



August 28, 2009

Green Seal completed a revision to the Environmental Standard for Institutional and Industrial Cleaners, GS-37, in August 2008. Since then a number of companies have submitted new products and previously certified products (which may have been reformulated) for certification. During this process, a technical issue has arisen that was not apparent during the revision process and to the hundreds of stakeholders and experts involved. The technical issue relates to criterion 4.17 Color Components. Some FD&C colors are not stable in concentrated cleaning products due to unfavorable ingredient interactions or in products that are more alkaline or acidic. This document outlines the proposed revision to address this technical issue.

Included in this document are the comments received on the Proposed Revised Criterion with responses and explanation on how the Proposed Revision 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.

Brulin and Company
Chromatech Incorporated
City of Santa Monica California
Consumer Specialty Products Association
Ecolab, Inc.
EcoLogo
Essential Industries
Milliken
Nyco Products Co.
Soap and Detergent Association
Sunshine Makers, Inc.

Project documents are available on the web site, including the background information on the Proposed Revised Criterion: http://www.greenseal.org/certification/GS-37_Industrial_and_Institutional_Cleaners_Colorant_Revision.cfm

Current criterion:

4.17 Color Components. Any color component shall be FDA certified and permitted for food, drug, and cosmetic (FD&C) use or be a natural color component.

The proposed revised criterion:

4.17 Color Components. Any color component shall be FDA certified and permitted for food, drug, and cosmetic (FD&C) use, be a natural color component, or not have heavy metal components.

Comment:

We strongly opposes the proposed revision to GS-37 4.17 for colorants. Such a revision would be a significant detriment to Green Seal, our industry, and our company's green initiative.

During the development of GS-37, 2008 revision, we voiced our concerns, as did other concerned members, about using FD&C dyes. Green Seal took all the member recommendations into consideration and set the best new GS-37 standard possible to further the mission of Green Seal and our industry as a whole. Since the new GS-37 (2008) was released, we have demonstrated great support to the new GS-37 standards by 1) taking on the enormous amount of challenges imposed by the FD&C dye requirement; and 2) becoming the first national brand company to complete all the product conversions. During the conversion, we encountered all the limitations of FD&C dye mentioned in your proposal: instability, staining and limited choices. However, instead of going back to GS and complaining, we chose to invest significant amount of time, cost and labor to produce a quality product for the good of supporting the GS-37 standard. In order to comply with new GS-37 and, at the same time maintain our product safety/communication by color program, we have had to modify or change our product colors. In some cases it was a modification of intensity or shade, but with one product we actually had to change the product color. This change created a series of manufacturing, sales, training and cost issues including:

- Dilution Control Dispenser Label Changes - Manufacturing needed to insert in every case Color Product ID stickers for dilution control dispensers as they are changed of course, users then needed to change the stickers on their dispenser.
- Secondary Label Changes - Manufacturing needed to also insert in every case 3 secondary labels for spray bottles. Of course users needed to relabel all spray bottles.
- Shipping Carton Changes - we needed to prominently indicate on the shipping carton label the new color as end user and distributor inventories could include both colors for the same product. Distributors needed to manage inventory to ensure the all end users had switched to the new color.
- Wall Chart Changes -Wall charts needed to be reprinted, laminated and shipped to the end user and then installed on walls.
- Sales Literature Changes – All sales literature needed to be reprinted

In addition, we went to great pains to convince our customers that the change in color was not any indication of reduced product performance. Not an easy task!

Under the new proposed revision to 4.17 for colorants, we would not have had to make any changes to our product colors. That means that the considerable cost, time, efforts and customer confusion that went into reconciling the product color change could have all been avoided. However, at this point, as a practical matter, we cannot revert to the prior color as this again would sadly create an almost humorous communication issue.

In summary, we, along with other companies listed on the GS website, have met the previously debated, but industry agreed upon, FD&C requirement at considerable R&D and operational complexity. We are very proud of our prompt responses and ongoing support of the GS-37 (2008) standard. We feel that the proposed change to 4.17 for colorant is unfair to those of us who have already bitten the bullet for these changes. It'll also put us in competitive disadvantage. It would greatly devalue our support to GS-37 as demonstrated by our quick response in the product conversion. We also believe that this type of change midstream to the well thought out original revision weakens the position of Green Seal as a whole as a leader in our industry.

