



May 7, 2009

Green Seal has been developing an Environmental Standard for Soaps, Cleansers, and Shower Product, GS-44 since August 2007. The development of this standard is now complete. This standard includes health and environmental protection and comprehensive labeling and claim requirements. The result is that this standard will enable consumers to make more informed purchasing decisions and shift the marketplace to more responsible products. Certification applications to the standard will be accepted beginning May 7, 2009.

The last step to completing this standard was a final review by the stakeholders involved in the development of the standard. The stakeholders were invited to comment on the Draft Final Standard with modifications made since the last version they reviewed (Proposed Standard). These modifications were made as a result of the comments received on the Proposed Standard. This period was intended to serve as a final opportunity for stakeholders to review the modifications made in response to the stakeholder comments on the Proposed Standard before the standard was issued. Since this was not an official commenting period, a formal response to comments document will not be provided. All comments received were considered and may have resulted in slight modifications to the final standard. Below are the notes on the slight modifications made as a result of this final review period. This is also followed by the comments received from the stakeholders.

Note, that the project web site includes progress throughout the standard development process that led to this final version of the standard; scoping, proposed standard, response to comments, draft final standard, and issued standard.

Summary of Modifications to the Draft Final Standard

The Federal Trade Commission has not issued a perspective on natural or biobased claims. They may not do so in the near future. It is important that products that do get certified and carry the Green Seal mark (inherently a claim) also carry substantiated and meaningful claims for other attributes of the product (like natural). Since natural and biobased claims are commonly made on products in the scope of the standard, Green Seal needed to include guidance on what these mean. The definitions used in this standard are consistent with others available throughout the industry globally. However, there was concern expressed in the comments on the Draft Final Standard about allowing a “made-with” claim if it were to be permitted on products containing 70% or less natural or biobased material. This was removed and clarified by allowing claims on specific ingredients that are natural or biobased. Further, with the recent issuance of the American National Standard NSF-302, organic claims that meet that standard or the USDA National Organic Program requirements may be permitted.

There was expressed concern by comments on the Draft Final standard for nanoscale ingredients (also known as engineered nanomaterials) and their safety. These ingredients are currently not found in the products included in the scope of this standard, but are growing in use in other personal care products. The research on the safety of these materials is limited. According to NIOSH, “Studies have indicated that low solubility ultrafine particles are more toxic than larger particles on a mass for mass basis. There are strong indications that particle surface area and surface chemistry are primarily responsible for observed responses in cell cultures and animals. There are also indications that ultrafine particles can penetrate through the skin or translocate from the respiratory system to other organs. Research is continuing to understand how these unique modes of biological interaction may lead to specific health effects.” (<http://www.cdc.gov/niosh/topics/nanotech/ohrisks.html>) NIOSH recently issued interim guidance until the research is sufficient to provide more. As a result, Green Seal will take a similar approach and reserve a place for requirements on these materials in the future, with no specific requirements at this time.

Ethoxylated alcohols were prohibited due to their inherent contamination with 1,4-dioxane, a known carcinogen. In a recent survey conducted on soap products for children, it was found that 67% of products contained 1,4-dioxane (Campaign for Safe Cosmetics, 2009. No More Toxic Tub: <http://www.safecosmetics.org/article.php?id=414>). The comments received on the Draft Final standard pointed out that personal care products may contain ethoxylated chemicals beyond alcohols that have the same health issues, thus the prohibition was modified to include ethoxylated chemicals.

It was noted by comments on the Draft Final Standard that bioaccumulation could effectively be determined with modeling and structural analog data, similar to biodegradability. As a result, such data may be accepted for these requirements. This was added to the animal testing criterion where alternative methods were described.

As suggested by comments on the Draft Final Standard, the product definition used in this standard for shampoo was expanded to include combination products (those that shampoo and condition) and the conditioner definition was expanded to include rinse products, to align with the Personal Care Products Council’s terminology.

Comments received on the Draft Final Standard pointed out that the vapor pressure cut-off for determining acute and chronic inhalation toxicity was different. This was an unintentional error and has been corrected, to be 1 mm Hg. A typing error was noted in the Appendix, and this was fixed, listing acylation. The fragrance requirement had an incorrect reference to another requirement in the standard, this has been corrected. The definition for natural included a redundant term “renewable” that was removed.

