KOHL'S TEST PROTOCOL

Approved: June 16th, 2016

Title: **Nail Polish**
Protocol Number: **KOHL'S – 509-A**

Test Property	Test Method	Samples	Test Principle / Requirements	Rating (Section or exec. Summary which failed items can be referenced)
LABELING				
*Cosmetic Labeling Review	FDA 21 CFR 701 & 740 & FPLA 16 CFR 500	All Samples	**Outer package** - Principle Display Panel • Statement of identity • Net quantity of contents • Warning statement (21 CFR 740.10) - Information Panel • Name and place of business of manufacturer, packer, or distributor • Declaration of ingredients • Directions for safe use (If applicable) • Warning statement (if applicable) **Inner Package** - Front Panel • Statement of identity - Information Panel • Name and place of business of manufacturer, packer, or distributor • Net quantity of contents • Warning statement (If applicable) • 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				
Net Weight/Net Content *(oz./g or 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. *Note: Preferred range is 5 to 8.*	
Fragrance	Organoleptic/ Document Review	All Samples	Must comply with claim and conform to IFRA guidelines. *Vendor to submit IFRA test report for review.*	

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CONSTRUCTION QUALITIES				
Kohl's Workmanship Review	Visual & Sensory	All Samples	Product • Free from sediment, contamination, dirt or foreign matter • Free from objectionable odor • Free from stain, discoloration or uneven color Container • 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 *(applicable to ALL cosmetics products)*	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 *(applicable to cosmetics products sold in California States)*	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/manufacturer may need to report to the authority if there is CSCA substances and if the product meets the reporting rules.	
*Ingredient review *(applicable for toys-cosmetics products sold in Washington)*	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/manufacturer 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	FD&C Act 16 CFR 1500.3 21 CFR740.10	All samples	Evaluate the safety of the product by a toxicologist. Review the hazard, exposure and risk associated with the ingredient. *Vendor can submit a 3rd party test report for review if it is within two years of the report issue date.*	
*Skin Irritation *(Applicable If Material Documentation Is Not Available for TRA)*	In-vitro test method	1 sample	Upon request. No skin irritation.	
STABILITY				
*Accelerated Stability Study	Evaluate the stability of product in	6 Samples	Study the following test parameters at t=0, 6th and 12th weeks @40^{o} C/75% R.H.	

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	specific storage condition		For Color Cosmetics - Appearance - Odor - pH - Net Weight/Net Content - Total bacterial count - Total combined molds & yeast count For Packaging - Appearance *Generally accepted industrial requirement: No observable change of sample against the control.*	
*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. *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).*	

ANALYTICAL				
*Heavy Metal Contamination *(Lead And Mercury)*	Acid digestion followed by ICP analysis	1 sample	Lead ≤ 5 ppm lead content (Lipstick & Lipliner) ≤ 10 ppm (eye shadow and blush**)** (State of California, County of Alameda, Court Case No. H217587 [consolidated with 01-032306]) Mercury Less than 1 ppm for general cosmetics Less than 65 ppm for cosmetics intended to be used on the eye area (FDA – 21 CFR 700.13)	
*Lead In Scrapable Surface Coating	CPSIA Section 101 CPSC-CH-E1003-09.1	1 Sample	≤90 ppm (0.0090% by weight) (CPSA – 16 CFR 1303)	
*Free Formaldehyde Content (applicable for toys-cosmetic and products sold in Minnesota state)	Chemicals of High Concern to Children (CHCC)	1 Sample	Imported/manufacturer may need to report to the authority if formaldehyde is found in the formulation and if the product meets the reporting rules.	

MICROBIOLOGICAL					
*Microbial Contamination *(Total Bacterial Count ,*	USP <61> & <62>	1 sample	**Microbial**	**Limit Value**	
			Total viable count for	≤5X10^3 cfu/g	

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Total Combined Molds & Yeast Count, E.coli)			aerobic mesophyllic micro-organism	(for non-eye-area products) ≤5X10^2 cfu/g (for eye-area products)	
			Escherichia coli	Absent/ g	
*Microbial Contamination *(Additional pathogens)*	USP<62>	1 sample	Staphylococcus aureus	Absent/ g	
			Pseudomonas aeruginosa	Absent/ g	
			Candida albicans	Absent/ g	
*Efficacy of antimicrobial preservation	USP <51> + CTFA	10 samples	*For Topical products*: 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		

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Protocol Version	Description of Change	Revised by / Date	Approved by / Date
506-A	Initial Release	Queenie Tse 25 Mar, 2016	June 21, 2016, Dana Leair