Order of Ingredient Declaration – Descending order of predominance

Exceptions...
Active drug ingredients
Ingredients with less than 1% concentration
Color additives
"And other ingredients"

21 CFR 701.3(a), (d), (f) (2), (f) (3)

The ingredients must be listed in descending order of predominance. However, there are a few exceptions to this requirement.

1. If the cosmetic is also a drug, section 502(c) of the FD&C Act requires that the active drug ingredient(s) be declared before declaration of the cosmetic ingredients. A declaration, thus, would read as follows: "Active Ingredient: ... (Name of drug ingredient). Other (or Cosmetic) Ingredients: ... (Names of cosmetic ingredients in descending order)." [§ 701.3(d)]

2. Ingredients present at a concentration not exceeding 1% may be listed in any order after the listing of the ingredients present at more than 1% in descending order of predominance. [§ 701.3(f)(2)]

3. Color additives of any concentration may be listed in any order after the listing of the ingredients which are not color additives. [§ 701.3(f)(3)].

4. The name of an ingredient accepted by FDA in accordance with the procedure established in § 720.8 as a trade secret need not be disclosed on the label. In lieu of declaring the name of that ingredient, the phrase "and other ingredients" may be used at the end of the ingredient declaration [§ 701.3(a)].

Declaration of Color Additives and Ingredients Present at One Percent or Less

The hypothetical pressed powder formulation portrayed in this example illustrates the two options for the listing of ingredients.

On the left side, the ingredients are listed in descending order of predominance according to § 701.3(2).

On the right side, the ingredients are listed according to § 701.3(f)(1), (2), and (3), i.e., ingredients other than colors present at a concentration exceeding 1% in descending order or predominance, followed by ingredients other than colors present at 1% or less in any order, followed by colors present at any concentration listed in any order.

Pressed Powder	
Label Declaration:	Alternate Declaration:
Talc (75)	Talc
Kaolin (7.5)	Kaolin
Zinc Stearate (5)	Zinc Stearate
Titanium Dioxide (5)	Mineral Oil
Mineral Oil (3)	Lanolin
Iron Oxides (2.5)	Isopropyl Myristate
Isopropyl Myristate (0.9)	Fragrance
Lanolin Oil (0.5)	Lanolin Oil
Lanolin (0.2)	Titanium Dioxide
Fragrance (0.1)	Ultramarine Blue
Ultramarine Blue (0.05)	Iron Oxides

You have the following micas on hand. What can they be used for?

1. Green Vibrance Mica - Mica, titanium dioxide, chromium oxide green
2. Pink Vibrance Mica - Mica, titanium dioxide, iron oxide, manganese violet

Can they be used in lipstick?
Can they be used in eye shadow?
Can they be used in soap?
Can they be used in body butters?
Can they be used in bath bombs?

You are making a cold process soap with the above micas with no cosmetic claims such as moisturizing. What color additive label requirements do you need to follow?

You are making melt and pour soap containing the above micas that has the following ingredients with no cosmetic claims such as moisturizing:

Sorbitol, Propylene Glycol, Sodium Laureth Sulfate, Sodium Stearate, Sodium Laurate, Glycerin, Water + Green Vibrance + Pink Vibrance. What should your label look like?

Answer on Next Page

Melt and Pour Label
Label Declaration:
Sorbitol
Propylene Glycol
Sodium Laureth Sulfate
Sodium Stearate
Sodium Laurate
Glycerin
Water
Mica
Titanium Dioxide
Iron Oxide
Chromium Green Oxide
Manganese Violet

You are making melt and pour soap containing the above micas that has the following ingredients with no cosmetic claims such as moisturizing:

Safflower Oil, Glycerin, Purified Water, Sodium Hydroxide, Sorbitol, Propylene Glycol, Sorbitan oleate, Oat protein + Green Vibrance + Pink Vibrance. What ingredient labeling requirements are necessary?

The Regulatory Definition of Soap:

Whether a product is a “soap” in the traditional sense, or is really a synthetic detergent, helps determine how the product is regulated. So, let’s look at how “soap” is defined in FDA’s regulations;

To meet the definition of soap in FDA’s regulations, a product must meet three conditions:

What it’s made of: To be regulated as “soap,” the product must be composed mainly of the “alkali salts of fatty acids,” that is, the material you get when you combine fats or oils with an alkali, such as lye.

What ingredients cause its cleaning action: To be regulated as “soap,” those “alkali salts of fatty acids” must be the only material that results in the product’s cleaning action. If the product contains synthetic detergents, it’s a cosmetic, not a soap. You still can use the word “soap” on the label.

How it's intended to be used: To be regulated as soap, it must be labeled and marketed only for use as soap. If it is intended for purposes such as moisturizing the skin, making the user smell nice, or deodorizing the user’s body, it’s a cosmetic. Or, if the product is intended to treat or prevent disease, such as by killing germs, or treating skin conditions, such as acne or eczema, it’s a drug. You still can use the word “soap” on the label.

If a product meets these criteria it is regulated as soap and an ingredients listing is not required. True soap is regulated by the Consumer Product Safety Commission and not the FDA.