Response:

Green Seal appreciates your support and leadership in the marketplace. Your quick response to revisions to the standard completed in 2008 is impressive and commendable. Green Seal knows of manufacturers which have made similar efforts to reformulate their products to make the FD&C colors work in their products. Some of these efforts have involved a simple replacement of colors. Some efforts have resulted in use of additional chemicals in the product to permit the use of the FD&C colors. Other efforts have not been successful. Further, and notably, we have learned that safer color options cannot be used in products due to the restriction to FD&C or natural colors. This was not the intention of the requirement.

Having this understanding, Green Seal believes it is necessary to make the proposed revision in order to maintain the level of protection and feasibility of the standard. The response to the proposed revision, noted in the comments below, was overwhelming support for a change from just allowing FD&C colorants and natural colors. As a result, Green Seal will be moving forward with a revision to the criterion.

The proposed revision, and modified version noted below, does not compromise the level of protection in the standard. For example, there is a food-grade color that is a carcinogen. The requirements in GS-37 do not permit the use of carcinogens, thus this color would not be permitted. However, food grade approval (by the FDA) for colors includes repeated oral feeding and limits on heavy metals for color components that GS-37 may not include. The repeated oral feeding concerns are not relevant to GS-37 products, but the heavy metals

are. As a result, the revision fills this potential gap by imposing further limits on heavy metals for colors.

Comment:

I agree that the concerns with non-FD&C colorants, except for heavy metals content, are well-covered by other sections of the standard. I would endorse this revision.

Comment:

We have been diligently looking into the FD&C colorant for our current GS-37 registered products but have found it impossible to find FD&C dyes that would remain stable. However we have found D&C dyes or a mixture of FD&C and D&C dyes are generally stable and provide a good color match to our products. We believe that D&C dyes are more than adequate for the Green Seal Standard, they are still FDA approved and better for the environment than many other dyes that were previously used to meet the standard.

The consideration of this revision is important for keeping products marketable in today market place.

Comment:

I personally support the revision. Some outcomes are difficult to predict and I think the change allows a more reasonable and still safe means to introduce colorants to cleaning products.

Comment:

The EcoLogo program has recently launched the revisions of the EcoLogo Hard Surface Cleaners standard (CCD-146). It was Green Seal's efforts (supported by EcoLogo) to increase the harmonization between North America's two leading environmental standards that led to Green Seal's inclusion of the food grade dye requirements in the revised GS-37. It is a requirement that has been part of the EcoLogo standard (CCD-146) for some time without significant opposition.

The EcoLogo program has learned that some EcoLogo certified products did successfully change product formulations (and possibly color choices) in order to meet the EcoLogo standard, specifically the food grade dye requirement. It appears that some Green Seal clients and prospective clients are now facing similar needs.

Continuing efforts at harmonization, EcoLogo is announcing its intention to respect the outcome of Green Seal's stakeholder process to clarify the dye issue. It is EcoLogo's intention to make sure both the EcoLogo and Green Seal standards remain consistent on this issue.

Comment:

The Introduction, Safety Considerations, Feasibility Issues sections are well written, factual statements supported by sources that make the issues relevant and easy for stakeholders to understand.

However, the proposed language, 4.17 is confusing. Is it a reality that any technology is suitable if it doesn't contain heavy metals that have been deliberately added? If so, then the statement could read: Any color component shall be permitted for use if it does not contain heavy metal components that have been deliberately added.

If you feel strongly that the FD&C dyes need mentioning, I would like to offer the following statement for potential clarity. Any color component shall be permitted for use if it meets one of the following criteria: FDA certified and permitted for food, drug, and cosmetic (FD&C) use, or be a natural color component, or not have heavy metal components.

Going forward, formulators will only see the 4.17 language in the standard. They won't see the background information. My fear is that formulators will read the requirement in advance and since they likely won't have clarity on the heavy metal issue, then they will assume the safest route to take will be FD&C colorants. Would it be possible to clarify in the language of 4.17 that commonly used colorants meet the definition of "no heavy metal components"? Any color component shall be permitted for use if it does not have heavy metal components that have been deliberately added: FDA colorants certified and permitted for food, drug, and cosmetic (FD&C) use, a natural color component, and polymeric colorants currently meet this requirement.

Some colorants are of a class known as copper phthalocyanine. These are generally blue and green structures which provide necessary light and thermal stability needed for cleaning products. Since the copper is bound to the molecule, it is not "free" and should be allowed for use under the standard. Without these molecules, it is not possible to achieve an alkaline stable or light stable cyan shade blue.

