



NPA Standard and Certification for Personal Care Products

In order to protect the consumer and best equip her to maximize her well-being, we have developed ***Natural Products Association Standard and Certification for Personal Care Products***. It is a set of guidelines that dictates whether a product can be deemed truly “natural.” It encompasses all cosmetic personal care products regulated and defined by the FDA.

All products that are labeled or branded “Natural” **must**:

- Be made with **at least 95%** natural ingredients – excluding water
- Contain only synthetic ingredients specifically allowed under this standard and environmentally-friendly products that are nurturing to us and as harmless as possible to the earth (see Appendix I)

What is “Natural”:

- **Ingredients** that come or are made from a **renewable resource found in nature** (Flora, Fauna, Mineral), with absolutely no petroleum compounds. (See Appendix IV for allowed processes)

A synthetic non-natural ingredient **can** be used:

- Only when there is not a readily available natural alternative ingredient (See Appendix II for a list of allowed synthetics)
- Only when there are **no** suspected human health risks as indicated by peer-reviewed third-party scientific literature

Ingredients that are prohibited:

- Ingredients that have suspected human health risks as indicated by peer-reviewed third-party scientific literature
- Ingredients that incorporate synthetic silicone or petroleum compounds
- The following is an illustrative list of ingredient classes that are prohibited (see Appendix III for a longer list of prohibited ingredients):
 - **Parabens** — Synthetic preservatives that are potential endocrine disrupters (1-8)
 - **Sodium Lauryl Sulfate** — Harsh cleansing agent that can potentially damage the lipid layer of your skin and cause irritation (9-12)
 - **Petrolatum/Mineral Oil/Paraffin** — Non-renewable byproducts of crude oil with potentially dangerous impurities (13-18)
 - **Chemical Sunscreens (Avobenzone/Oxybenzone)** — Synthetic sunscreens that get absorbed and potentially disrupt hormone balance (19-22)
 - **Glycols** — Petroleum derived synthetic chemicals that can potentially draw other chemicals into the bloodstream (23, 24)
 - **Phthalates** — Synthetic fragrance components that are potential toxins (25-34)
 - **Ethoxylated ingredients like Sodium Myreth Sulfate and Sodium**



Laureth Sulfate, PEGs or PPGs — Ingredients that are made in part with the petrochemical ethylene oxide, that results in 1,4 Dioxane as a trace contaminant, classified as a possible carcinogen (35-37)

- **Ethanolamines like MEA/DEA/TEA** — Foam and viscosity boosting ingredients that can interact with other ingredients to form nitrosamines, a known carcinogen (37)
- **Synthetic polymers (PVP/Acrylates)** — Synthetic stabilizers that may contain residual PAHs (polycyclic aromatic hydrocarbons), a widespread organic pollutant
- **Formaldehyde Donors** (DMDM Hydantoin/Diazolidinyl Urea) — Preservatives that work by releasing formaldehyde (5)
- **Synthetic Fragrances** — Fragrances that use petroleum-based solvents for extraction as well as purely synthetic additives. Prohibited fragrance ingredients include absolutes, concretes, gums, resins, exudates, essential oils, isolates and chemicals*

Other requirements:

- For each ingredient, the substance is listed as generally recognized as safe (GRAS) by Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA or EPA or has been reviewed using criteria in this Standard.
- Companies must be transparent, fully disclosing their ingredients accurately and truthfully on product labels using formal INCI nomenclature to describe all cosmetic ingredients.
- Companies must use a majority of recyclable and post-consumer recycled content in their packaging.
- Companies must avoid animal testing of ingredients or products except where required by law.
- Companies need at least 60% of their product line to qualify (meet the criteria) for Natural certification, before any products are certified. Additional sizes of a certified product or kits/packs made up of certified products are not included in the calculation of the 60% requirement.
- Companies must provide full documentation for certified products upon request of NPA staff.
- Any changes to the certified formula must be made known to NPA staff before production begins on the adjusted formula. Formulation changes include, but are not limited to, changing ingredients/raw materials in the formulation, changing percentage of the same ingredients in the formulation, changing and/or adding a raw material supplier, the supplier changing an ingredient/raw material, etc.



