







# EWG'S LICENSING CRITERIA Personal care products

EWG's science team has developed a set of strict criteria for all products that bear the EWG Verified® mark, which demonstrates that a product meets our highest standards for health, as outlined below.





# EWG's licensing criteria: Personal care products

Products bearing the EWG Verified® licensed mark meet all the following criteria.

# 1. Products must fall into one of the EWG personal care product categories approved for licensing.

EWG will license only those personal care products that fall into one of the following categories.

- I. Baby products: baby bubble bath, body spray, diaper cream, lotion, oil, shampoo, soap, toothpaste, wipes
- II. Hair products: conditioner, detangler, gel, hair color, hair spray, hair removal wax, mousse, shampoo
- III. Makeup: BB/CC cream, blush, bronzer/ highlighter, body art, brow liner, concealer, eyeliner, eye shadow, facial powder, foundation, glitter, lip balm, lip balm with SPF, lip gloss, lip liner, lip plumper, lipstick, mascara, makeup remover, makeup remover wipes
- IV. Nail products: cuticle products, nail polish, nail polish remover, nail products
- V. Skin products: aftershave, after-sun products, antiperspirants and deodorants, anti-aging products, around-eye creams, bath oils/salts/ soaks, body-cleansing wipes, body-firming lotion, body powder, body oil, body wash/cleanser, bubble bath, callus products, exfoliant/scrub, facial cleanser, facial-cleansing wipes, facial moisturizer, foot cleanser, hand cream, hand sanitizer, liquid and bar soaps, lotion, masks, moisturizer, moisturizer with SPF, oil controller, redness products, scar products, shaving cream, toner/astringent
- VI. Oral care products: breath freshener, mouthwash, toothpaste
- VII. Over-the-counter, or OTC, eczema products
- VIII. Other: body spray, foot odor control, fragrance, muscle/joint soreness, vapor rub

#### IX. Sunscreens: baby and kid sunscreens, recreational sunscreens.

Note: A manufacturer of a product meeting our definition of concentrate\* may use a dilution ratio to substantiate compliance with our health and environmental requirements. When calculating ingredient concentrations (in the refill container), dilution according to the lowest water to greatest solution ratio, as recommended by the company, shall apply.

\* EWG defines concentrate as a product that, as sold, should be diluted by water before its intended use.

The product must continue to meet the remainder of EWG's requirements, including pH, in the "as sold" state. Manufacturers may calculate pH with a minimum 50% solution for solids and powders, if necessary. Concentrates intended for use in spray bottles will also be required to meet EWG's ingredient concentration restrictions for spray products. Corresponding spray restrictions, where applicable, can be found on EWG's restricted ingredient list.

#### Product categories that are not eligible for EWG licensing include:

- I. Product types not eligible for inclusion in Skin Deep® (for more details, see <a href="ewg.org/skindeep/learn">ewg.org/skindeep/learn</a> more/about).
- II. Medical and semi-medical products, including products making claims of a medical nature: acne treatment, wound treatment, hormonal cream, pain relief, anti-fungal treatment, anti-itch/rash cream, athlete's foot treatment, hemorrhoids, denture care, contact lens all-in-one clean and rinse, contact lens cleaners, contact lens saline solution, eye drops/artificial tears, eye drops/ artificial tears for contacts, eye wash, hair loss treatment, lice treatment shampoo, ear wax removal, oral pain relief, wart removal, cradle cap treatment, nipple cream, "personal cleansing," genital moisturizer, genital powder/ deodorant, lubricant/spermicide, hair growth inhibitor, hair growth treatment/stimulant, varicose/spider vein treatment, bandages, dental floss, pore strips
- III. Categories of products that tend to be caustic or harsh, such as skin fading/lightener, chemical depilatory, hair straighteners (hair relaxer, hair perm), baby powder, facial hair bleach, chemical peel, sunless tanning products, tanning oils
- IV. Some categories of products with health concerns, such as eyelash glue and nail glue

V. Aerosols of any kind, because of respiratory concerns. For purposes of this program, aerosol products are those that are pressurized, through the use of a propellent or mechanical force, to dispense product. This definition of aerosol does not include pump spray products

#### 2. Products must rate "Green" in Skin Deep.

EWG will license only products that pose few potential health hazards and receive a hazard rating in the "Green" range of EWG's Skin Deep database. Products in Skin Deep are rated 1 to 10, with 1 being the best and 10, the worst. In Skin Deep, products that rate "Green" are those that receive either a 1 or a 2. A product's hazard rating is not an average of the ingredients' hazard ratings. It is calculated using a weight-of-evidence approach that factors in all of the hazards or health impacts associated with the ingredients. Although many of the ingredients in Greenrated products have low hazard ratings and rate in the Green range, it is not a criterion that all ingredients within a licensed product rate Green. For products that have ingredients with limited data, EWG may request additional human health data from the brand. Due to the variable composition of many botanical ingredients, brands will be asked to submit composition information for the botanical ingredient(s) used in their products.

