



December 7, 2007

**CALL FOR COMMENTS: Proposed Green Seal™ Environmental Standard for Soaps, Cleansers, and Shower Products, GS-44**

Green Seal is developing a new environmental standard on soaps, cleansers, and shower products. Green Seal is a non-profit organization devoted to working towards environmental sustainability through environmental standard setting, product certification, and public education. The intent of Green Seal's standards is to reduce, to the extent technically and economically feasible, the environmental impacts associated with the manufacture, use, and disposal of products. With the rapid growth of environmentally preferable products in this category, and high consumer demand, an environmental label could provide clarity on which products are environmental leaders and assist consumers in their purchase decisions.

The Proposed Standard is now available for public review. Following this letter, is background information about the proposed standard. The Proposed Standard is available in a separate document. The public review process is a key step to involve all stakeholders in the development of this standard. Green Seal welcomes comment from all interested parties. Green Seal is soliciting suggestions and comments on these proposed revisions from the diverse stakeholders, including producers, users, and general interest groups. For public review of its standards, Green Seal considers each written comment, conducts follow-up research as needed, and revises the proposed standard accordingly, with a written response to the comment or group of comments on the issue. In Green Seal's experience, the process of commenting, discussing issues, and resolving issues is most critical for the success of a standard. Green Seal, therefore, encourages all interested parties to provide substantive comments on the proposal.

**The Proposed Standard is open for comment until February 1, 2008.**

Comments will be submitted through an online forum system. To post comments on the on-line forum, one must register to use the forum. All users will be able to view all the comments and the name of the commenter. Forum registration is open to all interested parties until the deadline. To register as a user and access the forum:

- Get on the following URL: <http://green-seal.org/standards>
- Register an account; for the username please use first initial and full last name (e.g., J Smith); select "GS-44 Consumer Soaps"; review the disclaimer information; click Register.
- You should receive a welcome email from the Green Seal Forum within one business day.
- Then post your comments in the appropriate section of the standard.

Additional information on this project and the proposed standard can be found at the project web site: [http://www.greenseal.org/certification/g44\\_consumerstandard\\_dev.cfm](http://www.greenseal.org/certification/g44_consumerstandard_dev.cfm)

By participating in the process of setting environmental standards, you play an important role in our efforts to encourage the design, manufacture, and use of environmentally responsible products and services. Thank you in advance for your participation.

Sincerely,  
Cheryl Baldwin, Ph.D.  
Director of Science and Standards

## **BACKGROUND INFORMATION ON PROPOSED STANDARD**

### **SCOPE**

The scope of the proposed standard includes personal care products that are rinsed off the body, including liquid and solid soaps and cleansers, shampoos, conditioners, shower products, any combinations of the above mentioned products, and other rinse-off products (solid, liquid or gel) for cleaning human body and hair. This would include consumer retail products as well as institutional or professional products. This is a similar scope to the standards in the Nordic Swan and EU Flower ecolabel programs. These programs also include similar products used for pets. As a result, the proposed standard will include pet products. Antimicrobial products are not included in this standard. Other active products, such as antidandruff products may be included in the standard, if they meet all the criteria in the standard.

The United States Food and Drug Administration (FDA) defines a soap as a product in which most of the nonvolatile matter consists of an alkali salt of fatty acids and whose detergent properties are due to these alkali-fatty acid compounds (21 CFR 701.20). Soap is regulated by the Consumer Product Safety Commission under authority of the Hazardous Substances Act. However, there are many products on the market that are not soaps, rather detergent products that are commonly called cleansers. These products, if intended to be used on the body for cleansing, beautifying, promoting attractiveness, or altering the appearance are considered cosmetic; thus, a non-soap product intended for any of these purposes is automatically classified as a cosmetic and regulated by the FDA. Further, these products may also be classified as drugs and further regulated by the FDA. While there are many regulatory bodies and regulations that apply to this product category, other ecolabel programs have incorporated both soaps and cleanser products by including comprehensive health and environmental criteria.