FD&C colorants have heavy metal specifications as set by the FDA. These specifications were put in place because some of these colorants can be made use heavy metals as catalysts during the manufacturing process.

Also, most analytical measurements for detecting the presence of heavy metals don't have the sensitivity necessary to measure an absolute value of zero. In some cases, a report of less than a specified number indicates that the analytical method did not detect the presence of that metal at levels about its sensitivity point.

Comment:

I agree with the revision as it allows stable color options without harming the environment. I would like to add that the definition of "no heavy metals" should be defined precisely. For example, a typical certificate of analysis of a FD&C dye can list 8 ppm of Lead & 7 ppm of Mercury. FD&C C of A's with less than 40 ppm total heavy metal content have also been published. Therefore, the term "no heavy metals" should have established oom limits comparable to current FD&C limits.

Comment:

While I appreciate the comments made in this post I do not support the original wording of GS-37 section 4.17, nor do I support the proposed changes.

I do agree that the suggested change given in the post to have the section read "Any color component shall be permitted for use if it meets one of the following criteria: FDA certified and permitted for food, drug, and cosmetic (FD&C) use, or be a natural color component, or not have heavy metal components." is a more clear representation of the standard's intentions (or what I think they are), I think an additional change would be better suited for the industry and the standard.

Can the standard specify FD&C or D&C dyes rather than just FD&C dyes? D&C dyes are FDA approved for use in drugs and cosmetics, both things being placed on or in peoples bodies. These dyes also have a greater pH stability range. Do cleaning products have to use ingredients that are OK to eat? Nothing else in our products are considered safe to eat nor would anyone ever recommend doing so. The dyes are present in very low concentrations and have tangible safety effects. If we avoid the use of intentional free heavy metals isn't the intention met and isn't there an improvement to the standard?

Comment:

The sentence seems to propose three separate and alternative conditions for a color component; the substitution of semicolons for commas clarifies that intent. Secondly, the interpretation of components that conceivably could be excluded by "heavy metal components" is ambiguous. To ensure that the provision targets the intended components, we urge the following changes:

4.17 Color Components. Any color component shall be FDA certified and permitted for food, drug, and cosmetic (FD&C) use; be a natural color component; or not have any intentionally-added heavy metal components.

Comment:

As this criterion is part of an environmental standard, it would be appropriate that the same level of environmental safety be applied to all color components. As such, we support the adequate aquatic testing of all color components. We therefore recommend the criterion state, "Any color component must meet all relevant ingredient criteria of this standard". This would also cover heavy metals and therefore would not need further mention in this section. Our comments reflect our continuing efforts to protect human and environmental health and safety.

Comment:

Regarding the new proposed language for GS-37 4.17,

4.17 Color Components. Any color component shall be FDA certified and permitted for food, drug, and cosmetic (FD&C) use, be a natural color component, or not have heavy metal components.

Green Seal should address the following questions on how the proposed language will be

applied.

The "proposed revision" document seems to indicate that colorants will be treated like any other ingredient:

"...the requirements in GS-37 can be used to ensure use of appropriate color components."

The Document later states that the primary difference between standard and FD&C dyes is the restriction of "heavy metals" in the dye:

"Colorants shall not contain the heavy metals lead or arsenic and in some cases chromium, manganese, and mercury.³ There is a heavy metal limitation in GS-37, but it may not address all colorants since this specific requirement applies only to "ingredients," those components at or above 0.01% in the product. "

Are the underlined metals above the group to be considered "Heavy metals" by criterion 4.17? Many dyes are salts of other metals that are not generally considered "heavy metals", such as sodium, iron, or copper; such dye ingredients would generally not impact the formula's ability to meet the GS-37 criteria, and should not be restricted if a specific environmental concern has not been identified.

Previous comments have stressed enhanced clarity around the precise wording of this criterion to indicate a choice between FD&C, natural, or dyes without heavy metals, which we would support.

Additionally, the current wording and background suggests colorants be considered "Ingredients" when evaluated against the standard GS-37 criteria that normally are applied to "ingredients" (i.e. toxicity, biodegradation, etc), aside from the heavy-metal language in 4.17. This should be made explicit as there is confusion by labeling colorants "components"; clearly the intent is to avoid finite heavy metal content < 100 ppm, but the intent does not appear to evaluate all GS-37 endpoints of colorants at < 100 ppm.

