



December 16, 2008

Green Seal is in the process of developing an Environmental Standard for Soaps, Cleansers, and Shower Products, GS-44. Comments from the public were solicited on a Proposed Standard from December 7, 2007 until February 1, 2008.

Included in this document are the comments received on the Proposed Standard for Soaps, Cleansers, and Shower Products GS-44, December 7, 2007 with responses and explanation on how the Proposed Standard was modified accordingly.

By participating in Green Seal's standard setting process, the following organizations that provided comments played an important role in Green Seal's effort to encourage the design, manufacture and end use of environmentally superior products. Their assistance and involvement is greatly appreciated.

California Department of Public Health, Indoor Air Quality Section  
California Office of Environmental Health Hazard Assessment  
The Dial Corporation  
Fragrance Materials Association of the United States  
GOJO Industries, Inc.  
Lonza Group, Ltd.  
L'Oréal Paris  
Method  
The Soap and Detergent Association  
Individuals

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## 1.0 Scope

**This standard establishes environmental requirements for hand, hair, and body soaps and cleansers used and rinsed after use. This includes liquid and solid soap and cleansers, shampoo, conditioner and related shower products for baby, child, adult, commercial, professional, and pet use. Antimicrobial soaps and cleansers are not included in the scope of this standard.**

Comment:

The standard looks good. However, as a Veterinarian, we use a lot of medicated products, is there a way to include these or have a separate standard for medicated (specifically antimicrobial and disinfecting) shampoos?

Comment:

We believe that it is necessary to further narrow the scope of the standard. As Green Seal correctly points out in the background document, soaps are regulated under a different regulatory program than personal care products, like personal care cleansers and shampoos and, therefore, should not be held to the same standards. Additionally, we found it interesting that conditioners are included in the scope when they have no cleansing efficacy. If the scope is truly cleansing, then conditioners should be excluded from the standard.

Products for humans differ significantly from products for animals. For that reason, pet products should be removed from the standard. Many shampoos intended for animals contain insecticides or other medications for treatment of skin conditions or parasite infestations such as fleas or mange. Because these products are regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), they are clearly outside the scope of this standard. We also recommend that antimicrobial shower products also be excluded from the standard for the same reasons antimicrobial soaps and cleansers are excluded.

Comment:

The scope of products covered in the standard is too broad. As Green Seal correctly points out in the background document, soaps are regulated under a different regulatory regime than personal care products such as personal care cleansers and shampoos and, therefore, should not be held to the same standards. We also recommend that pet products be removed from the standard. Many shampoos intended for animals contain insecticides or other medications for treatment of skin conditions or parasite infestations such as fleas or mange. Because these products are regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), they should also be excluded from the scope of this standard. We also recommend that antimicrobial shower products also be excluded from the standard for the same reasons antimicrobial soaps and cleansers are excluded.

Comment:

I agree with the previous commenter that this standard should be clearer on what "pet products" are covered. Soaps and shampoos for pets often contain medications etc to treat skin and pest infestations. A lot of thought has been given to the document especially the

"Background Information on Proposed Standard". However, this should be expanded in areas such as asthma and children's health. I would like to see additional information that is in the background document of GS-37 be included in this document.

**Response:**

Animal products will be removed from the scope of this standard and will be included in a different standard in the future. FIFRA products will also be excluded from the scope of the standard, since other antibacterial products were already prohibited in the standard.

Children's products are included in the scope of the standard, and an evaluation of their vulnerabilities was included during the development of the criteria.

Soaps' different regulatory status does not mean their environmental and health considerations are different. Further their use is similar to the other products in the scope. As a result, they will remain in the standard along with the other types of rinse off body cleansers. Hair conditioners are used to balance the effects of shampoos and thus used in conjunction with shampoos. Further, their environmental and health effects are similar to shampoos, and thus will remain in the standard. However, its worth noting that only conditioners intended for rinsing off are included in the scope of this standard. Conditioners that would be left in the hair are not included in the scope of the standard.

*This standard establishes environmental requirements for hand, hair, and body soaps and cleansers used and rinsed after use. This includes liquid and solid soap and cleansers, shampoo, conditioner and related shower products for baby, child, adult, and professional-use. This standard does not apply to products used for animal or pet use, those used in commercial or institutional facilities where the products are not intended to be sold to consumers, or products required to be registered under the Federal Insecticide, Fungicide, and Rodenticide Act, such as those making claims as sterilizers, disinfectants, or sanitizers, or antimicrobial soaps and cleansers.*

**Comment:**

It is interesting to note that the scope of the GS-44 Standard is very similar to that of the new European Union eco-label for Soaps, Shampoos, and Hair Conditioners (Commission Decision 2007/506/EC of June 21 2007 establishing the ecological criteria for the award of the Community Eco-label to soaps, shampoos and hair conditioners, to be downloaded at <http://eur-lex.europa.eu>).

With this information in mind, and acknowledging the global nature of today's personal care marketplace, it may be beneficial for a U.S. standard covering the same product categories to consider harmonization of its environmental assessment methodologies/criteria with those used by environmentally responsible manufacturers operating in or exporting to the E.U.

**Response:**

The EU standard was used as reference during the development of the proposed standard, and since both programs are Global Ecolabelling Network (GEN) members, attempts to harmonize the standards were done. However, there are components in that standard that do not translate into the US market, and there are components needed in the US standard that are not included in the EU standard. As a result, this standard will retain some differences. However, GEN members offer mutual recognition in areas where the programs are compatible. This may prove to be an option for global companies to get certification across multiple countries.

**Comment:**

The scope should clarify the difference between GS-41 and GS-44 by specifying GS-44 is for consumer products. The terms “professional” and “commercial” are ambiguous and should be defined.

**Response:**

The term commercial will be removed and the term professional-use will be used. Further, this term will be further clarified so that it does not include institutional use or uses for which consumers are not purchasing the products (office buildings, hospitals, etc.).

*Professional-Use. Trained or paid workers, such as hair stylists, that use the products included in the scope of the standard and such products are available for sale to the consumer.*

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## **2.0 Definitions**

### **Comments on definitions.**

**Comment:**

We recommend Green Seal draft terms related to all the products within the scope of this standard. Currently, only cleansers and soaps are defined in this standard. The definition for “cleansers,” in particular, would capture a very wide range of maintenance and personal care products.

**Comment:**

We recommend Green Seal draft terms related to all the products within the scope of this standard. Currently, only cleansers and soaps are defined in this standard. The definition for “cleansers,” in particular, would capture a very wide range of maintenance and personal care products.

**Response:**

The definitions that weren’t included were added, and the definition for cleanser was clarified to include only those that are intended to clean the body or hair.

*Cleanser: A product intended to clean the body or hair that has detergent properties that are not necessarily due to alkali-fatty acid compounds, and may contain synthetic detergents.*

*Conditioner. A product that is intended to alter the texture or appearance of hair or scalp, used after shampoo and rinsed off after use. This does not include leave-in products.*

*Shampoo: A soap or cleanser used to wash the hair and scalp and rinsed off after use.*

*Shower Products: Products that are used on the body or hair with the intention that they are washed off the body. This may include bubble bath, exfoliating scrubs, and other rinse-off products.*

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## **2.01 Allergens**

### **Allergenic substances listed by the European Commission and cited in the Cosmetic Directive.**

#### **Comment:**

Regarding the proposed prohibition of 26 EU allergens, we believe that this represents a labeling, rather than a safety, concern. The EU requires the names of these allergens to be on label if present at or above 0.01% in finished rinse-off products (0.001% for leave-on) for notification to consumers who may be allergic to these specific allergens (thus not actually prohibiting usage).

In addition, we believe that prohibiting only the known allergens that appear on the European Commission's Cosmetic Directive allergen list is not an approach consistent with global standards. For example, there are allergens of natural origin (such as peanut protein) which require labeling in the United States and which do not appear on the EU allergen list. A more comprehensive approach might be to require the labeling of clinically relevant allergens, rather than only prohibiting those which are on the EU list.

#### **Comment:**

In the "background" document (page 3, "Allergens"), it states that, "This standard proposes the prohibition of these compounds to provide an enhanced level of protection..." However, there's no evidence that prohibiting the EU "26 allergens" will provide an enhanced level of protection. All allergens can be used safely when included at levels that are below the sensitization threshold level. Further, a European dermatologist, Dr. Axel Schnuch, recently published a paper that reviewed the incidence of allergy to the "26 allergens" as reported by dermatology clinics in the European Union. Dr. Schnuch concluded that, while some materials continue to be important allergens, others are of little or no concern. In addition, even the EU only has a labeling

requirement for the allergens (and only above certain thresholds – 10 ppm for leave-on products and 100 ppm for rinse-off products), NOT a total prohibition. Therefore, the GS-44 standard should limit some of the materials and not ban them, and not restrict those allergens identified to be of no concern by Dr. Schnuch.

**Response:**

The criterion will be modified to be aligned with the EU and require labeling of known allergens present at or above 0.01%. In addition, labeling will be required for allergens listed in the US (Food Allergen Labeling and Consumer Protection Act). While this protection was aimed for food, it is known that some of these allergens are included in the products in the scope of this standard (ex. soy).

*Allergen. Allergenic substances listed by the European Commission and cited in the Cosmetic Directive and those listed by the FDA (including food allergens).*

*Fragrance and Allergen Labeling. The product label shall declare, separate from the ingredient line, if a fragrance has been added or if no fragrance has been added and if it contains any allergen ingredients.*

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**2.02 Antimicrobial**

**Substances which can kill or inhibit the growth of microorganisms.**

Comment:

The definition of antimicrobial agents would be strengthened by limiting these materials to those registered by the EPA as pesticides. All products that make anti-bacterial, anti-microbial, sanitizing claims must contain ingredients that are registered as such. The definition as is is very broad and would include a number of materials that would not necessarily be used for antimicrobial purposes.

**Response:**

The EPA does not solely oversee antimicrobial ingredients or products, the FDA has oversight for antimicrobial soaps and cleansers which are regulated as Over the Counter Drugs. As a result, the EPA reference will not be used.

Comment:

We recommend the definition to read, “Substances which are intended to kill or inhibit the growth of microorganisms, including antiseptic, disinfectant and sanitizer substances.”

**Response:**

This modification will be made.

*Antimicrobial: Substances that are intended to kill or inhibit the growth of microorganisms including antiseptic, disinfectant, and sanitizer substances.*

## 2.03 Antiseptic

**Substances that prevent or arrest the growth of microorganisms.**

Comment:

We recommend the definition to read, “Substances that are intended to prevent or arrest the growth of microorganisms.”

**Response:**

This modification will be made.

*Antiseptic. Substances that are intended to prevent or arrest the growth of microorganisms.*

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## 2.04 Asthma

**A chronic respiratory illness that intermittently impairs breathing. It is characterized by variable airflow obstruction, commonly presenting with symptoms of cough, wheeze, shortness of breath, or chest tightness, which may be mild, moderate, severe and even life-threatening. Symptoms may resolve completely between active episodes. Symptoms may occur during exposure, immediately after exposure or up to 24 hours later in a “late phase,” even interrupting sleep.**

**A chemical is considered capable of causing asthma if it is specifically listed as an Asthmagen by the Association of Occupational and Environmental Clinics (AOEC).**

Comment:

The definition that appears in the standard is that for occupational asthma. We recommend removing the section on exposure, or defining “occupational asthma” in the standard as well as citing the source.

Comment:

The second paragraph of this section establishes the Association of Occupational and Environmental Clinics (AOEC) as the authority for defining “asthmagens” and bases the criteria for asthmagens on the AOEC list. Green Seal believes that this list is based on “clear criteria” that are utilized in a peer-reviewed process. However, it is not clear to us how the list was generated and what the specific columns mean. We therefore question the validity and relevance of the criteria and the list itself to determine limitations on ingredients used in fragrance formulations.

There are few points to consider. First, in the definition of asthma it is important to note that, while it is correct that it is a chronic respiratory condition, variable airflow obstruction is reversible. Second, although the criteria have been developed by a well-respected epidemiologist/physician, Dr. Bill Beckett, who specializes in occupational asthma research, the language he uses in his “asthmagen protocol” document clearly indicates that he is hesitant to conclude that any of the materials on the AOEC list are

truly asthma-causing. He further states that asthma-exacerbation can even be induced “by inhalation to non-specific substances such as nuisance dust or cold, dry air.” Dr. Beckett specifically notes that while the AOEC list has been developed in an attempt to identify materials that may cause de novo asthma, the fact that pre-existing asthma can confound the finding of a new irritant airways response precludes the ability of the AOEC list to address work-aggravated asthma in all scenarios. Third, Dr. Beckett wisely states that asthma is diagnosed on the basis of clinical signs/symptoms and not by a “single test, biomarker, or gene specific for asthma.” Therefore, we strongly object to the use of the AOEC list as a bright line criterion for identifying materials that should not be present. We further question the need to include asthma as a criterion in the standard at all.

**Comment:**

The definition that appears in the standard is that for occupational asthma. We recommend removing the section on exposure, or defining “occupational asthma” in the standard.

**Response:**

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, higher breathing rates, and/or greater susceptibility to hazardous effects from chemicals in the environment. An article by Mendell (2007) reviewed 21 published epidemiologic studies on associations between indoor residential chemicals and respiratory health and/or allergy in children. Mendell’s previous research had documented an association between indoor pollutants in schools and poorer student performance (Mendell and Heath, 2005). Research has also shown adverse effects on children born to women with higher household chemical use (Henderson 2007). Despite this described research, there is little information about the effects of chemicals and other product ingredients on children. Literature about asthma in relation to workplace exposures is the best available evidence. While this information may not be sufficient to protect all vulnerable populations, using the existing information is an important first step to address the hazards of specific ingredients that have been documented to cause asthma among those most exposed. Their exposures and adverse outcomes provide the early warning that may be used to protect workers and others less intensively exposed. Thus, the occupational research for asthma will continue to be used – via the AOEC.

The Association of Occupational and Environmental Clinics (AOEC) has peer-reviewed criteria to identify asthmagens. An expert panel reviews chemicals to those criteria. The robustness of such an approach provides scientific validity to any chemical prohibition that may result. The AOEC has been systematically reviewing chemicals since the criteria were formally adopted, as revised, by the AOEC board in 2005. While the list previously lacked the necessary validity, it now includes validity needed for product review with the criteria and panel

review. It was confirmed with various experts, including the AOEC, such as Dr. Beckett, Dr. Rosenman, and Ms. Kirkland, that the evidence supporting a chemical's listing as an asthmagen was very strong and transparent in their criteria for listings. Those chemicals listed as "A" chemicals AND "Rs" are those that meet the criteria, and would be prohibited. This includes diethanolamine and triethanolamine.

