

Title: **BODY LOTION/MOISTURIZER**
 Protocol Number: **KOHL'S -503-E**

Test Property	Test Method	Samples	Test Principle / Requirements	Rating (Section or exec. Summary which failed items can be referenced)
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LABELING				
*Cosmetic Labeling Review	FDA 21 CFR 701 & 740 & FPLA 16 CFR 500	All Samples	<p><u>Principle Display Panel</u> (Outer or immediate package)</p> <ul style="list-style-type: none"> • Statement of identity • Net quantity of contents <p><u>Information Panel</u></p> <ul style="list-style-type: none"> • Name and place of business of manufacturer, packer, or distributor • Declaration of ingredients • Directions for safe use (If applicable) • Warning statement (if applicable) <p><u>Inner Package</u></p> <ul style="list-style-type: none"> • Name and place of business of manufacturer, packer, or distributor • Statement of identity • Net quantity of contents • Warning statement and directions for safe use (If applicable) 	
Country of Origin Marking (If Imported)	19 CFR 134	All Samples	Shall indicate country of origin legibly and permanently and in a conspicuous place. It must also be in a close proximity and in comparable size to the name of country or locality other than the country of origin appears on the marking. It must be visible at point of purchase.	

PHYSICAL CHARACTERISTICS				
Capacity (fl. oz./ mL)	Std. Measure	All Samples	As claimed (Max. +5% / -0%)	Claimed: Actual:
pH Value	Water extraction, followed by analysis using pH meter	All Samples	Report actual finding. <i>Note: Preferred range is 5 to 8.</i>	
Fragrance	Organoleptic/ Document Review	All Samples	Must comply with claim and conform to IFRA guidelines. <i>Vendor to submit IFRA test report for review.</i>	

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CONSTRUCTION QUALITIES				
Kohl's Workmanship Review	Visual & Sensory	All Samples	<u>Product</u> <ul style="list-style-type: none"> Free from cake formation, contamination, dirt or foreign matter Free from objectionable odor Free from stain, discoloration or uneven color <u>Container</u> <ul style="list-style-type: none"> Shall not be deformed or fractured Shall not contain any burrs or sharp edges (test by touch or sight) Shall not contain any loose components or unsecured enclosure where structural rigidity and product sealing is required 	

TOXICITY				
*Ingredient Review <i>(applicable to ALL cosmetics products)</i>	FDA 21 CFR 73, 74, 81, 82, 250 & 700 to 740	All Samples	All the colorants and ingredients of cosmetic products must comply with FDA Food Drug and Cosmetic Regulations.	
*Ingredient review <i>(applicable to cosmetics products sold in California States)</i>	California Safe Cosmetics Act (CSCA)	All samples	Review the formulation and check whether the ingredients fall into the chemical list of California Safe Cosmetics Act. Imported/manufacture may need to report to the authority if there is CSCA substances and if the product meets the reporting rules.	
*Ingredient review <i>(applicable for toys-cosmetics products sold in Washington)</i>	Chemicals of High Concern to Children (CHCC)	All samples	Review the formulation and check whether the ingredients fall into list of Chemicals of High Concern to Children. Imported/manufacture may need to report to the authority if there is CHCC substances and if the product meets the reporting rules.	
*Toxicological Risk Assessment (TRA) On The Formulation	Document Review	All samples	Evaluate the safety of the product by a toxicologist. Review the hazard, exposure and risk associated with the ingredient. <i>Vendor can submit a 3rd party test report for review if it is within two years of the report issue date.</i>	
*Skin Irritation <i>(Applicable If Material Documentation Is Not Available For TRA)</i>	In-vitro test method	1 sample	Upon request. No skin irritation.	

