

Michael McGuffin

From: Lambert, Lark A [Lark.Lambert@fda.hhs.gov]
Sent: Friday, August 21, 2009 4:45 AM
To: Michael McGuffin
Subject: RE: Soap

Dear Mr. McGuffin:

Since, under 21 CFR 701.3, all ingredients must be listed in descending order of predominance for a cosmetic (except flavor or fragrance which can be listed as flavor or fragrance), soap ingredients must be listed per the examples given previously. The sentence Additionally, any other added ingredients must be listed such as antioxidants, chelating agents, or pH adjusters could also be expanded to include the other ingredients to which the "soap" was added. Neither of the terms "soap" nor "saponified oil" are included in the INCI dictionary.

Sincerely,

Mr. Lark A. Lambert
FDA, HFS-125, CPK-2
Office of Cosmetics and Colors
5100 Paint Branch Parkway
College Park, MD 20740-3835
Phone: 301-436-1143
Fax: 301-436-2975
Lark.Lambert@fda.hhs.gov

From: Michael McGuffin [mailto:MMcguffin@ahpa.org]
Sent: Thursday, August 20, 2009 1:31 PM
To: Lambert, Lark A
Subject: RE: Soap

Hello again,
I am in need of additional clarification when soap becomes an ingredient in another cosmetic product.

If soap is included as an ingredient in another cosmetic, is the common or usual name of that ingredient "soap" or would a labeler be able to identify the ingredient as "saponified oil"? And in listing the soap ingredient in that cosmetic's ingredients list, would parenthetical information as to its starting materials or reaction products be either required or allowed?

Thanks again for your time and attention.

Sincerely,
Michael McGuffin
President, American Herbal Products Association
8630 Fenton Street, #918
Silver Spring, MD 20910
mmcguffin@ahpa.org
Phone in MD: 301-588-1171 x201

Phone in CA: 310-745-8401

From: Lambert, Lark A [mailto:Lark.Lambert@fda.hhs.gov]

Sent: Thursday, August 20, 2009 9:23 AM

To: Michael McGuffin

Subject: Soap

Dear Mr. McGuffin:

The following information is provided to answer your questions about soap.

A regulation concerning "soap" in the Code of Federal Regulations (CFR) states:

21 CFR § 701.20 Detergent substances, other than soap, intended for use in cleansing the body.

(a) In its definition of the term *cosmetic*, the Federal Food, Drug, and Cosmetic Act specifically excludes soap. The term *soap* is nowhere defined in the act. In administering the act, the Food and Drug Administration interprets the term "soap" to apply only to articles that meet the following conditions:

(1) The bulk of the nonvolatile matter in the product consists of an alkali salt of fatty acids and the detergent properties of the article are due to the alkali-fatty acid compounds; and

(2) The product is labeled, sold, and represented only as soap.

(b) Products intended for cleansing the human body and which are not "soap" as set out in paragraph (a) of this section are "cosmetics," and accordingly they are subject to the requirements of the act and the regulations thereunder. For example, such a product in bar form is subject to the requirement, among others, that it shall bear a label containing an accurate statement of the weight of the bar in avoirdupois pounds and ounces, this statement to be prominently and conspicuously displayed so as to be likely to be read under the customary conditions of purchase and use.

Soap products meeting **both of the above conditions** would fall under the jurisdiction of the U.S. Consumer Product Safety Commission (CPSC), and need not comply with FDA regulations. Soaps making cosmetic claims (e.g., beautifying, moisturizing) which include products such as deodorant soaps, bath soaps, hand and toilet soaps, and detergent bars are regulated as cosmetics (and must follow the cosmetic labeling requirements). Medicated and antimicrobial soaps are regulated as drugs. Soap products that are both cosmetics and drugs (those making both cosmetic and drug claims e.g., moisturizing and antibacterial claims) must meet the requirements of both cosmetics and drugs (including labeling).

In regards to the declaration of cosmetic soap ingredients in cases where ingredients react with one another upon mixing in a formulation, an ingredient formed *In situ* may be declared either by its "starting materials" or by the "reaction products."

A simple example involving a cosmetic soap would be one made from two oils (olive and coconut) and saponified by sodium hydroxide. When a soap is superfatted (some the oils or fats remain unsaponified) through a reduction of added lye to the soap batch (lye discount) resulting in residual free fatty acid content, the ingredients can be declared as ("starting materials" ingredient declaration) "water, olive oil, coconut oil, sodium hydroxide." An example of a superfatted soap "reaction products" ingredient declaration might be "sodium olivate, sodium cocoate, olive oil, coconut oil, water, glycerin."

A soap can also be superfatted by the addition of oils at trace (in the soap making process, the point at which the lye has been mostly neutralized allowing added oils to remain basically unchanged). These added oils must also be listed as ingredients.

Additionally, any other added ingredients must be listed such as antioxidants, chelating agents, or pH adjusters. Added fragrances may be listed as "fragrance," but if the manufacturer wishes, ingredients such as essential oils may be listed individually e.g., sweet almond oil, rosewood oil, etc.

We hope this information answers your questions. If you need further clarification please contact us.

Sincerely,

Mr. Lark A. Lambert

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From: Michael McGuffin [mailto:MMcguffin@ahpa.org]
Sent: Wednesday, August 19, 2009 8:30 PM
To: Lambert, Lark A
Subject: FDA article (1995) on soap

Hello again Lark,
I stumbled across this page this evening: <http://www.foodsafety.gov/~dms/cos-215.html>.
It says that true soaps "are regulated by the Consumer Product Safety Commission, not FDA, and do not require ingredient labeling."

Either I misunderstood you Monday or this contradicts part of what I recall you saying. I thought you said that all soaps (cosmetic soaps and non-cosmetic soaps) must comply with FPLA, and that FPLA requires (even for soaps exempt from the FFDCa definition of "cosmetic") at 1454 (c)(3) label identification of all ingredients.

I will appreciate your clarification of this detail. Also, my comments to USDA on the organic soap issue is due next Monday. I will therefore also appreciate any estimate that you can provide as to when you might be able to reply to my original email to you (copied below).

Thanks,
Michael McGuffin
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From: Michael McGuffin
Sent: Monday, August 17, 2009 12:15 PM
To: Lark Lambert
Subject: Regulation of the labeling of soap

August 17, 2009

Lark Lambert
U.S. Food and Drug Administration
Office of Cosmetics and Colors

Dear Mr. Lambert,
This email serves as a follow up to our telephone communication this morning. I am writing to request information on how soap should be labeled to comply with any and all FDA regulations that cover such labeling.

In responding to this request, I will appreciate attention to the following issues:

- Differences, if any, between FDA labeling regulations for soap that is excepted from the definition of “cosmetic” at 21 U.S.C. 321(i) and soap that is not so excepted, as specified in 21 CFR 701.20.
- Differences, if any, between FDA labeling regulations of soap when sold simply as a soap, and soap when included as an ingredient in another cosmetic product (e.g., in a face wash product).

If it is useful in your reply, one example of soap sold in the marketplace is produced from the following ingredients: coconut oil and sodium hydroxide.

Thanks in advance for your time and attention to this request.

Sincerely,

Michael McGuffin

President, American Herbal Products Association

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