Cleansers, including soaps, shampoos, and conditioners, typically contain water (80-85% of the product), surfactants (anionic, amphoteric, or nonionic), fragrance, color, viscosity agents, preservatives, chelators, emollients, humectants, and pH regulators. Soaps (saponified oil or fat) include only 5-10% water, and typically also include an added fragrance. These products are typically packaged in ready-to-use containers. Reusable packages with refill product are also available. Concentrated products intended for dilution prior to use are available only on a limited extent.

### **PRODUCT PERFORMANCE REQUIREMENTS**

Product effectiveness is an important component of the marketability of the product and is an essential requirement for ecolabel programs, such as Green Seal's. However, there are no standardized methods, such as ASTM or ISO methods used to evaluate the performance effectiveness of the products in this standard. There are tests to determine antibacterial or other active product (ex. delousers) effectiveness. These however, are not included in the standard and thus cannot be applied. As a result, to demonstrate effectiveness, products shall perform as good as or better than a competitive product, using a fixed, repeatable procedure. The testing protocol shall include, at a minimum: cleaning ability, lathering/rinsing, and skin or hair condition after use. A standard soil shall be used and conclusions shall be derived from at least six separate samples. All results, a summary of conclusions, and a description of how panelists were chosen shall be submitted.

### **ENVIRONMENTAL AND HEALTH REQUIREMENTS**

Life cycle research shows that the highest environmental impacts are caused during raw material extraction and production and during the use-phase of the product with the use of heated water (EU, 2005). However, these products are used in high quantities. According to the Soap and Detergent Association, 42 percent of Americans wash their hands more than 10 times a day (Harper, 2007). As a result, other impact areas become significant. Further, these products are discharged to water after use.

Accordingly, properties such as biological degradability, bioaccumulation and toxicity in aquatic environments are key considerations. Further, shampoo and soap come into direct contact with the skin, even though they are eventually rinsed off the body. As a result, their content should be as safe as possible, with limitations of skin irritants, allergens, along with or other harmful components and pollutants should be as low as possible.

### Toxicity

To begin with, the Consumer Product Safety Commission (CPSC) has established criteria for hazardous substances. This includes definitions on what a “toxic” and “highly toxic” product are. To follow this guidance, this standard requires that the product shall not have toxic characteristics such that it falls under the labeling requirements as a toxic or highly toxic product, as defined by CPSC regulations found at 16 Code of Federal Regulations (CFR) Chapter II, Part 1500. For example, this would exclude such products that have an oral LD<sub>50</sub> ≤ 5 g/kg (rat); inhalation LC<sub>50</sub> ≤ 20,000 ppm (1 hr, rat, vapor) or ≤ 200 mg/L (1 hr, rat, mist or dust); Dermal LD<sub>50</sub> ≤ 2 g/kg (rabbit); and contain a known or probable human neurotoxin.

### Carcinogens, Mutagens, and Reproductive Toxins

The use of ingredients and intentional additives that are suggestive, likely, potential, possible, probable, reasonably anticipated, or known human carcinogens will be prohibited. Green Seal references known lists for carcinogens with the priority for international and national lists to follow the guidance of ISO 14024. This includes IARC, NTP, EPA, and OSHA.

Chemicals known to cause reproductive toxicity and include both male and female reproductive toxins and developmental toxins shall be prohibited. California Prop 65 is the most readily available and accepted source for these compounds and shall be cited. Further, mutagens will also be prohibited and defined according to the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) criteria for germ cell mutagenicity. Category 1 criteria are consistent with the EU classification and labeling criteria for Category 1 and 2 mutagenic substances (Langezaal, 2002), which are required to be labeled as follows: R46 May cause heritable genetic damage.

For all of these prohibitions, existing information is used for the evaluation. Product testing and ingredient testing is not conducted. These prohibitions apply to ingredients of the product, as defined in the standard, as well as intentional components. An intentional component is considered to be a deliberately added product component, where it is added for its continued presence in the final product to provide a specific characteristic, appearance, or quality. These prohibitions follow the common, protective approach for these materials in other ecolabel programs.