In addition to scoring Green, OTC eczema products must 1) have an OTC drug facts panel to indicate that the product aligns with the U.S. Food and Drug Administration's <u>Over the Counter Monograph</u>: <u>Skin Protectant Drug Products for Over-the-Counter Human Use</u>, 2) provide clinical skin testing of the product based on participants with sensitive skin (see Criterion 8), 3) avoid certain contact allergens (see Appendix III), and 4) use only colloidal oatmeal as the active ingredient. Steroids are not permitted to be used in EWG Verified OTC eczema products, and OTC eczema products submitted to the EWG Verified program must also meet the other criteria laid out in this document.

Additionally, if any Appendix III contact allergens or European Union fragrance allergens are components of ingredient(s) permitted in EWG Verified OTC eczema products, that substance will be limited to less than 10 part per million, or ppm, (0.001%) in the final product for leave-on products and less than 100 ppm (0.01%) in the final product for rinse-off products and products requiring dispersal in water.

EWG also rates sunscreens with hazard ratings but uses additional sunscreen-specific factors and modeled product efficacy to evaluate these products.

Only products rated Green in EWG's Guide to Sunscreens qualify for licensing. Sunscreen efficacy is determined through an analysis of four contributing factors:

- I. Expected ultraviolet B, or UVB, protection, or labeled SPF
- II. Modeled ultraviolet A, or UVA, protection
- III. The balance of modeled UVA protection to labeled SPF, or UVB protection
- IV. Sunscreen stability.

EWG has given more weight to factors that raise particular concerns for sunscreens. EWG Verified sunscreens may not:

- I. Be in an aerosol or powder form, given the potential for inhalation
- II. Have an SPF value below 15 or higher than 50+
- III. Include a marketing claim on the label, such as the word "sunblock," that has been banned by the FDA.

Although a cosmetic company pursuing EWG Verified is not required to make products available to consumers in the U.S., the company must comply with all FDA cosmetics regulations applicable to products sold in the U.S.,\* including the use of U.S.-allowed active ingredients and appropriate FDA-required labeling language and Drug Facts label for product categories that are regulated as over-the-counter drugs.

\* With exceptions granted to sunscreen products not sold in the U.S.

For more information on FDA regulation of cosmetics, see: fda.gov/cosmetics/cosmetics-quidance-regulation/cosmetics-laws-regulations.

For more information on FDA- required Drug Facts label, see: <a href="mailto:fda.gov/drugs/information-consumers-and-patients-drugs/otc-drug-facts-label">fda.gov/drugs/information-consumers-and-patients-drugs/otc-drug-facts-label</a>

## 3. Products cannot contain any ingredients on EWG's list of unacceptable ingredients.

EWG's list of unacceptable ingredients may include substances from authoritative safety evaluations at the discretion of EWG scientists and toxicologists. EWG's list includes:

I. Certain ingredients with health, ecotoxicity and/ or contamination concerns

- II. Substances falling within any of the following categories because of scientific safety evaluations (with certain, limited exceptions):
  - Cosmetic ingredients banned by Health Canada, appearing on the Cosmetics
     Ingredient Hotlist
  - Ingredients designated as banned in the European Commission's database of cosmetic substances, CosIng
  - Chemicals on California's Proposition 65 list of known carcinogens and reproductive toxins
  - Substances classified by the International Agency for Research on Cancer as known, probable and possible carcinogens (categories 1, 2A and 2B)
  - Substances listed in the National Toxicology Program's Report on
     Carcinogens (reasonably anticipated and known human carcinogens)
  - Substances classified by the EPA's IRIS program as "carcinogenic to humans," "likely to be carcinogenic to humans," or having suggestive evidence of carcinogenic potential
  - Ingredients the FDA does not allow for use in cosmetics
  - o Fragrance chemicals prohibited by the International Fragrance Association
  - Mineral pigments not allowed for use as colorants by the FDA, Health Canada and/or the EU
  - EU Category 1-designated endocrine disruptors
  - Substances that fall under the EU's Globally Harmonized System hazard codes H340-362 (hazard codes for genotoxicity, cancer and developmental/ reproductive endpoints)
  - Substances designated as sensitizing asthmagens by the Association of Occupational and Environmental Clinics (applies only

# 4. Products with ingredients on EWG's list of restricted ingredients must meet the restrictions set by authoritative bodies, industry institutions and EWG.

