REVISED 5.19.20

Cosmetics - Qurate Protocols

Includes - Eye masks, nail polish, perfumes, eye shadow, eye liners, nail polish remover, shampoo, conditioner, mascara, blush, foundation, concealer, highlight/ contour, brozer, lip color (lipstick, lip stain, lip gloss, lip liner, etc.)

Protocol also includes OTC products which are also cosmetics: Anti Dandruff shampoo, lip balm, sun screen, etc.

QRG Test	Section	QRG Requirement Limit	Testing Method/Citation	Sample Amount Needed
CA Prop 65 Supplemental (All colorways) (Mandatory in state California) Lab must perform on all samples that are applicable under the relevant settlement.	Supplemental	Consent Judgment of related court case based on California Proposition 65 (Supplemental) Testing must be performed for all products where there is a consent judgement. In lieu of testing, valid test reports dated within 1 year may be submitted.	Supplemental Protcol	1 unit of final product
Toxic Elements in Packaging	Regulatory	Letter of guarantee is acceptable. Shall comply with TPCH in those states in the US with legislation. Total concentration of Pb, Cd, Hg and hexavalent Cr ≤ 100ppm. In lieu of testing, valid test reports dated within 1 year may be submitted. NOTE: Upon request only. Applies only to produts with packaging submitted to the laboratory	Model Toxics in Packaging Legislation	2 unit of final packaging material
Producer Identity on Product/Packaging	Regulatory	Manufacturer, packer, or distributor's Full Name & Address. Product Identification, Net quantity of contents (expressed in weight, mass, measure, numerical count, metric units or combination) (U.S. and metric units)	F.P. & L. Act, 16 CFR 500 (For one time use products) OR NIST Handbook 130 Uniform Laws and Regulations (For others)^	1 unit of final product
Country of Origin Marking	Regulatory	Indicate country of origin legibly, permanently, and in comparable size and close proximity to any mention of country other than country in which the article was manufactured or produced. Must be visible at point of sale.	19 CFR 134.11^	1 unit of final product
Plastic Bag Warning (if applicable)	Regulatory	Plastic bags < one mil thickness (0.001 inch), in which a diameter is =>5 inches (when formed into a circle) used as packaging/packaging article for domestic/household use (e.g. laundry bag, garbage bag) shall contain a warning statement as following or equivalent to below, visible on both sides of each bag:- Warning: To avoid danger of suffocation, keep this plastic bag away from babies and children. Do not use this bag in cribs, beds, carriages or playpens. The thin film may cling to the nose and mouth and prevent breathing. This bag is not a toy. The warnings shall be printed clearly as to prevent the ink from smearing or upon a gummed label securely attached to the bag. It shall be contrasted by typography, layout or colour from the contents of the bag and from other printed matter on the bag, if any. If the total length and width of the bag is more than 40 inches, the warning shall be repeated at 20 inches intervals. Except laundry bag, the font size of the warning must adhere to the chart listed below: Total Length and W width of Bag Size of Print 60 inches or more at least 24 point 40 to less than 60 inches at least 18 point 25 to less than 40 inches at least 14 point Less than 25 inches at least 10 point For laundry bag, the font size of the warning should be at least 36 points.	105 CMR 630.000 (Massachusetts) / 10 NYCRR § 12.12 (New York) / R.I. Gen. Laws § 11-9-16 (Rhode Island) / Cal Bus & Prof Code § 22200 (California)^	1 unit of final product
Cosmetics Labeling Review	Regulatory	Verify the following is present and compliant with the noted CFR's **GENERAL LABELING** •Identity Statement - 21 CFR 701.11 •Net Qty - 21 CFR 701.13 •Name/ Distributor and place of business - 21 CFR 701.12	21 CFR 701	1 unit of final product
OTC Labeling Review	Regulatory	Verify the following is present and compliant with the noted CFR **LABELING - 21 CFR 201** •Drug Facts label •Active ingredients •Purposes •Uses •Warnings •Directions •Other Information •Inactive Ingredients •Questions/ comments **OTC PRODUCTS SPECIFIC** •OTC Expiration Date 21 CFR 211	21 CFR 201 & 21 CFR 211	1 unit of final product
Cosmetics Warning Label Review if applicable	Regulatory	Verify compliance of Cosmetic label - 21 CFR 740 •Cosmetics - self pressurized containers •Feminine deodorant sprays •Foaming detergent bath products •Coal tar hair dyes •Suntanning preparations	21 CFR 740	1 unit of final product
Pressurized Container Labeling (as applicable)	Regulatory	Self-pressurized containers shall conform to the labeling requirements as defined in 16 CFR 1500.130.	16CFR1500.130	1 unit of final product