This standard does not prohibit chemicals that may exacerbate asthma, including irritants such as acids and bases. Once an individual is sensitized, and airways are hyper-reactive, there are many possible triggers regardless of the initiating cause, and there is great individual variation.

The definition for asthma and asthmagen included in the standard has been clarified as follows:

*Asthma. Asthma is a chronic inflammatory disorder of the airways that impairs breathing. Asthma affects children and adults, may be intermittent or persistent, and is further classified as mild, moderate, or severe. The chronic inflammation associated with variable airflow obstruction commonly causes difficulty breathing, coughing, wheezing, shortness of breath, and/or chest pain. Symptoms may resolve completely between active episodes. Symptoms may occur during exposure, immediately after exposure, or up to 24 hours later in a "late phase," frequently interrupting sleep.*

*Asthmagens. Substances designated as asthma causing agents by the AOEC, which after review by AOEC have met the AOEC sensitization criteria.*

Henderson J, Sherriff A, Farrow A, Ayres JG. 2007. Household chemicals, persistent wheezing and lung function: Effect modification by atopy? *European Respiratory Journal Express* (online prior to publication) 10.1183/09031936.00086807 [Accessed 31 October 2007]

Mendell, M.J. 2007. "Indoor residential chemical emissions as risk factors for respiratory and allergic effects in children: a review." *Indoor air*.17:259-277.

Mendell, M.J., Heath, GA. 2005. "Do indoor pollutants and thermal conditions in schools influence student performance? A critical review of the literature." *Indoor air*. 15(1):27-52

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## 2.05 Carcinogens

**Chemicals listed as a known, probable, reasonably anticipated, or a possible human carcinogen by the International Agency for Research on Cancer (IARC) (Groups 1, 2A, and 2B), the National Toxicology Program (NTP) (Groups 1 and 2), the United States (US) Environmental Protection Agency (EPA) Integrated Risk Information System (IRIS) (weight-of-evidence classifications A, B1, B2, C, carcinogenic, likely**

**to be carcinogenic, and suggestive evidence of carcinogenicity or carcinogen potential), or the Occupational Safety and Health Administration (OSHA).**

Comment:

1. Expand the definition of Carcinogens used (Section 2.5)

Currently, the definition states “Chemicals listed as a known, probable, reasonably anticipated, or a possible human carcinogen” by the International Agency for Research on Cancer (IARC) plus the three U.S. programs.

A. Include chemicals listed as carcinogens by the State of California under the Safe Drinking Water and Toxic Enforcement Act of 1986 (California Code of Regulations, Title 22, Division 2, Subdivision 1, Chapter 3, Sections 1200, et. Seq.) (compounds with NSRLs, <http://oehha.ca.gov/prop65/pdf/October2007StatusRpt.pdf> )

B. Explicitly define that the most current lists shall be applied and that product certifications are subject to changes in these lists.

C. Although the proposed criteria appear to prohibit carcinogens, the way that an ingredient has been defined to mean any compound that is 0.01% by weight means that many carcinogens at levels of concern may be in GS-44 formulations. The list of safe harbor levels published by CA EPA OEHHA, <http://www.oehha.ca.gov/prop65/pdf/October2007StatusRpt.pdf> clearly lists the daily Levels for no significant risk levels (NSRLs) for carcinogens. This list shows many chemical limits that are well below the 100 ppm limit (0.01%) that is the cut off for the GS 44 definition of an ingredient.

**Response:**

This standard follows the rules included in the ISO 14024 standard, for development of ecolabel standards. ISO provides a hierarchy of international and national methods before industry, state, or other methods. As a result, Green Seal will retain the use of national and international lists for carcinogenicity, and not use California’s Prop 65 to identify carcinogens.

Green Seal uses the most up to date lists, as indicated in the Forward to the standard: J. Referenced Standards. Standards referenced in this document may have been superseded by a later edition, and it is intended that the most recent edition of all referenced standards be used in determining compliance of a product with this standard. Further, the various EPA IRIS cancer guidelines weight of evidence classifications used throughout the years have been included in the definitions for carcinogens since they are all still active. From the IRIS web site, “... the 1986, 1996, 1999, and 2005 Guidelines for Carcinogen Risk Assessment. These guidelines reflect the evolution of the science in this area and the corresponding evolution of the Agency’s approach to characterizing weight-of-evidence for human carcinogenicity.” A chemical classified A in 1986 was not relisted in 1996, 1999 and 2005. So each classification must be included. As a result, all the classifications will remain in the definition for carcinogen.

The standard prohibits any intentionally added components that may be carcinogens, not just those that are above 0.01%.

### 2.06 Cleanser

**A product that has detergent properties that are not necessarily due to alkali-fatty acid compounds, and may contain synthetic detergents.**

Comment:

The proposed definition is too broad. It would capture a very broad range of maintenance and personal care products. To be meaningful, the definition should be specific enough to clearly identify the products targeted by the standard.

Comment:

The proposed definition is too broad. It would capture a very broad range of maintenance and personal care products.

**Response:**

The definition has been modified to specify cleansers used for the body and hair.

*Cleanser: A product intended to clean the body or hair that has detergent properties that are not necessarily due to alkali-fatty acid compounds, and may contain synthetic detergents.*

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### 2.07 Disinfectant

**An antimicrobial agent capable of destroying pathogenic and potentially pathogenic microorganisms on inanimate surfaces.**

Comment:

We recommend the definition to read, “An antimicrobial agent intended to destroy pathogenic and potentially pathogenic microorganisms on inanimate surfaces.

**Response:**

This modification will be made.

*Disinfectant. An antimicrobial agent intended to and capable of destroying pathogenic and potentially pathogenic microorganisms on inanimate surfaces.*

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### 2.10 Fragrance

**An additive, often (but not limited to) a multi-component additive, used in a product with the purpose of changing the scent of the product.**

Comment:

This should be revised to read, “An additive, often (but not limited to) a multi-component additive, used in a product with the purpose of imparting a scent to the product.”

**Response:**

This modification will be made.

*Fragrance. An additive, often (but not limited to) a multi-component additive, used in a product with the purpose of imparting or neutralizing a scent in the product.*

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**2.11 Ingredient**

**Any constituent of a product that is intentionally added or known to be a contaminant that comprises at least 0.01% by weight of the product.**

Comment:

To remain consistent with the international practice of labeling in the personal care industry, the term “ingredient” should only apply to those constituents of a formula which are intentionally added and are present at concentrations of 0.1% or greater.

Comment:

First, the definition of ingredient should be consistent with current laws/regulations. This would mean that 1) the ingredient is intentionally added, and 2) it is present in the formula at 0.1% or greater. Also, we recommend removing the phrase, “...or known to be a contaminant...” from this definition. Contaminant should be separately defined.

Comment:

The current Green Seal definition includes contaminants as ingredients – this is not correct. Contaminants are “unintended constituents that are technically unavoidable and present at greater than 0.1% in the product.” The 0.1% level is based on current Occupational Safety and Health Administration (OSHA) requirements for identifying specific hazardous constituents in a mixture (carcinogens, mutagens or reproductive toxins).

Comment:

We recommend removing the phrase, “...or known to be a contaminant...” from this definition. Contaminant should be separately defined.

**Response:**

Green Seal uses the level of an ingredient at 0.01% because it promotes a higher level of performance than that required by OSHA (0.1%). Several states already have more stringent reporting requirements than OSHA under their right-to-know laws. For example, California’s Proposition 65 requires reporting of hazardous substances that are present above any detectable amount. Massachusetts requires extraordinarily hazardous substances be reported if they are present at a level of 0.0001% or greater. The Pennsylvania right-to-know law requires that special hazardous substances be reported at a 0.01% level or greater. However, to provide greater clarity of this definition, the term contaminant will be defined, but its treatment in the standard will not change.

*Contaminant. A product constituent that was not added for its functionality, but is known to be present.*

Comment:

The definition here indicates that an ingredient (includes contaminants) comprises at least 0.01% by weight. Does this mean that a chemical below 0.01% (100 ppm) need not be made known? My concern is that toxic chemicals or "contaminants" below this concentration are not reported because they are not considered to be an ingredient of the product. Moreover, the toxic effects of a mixture may not be that of their individual components, they may be additive.

**Response:**

Green Seal requires all manufacturer's to disclose the added components (not just those above 0.01%) for evaluation. Green Seal staff works with a company's suppliers to ensure all the information is available. This has been done for hundreds of currently certified products. The standard includes prohibitions of any toxic components, not just those above 0.01%. Known toxic by-products or reaction products of the product will also be prohibited (they were previously through the prohibited ingredients) according to:

*Carcinogens, Mutagens, and Reproductive Toxins. The undiluted product shall not contain any ingredients or components that are carcinogens, mutagens, or reproductive toxins. The product shall not contain any ingredients or components known to produce or release carcinogens, mutagens, or reproductive toxins.*

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## **2.12 Intentional Introduction**

**The act of deliberately utilizing a material in the formation of a package or packaging component where its continued presence is desired in the final package or packaging component to provide a specific characteristic, appearance, or quality.**

Comment:

It is unclear to us why this term is restricted to packaging. We believe it should be revised to also address intentional introduction into a product formulation.

Comment:

This term is currently restricted to packaging. It should be revised to also address intentional introduction into a product formulation.

**Response:**

This term is used to define what is meant for the packaging restrictions. There is already a term for products – component.

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## **2.13 Intentional Component**

**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. Naturally occurring elements and chlorinated organics, which may be present as a result of chlorination of the water supply, are not considered intentional components if the concentrations are below the applicable maximum contaminant levels in the National Primary Drinking Water Standards found in 40 Code of Federal Regulations (CFR) Part 141.**

Comment:

We recommend deleting this definition. If the standard defines “ingredient” and “contaminant”, this term becomes unnecessary.

Comment:

We recommend removing this definition. By defining “Ingredient” and “Contaminant”, this term is unnecessary.

**Response:**

This term is needed to capture the additions to the product below the “ingredient” level. These are not the same as “contaminants” since they are intentionally added. This term will remain in the standard, but will be modified slightly to be more clear.

*Component: A deliberate addition to the product, where it is added for its continued presence in the final product to provide a specific characteristic, appearance, or quality. Naturally occurring elements and chlorinated organics, which may be present as a result of chlorination of the water supply, are not considered intentional components if the concentrations are below the applicable maximum contaminant levels in the National Primary Drinking Water Standards found in 40 Code of Federal Regulations (CFR) Part 141.*

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## **2.16 Natural Ingredients**

**Ingredients 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.**

Comment:

The definition of a natural ingredient may be unrealistically stringent or at least subject to varied interpretations. Relatively few ingredients can claim not to have been processed with synthetic materials. Under the strictest interpretation of this definition, even simple castile soap would not be considered natural since it is converted from the natural oil using either NaOH or KOH, that many would not consider natural materials since they are also converted from their natural state. More relevantly, secondary surfactants such as betaines, sulfates and others would also be excluded from this definition, making the standard unrealistic for the vast majority of personal care products, even for

environmentally preferable ones. Greater specificity would require defining the permitted conversion operations (see eg. IFRA natural definition, or ‘the natural standard’). Alternatively, a general rule could state that at least half of the molecule must come from natural sources to be called natural. Or possibly, removing the reference to ‘processing without synthetic chemicals’ would be appropriate, but maybe replace it with a statement that the materials not be altered to such an extent that they are no longer biodegradable, non-toxic, etc. Alternatively, you could designate an additional definition of “naturally derived”, which would be natural materials that have been processed. The natural materials definition should also mention that materials of mineral origin (eg. baking soda) could be considered natural.

Comment:

Consistent with the approach taken by many natural cosmetic manufacturers, minerals should also be included within the definition of what is considered a natural ingredient. Provided that they are minimally processed, mineral ingredients such as iron oxides or clays should be allowed as constituent ingredients in natural products.

Comment:

We support the comments regarding the addition of minerals to the class of natural ingredients

Comment:

The draft definition is more accurate for “Biobased” ingredients. We would argue that natural ingredients can include any organic or inorganic compound from nature, such as minerals and salts. We recommend this definition be revised and clarified to include natural inorganic materials. Natural has more to do with "minimally processed."

Comment:

The proposed Green Seal definition of natural excludes genetically modified organisms (GMOs) and/or processing using irradiation. There is no compelling safety reason to exclude GMO products and the use of irradiation.

Comment:

This definition is more accurate for “Biobased” ingredients. Natural ingredients can also include any organic or inorganic compound from nature, such as minerals and salts. We recommend this definition be revised and expanded to include natural inorganic materials.

**Response:**

The definition will be modified to include minerals. This is consistent with the Natural Products Association, BDIH Natural Guidelines, and the Natural Ingredient Resource Center. In addition, a separate definition for naturally-derived components will be included to clarify the extent of processing acceptable – excluding genetic modification and irradiation (again, consistent with natural guidelines currently available).

*Natural Components. Components that come from renewable materials and found in nature including mineral, forestry, agricultural, or biological materials, do not contain transgenic hybrid organisms, have been processed without irradiation; and not chemically altered.*

*Naturally-Derived Components. Components that are partially chemically altered, but without petroleum components, and have been minimally processed such that they not be altered to such an extent that they are no longer biodegradable and non-toxic (examples of potentially acceptable processes are included in Appendix A.)*

#### *Appendix A*

*Examples of Potentially Acceptable Processing of Naturally-Derived Components (any products must also meet all the requirements in the standard)*

- *Esterification, Etherification, and Transesterification (to produce esters and ethers like polyglycerols)*
- *Glucosidation (to produce glucosides)*
- *Hydrogenation (of fats and oils)*
- *Hydrolysis and Hydrogenolysis (to produce hydrolyzed proteins, glycerin and fatty acids, and fatty alcohols)*
- *Other Condensation Reactions like Akylation and Sulfation*
- *Saponafication (to produce soap)*

*Natural and Biobased Claims. Only the following natural and biobased, or related, claims are allowed when the product meets the criteria outlined:*

- *“100 percent Natural,” “All Natural,” “100 percent Biobased,” or “All Biobased” shall only contain natural or biobased components, respectively, with no synthetic, petroleum, silicone, or artificial components. An exception is permitted for lye used to produce soap.*
- *“Natural” or “Biobased” products shall contain 95% natural, naturally-derived, or biobased components, respectively, with no synthetic, petroleum, silicone, or artificial components.*
- *“Made with/from Natural Ingredients” or “Made with/from Biobased Ingredients” shall contain at least 70% natural, naturally-derived, or biobased components, respectively, with no synthetic, petroleum, silicone, or artificial components.*

## 2.19 Organic Ingredients

**Ingredients, produced and handled, certified by a USDA-accredited certifying agent.**

Comment:

Many ingredients are organic without having anything to do with the USDA. USDA owns the "certified organic" program, so we recommend this definition be "Certified Organic Ingredients" instead of simply "organic ingredients."

