

### Directions

#### **Product Information:**

Fill in the top information for one specific product. The same Product Safety Substantiation Record can be used for multiple products with the same ingredients but different colors and/or fragrances.

Note the date the record was created and keep track of the date(s) when it is checked or updated (so you know how up-to-date the information is).

#### **Ingredient Safety Substantiation:**

List each ingredient used in all variations of the product, with the percentage used. Then list color or fragrance ingredients that are used in one or more of the product variations.

For each ingredient, state what you are using to substantiate the safety of the ingredient. Using a standardized citation will make it easier to locate the information in the future. Note that for soap, documentation of the safety of the saponified oil and glycerin is easier to document than explaining the components (oil and lye).

If any testing of the final product has been done, that should be included in the documentation.

#### Paper Records

If you are keeping paper records, you may want to print a copy of the safety data (or at least the pertinent portion) and your Manufacturer's Certificate of Analysis and keep them with the Product Safety Substantiation Record. Depending on how you deal with paper, you could create a binder with sections for each product or a file folder in which all of the materials are kept.

#### Electronic Records

If you are keeping electronic records, you could link the document in the form. If you keep the safety data documents on your computer, it is very important that you don't move them around and break the link. If you are linking to external information on the web, you should periodically check to ensure the links all still work. Using a DOI (Digital Object Identifier) will help to find and identify the article in the future.

## Product Safety Substantiation Record

Product Name: Basic Soap

Date Created: Aug 30, 2023 Last Checked/Updated: \_\_\_\_\_

Ingredient Name	% used	Safe level	Source
Sodium <u>Olivate</u>	40%	Safe at current usage levels	Burnett CL, Fiume MM, Bergfeld WF, et al. Safety Assessment of Plant-Derived Fatty Acid Oils. International Journal of Toxicology. 2017;36(3_suppl):51S-129S. <a href="https://doi.org/10.1177/1091581817740569">doi:10.1177/1091581817740569</a>
Sodium <u>Cocoate</u>	30%	Safe at current usage levels	<i>Ibid.</i>
Sodium Palmate	20%	Safe at current usage levels	<i>Ibid.</i>
Glycerin	7% (approx.)	Safe as used as described in safety assessment, at levels up to 90% in rinse-off products	Becker LC, Bergfeld WF, Belsito DV, et al. Safety Assessment of Glycerin as Used in Cosmetics. International Journal of Toxicology. 2019;38(3_suppl):6S-22S. <a href="https://doi.org/10.1177/1091581819883820">doi:10.1177/1091581819883820</a> Manufacturer's certificate of analysis
Lavender Essential Oil	1.5%	Safe in Category 9 products (bar soap) at up to 100%	Manufacturer's IFRA Standards Conformity Certificate
Ultramarines	0.5%	Approved for external cosmetics, including eye area	21 CFR 73.2725 Manufacturer's certificate of analysis