Ingredient Review - Labeling Cosmetics ONLY	Regulatory	**COSMETICS** Must meet all labeling requirements under 21 CFR Section 701 & 740 **NOTE** Products that are classified as Cometics and OTC Drugs must meet both regulations noted above.	21 CFR 701 & 740 - Cosmetics	1 unit of final product

Ingredient Review - Labeling OTC Drugs ONLY	Regulatory	**OTC DRUGS** Must comply with 21 CFR 201.60 - 80 (Subpart C) **NOTE** Products that are classified as Cometics and OTC Drugs must meet both regulations noted above.	21 CFR 201.60 - 80 - OTC Drugs	1 unit of final product
Ingredient review - Labeling color additives (as applicable)	Regulatory	Color additivies listed must be in line with APPROVED use and restrictions published by the FDA under 21 CFR Part 73,74,81,and 82 https://www.fda.gov/industry/color-additive-inventories/summary-color-additives-use-united-states-foods-drugs-cosmetics-and-medical-devices	21 CFR Part 73,74,81,and 82	1 unit of final product
FDA Approved Claims Not Accepted	Regulatory	No, FDA Approved claims or similar statements shall be labeled on a product meeting the definition of a Cosmetic	Visual Check	1 unit of final product
SPF-Sunscreen Drug Products (as applicable)	Regulatory	SPF products shall meet the requirements of 21CFR Part 352-Sunscreen Drug Products for Over-The-Counter Human Use. Qurate Retail Group requires testing / documentation to substantiate SPF determination claim. All SPF labeling claims must be substantiated In lieu of testing, documentation may be submitted for review. Test results and date that the test was performed will be documented in the report. **Up to 8 weeks to complete test if no testing is already on hand**	21CFRPart 352	4 oz or 113 grams of product in bulk
Water Resistance Testing (as applicable)	Regulatory	**21 CFR 201.327** Perform testing as outlined in 21 CFR 201.327(7)(i) & (ii) (7) Determination of water resistance. The following procedure should be performed in an indoor fresh water pool, whirlpool, and/or hot tub maintained at 23 to 32 °C. Fresh water is clean drinking water that meets the standards in 40 CFR part 141. The pool and air temperature and the relative humidity should be recorded.In lieu of testing, documentation may be submitted for review. Test results and date that the test was performed will be documented in the report. **Up to 8 weeks to complete test if no testing is already on hand**	21 CFR 201.327 (i)(7)(i) & (i)(7)(ii)	4 oz or 113 grams of product in bulk
Broad Spectrum Labeling if applicable	Regulatory	OTC Sunscreen products ONLY Verify labeling is compliant to 21 CFR 201.327	21 CFR 201.327	4 oz or 113 grams of product in bulk
Broad Spectrum Testing if applicable	Regulatory	OTC Sunscreen products ONLY Conduct testing outlined in within 21 CRF 201.327 (a)(1)(j) In lieu of testing vendor can provide testing if dated within past 5 year.	21 CFR 201.327 (a)(1)(j)	4 oz or 113 grams of product in bulk
Active Ingredients (as applicable/OTC Drugs only)	Regulatory	OTC products shall meet label as claimed with active ingredients. In lieu of testing, documentation may be submitted for review. Test results and date that the test was performed will be documented in the report.	21 CFR 211.165	1 unit of final product
Preservative Effectiveness (as applicable-not required for anhydrous products)	Regulatory	For all water based products must be tested to USP <51> or valid test report must be submitted in lieu of testing. All AET reports must state that the test was validated. The validation report must be included. Any universally recognized compendia method may be used provided the method was run as written, including proof of neutralization. Method run must be clearly stated on the report. In lieu of testing, documentation may be submitted for review. Test results and date that the test was performed will be documented in the report.	Current USP <51>, PCPC (CTFA), JP (Japanese Pharmacopeia), EP (European Pharmacopeia), or BP (British Pharmacopeia) including Validation (current applicable monograph should be followed)	9 oz or 255 grams of product in bulk or finished goods
Sterilization Certificate (applicable to brushes)	Regulatory	Documentation that all products containing natural hair have been sterilized. Sterilization certificate.	Document Review	