Comment:

Many ingredients are organic. We recommend this definition be made clearer by using the term "Certified Organic Ingredients".

**Response:**

The definition clarifies that the term refers to certified materials, and thus will not be changed. However, to be consistent with the terminology throughout the standard, component will be used instead of ingredient.

*Organic Components. Components, produced and handled, certified by a USDA-accredited certifying agent.*

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## 2.25 Reproductive Toxin

**A chemical listed as a reproductive toxin (including developmental, female, and male toxins) by the State of California under the Safe Drinking Water and Toxic Enforcement Act of 1986 (California Code of Regulations, Title 22, Division 2, Subdivision 1, Chapter 3, Sections 1200, et. Seq.).**

Comment:

Reference is made to the list of chemicals known to cause reproductive toxicity by the State of California (Prop 65), but dismisses the process under the California law that allows a risk assessment to reach a conclusion of "no significant risk." At a minimum, Green Seal should allow substances on the Prop 65 list to be present in products when their use does not trigger labeling under the process of the California regulations.

Comment:

Reference is made to the list of chemicals known to cause reproductive toxicity by the State of California, but ignores the process under the California law that allows a determination of "no significant risk" to be made through risk assessment. At a minimum, Green Seal should allow reproductive toxins to be present in products when their use does not trigger labeling under the process of the California regulations.

**Response:**

According to the California Environmental Protection Agency Office of Environmental Health Hazard Assessment (OEHHA) the OEHHA "has

established safe harbor levels (levels of exposure that trigger the warning requirement) for some, but not all, listed chemicals.” “A business may choose to provide a warning simply based on its knowledge, or assumption, about the presence of a listed chemical without attempting to evaluate the levels of exposure.” “Proposition 65’s warning requirement has provided an incentive for manufacturers to remove listed chemicals from their products.” As a result, prohibiting chemicals listed as reproductive toxins is aligned with current leadership industry practices. Further, this approach has been used for other Green Seal standard and successfully applied to hundreds of certified products.

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### **2.27 Sanitizer**

**A product that reduces the level of microorganisms present to acceptable levels established by federal authorities.**

Comment:

We recommend the definition to read, “A product intended to reduce the level of microorganisms present to acceptable levels established by federal authorities.”

**Response:**

This modification will be made.

*Sanitizer. A product intended to reduce the level of microorganisms present to acceptable levels established by federal authorities.*

---

### **2.31 Skin Sensitizer**

**A substance that causes an immunologically mediated cetaceous reaction, also known as allergic contact dermatitis.**

Comment:

The current definition of Skin Sensitizer is not complete. Proposed wording: A substance that causes a cell-mediated inflammatory reaction occurring at the site of challenge with a contact allergen in sensitized individuals

Comment:

Green Seal defines a “skin sensitizer” as a “substances that causes an immunologically mediated cetaceous reaction...” We are not aware that sensitization testing was ever conducted in whales. This should be changed to read “cutaneous.”

Comment:

The word “cause” in the definition should be clarified to include substances that “induce or elicit” immunologically mediated cetaceous reaction, also known as allergic contact dermatitis.

**Response:**

These modifications will be made.

*Skin Sensitizer. A substance that will lead to an allergic response following skin contact.*

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### **3.0 Product-Specific Performance Requirements**

**Using standard test methods conducted under objective, reproducible laboratory conditions, a manufacturer can demonstrate that its product performs as well as or better than a conventional, nationally-recognized product in its category. 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.**

Comment:

The Background Information on Proposed Standard document correctly states that no adequate standardized methods exist for judging the performance of these products, which span a wide range of uses. Therefore, Green Seal will not have a common benchmark against which to judge whether performance is being compromised to the extent that potential benefits of certified products outweigh environmental impacts due to poor performance.

**Response:**

Green Seal includes performance requirements for all product types to ensure the product can function for its intended use. The testing requirement for this standard includes a benchmark of a comparison to a conventional, nationally-recognized product with a standardized soil and laboratory conditions, demonstrating cleaning ability, lathering/rinsing, and skin or hair condition after use.

*Product-Specific Performance Requirements. The product shall perform as well as or better than a conventional, nationally-recognized product in its category and at equivalent concentration using an objective, scientifically-validated method conducted under controlled and reproducible laboratory conditions. 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.*

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### **4.0 Product-Specific Health and Environmental Requirements**

**Comments on health and environmental requirements.**

Comment:

Please correct the spelling of “Environmental” (Environmetnal).

**Response:**

This correction has been made.

## Comment:

Currently, there are no criteria for Inhalation Toxicity in GS 44. Criteria should be added since the allowable VOC content is 1%. Inhalation toxicity is expected if irritant chemicals are added to the allowable 1% limit. All products with VOC content should be tested for inhalation toxicity including endpoints that address disease risks and damage to body systems, and inhalation toxicity. The chamber testing provisions are needed for formulations with VOCs. Products with VOC content should be required to meet acceptable room air concentrations for product dilutions that occupants are expected to encounter during use. Products should be required to meet the limits established by the following toxicity lists: including (i) Agency for Toxic Substance Disease Registry (ATSDR) Minimum Risk Levels (MRLs); (ii) California EPA's Office of Environmental Health Hazard Assessment (OEHHA) Acute Reference Exposure Levels (ARELs); (iii) California EPA's OEHHA non-cancer chronic Reference Exposure Levels (RELs); and (iv) U.S. EPA RfC4; and (v) ASTM E981 RD 50 levels (to ensure protection from lung irritant toxics that are associated with asthma exacerbation and other lung dysfunction).

**Response:**

Since the products in this standard contain volatile organic compounds, the content is limited, but additional measures can be taken to ensure inhalation exposure from such volatile components is not harmful. As a result, the volatile organic compound requirements will be expanded to include a chronic inhalation toxicity requirement. Since there is no accepted chamber test method for this product category, inhalation toxicity will be determined from the chronic inhalation toxicity of the individual ingredients.

*Chronic Inhalation Toxicity. The product as used shall not contain ingredients with a vapor pressure above 1 mm mercury at ambient conditions (1 atm pressure and 20-25° C) that cause chronic inhalation toxicity as evidenced by either of the following:*

- Listed by the European Chemicals Bureau as R48/23: Danger of serious damage to health by prolonged exposure through inhalation.*
- Classified as producing significant toxic effects in mammals from repeated inhalation exposure at or below 1.0 mg/L as a vapor according to OECD Harmonized Integrated Classification System for Human Health and Environmental Hazards of Chemical Substances and Mixtures. For the purposes of this standard, significant toxic effects in mammals from repeated inhalation exposure at or below 1.0 mg/L as a vapor shall be established by a NOAEL, based on a test duration of 90 days at 6 hours per day; values from other exposure regimes shall be estimated (extrapolated) per the principles of Haber's rule. In lieu of a NOAEL, the LOAEL can be used with a ten-fold safety factor (i.e., LOAEL/10).*

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**4.01 Toxicity**

**The undiluted product shall not have toxic characteristics such that it falls under the labeling requirements as a toxic or highly toxic product, as defined by Consumer Product Safety Commission regulations found at 16 Code of Federal Regulations (CFR) Chapter II, Part 1500.**

Comment:

With the exception of soap, all of the products covered by the scope of this proposed standard are regulated by the FDA. It is inappropriate, therefore, to use CPSC's toxicity definition. The assessment of the toxicity of these products should be consistent with FDA regulations.

Comment:

With the exception of soap, all of the products covered by the scope of this proposed standard are regulated by the FDA. Therefore, the assessment of the toxicity of these products should be consistent with FDA regulations, not CPSC's. For soap, which is regulated by CPSC, Green Seal should only recognize that agency's criteria for "highly toxic" and apply those criteria to this product category.

**Response:**

The requirements in this standard go beyond those included in regulations. So, any products regulations still apply. The CPSC's requirements used for 'toxic' are consistent with the levels used in other Green Seal standards, and thus have been demonstrated achievable and consistent with the aim of protecting human health and the environment. The FDA does not provide a definition comparable to CPSCs, nor do they require safety testing for all the products in the scope of this standard. The FDA states that "the FD&C Act does not require that cosmetic manufacturers or marketers test their products for safety, the FDA strongly urges cosmetic manufacturers to conduct whatever toxicological or other tests are appropriate to substantiate the safety of their cosmetics." According to the Campaign for Safe Cosmetics, "Currently only 11% of the ingredients used in cosmetics have ever been tested for safety." Further, since the FDA does not oversee all products included in the scope, CPSC will be used for this baseline toxicity assessment. However, to be clearer, these requirements will be itemized instead of referencing the CFR.

*Acute Toxicity. The undiluted product shall not be toxic to humans. A product is considered toxic if any of the following criteria apply:*

<i>Oral lethal dose (LD<sub>50</sub>)</i>	<i>≤ 5,000 mg/kg</i>
<i>Inhalation lethal concentration (LC<sub>50</sub>)</i>	<i>≤ 20 mg/L at 1 hr</i>
<i>Dermal lethal dose (LD<sub>50</sub>)</i>	<i>≤ 2,000 mg/kg</i>

*Toxicity shall be measured on the product as a whole. Alternatively, a mixture need not be tested if existing toxicity information demonstrates that each of the ingredients complies. The toxicity testing procedures should meet the requirements put forth by the OECD Guidelines for Testing of Chemicals. These*

*protocols include Acute Oral Toxicity Test (TG 401), Acute Inhalation Toxicity Test (TG 403), and Acute Dermal Toxicity Test (TG 402). Testing is not required for any ingredient for which sufficient information exists.*

*To demonstrate compliance with this requirement. It is assumed that the toxicity of the individual ingredients is additive. The toxicity values are adjusted by the weight of the ingredient in the product and summed using the following formula:*

$$TP = \left( \sum_{i=1}^n \frac{wt_i}{TV_i} \right)^{-1}$$

*Where,*

*TP = toxicity of the product*

*wt<sub>i</sub> = the weight fraction of the ingredient*

*TV = the toxicity value for each ingredient (LD<sub>50</sub>)*

*n = number of ingredients*

*For inhalation toxicity, it is determined from all ingredients with a vapor pressure greater than 0.1 mm Hg at standard conditions.*

FDA <http://www.cfsan.fda.gov/~dms/cos-lab1.html>

Campaign for Safe Cosmetics

<http://www.safecosmetics.org/companies/compactguide.cfm>

#### **4.02 Allergens, Carcinogens, Mutagens, and Reproductive Toxins**

**The undiluted product shall not contain any ingredients or intentional components that are allergens, carcinogens, mutagens, or reproductive toxins.**

Comment:

Would it be possible to provide clarification on what is meant by "known allergens, carcinogens, mutagens, or reproductive toxins"? As it currently reads, this phrase may be interpreted to encompass all known CMR 1, 2, or 3 compounds (classifications used by the European Commission).

The European Commission already prohibits the use of intentionally introduced CMR 1 or CMR 2 category ingredients in cosmetic products. However, CMR 3 ingredients are allowed (up to certain specified thresholds) in finished cosmetic products if they have received a favorable opinion after review by the Commission's Scientific Committee on Consumer Products (SCCP).

Comment:

This section prohibits the presence of any allergens in the (undiluted) product. Such a prohibition is not scientifically based and would eliminate the use of several key fragrance materials (e.g., orange oil, which contains limonene).

Comment:

The requirement that the product not contain any ingredients that are known to cause these toxicities without consideration of the risk posed by those ingredients is inappropriate.

Response:

Allergens will not be prohibited, rather they shall be labeled, consistent with the movement of right-to-know and the EU standards.

The prohibition of carcinogens follows such prohibition in other Green Seal standards and global ecolabel standards. Further, one of the purposes of this standard is to address the health concerns of cosmetic products like soaps and shampoos. It has been noted that 1/3 of personal care products contain at least one ingredient linked to cancer and 45% to reproductive toxins ([www.cosmeticsdatabase.org](http://www.cosmeticsdatabase.org)). Yet, these products are in close contact to the user, including infants and children. The science and approaches to assessing health risks from exposure to chemicals has primarily focused on adults. For example, adult laboratory animals are typically used to determine dose-response relationships for chemicals, and exposure assessment assumptions have typically been based on adult behavior patterns and physiology. The uncertainty (inability) of risk assessment approaches to protect children in all stages of development must be considered. The many uncertainties inherent to health risk assessment are compounded when applied to children. Predictable and quantifiable dose-response data are required in order to determine safe or acceptable exposure limits, or thresholds, for toxic chemicals. The differences between children and adults, critical developmental windows, and uncertainty in the risk assessment process, all of these factors support taking a precautionary approach to protecting children from environmental chemical exposure, including those from personal care products. As a result, the most protective approach would be where an ingredient or its class exhibits potentially harmful characteristics is to specifically prohibit it or substantially reduce that ingredient or class of ingredients in products rather than attempting to determine risk-based acceptable levels. In addition, known toxic by-products or reaction products of the product should be prohibited (they were previously through the prohibited ingredients). This will be clarified according to:

*Carcinogens, Mutagens, and Reproductive Toxins. The undiluted product shall not contain any ingredients or components that are carcinogens, mutagens, or reproductive toxins. The product shall not contain any ingredients or components known to produce or release carcinogens, mutagens, or reproductive toxins.*

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#### 4.04 Skin Irritation

**The undiluted product shall not be a skin irritant as tested by OECD Guidelines for Testing Chemicals, Section 404 or other peer-reviewed or standard test methods.**

**The product shall not be considered a skin irritant under the following scenarios:**

- **if test data shows that the whole-product is not a skin irritant,**
- **if test data shows that each ingredient present at or above a concentration of 5% is not a skin irritant, or**
- **if test data shows that any known skin irritants are non irritating when present in the product.**

Comment:

Require Test Products To Be Diluted When Tested. The proposed guideline states that the product should be tested undiluted. Testing a soap, cleanser or shower product in the undiluted form will almost certainly result in skin irritation as the product is surfactant based and intended to be diluted in use. Therefore, requiring undiluted testing will result in the inability of the products to pass skin irritation testing and will not reflect the actual irritation potential of the product. For soaps, cleansers and shower products, test products should be diluted to 0.5%-1% aqueous solution (v/v) in deionized water, applied to the skin and wiped off with a damp cloth prior to the application of the occlusive patch.

Recommend Human Patch Testing As The Preferred Test Method. Patch testing is the current industry standard for evaluating the dermal irritation of soaps, cleansers and shower products. The most common patch test, the 21-Day Cumulative Irritation Test, was described by Berger and Bowman in 1982.1

References:

1. Berger RS, Bowman JP. A reappraisal of the 21-day cumulative irritation test in man. J. Toxicol. – Cut. & Ocular Toxicol. 1982;1(2):109-115.