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Appendices

I. Illustrative “Positive List” of allowed natural ingredients (see attached)

- Ingredients included on this list, may not be accepted in all available forms.
- NPA will need documentation that the ingredient has been sourced naturally and processed within the list of allowed processes (see Appendix IV).

II. Allowed synthetic ingredients — those temporarily allowed in this phase of the standard:

- Quaternary anti-static hair conditioners (only in hair conditioning products)
 - Guar Hydroxypropyltrimonium Chloride
 - Hydroxypropyltrimonium Honey
 - Shea Butter Amidopropyltrimonium Chloride
- Benzyl Alcohol
- Coco Betaine
- Dehydroacetic Acid
- Phenoxyethanol
- Potassium Sorbate
- Sodium Benzoate

Notes:

- Total use of allowed synthetic ingredients may not exceed 5.0% of the total formula - excluding water.
- Synthetic definition is based on the NOP definition and is a substance which has been formulated or manufactured by a chemical process outside of the list of allowed processes or was derived from a source other than a naturally occurring plant, mineral or animal source.
- These allowed synthetic ingredients are consistently evaluated by the steering committee to be eliminated in future phases of the standard – once appropriate natural alternatives are commercially available. Any changes to this list will be well-publicized by the NPA and companies with certified products will be given advance notice before changes are implemented.



III. Prohibited ingredients — illustrative (i.e., non-exhaustive) list

A. By Types/Classes:

- Synthetic Silicone Ingredients
- Synthetic Fragrances
- Synthetic Preservatives not otherwise specifically allowed
- Compounds with "ethoxylate", "PEG", "PPG" or the suffix "-eth" in the ingredient name
- Compounds with "sarcosinate" in the ingredient name
- Compounds with "MEA", "DEA" or "TEA" in the ingredient name
- Compounds with "taurate" in the ingredient name
- Compounds with "sultaine" in the ingredient name
- Compounds with "Sulfosuccinate" in the ingredient name

B. Specific ingredients:

- Ammonium Lauryl Sulfate
- Amodimethicone
- Behentrimonium Methosulfate
- Butylene glycol
- Carbomer
- Ceteareth-20
- Cetrimonium Chloride
- Coco DEA
- Cocoamidopropyl Betaine
- Cyclopentasiloxane
- Dimethicone
- Disodium Cocoamphodiacetate
- EDTA
- Ethylene glycol
- Glycereth-7 Cocoate
- Isoceteth 20
- Isopropyl Palmitate
- Lauramide MEA
- Lauryl DEA
- Methoxycinnamate
- Methylisothiazolinone
- Olefin Sulfonate
- Oleyl Betaine
- Parabens (methyl, propyl, butyl, etc.)
- PEG-150 Distearate
- PEG-7 Glyceryl Cocoate
- Polyquaternium 10
- Polysorbate
- Sodium Cocoyl Sarcosinate
- Sodium Hydroxymethylglycinate
- Sodium Laureth Sulfate
- Sodium Lauroyl Sarcosinate
- Sodium Lauryl Carboxylate
- Sodium Lauryl Sulfate



- Sodium Lauryl Sulfoacetate
- Sodium Myreth Sulfate
- Soyamidopropalkonium Chloride
- Stearamidopropyl Dimethyl Amine

Note:

- Includes synthetic silicone or petroleum compounds that are not specifically mentioned elsewhere in the standard.
- The Natural Standard requires all fragrances in finished products to be all natural to receive certification. This effectively eliminates fragrance ingredients that require the use of petrochemical solvents for extraction, as well as purely synthetic additives, these fragrance ingredients include absolutes, concretes, gums, resins, exudates, essential oils, isolates and chemicals*.

*Any natural fragrance ingredients are allowed, if the extraction/processing uses an allowed process as stated in The Natural Standard.



IV: Illustrative List of Allowed Processes

Detail of Processes Allowed Under this Standard that Produce Many of the Ingredients on the Attached Positive List (rev. 01/01/13)

Distillation of Essential Oils

Reagents: Water (high-pressure steam)

Catalysts: None

Agricultural Inputs: plant material (flowers, herbs, spices, etc.)

Description: The physical process to acquire essential oils from plant material.

