Lip Balm Regulatory Information

Ailis Clyne, 2023

Overview

Making maple lip balm for sale to consumers requires strict adherence to all applicable regulations. The following is for informational purposes only; producers are responsible for adhering to the most current regulations. Legal information was retrieved July 2023.

Cosmetics are regulated by the US Food and Drug Administration (FDA) under the Federal Food, Drug & Cosmetic Act (FD&C Act). Cosmetics that are marketed retail are required to meet ingredient labeling requirements under the Fair Packaging and Labeling Act which was proposed by the Federal Trade Commission (FTC) to amend the FD&C Act. A succinct guide on these regulations which is specifically tailored to small businesses can be found on the FDA website. More detailed information on the FD&C Act can be found in the Notebook. The pertinent information to maple lip balm is summarized below.

The law states that cosmetic products must not be **adulterated** or **misbranded**, and they must be **safe** for consumers, and **properly labeled**. They are not subject to approval by the FDA before they go on the market. It is the producer's responsibility to make sure that they are adhering to these laws, their labels are compliant, their products are safe under customary use, and that they are not misleading the consumer.

The FDA is currently defining Good Manufacturing Practices (GMPs) for cosmetics under the Modernization of Cosmetics Regulation Act of 2022, however, small businesses are not required to adhere to them, and they will not be inspected by the FDA (see "Small Business Exemption" below). Regardless, adhering to GMPs voluntarily will help to maintain the safety and stability of your products and prevent adulteration by unwanted contamination.

Adulteration

Adulteration means that the product has been made unsafe by addition of unsafe ingredients or contamination by things that should not be in the product. The FDA's "Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist for Cosmetics" lists four reasons that a cosmetic may be deemed adulterated:

> *1. It may be injurious to users under conditions of customary use because it contains, or its container is composed of, a potentially harmful substance.*

To prevent this, avoid using prohibited and restricted ingredients. This product formulation does not contain any prohibited, restricted, or unsafe ingredients. Fragrances (not included in the basic version of this product) are regulated as described in the **Safety & Record Keeping** section below.

2. It contains filth.

This can be avoided by adhering to GMPs, including keeping a clean work space and wearing sterile gloves. More GMPs are described in the FDA Guidelines linked above.

3. It contains a non-permitted [...] color additive.

This product contains no color additives, so, unless poor manufacturing practices enable contamination with a prohibited color additive, this is not a concern. This regulation becomes more important in production of a lipstick or a tinted lip balm. It is worth noting that some FDA approved color additives are legal only for external application; these color additives are not legal for use in lip products as they may be inadvertently ingested.

4. It is manufactured or held under insanitary conditions whereby it may have become injurious to users or contaminated with filth.

Again, GMPs will prevent these issues. Consider how products are stored while setting or drying. If manufacturing in the home, do not allow pets in the workspace. Be cognizant of the nature of the workspace and any potential for contamination.

Misbranding

Misbranding is misleading the consumer. Some examples include: lying about or failing to disclose the contents of the product, claiming falsely to have certain certifications such as organic or cruelty-free, and making unproven claims about what the product can achieve (e.g., anti-aging effects).

According to the FDA's "Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist for Cosmetics":

A cosmetic may be deemed misbranded (Sec. 602) for reasons of:

1. False or misleading labeling.

2. Failure to state prominently and conspicuously any information required by or under authority of this act.

3. Misleading container presentation or fill.

These are fairly straight forward regulations, and they are explained in more detail in the Notebook. The information referred to that is required to be prominently displayed on the label are: product identity, net contents, contents (ingredients), company name, and the manufacturing location. More information on and visual examples of how to include this information on the label is presented in the **Proper Labeling** section below. For more information on regulations regarding claims that can be made on the product label, see **Label Claims** below.

Safety & Record Keeping

The product must not be "injurious" or cause serious adverse events (e.g., death, hospitalization) under "customary" or conventional use. Under this law, "minor and transient" reactions or skin irritation in some users does not qualify the product as "injurious to health". For lip balm, customary use is applying it to the lips, and because this usage is widely understood by consumers, instructions are not required on the product label. Consumers who use the product in an unconventional way (such as applying it to the eyes, using it on a wound, or eating it), are not protected under this law.