A definition was added for “concentrate” to provide clarity on the packaging requirements referring to concentrates. A sourced-reduced packaged (one with 50% less weight) is now permitted to meet the post-consumer material requirement since flexible pouches with potentially significantly less environmental impact may not feasibly contain 25% post-consumer content.

Comments from Stakeholders on the Draft Final Standard

COMMENT:

The problem is the “made with” category, in that insofar as it allows the non-natural 30% to be petrochemical, synthetic silicone, etc. which makes up the main cleansing ingredients, than the label claim is problematic because it sounds like ALL ingredients in the product are natural when the most important are not. The made with claim category should be restricted to SPECIFIC ingredients which are natural in the product, eg. “Shampoo made with Natural Aloe Vera and Peppermint Oil”, which doesn’t imply the non-natural petrochemical surfactants are natural the same way “Shampoo made with Natural Ingredients” does. Really, there should be no “made with Natural” category in the first place.

COMMENT:

I agree with the above comment, section 6.4 is problematic, especially the “made with” and “biobased” claim.

COMMENT:

For section 4.1 and section 4.9 they list to different vapor pressures, one for Determining inhalation toxicity and the other for determining usability of an ingredients that is a known toxic when inhaled. This should be unified.

Section 4.16 Should remark, any preservatives that are known to exhibit intrinsic estrogenic effect in humans, or release potential carcinogens i.e. formaldehyde, are not allowed.

Appendix A should include Protein Acylation and neutralization

COMMENT:

Nano-scale ingredients are emerging in personal care products. Their safety is potentially an issue. Studies on and listings of nano-scale ingredients in personal care products:
<http://www.safecosmetics.org/article.php?id=307>
and <http://www.nanotechproject.org/inventories/consumer/>

No ethoxylated ingredients should be allowed due to their many health concerns, including 1,4-dioxane content. Report on ingredients likely to contain hazardous impurities (including ethoxylated ingredients likely to contain 1,4 dioxane):
<http://www.cosmeticsdatabase.com/research/impurities.php>

In terms of ingredients used in the product categories in the standard with evidence of neurotoxicity (or other categories of concern), the Skin Deep database advanced search function is a great resource. You have probably already captured these chemicals of concern in your standard, but it might be worth a quick cross check. Here’s one example:
Phenol:
http://www.cosmeticsdatabase.com/ingredient.php?ingred06=704805&refurl=%2Fsearch.res.php%3Fsearchtype%3Dingredients%26rs_cats2%255B%255D%3Dneuro%253E10%

[26submit%3DFIND%2BINGREDIENTS%26showmore%3Dingredients%26start%3D20%26order%3Dwebscore%2BDESC%26](#)

and 2-BROMO-2-NITROPROPANE-1,3-DIOL

http://www.cosmeticsdatabase.com/ingredient.php?ingred06=700019&refurl=%2Fsearchres.php%3Fsearchtype%3Dingredients%26rs_cats%255B%255D%3Dneuro%253E10%26submit%3DFIND%2BINGREDIENTS%26showmore%3Dingredients%26start%3D40%26order%3Dwebscore%2BDESC%26

COMMENT:

4.8 We encourage GreenSeal to adopt VOC standards which are inline with other Consumer Product Regulations for limiting VOC content. Specifically the standards set forth by CARB which include a 2.0% fragrance exemption that allows formulators to use fragrance which is necessary for the brand presence of their product.

4.14 We question the prohibition fo Ethoxylated Alcohols as there is no regulatory precedence for this action. Linear Alcohol Ethoxylates are an excellent alternate emulsifying agent for fragrances when needed.

We further object to the broad category of Phthalates as it encompasses Diethyl Phthalate, a common use item in the fragrance industry with a proven and validated safe use record.

6.5 We encourage GreenSeal to adopt a labeling requirement that is in accordance with other Consumer Product regulations. Specifically the EU Detergents and Cosmetic Directives that sets a deMinimus for the presence of Allergens with respect to labeling requirements. It is unnecessarily restrictive to require the labeling for the presence of ANY allergens.

COMMENT:

2.4 Asthma and 2.5 Asthmagens. The draft final standard definition for “asthmagens” remains the same -- establishing the Association of Occupational and Environmental Clinics (AOEC) as the authority for defining “asthmagens” and bases the criteria for asthmagens on the AOEC list. Once again, 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 ban any components in the undiluted product that have been identified as “asthmagens.” (4.6 Components that Cause Asthma)

Also, the definition in section 2.5 refers to “AOEC sensitization criteria”. Asthma is not a “sensitization” response but, as the definition of asthma in section 2.4 clearly states, “...is a chronic inflammatory disorder of the airways that impairs breathing.” Therefore, use of the term “sensitization criteria” is inappropriate and should be eliminated.