Esterification OR Transesterification to Produce Esters

Reagents: None

Catalysts: Sulfuric/Phosphoric Acid; KCO₃, NaCO₃, NaOH, KOH, CH₃ONa, or CH₃CH₂ONa

Agricultural Inputs: Acid and Alcohol, e.g. Fatty Alcohol, Glycerin, Ethanol, Acetic Acid

Description: The process of forming an ester bond between an acid and an alcohol, can be catalyzed by either an alkali or acid.

Etherification of Glycerin making PolyGlyceryls

Reagents: None

Catalysts: Alkali (NaOH or KOH)

Agricultural Inputs: Glycerin (product of fat-splitting)

Description: The process of forming ether bonds between two compounds of natural glycerin (see fat-splitting) to form polyglyceryls by heating with an alkali. Polyglyceryl products are indicated with a number to represent the number of glycerin molecules linked together.

Expression

Reagents: None

Catalysts: None

Agricultural Inputs: Plant material (flowers, herbs, spices, fruit, etc.)

Description: The physical process of cold-pressing plant material to acquire essential oils.

Extraction

Reagents: CO₂, alcohol

Catalysts: None

Agricultural Inputs: Plant material (flowers, herbs, spices, etc.)

Description: The physical process to acquire plant extracts from original plant material.

Fat-Splitting of Oils to Produce Glycerin and Fatty Acids

Reagents: Water (high-pressure steam)

Catalysts: Metal/Metal Compound Catalysts (Zinc Oxide, Nickel, Palladium, Platinum)

Agricultural Inputs: Triglyceride fats and oils; Carbohydrates, Sugars

Description: The process of splitting natural fats and oils into glycerin and fatty acids, a kind of hydrolysis.

Fermentation

Reagents: None

Catalysts: Enzymes

Agricultural Inputs: Carbohydrates, Sugars, Bacteria, Yeasts, Fungi

Description: The process of converting carbohydrates into alcohol and carbon dioxide or organic acids.

Glucosidation of Fatty Alcohol and Glucose

Reagents: None

Catalysts: Toluene Sulfonic Acid

Agricultural Inputs: Glucose and Fatty Alcohol

Description: The process of attaching glucose to an alcohol, a type of etherification (e.g. Coco Glucoside).

Hydrogenation of Oils

Reagents: Hydrogen

Catalysts: Nickel, Platinum or Palladium

Agricultural Inputs: Triglyceride fat/oil usually

Description: The process by which unsaturated bonds are reduced by the addition of hydrogen with a catalyst, specifically converting unsaturated fatty acids to saturated ones or waxes to oils.

Hydrogenolysis of Methyl Esters of an Oil to Make Fatty Alcohols

Reagents: Hydrogen from Natural Gas

Catalysts: Methanol; Nickel, Platinum, Palladium

Agricultural Inputs: Methyl or Ethyl Ester of Triglyceride fat/oil (fat/oil original ag input)

Description: The process by which hydrogen is utilized to break chemical bonds converting a fatty acid ester into the fatty alcohol and methyl or ethyl alcohol (whichever is used for the ester). This process can also be utilized directly on the fatty acid without conversion to the ester first.

Hydrolysis of Complex Proteins into Simple Amino Acids

Reagents: Water

Catalysts: Enzymes or Alkali (KOH or NaOH)

Agricultural Inputs: Proteins, Carbohydrates, Sugars

Description: The process of breaking down complex proteins into water-soluble amino acids or peptides (if partially hydrolyzed).

Oxidation with Mild Agents

Reagents: Dilute H₂O₂, O₂, Silver and Copper salts

Catalysts: Silver, Copper

Agricultural Inputs: Plant-based Alcohols, Aldehydes

Description: The process by which alcohols and aldehydes are converted to acids by oxidation.



Protein Fragment Acylation

Reagents: KOH or NaOH

Catalysts: Phosphorous Trichloride or Thionyl Chloride

Agricultural Inputs: Fatty Acid and Protein Fragment

Description: The process of attaching a fatty acid to a nitrogen-containing compound. The fatty acid is converted to a fatty acid chloride before attachment to the nitrogen of a protein fragment (e.g. glutamic acid to make Cocoyl Glutamate).