The FDA requires that the manufacturer keeps records of adequate evidence that the product and its ingredients are safe. Adequate evidence includes scientific studies and safety evaluations. All of the ingredients in this recipe are considered safe at the concentrations provided. When sourcing ingredients from suppliers, download the Safety Data Sheets (SDS) for each ingredient and keep for your records. Some suppliers require that you send an email requesting safety documents for their products. Avoid purchasing ingredients from suppliers who do not provide Safety Data Sheets. For ingredients that are not often sold by cosmetics ingredients suppliers because they are more often used as foods, such as lecithin, you will need to find other forms of safety substantiation. The FDA suggests the CIR (Cosmetic Ingredient Review, https://www.cir-safety.org/ingredients), and PubMed (https://pubmed.ncbi.nlm.nih.gov/) for finding such safety information. The CIR is an independent safety review program for cosmetics, and PubMed is a search engine for biomedical research that is hosted by the National Library of Medicine. Ensure that you are looking at reports on use in cosmetic products; dermal toxicity is more relevant than oral toxicity. For example, the following two articles retrieved from PubMed can be used as safety substantiation for lecithin and maple syrup:

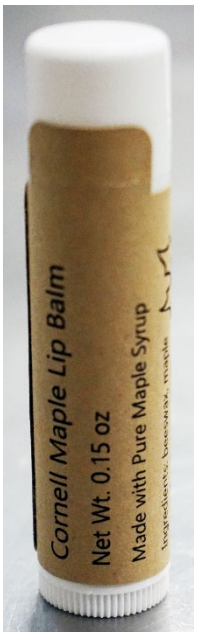
- Maple Syrup: https://pubmed.ncbi.nlm.nih.gov/31170840/
- Lecithin: https://pubmed.ncbi.nlm.nih.gov/32975152/

You may wish to include a fragrance, marketed as "flavor oil" when designed for use in lip balm, in your product. Fragrances are regulated by the type of product they will be added to, depending on the customary area of application and duration of exposure (rinse-off vs leave-on products). The ingredient supplier will provide the IFRA (The International Fragrance Association) standards for any fragrance they sell. IFRA standards dictate the concentration (by weight) of the fragrance permitted for use in lip products, and all other cosmetic products. Exceeding these concentrations would constitute adulteration. Do not use fragrances for which IFRA standards are unknown. Furthermore, be careful with essential oils as many are common skin irritants. More information on essential oils can be found in the Notebook.

Keep in mind that an ingredient being "natural" (an unregulated term), or even safe to eat does not necessarily make it safe for use in a cosmetic product. For example, hot peppers are natural and safe to eat, but prolonged contact with the skin can cause dermatitis.

Furthermore, it is important to keep excellent records, especially in the case of client complaints. Designate batch numbers to all of your products, and make note of Lot numbers for all ingredients in each batch in case of recalls or other issues. Additionally, the FD&C Act requires that manufacturers make it easy to receive reports of adverse health-related events and to keep records of those reports. According to the act "Each cosmetic product shall bear a label that includes a domestic address, domestic phone number, or electronic contact information, which may include a website, through which the responsible person can receive adverse event reports with respect to such cosmetic product" (21 U.S. Code § 364e).

Proper Labeling

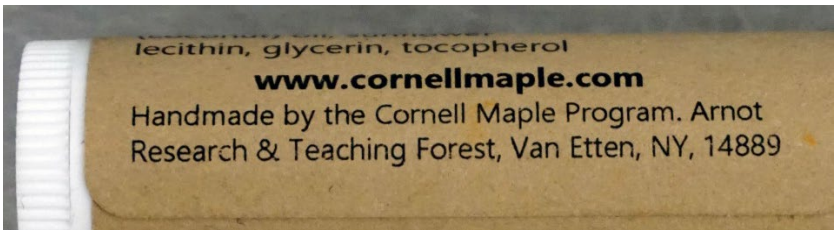


The information that is required under the Fair Packaging and Labeling Act to appear prominently on the label are: product identity, net contents, contents (ingredients), manufacturer name, and manufacturing location. This information is described in great detail in Title 21 CFR § 701.

