schedule II of the *Consumer Chemicals and Containers Regulations*, as they read on September 30th, 2001, in accordance with paragraphs 16(a) and (b) of those regulations; and

(b) for each of the particulars set out in column 1 of items 1 to 5 of the *Consumer Chemicals and Containers Regulations*, the signal word and statements set out in column III and IV of those items which shall be located on the labels in accordance with paragraphs 15(2)(a) to (c) of those regulations and printed in accordance with paragraphs 17(a) and (b), 18(a), (b) and 19(1)(a) and (b) and subsection 19(2) of those regulations.

α-Methylanisalacetone (104-27-8)

Methyl-trans-2-butenoate (623-43-8)

Methylene chloride (75-09-2)

Not permitted in aerosol preparations.

Methyl eugenol (93-15-2)

Permitted as a naturally occurring component in botanical extracts at concentrations equal to or less than 0.01% in fine fragrances, 0.004% in eau de toilette, 0.002% in a fragrance cream, 0.0002% in other leave-on products and in oral hygiene products, and 0.001% in rinse-off products.

2-Methylheptylamine (540-43-2) and its salts

5-Methyl-2,3-hexanedione (13706-86-0)

Methylisothiazolinone (2682-20-4)/ Methylchlorisothiazolinone (26172-55-4), in combination

Permitted at concentrations equal to or less than 0.0015% (15 µg/mL or 15 ppm) in rinse-off products and 0.00075% (7.5 µg/mL or 7.5 ppm) in leave-on products.

Methylisothiazolinone (2682-20-4)

Permitted at concentrations equal to or less than 0.01% for use as a preservative.

Methyl methacrylate monomer (80-62-6)

Methyl N-methyl anthranilate (85-91-6)

Permitted at concentrations equal to or less than 0.1%.

Methylphenidate (113-45-1) and its salts

2-Methyl-m-phenylenediamine (823-40-5)

4-Methyl-m-phenylenediamine (95-80-7) and its salts

Methyl salicylate (119-36-8)

Permitted at concentrations equal to or less than 1%.

Methyprylon (125-64-4) and its salts

Metypapone (54-36-4)

Minoxidil (38304-91-5), its salts and derivatives

Mixed cresols (1319-77-3) and derivatives

Mofebutazone (2210-63-1)

Morpholine (110-91-8) and its salts

Musk ambrette (4-*tert*-butyl-3-methoxy-2,6-dinitrotoluene) (83-66-9)

Musk tibetene (5-*tert*-butyl-1,2,3-trimethyl-4,6-dinitrobenzene) (145-39-1)

Nail adhesives that have the capability to quickly bond skin

The innermost package, sold alone or as part of a kit, must be child resistant. Refer to part 4 of the *Consumer Chemicals and Containers Regulations* as they read on September 30th, 2001 for requirements.

Nalorphine (62-67-9), its salts and ethers

Naphazoline (835-31-4) and its salts

2-Naphthol (135-19-3)

1-and 2-Naphthylamines (134-32-7 and 91-59-8, respectively) and their salts

3-(α -Naphthyl)-4-hydroxycoumarin (39923-41-6)

Narcotics, natural and synthetic

Neodymium (7440-00-8) and its salts

Neostigmine (59-99-4) and its salts

Nicotine (54-11-5) and its salts

Nitrites, amyl

Nitrites (14797-65-0), inorganic, except sodium nitrite

Nitrobenzene (98-95-3)

Nitrocresols (12167-20-3) and their alkali metal salts

Nitrofurantoin (67-20-9)

Nitroglycerin (55-63-0)

Nitrosamines

Nitrostilbenes, their homologues and their derivatives

Nitroxoline (4008-48-4) and its salts

Noradrenaline (51-41-2) and its salts

Noscapine (128-62-1) and its salts

Octamoxin (4684-87-1) and its salts

Octamylamine (502-59-0) and its salts

Octodrine (543-82-8) and its salts

Oleandrin (465-16-7)

Oxanamide (126-93-2) and its derivatives

Oxypheneridine (546-32-7) and its salts

PABA (4-aminobenzoic acid), esters of; with a free amino group

Paramethasone (53-33-8)

