



July 24, 2009

**PROPOSED CRITERION REVISION: Green Seal Environmental Standard for Industrial and Institutional Cleaners, GS-37: 4.17 Color Components**

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.

Introduction:

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 U.S. “food-grade” colorants are those permitted for use in food by the FDA and includes natural or certified synthetic colors (aka FD&C). The FD&C colors do not necessarily include the safest synthetic coloring options from a human health or environmental perspective. The FD&C colors include the synthetic options that were being used when the regulation was enacted, over 45 years ago. Since then, only one new color was added, in 1971 (Red #40). The lack of new FD&C colors is not due to safety concerns, but primarily because the demand for FD&C options hasn’t warranted the cost and process of FD&C certification.<sup>1</sup>

FD&C colorants are typically ionic, have stability limitations, and are staining.<sup>12</sup> Most natural color options are unstable.<sup>1</sup> As a result, other colorant options have traditionally been used in cleaning products and are usually variations of the FD&C colors. For example, some colorants for cleaning products are based on chemicals that are the same or analogous to FD&C colors. Such chemicals can be reacted with non-toxic polymers to result in highly water soluble liquids that are less aquatically toxic than the FD&C base and are generally non-ionic and non-staining.

Safety Considerations:

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 are not included, 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).

<sup>1</sup> Ghorpade, VM, SS Deshpande, and DK Salunkhe. Food Colors in Food Additive Toxicology Ed by JA Maga and AT Tu. Marcel Dekker. New York, NY. 1994.

<sup>2</sup> JE Noonan and H. Meggos. Synthetic Food Colors in CRC Handbook of Food Additives 2<sup>nd</sup> Edition Volume II Ed by TE Furia. CRC Press. 1980.

Toxicity Requirements of FD&C colors, compared to GS-37:

1. Colorants shall not be carcinogens, mutagens, or reproductive toxins, or release such toxins. *This is already included in GS-37, criterion 4.3, regardless of concentration in the product.*
2. Colorants shall not be acutely toxic (e.g. LD<sub>50</sub>). *Colorants are already included in the product review for acute toxicity, criterion 4.1.*
3. Sub-chronic and chronic feeding studies shall have no adverse effects. *This is not included in GS-37 since cleaning products are not intended for consumption nor consumed over time.*

Additional concern for colorants addressed in the FD&C batch certification process, compared to GS-37:

4. Colorants shall not contain the heavy metals lead or arsenic and in some cases chromium, manganese, and mercury.<sup>3</sup> *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.*

#### Feasibility Issues:

Colorants are used in cleaning products as a safety mechanism, using color as a means of communication. The communication has also been linked with training of cleaning staff; specifically colored products are used for specific cleaning applications, further ensuring appropriate and safer use of these products.

However, it has been found, over the course of reformulating products since the issuance of the revised standard in August 2008, that some FD&C colors (e.g., Blue #1, Blue #2, Red #40, Yellow #5) are not stable in concentrated cleaning products due to unfavorable ingredient interactions or in products that are more alkaline (pH greater than 8) or acidic (pH around 2).

#### Proposed Revision:

To retain the safety/communications controls colorants provide in some cleaning products and also allow for non-FD&C colorants that are as safe as or safer than FD&C colors, Green Seal is proposing an isolated revision to criterion 4.17 due to the unforeseen feasibility issues of the existing criterion and potential limit the criterion unintentionally created (i.e., limiting use of safer colorants). In addition, the CCD-146 standard is undergoing revision and EcoLogo is investigating the same colorant feasibility issues, as well as many other issues, so the CCD-146 requirements may potentially also change depending on the outcome of the stakeholder consultation process.

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 (see items 1 and 2 above). 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. As a result, the only remaining toxicity screens the FD&C colors provide are repeated oral dose testing (see item 3 above), which is not warranted for this standard, and the restriction on heavy metals (see item 4 above), which can be added in the requirement for color components. Therefore, the 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.

The proposed revised criterion is as follows:

***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.***

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<sup>3</sup> 21 CFR 74:101-74.706