The AOEC list should not be used as a bright line criterion for identifying materials that should not be present in GS-44 endorsed products. We further question the need to include asthma as a criterion in the standard at all.

With respect to the definition of asthma, the American Thoracic Society, European Respiratory Society and the National Asthma Educator Certification Board have

approved the following definition which we recommend that Green Seal adopt as part of the GS-44 standard:

“Asthma is a chronic inflammatory disorder of the airways in which many cells and cellular elements play a role, in particular, mast cells, eosinophils, T lymphocytes, macrophages, neutrophils and epithelial cells. In susceptible individuals, this inflammation causes recurrent episodes of wheezing, breathlessness, chest tightness and coughing, particularly at night or in the early morning. These episodes are usually associated with widespread but variable airflow obstruction that is often reversible either spontaneously or with treatment. The inflammation also causes an associated increase in the existing bronchial hyper-responsiveness to a variety of stimuli (NHLBI 1995).

2.17 Ingredient. As noted in our comments of February 1, 2008, the 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).

2.20 Natural Components. Again, we disagree with the proposed Green Seal definition of natural which 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. Also, how is the term “renewable materials” defined?

4.2 Carcinogens, Mutagens and Reproductive Toxins. This section prohibits the presence of any carcinogens, mutagens and reproductive toxins in the (undiluted) product. We would appreciate knowing why the standard prohibits the presence of CMRs in the undiluted product. Since there is no allowable threshold for CMRs in the standard, such materials would be prohibited regardless of whether the product is neat or diluted.

4.4 Skin Sensitization. First and foremost, the use of the LLNA to test mixtures is not appropriate. In addition, 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.

4.6 Components that Cause Asthma. See our comments above regarding asthmagens (section 2.5).

4.8 Volatile Organic Compounds Content. Once again we strenuously object to the elimination of the existing fragrance exemptions under CARB 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. Otherwise, this requirement has the effect of essentially banning the use of fragrances in these products.

4.10 Toxicity to Aquatic Life Green Seal does not indicate in this section whether or not QSARs or data from analogues would be acceptable. Absent available toxicity data, on the basis of animal welfare issues, we support the use of appropriate validated models and read-across from structural analogues.

4.11 Bio-accumulating Compounds The criterion proposed by Green Seal is an order of magnitude lower than the classification of a bio-accumulating material under TSCA. We object to this arbitrary selection of criterion without scientific justification. Furthermore, we reiterate our position in 4.10 above regarding the use of QSARs or data from analogues.

4.12 Aquatic biodegradability. We agree with the use of models, as appropriate, but would again include the use of data from structural analogues as an appropriate methodology for acquiring data. We also object to the use of the “10-day window” in assuring acceptability of biodegradation from standard studies. This criterion is falling into disuse among the regulatory community and does not provide additional assurance of the biodegradability of a chemical. The addition of a chronic toxicity threshold (the same as the acute toxicity threshold) appears arbitrary and is not defined elsewhere in the criteria document.

4.14 Prohibited and Restricted Ingredients. We again object to the requirement 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. See comments from February 1, 2008.

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. See comments from February 1, 2008.

4.19 Animal Testing. This section requires the testing of all ingredients in the product, but indicates that “a mixture need not be tested if existing information demonstrates that each of the ingredients complies with a criterion.” The term “criterion” is not explained. Also, 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.

5.1.4 Other Restrictions. See the comments in section 4.14 above regarding phthalates.

COMMENT:

2.5 Asthmagens

We object to the use of the AOEC list of asthmagens as the basis for determining if a substance is capable of causing asthma in the products covered by this standard.

The approach used by Green Seal needs to be more scientifically valid and transparent. Green Seal's final revised definition of "asthmagen" appears arbitrary and capricious by reducing the almost 300 AOEC 'asthmagens' to diethanolamine and triethanolamine with insufficient clarity on the review process performed by AOEC. The AOEC review process is not sufficiently transparent to Green Seal stakeholders and raises questions about the quality of the AOEC list as it applies to the products covered in this standard. It is not evident to stakeholders how many materials have been reviewed by AOEC in this "systematic validation", which materials have yet to be reviewed, when they will be reviewed, and how the new findings be incorporated into Green Seal. More certainty needs to be provided to Green Seal stakeholders for the revised standard to meet the ISO 14020 requirement for methodology to be verifiable.