Eye Safety	Regulatory	Proof of product safety testing for irritation and allergic response is required. Eye area products require in-vitro safety testing as listed below. For products specifically made to be used around the eye (peri-orbital area) No claims can be made with in-vitro testing. They are done for liability purposes to prove product safety. For water based mascara/eye liners; eye gels, creams, serums, lotions, eye make-up removers that are meant/directed/intended to be used in the eye orbital area. Vendor can provide any of the below acceptable eye safety test: (review under documents) Het-Cam; CAMVA; Ocular Irritation; Ophthalmologist use test; Neutral Red Uptake If testing is not provided by vendor, any of the above should be included in the protocol by the lab. For anhydrous mascara or eye shadows. The vendor can provide a signed attestation from the manufacturer affirming that the product is formulated using common ingredients known to be safe around the eyes. The signee must be a company official able to make the assessment, i.e. compliance officer, R&D official, Quality Manager. Otherwise the vendor can provide eye safety testing using an approved method. (review under documents) If an assessment is not made or an eye safety test was not provided, then the lab will need to test using one of the approved methods.	Neutral Red Uptake In-Vivo Ophthalmologist use test 30 subjects In-vitro HET-CAM In-vitro CAMVA, In-vitro Ocular Irritaition Optisafe	1 unit of final product or 1 oz or 28 grams minimum
Toxicological Risk Assessment	Regulatory	Conduct TRA on all cosmetic and OTC formulations **Focus:** Assessment of formulation for dermal and oral (accidental) toxicological safety Irritation assessment and required safety labeling In lieu of testing vendor provided TRA will be accepted if dated within the past 5 years	FDA/ EPA	
Micro Beads	Regulatory	Man-made plastic micro beads are not allowed. If Micro Beads are suspected in the product, the vendor is to provide a letter certifying that Micro Beads are not in the product. If confirmatory testing is required, additional changes may be incurred.		
Flash Point (only as applicable)	Regulatory	Report actual. The products must be labeled appropriately with symbol if the flammability results are as follows: Extremely Flammable: flashpoint at or below 20°F Flammable: flashpoint above 20°F and below 100°F Combustible: flashpoint at or above 100°F to 150°F In lieu of testing, SDS may be submitted for review. Test results and date that the test was performed will be documented in the report. **Up to 15 days to complete test if testing is not already on hand by vendor**	16 CFR 1500.43a 16 CFR 1500.3 (c) (6)	1 unit of final product
Flammability (aerosol only)	Regulatory	Self pressurized container must meet the flammability requirements of 16 CFR 1500.3 (c) (6). In lieu of testing, documentation may be submitted for review. The product must be either labeled as "extremely flammable" or "flamable".	16 CFR 1500.3 (c) (6)	
Freeze/Thaw Stability (as applicable-not required for anhydrous products)	Regulatory	Shall have no change in appearance, fragrance, pH, or viscosity and have no visual separation. Testing that determines the low temperature stability of a product and that adequate packaging headspace has been afforded (if applicable to the product). The general procedure includes exposure to -10° to -15°F temperatures for twelve hours followed by a twelve hour thawing period at ambient temperature (72°F). This cycling should be repeated two more times for a total of three cycles. After the third cycle is complete, the product is compared to samples that have not undergone freeze/thaw testing and examined for any chemical or physical changes such as emulsion breakage/separation and/or viscosity changes, etc. Additionally, if container breakage occurs, head spacing or product formulation should be modified and the test repeated. In lieu of testing, documentation may be submitted for review. Test results and date that the test was performed will be documented in the report. (Testing must be performed with packaging, fill volume, and closure torque specification that is representative of that which will be used during the filling operation). **Up to 15 days to complete test if testing is not already on hand by vendor**	Industry Standard	6 units of final product
Elevated Temperature Stability	Regulatory	Shall have no change in appearance, fragrance, pH, or viscosity and have no visual separation. Testing that determines the elevated temperature stability of a product and that adequate packaging headspace has been afforded (if applicable to the product). The general procedure includes exposure to 115°F temperatures for 72-hours followed by examination of the product. After 72-hours the product is compared to samples that have not undergone elevated temperature testing and examined for any physical, chemical or microbiological changes. Additionally, if container breakage occurs, head spacing or product formulation should be modified and the test repeated. Storage of cosmetic products at elevated temperatures will also provide an accelerated shelf-life profile for the product, usually showing quickly the reactions that may occur over the next 6 or 9 months. Such reactions could be emulsion breakage, separation, precipitation, microbial growth, color or odor changes, viscosity changes and other product modifications that would occur over time or upon exposure to high temperatures. In lieu of testing, documentation may be submitted for review. Test results and date that the test was performed will be documented in the report (Testing must be performed with packaging, fill volume, and closure torque specification that is representative of that which will be used during the filling operation). **Up to 15 days to complete test if testing is not already on hand by vendor**	Industry Standard	6 units of final product