**Response:**

This requirement is included in Green Seal’s standard for institutional hand cleaners, GS-41. Products have been able to meet this at the undiluted level. This is also a reasonable exposure level, and thus will be retained as is. Typically, the evaluation for this requirement is done on the individual ingredients with existing data, whole product testing would not be needed.

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#### **4.05 Skin Sensitization**

**The undiluted product shall not be a skin sensitizer, as tested by the local lymph node assay (LLNA) or following EPA test guidelines for skin sensitization (OECD Guideline 429, OPPTS 870.2600). Green Seal will accept the results of other standard test methods, such as the guinea pig maximization test (OECD Guideline 406) or the Buehler test (OECD 406), as proof that the product in its most concentrated form is not a skin sensitizer when data from LLNA tests are not available. Any new product or ingredient testing should use the LLNA. Testing is not required for any ingredient for which sufficient information exists.**

Comment:

Do Not Require Animal Testing For Sensitization Data. At the present time, the personal care industry is moving away from animal testing should a reliable and valid non-animal test be available. The Local Lymph Node Assay (LLNA) is an invasive animal test that has become obsolete for evaluating the sensitization potential of soaps, cleansers and shower products as a result of its correlation to the Human Repeat Insult Patch Test (HRIPT).<sup>1</sup> Therefore, HRIPT data should be required to substantiate that a product is not a sensitizer. For soaps, cleansers and shower products, test products should be diluted to 0.5%-1% aqueous solution (v/v) in deionized water, applied to the skin and wiped off with a damp cloth prior to the application of the occlusive patch.

Require Test Products To Be Diluted When Tested. The proposed guideline states that the product should be tested undiluted. Testing a soap, cleanser or shower product in the undiluted form is more likely to result in skin sensitization as the product is being applied at a significantly higher concentration than in actual use. Therefore, requiring undiluted testing will result in the inability of the majority of products to pass skin sensitization testing and will not reflect the actual sensitization potential of the product.

Require Products To Be Tested With A 10x Fragrance Concentration. It has been well established that fragrance is most often the cause of skin sensitization for personal care products.<sup>2-3</sup> Therefore, increasing the fragrance concentration in the formulation will provide a worst case scenario of sensitization potential for the product being tested. This approach is the typical way major personal care manufacturers ensure skin safety.

1. Basketter DA, Clapp C, Jefferies D, Safford RJ, Ryan CA, Gerberick GF, Dearman RJ, Kimber I. Predictive identification of human skin sensitization thresholds. *Contact Dermatitis* 2005;53:260-267.
2. de Groot A. Sensitizing substances in dry skin and moisturizers: Chemistry and function. Eds. Lodem M, Maiback H. CRC Press, Boca Raton, 2000, 404-411.
3. Goossens A, Beck MH, Haneke E, et. al. Adverse cutaneous reactions to cosmetic allergens. *Contact Dermatitis* 1999;40:112-113.

Comment:

This section states that the product shall not be a skin sensitizer as tested by the Local Lymph Node Assay (LLNA). The fragrance industry through the Research Institute for Fragrance Materials, Inc. (RIFM) evaluates fragrance ingredients for dermal sensitization. A dermal sensitization quantitative risk assessment approach is employed so that fragrance raw materials which have the potential for dermal sensitization are used at levels that will NOT induce sensitization. As such, it is not necessary to test the final fragrance compound. Further, the use of the LLNA to test mixtures is not appropriate.

Comment:

Specify full mixture and undiluted testing for skin sensitization criteria

- A. Ingredient-by-ingredient testing should be disallowed for skin sensitization because of synergistic effects.
- B. The local lymph node assay (LLNA) according to the test guidelines for skin sensitization in the OECD Guideline 429 and the US EPA OPPTS 870.2600 are sufficient

and should be used as the criteria for the GS-37 skin sensitization criteria.. The OECD Guideline 429, and US EPA's OPPTS 870.2600 are the most up-to-date test protocols. It is essential that these criteria be used to ensure fairness and uniformity in third party certification for skin sensitization to allow a level playing field

C. Remove the allowance to "Testing is not required for any ingredient for which sufficient information exists."-- "sufficient information" is not defined.

**Response:**

This requirement is included in Green Seal's standard for institutional hand cleaners, GS-41. Products have been able to meet this at the undiluted level. This is also a reasonable exposure level, and thus the undiluted evaluation will be retained as is.

Typically, the evaluation for this requirement is done on the individual ingredients with existing data, and testing is usually not needed. Positive effects seen in either humans or animals will normally justify classification. Evidence from animal studies is usually much more reliable than evidence from human exposure. However, in cases where evidence is available from both sources, and there is conflict between the results, the quality and reliability of the evidence from both sources must be assessed in order to resolve the question of classification on a case-by-case basis. Both EPA and OECD recommend the local lymph node assay (LLNA) as the preferred method for assessing skin sensitization. However, Green Seal does provide testing alternatives, as noted in the Animal Testing criterion.

---

#### 4.06 Skin Absorption

**The undiluted product shall not contain ingredients, present at 1% or more in the product, that are listed on the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value list (TLV) carrying a skin notation, or substances that are listed on the German Deutsche Forschungsgemeinschaft (DFG) Maximum Allowable Concentrations (MAK) list with a skin absorption H notation.**

Comment:

Skin absorption criteria will not work as intended

Skin absorption criterion are needed since several products certified under the current GS-44 standard contain chemicals that can penetrate the skin and damage the central nervous system (CNS), blood and internal organs, or cause other serious health effects. We recommend that Green Seal consider the use of OECD Test 427 and 428 to screen out skin absorbing chemicals. Seal include a "cap" on the total amount of skin absorbing chemicals that can be in a product to prevent the cumulative amount from surpassing the standard when several skin absorbing chemicals are added to a product, each of which falls under the 1% limit.

**Response:**

Both the ACGIH and DFG lists are used. So if a chemical is listed on one of these lists, it is restricted (diethanolamine and ethylene glycols are on the DFG list). The OECD tests suggested were considered but found to not be adequate for products with mixed compositions and the costs would be exceptional with the results misleading.

The “cap” modification was included since there is a chance that multiple ingredients in a product could have the same target organ, thus having the potential to cause systemic toxicity even if the single ingredients were below 1%. So the suggested “cap” will be specific to a target organ.

*Skin Absorption. The undiluted product shall not contain ingredients, present at greater than or equal to 1% in the product, that are listed on the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value list (TLV) carrying a skin notation, or substances that are listed on the German Deutsche Forschungsgemeinschaft (DFG) Maximum Allowable Concentrations (MAK) list with a skin absorption H notation. Further, the product shall not contain ingredients that sum to 1% in the formula that are listed on ACGIH or DFG with the same target organ.*

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#### **4.07 Ingredients that Cause Asthma**

**The undiluted product shall not contain any ingredients that cause asthma.**

Comment:

Due to the potential for revision of the AOEC list, it should be provided as a guideline rather than a requirement. Safety data should be available to support the use of ingredients appearing on the AOEC list. Additionally, a grace period should be specified for manufacturers to update formulations.

Comment:

We recommend this criterion be deleted. This term is not standardized. The designation of substances as “asthmagens” is under constant review by the Association of Occupational and Environmental Clinics (AOEC) as stated on their website. Therefore, this criterion is a moving target with ingredients being added and deleted from AOEC’s list and should not be included in the standard.

**Response:**

The AOEC was chosen due to their criteria-based method of identifying asthmagens and the expert panel review process for evaluating chemicals to those criteria. The robustness of such an approach provides scientific validity to any prohibition that may result. This addresses concerns about lack of a consistent definition. Further, the versatility of a list like the AOEC is that chemicals are continually reviewed and that chemicals of concern can be added or removed as

the weight of evidence grows. As a result the AOEC will continue to serve a source for asthmagen information.

The list is publicly available on the AOEC web site for anyone to download, and thus provides an easy tool for use. Those chemicals listed as “A” chemicals AND “Rs” are those that meet the peer-reviewed criteria, and would be prohibited. Of the chemicals commonly used in personal care products, this includes diethanolamine and triethanolamine. The data used for review by the AOEC to classify a chemical as an asthmagen is publically available.

Comment:

Exclude ingredients that cause asthma

Add the provision that “the undiluted product shall not contain any ingredients that cause asthma.” Chemicals on the Association of Occupational and Environmental Clinics (AOEC) would easily be able to slip-through. As used MSDS requires only compounds more than 1% by weight- this is 10,000 ppm! All detectable hazardous chemicals found on the AOEC list in the undiluted formulations should be prohibited. Inhalation toxicity occurs at levels less than 1 ppm several orders of magnitude below the 10,000ppm level now proposed.

**Response:**

The criterion applies to the undiluted formula, but will be clarified to include intentionally added components as well.

*Components that Cause Asthma. The undiluted product shall not contain any components that have been identified as asthmagens.*

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#### **4.08 Volatile Organic Compounds**

**The product as used shall contain no more than 1% Volatile Organic Compounds (VOCs), substances that contribute significantly to the production of photochemical smog, tropospheric ozone, or poor indoor-air quality. The VOC content shall be determined by California Air Resources Board Method 310, modified to measure fragrances and low vapor pressure organic compounds specified under Method 310 or calculated based on available data.**

Comment:

While we appreciate the U.S. focus of the GS-44 Standard, using a broader, more international approach would take into consideration that many personal care companies today formulate products for a global environment. When determining the definition of a VOC and its allowed maximum limits, a global approach not necessarily limited to the California Air Resources Board’s methodology should be used. Restricting the VOC content based on the limited California method 310 would be unnecessarily burdensome to many manufacturers.

Mentioning Method 310 alludes to a testing program that will need to be instituted. Right

now Method 310 allows for exemptions of certain types of compounds. The elimination of existing exemptions (i.e., for fragrances and LVP compounds), would make formulating products to meet the Standard extremely difficult.

**Response:**

A calculation method is an option for meeting the requirement, so Method 310 is not necessary. This will be further clarified in the standard.

*Volatile Organic Compound Content. The undiluted product shall not contain more than 1% of volatile organic compound content that contributes significantly to the production of photochemical smog, tropospheric ozone, or poor indoor-air quality. The volatile organic compound content shall be determined either by summing the percent by weight contribution from all components of the product that have a vapor pressure of greater than 0.1 mm mercury at standard conditions or by the California Air Resources Board Method 310, modified to not allow the exemption for fragrances specified under Method 310.*

**Comment:**

A significant effort has been made to study and regulate VOCs by the California Air Resources Board (CARB), EPA, Ozone Transport Commission (OTC), and Lake Michigan Air Directors Consortium (LADCO), to name a few. It is ill-advised for Green Seal to completely disregard rules carefully crafted based on the science relating to ground level ozone formation. The standard should align with current regulatory requirements, current exemptions and all, unless Green Seal plans to conduct its own research and evaluation on these substances.

**Comment:**

Concerns exist with the proposed VOC limits for products. Green Seal should consult the rules as applied by CARB, EPA and other regulatory bodies in determining VOC levels and align the proposed standard with those rules specific to each product category within the scope of this standard

**Response:**

As an environmental leadership standard, this standard goes beyond regulatory compliance. This standard includes total volatile organic compound (VOC) content limits to address indoor air quality, not simply those materials identified as having air pollution and outdoor concerns, which are the basis for the California Air Resources Board (CARB) or EPA regulations. The determination of VOC content will include all compounds with a vapor pressure of at least 0.1 mm of mercury (mm Hg) – a definition that is consistent with the European Union Directive 1999/133/EC Solvent Emissions Directive.

**Comment:**

The “Background” document notes that the existing fragrance exemptions under CARB are not allowed for products seeking compliance with the Green Seal Standard. We strenuously object to this proposed revision and question the basis for it. The 2 percent

fragrance exemption has been in place in California for many years; it is based on technical feasibility and must be retained.

**Response:**

Poor indoor air quality has demonstrated health effects on the population. The health effects are not limited to non-fragrance ingredients. Further, the CARB regulations were developed for air pollution and outdoor concerns, rather than indoor air concerns. Finally, Bridges (2002) noted many health concerns including skin sensitization, skin irritation, respiratory sensitization, respiratory irritation, neurological, and systemic effects from fragrance ingredients. Many of the cited health concerns were linked to air quality issues with fragrances including total VOC's. As a result, they will be included in the VOC limits, along with all other volatile components.

The mathematical summation includes all compounds with a vapor pressure greater than 0.1 mm Hg (but not those less than 0.1 mm Hg). Low vapor pressure volatile organic compounds (LVP-VOCs) are defined as compounds with a vapor pressure of less than 0.1 mm Hg, and therefore the exemption in CARB 310 will remain. Fragrances with a vapor pressure greater than 0.1 mm Hg will be measured (not exempted) if the product is tested via CARB 310.

Bridges, B. 2002. "Fragrance: emerging health and environmental concerns." *Flavour and Fragrance Journal*. 17: 361-371.

**Comment:**

The definition of VOC should include all VOCs measured by Method 310 and exclude all exempt compounds including Method 310 prohibited compounds and Low vapor pressure VOCs and ketones and alcohols. A chemical should NOT be exempted from the definition of a VOC.

**Response:**

The determination of VOC content will include all compounds with a vapor pressure of at least 0.1 mm of mercury (mm Hg) – a definition that is consistent with the European Union Directive 1999/133/EC Solvent Emissions Directive.

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#### **4.09 Toxicity to Aquatic Life**

**The product as used shall not be toxic to aquatic life. A compound is considered not toxic to aquatic life if it meets one or more of the following criteria:**

**Acute LC50 for algae, daphnia, or fish >100 mg/L**

**For purposes of demonstrating compliance with this requirement, aquatic toxicity testing is not required if sufficient aquatic toxicity data exist for each of the product's ingredients using a weighted average. Aquatic toxicity tests shall follow the appropriate protocols in ISO 7346-2 for fish/OECD test guidance 203 for fish,**

OECD test guidance 201 for algae, and OECD test guidance 202 for daphnia.

Alternatively, the product shall not be toxic to aquatic life defined as  $IC_{50} > 1000$  mg/L as measured by whole formulation short-term sensitive toxicity test performed on the bacteria *Photobacterium phosphoreum*. Aquatic toxicity shall be measured by one of the following test methods: Biological Test Method: Toxicity Test Using Luminescent Bacteria (*Photobacterium phosphoreum*), ISO 11348 or ASTM D5660-96.

Comment:

According to the current definition of toxicity proposed in this Standard, a compound is considered non-toxic if it meets either one of the algae, daphnia, or fish tests for acute  $LC_{50} > 100$  mg/L.