Additionally, the concerns we have raised about use of the AOEC list (a database not intended for this use) have not been adequately addressed.

As stated by AOEC itself, "...it is not desirable to use AOEC list as a basis for banning substances. As (explained) a number of times, the AOEC's list was designed to be used after the diagnosis of asthma was made or strongly suspected to help clinicians identify potential triggers for asthma. It was not designed to point to substances and say substance X causes asthma, since people then have a natural tendency to take that to mean that in all cases, substance X causes asthma. (Our) list doesn't include any PEL or TLV information or any other detail that would be needed to ban or even seriously limit use of a substance."

Further, AOEC's list of asthmagens was misapplied since the list is intended for the neat materials in a production environment, not aqueous mixtures in consumer products.

Therefore, the use of this list and its criteria are inappropriate for the standard. We recommend that Green Seal should recognize and adopt the criteria for the classification and labeling of respiratory sensitizers under the Global Harmonized System of Classification and Labeling of Chemicals (GHS, specifically Chapter 3.4.3). The criteria for classification of respiratory sensitizers have been adopted by the United Nations.

2.6 Biobased

The criterion should follow the guidelines set by the USDA BioPreferred Program.

2.8 Cleanser

We recommend that Green Seal consult the Personal Care Products Council (formally CTFA) for a more accurate definition of this product category.

2.11 Conditioner

We recommend that Green Seal consult the Personal Care Products Council (formally CTFA) for a more accurate definition of this product category.

2.20 Natural component

The inclusion of this definition propagates the incorrect notion that natural components are in some way safer than their synthetic counterparts.

2.21 Naturally-Derived Components

Non-toxic is not defined and too ambiguous for a definition.

2.34 Shampoo

We recommend that Green Seal consult the Personal Care Products Council (formally CTFA) for a more accurate definition of this product category.

2.35 Shower Products

We recommend that Green Seal consult the Personal Care Products Council (formally CTFA) for a more accurate definition of this product category.

4.1 Acute Toxicity

We believe that ignoring exposure- and hazard-based risk assessment does not provide 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 more human health 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 human health or safety improvements. Further, this standard provides a much lower level of safety and human health protection than exposure and risk-based safety assessment methodology widely used by the industry to assess safety of products on a routine basis. Human exposure assessments of chemicals consider many more products and exposure routes, collecting data from a number of sources including US EPA Exposure Factors Handbook, US EPA VERSAR Reports, European Union Technical Guidance Documents, OECD SIDS/SIAR Assessments, peer reviewed literature, 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

4.2 Carcinogens, Mutagens, and Reproductive Toxins

Substances known to produce or release carcinogens, mutagens, or reproductive toxins must be assessed case by case basis. Ethoxylated alcohols are not recognized as carcinogens by IARC, NTP, EPA, NTP etc and therefore should not be banned because of potential to contain 1,4-dioxane at extremely low levels. PEGS >MW400 (PEG-8) which are known to be contaminated with 1,4-dioxane have not been shown to be carcinogenic in animal studies (Polloth 2005).

4.2.1 Ethoxylated Alcohols

These ingredients do not have any health or environmental requirements stated, nor does this section contain scientific reasoning for inclusion under carcinogens, mutagens, and

reproductive toxins. Since stakeholders cannot evaluate the criterion for ethoxylated alcohols we object to their inclusion without stakeholder assessment.

4.2.2 Formaldehyde Donors

These ingredients do not have any health or environmental requirements stated. Since stakeholders cannot evaluate the criterion for formaldehyde donors we object to their inclusion without stakeholder assessment.

4.10 Toxicity to Aquatic Life

We continue to object Green Seal's disregard to the use of risk assessments. 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 these 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. 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 more 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 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

4.12 Aquatic Biodegradability

We also recommend that QSAR information from EPA's BioWIN (EpiSuite) models be considered appropriate to demonstrate ready biodegradability.

We do not support making exceptions for "natural" components as this undermines the purpose of this standard and perpetuates the misconception that "natural" products are safer for people and the environment. Ingredients should be evaluated based on their properties not by source.

4.14 Prohibited Components

We object to the inclusion of this section. The standards should be sufficiently robust to catch most ingredients that should be prohibited and it is not necessary to list them in the prohibited ingredients section also. Thus, most of the chemical should be removed from the prohibited chemicals section. In addition, banning whole chemical classes is

inappropriate and unnecessary as there may be member of any chemical class that should not be banned.