### Allergens

The EU Cosmetic Directive (and Detergent Directive) lists compounds that require labeling due to their known ability to cause allergic reactions. This standard proposes the prohibition of these compounds to provide an enhanced level of protection, like the prohibition of carcinogens, and will reference the EU allergen list. Below is the EU list of allergens:

- Amyl cinnamal (CAS No 122-40-7)
- Benzyl alcohol (CAS No 100-51-6)
- Cinnamyl alcohol (CAS No 104-54-1)
- Citral (CAS No 5392-40-5)
- Eugenol (CAS No 97-53-0)
- Hydroxy-citronellal (CAS No 107-75-5)
- Isoeugenol (CAS No 97-54-1)
- Amylcinnamyl alcohol (CAS No 101-85-9)
- Benzyl salicylate (CAS No 118-58-1)
- Cinnamal (CAS No 104-55-2)
- Coumarin (CAS No 91-64-5)

Geraniol (CAS No 106-24-1)  
Hydroxy-methylpentylcyclohexenecarboxaldehyd (CAS No 31906-04-4)  
Anisyl alcohol (CAS No 105-13-5)  
Benzyl cinnamate (CAS No 103-41-3)  
Farnesol (CAS No 4602-84-0)  
2-(4-tert-Butylbenzyl) propionaldehyd (CAS No 80-54-6)  
Linalool (CAS No 78-70-6)  
Benzyl benzoate (CAS No 120-51-4)  
Citronellol (CAS No 106-22-9)  
Hexyl cinnam-aldehyd (CAS No 101-86-0)  
d-Limonene (CAS No 5989-27-5)  
Methyl heptin carbonate (CAS No 111-12-6)  
3-Methyl-4-(2,6,6-tri-methyl-2-cyclohexen-1-yl)-3-buten-2-one (CAS No 127-51-5)  
Oak moss and treemoss extract (CAS No 90028-68-55)  
Treemoss extract (CAS No 90028-67-4)

### Skin and Eye Irritants and Sensitizers

Damaging, irritating, and sensitizing ingredients used in hand soaps and other body care products affect user safety and comfort. These should be avoided when possible. The GHS includes definitions and classification criteria for skin corrosion and "serious eye damage" (UN, 2005). These definitions are consistent with the definitions used by the US and the European Union for acute dermal irritation/corrosion (EPA, 1998a; OECD 2002a) and for acute eye irritation/corrosion (EPA, 1998b; OECD 2002b). However, the GHS more precisely defines these terms and uses the term "serious eye damage" instead of "eye corrosion." OECD defines skin (dermal) irritation in OECD Guidelines for Testing Chemicals, Section 404. A skin sensitizer is a substance that causes an immunologically mediated cutaneous reaction, also known as allergic contact dermatitis. Green Seal uses existing data to evaluate for these effects, so testing is typically not required, unless data is not available or indicate a need for testing.

### Skin Absorption

Since the nature of these products is to contact the skin, skin absorption potential and then potential for systemic toxicity needs to be considered. The potential for skin absorption can be estimated for individual ingredients using peer reviewed lists of chemicals with skin absorption potential from credible scientific sources. There is a list from the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values for Chemical Substances (TLV) that includes substances with a high potential for skin absorption (skin notation) and systemic health effects. Another is from the German Deutsche Forschungsgemeinschaft (DFG) Maximum Allowable Concentrations (MAK) list for chemicals with a high potential for skin absorption H notation. Both of these lists will be used to limit use of such substances, to less than 1% of the product formula. Thus, no testing is needed to meet this requirement.

