[Note – the recommended changes to the standard which include the current text of the relevant section(s) indicate deletions by use of ~~strikeout~~ and additions by grey highlighting. Rationale Statements are in *italics* and only used to add clarity; these statements will NOT be in the finished publication.]

NSF/BSR Standard
for Personal Care Products –

Personal Care Products

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1 General

1.1 Purpose

The purpose of this standard is to substantiate the quality of finished products and the safety of ingredients used in personal care products intended for human use. Products eligible for certification under this standard shall be in their finished form and undergo comprehensive assessments to ensure that they meet the necessary safety and quality criteria. This standard provides specific standards for the verification of a product's safety profile through quantitative testing and technical review.

Key components of this standard include a product safety evaluation, ingredient review, ingredient verification, label review, claims review, GMP verification, and quality testing (microbiological contaminants, metals, known adulterants, physical properties, etc.). These measures provide consumers with assurance that personal care products bearing this certification are manufactured with integrity, transparency, and attention to quality and safety.

Specific criteria for product evaluation depend upon several factors, including the contents of this standard, an accredited ISO 22716 [1] or NSF/ANSI 455 GMP certification, and the product category. Although regulatory compliance is not evaluated under the scope of this program, regulatory data and references may be evaluated to assist with safety substantiation.

1.2 Scope

[1] International Organization for Standardization. Chemin de Blandonnet 8, Case Postale 401, 1214 Vernier, Geneva, Switzerland. <iso.org>

This standard contains requirements for eligible consumer and professional-grade personal care product categories including, but not limited to, moisturizers, makeup, perfumes, cleansers, shampoo, conditioner, tonics/essences, serums, facial oils, facial masks, deodorant, oral hygiene, and topical non-prescription drugs under a regulated monograph system.

1.3 Conflicts

Where there is a demonstrated conflict between any requirement of this standard and a regulatory requirement of a country of distribution, the regulatory requirement shall take precedence. Where a requirement of this standard is more restrictive than a regulatory requirement and does not represent a violation of regulation, this does not represent a conflict, and the standard requirement shall prevail.

1.4 Exclusions from program

The scope of this standard does not include personal care tools or devices such as clippers, toothbrushes, nail files, and soap, etc. Furthermore, this standard does not include the evaluation of regulatory compliance, packaging materials, prescription (Rx) drugs that are also classified as personal care products, medical and personal care devices and tools, compounded cosmetics, or individual ingredients for use in personal care products. Injectables, tattoo inks, chemical hair dyes, and non-prescription drug products that do not follow a regulated monograph are excluded from the scope of this standard.

Concentrations of products and ingredients that have been deemed hazardous to public health or safety based on scientific data or by a regulatory agency having jurisdiction shall be excluded from the scope of this standard. Compliance with this standard does not imply that relevant regulatory requirements have been met, and evaluation of regulatory statements (e.g. California Proposition 65 [2] warnings) are out of the scope of this standard. Manufacturers and brands shall exercise due diligence to ensure compliance with all applicable regulatory requirements.

Puffery and marketing claims that do not relate to product performance or efficacy are excluded from the scope of this standard. Products making organic, cruelty-free, or similar claims shall provide relevant documentation to substantiate the claim. Products bearing a certification mark for organic, cruelty-free, or similar claims shall substantiate they are certified by an appropriate regulatory authority or certifying body to be eligible for certification to this standard.

Products with claims establishing an intended use rendering it a drug as defined by this standard, excepting those defined in the scope of this document, are excluded from this standard.

1.5 Document submission

[2] State of California, Office of Administrative Law. 300 Capitol Mall, Suite 1250, Sacramento, CA 95814. <govt.westlaw.com/calregs>

To inform the product review, the company shall submit the following documentation (required unless otherwise noted) for each product:

- GMP site compliance records (proof of current certification by an accredited certifying body to accredited ISO 22716, NSF/ANSI 455-3, or NSF/ANSI 455-4 program)
- product formulation file: Complete formulation information for all ingredients, which includes:
    - raw material number assigned by the manufacturer
    - INCI[3] name of substance
    - trade name (including those of blend subcomponents if applicable)
    - supplier name
    - intended function of the ingredients
    - CI[4] number for pigments and colors
    - nanomaterial disclaimers (Y/N)
    - CMR disclaimer (Y/N)
    - CAS #
    - European Community #
    - percentage of ingredients present in the final product in descending order (wt/wt):
        - Ingredients shall amount to 100%.
        - Separate each ingredient if it is a mixture or blend.
- raw material assessment files: For each raw material present in a product formulation, the following documents shall be provided to validate the safety of the ingredient:
    - COA containing:
        - identity assay (if applicable)
        - analytical and microbiology specification
        - analytical/chemistry testing data
        - microbiological testing data (if applicable).

[3] Personal Care Products Council. 1620 L Street NW, Suite 1200, Washington, DC 20036. <personalcarecouncil.org>

[4] Colour Index™. Society of Dyers and Colourists (SDC) and American Association of Textile Chemists and Colourists (AATCC). <colour-index.com>

- technical data sheet (if available)
- SDS containing:
  - raw material toxicological data
- raw material allergen declaration (if applicable)
- IFRA[5] certificate for flavors (if applicable)
- IFRA certificate for fragrances (if applicable)
- Prop 65[2] statement (if applicable)
- no presence of nanoparticle statement (if applicable)
- no animal testing statement (if applicable)

- finished product safety assessment files: Each product being certified to this standard shall provide the following documents to assess the safety of the finished product:
  - finished product COA containing:
    - finished product analytical testing specification
    - finished product microbiology testing specification.