However, the internationally accepted GHS definition of a non-toxic compound is that it must pass all three toxicity tests simultaneously (a chemical cannot be toxic to one particular organism, but not to another).

It is also proposed that a compound be considered non-toxic if obtains an  $IC_{50}$  value  $> 1000$  mg/L using the organism *Photobacterium phosphoreum*. However, the *Photobacterium phosphoreum* ISO 11348 microbial inhibition test has not been validated as an alternative to acute toxicity tests on fish, daphnia or algae. This test is also not used in the GHS or EU regulations to classify and label chemical substances and preparations.

**Response:**

GHS classifies aquatic toxicity as follows:

Class 3

96 hr  $LC_{50}$  (for fish)  $> 10$  to  $= 100$  mg/l and/or

48 hr  $EC_{50}$  (for crustacea)  $> 10$  to  $= 100$  mg/l and/or

72 or 96hr  $ErC_{50}$  (for algae or other aquatic plants)  $> 10$  to  $= 100$  mg/l

(can extend this range to include other classes)

Thus, failing any one test would qualify as toxic, but data is not typically available for all organisms (its generally more available for daphnia or fish). As a result Green Seal evaluates the product as a whole with the available data, ensuring that, at least, the product is not toxic to the organisms for which data is available.

The preference is to use the OECD method, however, the *Photobacterium* method was included to provide harmonization with the institutional hand cleaner standard used in the US (by Green Seal) and Canada (by EcoLogo).

GHS

[http://www.unece.org/trans/danger/publi/ghs/ghs\\_rev02/English/04e\\_part4.pdf](http://www.unece.org/trans/danger/publi/ghs/ghs_rev02/English/04e_part4.pdf)

Comment:

Consideration of aquatic toxicity should only be done in the context of environmental risk assessment. Directly applying these criteria for aquatic toxicity to products fails to

consider the environmental fate of aqueous cleaning products which are typically disposed into wastewater treatment systems and, thus, do not directly enter the environment. The ability of a product to exert aquatic toxicity in the environment is a function of many factors beyond just its toxicity, including the mitigation due to fate mechanisms and dilution levels upon discharge into the environment.

**Response:**

The environmental evaluation at an as used concentration represents an appropriately conservative approach – from a life cycle perspective (including all phases of the product). This is an achievable requirement; it is already included in the Green Seal standard for institutional hand cleaners, GS-41. Thus, it will remain unchanged.

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#### 4.10 Aquatic Biodegradability

The product as used shall be readily biodegradable as determined by whole formulation testing or based on evidence of the ready biodegradability of each ingredient.

Biodegradability shall be measured according to any of the following methods: ISO 7827, 9439, 10707, 10708, 9408, 14593; OECD Methods 301A – F; or OECD 310. Specifically, within a 28-day test, the ingredient shall meet one of the following criteria within 10 days of the time when biodegradation first reaches 10% (the 10-day window requirement does not apply to structurally-related surfactants):

- Removal of dissolved organic carbon (DOC) > 70%
- Biological oxygen demand (BOD) > 60%
- % of BOD of theoretical oxygen demand (ThOD) > 60%
- % CO<sub>2</sub> evolution of theoretical > 60%

An exception shall be made for an organic ingredient that does not exhibit ready biodegradability if it has low aquatic toxicity, is not bioaccumulating, and exhibits biodegradation rates above 70% (measured as BOC, DOC, or COD), per ISO test methods 9887 or 9888; or OECD 302A, B, or C.

For purposes of this section, low aquatic toxicity is defined as having an acute and chronic aquatic toxicity >100 mg/L where chronic aquatic (fish) toxicity is measured per OECD Method 204. Bioaccumulating is defined as having a bioconcentration factor (BCF) greater than 100 (or log BCF >2).

Comment:

Ready Biodegradation Testing:

According to the current definition of product ready biodegradability in this Standard, this may be measured by using either “whole formulation testing” or by measuring the biodegradability of each ingredient.

However, the GHS regulations and international scientific consensus have not been able to validate any biodegradability data obtained from the testing of mixtures, due to the

difficulty of interpreting these results. Therefore, we would recommend restricting the language in 4.10 to exclude mention of whole formulation biodegradation testing.

**Definition of Low Aquatic Toxicity:**

The proposed definition of low aquatic toxicity requires that an OECD 204 assay is used to measure chronic toxicity in fish. It should be noted that the OECD 204 assay is not a fish chronic toxicity test – these are captured by OECD 210 and 215 series assays. In addition, because fish are not systematically more sensitive than daphnia or algae to chronic effects, there should be no reason to prefer a chronic fish test over a test conducted with daphnia or algae.

When discussing exceptions for organic ingredients, the Standard currently states that OECD 302 A, B, or C assays may be used to measure inherent biodegradability. It should be noted that the pass levels for these selected assays are set at a less severe threshold than what would be required under the GHS system.

**Definition of Bioaccumulation:**

The use of a bioconcentration factor, or BCF, to measure a substance's ability to bioaccumulate is a difficult and time-consuming process. Measured BCF data for most existing substances is very scarce. Conducting new BCF testing could cost up to as much as \$100,000 per test. Finally, requiring BCF testing would significantly increase the use of fish in experiments – and reducing animal testing is one of the most important principles manufacturers should uphold.

Perhaps a better option would be to either measure or calculate the bioaccumulation potential of a substance using the log Kow approach. A log Kow value of < 3 is generally considered to be proof of absence of bioaccumulation potential.

**Comment:**

The above does an excellent job of explaining the specific issues with a biodegradability endpoint, we concur and will not repeat his explanation.

A comment of a more general nature is the proposed revision to the standard requires that all organic ingredients are readily biodegradable, effectively excluding the use of certain performance chemicals such as polymers and chelants. These ingredients provide significant performance efficacy, which meets the product specific performance requirements while using less product. As Green Seal itself points out, using more of a product to obtain the same benefit as a more efficacious product is wasteful and detrimental to the environment.

**Comment:**

Green Seal proposes that all ingredients shall be readily biodegradable. As currently written, this must be determined by actual testing. If every fragrance ingredient must be physically tested for biodegradability, with no de minimis level for ingredients in products, fragrances will effectively be banned because the fragrance industry routinely uses computerized QSAR models such as the U.S. EPA's "PBT Profiler" and "EpiWin" to predict the biodegradability and ecotoxicity of fragrance materials.

Regarding the section on the testing of mixtures, under some conditions some mixtures have been tested with modifications to the procedures. For example, petroleum products use an approach referred to as “water accommodated fractions” – essentially an equilibrium solution of the test material. Furthermore, whole effluent test methods used to monitor waste water might be worth investigating for the testing of mixtures. However, for complex fragrance mixtures, testing will be difficult if not impossible. An additional assessment option for multi-component materials might be an analysis by parts, i.e. summation of the aquatic toxicity by weighted average.

**Comment:**

The proposed revision to the standard requires that all organic ingredients are readily biodegradable, effectively excluding the use of certain performance chemicals such as polymers and chelants that are safe at the low levels that they are used but provide significant performance improvements allowing the use of less product for the same standard cleaning job. From a holistic Life Cycle Analysis (LCA) viewpoint, products without these performance chemicals may not have a superior environmental profile than products containing them.

**Response:**

Bioaccumulation will be separated out to provide more clarification. Kow will be accepted for bioaccumulation data.

*Bioaccumulating Compounds. The product as used shall not contain any ingredients that bioaccumulate or that form degradation products that bioaccumulate. A chemical is considered to bioaccumulate when it has a BCF greater than 100 (or log BCF >2) as determined by ASTM E-1022-94(2007) Standard Guide for Conducting Bioconcentration test with Fishes and Saltwater Bivalve Mollusks or OECD 305 Bioconcentration: Flow-through Fish Test. If the chemical meets the requirement for biodegradability, 4.13, it may be considered to not bioaccumulate. Testing is not required for any ingredient for which sufficient information exists. If no test results are available, a chemical with a log octanol/water partition coefficient log Kow > 3 may be considered to bioaccumulate.*

For biodegradation, whole product testing was removed and only components that meet the ingredient definition at the as used level would be evaluated. So for fragrances, this is limited to only those used at high levels. The data on these components, along with all other chemicals in the product, has been available and not limited certification of the existing certified products. While biodegradability data has been available for the hundreds of cleaners and soaps already reviewed by Green Seal, Green Seal may accept QSAR data from EPA’s BioWin model when data is not available.

Biodegradability is an achievable requirement; it is already included in the Green Seal standard for institutional hand cleaners, GS-41. Thus, it will remain without exceptions beyond those already permitted (for natural or naturally-derived

components that aren't toxic and do not bioaccumulate). The toxicity requirement used for the exception for natural components will include a choice of all three organisms.

*Aquatic Biodegradability. Each of the individual organic ingredients in the product as used shall exhibit ready biodegradability in accordance with the OECD definition. Biodegradability shall be measured according to any of the following methods: ISO 7827, 9439, 10707, 10708, 9408, 14593; OECD Methods 301A – F; or OECD 310. Specifically, within a 28-day test, the ingredient shall meet one of the following criteria within 10 days of the time when biodegradation first reaches 10%:*

- *Removal of DOC* > 70%
- *BOD* > 60%
- *% of BOD of ThOD* > 60%
- *% CO<sub>2</sub> evolution of theoretical* > 60%

*Per OECD guidance the 10-day window requirement does not apply to structurally-related surfactant homologues. For organic ingredients that do not exhibit ready biodegradability in these tests the manufacturer may demonstrate biodegradability in sewage treatment plants using the Coupled Units Test found in OECD 303A by demonstrating DOC removal > 90%.*

*An exception shall be made for a natural or naturally-derived component that does not exhibit ready biodegradability if it does not have acute aquatic toxicity <100 mg/L (according to 4.10), a chronic toxicity <100 mg/L (tested according to OECD 210, 211, or 201), is not bioaccumulating (4.11), and exhibits biodegradation rates above 70% (measured as BOC, DOC, or COD), per ISO test methods 9887 or 9888; or OECD 302A, B, or C.*

*Testing is not required for any ingredient for which sufficient information exists concerning its biodegradability, either in peer-reviewed literature or databases. In the absence of experimental data, QSAR data from EPA's BioWin (EpiSuite) models may be considered.*

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#### **4.11 Prohibited and Restricted Ingredients**

**The undiluted product shall not contain the following ingredients:**

- **Phosphates**
- **Nitrilotriacetic acid or any of its salts**
- **Ethylene diamine tetra acetic acid or any of its salts**
- **Alkylphenol ethoxylates**
- **Ethoxylated alcohols**
- **Halogenated organic solvents**
- **Heavy metals including, lead, hexavalent chromium, or selenium both in the elemental form or compounds.**
- **Ozone-depleting compounds**

- **Optical brighteners**
- **Phthalates**
- **Nitro-musks**
- **Polycyclic musks**
- **2-butoxyethanol**
- **Formaldehyde-donors**
- **Monoethanolamine**
- **Diethanolamine**
- **Triethanolamine**
- **Parabens**
- **Methyldibromo glutaronitrile**
- **Butylated hydroxytoluene**

Comment:

Under which criteria are ethoxylated alcohols excluded from the standard? If this is primarily related to the content of the process reagent ethylene oxide and its byproduct, dioxane, these materials could then be used if the manufacturer specifies purchase of ingredients that are tested to ensure a minimal level of dioxane/EO.

Comment:

Parabens are an important class of preservatives which are used in many cosmetic formulations. We believe that the proposal to ban all parabens from inclusion in rinse-off products is not based on international scientific consensus. Risk assessment studies have been completed by both the U.S. CIR panel and the EU's SCCP to confirm the safety of methyl and ethyl-parabens as currently used in personal care products.

While it is true that parabens have been shown to bind to estrogen receptors to some degree, it is important to put this observation in context. According to Golden, et al, parabens are 2 orders of magnitude less potent than phytoestrogens such as genistein that occur naturally in food. The relative binding affinity for the Estrogen Receptor alpha ranged from 0.011 to 0.110 for the parabens and between 0.011 and 0.093 for the Estrogen Receptor beta. In contrast, the binding affinity of genistein was 4 and 87 respectively. (Golden, R, Gandy, J, Vollmer, G, Critical Reviews in Toxicology, 35: 435-458, 200) Since dietary phytoestrogen intake has not been found to increase the risk of endocrine related effects, there should be even less concern about exposure to parabens.

It is also important to note that parabens do not bioaccumulate and are easily excreted after conversion into polar metabolites.

Comment:

TEA has been shown to be safe in personal care formulations at concentrations up to 5% according to the CIR in the US. However, to be consistent with international practice in most countries, TEA should be allowed in rinse-off formulations at concentrations up to only 2.5%, as long as nitrosating agents are not included in the formulation.

Comment:

First, we recommend Green Seal separate the list into “Prohibited” and “Restricted” to clearly identify an ingredient’s status.

Second, prohibiting an entire class of ingredients (e.g., phthalates) without regard to differences within the class is not sound science. For example, a significant body of data exists for diethyl phthalate, which confirms its safe use in consumer products, both personal cleansing and household products. While Green Seal notes there are substitutions, the substitutes are not as well-studied. It seems short-sighted to throw away a well-studied substance that effectively performs and has been identified as safe for use in cosmetic products, for a lesser-known, less studied substitute.

Further, we strongly recommend that ethoxylated alcohols (EAs) be removed from this list. According to the background document, EAs are prohibited because of the possible contamination with 1,4-dioxane. We recommend Green Seal set limits on contaminants in ingredients. For instance, Sodium Laureth Sulfate (SLS) is in the National Formulary with a limit on organic volatile impurities including chloroform, 1,4-dioxane, methylene, chloride, and TCE. It has been used safely in personal care products for decades. Again, trading well-known, well-understood substances for the unproven and unknown seems unwise.

We fully support the comments from another stakeholder on formaldehyde releasing preservatives.

Comment:

We agree with the above comment regarding ethoxylated alcohols (EAs). Specify limiting impurities instead of banning particular ingredients through a requirement to meet USP/NF standards.

Comment:

This section recommends that the undiluted product not contain phthalates and polycyclic musks, among others. Phthalates is a broad term that refers to a wide variety of compounds of differing chemical structure. Not all phthalates are the same; the chemical profiles of phthalates differ significantly.

While some reports continue to raise questions about “phthalates” in general, it is important to define the specific chemicals of concern, as well as the scientific legitimacy of the associated data. The scientific validity of some frequently cited research has been seriously questioned through the process of scientific peer review. For example, recent studies reporting the potential association of “phthalates” with male reproductive biomarkers are inconsistent and have been rejected by government experts who have reviewed these data and found the conclusions to be based on insufficient evidence. In addition, a recent study found no effects on reproductive or thyroid hormone levels in males who topically applied diethyl phthalate (DEP) repeatedly for 28 days.