### Asthma

Children have a higher rate of asthma than adults. There are a number of developmental and physiological factors that may contribute to this higher rate, including incomplete metabolic defenses and immunological mechanisms, a higher breathing rate, greater surface area to volume ratio as well as behavioral differences including hand to mouth activities and more time on the ground. Some of these characteristics may contribute to greater exposure and/or to greater susceptibility to hazardous effects from chemicals in the environment.

The criteria for designating substances as asthmagens have been made available for review and are accessible on the Association of Occupational and Environmental Clinics (AOEC) website (Beckett, 2005). The AOEC list provides valuable information that is not readily available elsewhere. It is periodically updated through a peer-reviewed process, and new chemicals are added and inaccurate listings are deleted. It has clear criteria, is accessible online, and oversight is provided by medical professionals with no financial incentive. Thus, it is sufficiently authoritative to address this very import

health concern for personal care products. As a result, this standard shall use the AOEC list to prohibit ingredients that are known to cause asthma. Testing is not needed to meet this requirement.

### Volatile Organic Compounds

Volatile organic compounds (VOCs) are carbon-based chemicals characterized by boiling points ranging from about 50-260°C and include alcohols, aldehydes, straight chain and cyclic alkanes, aromatic hydrocarbons, halogenated hydrocarbons, terpenes, ketones, and esters. VOCs are common ingredients in products with fragrances (and common cleaning products) and minimization of VOC exposure has been recognized as a key indoor air quality strategy (Franke, *et. al.*, 1997). Poor indoor air quality as a result of VOCs is also one of the biggest contributors to asthma and other respiratory ailments in school aged children. VOC content is typically low for the products in the scope of this standard. However, a limit has been included to ensure that any additives, such as fragrances, do not negatively impact indoor and outdoor air quality. This criterion specifies the California Air Resources Board method 310 for determining the acceptable levels of VOC content allowed in the various product classes. This method is established and well known. Currently existing exemptions for fragrances and low vapor pressure components of a product allowed under CARB 310 are not allowed under this standard, thus the designated thresholds for each product class consider all VOC content detected under the test method. Further, calculation of the VOC content may be done if all the ingredient data is available.

### Aquatic Safety

Many of these products contain parabens, EDTA, triclosan, and other compounds known to be poorly biodegradable. Further, since all of these products end up going down the drain, aquatic toxicity, biodegradation and bioaccumulation are important criteria to ensure environmental safety. Eutrophication is also an important consideration. However, low biodegradability may not be a problem if the toxicity is low. Materials such as abrasive agents would fit in such a category. As a result, the ingredients shall be readily biodegradable. To follow the EU Detergents Directive, surfactants are accepted as readily biodegradable if they reach the final degradation requirement even in the 10-day window criterion is not fulfilled. An exception is allowed for natural ingredients that are ultimately biodegradable, but not toxic to aquatic life. Further, ingredients shall not be bioaccumulating or toxic to aquatic life.

### Prohibited Compounds

There are several compounds that may not be prohibited from as a result of the other criteria in the standard but may warrant exclusion in an environmentally preferable product. Further, there may not be a means to prohibit the compounds based on their undesired end point. For example, there are several known endocrine disruptors used in these products (EU Cosmetics Directive). However, there is not an accepted test for such activity. As a result, known endocrine disruptors will be specifically prohibited. By far the largest group of ingredients with endocrine disruptor effects are phthalates including, but not limited to dibutylphthalate, diethylhexylphthalate, butyl benzyl phthalate, and bis-(2-ethoxymethyl) phthalate. TNO conducted a market survey in the Netherlands and found that phthalates were in 49 out of 55 cosmetic products and 15 out of 19 studied shampoos contained phthalates, with diethyl phthalate as the most common (2004). Diethyl phthalate is used as a solvent in fragrance ingredients, and it has no demonstrated endocrine activity. However, there are alternative solvents for fragrances, thus the group of phthalate ingredients is prohibited.