Parathion (O,O'-diethyl O-4-nitrophenyl phosphorothioate) (56-38-2)

Parethoxycaine (94-23-5) and its salts

Pelletierine (2858-66-4) and its salts

Pemoline (2152-34-3) and its salts

Pentachloroethane (76-01-7)

Pentaerythrityl tetranitrate (78-11-5)

Pentamethonium salts

Pentyl dimethyl PABA (14779-78-3) (amyl 4-dimethylaminobenzoate), mixed isomers

2-Pentylidenecyclohexanone (25677-40-1)

Peroxide and peroxide-generating compounds (including, but not limited to urea (carbamide) peroxide (124-43-6), calcium peroxide (calcium dioxide) (1305-79-9), hydrogen peroxide (7722-84-1), magnesium peroxide (1335-26-8), sodium perborate (7632-04-4), and zinc peroxide (1314-22-3).

The labels of oral cosmetics containing peroxides or peroxide generating compounds shall carry cautionary statements to the effect:

"If irritation (such as redness, swelling, soreness) of the gums or the mouth occurs, discontinue use and consult a dentist, products containing peroxides are not recommended for use by children under 12 years of age, use for periods of longer than 14 days is to be only under the supervision of a dentist, avoid swallowing the cosmetic or part thereof and, avoid contact of the product with the eye".

Tooth whitening system cosmetics shall carry an additional cautionary statement to the effect: "Avoid direct contact of the active surface of the tooth whitening product with the gums and/or salivary flow."

Manufacturers of oral products containing peroxides or peroxide-generating compounds must submit the following information to the Cosmetics Division of the Consumer Product Safety Bureau:

- (a) data on the pH of the cosmetic product, when it is applied to the tooth or teeth, to ensure that the product is in compliance with section 13 of the *Cosmetic Regulations*, i.e. that the pH is greater than or equal to 4.0; and
- (b) product labelling demonstrating that all warning/cautionary statement requirements have been met.

If an oral cosmetic contains more than 3% hydrogen peroxide (or equivalent), notifiers must submit evidence that the product does not cause the saliva or soft tissue of the oral cavity to exceed 3% hydrogen peroxide, and is safe when used as directed. Evidence may include analog studies from recognized sources or independent clinical research.

NB:

Please be aware of the conversion factor between hydrogen peroxide and other peroxide-generating compounds. For example, 10% carbamide (urea) peroxide is approximately equivalent to 3% hydrogen peroxide.

Petrichloral (78-12-6)

Phenacemide (63-98-9)

Phenaglycodol (79-93-6)

Phenetamine (3590-16-7)

Phenindione (83-12-5)

Phenmetrazine (134-49-6), its derivatives and salts

Phenol (108-95-2)

Phenolphthalein (77-09-8)

Phenothiazine (92-84-2) and its compounds

Phenprobamate (673-31-4)

Phenprocoumon (435-97-2)

Phenylbutazone (50-33-9)

o-Phenylenediamine (95-54-5) and its salts

p-Phenylenediamine (106-50-3)

Permitted only in oxidative hair dyes provided:

(a) the inner label and the outer label of the cosmetic products carry the following warning:

“CAUTION: This product contains ingredients that may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows. To do so, may cause blindness.

MISE EN GARDE: Ce produit contient des ingrédients qui peuvent causer de l'irritation cutanée chez certaines personnes: il faut donc d'abord effectuer une épreuve préliminaire selon les directives ci-jointes. Ce produit ne doit pas servir à teindre les sourcils ni les cils: en ce faisant, on pourrait provoquer la cécité.”, and

(b) instructions to the following effect accompany each package of hair dye:

(i) the preparation may cause serious inflammation of the skin in some persons and a preliminary test should always be carried out to determine whether or not special sensitivity exists; and

(ii) to make the test, a small area of skin behind the ear or on the inner surface of the forearm should be cleansed, using either soap and water or alcohol, and a small quantity of the hair dye as prepared for use should be applied to the area and allowed to dry. After 24 hours, the area should be washed gently with soap and water. If no irritation or inflammation is apparent, it is usually assumed that no hypersensitivity to the dye exists. The test should, however, be carried out before each application. On no account should the hair dye be used for dyeing eyebrows or eyelashes as severe inflammation of the eye or even blindness may result.