- preservative efficacy/challenge testing (if applicable):
  - If available at initial certification application, applicants may provide previously performed preservative efficacy/challenge testing data in compliance with the criteria outlined in Section 7.1 of this standard. If data is not available at initial certification, challenge testing will be performed to determine initial program eligibility. Applicants may not supply subsequent challenge testing data performed after the initial certification application.

- preservative efficacy/challenge testing exemption data (if applicable)
- stability study specification and stability study data

[5] International Fragrance Association. Cours de Rive 11, 1204 Geneva, Switzerland. <ifrafragrance.org>

- heavy metals/elemental impurities USP <232> or <233> [6]
- RIPT or sensitivity study (if applicable)
- finished product clinical studies
- finished product SDS
- use after opening study (if applicable)
- API testing and method validation (if applicable)
- finished product API testing (if applicable)
- characterization of the normal and customary use of the product including:
    - site of application
    - surface area of application (if applicable)
    - amount of product applied (if applicable)
    - duration and frequency of use
    - targeted population.
- product artwork and claims substantiation files: Each product being certified to this standard shall provide the product label, relevant marketing artwork, and claims substantiation documentation to verify claims and labeling. These documents shall include the following information:
    - name and address of the manufacturer
    - name and address of the packer
    - primary and secondary packaging specification
    - packaging declaration
    - claims and substantiation studies (if applicable)
    - directions for use
    - warnings (if applicable)
    - final artwork for primary packaging
    - final artwork for secondary packaging
    - fill weight study
    - country of origin
    - additional documentation can be required depending on claims and region of sale:

[6] United States Pharmacopeia. 12601 Twinbrook Parkway, Rockville, Maryland 20852-1790. <usp.org>

- no animal testing statement (if applicable)
- non-presence of nano particle statement (if applicable)
- Prop 65 [2] statement (if applicable).

2 Normative references

The following documents contain requirements, which by reference in this text, constitute requirements of this standard. At the time this standard was balloted, the editions listed below were valid. All documents are subject to revision, and parties are encouraged to investigate the possibility of applying the recent editions of the documents indicated below. The most recent published edition of the document shall be used for undated references.

21 CFR, *Food and Drugs* (Federal Food, Drug, and Cosmetic Act (FD&C Act)). [7]

Duarte, Ida, Jéssica Eleonora P. S. Silveira, Mariana de Figueiredo Silva Hafner, Raquel Toyota, and Debora Midori M. Pedroso. "Sensitive Skin: Review of an Ascending Concept." *Anais Brasileiros de Dermatologia* 92 (4): 521–25. 2017. [8]

European Commission, *Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products*. [9]

European Commission, *Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products* [9]

Health Canada, *Guidance on Heavy Metal Impurities in Cosmetics*, 2012. [10]

ISO 11930:2019, *Cosmetics – Microbiology – Evaluation of the antimicrobial protection of a cosmetic product* [1]

ISO 16212:2017, *Cosmetics — Microbiology — Enumeration of yeast and mold* [1]

ISO 16128-1:2016, *Standards on technical definitions and criteria for natural and organic cosmetic ingredients and products — Part 1: Definitions for ingredients* [1]

ISO 16128-2:2017, *Cosmetics — Standards on technical definitions and criteria for natural and organic cosmetic ingredients — Part 2: Criteria for ingredients and products* [1]

[7] Code of Federal Regulations, Office of the Federal Register, National Archives and Records Administration. 7 G Street NW, Suite A-734, Washington, DC 20401. <ecfr.gov>

[8] Anais Brasileiros de Dermatologia. <doi.org/10.1590/abd1806-4841.201756111>

[9] European Commission, European Union. Charlemagne Building, Rue de la Loi 170, 1040 Brussels, Belgium. <commission.europa.eu>

[10] Health Canada. Address Locator 0900C2, Ottawa, Ontario K1A 0K9, Canada. <canada.ca/en/health-canada.html>

ISO/TR 17276:2014, *Cosmetics — Analytical approach for screening and quantification methods for heavy metals in cosmetics* [1]

ISO 17516:2014, *Cosmetics – Microbiology – Microbiological limits* [1]

ISO 18416:2015, *Cosmetics — Microbiology — Detection of Candida albicans* [1]

ISO 21148:2017, *Cosmetics – Microbiology – General instructions for microbiological examination* [1]

ISO 21149:2017, *Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria* [1]

ISO 21150:2015, *Cosmetics — Microbiology — Detection of Escherichia coli* [1]

ISO/DIS 21392, *Cosmetics — Analytical methods — Measurement of traces of heavy metals in cosmetic finished products using ICP/MS technique* [1]

ISO 22715:2006, *Cosmetics – Packaging and labeling* [1]

ISO 22717:2015, *Cosmetics — Microbiology — Detection of Pseudomonas aeruginosa* [1]

ISO 22718:2015, *Cosmetics — Microbiology — Detection of Staphylococcus aureus* [1]

ISO 23674, *Cosmetics — Analytical methods — Direct determination of traces of mercury in cosmetics by thermal decomposition and atomic absorption spectrometry (mercury analyser)* [1]

ISO 23821, *Cosmetics — Analytical methods — Determination of traces of mercury in cosmetics by atomic absorbtion spectrometry (AAS) cold vapour technology after pressure digestion* [1]

ISO 29621:2017, *Cosmetics – Microbiology – Standards for the risk assessment and identification of microbiologically low-risk products* [1]

IUPAC. Compendium of Chemical Terminology, 2nd ed. (the "Gold Book"). Compiled by A. D. McNaught and A. Wilkinson. Blackwell Scientific Publications, Oxford (1997). Online version (2019-) created by S. J. Chalk. ISBN 0-9678550-9-8. https://doi.org/10.1351/goldbook