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STABILITY				
*Photo Stability (Applicable To Products With Transparent Container Or Packaging)	Evaluate the stability of product in specific storage condition	1 Sample	Exposure under 450W Xeon lamp or lamp using ICH Guideline for 24 hrs. <i>Generally accepted industrial requirement: No observable change of sample against the control. For any surface color change it should be class 3.0 minimum (AATCC grey scale).</i>	
*Accelerated Stability Study	Evaluate the stability of product in specific storage condition	6 Samples	Study the following test parameters at t=0, 6th and 12th weeks @40° C/75% R.H. <u>For Body Lotion/Moisturizer</u> - Appearance - Odor - pH - Capacity - Total bacterial count - Total combined molds & yeast count <u>For Packaging</u> - Appearance <i>Generally accepted industrial requirement: No observable change of sample against the control.</i>	
*Freeze Thaw Test	Evaluate the stability of product in specific storage condition	2 Samples	Test duration lasts for 1 week. 1 cycle is from 0° C to 40° C and back to 0° C for 24hrs. <i>Generally accepted industrial requirement: No observable change of sample against the control. For any surface color change it should be class 3.0 minimum (AATCC grey scale).</i>	

ANALYTICAL				
*Heavy Metal Contamination (Lead And Mercury)	Acid digestion followed by ICP analysis	1 sample	Lead: Less than 10 ppm (State of California, County of Alameda, Court Case No. H217587 [consolidated with 01-032306]) Mercury: Less than 1 ppm (FDA – 21 CFR 700.13)	
*Lead In Scrapable Surface Coating (If Applicable)	CPSIA Section 101 CPSC-CH-E1003-09.1	1 sample	≤600ppm (0.06% by weight)	
*Phthalates	GCMS	1 Sample	Not exceeding 0.1% by weight (each)	

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(DEHP, BBP, DBP, DIDP, DINP, DnOP, DnHP)	analysis		(Calif. Prop 65)	
* Free Formaldehyde Content	HPLC-DAD analysis	1 sample	Report actual finding. Minnesota State Law For product used by children under 8 Aug 2014 Ban of selling children's product by manufacturers and wholesalers that intentionally contain formaldehyde or chemical that under normal conditions would degrade to release formaldehyde Aug 2015 Ban of selling children's product by retailers that intentionally contain formaldehyde or chemical that under normal conditions would degrade to release formaldehyde	

MICROBIOLOGICAL					
*Microbial Contamination (Total Bacterial Count , Total Combined Molds & Yeast Count, E.coli)	USP <61> & <62>	1 sample	Microbial	Limit Value	
			Total viable count for aerobic mesophyllic micro-organism	≤5X10 ³ cfu/g (for non-eye-area products)	
*Microbial Contamination (Additional pathogens)	USP<62>	1 sample	Escherichia coli	Absent/ g	
			Staphylococcus aureus	Absent/ g	
			Pseudomonas aeruginosa	Absent/ g	
*Efficacy of antimicrobial preservation	USP <51> + CTFA	10 samples	Candida albicans	Absent/ g	
			<i>For Topical products:</i> a. Bacteria (Staphylococcus aureus, E. Coli, Pseudomonas aeruginosa) - Not less than 2.0 log reduction from the initial count at 14 days, and no increase from the 14 days' count at 28 days b. Yeast and Molds (Candida albicans & Aspergillus niger) - No increase from the initial calculated count at 14 and 28 days		



KOHL'S TEST PROTOCOL

Approved: May 26, 2016

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ADDITIONAL NOTE:

*Please refer to Kohl's preferred third party labs for individual pricing and samples.



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Protocol Version	Description of Change	Revised by / Date	Approved by / Date
503- A	Initial Release	Simon Leung April 1, 2010	Ro Jain April 1, 2010
503- B	Price adjustment on Ingredient Review (per additional color) & Toxicological Risk Assessment (per additional color) Updated lead and phthalates pricing	Candy Chan Jul 30, 2014	Jeetendra Shelatkar Aug. 4, 2014
503-C	Addition of test line of free formaldehyde & Delete the duplicated test line of ingredient review from sub-section of Stability	Queenie Tse Apr 21, 2015	Dana Leair, Apr 24, 2015
503-D	Update the description of in-house test method	Queenie Tse Mar 25, 2016	Dana Leair, Mar 26, 2016
503-E	Addition of ingredient review according to CSCA and CHCC	Queenie Tse May 25, 2016	Dana Leair, May 26, 2016