For this product, the **identity** is "lip balm". Because this is a solid product, the **net contents** must be listed by weight, not volume of the container. The product weight can be determined by weighing an empty lip balm tube and a full lip balm tube and subtracting the difference; this weight will vary depending on the volume of the tube used, which varies by manufacturer. Because this is a hand-filled product, the weight will also vary slightly from tube to tube; weigh several finished lip balms and determine the lowest weight to list on your label. Weigh in grams and convert to ounces, rounded to the hundredths, for the label. The FDA requires that weight be expressed in avoirdupois pounds and ounces, but you may also include the gram weight on the label if desired.

The **manufacturer name** is your business name, not the name of an individual who makes the product. The **manufacturing location** should include the street address, city, state, and zip code. A P.O. Box or website address is not sufficient for this labeling requirement, however, the street address may be omitted if it is easily accessible online (e.g., if it appears on Google Maps, or prominently on your business website). As of 2015, the FTC modernized some of the language in this regulation to include web-based resources as adequate sources of your business street address, "the street address may be omitted if it is listed in a readily accessible, widely published, and publicly available resource,

including but not limited to a printed directory, electronic database, or Web site" (Title 16 CFR § 500.5). However, Title 21 § 701.12 of the Code of Federal Regulations (CFR) has not yet been updated to reflect this change. Regardless, the label would still need to display the city, state, and zip code of the manufacturing location (see example below).



Ingredients must be listed on the label by "prominence" or in other words, by percentage of weight in order from most to least prominent. Ingredients must be listed by their common or usual names in order to be easily understood by consumers. You may not include descriptive terms, such as "natural", "pure", "fair trade", or "organic", in the ingredient names. However you may use superscripted symbols to denote which ingredients fall under certain descriptions. For example, this lip balm uses an asterisk to denote certified organic ingredients:

Note that this ingredient statement uses INCI names and is not in compliance with the US requirement to list ingredients by their common names. The FDA specifies that the INCI names or Latin names can be printed in parentheses after the common names, but not the other way around as displayed above.

Many companies list their ingredients using the INCI naming convention because they also market or manufacture their products in the EU, Canada, and any other countries that require this convention. As the INCI naming convention becomes more and more ubiquitous, cosmetics consumers are becoming accustomed to seeing the INCI names on the products they buy. Some consumers may expect to see the INCI names on the label. However, including these names takes up more space on the label and is not required by the FDA. Note that under both naming conventions, you are not required to list the source of the lecithin (in this case, sunflower); it is perfectly in compliance to just list, "lecithin" on the label. However, the source may be a selling point to some consumers who avoid soy.

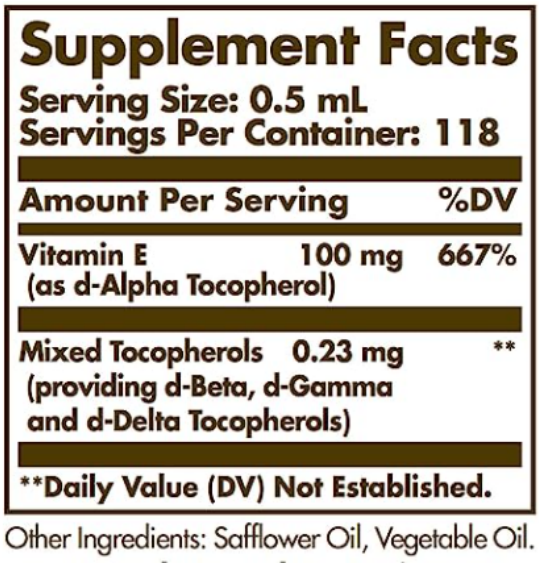
To sum up, if using the recipe exactly as written, you can list the ingredients on the label as follows:

> Beeswax, maple syrup, cocoa butter, sweet almond oil, coconut oil, sunflower lecithin, liquid vitamin E (safflower oil, vegetable oil, tocopherol), glycerin