NSF/ANSI 455-3: *Good Manufacturing Practices for Cosmetics*

NSF/ANSI 455-4: *Good Manufacturing Practices for Over the Counter (OTC) Drugs*

Roberts, Ka Roach. "A Comprehensive Summary of Disease Variants Implicated in Metal Allergy." *Journal of Toxicology and Environmental Health. Part B, Critical Reviews* 25 (6): 279–341. 2022.[11]

Scientific Committee on Consumer Safety (SCCS), Scientific Opinion on The Report of the ICCR Working Group: Considerations on Acceptable Trace Level of 1,4-Dioxane in Cosmetic Products

[11] <doi.org/10.1080/10937404.2022.2104981>

Scientific Committee on Consumer Safety (SCCS), Opinion on Nitrosamines and Secondary Amines in Cosmetic Products

Scientific Committee on Consumer Safety (SCCS), Opinion on Phthalates in Cosmetic Products

Scientific Committee on Consumer Safety), SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation 12th revision, 15 May 2023, corrigendum 1 on 26 October 2023, corrigendum 2 on 21 December 2023, SCCS/1647/22

State Of California Environmental Protection Agency Office Of Environmental Health Hazard Assessment (OEHHA) Safe Drinking Water And Toxic Enforcement Act Of 1986, Chemicals Known To The State To Cause Cancer Or Reproductive Toxicity [2]

U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER). Control of Nitrosamine Impurities in Human Drugs Guidance for Industry. Pharmaceutical Quality/Manufacturing Standards (CGMP), Revision 2.

United Nations (UN), Globally Harmonized System of Classification and Labelling of Chemicals (GHS) revision 8

3 Definitions

Terms used in this standard that have a specific technical meaning are defined here.

adulteration: As defined by the Federal Food, Drug and Cosmetic Act.

adverse event: Any harmful health-related event associated with the use of a product.

animal testing: Any testing of a finished product formulation or any of its ingredients on non-human animals. Animals include all non-human invertebrate and vertebrate members of the taxonomic kingdom Animalia. This includes but is not limited to non-human mammals, reptiles, amphibians, birds, fish, crustaceans, and insects.

audit: A systemic evaluation to determine if programs and related activities achieve planned expectations, including the review or challenging of written programs, documentation of activities, corrective actions, and trends to determine the correlations between documented procedures and activities and actual execution.

amine group: Compounds with a functional group consisting of a nitrogen atom bonded to one or more hydrogen atoms and possibly to carbon-containing groups (such as alkyl or aryl groups) with the general structures of RNH2 (primary amines), RR'NH (secondary amines), RR'R''N (tertiary amines).

baby products: Products intended for children under 3 yr of age, unless defined differently by state laws.

Chemical Abstracts Service (CAS) Registry Number: A universally recognized, unique identifying number for a chemical substance or molecular structure.

compounded cosmetic: Cosmetic product result of the combination, mix or alteration of ingredients to create a product tailored to the needs of an individual.

colorant: *(1)* a dye, pigment, or other substance made by a process of synthesis, or similar artifice; or extracted, isolated, or otherwise derived; with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source; and *(2)* when added or applied to a cosmetic is capable (alone or through reaction with other substances) of imparting color thereto.

cosmetic: A product that:

- is an "article intended to be rubbed, poured, sprinkled or sprayed on, introduced into, or otherwise applied to the human body, or any part thereof, for cleansing, beautifying, promoting attractiveness, or altering the appearance… except that such term shall not include soap" [FD&C Act, Sec. 201(i)]

- includes, but is not limited to, products such as: skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, cleansing shampoos, permanent waves, hair colors, oral hygiene, and deodorants; as well as any substance intended for use as a component of a cosmetic product.

cosmetic device: An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is used to improve appearance, and do not impart any health benefits. [21 USC 321]

cosmetic ingredient: An ingredient intended for use or used in a cosmetic or personal care product, including any excipient (inactive) ingredients that can be necessary for the manufacturing of products.

Cruelty-free: A marketing term for the finished product produced without animal testing and which contains no animal-derived ingredients for which the production resulted in harm or killing of any animal, excluding microorganisms and invertebrates.

drug: Any product intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or that has a purpose to restore, correct, or modify physiological functions by exerting a pharmacological, immunological, or metabolic action.

eye area: The area enclosed within the circumference of the supra-orbital ridge and the infra-orbital ridge, including the eyebrow, the skin below the eyebrow, the eyelids and the eyelashes, the conjunctival sac of the eye, the eyeball, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge.

finished product: A product requiring no further processing prior to sale to the consumer.

fragrance: A blend of aromatic compounds, essential oils, or synthetic chemicals that are intentionally added to a product to alter the smell or odor.

flavor: A substance or mixture of substances intentionally added to a product to provide a taste or enhance the taste experience when applied.

free from: A claim indicating that a finished product does not contain any intentionally added amount of the material the claim is being made about. This does not indicate that the material is completely not present, but rather that it was not added to the product directly.

Good Manufacturing Practices (GMP): The aspect of quality assurance to create and implement accredited quality systems and ensure proper design, monitoring and controlling of manufacturing process and facilities while focusing to ensure the final product has the identity, strength, composition, quality, safety, and purity as specified.

hypoallergenic: A product that has been designed to minimize the potential of eliciting an immune response in a sensitized individual after exposure.