Another group of compounds used in these products with endocrine disruptor activity are parabens, such as methylparaben, ethylparaben, propylparaben, butylparaben, isobutylparaben, isopropylparaben, and benzylparaben. These compounds are commonly used as preservatives in personal care products. According to the National Institutes of Health (NIH, 2004), parabens bind with to estrogen receptors and regulate estrogen-responsive reporter gene expression in experimental cell systems. The estrogenic activities of the parabens increase as the length and branching of the alkyl ester increase. The ER relative binding activity of parabens is in the following approximate order: 2-ethylhexyl > heptyl > benzyl > butyl > propyl = ethyl > methyl. Parabens also can cause skin irritation and contact dermatitis in individuals with paraben allergies, a small percentage (Nagel et al., 1977). As a result, the class of parabens will be prohibited.

Scientific Committee on Cosmetic Products (SCCP) in Europe evaluated the data on methyldibromo glutaronitrile (1,2-Dibromo-2,4-dicyanobutanone) and concluded that its use should be limited due to its demonstrated contact allergy effects (SCCP, 2005). It however, is not on the EU list of allergens that prohibits allergens in this standard.

2-butoxyethanol was listed as a possible human carcinogen by the EPA (classification 3) and as a result would be prohibited, however its inclusion on this list changes so it should be included in the list of other prohibited ingredients.

Formaldehyde is carcinogenic to humans (IARC group 1) and would be a prohibited ingredient according to the carcinogen criterion proposed. However, there are commonly used preservative ingredients that are known to release formaldehyde over time (Bronopol; DMDM-hydantoin; Tris Nitro, 2-bromo-2-nitropropane-1,3-diol; 5-bromo-5-nitro-1,3-dioxane; diazolidinyl urea; imidazolidinyl urea; sodium hydroxy methyl glycinate). To further limit the content of known carcinogens, these formaldehyde-donor compounds were added to the list of other prohibited ingredients.

Ethoxylated alcohols are prohibited. It is known that ethoxylated alcohols can be contaminated with 1,4-dioxane. In testing conducted by Aubrey Organics they found that about half of the cosmetic products were contaminated with 1,4-dioxane (Aubrey). 1,4-dioxane is a possible carcinogen on the IARC list (and would be prohibited if it were directly added to the product under this standard). Aubrey Organics suggested that the 1,4-dioxane is due to the contamination of ethoxylated alcohols with 1,4-dioxane. Ethoxylated alcohols include ingredients PEGs, Polyethylene, Polyethylene Glycol, Polyoxyethylene, or sodium laureth sulfate.

The following chemicals are prohibited specially due to their aquatic hazards. Musks, nitro-musks and polycyclic musks are prohibited because of their bioaccumulation and aquatic effects. Phosphates are prohibited due to their contribution to eutrophication. Nitrioltriacetic acid (NTA) and ethylene diaminetetra-acetic acid (EDTA) are poorly degradable and are suspected of remobilizing heavy metals in e.g. riverbeds. NTA is also a suspected carcinogen. There have been issues with the biodegradation, effects on microflora and fish, and skin sensitization or irritation of traditional, fluorescent, optical brighteners. Alkylphenol ethoxylates (APEs) degrade into nonylphenol and other products which are known to persist and bioaccumulate in waterways and aquatic life and act as endocrine disruptors.

Diethanolamine (DEA) is on the TLV list with a skin notation, however it is included in the list of prohibited compounds since it along with triethanolamine (TEA) and monoethanolamine (MEA) may cause the formation of cancer-causing nitrosamines in products. It is thought that the specific nitrosamine formed is known as N-nitrosodiethanolamine or NDELA. Most nitrosamines, including those formed from DEA or TEA, are carcinogenic. Further, the National Toxicology Program (NTP) completed a study in 1998 that found an association between the topical application of diethanolamine (DEA) and some DEA-related ingredients and cancer in laboratory animals (FDA, 2006). For the DEA-related ingredients, the NTP study suggests that the carcinogenic response is linked to possible residual levels of DEA. As a result, these compounds are prohibited.