Or, to include INCI names while staying in compliance with the Fair Packaging and Labeling Act:

> Beeswax, maple syrup, cocoa (theobroma cacao) seed butter, sweet almond (prunus amygdalis dulcis) oil, coconut (cocos nucifera) oil, sunflower (helianthus annuus) lecithin, liquid vitamin E (safflower [carthamus tinctorius] seed oil, vegetable oil, tocopherol) glycerin

The ingredients listed in parentheses after "liquid vitamin E" are those found in the Liquid Vitamin E from Solgar used by the Cornell Maple Program in development of this product. The ingredients in your source of tocopherol must be included on the label and in descending order.



The nutrition panel for Solgar Liquid Vitamin E used as a source of tocopherol is displayed at left. The serving size is 0.5 mL. 0.5 mL of this product weighs about 400 mg, so the product contains approximately 25% tocopherol and 75% of the other ingredients (safflower oil, vegetable oil). 0.5% tocopherol is desired in the product; in a 500 g batch, that is 2.5 g. Because tocopherol makes up ¼ of this product, multiply 2.5 g by 4 to obtain the amount of this product needed to achieve the desired tocopherol level. Of the 10 g used in the lip balm formulation, approximately 7.5 g are oil, and 2.5 g are tocopherol.

Should you use a different source of tocopherol in your product, you can employ the above method to determine how much product to use to achieve a minimum of 0.5% tocopherol, and how to list the ingredients on the lip balm label.

The ingredients statement must use lettering that is a minimum of 1/16 of an inch in height, or 1/32 of an inch if the total surface area available to bear labeling is less than 12 square inches in area. This is the case of the typical cylindrical lip balm tube. If you are having trouble designing a label that fits all of the required information

neatly at the required lettering size, consider packaging your product in a folding cardboard container (depicted at right, previous page) which provides much more space for product information.

Label Claims

It is important to know that not all "personal care products" are regulated as cosmetics under US law. Products that are regulated as cosmetics, drugs, soap, or more than one of these designations, often share the same store-shelf. If your product is a drug under US law, it must meet certain requirements, such as premarket approval and shelf-life dating.

If a cosmetic product is marketed with certain claims, the claims themselves classify the product as a drug according to law, and require that product to meet new regulatory requirements. Some such claims include: anti-aging, wrinkle removal, scar removal, acne treatment, sunscreen (SPF). Avoid any claims suggesting that the product can treat or prevent disease, or that it affects the structure or function of the body, including the skin.

Many terms commonly found on cosmetic product labels are not regulated. Some examples include: "cruelty-free", "natural", and "vegan". You can use these unregulated terms on your product label, however, any and all claims on the label must be accurate, true, and not misleading. Because you will not be able to find a legal definition of these terms, you must assess what the commonly accepted definition of these terms are. Some terms are regulated by federal agencies other than the FDA; the term "organic" is regulated by the USDA, and the claim "Made in USA" is regulated by the FTC. Cruelty-free certification is run by a few independent organizations who permit qualifying manufacturers to use their widely recognized official logos. Most consumers who look for cruelty-free products are looking for these logos on the label. Claiming that your product is cruelty-free without one of these logos and certifications may indicate to the consumer that you are making a false claim. More information on cruelty-free certification can be found in the Notebook. When in doubt, leave it out, and instead, brag about the inclusion of maple syrup in your product.

Small Business Exemption (21 U.S. Code § 364h - Small businesses)

Under the FD&C Act, small businesses are defined by gross annual sales. A business that makes less than $1,000,000 over the previous 3-year period (adjusted for inflation) from sales of cosmetic products is exempt from adhering to Good Manufacturing Practices, and from registering their business and listing their products with the FDA. Such small businesses will not have their facilities inspected by the FDA. However, they are still required to adhere to all other cosmetic regulations and to ensure that they are producing safe products. There are a few exceptions to small business exemption, including

manufacturers of some inherently risky products, such as products that come into contact with the eye or that are meant to be injected; lip balm does not fall under this list.

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