California: Volatile Organic Compounds (VOC) (if applicable nail polish, fragrances, aerosols)	Regulatory	**Verify SDS if VOC is within acceptabled limites** The VOC standard shall comply with the table of standards given under: •Title 17, California Code of Regulations, Division 3, Chapter 1, Subchapter 8.5, Article 1, Antiperspirants and Deodorants, Sections 94500-94506.5. •Title 17, California Code of Regulations, Division 3, Chapter 1, Subchapter 8.5, Article 2, Consumer Products, Sections 94507-94517. •Title 17, California Code of Regulations, Division 3, Chapter 1, Subchapter 8.5, Article 3, Aerosol Coating Products, Sections 94520-94528. Title 17, California Code of Regulations, Article 1, Tables of Maximum Incremental Reactivity Values, Sections 94700-94701. •Title 17, California Code of Regulations, Division 3, Chapter 1, Subchapter 8.5, Article 4, Alternative Control Plan, Section 94540-94555. **NOTE** In lieu of testing with client approval, test report or certification of compliance may be submitted if dated within 1 year	**Verify compliance with:** Citation: CA Code of Regulations: Title 17, Division 3, Chapter 1, Sec. 94500-94575	1 unit of final product
National Volatile Organic Compounds (VOC) (if applicable nail polish, fragrances, aerosols)	Regulatory	**Verify SDS if VOC is within acceptabled limites** Product shall comply with current VOC requirements specified under Subpart C: National Volatile Organic Compound Emission Standards for Consumer Products of 40 CFR 59. - Table 1 (Subpart C): VOC Content Limits by Product Category - Table 2 (Subpart C): Content Limits for Underarm Deodorants and Underarm Anti-Perspirants. **NOTE** In lieu of testing, test report or certification of compliance may be submitted if dated within 1 year with client approval.	**Verify compliance with:** Citation: 40 CFR 59, Part C	1 unit of final product
Mercury in Cosmetics "Elemental Impurities in Cosmetics	Regulatory	Shall not exceed the limits of: • Mercury 1 ppm for product used other than eye area (21 CFR 700.13) Lead 5 ppm, Antimony 5 ppm, Cadmium 3 ppm and Arsenic 3 ppm In liue of testing test report can be submited and accepted if dated within the past 1 year.	21 CFR 700.13 & Illinois Mercury Added Prohibition Act	1 unit of final product
FDA Registration OTC products ONLY	Regulatory	All OTC products must be verified to ensure the facility where it is produced is FDA registered. - **21 CFR 207.17** Certificate of registration is acceptable	Verify certificate	
Poision Prevention Pacakging Act (PPPA) Child-Resistant Packaging	Regulatory	**Verify products meeting any of the below criteria have child-resistant pacakging** **<u>Chemical and Cosmetic Products</u>** •the following products that contain 10 percent or more by weight of petroleum distillates: furniture polish and kindling and illuminating products, such as lighter fluid and lamp oil, •paint solvents that contain 10 percent or more by weight of benzene, toluene, xylene, or petroleum distillates; •products containing 10 percent or more by weight of low viscosity hydrocarbons, such as some baby oils, bath oils, and cleaning solvents; dry products such as granules, flakes, or powders that contain 10 percent or more by weight of sodium or potassium hydroxide, and all other products containing 2 percent or more of these chemicals; •liquid products containing 4 percent or more by weight of methyl alcohol; •liquid products containing 10 percent or more by weight of turpentine; •products containing 10 percent or more by weight of sulfuric acid; •liquid products containing 10 percent or more by weight of ethylene glycol; •liquid home permanent wave neutralizers that contain more that 600 mg of sodium bromate or more than 50 mg of potassium bromate; •liquid glue removers containing more than 500 mg of acetonitrile; •liquid products containing more than 5 percent methacrylic acid on a weight-to-volume basis; •products containing more than 50 mg of elemental fluoride in a concentration that is more than 0.5 percent on a weight-to-volume basis for liquids and a weight-to-weight basis for solid products. Please note that drugs and dietary supplements that meet these specifications also require child-resistant packaging;	Verify compliance PPPA	