International Nomenclature of Cosmetic Ingredients (INCI): Systematic name for waxes, oils, pigments, chemicals, and other ingredients used in personal care or cosmetic products.

lot number (control number or batch number): Any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined. [7]

nitrosamine: A class of compounds having the chemical structure of a nitroso group bonded to an amine (R1 N(-R2)-N=O).

organoleptics: The sensory characteristics of a product perceived through the senses of sight, smell, taste, and touch.

over-the-counter (OTC) drug: Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals" [FD&C Act, sec. 201(g)(1)].

personal care product: A cosmetic or OTC Drug product applied externally that is for use in such activities as cleansing, toning, moisturizing, hydrating, exfoliating, conditioning, anointing, massaging, coloring/decorating, soothing, deodorizing, perfuming, and styling.

perfluoroalkyl and polyfluoroalkyl substances or "PFAS": Chemical substances containing at least one of the following structures:

- R-(CF_2)-CF(R′)R″, where both the CF_2 and CF moieties are saturated carbons.
- R-CF_2OCF_2-R′, where R and R′ can be F, O, or saturated carbons.
- $CF_3C(CF_3)$R′R″, where R′ and R″ can be F or saturated carbons.

puffery claim: An extremely broad, vague, and subjective statement that is so exaggerated that it is not likely to be believed and cannot be testable from the standpoint of measurement operations or from a practical standpoint.

quality: For the purposes of this standard refers to finished personal care products that are demonstrated to be below microbial, heavy metal, and adulterant thresholds appropriate for the population to which they are marketed, as defined within this standard

safe: The finished product, including any ingredient, is not injurious to consumers under the conditions prescribed in the labeling or under normal and customary use. A cosmetic ingredient or cosmetic product is not considered "unsafe" to consumers solely because it can cause minor and transient reactions or minor and transient skin irritations in some users. [21 USC 364d]

safety assessment data: Information to support the product's safety for intended applications. This support includes but is not limited to relevant chemical data, toxicological review, microbiological studies and exposure assessments.

secondary amine: Compounds formally derived from ammonia by replacing two hydrogen atoms with hydrocarbyl groups (e.g. ethyl, phenyl) and having the general structure RR'NH.

sensory claim: An advertising message about a product's sensory attributes, its functionality or performance, or the consumers' affective or perceptual responses to a product before, during, or after use.

sensitive skin: A condition in which the skin becomes easily red, swollen, dry, cracked, or irritated, including sensations such as stinging, tingling, burning, or itching that is not associated with an allergic immune response and that does not typically occur in the general population (Duarte et al., 2017)

skin sensitizer: A substance or mixture that can induce an immune response in an individual after one or typically multiple exposures (i.e. the individual becomes sensitized) that can lead to an inflammatory allergic reaction (elicitation of an immune response) upon subsequent exposure.

soap: Products that consist primarily of alkali salts of fatty acids, making no label claim other than cleansing of the human body, and sold and labeled only as soap.

specification: Written statement of the ingredient, in-process material, or finished product's required characteristics documented in a manner that facilitates its proper production and acceptance.

toxic: Having the potential to cause harm or negative side effects to the humans, animals, or the environment at the exposure level that can reasonably be expected based upon the product formula and use instructions.

vegan: Finished product that does not contain any animal-derived ingredients or by-products and was not processed using animal-derived processing aids.

4 Labeling and literature requirements

4.1 Labeling requirements

The product's packaging shall declare the following labeling requirements, at a minimum:

- manufacturer/brand owner name
- manufacturer/brand owner address
- consumer complaint contact information
- ingredients listed in descending order of weight (if present at greater than 1%) using INCI
- fragrances (perfumes and aromatic compositions) may be listed as a single ingredient
- colorants may be listed in any order following the other ingredients
- product's intended use/function
- storage conditions (when appropriate)
- weight or volume at time of packaging
- batch number, date of manufacture, or any reference identifying the product
- precautions and warning statements (when appropriate)
- instructions for use (when appropriate)
- expiration date (if applicable)
- all products shall bear proper storage directions
- for cosmetic products that are also OTC drugs, a fully compliant Drug Facts panel according to country of sale's regulatory requirements
- OTC drugs making cosmetic claims shall comply with correct Inactive ingredient listing under Drug Facts regulations. All OTC drugs shall comply with PL 109-462.

All labeling requirements shall be present in the official language of the region(s) where the product is distributed and comply with any requirements for the market where the product is intended to be sold.

Marketing materials may also be reviewed to ensure consistency with labeling materials.

4.2 Product requirement claims

4.2.1 General

The word "claim" in this standard refers to both explicit and implied claims, and an equivalent level of substantiation applies. Claims shall include words, trademarks, pictures, branding or any imagery that conveys meaning, and implied claims can be evaluated within the overall context of these.

Product and ingredient claims shall not represent or imply prevention, healing or treatment of any disease state or injury, except that if a product contains claims of such nature, they shall be aligned to an existing OTC monograph for that specific type of product.

If a product is marketed as containing a specific ingredient, it shall be deliberately present in the INCI listing and product formulation documents.

4.2.2 Unauthorized claims and language

The following claims (or variants of) shall not be allowed for any product certified under this standard:

- preservative-free
- chemical-free
- permanent results
- 100% "safe"
- zero PFAS
- zero THC
- toxin-free

Claims may be permissible with a statement qualifying a defined to be below a specific limit of detection.

4.2.3 "Organic" and "cruelty-free" claims

Products claiming to be organic or cruelty-free (or similar) shall be independently certified by a third party or require documentation supporting the organic and cruelty-free status of relevant raw materials.

4.2.4 "Made for sensitive skin" claims

To support claims such as "made for sensitive skin," whether direct, similar, or implied, this standard requires a list of product ingredients for blended products or the components of the finished product composition for reacted products. This requirement applies only when there is no evidence suggesting that these ingredients or components work synergistically to cause sensitivity. Where data is not available to substantiate the full formulation or final product composition, an appropriate in-human trial with a cohort of self-perceived sensitive skin participants on the finished product is required.