Moreover, since DEP has not been demonstrated to have a potential for adverse

reproductive effects, it is inaccurate to imply that there are concerns similar to those for other phthalates. DEP presents no safety concern from use in fragrances; it has a very strong safety profile. DEP is commonly used in cosmetics, toothbrushes and food packaging. It is used in fragrances as a solvent to blend fragrance ingredients and as a fixative to make fragrances last longer when applied to the skin. DEP has been extensively tested and subjected to a wide array of technical reviews in both the United States and Europe.

In a recent review completed in March of 2007 by the European Commission's Scientific Committee on Consumer Products (SCCP), the SCCP reconfirmed that DEP is safe for use in cosmetics and represents no quantifiable risk for the consumer. The SCCP also found that none of the latest information on DEP would change its longstanding conclusion. The SCCP is the regulatory arm of the European Union comparable to the U.S. Food and Drug Administration. We would be happy to provide a copy of the SCCP opinion upon request.

In another re-review of diethyl phthalate, the Cosmetic Ingredient Review Panel (CIR) concluded that this material is safe under conditions of use in cosmetic products. This review was published in 2005 and can be provided if you would like a copy.

For the above reasons, we believe it has been demonstrated that diethyl phthalate is safe for use in fragrances and is among the most thoroughly tested substances in the class of phthalates. Therefore, we strongly object to the Green Seal proposal to ban the use of ALL phthalates, including DEP, in GS-44 products.

With respect to the proposed ban on the use of polycyclic musks, again we must object to this as there are over 40 publications in the scientific literature that demonstrate the human health and environmental safety of the PCMs and they should not be restricted or prohibited. The European Chemicals Bureau has twice assessed these materials and found them not to be persistent, bioaccumulative and toxic materials (PBTs). In addition, the European Scientific Committee for Cosmetics and Non-Food Products has affirmed their continued safe use in consumer products (SCCNFP, 2002a and SCCNFP, 2002b), and a recent summary of the environmental risk assessments of these materials is available at the HERA website (<http://www.heraproject.com/RiskAssessment.cfm>). In addition to the determination that these materials are not persistent, bioaccumulative and toxic, data are available to indicate that they are also not subject to long range transport; a key parameter in identifying a material as a "POP". (Aschmann et al., 2001)

**Comment:**

We recommend Green Seal separate the list into "Prohibited" and "Restricted" for clearer delineation. All product ingredients should be assessed against the same criteria. Also, prohibiting all members of a class of ingredients (e.g., optical brightener) without regard to differences within the class inappropriately captures chemicals of varied environmental impacts and creates disincentives to innovation within the class. For example, optical brighteners should be removed from the list of prohibited ingredients. Innovation may in the future offer a fully biodegradable and non-toxic brightener, which under this standard

would be banned. Finally, this criterion inappropriately focuses on the hazard potential of ingredients and not the risk they pose as a result of use in cleaning products. Data show that APEs biodegrade under anaerobic conditions and that removal is greater than 99% in sewage treatment plants (Nimrod and Benson 1996; Keith 1997). Therefore, APEs are in the environment at concentrations well below effects concentrations. Because there is low likelihood of injury to the environment, this ingredient should be deleted from the criterion. We strongly recommend that ethoxylated alcohols (EAs) be removed from this list. According to the background document, EAs are prohibited because of the possible contamination with 1,4-dioxane. We recommend Green Seal set limits on contaminants in ingredients. For instance, Sodium Laureth Sulfate (SLS) is in the National Formulary with a limit on organic volatile impurities including chloroform, 1,4-dioxane, methylene, chloride, and TCE. Monoethanolamine and Triethanolamine should not be considered prohibited ingredients. Instead direction for safe use should be provided such as, “All nitrogen containing compounds should be formulated so that nitrosamines will not occur”. It is common formulator knowledge that when Monoethanolamine and Triethanolamine are formulated properly they will not cause nitrosamines. Monoethanolamine and Triethanolamine offer a unique functionality offering mild and effective skin care products. Please see the Journal of the American College of Toxicology report “Final Report on the Safety Assessment of Triethanolamine, Diethanolamine, and Monoethanolamine” Volume 2, Number 7, 1983 for further details.

Comment:

We agree with the comment regarding optical brighteners. If these ingredients will be prohibited or restricted a specific list of types of optical brighteners must be provided.

Comment:

Lists of prohibited and restricted ingredients

Add several important chemicals to the standard’s lists of prohibited and restricted ingredients (Section 4.13). Although the prohibited ingredients include phthalates, nitro-musks, polycyclic musks, 2-butoxyethanol, and formaldehyde-donors this list is not specific enough for phthalates, nitro-musks, polycyclic musks, and formaldehyde-donors. GS-44 should use these general categories and list the specific CAS numbers of the compounds in these categories that are currently known to be found in soaps, cleansers, and shower products. The following compounds should be prohibited: monoethanolamine, diethanolamine, and triethanolamine, since these chemicals have multiple serious health consequences such as causing new cases of asthma, triggering asthma among people who currently have it (by being corrosive to the respiratory system), and absorbing through the skin to cause central nervous system effects. We also urge Green Seal to add to the prohibited ingredients list any chemical that is currently prohibited in similar products under Canada’s EcoLogo for “green” hard surface cleaners (CCD-146); These include specific ingredients of concern such as ammonia and any ammonium compounds, aromatic solvents, halogenated solvents, ethylene diamine tetra acetic acid (EDTA), ethylene dinitrilotetra acetic acid, nitrilotriacetic acid or the salts of these compounds. Allow only the use of food grade dyes, which are known to be safe; do not allow chlorinated (PVC) plastic in packaging

Prohibit mercury concentrations appearing via unintentional ingredients  
Exclude fly ash and other pollution control residues as examples of ingredients with “intentional content” if they have toxic content. Even though heavy metals appear to be prohibited in this standard, mercury may be allowed in the certified soaps, cleansers, and shower products via unintentional ingredients if fly ash and other coal combustion pollution control byproducts are permitted as ingredients in the standard. Fly ash and other pollution control based injection sorbents from power plants and incinerators may contain unintentional quantities of mercury. These materials are currently being promoted, and added to many commercial, institutional, and residential products including wall boards, toothpaste, flooring kitchen counters and concrete and may likewise be a candidate additives used for scrubbing and other attributes in cleansers. Because there is currently no regulatory mercury testing requirements on these exempt materials they should be explicitly prohibited from use unless tested for their toxic content before adding into the formulation. Scientific evidence has been published showing that these unregulated substance may contain mercury concentrations in different quantities depending on the coal type and the power plant pollution control devices. GS-44 criteria should explicitly prohibit the use of these materials if they contain mercury concentrations and should require these materials to be tested prior to being added into formulations. If there are not explicitly described in the standard then they may be used as additives via the “Naturally occurring elements” clause in the “intentional ingredient” definition.

Comment:

We agree with the above comment regarding Triethanolamine and would like to extend the scope to include Monoethanolamine.

Monoethanolamine and Triethanolamine should not be considered prohibited ingredients. Instead direction for safe use should be provided such as, “All nitrogen containing compounds should be formulated so that nitrosamines will not occur”. It is common formulator knowledge that when Monoethanolamine and Triethanolamine are formulated properly they will not cause nitrosamines. Monoethanolamine and Triethanolamine offer a unique functionality offering mild and effective skin care products. Please see the Journal of the American College of Toxicology report “Final Report on the Safety Assessment of Triethanolamine, Diethanolamine, and Monoethanolamine” Volume 2, Number 7, 1983 for further details.

We also agree with the above comment regarding parabens as an important class of preservatives. Inadequately preserved products can pose a larger risk to users than the use of preservatives, such as Parabans and formaldehyde-donors, at safe and effective level. Eliminating effective preservatives will result in an inability to formulate products safe for consumers.

Comment:

Comments on the Safety of Formaldehyde Releasing Preservatives

## Background

Formaldehyde is a naturally occurring gas that is present in every human cell, as well as in many common foods, such as meat, apples, and carrots. There are four forms of formaldehyde – gas, liquid, aqueous solution or methylene glycol, and the paraformaldehyde polymer. Starting in the 1920's, formaldehyde liquid and aqueous solutions have been used as preservatives in consumer products. However, in these forms, formaldehyde is very volatile and has a severe odor. Formaldehyde releasing preservatives (FRPs) were developed as an odorless form of formaldehyde. This class of preservatives acts by releasing small amounts of formaldehyde over time.

## Gaseous Formaldehyde versus Liquid Formaldehyde

It is important to distinguish between gaseous formaldehyde and liquid formaldehyde. The potential carcinogenicity of formaldehyde has solely been associated with gaseous formaldehyde. Safety studies (oral) conducted with liquid formaldehyde have clearly established that oral uptake of formaldehyde is not carcinogenic. In this regard, it should be noted that the U.S. Food and Drug Administration (USFDA) does not consider formaldehyde a carcinogen by the oral route of exposure. Moreover, there is no evidence that dermal exposure to formaldehyde is carcinogenic.

The distinction between the health risks from liquid and gaseous formaldehyde has also been made by California's Office of Environmental Health Hazard Assessment pursuant to the Proposition 65 listing of formaldehyde. The Prop 65 listing for formaldehyde is limited to its gaseous form.

## Formaldehyde Releasing Preservatives (FRPs)

Some of the preservatives that release formaldehyde are DMDM Hydantoin (DMDMH), imidazolidinyl urea, diazolidinyl urea, quaternium-15, sodium hydroxymethylglycinate and hexamethelentriamine.

For this class of preservatives, the amount of formaldehyde that is released in water is dependent on the formaldehyde content of the parent molecule, use concentration and hydrolysis chemistry. In water, the parent molecule hydrolyzes to methylene glycol (hydrated formaldehyde). The table below provides typical use levels for some of the formaldehyde releasing preservatives that are in use today:

Name	"Equivalent" wt% formaldehyde	Typical Use Level (%)
Formaldehyde	100	
DMDMH	31.9	0.4
Imidazolidinyl urea	15.5	0.3
2-bromo-2-nitro-1,3-propanediol	30	0.05
Quaternium-15	71.7	0.1

## Summary

We are requesting that Green Seal revise the proposed Environmental Standard for

Soaps, Cleansers and Shower Products ("GS-44") by removing from the prohibited compounds list the formaldehyde releasing ingredients. The basis for this position is that formaldehyde is considered carcinogenic to humans by inhalation, which does not occur when the formaldehyde releasing ingredients are used as preservatives in soaps, cleansers and shower products. This position is consistent with the listing of formaldehyde, as a carcinogen, under California's Proposition 65, which is limited to inhalation exposure. It is patently unfair to prohibit the use of highly efficacious ingredients under such circumstances.

**Response:**

The approach taken in this standard is where an ingredient or its class exhibits potentially harmful characteristics, to specifically prohibit it or substantially reduce that ingredient or class of ingredients in products rather than attempting to determine risk-based acceptable levels. This remains an area of disagreement with those who prescribe to the risk assessment approach. This risk assessment approach reflects a fundamental philosophical difference between what Green Seal is trying to do with its leadership environmental standards and what is conventionally done in risk assessment. Green Seal's approach is to minimize the use of more harmful ingredients or products rather than determine at what levels they may be used safely or with an acceptable amount of risk. Such a protective approach is appropriate for products with the level of direct exposure that these products present, and especially since they are used by infants and children who are particularly susceptible to hazards (and not effectively protected through risk assessments methods).

Some of Green Seal's principles of standard development are that the criteria are scientifically-justified and measurable/verifiable. However, if development of test methods is not yet in a state where it is widely recognized as the standard for a particular end point of concern and there is not widespread data available then use of such a method may not be scientifically-justified or verifiable. As a result, Green Seal, and other ecolabel programs, use a prohibited ingredient list when specific chemicals have a recognized hazard (ex. Endocrine disruptors and neurotoxins).

For example, the EPA is currently developing and validating screening and testing assays for the Endocrine Disrupter Screening program. A variety of assays are being validated

([www.epa.gov/oscpmont/oscpendo/pubs/assayvalidation/status.htm](http://www.epa.gov/oscpmont/oscpendo/pubs/assayvalidation/status.htm) [accessed June 20, 2007]), but none have achieved regulatory acceptance by EPA. The Organization for Economic and Cooperation and Development (OECD) has also been working for about 10 years to develop new or revise existing Test Guidelines to detect endocrine disrupters ([www.oecd.org/document/62/0,2340,en\\_2649\\_34377\\_2348606\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/62/0,2340,en_2649_34377_2348606_1_1_1_1,00.html) [accessed June 20, 2007]). Although several test methods are in the final stages of acceptance by the OECD, none have been published as a validated, approved method. In October 2004, the European Commission accepted a staff working

document on implementation of the Community Strategy for Endocrine Disrupters (European Commission, 2004). Part of the strategy entailed a literature review of chemicals that identified those chemicals with evidence of endocrine disruption or potential endocrine disruption in humans or wildlife. Annex 3 of the document includes a listing of “substances with evidence (Category 1) or evidence of potential endocrine disruption (Category 2).” Dicyclohexyl phthalate and diethyl phthalate were identified as substances with evidence of endocrine disruption (Category 1). NAS (1999) identified several chemicals that might be used in personal care products to have the potential endocrine: alkylphenol ethoxylates, butyl benzyl phthalate (BBP), dibutyl phthalate (DBP). In 2000, the Canadian Depository Services Program reviewed literature to summarize information about endocrine disrupters and included a list of eight phthalates as “known and suspected hormone disruptors.” In 2004, the Australian CSIRO and Australian Water Association reviewed endocrine disrupting chemicals associated with recycled water, and the report included a list of “suspected/known endocrine disrupting chemicals” that also included the same list of eight phthalates. While it is recognized that the class of phthalates includes a range of physical and chemical characteristics, hormone disruptor potential is evident across the class. A number of phthalates are prohibited due to their reproductive toxicity (dibutyl phthalate, diethylhexyl phthalate, etc). Others have demonstrated hormone disrupting potential, such as with in vitro estrogen receptor binding activity (diethyl phthalate). There are no phthalates that are necessary for performance or consumer acceptability of the products included in this standard. As a result, phthalates shall continue to be prohibited.

Optical brighteners (with their current environmental and health concerns) are not needed to meet product performance requirements. Optical brighteners have been defined in the standard, to include fluorescing compounds. Thus, innovation is not limited. There are opportunities for new components to be used to deliver a future functionality (though at this time optical brightening is not needed for this product category) if they meet the other requirements in the standard.