## Fragrances

Fragrances are used to a great extent in these products. The industry estimates between 90 and 95% of the hand soap products contain fragrances. These ingredients aren't functional for the product's performance, but are used for consumer acceptability. There are many known health and environmental concerns with fragrance ingredients. The International Fragrance Association (IFRA) Guidelines in the Code of Practice aim to limit the use of fragrance ingredients with undesirable effects. However, the IFRA Code is limited to the substances that have been comprehensively evaluated by the Research Institute for Fragrance Materials (RIFM). As a result, the concerning effects of fragrances should be included as criteria in the standard, not only to limit the use of such fragrance ingredients, but for other components of the product. This includes VOC limits, allergens, and asthmagens. Further, the EU and Nordic ecolabel programs found that it was best to reduce the general exposure to fragrances to babies and small children. Children do not need the fragrance for acceptance and the fragrance isn't needed for the

function of the product. The EU (2005) stated that while “we have no data to support the claim that exposure to fragrances at such an early life stage pose a health risk...we know that babies and small children are very sensitive.” As a result, they chose to prohibit the use of fragrances for products intended for small children (<3 years) and babies, using the precautionary approach to ensure the most protection for children.

### Antimicrobial Agents and Preservatives

Preservatives are added to the product to inhibit microorganisms and maintain the color and appearance of the products. They are often very toxic and poorly biodegradable. Antimicrobial agents can be preservatives, or other compounds, used at high enough levels to kill or inhibit the growth of microorganisms.

Numerous medical groups, including the American Medical Association and the Centers for Disease Control and Prevention (CDC) have stated that antibacterial soaps are not more effective in preventing disease than ordinary soap and water. Further, there is concern about the use of such components contributing to resistant microorganisms (Aiello et al., 2007). These compounds also have demonstrated effects on aquatic life. As a result, the use of such materials for activity beyond preserving the product is prohibited, and they must meet the other criteria of the standard including aquatic toxicity and biodegradability. Antimicrobial products are not included in the scope of this standard; this is further emphasized with the prohibition of claims about antimicrobial, disinfecting, antiseptic or sanitizing properties.

### Colors

The Food and Drug Administration (FDA) is responsible for regulating all color additives used in the United States. Color additives permitted for use are classified as "certifiable" or "exempt from certification" (FDA, 1993). Color additives that are exempt from FDA certification include pigments derived from natural sources such as vegetables, minerals or animals, and man-made counterparts of natural derivatives. Certifiable color additives are synthetic. Since soaps may not be regulated by FDA, the standard will include the requirement that all colors be FDA certified or derived from natural sources.

## **PACKAGING REQUIREMENTS**

The most common packaging materials are high density polyethylene (HDPE) and to a lesser extent paper, polyethylene terephthalate (PET), polypropylene (PP), and polyvinyl chloride (PVC). The EU life cycle research demonstrated that the environmental impact of packaging is quite large compared to that of the soap or shampoo itself (EU, 2005). They suggest that this is because shampoos consist primarily of water. They found that the packaging accounted for twice as much resource depletion as the production of the ingredients in the product, along with greater global warming, acidification, and eutrophication. As a result, reducing the total packaging and material from virgin sources is a key approach. Minimum recovered and post-consumer content is proposed in this standard.

Reusable packaging (and corresponding refills) shall be encouraged. Also, it is desired that the package design allows consumers to easily get the desired amount of product out of the bottle, and not too much. However, it is difficult to include criteria to encourage such practices. To attempt to cover these concerns, labeling requirements are proposed including; “Proper dosage saves costs and minimizes environmental impacts” and “Using reusable packaging minimizes environmental impacts.”

Packaging shall also not include known toxins such as heavy metals. The Northeastern Governments' (CONEG) suggested restriction on heavy metals is proposed in this standard, along with prohibition on the use of endocrine disrupters such as Bisphenol A and phthalates in packaging.