4.2.5 "Hypoallergenic" claims

For direct, similar, or implied claims of "Hypoallergenic" claims shall be made only where a product formulation (for blended products) or finished composition (for reacted products) includes no ingredients (including components of fragrances) classified as dermal sensitizers under the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) nor fragrance ingredients classified as allergens under EU Regulation No. 1223/2009 Annex III. In addition, the product shall be tested to demonstrate the absence of allergenic metal ingredients or contaminants, including nickel, cobalt, chromium and gold (Roberts, 2022). The client shall provide scientifically robust and statistically reliable data to support the claim.

In the absence of ingredient or component data that support a lack of sensitization potential, this standard mandates finished product testing using the HRIPT on a minimum panel of 200 individuals. The testing shall demonstrate that the product formulation does not induce dermal sensitization.

It is noted that the term "hypoallergenic" has no legal definition. As such, meeting these testing requirements and using the term "hypoallergenic" do not guarantee the absence of risk of an allergic reaction to the product.

4.2.6 "Free of" claims

"Free of" claims may be explicit or implied by the use of imagery or marketing terms such as "vegan" (e.g. free of animal-sourced materials), "all natural" (i.e. free of synthetic ingredients), or "hypoallergenic" (i.e. free of skin sensitizers and allergen precursors). Indirect "free of" claims can have other implied claims within them, which are out of the scope of this certification.

Products claims to be "free of" a substance shall:

- be clearly and prominently qualified to the extent necessary to avoid deception
- not contain the substance as an intentional ingredient in the formulation
- not contain or use substances that pose the same or similar risks as the substance that is not present (e.g. contains skin sensitizing ingredients while making "fragrance-free" claims)
- not contain detectable levels of the specified substance except in the case that the substance is a naturally occurring constituent of one or more product ingredients. In this case, the substance shall:
  - not be present more than that which would be found as an acknowledged trace contaminant or background level, which shall be demonstrated by finished product specifications or raw material specifications that control for this presence
  - not cause material harm that consumers typically associate with that substance based on the trace levels of the substance that can be present. This shall be justified in the product safety assessment. Approaches that may be used include, as appropriate:

- If an acceptable safety exposure level has already been established by a regulatory agency or recognized scientific organization, this acceptable exposure level can be considered for adoption if relevant to the product class or use instruction.
- Acceptable trace exposures can be established based on available toxicological data and appropriate risk-assessment methods, which may include a read-across approach where structural analogs exist.

- In the case of sensitizers, quantitative risk assessment demonstrating the trace level is below the NOAEL.

"Free of" claims shall not be used if the substance has not been associated with the product category or if there is the prohibition of its use in the jurisdiction of sale.

"Free of" claims that are unverifiable are excluded from products certified under this standard.

5 Formulation requirements and ingredient identity

5.1 Ingredient acceptability

Ingredients permitted in personal care products shall comply with EC 1223/2009, [9] 21 CFR Part 700.11-700.27, [7] and any other applicable regulatory body as described below:

- Prohibited ingredients listed in EC 1223/2009, Annex II: *List of substances prohibited in cosmetic products* or 21 CFR 700 are not permitted for use in personal care products undergoing certification to this standard.
- Restricted ingredients listed in EC 1223/2009, Annex III: *List of substances which cosmetic products must not contain except to the restrictions laid down*, colorants listed in EC 1223/2009, Annex IV: *List of colorants allowed in cosmetic products*, preservatives listed in EC 1223/2009 Annex V *List of preservatives allowed in cosmetic products*, and UV filters listed in 21 CFR § 352 shall meet any applicable limitations provided by the directive including, but not limited to, use level and product type limitations and required warning statements. If an ingredient has a contamination limit less restrictive than that required by this standard, the limit imposed by this standard shall take precedence.
    - Dual purpose or natural ingredients used as preservatives and complying with all other appendices are acceptable in addition to those listed in EC 1223/2009 Annex V.
- Personal care products shall not contain intentionally added perfluoroalkyl and polyfluoroalkyl substances (PFAS). Intentionally added PFAS means either of the following:

- PFAS chemicals that a manufacturer has intentionally added to a product and that have a functional or technical effect on the product
- PFAS chemicals that are intentional breakdown products of an added chemical.

The maximum allowed intentionally added secondary amine content in finished cosmetic products shall not exceed 0.5%. The maximum content limit for traces of nitrosamines shall not exceed 50 µg/kg (50 ppb) in raw materials and finished products.

To protect against bovine spongiform encephalopathy (BSE), also known as "mad cow disease," personal care products may not be manufactured from, processed with, or otherwise contain prohibited cattle materials. These materials include specified risk materials material from non-ambulatory disabled cattle, material from cattle not inspected and passed, or mechanically separated beef. Prohibited cattle materials do not include tallow that contains no more than 0.15 % insoluble impurities, tallow derivatives, hides and hide-derived products, and milk and milk products (21 CFR § 700.27[7]).

5.2 Content claim verification

Any raw material or ingredient for which a content claim is made on the finished product, including but not limited to "contains," "made with," or bold print for the ingredient name within the ingredient list, shall have its identity tested in compliance with Section 7. The active API(s) in non-prescription drug products following regulatory monographs are excluded from this testing.

If the content claim cannot be verified by finished product testing, the certifying body may test raw materials. If no scientifically valid or acceptable method is available for raw material testing, the manufacturer or their supplier may provide test data to be used for evaluating ingredients.

Manufacturing records for a representative production batch shall be reviewed and considered sufficient for evaluation of content claim verification in instances where manufacturer or supplier test data is not sufficient.

Manufacturer test data shall be generated using methods meeting the requirements of Section 7 of this standard.

6 Product physical characterization

6.1 Contaminants

6.1.1 Microbiological contaminants

Personal care products shall not contain microorganisms at quantities that can compromise consumer safety or product quality during intended use.