EWG's list of restricted ingredients includes cosmetics ingredients that have been restricted by national and international governments, authoritative bodies, and certain cosmetics and fragrance industry institutions. The restrictions include, but are not limited

to, acceptable product-use categories, concentration limits and contamination restrictions established by the following groups:

- I. FDA
- II. EU (as listed in the CosIng database);
- III. Health Canada (as listed in the Cosmetic Ingredient Hotlist)
- IV. Japan's Ministry of Health, Labour and Welfare
- V. Personal Care Products Council's Cosmetics Ingredient Review
- VI. International Fragrance Association
- VII. Research Institute for Fragrance Materials.

Should the guidance of authoritative bodies conflict, EWG shall use the most health-protective limit. In lieu of established restrictions for ingredients that EWG determines to be of concern, additional restrictions or prohibitions may be put in place based upon review of the available science and best professional judgment.

# 5. Products must follow standard ingredient naming guidelines.

- I. Each ingredient name should be listed using International Nomenclature for Cosmetics Ingredients, or INCI, labeling guidelines, as found in the most recent edition of the International Cosmetics Ingredient Dictionary and Handbook. Soaps may use common names on the product label, provided that a full list of INCIs is available on the product website with the phrase "View EWG Verified® Ingredient Disclosure Requirements".
- II. Mixtures must be listed by their component INCI names. For example, the mixture "Geogard Ultra" must be listed as "Gluconolactone, Sodium Benzoate." No reference to trademark ingredient mixtures may appear in the ingredient list.
- III. If INCI names are not available, ingredients must be listed using a unique chemical name. (Note: Trade names and registered trademark names will not be allowed.)
- IV. All botanicals must include the scientific name followed by the chemical modification, such as extract or oil. A company may decide whether it will also list the common name. The general naming structure should be as follows:

[Botanical name] [(Common name), optional] [Name of relevant plant part, such as leaf or stem, if applicable] [Chemical modification]

For example, Aloe Barbadensis (Aloe Vera) Leaf Extract

# 6. Products must fully disclose all ingredients, including ingredients used in fragrance and flavor mixtures and chemicals used to coat mineral ingredients.

EWG will license only those products that fully disclose their ingredients. This provision includes complete disclosure of fragrance and flavor mixtures, as well as chemicals used to coat mineral ingredients and non-chemical materials or substrates, such as wipes. For the purposes of this agreement, an ingredient is defined as any substance used in the preparation of the product that remains in the final commercial product.

For fragrance and flavor mixtures, all ingredients above and below 100 parts per million, or ppm (or 0.01% of the final product), must be disclosed to EWG. Only those ingredients above 100 ppm must be listed on the company's website and in Skin Deep.

Packaging ingredient list disclosure requirements

- I. For fine fragrance products only: The company must include one of the following disclosure requirements on the final product packaging:
  - A fully disclosed ingredient list.
  - The term "fragrance" followed by an asterisk or equivalent, as well as an asterisk directly beneath the ingredient list preceding the first five ingredients in the mixture, based on concentration, and instructions on where to find the fully disclosed list of ingredients online. (See example below for details on placement and wording.).

Example of product ingredient list Ingredients: Water, Butyrospermum Parkii (Shea) Butter, Fragrance,\* Tocopherol.

\* Fragrance ingredients include: Citrus Paradisi (Grapefruit) Extract, Citrus Limon (Lemon) Extract, Lavandula Angustifolia (Lavender) Extract, Camellia Sinensis (Green Tea) Extract, Mentha Piperita (Peppermint) Leaf Extract, and others. (See full fragrance ingredient list on company website.)

- II. For all product types other than fine fragrances: The company must include one of the following disclosure requirements on the final product packaging:
  - A fully disclosed ingredient list
  - The term "fragrance" or "flavor" followed by an asterisk or equivalent, as well as an asterisk directly beneath the ingredient list preceding instructions on where to find the fully disclosed list of ingredients online and the EWG Verified mark prominently displayed on the product packaging. (See example below for details on placement and wording.)

Example of product ingredient list Ingredients: Water, Butyrospermum Parkii (Shea) Butter, Fragrance,\* Tocopherol.

- \* Fragrance ingredients disclosed online.
  - The term "fragrance" or "flavor" followed by an asterisk or equivalent, as
    well as an asterisk directly beneath the ingredient list preceding the first five
    ingredients in the mixture, based on concentration, and instructions on
    where to find the fully disclosed list of ingredients online. (See example
    below for details on placement and wording.)

Example of product ingredient list Ingredients: Water, Butyrospermum Parkii (Shea) Butter, Fragrance,\* Tocopherol.