Ethoxylated alcohols should not be prohibited. They have acceptable aquatic toxicology and the alkyl group can be naturally derived. They are also no more irritating to skin or eyes than most surfactants. These substances should not be prohibited based on possible contamination with 1,4-dioxane. Substances known to produce or release carcinogens, mutagens, or reproductive toxins must be assessed case by case basis. Ethoxylated alcohols are not recognized as carcinogens by IARC, NTP, EPA, NTP etc and therefore should not be banned because of potential to contain 1,4-dioxane at extremely low levels.

In Green Seal's response to comments, they note a prohibited ingredient list is used when specific chemicals have a recognized hazard. Ethoxylated alcohols may contain trace amounts of 1,4-dioxane, however they have not exhibited the carcinogenic hazard of 1,4-dioxane at the low levels present. Ethoxylated alcohols have not shown positive results in carcinogen testing [HERA Project document cites 3 carcinogen studies (2 with C14-15AE7 and 1 with C12-13AE6.5); no carcinogenicity observed.]. PEGS >MW400 (PEG-8) which are known to be contaminated with 1,4-dioxane have not been shown to be carcinogenic in animal studies (Polloth 2005).

Additionally, 1,4-dioxane is listed on California Proposition 65 with a Safe Harbor No Significant Risk Level of 30 µg/day. Calculated exposures are below the Safe Harbor NSRLs for 1,4 dioxane for ethoxylated alcohols used as surfactants.

Many have argued that "heavy" in the term heavy metals is meaningless or at best nonspecific (see <http://old.iupac.org/publications/pac/2002/pdf/7405x0793.pdf>). Thus, the standard needs to be made more specific since readers may not be sure what "heavy metal" refers to; all metals including the alkali earth metals? The specific metals being banned should be listed (i.e., Hg, Pb, Cu, Cd).

Monoethanolamine, Diethanolamine, and Triethanolamine alone or n compounds should not be prohibited. Amine salts of anionic surfactants are milder to the skin and much more soluble than the sodium salts. These amines are also used in emulsions where other cations are ineffective. It is common formulator knowledge that when Monoethanolamine and Triethanolamine are formulated properly they will not cause nitrosamines. Direction for safe use should be provided such as, "All nitrogen containing compounds should be formulated so that nitrosamines will not occur". 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. The supposed DEA cancer study has been proven to be scientifically unsound and California agreed that DEA did not belong on their Prop 65 list. There is no scientific rationale for not allowing these ingredients.

All parabens should not be prohibited. Methyl and ethylparaben have been shown to be safe according to CIR review and the European SCCP review.

Prohibiting all phthalates is inappropriate, especially diethyl phthalate. Green Seal comments suggest DEP has shown ER binding, but ER binding is not part of the

standard. Further, ER binding has to be carefully considered as there are studies showing no ER binding by DEP.

4.17 Color Components

These ingredients do not have any health or environmental requirements stated. Since stakeholders cannot evaluate the criterion for color components we object to their inclusion without stakeholder assessment.

6.4 Natural and Biobased Claims

We object to Green Seal setting standards for these terms prior to a statement by the Federal Trade Commission who has spent the last year evaluating these terms. Biobased criterion should follow the guidelines set by the USDA BioPreferred Program. Made with/from Natural Ingredients – What could the other 5-30% be? If “natural” or “biobased” components themselves cannot be chemically altered with synthetic or petroleum based chemicals, silicones, etc, there can only be “natural” or “biobased” ingredients available for this claim.

6.11 Statement of Basis for Certification

We do not support the claim of, “... increased health protection” without scientific basis. Please provide.

COMMENT:

2.5 Asthmagens

We object to the use of the AOEC list of asthmagens as the basis for determining if a substance is capable of causing asthma in the products covered by this standard. The approach used by Green Seal needs to be more scientifically valid and transparent. Green Seal’s final revised definition of “asthmagen” appears arbitrary and capricious by reducing the almost 300 AOEC ‘asthmagens’ to diethanolamine and triethanolamine with insufficient clarity on the review process performed by AOEC. The AOEC review process is not sufficiently transparent to Green Seal stakeholders and raises questions about the quality of the AOEC list as it applies to the products covered in this standard. It is not evident to stakeholders how many materials have been reviewed by AOEC in this “systematic validation”, which materials have yet to be reviewed, when they will be reviewed, and how the new findings be incorporated into Green Seal. More certainty needs to be provided to Green Seal stakeholders for the revised standard to meet the ISO 14020 requirement for methodology to be verifiable.