These quantitative microbiological limits for personal care products are summarized and described in Table 6.1.

Products that contain any ingredient intended for preservative function shall undergo a preservative efficacy test. Acceptance criteria are listed in Table 6.2. If a product meets criterion A, it meets the requirements of preservative efficacy for this standard. If a product meets criterion B but not A, other control factors related to the packaging shall be considered to determine acceptability per ISO 11930:2019, Annex B. These can include any of the following:

- single or multiple-use packaging
- size of the package
- mode of dispensing the product
- predicted use-up rate
- whether the package type allows for direct consumer contact
- whether the package is pressurized.

Certain products with characteristics that create a hostile environment for microbial growth may be exempt from preservative challenge testing. For a product to be eligible for exemption from preservative challenge testing, it shall meet one of the following criteria:

- products that are a soap or solid cleansing bar that is primarily the alkali salt of fatty acids
- products containing greater than or equal to 20% by volume or mass alcohol
- products with a water activity (aw) less than 0.6
- products containing ammonia level greater than or equal to 0.5 % or monoethanolamine level greater than or equal to 1 %
- products with pH less than or equal to 3 or greater than or equal to 10,
- products containing organic solvents (e.g. ethyl acetate and butyl acetate in nail enamel) greater than 10%
- products containing hydrogen peroxide (e.g. bleaching) greater than or equal to 3%
- products containing aluminum chlorohydrate and related salts (e.g. antiperspirants) greater than or equal to 25%.

If a product does not meet any of the above criteria, nor does it include a preservative, it shall meet the acceptable limits for microbial contaminants listed in Table 6.1 and the acceptable log reduction of microbial species outlined in Table 6.2 to be eligible for certification.

Table 6.1
Acceptable Limits for Microbial Contaminants

Microorganism	Products intended for children under 3 yr, the eye area, or mucous membranes	Other products
Total Aerobic Mesophilic Microorganisms (Bacteria plus yeast and mold)	≤ 1×10^2 CFU per g or mL [a]	≤ 1×10^3 CFU per g or mL [b]
Escherichia coli	absence in 1 g or 1 mL	absence in 1 g or 1 mL
Pseudomonas aeruginosa	absence in 1 g or 1 mL	absence in 1 g or 1 mL
Staphylococcus aureus	absence in 1 g or 1 mL	absence in 1 g or 1 mL
Candida albicans	absence in 1 g or 1 mL	absence in 1 g or 1 mL
Burkholderia cepacian	absence in 1 g or 1 mL	absence in 1 g or 1 mL
Aspergillus brasiliensis	absence in 1 g or 1 mL	absence in 1 g or 1 mL
Streptococcus pyogenes	absence in 1 g or 1 mL	absence in 1 g or 1 mL
Klebsiella pneumoniae	absence in 1 g or 1 mL	absence in 1 g or 1 mL
Salmonella	absence in 1 g or 1 mL	absence in 1 g or 1 mL

Note 1. When colonies of bacteria are detected on Sabouraud Dextrose agar, Sabouraud Dextrose agar containing antibiotics may be used (ref. SCCS/1564/15, Table 5).

Note 2. Due to inherent variability of the plate count method, according to USP Chapter 61 or EP Chapter 2.6.12, *Interpretation of results*, results considered out of limit if:

[a] Greater than 200 CFU/g or mL

[b] Greater than 2,000 CFU/g or mL

Table 6.2
Acceptable log reduction for preservative efficacy test

Log reduction values ($Rx = lgN_0 - lgN_x$) required [a]								
Micro organisms	Bacteria [b]			*C. albicans*			*A. brasiliensis*	
Sampling time	T7	T14	T28	T7	T14	T28	T14	T28
Criteria A	≥ 3	≥ 3 and NI [c]	≥ 3 and NI	≥ 1	≥ 1 and NI	≥ 1 and NI	≥ 0 [d]	≥ 1 and NI
Criteria B	Not performed	≥ 3	≥ 3 and NI	Not performed	≥ 1	≥ 1 and NI	≥ 0	≥ 0 and NI

[a] N_0 shall be between 1×10^5 CFU/mL and 1×10^6 CFU/mL or g for the bacteria, and between 1×10^4 CFU/mL and 1×10^5 CFU/mL or g for *C. albicans* and *A. brasiliensis*.

[b] Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, strains specified in ISO 11930:2019

[c] NI: no increase in the count from the previous contact time.

[d] R_x = 0 when $lgN_0 = lgN_x$ (no increase from the initial count)

6.1.2 Heavy metals

Finished personal care products shall not contain heavy metals in excess of the following concentrations, which are considered technically avoidable: [12]

- antimony shall not exceed 5 ppm
- arsenic shall not exceed 3 ppm
- cadmium shall not exceed 3 ppm
- lead shall not exceed 10 ppm
- mercury shall not exceed 1 ppm.

In addition, heavy metal limits shall meet federal, state, and local requirements for the jurisdictions where the product will be sold.

6.1.3 Allergenic metals

Finished personal care products bearing hypoallergenic or similar claims shall not contain metals that can elicit an allergic response in excess of the following concentrations, which are considered technically avoidable:

- nickel shall not exceed 1 ppm
- cobalt shall not exceed 1 ppm
- chromium shall not exceed 1 ppm
- gold shall not exceed 1 ppm.

6.1.4 Known adulterants

Products shall not contain known adulterants as raw materials or as impurities created within manufacturing processes. Where an impurity is associated with a raw material, and finished product testing is not feasible, testing may be performed on the raw material. Acceptability shall be extrapolated based on the formula composition.