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To allow companies to protect confidential business information about the product and fragrance formulation, EWG does not require disclosure of the weight or amount of an intentionally added ingredient outside of certifications necessary to satisfy concentration restrictions.

Note: EWG reserves the right to perform random product testing, including through qualified third-party testing services, to ensure that products fully disclose all ingredients on the label.

# 7. Products must disclose all fragrance allergens required on personal care product labels in the EU.

The EU requires companies to indicate the presence of 26 fragrance allergens in the list of ingredients when concentrations exceed 0.01% in rinse-off products and 0.001% in leave-on products, whether or not they were added directly as an ingredient or are present as a component of a fragrance ingredient. The allergens and their CAS numbers are attached in Appendix I.

EWG requires that companies list fragrance allergens meeting the EU criteria above at the end of their ingredient lists on the product package. If fragrance allergens are dispersed throughout the ingredient list rather than listed at the end, they must be clearly identified with an asterisk or similar symbol indicating that the allergen is a component of the parent ingredient. Companies may choose to indicate these allergens on the product package and/or on the product webpage. If companies choose to list the allergens solely on their website, they must also indicate on the product package the specific ingredients that have the relevant allergenic components with an asterisk or similar symbol and include a phrase at the end of the ingredient list that points to the website for the full list of allergens.

Note: EWG reserves the right to consider a transition period to allow for compliance with newly adopted EU allergen regulations from July 2023 and 2022 FDA Modernization of Cosmetics Regulation Act of 2022 legislation while the criteria are being further developed.

### 8. Products must follow EU labeling guidelines for nanomaterials used in cosmetics.

EWG requires that all licensed cosmetics products follow the EU 2009 labeling guidelines for nanomaterials in cosmetics, provided that any claims about nanomaterials are properly substantiated and comply with any applicable FDA regulations for cosmetics. For the purposes of this agreement, we refer to the EU's 2011 recommended definition: "Nanomaterial' means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm."

Manufacturers using ingredients that meet the 2011 EU definition of nanomaterials in their product(s) must include these ingredients on the product's ingredient list. The names of such ingredients should be followed by the word "nano" in parentheses.

For more information on the EU's guideline for nanomaterials in cosmetics products, see: <a href="health.ec.europa.eu/system/files/2020-10/sccs">health.ec.europa.eu/system/files/2020-10/sccs</a> o 233 0.pdf

# 9. Product labels must show an expiration date or a "period of time after opening."

EWG requires licensed products to address the product's shelf stability by including one of the following pieces of information on the label:

- I. An expiration date for products
- II. The period of time a product may be used after opening without any harm to the consumer. This "period of time after opening" must be indicated on products with a shelf life of 30 months or more.

# 10. Product manufacturers must develop, document and follow current good manufacturing practices.

EWG requires that licensed companies develop, document and follow a program of good manufacturing practices, in line with FDA Guidance for Industry: Cosmetic Good Manufacturing Practices. These practices include but are not limited to:

- I. Maintaining documentation and records
- II. Assessing the suitability of buildings, facilities and equipment
- III. Maintaining adequate filth and pest controls
- IV. Assessing raw materials
- V. Establishing standard operating procedures, or SOPs
- VI. Evaluation laboratory controls
- VII. Reviewing and documenting product complaints, adverse event reports and voluntary recalls.

Products that offer UV protection must also follow the FDA good manufacturing practices for SPF products.

For more information on the FDA's Guidance for Industry: Cosmetic Good Manufacturing Practices see:

<u>fda.gov/cosmetics/cosmetics-guidance-documents/good-manufacturing-practice-gmp-guidelinesinspection-checklist-cosmetics.</u>

## 11. Products must pass basic microbial challenge tests and repeat these tests as appropriate.

EWG will license only products that have:

- I. Specified to EWG which ingredients, if any, are intended as preservatives
- II. Passed microbial challenge tests for the finished product (current formulation). (Refer to U.S. Pharmacopoeia Antimicrobial Effectiveness Testing, or USP 51, for relevant challenge test). Companies must also have protocols in place to repeat microbial challenge tests if/when the product formulation, manufacturing process or packaging change. Companies must provide evidence of anhydrous formulations, when applicable.

In keeping with ISO 29621, products with the following characteristics are considered low-risk for microbial contamination and are therefore exempt from this criterion:

Physico-chemical characteristics or product components	Limits
рН	< 3.0 or > 10.0
Ethanol or other alcohol	> 20%
Filling temperature	> 65.0 °C
Water activity (aw)	< 0.75a
Solvent-based products	
Oxidizing products	
Aluminum chlorohydrate	> 25%

# 12. Wipe products must use substrates that are high purity, biodegradable, and pass wastewater compatibility standards, if applicable.