Not permitted in products intended for use on the skin.

Pheromones

Phosphorus (7723-14-0) and metal phosphides

***Physostigma venenosum* Ball.**

***Phytolacca* spp.** and their preparations

Picric acid (88-89-1)

Picrotoxin (124-87-8)

Pigment Orange 5 (CI 12075) (3468-63-1) and its lakes, pigments and salts

Pigment Red 53 (CI 15585) (2092-56-0)

Pilocarpine (92-13-7) and its salts

***Pilocarpus jaborandi* Holmes** and its galenical preparations

Pipazetate (2167-85-3) and its salts

Piper methysticum extract (kava kava) (9000-38-8)

Pipradrol (467-60-7) and its salts

Piprocuarium salts

Placental extracts (see Human origin, substances of)

Poldine methylsulfate (545-80-2)

Potassium bromate (2139-59-4)

The inner label and the outer label of a cosmetic that contains an amount of potassium bromate equal to or greater than 50 mg shall carry a cautionary statement to the effect: “This product contains potassium bromate, is poisonous, and is to be kept out of the reach of children and, in case of accidental ingestion, a Poison Control Centre or physician is to be contacted immediately.”

Cosmetics containing potassium bromate must be packaged in a child-resistant container, according to part 4 of the *Consumer Chemicals and Containers Regulations* as they read on September 30th, 2001.

Pramocaine (140-65-8)

Probenecid (57-66-9)

Procainamide (51-06-9), its salts and derivatives

Progestogens

PropylNitrate (2921-92-8)

Propyphenazone (479-92-5)

Prunus laurocerasus L.

Psilocybine (520-52-5)

Pueraria mirifica

Pyrethrum album L. and its galenical preparations

Pyrocatechol (catechol) (120-80-9)

Pyrogallol (87-66-1)

Radioactive substances

Rauwolfia serpentina alkaloids and their salts

Retinol (vitamin A) (68-26-8) and its esters; retinyl acetate (127-47-9), retinyl palmitate (79-81-2)

Permitted at concentrations equal to or less than 1%.

Safrole (94-59-7) except when naturally occurring in plant extracts

Salicylic acid (69-72-7)

Permitted at concentrations equal to or less than 2%.

α -Santonin (481-06-1)

Schoenocaulon officinale Lind. seeds and galenical preparations

Selenium (7782-49-2) and its compounds, excluding selenium sulfide (7488-56-4).

Siloxanes and Silicones, 3-[(2-aminoethyl)amino]-2-methylpropyl Me, di-Me, reaction products with N,N,N-trimethyloxiranemethanaminium chloride (495403-02-6),

For concentrations exceeding 4%, the company must submit a skin sensitization study and other data requirements to Environment Canada's New Substances Program at least 90 days prior to the manufacture of the product, as per Significant New Activity Notice No. EAU-135 under the *Canadian Environmental Protection Act's New Substances Notification Regulations*, November 13, 2004.

Silver (7440-22-4) and its salts

Restricted to concentrations equal to or less than 0.04% in mouthwash.

Any cosmetic containing silver and/or its salts shall carry cautionary statements to the effect: "This product contains silver and/ or silver salts, avoid contact with broken or abraded skin."

Sodium borate (1303-96-4)

Permitted at concentrations equal to or less than 5%.

The label of the cosmetic shall carry cautionary statements to the effect: "Do not use on broken or abraded skin, not to be used by children under three years of age." Warnings are not required where sodium borate is used as a pH adjuster, and the concentration is equal to or less than 0.1%.

Sodium bromate (7789-38-0)

The inner label and the outer label of a cosmetic that contains an amount of sodium bromate equal to or greater than 600 mg shall carry a cautionary statement to the effect: "This product contains sodium bromate, is poisonous, is to be kept out of the reach of children and, in case of accidental ingestion, a Poison Control Centre or physician is to be contacted immediately."

Cosmetics containing sodium bromate must be packaged in a child-resistant container, according to part 4 of the *Consumer Chemicals and Containers Regulations* as they read on September 30th, 2001.