Compliance with these requirements shall be evaluated using a risk-based approach, which includes third-party analytical testing or demonstrated control through material qualification and verification of ingredient CoA by the manufacturer.

6.1.4.1 Products containing hemp shall not contain total delta-9 THC exceeding 0.3% on a dry weight basis. The determination of the delta-9 THC concentration shall include the potential conversion of THCA into delta-9 THC using a factor of 0.8773:

[12] Health Canada, *Guidance on Heavy Metal Impurities in Cosmetics*, 2012

Total Δ9 THC% = Δ9 THC% + 0.8773 THCA%

6.1.4.2 Products shall not contain benzene exceeding 2 ppm (USP 467).

6.1.4.3 Products containing talc shall not contain detectable asbestos in the raw material (USP Talc monograph).

6.1.4.4 Products containing any alcohol shall not contain methanol exceeding 200 ppm (USP Alcohol monograph).

6.1.4.5 Products containing ethoxylated ingredients (e.g. containing "PEG," "polyethylene," "polyethylene glycol," "polyoxyethylene," "-eth-," or "oxynol" in their names) shall not contain 1,4-Dioxane exceeding 10 ppm.

In addition, 1,4 dioxane limits shall also meet federal, state and local requirements for the jurisdictions the product will be sold.

6.1.4.6 Products containing ethoxylated ingredients (e.g. containing "PEG," "polyethylene," "polyethylene glycol," "polyoxyethylene," "-eth-," or "oxynol" in their names) shall not contain ethylene oxide exceeding 1 ppm.

6.1.4.7 The maximum content limit for traces of nitrosamines will not exceed of 50 µg/kg (50 ppb) in raw materials and finished products.

6.1.4.8 All products seeking certification under this standard will be evaluated for the presence of perfluoroalkyl and polyfluoroalkyl substances (PFAS). Testing shall verify that specific PFAS compounds are present at concentrations below established safety thresholds, specifically:

- the concentration of perfluorooctanoic acid (PFOA) shall be less than 25 ng/g
- the concentration of PFOA related compounds shall be less than 1000 ng/g (including perfluoro-3-methylheptanoic acid
- the concentration for the sum of C9-C14 perfluorocarboxylic acids (PFCA) and their precursors shall be less than 25 ng/g, including:

    - perfluorononoic acid
    - perfluorodecanoic acid
    - perfluoroundecanoic acid
    - perfluorododecanoic acid
    - perfluorotridecanoic acid
    - perfluorotetradecanoic acid.

- The concentration for the sum of C9-C14 PFCA-related substances shall be less than 260 ng/g, including:
    - perfluoro-7-methyloctanoic acid
    - perfluoro-4-methyloctanoic acid
    - perfluoro-3,5,5-trimethylhexanoic acid
    - perfluoro-3,7-dimethyloctanoic acid.

Identifying PFAS adulteration is limited due to the hypothesized existence of over 8,000 compounds. The vast majority of these lack reference standards, test methods or safety data. A commonality among many of these chemicals is their persistence within the body and the environment. This persistence, along with the state of science, justifies evaluating specific PFAS that pose a known high risk to public health.

6.1.4.9 Products marketed for skin lightening or brightening shall not contain any of the following compounds at a concentration greater than 5 µg/g, verified by testing in accordance with Section 7.3. Other substances that are not cosmetic ingredients and have similar biological activity can be adulterants.

Substances
betamethasone dipropionate
betamethasone 17-valerate
betamethasone
clobetasol propionate
clotrimazole
halobetasol propionate
hydroquinone
fluocinonide
fluocinolone
fluocinolone acetonide

6.2 Product physical characterization

The product's physical characteristics shall meet the provided product specifications. Where applicable, the following characteristics will be verified prior to product certification based on the stability study protocols outlined in Section 7.

6.2.1 pH

Where appropriate, product pH shall be characterized to verify product specifications, determine microbiological testing requirements, or support advertising claims.

6.2.2 Viscosity

Where appropriate, product viscosity shall be characterized to match provided finished product specifications for the product.

6.2.3 Density/specific gravity

Where appropriate, product density/specific gravity shall be characterized to match the provided finished product specifications.

6.2.4 Odor/fragrance

The product odor/fragrance shall be characterized to match the provided finished product specifications for the product.

6.2.5 Color

The product color shall be characterized to match the provided finished product specifications for the product.

6.2.6 Product form/consistency

The product form and consistency shall be characterized to match the provided finished product specifications for the product.

6.2.7 Water activity

When applicable, water activity verification shall be required to exempt a product from microbiological challenge testing.

7 Test methods

Data used for evaluating contaminates and adulterants in a product certified against this standard shall be generated by labs compliant with ISO 17025, with applicable test methods reflected on the ISO scope.

Test methods shall be scientifically valid. Methods meeting this requirement are any of the following:

- compendial or ISO methods
- in-house methods validated according to international standards (e.g. AOAC International, IUPAC, ISO)
- in-house methods validated by an in-house validation procedure, with the procedure having appropriate documentation
- in-house methods demonstrated to be scientifically valid and fit for purpose using an in-house protocol. The protocol shall:
    - demonstrate precision, specificity, and accuracy
    - document the range of concentrations and applicable matrices
    - utilize certified reference standards or materials where available. Compendial methods may be modified, providing those modifications are properly verified.

Methods shall be utilized within their established scope of applicability, except where there is a scope extension documented.

Methods meeting the above requirements and demonstrated to yield equivalent or better results compared to methods specified in this standard may be utilized, including in place of those specified.