## Product Safety Substantiation Record

Product Name: Basic Lotion

Date Created: Aug 30, 2023 Last Checked/Updated: \_\_\_\_\_

Ingredient Name	% used	Safe level	Source
Water	80.8%		
Glycerin	4%	Safe as used as described in safety assessment, at levels up to 90% in rinse-off products	Becker LC, Bergfeld WF, Belsito DV, et al. Safety Assessment of Glycerin as Used in Cosmetics. International Journal of Toxicology, 2019; 38(3_suppl):6S-22S. <a href="https://doi.org/10.1177/1091581819883820">doi:10.1177/1091581819883820</a> Manufacturer's certificate of analysis
Xanthan Gum	0.5%		Fiume MM, Heldreth B, Bergfeld WF, et al. Safety Assessment of Microbial Polysaccharide Gums as Used in Cosmetics. International Journal of Toxicology. 2016;35(1_suppl):5S-49S. <a href="https://doi.org/10.1177/1091581816651606">doi:10.1177/1091581816651606</a> Manufacturer's Certificate of Analysis
EDTA	0.2%	Safe as used (0.02 to 2%)	Final Report on the Safety Assessment of EDTA, Calcium Disodium EDTA, Diammonium EDTA, Dipotassium EDTA, Disodium EDTA, TEA-EDTA, Tetrasodium EDTA, <u>Tripotassium EDTA</u> , Trisodium EDTA, HEDTA, and Trisodium HEDTA 1. International Journal of Toxicology, 2002; 21(Suppl.2):95-142. Manufacturer's Certificate of Analysis
Sunflower Oil	5%	Safe at .000007 to 96%	Burnett CL, Fiume MM, Bergfeld WF, et al. Safety Assessment of Plant-Derived Fatty Acid Oils. International Journal of Toxicology, 2017; 36(3_suppl):51S-129S. <a href="https://doi.org/10.1177/1091581817740569">doi:10.1177/1091581817740569</a> Manufacturer's Certificate of Analysis
Mango Butter	2%	Safe at current usage (0.005 to 6%) or in line with other oils in the safety assessment.	<i>Ibid.</i>
Emulsifying Wax NF	4%	Safe up to 21%	Cosmetic Ingredient Review. Final Report on the Safety Assessment of Fossil and Synthetic Waxes. Journal of the American College of Toxicology. 1984; 3(3):43-99, 1984. Confirmed in International Journal of Toxicology, 2005; 24(S1):67-74. Manufacturer's Certificate of Analysis

## Product Safety Substantiation Record

Product Name: Basic Lotion – Page 2

Ingredient Name	% used	Safe level	Source
<u>Cetyl Alcohol</u>	2%	Safe for use at current usage levels (0.1 to 25%) and with impurities not to exceed hydrocarbons 1.5%, ash 0.05%, lead 20 PPM, arsenic 3 PPM.	Cosmetic Ingredient Review. Final Report on the Safety Assessment of <u>Cetearyl Alcohol</u> , <u>Cetyl Alcohol</u> , <u>Isostearyl Alcohol</u> , <u>Myristyl Alcohol</u> , and <u>Behenyl Alcohol</u> . Journal of the American College of Toxicology. 1988; Vol 7(3):359-413. Manufacturer's Certificate of Analysis
Fragrance	1%		Manufacturer's IFRA Standards Conformity Certificate
<u>Germal Plus</u>	0.5%	Maximum recommended usage rate 0.5%; May be used in pH 3-8. Temp not to exceed 122°F.	See details of component ingredients below.
<u>Diazolidinyl Urea</u> (39.6% of <u>Germal Plus</u> 0.5%)	0.198%	Maximum usage rate 0.5%.	Cosmetic Ingredient Review. Final Report on the Safety Assessment of <u>Diazolidinyl Urea</u> . Journal of the American College of Toxicology. 1990; 9(2)
		Maximum usage rate 0.5%	Regulation (EC) No 1223/2009, Annex V, List of Preservatives Allowed in Cosmetic Products.
<u>Iodopropynyl Butylcarbamate</u> (0.4% of <u>Germal Plus</u> 0.5%)	0.002%	Should not be used in products for lips or oral care products or aerosolized products. Safe at 0.1% or less	Cosmetic Ingredient Review. Final Report on the Safety Assessment of <u>Iodopropynyl Butylcarbamate</u> (IPBC). Journal of the American College of Toxicology. 1998;17(Suppl. 5)1-37.
		For leave-on products: Maximum usage rate 0.01%. Not to be used in body lotion and body cream. Not to be used for children under 3 years. Add "contains iodine" to label.	Regulation (EC) No 1223/2009, Annex V, List of Preservatives Allowed in Cosmetic Products.
<u>Propylene Glycol</u> (60% of <u>Germal Plus</u> 0.5%)	0.3%	Safe for use up to 50%	Cosmetic Ingredient Review. Final Report on the Safety Assessment of Propylene Glycol and Polypropylene Glycols. Journal of the American College of Toxicology. 1994; 13(6):437-491.