## **LABELING REQUIREMENTS**

Green Seal requires that the FDA labeling rules are followed. For example, if a cosmetic claim is made on the label of a soap or cleanser, such as moisturizing or deodorizing, the product must meet all FDA requirements for a cosmetic, and the label must list all ingredients. If a drug claim is made on a cleanser or soap, such as antibacterial, antiperspirant, or anti acne, the product is a drug, and the label must list all active ingredients, as is required for all drug products. So long as no cosmetic representations are made for soap, other than that it cleanses, and no claims are made that it will affect the structure or functions of the body or treat a disease, it is beyond FDA regulation. With the aim to harmonize the ingredient information available to consumers, all products in this standard shall have their ingredients labeled, including those sold for professional use only. The format for ingredient labelling shall be listed in order of predominance (21 CFR 701.3), and include fragrance ingredients. For proprietary fragrance ingredients, the generic term "fragrance" can be used. All other regulatory rules shall apply to the product, for example products characterized as drugs shall follow FDA rules for drug labeling (21 CFR 201).

Organic claims are made on personal care products. Some claims include the USDA seal (and thus meet the USDA regulations), and some do not. The USDA National Organic Program (NOP) is a marketing program housed within the USDA Agricultural Marketing Service. NOP developed national organic standards and established an organic certification program. The definition for organic, developed by the National Organic Standards Board adopted in April 1995, is the "ecological production management system that promotes and enhances biodiversity, biological cycles and soil biological activity. It is based on minimal use of off-farm inputs and on management practices that restore, maintain and enhance ecological harmony." According to a memo of August 23, 2005 from Barbara C. Robinson the Deputy Administrator Transportation and Marketing Programs Agricultural Marketing Service on the subject of Certification of agricultural products that meet NOP standards, "There are agricultural products, including personal care products, that, by virtue of their organic agricultural product content, may meet the NOP standards and be labeled as "100 percent organic," "organic" or "made with organic" pursuant to the NOP regulations...Additionally, products that may be labeled "100 percent organic" or "organic" may also carry the USDA organic seal." As a result, Green Seal will require any product that makes an organic claim to follow the NOP standards and if applicable, use the USDA organic seal for their claims. Specifically, organic ingredients (production and handling) must be certified by a USDA-accredited certifying agent. Claims about the content of organic ingredients include,

"100 percent organic" must contain only organic ingredients, and may display the USDA Organic seal.

"Organic" products must consist of at least 95 percent organically produced ingredients and may display the USDA Organic seal.

"Made with organic ingredients" contain at least 70 percent organic ingredients and list up to three of the organic ingredients on the principal display panel. The USDA seal cannot be used anywhere on the package.

Further, products that contain less than 70 percent organic ingredients cannot use the term "organic" other than to identify the specific ingredients that are organically produced in the ingredients statement.

Natural claims currently are not regulated. The Natural Ingredient Resource Center (NIRC) has Natural Product Labeling Guidelines and Burt's Bees has proposed a Natural Standard as a means to harmonize the rules used for natural claims on personal care products. The criteria proposed in Green Seal's standard are based on these two approaches, and the USDA BioPreferred program. First, natural ingredients are those that come from biological products or renewable materials, forestry or agricultural materials (including plant, animal, and marine materials) and that do not contain genetically modified organisms and have been processed without synthetic chemicals or irradiation. With this definition of natural ingredients, the following claims would then be defined as:

"100 percent Natural" or "All Natural" can only contain natural ingredients with no synthetic ingredients.

"Natural" products can contain 95% of natural ingredients and not include synthetic fragrances, artificial colors or ingredients from petrochemicals.

"Made with/from Natural Ingredients" contains at least 70% natural ingredients and not include synthetic fragrances, artificial colors or ingredients from petrochemicals.

## MANUFACTURING

Good Manufacturing Practices (GMPs) shall be followed for all product production. Green Seal realizes that GMPs are required only for drug's (not cosmetic products), however to be consistent Green Seal is requiring this for all products in the scope. This requirement is not included in the standard, but will be included in the evaluation and audit for certification.

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