#### EWG will license only wipe products that have:

- Identified the substrate material and substrate contaminants for PAH less than 0.2 ppm, declaration of pesticides or "organic", statement on absence of dioxin and furans.
- II. if flushable, readily biodegradability tests by OECD or equivalent.
- III. if flushable, passed IWSFG flushability standards. If non-flushable, wipes must display the 'Do Not Flush' symbol on packaging as required by law.

#### ADDITIONAL CRITERIA FOR EWG-LICENSED COMPANIES

Companies with products licensed by EWG must agree to all of the following:

i. Companies must commit to submitting all reports of product problems or serious adverse events to the FDA and to EWG, with all personally identifiable information, such as names and addresses, redacted from such reports.

EWG requires companies with licensed products to submit all reports of product problems or serious adverse events resulting from the use of any of the company's products to the FDA through the MedWatch site (fda.gov/Safety/MedWatch/). Companies should also submit those reports, with all personally identifiable information redacted from such reports, to EWG.

Product problems include but are not limited to:

- A. product contamination
- B. questionable stability
- C. labeling concerns.

For the FDA definition of product problems and relevant examples, see: <a href="mailto:fda.gov/safety/reporting-serious-problems-fda/product-problems">fda.gov/safety/reporting-serious-problems-fda/product-problems</a>

#### Serious adverse events include:

- A. death
- B. a life-threatening event
- C. hospitalization
- D. a disability or permanent damage
- E. a congenital anomaly or birth defect
- F. disfigurement, including serious or persistent rashes, papules, desquamation, erythema, and infections.

For more details on serious adverse events, see: <a href="mailto:fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program.">fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program.</a>

ii. Companies must acknowledge that EWG's lists of unacceptable and restricted ingredients will be reviewed annually and updated as needed. A phase-in period will be provided to allow companies to comply with any updates.

EWG will review and update EWG's lists of unacceptable and restricted ingredients once annually to reflect the latest in science, regulations and other relevant considerations. If EWG makes changes, companies will be alerted that a new list is pending at least one (1) month before the changes go into effect. Any companies with currently licensed products that are affected will be notified six (6) months before their contract expires. Companies will then get eighteen (18) months to make the necessary changes to their formulation and packaging.

At the end of the 18-month period, products with EWG's licensed mark that do not comply with the new lists of unacceptable or restricted ingredients may no longer be manufactured or produced. If companies continue to distribute non-compliant products with EWG's licensed mark, this will be treated as a breach of EWG's licensing agreement. In the rare event that scientific evidence emerges showing that a personal care product ingredient will pose significant harm to human health, EWG reserves the right to ask

companies either to remove the ingredient or stop distributing the relevant products with EWG's licensed mark within a shorter period than specified above.

iii. Companies must acknowledge that as a condition of their participation in the licensing program, EWG will add all of their licensed products to EWG's Skin Deep database, if they are not already included.

iv. Companies must acknowledge that EWG's Skin Deep database is dynamic and the scoring algorithm may change over time.

EWG strives to make all of its consumer databases as robust as possible. For this reason, Skin Deep is a dynamic database and product and/or ingredient ratings are subject to change because of both emerging science and scoring algorithm improvements. In most cases, EWG will give companies notice of such changes to the scoring system; unforeseen circumstances may deem such notice impossible in rare situations. If changes to the Skin Deep scoring system render a company's product out of compliance with EWG's licensing criteria, the company will have 18 months either to regain compliance or to remove the EWG licensed mark from their product packaging and associated materials.

v. Companies must acknowledge and agree that EWG has the right to perform random product testing, including through qualified third-party testing services, to ensure that products meet the provisions outlined in EWG's licensing criteria.

EWG requires companies with licensed products to acknowledge that EWG has the right to perform random product testing, which may include the use of qualified third-party services, to ensure that products bearing the EWG licensed mark meet the provisions highlighted in this document.

vi. Companies must acknowledge that EWG has the right to approve, in advance, any use of the EWG Verified mark in advertising, marketing, artwork, packaging, point-of-sale materials, website content, promotions and other materials.

Before public use or distribution, companies must submit to EWG samples of the final licensed product, including all packaging, product inserts and other materials accompanying such licensed product or otherwise bearing the trademarks.

vii. Companies must acknowledge that, although product claims are not addressed in EWG's licensing criteria, EWG reserves the right to forbid use of the EWG Verified mark on any product marketed with claims that would harm or discredit EWG or the EWG Verified program.