Saponification of Oils to Make Soap

Reagents: Alkali (KOH or NaOH)

Catalysts: None

Agricultural Inputs: Triglyceride fats and oils

Description: The process by which fats or oils are split into the glycerin and the free fatty acids by the addition of an alkali, a type of hydrolysis.

Sulfation of Fatty Alcohol

Reagents: Sulfate/SO₃ and NaOH

Catalysts: None

Agricultural Inputs: Fatty Alcohol

Additional Note: Sodium Lauryl Sulfate (SLS) is not allowed

Description: The process of converting a fatty alcohol into the sulfate ester to produce a surfactant

Links to government resources:

<http://toxnet.nlm.nih.gov/>

<http://ntp.niehs.nih.gov/ntp/roc/toc11.html>

<http://www.cdc.gov/niosh/npg/search.html>

<http://cactus.nci.nih.gov/cgi-bin/lookup/search>



Reference:

1. Alexiades-Armenakas M. Parabens toxicity to skin and other organs. *J Drugs Dermatol* 2008;7:77-8.
2. Chen J, Ahn KC, Gee NA, Gee SJ, Hammock BD, Lasley BL. Antiandrogenic properties of parabens and other phenolic containing small molecules in personal care products. *Toxicol Appl Pharmacol* 2007;221:278-84.
3. El Hussein S, Muret P, Berard M, Makki S, Humbert P. Assessment of principal parabens used in cosmetics after their passage through human epidermis-dermis layers (ex-vivo study). *Exp Dermatol* 2007;16:830-6.
4. Harvey PW, Everett DJ. Regulation of endocrine-disrupting chemicals: critical overview and deficiencies in toxicology and risk assessment for human health. *Best Pract Res Clin Endocrinol Metab* 2006;20:145-65.
5. Kiec-Swierczynska M, Krecisz B, Swierczynska-Machura D. [Contact allergy to preservatives contained in cosmetics]. *Med Pr* 2006;57:245-9.
6. Lee HB, Peart TE, Svoboda ML. Determination of endocrine-disrupting phenols, acidic pharmaceuticals, and personal-care products in sewage by solid-phase extraction and gas chromatography-mass spectrometry. *J Chromatogr A* 2005;1094:122-9.
7. Prusakiewicz JJ, Harville HM, Zhang Y, Ackermann C, Voorman RL. Parabens inhibit human skin estrogen sulfotransferase activity: possible link to paraben estrogenic effects. *Toxicology* 2007;232:248-56.
8. Soni MG, Carabin IG, Burdock GA. Safety assessment of esters of p-hydroxybenzoic acid (parabens). *Food Chem Toxicol* 2005;43:985-1015.
9. Kartono F, Maibach HI. Irritants in combination with a synergistic or additive effect on the skin response: an overview of tandem irritation studies. *Contact Dermatitis* 2006;54:303-12.
10. Marrakchi S, Maibach HI. Sodium lauryl sulfate-induced irritation in the human face: regional and age-related differences. *Skin Pharmacol Physiol* 2006;19:177-80.
11. Dehelean C, Nastase V, Dragomirescu A, Hedges A, Dinte E. [Skin toxicity of sodium lauryl sulfate as evidenced in an animal model]. *Rev Med Chir Soc Med Nat Iasi* 2004;108:169-72.
12. Baert JH, Veys RJ, Ampe K, De Boever JA. The effect of sodium lauryl sulphate and triclosan on hamster cheek pouch mucosa. *Int J Exp Pathol* 1996;77:73-8.
13. Nguyen SH, Dang TP, Maibach HI. Comedogenicity in rabbit: some cosmetic ingredients/vehicles. *Cutan Ocul Toxicol* 2007;26:287-92.
14. Otsuki J, Nagai Y, Chiba K. Peroxidation of mineral oil used in droplet culture is detrimental to fertilization and embryo development. *Fertil Steril* 2007;88:741-3.
15. Song YF, Zhou QX, Song XY, Zhang W, Sun TH. [Evaluation of eco-toxicity of integral quality of soils]. *Huan Jing Ke Xue* 2005;26:130-4.
16. Steinsvag K, Bratveit M, Moen BE. Exposure to carcinogens for defined job categories in Norway's offshore petroleum industry, 1970 to 2005. *Occup Environ Med* 2007;64:250-8.
17. Sverdrup B, Klareskog L, Kleinau S. Common commercial cosmetic products induce arthritis in the DA rat. *Environ Health Perspect* 1998;106:27-32.
18. Martinez TT, Long C, Schmidt CJ. The dermal toxicity of industrial metal-working lubricants. *Proc West Pharmacol Soc* 1995;38:69-70.
19. Ziolkowska A, Belloni AS, Nussdorfer GG, Nowak M, Malendowicz LK. Endocrine disruptors and rat adrenocortical function: studies on freshly dispersed and cultured cells. *Int J Mol Med* 2006;18:1165-8.
20. Janjua NR, Mogensen B, Andersson AM, et al. Systemic absorption of the sunscreens benzophenone-3, octyl-methoxycinnamate, and 3-(4-methyl-benzylidene) camphor after whole-body topical application and reproductive hormone levels in humans. *J Invest Dermatol* 2004;123:57-61.