It is known that ethoxylated alcohols are contaminated with 1,4-dioxane (and ethylene oxide however it dissociates upon solubilization in water). 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. This standard prohibits the addition of carcinogens, as intentionally added components or as known contaminants. The routes of exposure of 1,4-dioxane have been demonstrated to include skin absorption and inhalation, both reasonable routes for the products included in this study. Further, there is no acceptable level for carcinogens,

especially when exposed to the skin and used by infants and children. As a result, ethoxylated alcohols will continue to be prohibited.

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. In addition, DEA, TEA are both asthmagens and MEA demonstrates chronic inhalation toxicity. As a result, specifying nitrosing compound limits is unnecessary as MEA, DEA, and TEA would be prohibited by other criteria in the standard (beyond this listing). However, it has been found that there is interest in listing these chemicals out specifically to facilitate formulation. As a result, they will remain on the list.

While nitromusks and polycyclic musks bioaccumulate and are not readily biodegradable (according to HERA) and would be limited by this standard already, they will remain listed on the prohibited list due to the sensitization and neurotoxicity of these materials (which is why some are already prohibited by IFRA).

Due to considerable evidence that APEs and their breakdown products (ex. nonylphenol) act as endocrine disrupters and given the availability of alternatives to APEs, Green Seal believes that there is sufficient evidence to exclude the use of APEs in an environmentally preferable products.

Parabens are preservatives used in personal care products. According to the National Institutes of Health (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). There are safer alternatives to parabens, including potassium sorbate and sodium benzoate. As a result, the class of parabens will continue to be prohibited.

Formaldehyde is recognized as a carcinogen (classification 1) by the International Agency for Research on Cancer (IARC). IARC is considered the international authority on carcinogenicity classification and they make no distinction on the form of the chemical – gaseous or liquid, like they do for other chemicals (ex.

“alcoholic beverages” rather than all alcohol and “silica, crystalline (inhaled in the form of quartz or cristobalite from occupational sources)” rather than any form of silica). Any intentional addition of a carcinogen is prohibited in the standard. However, since preservatives such as DMDM-hydantoin release formaldehyde they were, and will continue to be, specifically cited as prohibited components.

NTA was removed from the list since it was already prohibited as a carcinogen, listed by IARC. The FDA stated that “Mercury compounds are readily absorbed through the skin on topical application and have the tendency to accumulate in the body. They may cause allergic reactions, skin irritation or neurotoxic manifestations.” In addition, mercury is a known developmental toxin. As a result, mercury is already prohibited.

While the criteria have restricted the use of PVC packaging (not being recyclable according to the standard and contain phthalates), with developments there may be a means for PVC packaging to be allowed. Given the hazards associated with PVC from production to disposal, it will be specifically prohibited, in the packaging section.

European Commission. 2004. Commission Staff Working Document on Implementation of the Community Strategy for Endocrine Disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife. SEC(2004) 1372. Available [http://ec.europa.eu/environment/endocrine/documents/sec\\_2004\\_1372\\_en.pdf](http://ec.europa.eu/environment/endocrine/documents/sec_2004_1372_en.pdf) [accessed 21 June 2007].

NAS. 1999. Hormonally Active Agents in the Environment. National Academy Press, Washington, DC. Available <http://www.nap.edu/books/0309064198/html> [accessed 21 June 2007].

Aubrey Organics. How Safe if Your Children's Bubble Bath? [http://www.aubrey-organics.com/about/articles/bubble\\_baths.cfm](http://www.aubrey-organics.com/about/articles/bubble_baths.cfm)

HERA <http://www.heraproject.com/RiskAssessment.cfm>

Nagel J.E., et al. 1977. Paraben allergy. JAMA. April 11 1977; 237(15):1594-5.

National Institutes of Health (NIH). 2004. Butylparaben [CAS No. 94-26-8] Final Review of Toxicological Literature. June 2004.

FDA [http://www.fda.gov/ora/inspect\\_ref/igs/cosmet.html](http://www.fda.gov/ora/inspect_ref/igs/cosmet.html)

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#### 4.12 Fragrances

**Fragrances are prohibited in products intended for small children (<3 years). The product shall declare any fragrances on the product label in the ingredient line (see**

**6.2). Any fragrances used shall have been produced or handled following the Guideline in the Code of Practice of the International Fragrance Association.**

Comment:

4.12 We would appreciate knowing the scientific basis for the proposed prohibition on fragrances in products intended for children under 3 years old. There is no scientific reason to believe that fragrances are unsafe to the general population or select sensitive subpopulations. The “Background” document also includes a quote from the EU (2005) that acknowledges there is no data to support that fragrance exposure at an early age poses a health risk. Also in the “Background” document (page 6, “Fragrances”) it states, “However, the International Fragrance Association (IFRA) Code is limited to the substances that have been comprehensively evaluated by the Research Institute for Fragrance Materials (RIFM)...” The RIFM evaluations account for >95% of ALL fragrance materials in common use by volume, including those with structural alerts. Also, this section refers to the IFRA “Guideline.” This must be corrected to read “Standards.” This must also be corrected in the “Background” document.

Comment:

Fragrances are essential ingredients in products. Fragrances often conceal the base odor of the product, as well as impart pleasant hedonics. Most consumers base their purchase decisions on most products they buy, both personal care products and household products, on pleasant fragrances. We wonder what consumer preference data Green Seal has that shows that fragrances are not important considerations to small children. Children are especially observant about fragrances, and most children will not allow unpleasant smelling products near them without protesting. More importantly, we do not observe many children under the age of three making their own purchasing decisions. The fragrance of the product must meet the requirements of, in most cases, the purchaser (parent). It is unrealistic to believe that parents will purchase unpleasant smelling products for their children, regardless of age. We therefore recommend that fragrances be removed from the list of prohibited substances in products intended for small children (<3 years).

Comment:

Fragrances are essential ingredients in products; there are non-scented products that contain fragrances to mask malodors. We recommend that fragrances be removed from the list of prohibited substances in products intended for small children (<3 years). The requirement for fragrances to be disclosed on MSDSs could entail disclosure of confidential business information. Provisions should be included in the criterion to allow protection of fragrance information that is confidential.

**Response:**

The prohibition of fragrances for products intended for children was aimed to be consistent with European ecolabel standards. However, after review it was found that at this point, the research points to specific end points of concern for certain chemicals, rather than stating that in general, scent imparting chemical/fragrance component is an issue. Further, complex fragrances such as natural ingredients or

essential oils may contain known carcinogens and thus are not safer than other fragrance options (Jansson and Loden, 2001). Thus, the best approach is to use strict end point criteria, as is done throughout the standard. As a result, this standard includes the end points of concern (ex. skin sensitization, causing asthma, volatile organic compounds, and inhalation toxicity) and fragrances will be evaluated against these criteria. However, it is important that any use of fragrance components be disclosed to the public so they can make informed choices. As a result, use of fragrance ingredients, when added or not, shall be disclosed on the label. Given that some fragrances contain many components, and be proprietary, the complete list of fragrance components does not have to be on the product label, but all of the components need to be disclosed to Green Seal for review. As a result of the Green Seal review, consumers can know that a third party has reviewed the components for safety. The labeling requirements have been updated accordingly.

Jansson, T. and M. Loden. 2001. "Strategy to decrease the risk of adverse effects of fragrance ingredients in cosmetic products." *Am J Contact Dermat.* Sep;12(3):166-9.

*Fragrances. The product shall declare any fragrances on the product label in the ingredient line (see 6.2). Any fragrances used shall have been produced and handled following the code of practice of the International Fragrance Association. The product label shall reflect the use of fragrances (present or not) in accordance with sections 6.5 and 6.6.*

*Fragrance and Allergen Labeling. The product label shall declare, separate from the ingredient line, if a fragrance has been added or if no fragrance has been added and if it contains any allergen components.*

*Consumer Communication. The product ingredient line (6.2) shall be made available to consumers in an easily accessible means, such as the company website.*

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#### **4.14 Colors**

##### **Any color used shall be FDA certified or a natural ingredient.**

Comment:

All FD&C colorants are already FDA approved but a number of them are not preferable for their environmental and health attributes. This bar could be raised to state that all colorants should at least be non-accumulative and not aquatoxic (few colorants are likely to meet OECD standards for biodegradation due to their necessary stability).

Comment:

The standard should clearly state that all products regulated by FDA (e.g., cosmetics) must comply with FDA regulations, including using FDA regulated colorants. Further,

the standard should also state that any non-cosmetic product should comply with FDA regulated color additives and natural ingredients.

Comment:

This section needs clarification. First, any use regulated by FDA (cosmetic) must comply with FDA regulations. Second, any non-cosmetic use should allow any FDA regulated color additive and natural ingredients.

**Response:**

It is acknowledged that colors added to the products in this standard are regulated. Color components have to pass all the other requirements in the standard (no heavy metals). However, Green Seal would like to reserve this section in the standard for potential additional considerations specific to colors at a later date.

*Color Component. A product component whose only function is to change the product's color.*

*Color Components. [Reserved]*

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#### 4.15 Animal Testing

**Green Seal wants to discourage animal testing and will accept the results of past peer reviewed or standard tests demonstrating compliance with a criterion. A mixture need not be tested if existing information demonstrates that each of the ingredients complies with a criterion. Additionally, non-animal (in-vitro) test results may be accepted, providing that the test methods are referenced in peer-reviewed literature and the manufacturer provides the reasons for selecting the particular test method.**

Comment:

As this section currently reads, the endpoints and validity criteria of an acceptable animal-alternative in-vitro test have not been defined. Perhaps Green Seal could provide some specific examples of acceptable alternative test methods and pass criteria from peer-reviewed literature.

**Response:**

Available data is primarily used for evaluation. If such data is not available, preference is given to in vitro methods. As mentioned, such in vitro methods need to be sufficient to demonstrate meeting the criteria.

Comment:

The European Union Cosmetics Directive 76/768/EEC prohibits the use of animal testing on cosmetic products. It would be appropriate for Green Seal standards to align with EU legislation regarding animal testing.

**Response:**

Green Seal’s policy on animal testing is consistent with the EU. Testing (of any kind) is not used for any areas where existing data is available. Green Seal also accepts alternative methods to prevent the use of animals for testing. Further, whole product animal testing is not included in this standard.

Comment:

This section requires the testing of all ingredients in the product. However, given that a fragrance typically contains 100-1000 or more individual materials, this is an unrealistic expectation. There should be a de minimis level for the level of ingredients in a product, such as 0.1% or 0.01%, below which evaluation is not required. Otherwise, it will never be possible to meet the test criteria because we will never have a complete data set on every single ingredient in the fragrance, because the fragrance industry extensively uses chemical grouping, QSAR and read-across as tools to evaluate fragrance material safety.

**Response:**

Testing is only required when there is not sufficient information. Green Seal has evaluated hundreds of products that contain fragrances and have not had issues with data availability.

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## **5.0 Packaging Requirements**

### **Comments on packaging requirements.**

Comment:

"The proposed packaging provisions are extremely vague. Manufacturers would be unable under the proposed definitions and provisions to ascertain which products would be covered. While favorable references are made to the California Rigid Plastic Packaging Container Act, with the goal of “allowing industry to select from those environmental-preferred packaging options,” it is unclear what “options” would be permitted: what specific provisions and exemptions, if any, would apply? Moreover, how would the GS-37 standard interact with recognized U.S. Department of Transportation (DOT) and United Nations packaging rules and provisions? Without further clarification, SDA is unable at this time to provide more substantive comment on specific aspects of the standard."

**Response:**

This comment appears to refer to a different standard.

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### **5.1.1 Recyclable Primary Package**

**The primary package shall be a recyclable package. If the primary package is not a recyclable package it must be a reusable package. An exception may be made for lightweight packaging (e.g., pouches or bags) that represent a 50% reduction in material use when compared with rigid packaging.**

Comment:

We believe there is an unintended consequence of promoting reusable packaging because it directs the market toward dispensing methods that are associated with potential human health risks. There is an increased potential for microbiological contamination with the use of open refillable soap dispensers. Recent research by the University of Arizona<sup>1</sup> has demonstrated that high levels of bacterial contamination of open, refillable soap dispensers is widespread in public restrooms. High level contamination of open, refillable soap dispensers with coliforms and other organisms represents an unnecessary health risk therefore promotion of reusable packaging is discouraged.

<sup>1</sup>C.P. Gerba. The Occurrence of Heterotrophic Bacteria, Coliforms and Staphylococcus Aureus in Liquid Soap Samples From Public Restrooms. Unpublished study. University of Arizona. 2006.

**Response:**

The reusable option has been removed.

*Source Reduction in Primary Package. The primary package shall be recyclable or a source-reduced package.*

*Source-Reduced Package. A package that has at least 50% less material (by weight) compared to containers commonly used for that product type.*

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**5.1.2 Recovered Material Content.**

**The primary package shall contain the state-of-the-art amount of recovered and post-consumer content. Where a product’s package is below these levels, the manufacturer must demonstrate that efforts have been made to use the maximum available post-consumer material in the package.**

Comment:

We are concerned that the human health risk of chemical leaching outweighs the value using PRC in primary packaging. We also request a more explicit definition of “state-of-the-art”.

**Response:**

Post-consumer content has been included in food-contact packages and thus present a safe option for personal care products.

*Post-Consumer Content. The primary package, shall contain at least 25% post-consumer material or demonstrate that efforts were made to use the maximum available post-consumer material in the package.*

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**5.2 Secondary Packaging**

**Secondary packaging shall only be used for concentrates. An exception may be made for packaging of multiple units when only one of the units is a ready-to-use form, including but not limited to pump-dispenser bottles, and total packaging (primary plus secondary) is a reduction in packaging material use.**

Comment:

A more precise definition of what is meant by “primary” and “secondary” packaging is needed. For example, if the cap or lid is not considered part of the primary packaging (as is defined in 2.23), are these considered secondary packaging?

Comment:

We request a more explicit definition of secondary packaging. Secondary packaging should be used when required for structural integrity and/or when the primary packaging is not conducive to distribution. The additional cost, materials, and transportation to replace damaged product not adequately protected would be wasteful.

**Response:**

A definition for secondary packaging has been added. Secondary packaging does not include shipping containers and thus the requirement should not effect distribution protection.

*Secondary Packaging. Packaging used to contain primary package/s and typically used for merchandizing. This does not include case or shipping packaging or the primary package, cap, or lid.*

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## **6.0 Labeling Requirements**

### **Comments on labeling requirements.**

Comment:

Add labeling requirements for the toxic chemical content  
Labeling should be added to require the list of toxic chemical ingredients contained in the product on their label for users to read. Additionally, all of the toxic chemical ingredients and their associated concentrations by weight percent should be posted with the product information on the Green Seal and product manufacturer website given on the label. We recommend that Green Seal require full-disclosure of ingredients listed on the MSDSs of certified products to be put on product labels and GS website should provide direct links to the MSDSs for all certified products.