In light of these questions, we support broadening the color component language to be more inclusive, though the intent of the standard must be clearer in terms of heavy metal identification and thresholds, and their treatment with regard to remaining GS-37 criteria (i.e., do they become "ingredients" for toxicity & biodegradation, assuming the colorant meets the heavy metal requirement as a "component").

Response:

During the GS-37 revision process completed in 2008, stakeholders expressed interest in addressing potential safety concerns with colorants and harmonizing with the EcoLogo CCD-146 standard (that requires “food-grade” colorants). The result was:

4.17 Color Components. Any color component shall be FDA certified and permitted for food, drug, and cosmetic (FD&C) use or be a natural color component.

In the US, “food-grade” colorants are those permitted for use in food by the FDA and include natural or certified synthetic colors (aka FD&C). FD&C colors have undergone toxicological testing over the years of their use. These human health considerations are addressed in GS-37, such as with the criterion 4.3 Carcinogens, Mutagens, and Reproductive Toxins. FD&C certification applies to the production batch of the color produced and includes verification that heavy metals that may have been used to produce the colors do not exceed defined limits, along with other quality controls like purity and moisture content. FD&C colors, however, have not undergone a similar level of ecotoxicity or environmental fate testing (e.g. aquatic toxicity) since they are not part of the regulation. As a result, FD&C colors are not necessarily the safest options available for cleaning product colorants. There are non-FD&C colorant options that may be safer (based on human and ecological toxicity).

Rather than relying on the toxicity testing needed for FD&C approval for colors, the requirements in GS-37 can be used to ensure use of appropriate color components. Toxicity concerns already included in the GS-37 standard do not need to be itemized in the colorant criterion, such as carcinogenicity, mutagenicity, reproductive toxicity, and acute toxicity. Further, colorants shall continue to be evaluated according to all other existing requirements in the standard that apply such as being included in the VOC content, aquatic toxicity, and eutrophication evaluations. Each criterion defines which components or ingredients are evaluated. The revised criterion will not provide a clarification that color component must meet all relevant criteria of this standard that apply. This is inherent in the standard.

The toxicity screens the FD&C colors potentially provide beyond GS-37 existing requirements include repeated oral dose testing, which is not warranted for this standard, and a restriction on heavy metals, which can be added in the requirement for color components. Therefore, an added heavy metal restriction could serve as an equivalent screen to FD&C colorants, so both options, along with the natural color components, could be accepted. Heavy metals: sodium, iron, and copper are not included in the class of prohibited heavy metals. The heavy metals of concern will be explicitly listed to reduce uncertainty about which metals are prohibited. The heavy metals included in the list are those with limits with the FDA, carcinogens, mutagens, developmental toxins, and hazardous

air pollutants (arsenic, cadmium, cobalt, hexavalent chromium, lead, manganese, mercury, nickel, selenium). These metals are prohibited for use in the production of colors (so that they are not present). The idea of ensuring that intentional addition of heavy metals will be clarified in the revised criterion by using these words, and thus limits are not necessary. The manufacturer of the colors shall demonstrate that it meets the requirement. Green Seal works with suppliers of other product components for verification of other requirements in the standard. This is done through a confidentiality agreement, thus providing such evidence should not be an issue.

The FDA also has oversight over D&C colors (those allowed for use in drugs and cosmetics). However, since not all drug and cosmetic uses are internal or ingested, not all D&C colors have had the same level of toxicity testing as FD&C colors. As a result, a clarification will be made in the standard that colors approved for ingestion uses are permitted. If a D&C color is not approved for ingestion, it would need to meet the heavy metal option that is being added, or it cannot be used.

The revised criterion states that colors are considered for all the other requirements in the standard and can be either of the following: FD&C; or natural colors; or any other color that meets the heavy metal limits. For the “any other color” option, specific options like polymeric colors will not be itemized, since such an itemization would not be comprehensive and appear to restrict options. Rather, the general reference will continue to be used.

FINAL REVISED CRITERION

4.17 Color Components. Each color component shall meet one of the following:

- be FDA certified and permitted for ingestion
- be a natural color
- not have any of the following heavy metals intentionally added during its production: Arsenic, Cadmium, Cobalt, Hexavalent Chromium, Lead, Manganese, Mercury, Nickel, and Selenium.