21. Schlecht C, Klammer H, Jarry H, Wuttke W. Effects of estradiol, benzophenone-2 and benzophenone-3 on the expression pattern of the estrogen receptors (ER) alpha and beta, the estrogen receptor-related receptor 1 (ERR1) and the aryl hydrocarbon receptor (AhR) in adult ovariectomized rats. *Toxicology* 2004;205:123-30.
22. Wada H, Tarumi H, Imazato S, Narimatsu M, Ebisu S. In vitro estrogenicity of resin composites. *J Dent Res* 2004;83:222-6.
23. Final report on the safety assessment of Triethylene Glycol and PEG-4. *Int J Toxicol* 2006;25 Suppl 2:121-38.
24. Zesch A. Adverse reactions of externally applied drugs and inert substances. *Derm Beruf Umwelt* 1988;36:128-33.
25. NTP Toxicology and Carcinogenesis Studies of Diethylphthalate (CAS No. 84-66-2) in F344/N Rats and B6C3F1 Mice (Dermal Studies) with Dermal Initiation/ Promotion Study of Diethylphthalate and Dimethylphthalate (CAS No. 131-11-3) in Male Swiss (CD-1(R)) Mice. *Natl Toxicol Program Tech Rep Ser* 1995;429:1-286.
26. Api AM. Toxicological profile of diethyl phthalate: a vehicle for fragrance and cosmetic ingredients. *Food Chem Toxicol* 2001;39:97-108.
27. Api AM. Evaluation of the dermal subchronic toxicity of phenoxyethyl isobutyrate in the rat. *Food Chem Toxicol* 2004;42:307-11.
28. Api AM, Ford RA. Evaluation of the dermal subchronic toxicity of diphenyl ether in the rat. *Food Chem Toxicol* 2003;41:259-64.
29. Elsisi AE, Carter DE, Sipes IG. Dermal absorption of phthalate diesters in rats. *Fundam Appl Toxicol* 1989;12:70-7.
30. Kennedy GL, Jr., Lu MH, McAlack JW. Teratogenic evaluation of 1,1,3,3-tetrabutylurea in the rat following dermal exposure. *Food Chem Toxicol* 1987;25:173-6.
31. Koo HJ, Lee BM. Estimated exposure to phthalates in cosmetics and risk assessment. *J Toxicol Environ Health A* 2004;67:1901-14.
32. Latini G, De Felice C, Verrotti A. Plasticizers, infant nutrition and reproductive health. *Reprod Toxicol* 2004;19:27-33.
33. Melnick RL, Morrissey RE, Tomaszewski KE. Studies by the National Toxicology Program on di(2-ethylhexyl)phthalate. *Toxicol Ind Health* 1987;3:99-118.
34. Morrissey RE, Harris MW, Schwetz BA. Developmental toxicity screen: results of rat studies with diethylhexyl phthalate and ethylene glycol monomethyl ether. *Teratog Carcinog Mutagen* 1989;9:119-29.
35. Final report on the safety assessment of Hexamidine and Hexamidine Diisethionate. *Int J Toxicol* 2007;26 Suppl 3:79-88.
36. Safety) NNloOHa. International Chemical Safety Card. CDC (Centers for Disease Control), 1993.
37. Services USDoHaH, Service PH, Program NT. 11th Report on Carcinogens. 2005.