

# The 3 Most Frequently Asked Questions about Making Cosmetics

In this last 2006 issue I would like to share with you the 3 most frequently asked questions that have been posed during the last few years.

## 1. If I want to sell my products do they need to be approved by authorities?

No, selfmade cosmetics are not required to be tested by the FDA or other authorities. There are, however, some regulations that you need to follow. Homemade products can be sold if:

- The product is in compliance with the provisions of the Federal Food, Drug, and Cosmetic (FD&C) Act, the Fair Packaging and Labeling (FP&L) Act, and the regulations published under the authority of these laws. See at: <http://www.cfsan.fda.gov/~dms/cos-cfr.html>
- The product is properly labeled according to the FDA/CFSAN Labeling Manual: <http://www.cfsan.fda.gov/~dms/cos-lab1.html>
- The product does not contain any of the following prohibited ingredients: <http://www.cfsan.fda.gov/~dms/cos-210.html>
- The product is free of pathogens.

Although the FD&C Act does not require that cosmetic manufacturers or marketers test their products for safety, the FDA strongly urges cosmetic manufacturers to conduct whatever toxicological or other tests are appropriate to substantiate the safety of their cosmetics. If the safety of a cosmetic is not adequately substantiated, the product may be considered misbranded and may be subject to regulatory action unless the label bears the following statement: "Warning - The safety of this product has not been determined."

With the exception of color additives and a few prohibited ingredients, a cosmetic manufacturer may, on his own responsibility, use essentially any raw material as a cosmetic ingredient and market the product without approval. The law requires that color additives used in food, drugs and cosmetics must be tested for safety and approved by the FDA for their intended uses. A cosmetic containing an unlisted color additive; i.e., a color additive which has not been approved by the FDA for its intended use, is considered adulterated and subject to regulatory action. The color additives approved for use in cosmetics are listed at 21 CFR 73, 74 and 82.

Unlike drugs and medical devices, neither

cosmetic products nor cosmetic ingredients are reviewed or approved by the FDA before they are sold to the public. The agency only acts against cosmetic products found to cause harm after they are on the market.

## 2. How long is the shelf-life of homemade cosmetics?

The shelf-life of cosmetics depends basically on three factors:

- How clean you work (disinfection of tools and containers can significantly prolong shelf-life)
- What kind of container you use (dispensers are less prone to contamination than jars)
- The concentration of preservatives used

Many people think that truly all-natural products do not contain preservatives. Non-preserved cosmetic products, however, have typically a shelf-life of a few days or perhaps 2 - 3 weeks when stored refrigerated. Thereafter, the products will contain massive amounts of bacteria and/or fungi even if you don't see them.

There are both natural or synthetic agents that inhibit the growth of bacteria and/or fungi. In general, natural preservatives including grapefruit seed or rosemary extract, potassium sorbate, essential oils, and vitamin C & E are less effective than synthetic preservatives. There are, however, also new natural substances, such as the leaf oil of Cinnamom Cassia, that are effective against a broad spectrum of microorganisms.

Synthetic preservatives that are most often used include methylparaben, propylparaben, diazolidinyl urea, phenoxyethanol, DMDM hydantoin, benzyl alcohol, formaldehyde and triclosan. We recommend using phenoxyethanol, methylparaben, propylparaben and diazolidinyl urea because they are the mildest if used correctly. Thiomersal, quaternium-15 and formaldehyde have often been found to cause skin reactions.

## 3. Why is in recipes the amount of ingredients indicated in weight % and how can I convert them to more practical units?

The amount of ingredients in cosmetic recipes is always indicated as weight percentage rather than weights like ounces, pounds, grams etc. or volumes like liquid ounces, cups, tablespoons or milliliters etc. This has two reasons: not everybody wants to make the same amount of a cosmetic

product, and recipes are barely comparable and reproducible if they are calculated once in volumes and once in weights.

Weight percentages can be easily converted into weights. First determine the total weight of a product you would like to produce (e.g. 10 oz). This amount equals 100 %. If a certain ingredient is indicated with 5 %, you will have to add 5 % of 10 oz of this ingredient which equals 0.5 oz.

If your product is liquid you may prefer to convert the weight percentages into volumes. For example, if you want to make 1 cup of a product and an ingredient is indicated with 20 %, you will have to add 20 % of a cup (= 1/5 of a cup or 48 ml) of this ingredient. Please be aware that oils weigh less than aqueous liquids. As a rule of thumb add about 10% more as compared to aqueous liquids (in our example = 52.8 ml).

If you don't have a scale and want to convert the percentage of a solid ingredient into a volume unit (eg. teaspoons), you have to take the specific gravity into account for an accurate conversion. For example, 1 oz of carnauba wax gives 13 teaspoons, whereas 1 oz of sheabutter gives only 7 teaspoons. As you may not always know the specific gravity of all the ingredients used in the recipe, and such calculations may be rather time consuming, we definitely recommend using a scale for making a cosmetic recipe. It is easiest if you place the container directly on the scale and add the ingredients slowly one by one until the scale indicates the corresponding weight shown in the recipe.

T. Bombeli, MD BBA