Sodium hexacyclonate (7009-49-6)

Sodium perborate (7632-04-4) (see peroxide and peroxide generating compounds).

Sodium picramate (831-52-7)

Permitted at concentrations equal to or less than 0.1%

Sodium pyrithione (3811-73-2)

Solanum nigrum L. and its galenical preparations

Solvent Blue 35 (CI 61554) (17354-14-2)

Solvent Red 24 (CI 26105) (85-83-6)

Solvent Red 49:1 (CI 45170-1) (81-88-9)

Sparteine (90-39-1) and its salts

Spirolactone (19-00-0)

Steroids

Strontium (7440-24-6) and its salts, other than nitrite

Permitted at concentrations equal to or less than 6.6% in salt, or equal to or less than 2.1% elemental strontium, whichever represents the smallest amount of strontium (depending on the salt).

Permitted at concentrations equal to or less than 3.5% strontium in depilatory products.

Not permitted in aerosol products.

Strontium nitrite (13470-06-9)

Strontium polycarboxylate

Strophantines, their aglucones and derivatives

Strophantus spp. and their galenical preparations

Strychnine (57-24-9) and its salts

Strychnos spp. and their galenical preparations

Succinonitrile (110-61-2)

Sulfinpyrazone (57-97-5)

Sulfonamides (63-74-1) and their salts obtained by substitution of one or more H-atoms of the -NH₂ groups

Sultiame (61-56-3)

Sympathicomimetic amines

Symphytum spp. (Comfrey), with the exception of *Symphytum officinale*

Tagetes oil (8016-84-0) and absolute

Permitted at concentrations equal to or less than 0.01% in leave-on products.

Talc

The inner label and the outer label of baby powder products shall carry cautionary statements to the effect: "Keep out of reach of children, and keep powder away from child's face to avoid inhalation which can cause breathing problems."

TBHQ (t-butylhydroquinone) (1948-33-0)

Permitted at concentrations equal to or less than 0.1%.

Tefazoline (1082-56-0) and its salts**Tellurium** (13494-80-9) and its compounds**Tetrabenazine** (58-46-8) and its salts**Tetrabromosalicylanilides****Tetracaine** (94-24-6) and its salts**2,3,7,8-Tetrachlorodibenzo-p-dioxin** (1746-01-6)**Tetrachloroethylene** (127-18-4)**Tetrachlorosalicylanilides****Tetraethyl pyrophosphate** (107-49-3)**Tetrahydrozoline** (84-22-0) and its salts**Tetrylammonium bromide** (71-91-0)**Thalidomide** (50-35-1) and its salts**Thallium** (7440-28-0) and its compounds**Theophylline** (58-55-9)***Thevetia nerifolia* Juss.** glycoside extract**Thiamazole** (60-56-0)**Thimerosal** (54-64-8) (see mercury and its compounds)**Thioglycolic acid** (68-11-1) and its salts

Permitted at concentrations equal to or less than 8% with a pH of 7 to 9.5 in hair waving and straightening products.

Directions for use shall carry cautionary statements to the effect: "Avoid direct skin contact, wear suitable gloves".

Permitted at concentrations equal to or less than 11% with a pH of 7 to 9.5 in hair waving and straightening products for professional use.

The label of the cosmetic shall carry, in addition to the above directions, a statement to the effect: "For professional use only".

Permitted at concentrations equal to or less than 5% with a pH of 7 to 12.7 in depilatory products.

The label of the cosmetic shall carry cautionary statements to the effect: "Avoid contact with eyes and, in the event of contact with eyes, rinse immediately with plenty of water and seek medical attention".