### DOCUMENTING COMPLIANCE WITH EWG'S LICENSING CRITERIA FOR PERSONAL CARE PRODUCTS

To verify a product meets EWG's standards for health and transparency, a company must submit the following documentation for each EWG Verified criterion.

CRITERION 1. The product must fit into one of the approved licensing product categories.

CRITERION 2. The product must rate "Green" in Skin Deep.

CRITERION 3. The product must be free from any ingredients on the EWG list of unacceptable ingredients.

CRITERION 4. The product must follow standard ingredient naming and labeling guidelines.

DOCUMENTATION: Companies must submit a completed Product Submission Form with product name, ingredients and all package text. For verification purposes, companies must also submit legible images or pictures of their package as it appears on actual products for sale. In cases where the package text and/or artwork has yet to be finalized, EWG will review proof images during the application process. However, companies must submit final package images for EWG approval before the mark will be approved for use. (Product Submission Forms can be downloaded from the application page.)

EWG will upload product information to an internal platform that will highlight whether the product to be licensed meets the EWG criteria specified above.

### CRITERION 5. Be free from any of EWG's restricted ingredients that do not meet the relevant restrictions.

DOCUMENTATION: EWG will require companies to acknowledge our Safety Substantiation Notice and confirm that any restricted ingredients in the product meet the relevant restrictions set by authoritative bodies and industry institutions.

If the maximum concentration of an ingredient allowed in the formulation is restricted, we ask that you provide a signed statement from a formulator, regulatory specialist or other authorized company representative with knowledge of formulation details certifying that the percentage used is less than the restricted amount. The signed statement should address the specific restricted ingredient, product name, and associated percentage. For example, Product A contains less than x% of Ingredient Y. The statement should be dated and written on letterhead.

If an ingredient is restricted because of a component or because of impurity or contamination concerns, we require more than a signed statement only. We require test reports or a certificate of analysis or similar documentation addressing the restricted limit specifically. Please make sure the substantiation documents provided clearly show the name of the ingredient being documented. The name of the file sent to us must also include the name of the ingredient. All documentation should be dated within the past three years.

### CRITERION 6. Fully disclose all ingredients on the label, including those in fragrance and flavor mixtures and chemicals used to coat mineral ingredients.

DOCUMENTATION: Companies must submit a signed affidavit that they have fully disclosed all the intentionally added ingredients on the company's public-facing website (including fragrance or flavor ingredients at or above 0.01%) and product label (including at least the first five fragrance or flavor ingredients when the mixture exceeds five ingredients). EWG will supply companies with the necessary form, the Master Personal Care Products Affidavit, which can be downloaded from the application page.

### CRITERION 7. Disclose all fragrance allergens required on personal care product labels in the EU.

DOCUMENTATION: EWG will require companies to sign an affidavit stating that they will disclose all fragrance allergens that are required on labels in the EU. EWG will review the product's ingredients and determine whether fragrance allergens are likely present, whether as directly added ingredients or as a component of a fragrance ingredient. If EWG decides

fragrance allergens may be present, companies must either label them accordingly or submit a signed affidavit from their ingredient supplier stating that no allergen is present or, if present, all fragrance allergens meet EU concentration restrictions – 0.01% in rinse-off products and 0.001% in leave-on products. EWG will supply companies with the necessary form, the Master Personal Care Products Affidavit can be downloaded from the application page.

### CRITERION 8. Provide additional documentation as needed for certain product types.

DOCUMENTATION: Certain product types require specific documentation in addition to the other documentation required for the EWG Verified program more broadly.

To meet the clinical skin testing requirement for OTC eczema products, companies may submit a Repeated Insult Patch Test (HRIPT) panel for Self-Perceived Sensitive Skin. Any submitted Human Repeated Insult Patch Testing must meet EWG's criteria for accepting HRIPTs. Other clinical skin testing may be accepted to meet this requirement at the discretion of EWG.

In order for EWG to accept an HRIPT to substantiate a restriction, meet the requirements for a specific product type (ex. OTC eczema products), or fulfill other program requirements, a submitted HRIPT must meet the following criteria:

- I. At least 50 participants must complete all parts of the testing.
- II. The testing must demonstrate that no reactions related to the product were identified.
- III. The testing must be conducted on the formulation for which the HRIPT is being submitted.
- IV. Leave-on products may not be diluted for patch testing. Rinse-off products are permitted to be diluted 1:10 for patch testing.
- V. In line with our documentation requirements noted under Criterion 5, the HRIPT should be dated within the past three years.