7.1 Test methods for microbiological contaminants and challenge testing

Testing for total aerobic mesophilic microorganisms*, E. coli, P. aeruginosa, S. aureus, C. albicans, B. cepacian, A. brasiliensis, S. pyogenes, K. pneumoniae,* and *Salmonella* shall be performed in accordance with the currently promulgated version of the applicable Cosmetics Microbiology ISO standard and other listed methods. Testing methods shall adhere to those described in:

- ISO 21149: *Enumeration and detection of aerobic mesophilic bacteria*
- ISO 16212: *Enumeration of yeast and mold*
- ISO 21150: *Detection of* Escherichia coli
- ISO 22717: *Detection of* Pseudomonas aeruginosa
- ISO 22718: *Detection of* Staphylococcus aureus
- ISO 18416: *Detection of* Candida albicans
- PCPC M – 2 – *Method for detection of* Staphylococcus aureus, Escherichia coli *and* Pseudomonas aeruginosa *in cosmetic products*
- USP <60>:*Test for* Burkholderia cepacia *Complex*

- USP <61>: *Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests*
- USP <62>: *Microbiological Examination of Non-Sterile Products: Tests for Specified Organisms.*

Preservative efficacy testing shall be performed according to any of the following methods:

- ISO 11930: *Cosmetics — Microbiology — Evaluation of the antimicrobial protection of a cosmetic product*
- USP <51>: *Antimicrobial Preservative Effectiveness Test*
- PCPC M-1: *Determination of the Microbial Content of Cosmetic Products*
- PCPC M-3: *A Method for Preservation Testing of Water-Miscible Personal Care Products*
- PCPC M-4: *Method for Preservation Testing of Eye Area Cosmetics*
- PCPC M-5: *Methods for Preservation Testing of Nonwoven Substrate Personal Care Products*
- PCPC M-6: *A Method for Preservation Testing of Atypical Personal Care Products*
- PCPC M-7: *A Rapid Method for Preservation Testing of Water-Miscible Personal Care Products*
- *Bacteriological Analytical Manual* (BAM), 8th Edition, Revision A, 1998.

7.2 Test methods for heavy metals

The presence of antimony, arsenic, cadmium, lead, and mercury shall be measured in accordance with the currently promulgated version of the applicable Cosmetics ISO standard or USP standards. Testing methods shall adhere to those described in any of the following:

- ISO/DIS 21392: *Cosmetics — Analytical methods — Measurement of traces of heavy metals in cosmetic finished products using ICP/MS technique*
- ISO/TR 17276: *Cosmetics — Analytical approach for screening and quantification methods for heavy metals in cosmetics*
- ISO/AWI 23674: *Cosmetics — Analytical methods — Determination of traces of mercury in cosmetics by integrated mercury analytical systems*
- ISO/AWI 23821: *Cosmetics — Analytical methods — Determination of traces of mercury in cosmetics by atomic absorption spectrometry (AAS) cold vapor technology after pressure digestion*
- USP <233>: *Elemental Impurities – Procedures*.

7.3 Stability

Products with no expiration date are exempt from this requirement until the second annual certification renewal, as described in Section 8 of this standard. For initial certification, exempt

products shall submit a scientifically sound protocol or plan for a future stability study, to be started by the second annual review.

Acceptable stability data shall provide justification for determining storage instruction, expiration date, and physical specifications as applicable.

Data used for evaluation of product stability for a product bearing an expiration date shall demonstrate stability of physical integrity, microbiological stability, and packaging compatibility using one or a combination of the below-listed methods. Manufacturers may modify stability testing as needed based on knowledge of the specific product and formulation. Examples of acceptable study types include, but are not restricted to:

- temperature excursion or cycling
- real-time stability studies
- accelerated stability studies

7.4 Test methods for Adulterants

The identity of potential known adulterants shall be verified by the most appropriate chemical test method to evaluate product compliance with the applicable subsection within Section 6.1.3. Sources for methods include AOAC International, USP <21>, and other method sources. The selected method is to be scientifically valid and suitable for the purpose of analysis of the product being tested. Modification of an existing method to better suit the product under test is permitted. The development of a new method or application of improved technology is permitted. The use of any modified or new method shall require an assessment to verify its performance based upon its intended use. Replacing an established method is permitted provided the performance of the replacement method is equivalent to or better than the performance of the established method.

7.4.1 PFAS

PFAS compounds specified in Section 6.1.3.9 shall be measured by liquid chromatography-mass spectrometry using a scientifically valid and fit for purpose method.

7.4.2 “Free of” claims

When applicable, the identity and quantity of substances subject to “Free of” claims testing shall be verified by the appropriate test method. The methods and approaches used shall be scientifically valid and fit for the purpose of analysis of the specific substance and product type being tested. The qualified individual in each case shall identify and record reference(s) and in-house procedures used.

8 Test methods annual renewal of certification

To continue certification to this standard, products shall be reviewed annually to ensure finished products remain compliant with the NSF/ANSI 527 standard throughout their certification lifecycle. The Annual Review process will include the following key components.

8.1 Annual testing of product attributes

- physical and organoleptic properties
- microbial contamination
- heavy Metal contamination
- any relevant adulterants based on the product formulation
- if applicable, one-third of the relevant ingredient claims will be re-evaluated each year, ensuring all claims are verified over a 3-yr cycle.

8.2 Review of adverse events and complaints

Adverse event reports and consumer complaint data related to each certified product will be reviewed annually.

If a pattern of issues emerges, additional testing can be required to determine whether the product continues to meet the standard's safety requirements.

- Additional Testing to address adverse events & complaints can include but is not limited to:
    - HRIPT testing
    - 48-h patch testing
    - contamination testing
    - relevant clinical assays.

8.3 Stability data requirement by second annual review

If stability data for the finished product has not already been submitted, evidence of in-process or completed stability study shall be supplied.

Failure to provide acceptable stability data can impact the product's continued certification status.