Appearance	Performance	Report Actual	Visual Check	1 unit of final product
Fragrance	Performance	Report Actual. Shall have no objectionable or off odors.	Visual & Inspection Check	1 unit of final product
Defects	Performance	Shall have no components broken, cracked, missing, malformed, fractured, dirty, appearance of being used, leaking, over/under filled, non-functioning, illegible <u>print/markings</u>, etc.	Visual Check	1 unit of final product
Workmanship	Performance	Shall have no defects including separation, emulsion breakdown, film formation, drying, uneven color dispersion, precipitation, microbial growth, etc.	Visual Check	1 unit of final product
Dispense Function	Performance	Report actual. Shall function as intended as received. Test lab to report number of times a pump needed to be primed, when applicable. <u>Standard pumps</u> - must prime within 10 pumps and ensure consistent pump flow for 10 pumps after initial dispensing <u>Airless pumps</u> - must pump within 15-20 pumps to prime and ensure consistent pump flow for 15 pumps after initial dispensing	Functional Use	1 unit of final product
Packaging	Performance	Report Actual. Must have lot number or batch code on component packaging	Visual Check	1 unit of final product

Leak Protection	Performance	Report actual. Shall function as intended as received. <u>Leak Protection</u> HSN requires leak/tamper protection under the following conditions: • Product is a low viscosity liquid such as a toner, spray, oil, perfume, serum or similar product that poses a leak risk • Product is flammable • Product is packaged WITHOUT a form-fitting branded retail secondary carton • Product is packaged in a branded retail secondary carton BUT the carton does not possess locking flaps or the primary component is of sufficient weight to cause the secondary carton to open during manual handling or transit HSN does NOT require leak/tamper protection under the following conditions: • Product is packaged within a form-fitting branded secondary retail carton AND • Product does not present a leakage risk AND • Branded secondary retail carton is shelf-ready with all required labeling elements OR • Product utilizes a crimp seal (e.g. perfume bottle) <u>Application of Leak Protection</u> The appropriateness of leak protection will vary from product to product and must be reviewed /approved. • Bottle mouths should incorporate foil heat induction or pressure seals, or the entire bottle should be shrink-wrapped • Seals placed over the cap must include the juncture of the container and cap • Snap-top, push-pull, twist-to-open, dropper, dispenser plug, etc., caps normally without liners, should be shrink-wrapped or incorporate foil heat induction seals under the cap • Stopper type lids must be secured to the container body by a decorative cord or shrink-wrapped • Squeeze tubes and containers of soft creams or semi-liquid products should have an inner liner to the twist-cap, an interference seal snap-cap, a foil heat induction seal or shrink-wrap C54 • Flip-top lids should be shrink-wrapped to prevent opening or incorporate a foil heat induction seal under the lid • Oil based products such as body oils should be sealed with an induction seal or have a reduced orifice opening and shrink wrap to prevent leakage • Bottles tend to rotate loose from pump dispensers during shipment. Pumps should either be packaged separately and the bottle mouth sealed and capped, or the assembled pump and/or bottle should be fully shrink-wrapped to reduce rotation. If pump dispensers are installed when shipped, they must be in the “down and locked” position and should include a protective plastic cap over the pump. • Compacts must close securely, but be capable of opening without unreasonable damage to the customer’s fingernails. • Loose powder products must have a firm inner-seal separating the powder from the puff. In a shaker-type applicator the dispenser opening must be sealed with a removable tab of appropriate design. • Neckbands on aerosol cans/fragrance containers must be firmly, evenly and smoothly crimped to prevent leakage. • Flammable items must contain both leak protection and leak containment. Must be packed in a self-shipper carton and the carton should contain sufficient fill to absorb a potential leak. • Leak protection must be both aesthetic and effective • Screw on lids must have adequate torque to prevent leakage. Recommended minimum torque range is from: 6 inch-lbs for a 15 mm cap 15 inch-lbs for a 38 mm cap 53 inch-lbs for a 138 mm cap	Visual Check	1 unit of final product