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2.6 Biobased

The criterion should follow the guidelines set by the USDA BioPreferred Program.

2.8 Cleanser

Needed: PCPC input on definition

2.9 Conditioner

Needed: PCPC input on definition

2.10 Natural component

The inclusion of this definition propagates the incorrect notion that natural components are in some way safer than their synthetic counterparts.

2.11 Naturally-Derived Components

Non-toxic is not defined and too ambiguous for a definition.

2.12 Shampoo

Needed: PCPC input on definition

2.13 Shower Products

Needed: PCPC input on definition

1.1 Acute Toxicity

We continue to object Green Seal's disregard to the use of risk assessments. 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 these 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.

In order to prove that the undiluted product is not toxic to humans (i.e., below the value that is listed in GS-44), one needs to have either favorably conducted these actual tests

using undiluted product or have LD50/LC50 information on all ingredients in the product that are greater than 0.01%.

1.2 Carcinogens, Mutagens, and Reproductive Toxins

1.2.1 Ethoxylated Alcohols

These ingredients do not have any health or environmental requirements stated, nor does this section contain scientific reasoning for inclusion under carcinogens, mutagens, and reproductive toxins. Since stakeholders cannot evaluate the criterion for ethoxylated alcohols we object to their inclusion without stakeholder assessment.

1.2.2 Formaldehyde Donors

These ingredients do not have any health or environmental requirements stated. Since stakeholders cannot evaluate the criterion for formaldehyde donors we object to their inclusion without stakeholder assessment.

1.3 Skin and Eye Irritation

There may be instances where a product has a pH outside of ≤ 2 or ≥ 11.5 and the undiluted product is not skin corrosive or a severe eye irritant.

1.4 Aquatic Biodegradability

Making exceptions for “natural” components undermines the purpose of this standard and perpetuates the misconception that “natural” products are safer for people and the environment. Ingredients should be evaluated based on their properties not by source.

1.5 Prohibited Components

Butylated hydroxytoluene: BHT was reviewed by the PCPC CIR Expert Panel (IJT, 21 (Suppl. 2) 2002) and they concluded that it is safe for use in cosmetics up to 0.5%.

Ethoxylated alcohols should not be prohibited. They have acceptable acceptable aquatic toxicology and the alkyl group can be naturally derived. They are also no more irritating to skin or eyes than most surfactants. These substances should not be prohibited based on possible contamination with 1,4-dioxane.

Monoethanolamine, Diethanolamine, and Triethanolamine alone or in compounds should not be prohibited. Amine salts of anionic surfactants are milder to the skin and much more soluble than the sodium salts. These amines are also used in emulsions where other cations are ineffective. It is common formulator knowledge that when Monoethanolamine and Triethanolamine are formulated properly they will not cause nitrosamines. Direction for safe use should be provided such as, “All nitrogen containing compounds should be formulated so that nitrosamines will not occur”. 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. The supposed DEA cancer study has been proven to be scientifically unsound and California agreed that DEA did not belong on their Prop 65 list. There is no scientific rationale for not allowing these ingredients.

All parabens should not be prohibited. Methyl and ethylparaben have been shown to be safe according to CIR review and the European SCCP review.

Polycyclic musks: The polycyclic musks, AHTN and HHCB can be regarded safe for use as fragrance ingredients under the current conditions of use based on the safety assessment by the European Authorities (2008).

1.6 Color Components

These ingredients do not have any health or environmental requirements stated. Since stakeholders cannot evaluate the criterion for color components we object to their inclusion without stakeholder assessment.

1.7 Natural and Biobased Claims

We object to Green Seal setting standards for these terms prior to a statement by the Federal Trade Commission who has spent the last year evaluating these terms. Biobased criterion should follow the guidelines set by the USDA BioPreferred Program. Made with/from Natural Ingredients – What could the other 5-30% be? If “natural” or “biobased” components themselves cannot be chemically altered with synthetic or petroleum based chemicals, silicones, etc, there can only be “natural” or “biobased” ingredients available for this claim.

1.8 Statement of Basis for Certification

We do not support the claim of, “... increased health protection” without scientific basis. Please provide.