To show that their product provides proportional UVA and UVB protection, companies must also provide one of the following when submitting sunscreen products:

- I. An in vivo PPD test using the ISO 24442 protocol that shows a PPD value that is greater than or equal to one-third the labeled SPF
- II. A modified in vitro UVA test using the ISO 24443 methodology, where the product results indicate that the ultraviolet A protection factor is greater than or equal to

one-third the labeled SPF; and the coefficient of adjustment, "C," used to adjust the in vitro transmission measurement to the in vivo SPF must be within the range of 0.8 to 1.2, as recommended by Colipa 2012

To meet sensitivity and environmental testing requirements for wipe products, companies must submit contamination testing/summaries including residues of PAH, pesticides (or organic), dioxin, and furans, if any, readily biodegradability tests on the fiber materials by nationally or internationally recognized methods such as OECD, and pass IWSFG flushability standards, if applicable.

### CRITERION 9. Follow the EU's labeling guidelines for nanomaterials used in cosmetics.

DOCUMENTATION: Companies must sign an affidavit stating that they will follow EU labeling guidelines for nanomaterials in cosmetics within 1 year of signing the contract. At the end of the year, companies must either label nanoscaled ingredients or submit affidavits from ingredient suppliers stating that none of the ingredients in the licensed product is considered a nanomaterial, as defined by the EU in 2011: "a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm". EWG will supply companies with the necessary form, the Master Personal Care Products Affidavit, which can be downloaded from the application page.

### CRITERION 10. Indicate expiration date or the amount of time after opening within which the product must be used

DOCUMENTATION: EWG requires companies to sign an affidavit stating that product labels will indicate an expiration date or the period within which the product must be used after opening. The necessary form, the Master Personal Care Products Affidavit, can be downloaded from the application page.)

### CRITERION 11. Develop, document and follow current good manufacturing practices.

DOCUMENTATION: EWG will require companies to sign an affidavit stating they have developed and will document and follow good manufacturing practices or develop them if they have not yet done so. EWG will supply companies with the necessary form, the Master

Personal Care Products Affidavit, which can be downloaded from the application page. EWG may request a copy of a company's good manufacturing practices documentation at any time.

CRITERION 12. Pass basic microbial challenge tests and repeat them as necessary.

DOCUMENTATION: Companies must sign an affidavit stating their product either satisfies the requirements for exemption from this criterion or has passed basic microbial challenge tests. EWG also reserves the right to request either proof that the product meets the requirements for exemption or documentation of the challenge test results. The Master Personal Care Products Affidavit can be downloaded from the application page.

Additional criteria for EWG-licensed companies:

- I. Commit to reporting all product problems or serious adverse events to FDA.
- II. Acknowledge that EWG's lists of unacceptable and restricted ingredients will be updated once a year, with a phase-in period for companies to comply with updates;
- III. Acknowledge that as a condition of participating in the licensing program, EWG will add all of its licensed products to EWG's Skin Deep database if they aren't already.
- IV. Acknowledge that Skin Deep is dynamic, and the scoring algorithm may change;
- V. Acknowledge that EWG has the right to perform or commission random product tests, including through qualified third-party testing services, to ensure products meet the provisions outlined in EWG's licensing criteria.
- VI. Acknowledge that EWG has the right to approve any use of the EWG Verified mark in advertising, marketing, artwork, packaging, point-of-sale materials, website content, promotions and other materials.
- VII. Acknowledge that EWG reserves the right to prohibit use of the EWG Verified mark on any product making claims that would harm or discredit EWG or the EWG Verified program.

DOCUMENTATION: Companies must sign an affidavit stating that they acknowledge and agree to these criteria. EWG will supply companies with the necessary form, the Master Personal Care Products Affidavit, which can be downloaded from the application page.

### **APPENDICES**

# Appendix I: List of allergens required to be listed on product labels

Common name	CAS number
Amyl cinnamal	122-40-7
Amylcinnamyl alcohol	101-85-9
Benzyl alcohol	100-51-6
Benzyl salicylate	118-58-1
Cinnamyl alcohol	104-54-1
Cinnamal	104-55-2
Citral	5392-40-5
Coumarin	91-64-5
Eugenol	97-53-0
Geraniol	106-24-1
Hydroxycitronella	107-75-5
Hydroxymethylpentyl cyclohexenecarboxaldehyde	31906-04-04
Isoeugenol	97-54-1
Anisyl alcohol	105-13-5
Benzyl benzoate	120-51-4
Benzyl cinnamate	103-41-3
Citronellol	106-22-9
Farnesol	4602-84-0
Hexyl cinnamaldehyde	101-86-0
Lilial	80-54-6
d-limonene	5989-27-5
Linalool	78-70-6
Methyl heptine carbonate	111-12-6
3-Methyl-4-(2,6,6-trimethyl-2-cyclohexen-1- yl)-3-buten-2-one	127-51-5
Oak moss	90028-68-5
Tree moss	90028-67-4