Thiotepa (52-24-4)**Thiourea** (62-56-6) and its derivatives, with the exception of thioglycolic acid and its salts and esters**Thiuram** (137-26-8)**Thiuram** disulfides**Thiuram** monosulfides**Thyropropic acid** (51-26-3) and its salts

Thyothricine (1404-88-2)

Tiratricol (51-24-1)

Tolboxane (2430-48-8)

Tolbutamide (64-77-7)

Tolnaftate (2398-96-1)

Toluene-2,4-diamine (95-80-7)

Toluidines (26915-12-8), their isomers, salts and halogenated and sulfonated derivatives, except 4-hydroxy-2-nitro-toluidine and hydroxyethyl-2-nitro-p-toluidine

Toxins

Tranlycypromine (155-09-9) and its salts

Tretamine (51-18-3)

Tretinoin (retinoic acid) (302-79-4)

Triamterene (396-01-0) and its salts

Tribromoethanol (75-80-9)

Tribromosalicylanilide (1322-38-9)

Trichlormethine (817-09-4) and its salts

Trichloroacetic acid (76-03-9)

Trichloronitromethane (76-06-2)

Triclosan (3380-34-5)

Permitted at concentrations equal to or less than 0.03% in mouthwash and 0.3% in other cosmetic products.

All triclosan-containing products must meet the following conditions:

(a) chlorinated dibenzodioxin and dibenzofuran (PCDD/PCDF) impurities must not be present in quantities exceeding those described as follows:

(i) the concentration of the impurities, 2,3,7,8-tetra-chlorodibenzo-p-dioxin and 2,3,7,8-tetra chlorodibenzofuran, must not exceed 0.1 ng/g.

(ii) the total concentration of all other PCDD/PCDF impurities must not be greater than 10 ug/g, with no individual impurity greater than 5 ug/g.

(b) the labels of oral cosmetics shall carry statements to the effect: "The product is not to be used by children under the age of 12, in the case of mouthwashes, avoid swallowing"; and

(c) manufacturers must provide the following:

(i) raw material specifications for triclosan;

(ii) identification of the method of analysis used to determine the levels of PCDD's and PCDF's in triclosan;

(iii) finished product specifications; and

(iv) copy of product labelling

Tricresyl phosphate (tritolyl phosphate) (1330-78-5)

Trifluoperidol (749-13-3)

N,N,N-Trimethyloxiranemethanamonium chloride (495403-02-6) with **Siloxanes and Silicones, 3-[(2-aminoethyl)amino]-2-methylpropyl Me, di-Me, reaction products**

For concentrations exceeding 4%, the company must submit a skin sensitization study and other data requirements to Environment Canada's New Substances Program at least 90 days prior to

the manufacture of the product, as per Significant New Activity Notice No. EAU-153 under the *Canadian Environmental Protection Act's New Substances Notification Regulations*, November 13, 2004.

3,6,10-Trimethyl-3,5,9-undecatrien-2-one (1117-41-5)

Triparanol (78-41-1)

Tripelennamine (91-81-6)

Tuaminoheptane (123-82-0), its isomers and salts

Urea (57-13-6)

Permitted at concentrations equal to or less than 10%.

Urea (carbamide) peroxide (124-43-6) (see peroxide and peroxide generating compounds)

Uriginea scilla Stern. and its galenical preparations

Vaccines

Valnoctamide (4171-13-5)

Veratrine (62-59-9), its salts and galenical preparations

Veratrum spp. and their preparations

Versalide (88-29-9)

Vinyl chloride monomer (27-39-8)

Warfarin (81-81-2) and its salts

Xanthinol (2530-97-4)

Xylidines (1300-73-8), their isomers, salts and, halogenated and sulfonated derivatives.

Xylometazoline (526-36-3) and its salts

Yohimbine (146-48-5) and its salts

Zinc peroxide (1314-22-3) (see peroxide and peroxide generating compounds)

Zirconium (7440-67-7) and its compounds, except the complexes, zirconium lakes, salts and pigments of zirconium colouring agents

Aluminum zirconium chloride hydroxide complexes $Al_xZr(OH)_yCl_z$ and aluminum zirconium chloride hydroxide glycine complex are permitted only in deodorants in concentrations equal to or less than 25%, as anhydrous aluminum zirconium chloride and equal to or less than 5.45% as zirconium. The ratio of the number of aluminum atoms to that of the zirconium atoms must be between 2 and 10. The ratio of the number of (Al + Zr) atoms to that of the chlorine atoms must be between 0.9 and 2.1.

The inner label and the outer label of the cosmetic shall carry a cautionary statement to the effect: "Do not apply to irritated or damaged skin".

Not permitted in aerosol dispensers.

Zoxazolamine (61-80-3)