**Response:**

Ingredient labeling is included, along with separate allergen and fragrance disclosure. Toxic chemicals are not allowed in the product, and thus a separate labeling requirement is not needed.

As a third-party certification organization, Green Seal has refrained from distributing any safety, sales, or marketing literature for the products and services

certified. Green Seal does not get involved in pricing and does not post catalogs or product literature on our website. This also extends to Material Safety Data Sheets, which are considered technical literature and necessarily should be obtained directly from the product manufacturer.

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## 6.2 Ingredient Labeling

**The product shall list all ingredients in order of predominance as directed by 21 CFR 701.3, and include fragrance ingredients. Fragrance ingredients may be labeled generically as “fragrance”.**

Comment:

We recommend this section to read, “Cosmetic products shall list all ingredients in compliance with 21 CFR 701.3.” Restating regulatory requirements is unnecessary, and it prevents Green Seal from being in the position of having an outdated standard the instant FDA revises its labeling rules. Companies have no choice but to comply with regulations over voluntary standards. Incorporating by reference is adequate.

Comment:

Cosmetic products shall list all ingredients in compliance with 21 CFR 701.3

Comment:

We recommend this section to read, “Cosmetic products shall list all ingredients in compliance with 21 CFR 701.3.” It is confusing to try to restate the elements regulatory requirements.

### **Response:**

Ingredient labeling is not required by regulation for all the products in the standard. As a result, ingredient labeling was specified. However, it will now be a more generic requirement, following the International Nomenclature of Cosmetic Ingredients, and in order of predominance. Further, any applicable regulations for products should be followed.

*Ingredient Line. The product shall list all components using the naming convention of the INCI in order of predominance. The general term ‘fragrance’ may be used for fragrance components. The product shall also follow any additional ingredient labeling regulations that apply to that product*

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## 6.5 Use Labeling

**The product shall be accompanied by detailed instructions for proper use to maximize product performance and minimize waste. This shall include directions for proper use and recommended dose, and, if applicable, use with a sponge or washcloth.**

**6.5.1 The label shall include the following language, “Proper use and dosage saves**

costs and minimizes environmental impacts.”

**6.5.2 When the product is offered in reusable packages, the label shall include the following statement, “Using reusable packaging minimizes environmental impacts.”**

Comment:

6.5.1 “The label shall include the following language, “Proper use and dosage saves costs and minimizes environmental impacts.”

We believe that including this language as a mandatory requirement on all packaging would be an excessive requirement. As an environmentally responsible company, all of our products are already placed on the market with proper instructions on the recommended dosage and/or usage instructions.

**Response:**

This requirement is included to ensure all certified products address proper usage (and minimize over use). However, this requirement will be modified to provide more flexibility.

*Use Labeling. The product shall be accompanied by detailed instructions for proper use to maximize product performance and minimize waste.*

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**Addendum**

**A. SCOPE**

This criteria document establishes environmental requirements for optional verified claims on GS-44 certified products.

There is emphasis on demonstrated leadership in the following environmental impact areas: energy reduction, waste reduction, resource minimization (including water), emissions reduction, and biodiversity conservation.

**B. DEFINITIONS**

**B.1 Biobased:** The content of a product that is from biological products or renewable materials, forestry or agricultural materials (including plant, animal, and marine materials).

**B.2 Carbon offsets:** Mitigation of greenhouse gas emissions generated using reduction measures that may be purchased from a third-party carbon offset provider.

**B.3 Fragrance:** An additive, often (but not limited to) a multi-component additive, used in a product with the purpose of changing the scent of the product.

**B.4 Greenhouse gas (GHG):** Components of the atmosphere that contribute to the greenhouse effect including water vapor, carbon dioxide, methane, nitrous oxide, sulfur hexafluoride, hydrofluorocarbons, perfluorocarbons, chlorofluorocarbons, and ozone.

**B.5 Ingredient:** Any constituent of a product that is intentionally added or known to be a contaminant that comprises at least 0.01% by weight of the product.

**B.6 Renewable energy:** Energy from non-depleting sources and derived from natural processes that are replenished constantly including wind, solar, water, geothermal, and biofuels.

**B.7 Waste:** By-products from the manufacturing of the product and package not included in the finished product that are not salable and are disposed, including wastewater.

### **C. CLAIM CRITERIA**

**C.1 No Added Fragrance:** A product will be verified to contain no added fragrance when no fragrance ingredients are in the product. However, this does not imply that the product has no scent or odor.

**C.2 Manufactured with Green Energy:** A product shall be verified to be manufactured with green energy if the energy requirements for product and package production were directly fueled with a minimum of 75% renewable energy, not including any renewable energy certificate purchases.

**C.3 Made with Zero Waste:** A product shall be verified to be manufactured with zero waste when there was no disposal of waste (solid or water) during the production of the product and package. Responsible material management can be done within the company or with proven partnerships to result in zero net waste.

**C.4 Made with Zero GHG Emissions:** A product shall be verified to be manufactured with zero greenhouse gas emissions when there is no net GHG emissions during production of the product and package. This can be achieved within the company, with proven partnerships, or through carbon offset programs. If a carbon offset program is used for 100% of the emissions, a successful emissions reduction program must be demonstrated, with 10% or greater annual reductions in emissions.

**C.5 Biobased Product:** A product is verified to be a biobased product when its biobased carbon content is determined to be 100% of the total carbon, as determined with the ASTM International Radioisotope Standard Method D6866. Alternatively, the biobased components shall comprise 100% of the total weight of product, minus product water content, as determined with ingredient information.

### **D. LABELING REQUIREMENTS:**

**D.1** The verified claim may only appear on packaging, literature, or marketing materials for GS-44 certified products.

**D.2** The verified claim shall not be used in conjunction with any modifying terms, phrases, or graphic images that might mislead consumers as to the extent or nature of the verification.

**D.3** Whenever the verified claim appears on a package, the package shall contain a description of the basis for the claim verified along with the description of the basis of certification. The description shall be in a location, style, and typeface that are easily readable; shall be on the same side of the product label as the Green Seal certification mark; and not detract from the Green Seal certification mark. Unless otherwise approved in writing by Green Seal, the description shall, as applicable, read as follows:

**No Added Fragrances:** This product meets the Green Seal™ environmental standard for soaps, cleansers, shampoos, and conditioners based on its low impact on aquatic life, minimized use of hazardous substances, and increased health protection. This product was also verified by Green Seal to contain no added fragrance ingredients.

**Made with Green Energy:** This product meets the Green Seal™ environmental standard for soaps, cleansers, shampoos, and conditioners based on its low impact on aquatic life, minimized use of harmful substances, and increased health protection. This product was also verified by Green Seal to have been manufactured with at least 75% renewable energy.

**Made with Zero Waste:** This product meets the Green Seal™ environmental standard for soaps, cleansers, shampoos, and conditioners based on its low impact on aquatic life, minimized use of harmful substances, and increased health protection. This product was also verified by Green Seal to have been manufactured in a process that produced no net water or solid waste.

**Made with Zero GHG Emissions:** This product meets the Green Seal™ environmental standard for soaps, cleansers, shampoos, and conditioners based on its low impact on aquatic life, minimized use of harmful substances, and increased health protection. This product was also verified by Green Seal to have been manufactured with no net greenhouse gas emissions.

**Biobased Product:** This product meets the Green Seal™ environmental standard for soaps, cleansers, shampoos, and conditioners based on its low impact on aquatic life, minimized use of harmful substances, and increased health protection. This product was also verified to contain at least 100% biobased components.

Comment:

It would be challenging for any product to contain 100% biobased content as determined by ASTM International Radioisotope Standard Method D6866. Alignment with the USDA BioPreferred requirements would provide consistent standards.

The word “hazardous” is used in “No Added Fragrance” claim instead of “harmful” which is used in all other claims

Comment:

Many of the optional claims being proposed are either currently under review (USDA is designating the biobased content of many product categories such as hand cleaners and sanitizers), or are considering guidelines for making such claims (the Federal Trade Commission is looking at carbon offsets). At this time, we recommend that Green Seal avoid using these claims until regulations and/or guidance are established by government.

**Response:**

Green Seal appreciates the input on the optional claims. These will not be included in the Draft Final Standard since will be available to all certified products/standards as a separate program. However, the biobased claim was included in the labeling requirements to provide a means for validation of such claims.

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## **General Comments**

### **Comments in general about the proposed standard.**

#### **Comment:**

At the outset, we believe that the guidelines for fragrances must be identical from one Green Seal standard to another. As currently being developed, the GS-37 standard for Industrial and Institutional Cleaners differs in many respects from the proposed GS-44 standard – a completely new standard being put forth by Green Seal. If all the criteria agreed to originally in the GS-37 standard are revised in the final GS-44 standard, there will be not only a great deal of confusion about compliance with the guidelines, but the GS-44 standard, as currently drafted, would likely result in numerous and unnecessary fragrance reformulations, particularly given the goal of Green Seal to eliminate the use of any of the so-called 26 EU allergens. We therefore strenuously object to the establishment of any guidelines related to fragrances which vary from one Green Seal standard to another. There should be uniformity throughout current and future protocols for fragrance formulations which are used in Green Seal products.

Based on the comments provided herein, we respectfully requests that Green Seal make revisions to the GS-44 standard to allow the continued use of fragrances in those products.

People have enjoyed fragrances for thousands of years. Fragrances contribute to our individuality, self-esteem and personal hygiene. Fragrances are an intrinsic part of all consumer products and play a vital role in the acceptance of the finished product. Fragrances also function in covering what is often the malodor of the other materials necessary to manufacture a product. Fragrances date as far back as the Egyptians who used aromatic plants to create massage oils, medicines, embalming preparations, skin care products, fragrant perfumes and cosmetics.

Under conditions of intended use and even under reasonably foreseeable misuse, fragrance ingredients are safe. In addition to a long history of safe use, a well-established program exists within the fragrance industry for objective evaluation of the safety of its materials and this is backed up by government requirements that establish expectations for safety substantiation of chemicals. Green Seal need not reinvent this wheel.

#### **Response:**

Green Seal delayed the release of the Draft Final standard to ensure it would be consistent with other standards that have signification overlap, such as GS-37.

The allergens are no longer prohibited, rather declared, and fragrances are permitted for products if they meet the other requirements in the standard.

**Comment:**

Independent certification such as Green Seal serves a critical role in ensuring products that meet strong, credible, and meaningful criteria to protect and reduce risks to occupants from harm. GS-44 is an important certification that will be used for environmentally preferable products by government agencies, businesses, schools, hospitals and other institutions. GS-44 is also of importance since it may be integrated into many “green” credit systems from organizations including the US Green Building Council, the Collaborative for High Performance Schools, and others.

In our view, while the current Proposed Revised Standard for GS-44 does include many important new provisions that help address some issues of concern, it does not contain all the criteria necessary to adequately minimize exposures to toxic chemicals. We have multiple serious concerns about the proposed revised standard. The following outline our key concerns. We would like to emphasize that we look forward to continuing to work with Green Seal Staff and other stakeholders in this process to finalize the criteria. We believe that there is more work to be done and we have tried to be as specific as possible to provide you with what areas need to be addressed

**Response:**

The areas of concern have been addressed throughout this document and the standard appropriately modified including: inhalation toxicity, asthmagens, and other toxic chemicals.

**Comment:**

We believe that ignoring exposure- and hazard-based risk assessment does not provide environmental or human safety benefit, and in fact, could harm innovation, hampering the design of products which would provide a safety benefit. The criteria in the standard are hazard-based only, and the limits or cut-off values are not justified by any meaningful scientific rationale. As such, we do not believe that products that comply with this standard would have any environmental benefits when compared to products that do not meet the standard, and, to the best of our knowledge, no data exist to show that the Green Seal standards have led to real and measurable environmental improvements. Further, this standard provides a much lower level of safety and environmental protection than exposure and risk-based safety assessment methodology widely used by the soap and detergent industry to assess safety of products on a routine basis. Exposure and risk-based assessment often considers many more endpoints, including sorption, wastewater treatment removal, overall exposure (total volumes emitted to the environment and concentration at target sites), long-term toxicity, bioaccumulation, etc. Background materials and examples of these assessments can be viewed at:

[http://cleaning101.com/files/Exposure\\_and\\_Risk\\_Screening\\_Methods\\_for\\_Consumer\\_Product\\_Ingredients.pdf](http://cleaning101.com/files/Exposure_and_Risk_Screening_Methods_for_Consumer_Product_Ingredients.pdf) <http://www.sdahq.org/AMINEOXIDES/>  
<http://www.heraproject.com/Index.cfm> <http://www.heraproject.com/RiskAssessment.cfm>

**Comment:**

We appreciate the opportunity to comment on the proposed standard Green Seal(TM) Environmental Standard for Soaps, Cleansers, and Shower Products (GS-44).

We believe that exposure- and hazard-based risk assessments are critical to protecting human health and the environment. Dismissing risk assessments is dangerous and does not provide a true picture of what is going on, either with the consumer or in the environment. Further, narrowly written, short-sighted standards are the death knell of innovation. Some of the criteria in the standard are hazard-based, while others are clearly not science-based at all. As such, we are concerned that products that comply with this standard will provide any tangible environmental or human safety benefits when compared to products that do not meet the standard. While being costly and difficult to interpret and implement, we have not seen any data demonstrating that any of the Green Seal standards have led to tangible, measurable environmental improvements.

It is disappointing that this standard provides a much lower level of safety and environmental protection than exposure and risk-based safety assessment methodologies used by us to routinely assess the safety of our products. Thorough risk assessments often consider many endpoints that have roots in sound, demonstrated, proven, reproducible science.

**Response:**

A conventional risk assessment approach is not sufficient for an environmental leadership standard – which attempts to promote the safest alternatives, not to set so-called safe limits for questionable chemicals – it also inappropriate for protecting vulnerable populations that are not considered in standard risk assessment methodologies. This remains an area of disagreement with those who prescribe to the risk assessment approach and with what Green Seal is trying to do with its leadership environmental standards. Green Seal's approach is to encourage products which do not pose unacceptable risks because their ingredients or design are non-toxic. By minimizing the use of more harmful ingredients or products, rather than determining at what levels they may be used safely or with an acceptable amount of risk, is a more protective approach. Such a protective approach is appropriate for products with the level of direct exposure that these products present, and especially since they are used by infants and children who are particularly susceptible to hazards (and not effectively protected through risk assessments methods). Green Seal notes that this same philosophical difference has been raised with every standard development project since the early 1990's. Since then, the world has moved significantly toward more sustainable products and services, based on the principles Green Seal has espoused: minimizing hazard through green product identification and selection; green chemistry; precautionary principle; pollution prevention; and corporate social responsibility.