# Appendix II: The International Fragrance Association's product categories table

These categories are summarized in Table 9 of the guidance for the use of IFRA standards, as follows:

Category	Product type	Sample EWG Verified product categories
1	Products applied to the lips	Lipstick, lip gloss, lip balm
2	Products applied to the axillae	Antiperspirants and deodorants
3	Products applied to the face/body using fingertips	Facial makeup, eye makeup, eye cream, wipes, masks
4	Products related to fine fragrance	Fragrance, aftershave, body spray
5	Products applied to the face and body using the hands (palms), primarily leave-on:	
5A	Body lotion products applied to the body using the hands (palms), primarily leave-on	Body creams, moisturizers, foot creams
5B	Face moisturizer products applied to the face using the hands (palms), primarily leave-on	Facial moisturizer, serums, non-makeup face products
5C	Hand cream products applied to the hands using the hands (palms), primarily leave-on	Hand creams
5D	Baby cream, oil and talc	Baby cream, baby oil, and baby talc
6	Products with oral and lip exposure	Toothpaste, mouthwash
7	Products applied to the hair with some hand contact	
7A	Rinse-off products applied to the hair with some hand contact	Masks, hair dyes
7B	Leave-on products applied to the hair with some hand contact	Hair treatments, styling aides
8	Products with significant anogenital exposure	Baby wipes
9	Products with body and hand exposure, primarily rinse off	Soaps, facial cleansers, body wash, shampoo, conditioner, bubble bath, baby wash, shaving cream

For more details, see the IFRA Guidance for the Use of IFRA Standards:

<u>ifrafragrance.org/docs/default-source/ifra-code-of-practice-and-standards/49th-amendment/ifra-49th-amendment-(att-01)---guidance-for-the-useof-ifra-standardsa7006c445f36499bbb0</u> eb141e8c0d4be.pdf?sfvrsn=7fb244c8 2

# Appendix III: Additional list of contact allergens that must not be added to OTC eczema products

EWG scientists developed this list by reviewing the contact allergens identified in <u>Goossens 2016</u> and cross-checking those substances with the <u>NEA Ecz-clusion List</u> and the ingredients found in personal care products with harmonized H317 GHS classifications for skin sensitization. Duplicate substances, substances with functions unlikely to be included in eczema products (i.e. hair dyeing), and substances with limited data on skin sensitization were excluded.

The list in this appendix is in addition to the unacceptable and restricted lists in Criteria 3 and 5. Ingredients that are already Unacceptable in Verified personal care products are not relisted in this table, but OTC eczema products must also meet all criteria laid out in this document, including criteria 3 and 5. While the ingredients in this table must not be intentionally added to EWG Verified OTC eczema products, they may be present as components of allowable ingredients. If present as components, the concentration of these substances will be limited to less than 10 ppm in the final product for leave-on products and less than 100 ppm in the final product for rinse-off products and products requiring dispersal in water.

International Nomenclature for Cosmetics Ingredient (INCI)	CAS number
Amyl Cinnamal	122-40-7
Benzyl salicylate	118-58-1
Carvone	2244-16-8 (D-) 99-49-0 (misc.) 6485-40-1 (L-)
Cinnamal	104-55-2
Cinnamyl alcohol	104-54-1
Citral	5392-40-5
Citronellol	106-22-9
Colophonium	8050-09-07

Coumarin	91-64-5
Dodecyl gallate	1166-52-5
Eugenol	97-53-0
Evernia Prunastri (Oakmoss) ingredients	90028-68-5
Evernia Furfuracea (Treemoss) ingredients	90028-67-4
Farnesol	4602-84-0
Geraniol	106-24-1
Hexyl cinnamal	101-86-0
Hydroxycitronellal	107-75-5
Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde	31906-04-04
Lanolin Alcohol	8027-33-6
Lanolin	8006-54-0
Limonene	138-86-3
Linalool	78-70-6
Methylcyclopentadecenone	82356-51-2
Myroxylon Balsamum (Balsam Tolu) ingredients	8011-89-0 9000-64-0
Myroxylon Pereirae (Balsam Peru) Oil	8007-00-9
Myroxylon Pereirae (Balsam Peru) Resin	8007-00-9
Myroxylon Pereirae (Balsam Peru) Resin Extract	8007-00-9
Shellac	9000-59-3
Shellac Cera	97766-50-2
Shellac Wax	97766-50-2
Sodium Metabisulfite	7681-57-4 7757-74-6
Glucosylrutin	130603-71-3
Tris(Nonylphenyl)Phosphite	26523-78-4